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MINISTRY OF HEALTH MALAYSIA
INSTITUTE FOR PUBLIC HEALTH

POST-VACCINATION COVID-19 IMMUNITY AND DISEASE SURVEILLANCE IN MALAYSIA

TECHNICAL REPORT

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POST-VACCINATION COVID-19 IMMUNITY AND DISEASE SURVEILLANCE IN MALAYSIA (IMSURE)

POST-VACCINATION COVID-19 IMMUNITY AND DISEASE SURVEILLANCE IN MALAYSIA TECHNICAL REPORT

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Published by the Institute for Public Health, National Institutes of Health,
Ministry of Health, Malaysia

ISBN: 978-967-5340-94-9

Suggested citation
Institute for Public Health (IPH). Post-Vaccination Covid-19 Immunity and Disease Surveillance in Malaysia, Technical Report. 2024. 153 pages.

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The views expressed in this report are those of the authors alone and do not necessarily represent the opinions of other investigators participating in the survey, nor the views or policy of the Ministry of Health Malaysia.

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ACKNOWLEDGEMENT

The authors would like to thank the Director-General of Health Malaysia for his permission to publish this report. Our sincere appreciation to the Deputy Director General (Research and Technical Support), Director of Institute for Public Health and Institute for Medical Research for their unwavering support and guidance to bring this project to fruition.

We would like to express our utmost gratitude to the Ministry of Science, Technology and Innovation, Ministry of Education, Sabah Police, Sabah Ports and Harbours Department, state health departments, district health offices, public health clinics, private healthcare providers and community leaders involved, for providing important resources during the scouting and data collection phase.

Finally, we would like to extend our gratitude to all parties who implemented the surveillance including the Central Committee Team, Field Supervisors, Team Leaders, phlebotomists, and research personnel, for their commitment to make this project successful. Last but not least, we thank all of the recipients who participated in this surveillance from the bottom of our hearts.

Together, we have contributed to the fight against COVID-19 in Malaysia.

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EXECUTIVE SUMMARY

Vaccination was instrumental in the control of COVID-19 pandemic worldwide. It elicits antibody and cell response, conferring immunity to its recipients against the pathogen that causes COVID-19, the SARS-CoV-2. Malaysia started the mass vaccination of its population at the beginning of 2021. COVID-19 vaccines used here were developed by four different manufacturers, namely Pfizer-BioNTech, Sinovac Biotech, AstraZeneca-Oxford, and CanSino Biologics. While these vaccines were shown to be safe and able to generate immune response in clinical trials, local evidence from the ground was required to guide the implementation of the COVID-19 National Immunisation Program (PICK – Program Imunisasi COVID-19 Kebangsaan). As such, the Post-vaccination COVID-19 Immunity and Disease Surveillance (IMSURE) was commissioned to determine the immune response and safety of COVID-19 vaccination in Malaysia.

IMSURE has followed and observed more than 2,600 COVID-19 vaccine recipients for 6 to 7 times over a year, from right before the 1st vaccine dose (baseline) to 12 months from the baseline. For each of the four vaccines given through PICK, there were at least 600 adults who participated. The 5th vaccine cohort consisted of 153 adolescent Pfizer recipients. The participants were purposively sampled across Malaysia (Kedah, Pulau Pinang, Selangor, Melaka, Terengganu, Sarawak, and Sabah) for a more diverse representation of the country's population. The surveillance started recruiting its first participant in June 2021 and concluded the last follow up in November 2022.

Blood specimen was collected from each participant during each follow up and tested for the level of immunoglobulin G (IgG) antibody against two SARS-CoV-2 proteins, the spike and nucleocapsid proteins. The production of anti-spike IgG can be a result of both vaccination and infection, but the production of anti-nucleocapsid IgG follows either an infection or vaccination with the Sinovac inactivated vaccine. The safety of vaccines was determined using questionnaires after each vaccine dose for adverse events following immunisation (AEFI) and adverse events of special interest (AESI). Additionally, a subset of 30 participants were selected from each of the five cohorts to provide saliva specimen for immunoglobulin A (IgA) test and fresh blood specimen for T-cell reactivity. The data collection was conducted by the Institute for Public Health, while the Institute for Medical Research performed all the laboratory tests.

The anti-spike antibody results at baseline indicated that a varying proportion (7.5 - 52.8%) of participants in each cohort was previously infected. Subsequently, following vaccination, the anti-spike IgG increased and trended with some variations between different vaccine cohorts. It generally peaked at 14 days after the last vaccine dose, decreased and bottomed at three or six months from the first vaccine dose, and increased again at six to nine months, especially among those who were boosted and/or infected. The level of anti-nucleocapsid IgG antibody was generally lower and stable among all cohorts (except for Sinovac cohort, where the initial changes in the anti-nucleocapsid IgG were similar to its anti-spike IgG) until six or nine months, when it increased sharply. Majority of the vaccine recipients did not report any AEFI or AESI, or experienced mild AEFI not requiring treatment that were improving or had fully recovered. As for the subset participants, almost all of them had salivary IgA and T-cell reactivity after the first vaccine dose onward. However, the level of salivary IgA remained low throughout when compared to the baseline, while the increase in T-cell reactivity was more obvious.

With that, the immune response against SARS-CoV-2 and the safety of COVID-19 vaccination were demonstrated among different vaccine recipients through IMSURE.

ACRONYMS AND ABBREVIATIONS

AEFI	Adverse events following immunization
AESI	Adverse events of special interest
CO_2	Carbon dioxide
COVID-19	Coronavirus disease 2019
COI	Cut-off index
°C	Degree Celsius
DMSO	Dimethyl sulfoxide
ECLIA	Electrochemiluminescence immunoassay
ELISA	Enzyme-linked immunosorbent assay
ELISpot	Enzyme-linked immunospot
FBS	Fetal bovine serum
g	Gram
IMSURE	Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IMR	Institute for Medical Research
IKU	Institute for Public Health
IFN-ɣ	Interferon-gamma
JKJAV	Jawantankuasa Khas Jaminan Akses Vaksin
MREC	Medical Research and Ethics Committee
µL	Microlitre
mL	Millilitre
nm	Nanometre
NMRR	National Medical Research Registry
NPRA	National Pharmaceutical Regulatory Agency
PBMCs	Peripheral blood mononuclear cells
PBS	Phosphate-buffered saline
PICK	Program Imunisasi COVID-19 Kebangsaan
PPV	Pusat pemberian vaksin
RLUs	Relative light units
sCOVG	SARS-CoV-2 IgG
SAQ	Self-administrative questionnaires
SARS	Severe acute respiratory syndrome
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SFU	Spot forming units
SD	Standard deviation
SCS	Survey creation system
WHO	World Health Organization

INTRODUCTION

1.0 INTRODUCTION

1.1 Background

In late December 2019, an outbreak of pneumonia of unknown cause was documented in the city of Wuhan, China. The pathogen causing this pneumonia was later found to be a new strain of coronavirus (1). Due to its genetic parallels with the agent responsible for the SARS (severe acute respiratory syndrome) epidemic, the World Health Organization (WHO) named this new coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (2, 3). Additionally, the disease caused by SARS-CoV-2 was named coronavirus disease 2019 (COVID-19) (2, 4).

Within two weeks from the report of the outbreak in China, first cases of imported COVID-19 were reported in Thailand, Japan, and Korea (1). By the end of January 2020, COVID-19 outbreak was declared a public health emergency of international concern, as it has been detected in as many as 19 countries throughout the world, most of which were in Asia (5). By mid-March 2020, WHO officially declared COVID-19 outbreak a pandemic (6, 7). The number of notified cases has grown exponentially since. In early May 2023, WHO declared an end of COVID-19 as a public health emergency. As of October 2023, a total of 771 million confirmed COVID-19 cases were diagnosed worldwide, causing a staggering of over six million deaths (8). In Malaysia, the number of diagnosed cases and deaths were 5,071,840 and 37,028, respectively (9).

COVID-19 pandemic was proven difficult to contain. Apart from widespread testing, aggressive contact tracing, quarantine of close contacts, and isolation of diagnosed patients, countries around the world had to resort to drastic measures like societal lockdown and movement restriction, which led to more issues that in turn affect the well-being of the general population (9). Despite that, the number of cases and death tolls continued to rise with no end in sight (9). As such, vaccination against SARS-CoV-2 was one of the last hope humanities had to return to a sense of normalcy (9).

In Malaysia, the Special Committee for Ensuring Access to COVID-19 Vaccine Supply, or Jawatankuasa Khas Jaminan Akses Vaksin COVID-19 (JKJAV) was formed to plan and execute the COVID-19 National Immunisation Program, or Program Imunisasi COVID-19 Kebangsaan (PICK). Over time, four different types of COVID-19 vaccines developed by Pfizer-BioNTech, Sinovac Biotech, AstraZeneca-Oxford and CanSino Biologics were conditionally approved and given to all residents in Malaysia freely through PICK (10).

COVID-19 vaccination provides vaccine recipients protection against SAR-CoV-2 infection to varying degrees. This protection is conferred through the humoral and cell response of the human immune system (10, 11-14). Most vaccines were shown to have a seroconversion rate of close to 100% after administration in trials (15). But this early evidence of immune response and COVID-19 case detection were measured only over a short period of time using different methods at different places among different populations in a controlled environment (15). Longer term local evidence was required to support the PICK in Malaysia. Besides, it is also mandatory to ensure vaccine safety by monitoring the occurrence of adverse events following immunization (AEFI) and adverse events of special interest (AESI). This surveillance was therefore commissioned to determine post-COVID-19-vaccination immune response and vaccine safety, to inform health policy maker including JKJAV COVID-19 in its vaccination strategy moving forward (16, 17), as well as the National Recovery Plan in terms of the effect of COVID-19 vaccination.

1.2 Scope of study

1.2.1 General objective

To determine the immune response against SARS-CoV-2 and safety of Pfizer, Sinovac, AstraZeneca and CanSino COVID-19 vaccines up to 12 months among adult and adolescent recipients in Malaysia

1.2.2 Primary objectives

i. To determine the seropositive rate and antibody level of immunoglobulin G against SARS-CoV-2 spike protein at six to seven (6-7) different time points up to 12 months among different COVID-19 vaccine recipients
ii. To determine the seropositive rate and antibody level of immunoglobulin G against SARS-CoV-2 nucleocapsid protein at six to seven (6-7) different time points up to 12 months among different COVID-19 vaccine recipients
iii. To estimate the incidence of adverse events following immunization (AEFI) and adverse events of special interest (AESI) of different COVID-19 vaccines

1.2.3 Secondary objectives

i. To determine the positive rate and antibody level of salivary immunoglobulin A against SARS-CoV-2 spike protein at six to seven (6-7) different time points up to 12 months among different COVID-19 vaccine recipients

ii. To determine the T-cell reactivity at six to seven (6-7) different time points up to 12 months among different COVID-19 vaccine recipients

References

1. World Health Organization. (2020, January 20). Novel Coronavirus (2019-nCoV) Situation Report - 1. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200121-sitrep-1-2019-ncov.pdf?sfvrsn=20a99c10_4
2. World Health Organization. (2020). Naming the coronavirus disease (COVID-19) and the virus that causes it. Retrieved from https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it
3. Rothan, H. A., & Byrareddy, S. N. (2020). The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. Journal of Autoimmunity, 109, 102433. https://doi.org/10.1016/j.jaut.2020.102433
4. World Health Organization. (2020, February 11). Novel Coronavirus(2019-nCoV) Situation Report - 22. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200211-sitrep-22-ncov.pdf?sfvrsn=fb6d49b1_2
5. World Health Organization (2020, January 31). Novel Coronavirus(2019-nCoV) Situation Report - 11. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200131-sitrep-11-ncov.pdf?sfvrsn=de7c0f7_4
6. World Health Organization (2020, March 10). Novel Coronavirus(2019-nCoV) Situation Report - 50. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200310-sitrep-50-covid-19.pdf?sfvrsn=55e904fb_2
7. World Health Organization (2020, March 11). Novel Coronavirus(2019-nCoV) Situation Report - 51. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200311-sitrep-51-covid-19.pdf?sfvrsn=1ba62e57_10
8. World Health Organization (2023, October 27). COVID-19 epidemiological update - 27. Retrieved from https://www.who.int/publications/m/item/covid-19-epidemiological-update---27-october-2023
9. Mathieu, E., Ritchie, H., Rodés-Guirao, L., Appel, C., Giattino, C., Hasell, J., Macdonald, B., Dattani, S., Beltekian, D., Ortiz-Ospina, E., & Roser, M. (2020, March 5). Coronavirus pandemic (COVID-19). Our World in Data. Retrieved from https://ourworldindata.org/coronavirus
10. Ministry of Health Malaysia. (2022, October 6). Program Imunisasi COVID-19 Kebangsaan. Retrieved from https://covidnow.moh.gov.my/vaccinations
11. Logunov, D. Y., Dolzhikova, I. V., Zubkova, O. V., Tukhvatullin, A. I., Shcheblyakov, D. V., Dzharullaeva, A. S., Grousova, D. M., Erokhova, A. S., Kovyrshina, A. V., Botikov, A. G., Izhaeva, F. M., Popova, O., Ozharovskaya, T. A., Esmagambetov, I. B., Favorskaya, I. A., Zrelkin, D. I., Voronina, D. V., Shcherbinin, D. N., Semikhin, A. S., Simakova, Y. V., … Gintsburg, A. L. (2020). Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. The Lancet, 396(10255), 887–897. https://doi.org/10.1016/S0140-6736(20)31866-3
12. Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W., Hammitt, L. L., & Türeci, Ö. (2020). Safety and efficacy of the BNT162b2 mRNA COVID-19 vaccine. New England Journal of Medicine, 383(27), 2603–2615. https://doi.org/10.1056/nejmoa2034577
13. Voysey, M., Clemens, S. A. C., Madhi, S. A., Weckx, L. Y., Folegatti, P. M., Aley, P. K., Angus, B., Baillie, V. L., Barnabas, S. L., Bhorat, Q. E., Bibi, S., Briner, C., Cicconi, P., Collins, A. M., Colin-Jones, R., Cutland, C. L., Darton, T. C., Dheda, K., Duncan, C. J. A., Emary, K. R. W., … (2020). Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. The Lancet, 397(10269), 99–111. https://doi.org/10.1016/S0140-6736(20)32661-1
14. Zhang, Y., Zeng, G., Pan, H., Li, C., Hu, Y., Chu, K., Han, W., Chen, Z., Tang, R., Yin, W., Chen, X., Hu, Y., Liu, X., Jiang, C., Li, J., Yang, M., Song, Y., Wang, X., Gao, Q., & Zhu, F. (2021). Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine in healthy adults aged 18-59 years: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial. The Lancet Infectious Diseases, 21(2), 181–192. https://doi.org/10.1016/S1473-3099(20)30843-4
15. Malaysian Health Technology Assessment Section (MaHTAS), Ministry of Health, Malaysia. (2021, February 15). COVID-19 candidate vaccines (update). Retrieved from https://covid-19.moh.gov.my/kajian-dan-penyelidikan/mahtas-covid-19-rapid-evidence-updates/COVID-19_VACCINES_15022021.pdf
16. World Health Organization. (2022, April). WHO target product profiles for COVID-19 vaccines. Retrieved from https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines
17. World Health Organization. (2017). Guidelines on clinical evaluation of vaccines: regulatory expectations. Retrieved from https://www.who.int/publications/m/item/WHO-TRS-1004-web-annex-9

METHODOLOGY

2.0 METHODOLOGY

2.1 Study design

Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE) was a surveillance program designed and led by the Institute for Public Health (IKU) for the Malaysia COVID-19 National Immunisation Program (PICK). IMSURE was a post-vaccination sentinel surveillance that employed a prospective multi-arm cohort design to follow up selected COVID-19 vaccine recipients in Malaysia.

2.2 Study population

The study population was the general population eligible for COVID-19 vaccination at the selected study sites, namely:

1) adults aged 18 years old and above; and
2) adolescents aged 12 to 17 years old

The inclusion criteria were:

- individuals eligible to receive COVID-19 vaccination as determined by JKJAV; and
- individuals who consented and/or assented and/or given consent by guardians to receive COVID 19 vaccination; and
- individuals without contraindications towards COVID-19 vaccination (allergy history towards any vaccine or low immunity, and any other contraindications as determined by JKJAV); and
- individuals who agreed to follow up for one-year post-vaccination.

The exclusion criteria were:

- individuals who worked/resided away from the selected sites; or
- individuals who planned to work/live away from the selected sites within a year from the day of the first dose of his/her COVID-19 vaccination; or
- individuals who had previously received COVID-19 vaccination.

2.3 Study sites and duration

Multiple sentinel sites were selected purposively from across Malaysia for any COVID-19 vaccines administered in Malaysia. The principle for selection was such that each vaccine had participants from different parts of Malaysia, where different vaccines were distributed and administered as feasibility allowed. Vaccine centres (PPV – Pusat Pemberian Vaksin) were selected based on the actual PICK implementation and depended on other relevant factors. Types of vaccines involved in this surveillance were Pfizer, AstraZeneca, Sinovac, and CanSino given to the adult population. Meanwhile, the adolescent population was given the Pfizer vaccine. The type of vaccines and states/territories selected for this surveillance were as shown in Table 1 below:

Table 1 Type of vaccines and selected states or territories

TYPE OF VACCINES	SELECTED STATES OR TERRITORIES
Pfizer	Selangor Sarawak Terengganu
Sinovac	Selangor Melaka
AstraZeneca	Selangor Penang
CanSino	Selangor Kedah Sabah

The surveillance lasted from June 2021 to November 2022. Each cohort participants were followed up for six to seven times in one year, from and inclusive of the initial/first dose of vaccination. The gap between the first and second dose was as determined by the JKJAV to be three weeks for all two-dose vaccines, except AstraZeneca (1). The same principle was applied for definition of the day vaccination was considered complete, which was defined as 14 days after the second dose for two-dose vaccines and 28 days after the only dose for single dose vaccine (2, 3). The general adult population was recruited since June 2021 while the adolescents were recruited starting from September 2021. The follow up schedule is detailed out in Table 2.

Table 2 Participant follow up schedule

TIME POINT / VACCINE	1ST DOSE	2ND DOSE	DAYS SINCE LAST DOSE		MONTHS SINCE 1ST DOSE			
			14	28	3	6	9	12
Two-dose	X	X	X		X*	X	X	X
Single dose	X		X	X	X	X	X	X

*Not applicable to AstraZeneca (9-week gap between doses as compared to 3-week gap for other two-dose vaccines), as follow up for 14 days since the last dose approximated the 3-month follow up.

2.4 Sample size

The sample size calculation was carried out separately for the primary and secondary objectives. The seropositive rate of anti-SARS-CoV-2 antibody in the primary objective is a proportion and descriptive in nature. The single proportion sample size formula is given by:

$$n \geq \frac{z_{\frac{\alpha}{2}}^2 P(1-P)}{d^2}, \text{ where}$$

α = type I error
Z = critical value for two tails of α (1.96 for 95% CI)
P = the proportion estimate
d = acceptable margin of error (absolute precision)

The expected seropositive rate of anti-SARS-CoV-2 antibody after a year of vaccination was expected to be at 95% as the pandemic progresses. This was used to calculate the sample size as it would yield the highest number. The minimal sample size required to achieve 50% relative precision around 95% seropositive rate was 292 participants. By taking into consideration a 50% attrition rate, the target sample size would be at least 600 (584 rounded up to the nearest hundred) for each vaccine-cohort arm. Therefore, the total target sample size for four adult vaccine-cohort arms was 2400, and for the whole study – 3000.

For the secondary objective, the sample size calculator to estimate a single mean for cell response was used (available from http://statulator.com/SampleSize/ss1M.html) (4). By assuming the expected population standard deviation of spot forming cells to be 1000 cells/million peripheral blood mononuclear cells (PBMCs) (5) and employing t-distribution to estimate the sample size, a sample size of 19 was required to estimate a mean with 95% confidence and a precision of 500 cells/million PBMCs. By taking into consideration a 35% attrition rate due to smaller cohort in Klang Valley that made follow up easier, the target sample size for this secondary objective would be 30 (rounded up to the closest ten from 29) for each vaccine-cohort arm. Therefore, the total target sample size for four adult vaccine-cohort arms was 120, or 150 inclusive of the adolescents.

2.5 Study tools and variables

Laboratory tests and structured questionnaires (Annex A) were used to collect data based on the surveillance scopes. There were eight sets of questionnaires used at different time points including baseline, second dose, completed vaccination (14 days after two-dose and 28 days for single dose), 3 months, 6 months, 9 months, and 12 months follow up. These questionnaires were answered by the participants via face-to-face interview. AEFI and AESI modules were completed as self-administrative questionnaires (SAQ). The questions were bilingual, namely Bahasa Malaysia and English. The study variables were shown in Table 3 and Table 4 below:

Table 3 Exposure variables

VARIABLE (AT BASELINE)	TYPE
Vaccine type	Categorical
Vaccine date	String
Age	Continuous
Sex / Ethnicity / Nationality	Categorical
Comorbidity status	Categorical
COVID-19 history (symptom, close contact, infection, booster)	Categorical
Lifestyle (smoking, BMI)	Categorical/ Continuous

Table 4 Outcome variables

OBJECTIVE	VARIABLE	FREQUENCY OF MEASUREMENT
To determine the seropositive rate and antibody level	Humoral immunity test: IgG antibody level[1] against SARS-CoV-2 spike[2] and nucleocapsid[3] proteins	At baseline prior to the 1st dose, prior to the 2nd dose (if any), completed vaccination (14 days after two-dose vaccines and 28 days after single dose vaccine), 3-, 6-, 9- and 12-months from the baseline
	Seropositive rate of IgG against SARS-CoV-2 spike and nucleocapsid proteins	

OBJECTIVE	VARIABLE	FREQUENCY OF MEASUREMENT
To estimate the incidence of adverse events following immunization (AEFI)[4] and adverse events of special interest (AESI)	AEFI/AESI history as captured by the National Pharmaceutical Regulatory Agency (NPRA)	Prior to 2nd dose if any (for events after the 1st dose), 14 days after completed vaccination (for events after any 2nd dose), 6-, 9- and 12-months (for events after any booster dose)
To determine the positive rate and T-cell reactivity	Humoral immunity test: Positive rate and antibody level of salivary IgA against SARS-CoV-2 spike protein	At baseline prior to the 1st dose, prior to the 2nd dose (if any), completed vaccination (14 days after two-dose vaccines and 28 days after single dose vaccine), 3-, 6-, 9- and 12-months from the baseline
	Cellular immunity test: T-cell reactivity	

[1] In index, an arbitrary unit set by the manufacturers.
[2] Anti-spike antibody can be produced either after infection or vaccination.
[3] Anti-nucleocapsid antibody can be produced after infection or Sinovac vaccination.
[4] Any outward medical occurrence following vaccination, which may not be causally related to vaccine.

2.6 Field data collection

Participants in this cohort were recruited after they consented for vaccination and were screened for vaccination eligibility criteria. Additional eligibility criteria unique to this study was screened before the participant was recruited by the researcher. A written consent was sought together with the vaccination consent (Annex B). For adolescents and children aged <18 years old, an additional assent was taken where possible.

Prior to the blood collection, the exposure variables were captured using a structured questionnaire in a mobile tablet or in printed form. Sensitive variables were captured through SAQ or through proxy for individuals who cannot self-administer.

Next, research assistants prepared the compulsory documentations and labelled all the blood tubes (Annex C). For adults, phlebotomists collected 10 ml of blood in a gel with clot activator tube for immunoglobulin G (IgG) test. In order to achieve the secondary objectives, phlebotomists collected an additional 15 ml of blood in a heparin tube for T-cell reactivity test and 5 ml of saliva in a vial for immunoglobulin A (IgA) test.

The amount of blood taken for adolescents was according to the body weight and less than 1% of total blood volume (6). Meanwhile, the blood volume sampled for IgG assessment from the underaged participants with 20-29.9 kg, 30-39.9 kg and >40 kg weight were 4.0 ml, 6.0 ml and 8.0 ml. Additionally, the blood volume sampled for T-cell reactivity assessment from the underaged participants with 20-29.9 kg, 30-39.9 kg and >40 kg weight were 8.0 ml, 12.0 ml and 16.0 ml.

The heparin blood tubes and saliva samples collected were immediately chilled at 2-8 °C in a portable chiller, while the gel with clot activator tubes were left at room temperature for 30 minutes to form clot, after which they were centrifuged, processed and cryopreserved. The heparin blood tubes and saliva samples were sent to the Institute for Medical Research (IMR) once the target sample size was achieved on the day of data collection. Also, the gel with clot activator tubes were sent to IMR at the end of the day for field sites located nearer to the laboratory, or at the end of the field data collection (or on every third day if data collection was longer than three days) to be processed by the research assistants. The field data collection procedure was described as shown in Figure 1.

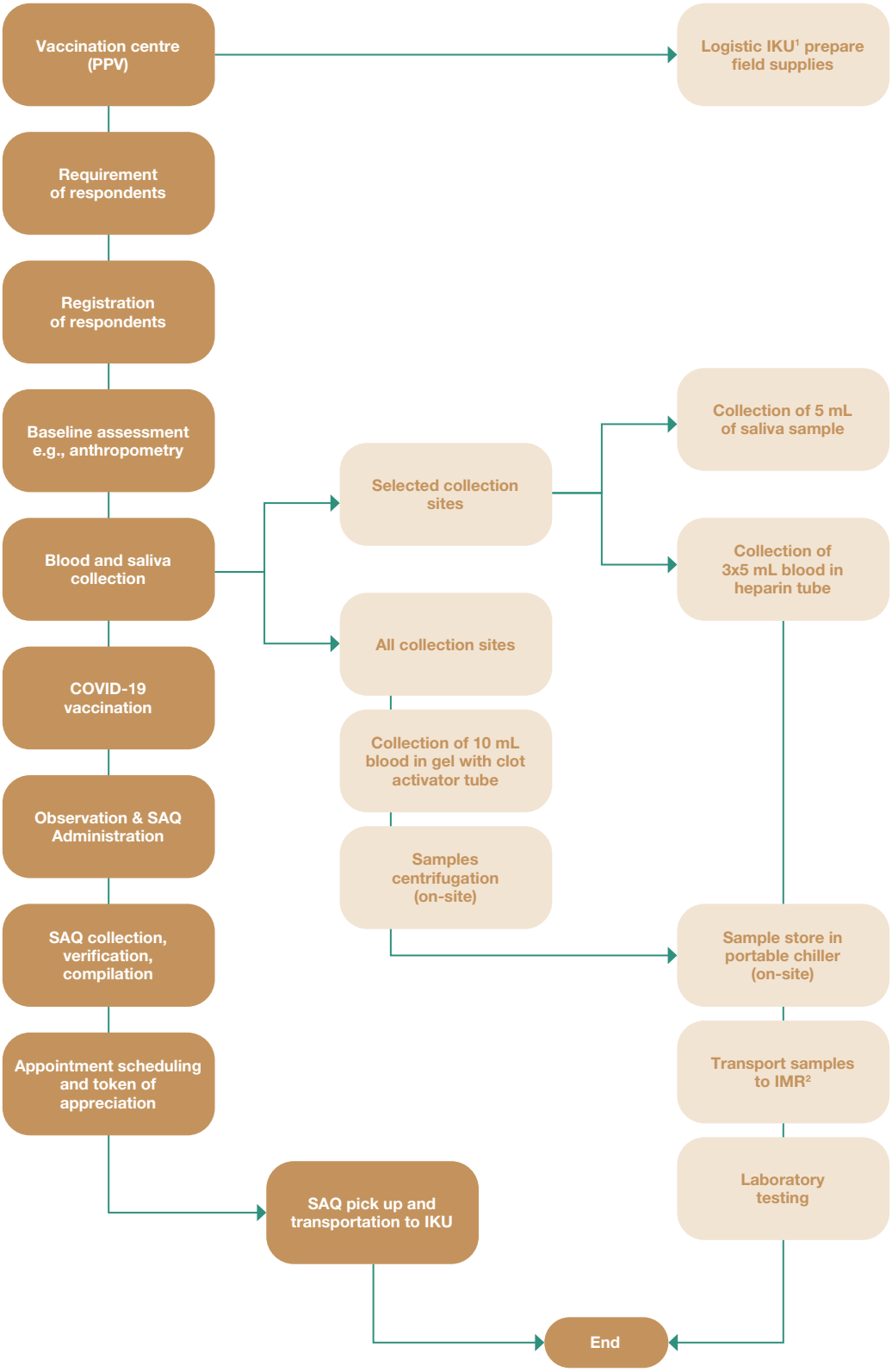


Figure 1 Flow chart of field data collection throughout the 12 months follow up of COVID-19 vaccines recipients

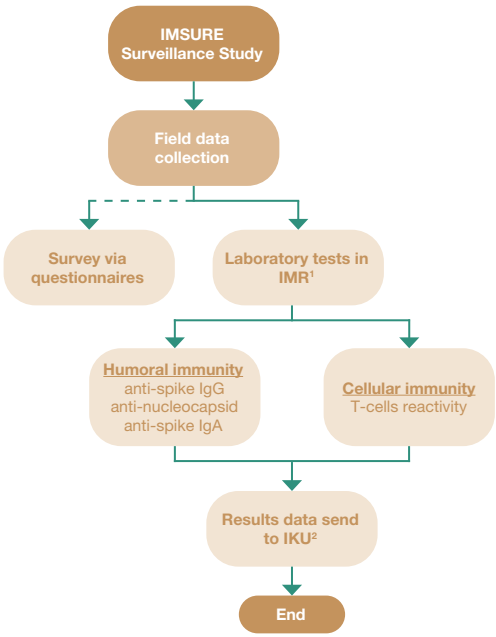
Table 5 shows the summary of the data that was collected throughout the 1-year follow up. All participants were contacted for every follow up, even if they missed any previous follow ups. For each subsequent follow up after the completion of vaccination, the participants were allowed to come within a range of ±5 days (except follow up for completed dose, where they can only come later but not earlier) from the actual date of follow up. However, if they could not make it within the given time due to delay in vaccination date, COVID-19 diagnosis, quarantine for close contact or positive COVID-19 etc., deviation from the above time range was considered on a case-by-case basis. In the case of loss to follow up or withdrawal, there was no replacement made.

Table 5 Plan of data collection

	TIME POINT	DOSE		DAYS SINCE LAST DOSE		MONTHS SINCE 1ST DOSE			
	Data Collected	1st	2nd (if any)	14 (for two-dose vaccine)	28 (for single dose vaccine)	3	6	9	12
	Consent	x							
Questionnaire	Sociodemography/ COVID-19 history + vaccination	x							
Questionnaire	Anthropometry/ Comorbidity/ Lifestyle factors	x							
Questionnaire	Adverse events following immunization and adverse events of special interest		x	x			x	x	x
Questionnaire	COVID-19 diagnosis and severity					x	x	x	x
Questionnaire	Booster						x	x	x
Specimen	Serum antibodies	x	x	x	x	x	x	x	x
Specimen	Salivary antibodies + T-cell reactivity (1 site in Klang Valley only)	x	x	x	x	x	x	x	x

2.7 Laboratory tests

In this cohort, the laboratory tests involved both humoral and cellular immunity (Figure 2). All tests were performed in the IMR. We assessed the humoral immunity by examining the blood serum to detect IgG antibodies against spike and nucleocapsid proteins of SARS-CoV-2 post vaccination. Moreover, we assessed the humoral immunity through detection of salivary IgA against SARS-CoV-2 spike S1 protein post vaccination. In addition, we assessed the cellular immunity by evaluating the T-cell reactivity via the measurement of cytokines, in particular, IFN-ɣ .



¹ IMR, Institute for Medical Research
² IKU, Institute for Public Health

Figure 2 Flow chart of laboratory sample management

2.7.1 Humoral immunity testing

2.7.1.1 Anti-spike Immunoglobulin G (IgG)

Anti-Spike IgG antibodies towards SARS-CoV-2 in plasma were identified by ADVIA Centaur® SARS-CoV-2 IgG (sCOVG) assay using the ADVIA Centaur XP Immunoassay Systems (Siemens Healthcare Diagnostic, NY, USA). Briefly, 40 µL of sample and 160 µL of diluent were dispensed into the cuvette. Then, 10 µL of the diluted sample was removed and dispensed into the second cuvette. Subsequently, 100 µL of Solid Phase containing a performed complex of streptavidin-coated microparticles and biotinylated SARS-CoV-2 recombinant antigens, as well as 100 µL of Ancillary Well Reagent were dispensed into the second cuvette and incubated for 18 minutes at 37°C. Washing was performed using ADVIA Centaur Wash 1. After washing, 100 µL of Lite Reagent consisting of an acridinium-ester-labelled anti-human IgG mouse monoclonal antibody was dispensed into the cuvette and incubated for 18 minutes at 37°C. The washing step was repeated. Finally, 300 µL each of ADVIA Centaur Acid Reagent and ADVIA Centaur Base Reagent was dispensed into each cuvette to initiate the chemiluminescent reaction. A direct relationship existed between the amount of SARS-CoV-2 IgG antibody present in the plasma and the amount of relative light units (RLUs) detected by the system. The results were reported in the form of a cut-off index (COI), with <1.00 index interpreted as non-reactive for anti-SARS-CoV-2 S antibodies and ≥1.00 index interpreted as reactive for anti-SARS-CoV-2 S antibodies as per manufacturer recommendations. Numeric results were reported for samples with value between 1.00 and 100.00 Index.

2.7.1.2 Anti-nucleocapsid Immunoglobulin G (IgG)

Qualitative detection of IgG nucleocapsid (D1, D2, D3, D4, D5 and D6) were measured by an electrochemiluminescence immunoassay (ECLIA) antigen test, Roche Elecsys Anti-SARS-CoV-2 assay. Briefly, 150 µL of serum samples were mixed with biotinylated SARS-CoV-2-specific recombinant antigen and SARS-CoV-2-specific recombinant antigen labelled with a ruthenium complex to form a sandwich complex. Next, streptavidin-coated microparticles were added to the complex. The reaction mixture was aspirated into the measuring cell where the microparticles were magnetically captured onto the surface of the electrode. ProCell was used to remove the unbound substances. Voltage was applied to the electrode to induce the chemiluminescent emission and a photomultiplier was used to measure the emission. The assay test was performed using cobas e 411 analyser with testing time of 18 minutes. The results were reported in the form of COI, with <1.00 index interpreted as non-reactive for anti-SARS-CoV-2 N antibodies and ≥1.00 index interpreted as reactive for anti-SARS-CoV-2 N antibodies as per manufacturer recommendations.

2.7.1.3 Anti-spike Immunoglobulin A (IgA)

Immunoglobulin A against SARS-CoV-2 spike protein (S1) in saliva was identified by an enzyme-linked immunosorbent assay (ELISA) test using a well plate coated with recombinant S protein antigen (Euroimmun Medizinische Laboradiagnostika, Lübeck, Germany). Approximately, 100 µL of positive and negative controls, calibrator, and diluted samples (1:2 dilutions) were transferred into the well and incubated for 60 minutes at +37°C ± 1°C. The sample was run in duplicate. Automatic washing was done by using TECAN HydroFlex. Reagent wells were washed 3 times with 450 µL of working-strength wash buffer. After washing, 100 µL of enzyme conjugate (peroxidase-labelled anti-human IgA) was pipetted into each of the microplate well and incubated for 30 minutes at +37°C ± 1°C. The washing step was repeated. Then, 100 µL of chromogen/substrate solution was pipetted into each microplate well and incubated in the dark for 30 minutes at room temperature. Finally, 100 µL of stop solution was pipetted into each microplate well, developing a colorimetric reaction. Photometric measurement of the colour intensity was made at a wavelength of 450 nm and a reference wavelength between 620 nm and 650 nm, within 30 minutes of adding the stop solution. The optical density was proportional to the quantity of the specific anti-SARS-CoV-2 IgA antibody present in the samples. The results were calculated semi-quantitatively by a ratio of the extinction of the control or subject sample over the extinction of the calibrator. The salivary IgA was considered negative for all the values <0.8 COI, borderline between 0.8 and 1.1 COI and positive >1.1 COI, as declared by the manufacturer.

2.7.2 Cellular immunity testing

2.7.2.1 T-cell reactivity

The interferon-gamma (IFN-ɣ) enzyme-linked immunospot (ELISpot) secreted cells were measured using human IFN-ɣ SARS-CoV-2 kit according to manufacturer (Mabtech AB, Sweden). The cryopreserved PBMCs were thawed and washed twice in 10 mL of completed RPMI-1640 (Sigma-Aldrich, USA) that was supplemented with 10% fetal bovine serum (FBS) (Sigma-Aldrich, USA) and 1% antibiotic-antimycotic (Gibco, USA) at 300 x g for 10 minutes and rested for 22 to 24 hours at 37°C in 5% CO_2 humidified incubator. The resting PBMCs were removed from the cell culture flask and washed with the same medium used for cell resting. The cells were resuspended in 500 µL of medium and counted using an automated cellometer (Cellometer K2, Nexcelom Bioscience, USA). The pre-coated plates with monoclonal anti-IFN-ɣ (mAb 1-D1K) were washed four times in 200 µl/well of sterile phosphate-buffered saline (PBS) (Sigma-Aldrich, USA) before conditioning with the medium (200 µl/well). The conditioned plate was incubated for at least 30 minutes at room temperature.

The peptides for the S1 scanning pool and SNMO-defined pool were reconstituted with 40 µl of dimethyl sulfoxide (DMSO) and 85 µl of PBS, making the final concentration of 2 µg/mL. The SARS-CoV-2 S1 scanning pool contained 166 peptides from the human SARS-CoV-2 virus (3629-1; Mabtech AB, Sweden). The peptides were 15-mers overlapping with 11 amino acids, covering the S1 domain of the S protein (amino acids 13–685). The S1 pool was supplied as S1_1 (1–83) and S1_2 (84–166) peptides. In addition, the SARS-CoV-2 SNMO-defined pool contained 47 synthetic peptides from the human SARS-CoV-2 virus, derived from the spike (S), nucleoprotein (N), membrane protein (M), open reading frame (ORF)-3a, and ORF7a proteins (3622-1; Mabtech AB, Sweden) (7).

The plates were incubated with 2.5 x 10^5 PBMCs per well in duplicate with mixed peptide pools, as well as anti-CD28 as a co-stimulator for 18 hours. Negative control consisted of media and PBMCs whilst positive control consisted of both anti-CD3 and anti-CD28. The plates were washed five times before incubation for 2 hours with anti-human IFN-ɣ biotinylated (100 µl/well). Then, the plates were washed five times and incubated with Streptavidin-ALP for 1 hour. Subsequently, a substrate solution (BCIP/NBT-plus) was added until distinct spots emerged and washed under running tap water to stop colour development. The substrate used was filtered upon using.

The results of the ELISpot assays were evaluated using an IRIS reader and analysed using IRIS software version 1.1.9 (Mabtech AB, Sweden). Spots in each sample were converted into the number of spots per million cells and considered reactive for IFN-ɣ if the average spot in both wells had values of more than 33 spot forming units (SFU)/10^6 cells. The cut-off value for reactivity scores was obtained from the mathematical approach's formula mean ± 2 SD (8) and calculated from unstimulated wells. The positive control measurement must be at least 3-fold higher than the SARS-CoV-2 peptide pool responses.

2.8 Data management and analysis

2.8.1 Data quality and confidentiality

Individual data was strictly confidential at all stages of the surveillance. The field supervisor or team leader verified the data on-site and uploaded the complete interview to the IKU Survey Creation System (SCS) server. Critical variables such as the participant's ID were compared to the study frame's in-list and further verified to ensure the participants had answered all questions. In addition, the data team also verified the completeness, accuracy and validity of the information captured. The data team used the descriptive statistics to examine the distribution and frequencies of the data, besides to identify outliers, inliers and incorrect data. All data discrepancies were validated and clarified by the field supervisors or team leaders when needed. Data cleaning was carried out according to the terms and working definitions developed. The cleaned data was securely stored and backup was regularly performed to ensure that data remained current.

2.8.2 Laboratory results management

The laboratory tests that were conducted used the laboratory serial number and participants' barcode as an identifier. The data manager pre-cleaned and merged all datasets before the hardcopy of laboratory results were released to the participants during the next follow up. Some results were sent to the participants by courier upon request.

2.8.3 Data analysis

Descriptive and subgroup analyses were performed using the SPSS version 23.0.

2.9 Ethical approval

This study was registered with the National Medical Research Registry (NMRR) and obtained approval from the Medical Research and Ethics Committee (MREC), Ministry of Health, Malaysia with the registration number NMRR-21-411-58817 (IIR).

References

1. Ministry of Health, Malaysia. (2021, October). Clinical guidelines on COVID-19 vaccination in Malaysia. (2021, October). Retrieved from https://covid-19.moh.gov.my/garis-panduan/garis-panduan kkm/ANNEX_48_CLINICAL_GUIDELINES_FOR_COVID_IN_MALAYSIA_4th_EDITION_19102021_FINALE.pdf
2. MySejahtera Unit, Ministry of Health, Malaysia. (2022). Latest COVID-19 vaccination policy. Retrieved from https://mysejahtera.moh.gov.my/en/covid-19/latest-malaysia-covid-19-vaccination-policy
3. World Health Organization. (2022, May 19). Interim recommendations for use of the CanSino Ad5-nCoV-S vaccine (Convidecia®) against COVID-19. Retrieved from https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad5-nCoV-Convidecia
4. Dhand, N. K., & Khatkar, M. S. (2014). Statulator: An online statistical calculator. Sample size calculator for estimating a single mean. Available from http://statulator.com/SampleSize/ss1M.html
5. Ramasamy, M. N., Minassian, A. M., Ewer, K. J., Flaxman, A. L., Folegatti, P. M., Owens, D. R., Voysey, M., Aley, P. K., Angus, B., Babbage, G., Belij-Rammerstorfer, S., Berry, L., Bibi, S., Bittaye, M., Cathie, K., Chappell, H., Charlton, S., Cicconi, P., Clutterbuck, E. A., Colin-Jones, R., …. (2020). Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): a single-blind, randomised, controlled, phase 2/3 trial. The Lancet, 396(10267), 1979–1993. https://doi.org/10.1016/S0140-6736(20)32466-1
6. Howie, S. R. (2011). Blood sample volumes in child health research: review of safe limits. Bulletin World Health Organization, 89(1), 46–53. https://doi.org/10.2471/BLT.10.080010
7. Peng, Y., Mentzer, A. J., Liu, G., Yao, X., Yin, Z., Dong, D., Dejnirattisai, W., Rostron, T., Supasa, P., Liu, C., López-Camacho, C., Slon-Campos, J., Zhao, Y., Stuart, D. I., Paesen, G. C., Grimes, J. M., Antson, A. A., Bayfield, O.

W., Hawkins, D. E. D. P., Ker, D. S., … Dong, T. (2020). Broad and strong memory CD4⁺ and CD8⁺ T cells induced by SARS-CoV-2 in UK convalescent individuals following COVID-19. Nature Immunology, 21(11), 1336–1345. https://doi.org/10.1038/s41590-020-0782-6

8. Dunstan, D. A., & Scott, N. (2019). Clarification of the cut-off score for Zung's self-rating depression scale. BMC Psychiatry, 19(1), 177. https://doi.org/10.1186/s12888-019-2161-0

GENERAL FINDINGS

3.0 GENERAL FINDINGS

3.1 MODULE A: HUMORAL IMMUNITY

3.1.1 Sociodemography, COVID-19 infection and lifestyle of recipients at baseline based on vaccine type

A total of 612 Pfizer, 608 Sinovac, 617 AstraZeneca, 676 CanSino and 153 Pfizer (Adolescent) vaccine recipients were recruited in this cohort with a mean age (SD) of 43.61±19.71, 37.18±12.52, 33.42±10.66, 36.93±11.50 and 14.2±1.67 (Table 6). Majority of the recipients were under the age group of 18-39 years old ranging from 53.8% among Pfizer recipients to 71.6% among AstraZeneca recipients. The majority of them were male ranging 52.5% from Pfizer to 55.6% from Pfizer Adolescents / Pfizer (A), except for AstraZeneca recipients. Almost all of Pfizer, Sinovac and AstraZeneca recipients came from Malay ethnic groups given that they were Malaysians with 99.3%, 98.5% and 99.2%, respectively. Meanwhile, the majority of CanSino and Pfizer (A) recipients consisted of non-Malaysians with 51.3% and 67.3%, respectively. The recruitment of recipients for all vaccines occurred mainly across Selangor. The other states involved in the recruitment were Terengganu and Sarawak for Pfizer recipients, Melaka for Sinovac recipients, Penang for AstraZeneca recipients, as well as Kedah and Sabah for CanSino recipients. Recipients reported having no comorbidity ranged from 60.8% among Pfizer to 90.8% among Pfizer (A), while the rest of them had at least one and two or more comorbidities.

The majority of recipients indicated no prior history of COVID-19 infections but were shown to manifest past COVID-19 symptoms ranging from 50.7% in Sinovac to 84.4% in AstraZeneca recipients. In fact, almost all vaccine recipients had no close contact with the infected COVID-19 individuals previously. As for smoking status, current smokers were seen the highest among CanSino recipients (42.5%) as compared to Pfizer (A) recipients (0.7%). According to the BMI profile, the most prevalent recipients under the overweight category were from Pfizer with 32.8%, followed by AstraZeneca (30.8%), Sinovac (28.5%), CanSino (28.1%) and Pfizer (A) (16.3%). Meanwhile under obese category, Sinovac recipients were the highest with 38.1%, followed by AstraZeneca (23.7%), Pfizer (19.1%), CanSino (17.5%) and Pfizer (A) (13.1%).

Table 6 Sociodemography, COVID-19 infection and lifestyle of recipients at baseline based on vaccine type

CHARACTERISTICS	ADULTS				ADOLESCENTS
	PFIZER n (%)	SINOVAC n (%)	ASTRAZENECA n (%)	CANSINO n (%)	PFIZER n (%)
Overall Participants	**612 (100.0)**	**608 (100.0)**	**617 (100.0)**	**676 (100.0)**	**153 (100.0)**
Age					
Mean age, SD	43.61 (19.71)	37.18 (12.52)	33.42 (10.66)	36.93 (11.50)	14.20 (1.67)
Median age (25, 75 percentiles)	37 (26, 68)	36 (27, 46)	32 (25, 41)	36 (28, 44)	14 (13, 15)
Below 18 years old	-	-	-	-	153 (100.0)
18-39 years old	329 (53.8)	344 (56.6)	442 (71.6)	418 (61.8)	-
40-59 years old	92 (15.0)	235 (38.7)	168 (27.2)	232 (34.3)	-
60 years old and above	191 (31.2)	29 (4.8)	7 (1.1)	26 (3.8)	-
Sex					
Male	321 (52.5)	320 (52.6)	276 (44.7)	359 (53.1)	85 (55.6)
Female	291 (47.5)	288 (47.4)	341 (55.3)	317 (46.9)	68 (44.4)
Ethnicity					
Malay	424 (69.3)	480 (78.9)	422 (68.4)	275 (40.7)	47 (30.7)
Chinese	82 (13.4)	70 (11.5)	145 (23.5)	1 (0.1)	1 (0.4)
Indian	64 (10.5)	39 (6.4)	41 (6.6)	0	2 (1.3)
Bumiputera Sabah & Sarawak	34 (5.6)	10 (1.6)	6 (1.0)	54 (8.0)	0
Others	8 (1.3)	9 (1.5)	3 (0.5)	346 (51.2)	103 (67.3)

CHARACTERISTICS	ADULTS				ADOLESCENTS
	PFIZER n (%)	SINOVAC n (%)	ASTRAZENECA n (%)	CANSINO n (%)	PFIZER n (%)
Nationality					
Malaysian	608 (99.3)	599 (98.5)	612 (99.2)	329 (48.7)	50 (32.7)
Non-Malaysian	4 (0.7)	9 (1.5)	5 (0.8)	347 (51.3)	103 (67.3)
Location					
Kedah	-	-	-	272 (40.2)	-
Melaka	-	212 (34.9)	-	-	-
Penang	-	-	279 (45.2)	-	-
Sabah	-	-	-	125 (18.5)	-
Sarawak	167 (27.3)	-	-	-	-
Selangor	230 (37.6)	396 (65.1)	338 (54.8)	279 (41.3)	153 (100.0)
Terengganu	215 (35.1)	-	-	-	-
Comorbidity status					
No comorbid	372 (60.8)	349 (57.4)	506 (82.0)	550 (81.4)	139 (90.8)
Any 1 comorbidity	119 (19.4)	129 (21.2)	82 (13.3)	91 (13.5)	14 (9.2)
2 or more comorbidities	121 (19.8)	130 (21.4)	29 (4.7)	35 (5.2)	0
Past COVID-19 infection					
Yes	16 (2.6)	34 (5.6)	20 (3.2)	30 (4.4)	9 (5.9)
No	596 (97.4)	574 (94.4)	597 (96.8)	646 (95.6)	144 (94.1)
Past COVID-19 symptoms					
Asymptomatic	207 (33.8)	300 (49.3)	96 (15.6)	230 (34.0)	53 (34.6)
Symptomatic	405 (66.2)	308 (50.7)	521 (84.4)	446 (66.0)	100 (65.4)
Past COVID-19 close contact					
Yes	57 (9.3)	90 (14.8)	97 (15.7)	45 (6.7)	22 (14.4)
No	555 (90.7)	518 (85.2)	520 (84.3)	631 (93.3)	131 (85.6)
Smoking status					
Not smoking	412 (67.3)	423 (69.6)	482 (78.1)	363 (53.7)	148 (96.7)
Past smoker	38 (6.2)	41 (6.7)	37 (6.0)	26 (3.8)	4 (2.6)
Current smoker	162 (26.5)	144 (23.7)	98 (15.9)	287 (42.5)	1 (0.7)
BMI by WHO 1998					
Underweight	42 (6.9)	33 (5.4)	39 (6.3)	68 (10.1)	13 (8.5)
Normal	252 (41.2)	170 (28.0)	241 (39.1)	300 (44.4)	95 (62.1)
Overweight	201 (32.8)	173 (28.5)	190 (30.8)	190 (28.1)	25 (16.3)
Obese	117 (19.1)	231 (38.1)	146 (23.7)	118 (17.5)	20 (13.1)

At 6 months follow up from baseline, additional booster shots (1 dose or 2 doses) for all COVID-19 vaccines were administered to the recipients involved in this cohort (Table 7). Most of CanSino (83.8%) and Pfizer (A) (68.0%) did not receive booster shot, unlike the majority of Pfizer, Sinovac and AstraZeneca recipients that received at least one booster dose with 53.8%, 83.6% and 68.7%, respectively. Subsequently, only two individuals among Pfizer and AstraZeneca recipients had received the second booster dose after.

Table 7 COVID-19 booster status of recipients based on vaccine type

CHARACTERISTICS	ADULTS				ADOLESCENTS
COVID-19 BOOSTER STATUS	PFIZER n (%)	SINOVAC n (%)	ASTRAZENECA n (%)	CANSINO n (%)	PFIZER n (%)
No booster	169 (45.7)	64 (16.4)	131 (30.8)	259 (83.8)	104 (68.0)
1 dose	199 (53.8)	327 (83.6)	292 (68.7)	50 (16.2)	1 (0.7)
2 doses	2 (0.5)	0	2 (0.5)	0	0

3.1.2 COVID-19 vaccination, recruitment and follow up

This cohort study followed up recipients up to 12 months; before the first dose, before the second dose or 14 days after single dose, completed vaccination (14 days after two doses and 28 days after single dose), 3 months, 6 months, 9 months and 12 months from baseline (Table 8).

Baseline

At baseline, a total of 2,513 adult recipients were recruited between 17th June 2021 to 30th September 2021 comprising 612 Pfizer recipients, 608 Sinovac recipients, 617 AstraZeneca recipients, 676 CanSino recipients. A total of 153 Pfizer (A) recipients were recruited between 24th September to 29th November 2021.

Before the second dose or 14 days after the first dose

At 14 days after the first dose, a total of 2,257 adult recipients were followed with an overall retention rate of 89.8%. At this time, retention rate was found highest among Pfizer recipients 94.3%, followed by Sinovac (91.3%), AstraZeneca (91.2%) and CanSino 83.1%. The retention rate of Pfizer adolescents was 93.5% (143 recipients).

Completed vaccination: 14 days after two doses or 28 days after single dose

Upon completed vaccination of two doses or 28 days after the single dose, approximately 1,922 adult recipients were followed with an overall retention rate of 76.5%. The retention rate was the highest among Pfizer recipients (82.8%), followed by Sinovac recipients (80.1%), AstraZeneca recipients (78.8%) and CanSino recipients (65.4%). The retention rate among Pfizer (A) adolescents was 81.0% (124 recipients).

3 months follow up

At 3 months from baseline, about 1,228 adult recipients were followed up with an overall retention rate of 48.9%. The retention rate was seen the highest among Pfizer recipients (72.1%), followed by Sinovac (68.9%) and CanSino (54.4%). There was no follow up for AstraZeneca at this time point. The retention rate of Pfizer adolescents was 71.9% (110 recipients). All groups showed a decline pattern in the retention rate pattern from the first dose.

6 months follow up

The follow up at 6 months from baseline was conducted among 1,396 recipients with an overall retention rate of 55.6%. The retention rate was highest among AstraZeneca recipients (63.9%), followed by Sinovac (62.5%), Pfizer (57.5%) and CanSino (39.9%). The retention rate of Pfizer (A) was 64.1% (98 recipients). For those who turned up, booster dose was reported among 63.4% of Sinovac recipients, followed by Pfizer (31.0%), AstraZeneca (27.7%) and CanSino (13.3%). No adolescent received a booster shot.

9 months follow up

At 9 months from baseline, about 1,193 adult recipients were followed up with an overall retention rate of 47.5%. The retention rate was highest among AstraZeneca recipients (54.3%), followed by Sinovac (52.6%), Pfizer (49.3%), CanSino (34.9%). The retention rate of Pfizer (A) was 58.8% (90 adolescents). Around 88.4% of Sinovac recipients present reported having at least one booster dose, followed by AstraZeneca (78.5%), Pfizer (62.3%) and CanSino (14.0%). There was one adolescent who reported the same.

12 months follow up

At 12 months from baseline, approximately 1,118 adult recipients were followed with an overall retention rate of 44.5%. The retention rate was seen highest among AstraZeneca recipients (51.2%), followed by Sinovac (50.7%), Pfizer (45.3%) and CanSino (32.1%). The retention rate of Pfizer (A) was 47.1% (72 adolescents). Booster status was reported the highest among Sinovac (87.3%), followed by AstraZeneca (76.9%), Pfizer (63.9%) and CanSino (16.6%). No adolescent present at this time point reported a booster dose.

Table 8 COVID-19 vaccination, recruitment and follow up

RECRUITMENT DATE		ADULTS					ADOLESCENTS
		OVERALL ADULTS (n=2513)	PFIZER (n=612)	SINOVAC (n=608)	ASTRAZENECA (n=617)	CANSINO* (n=676)	PFIZER (n=153)
Baseline (Before first dose)	Start date	17 June 2021	17 June 2021	12 July 2021	5 July 2021	5 Sep 2021	24 Sep 2021
	End date	30 Sep 2021	6 Sep 2021	30 July 2021	6 Aug 2021	30 Sep 2021	29 Nov 2021
	Recipient, n	2513	612	608	617	676	153
Second dose / *14 days after single dose	Start date	8 July 2021	8 July 2021	2 Aug 2021	6 Sep 2021	20 Sep 2021	14 Oct 2021
	End date	14 Oct 2021	4 Oct 2021	25 Aug 2021	8 Oct 2021	14 Oct 2021	27 Dec 2021
	Recipient, n	2257	577	555	563	562	143
	Mean (SD) duration from baseline, days	29.9 (19.4)	21.3 (2.0)	21.2 (1.5)	63.0 (0.2)	14.2 (0.7)	26.5 (3.3)
	Retention rate (%)	89.8	94.3	91.3	91.2	83.1	93.5
Completed vaccination (14 days after two-dose/*28 days after single dose)	Start date	22 July 2021	22 July 2021	16 Aug 2021	20 Sep 2021	4 Oct 2021	29 Oct 2021
	End date	28 Oct 2021	18 Oct 2021	9 Sep 2021	22 Oct 2021	28 Oct 2021	10 Jan 2022
	Recipient, n	1922	507	487	486	442	124
	Mean (SD) duration from baseline (days)	44.7 (19.5)	36.1 (2.9)	36.0 (2.8)	77.6 (1.3)	28.2 (0.8)	41.3 (3.1)
	Retention rate (%)	76.5	82.8	80.1	78.8	65.4	81.0
3 months	Start date	17 Sep 2021	17 Sep 2021	8 Oct 2021	N A	6 Dec 2021	24 Dec 2021
	End date	10 Jan 2022	11 Dec 2021	9 Nov 2021		10 Jan 2022	28 Feb 2022
	Recipient, n	1228	441	419		368	110
	Mean (SD) duration from baseline (days)	92.5 (3.8)	93.4 (5.5)	92.1 (2.3)		91.8 (2.3)	92.8 (2.4)
	Retention rate (%)	48.9	72.1	68.9		54.4	71.9
6 months	Start date	17 Dec 2021	17 Dec 2021	10 Jan 2022	3 Jan 2022	7 Mar 2022	4 Apr 2022
	End date	8 Apr 2022	7 Mar 2022	4 Feb 2022	12 Feb 2022	8 Apr 2022	30 May 2022
	Recipient, n	1396	352	380	394	270	98
	Mean (SD) duration from baseline (days)	185.2 (4.8)	187.1 (6.4)	182.7 (1.8)	185.7 (5.0)	185.5 (3.6)	184.5 (7.5)
	Retention rate (%)	55.6	57.5	62.5	63.9	39.9	64.1
	Booster status: n (%)	495 (35.5)	109 (31.0)	241 (63.4)	109 (27.7)	36 (13.3)	0
9 months	Start date	18 Mar 2022	18 Mar 2022	9 Sep 2022	4 Apr 2022	1 June 2022	5 July 2022
	End date	5 July 2022	10 June 2022	17 May 2022	18 May 2022	5 July 2022	25 Aug 2022
	Recipient, n	1193	302	320	335	236	90
	Mean (SD) duration from baseline (days)	275.5 (4.5)	275.3 (4.6)	273.9 (2.8)	278.3 (5.0)	273.8 (3.2)	272.8 (5.6)
	Retention rate (%)	47.5	49.3	52.6	54.3	34.9	58.8
	Booster status: n (%)	767 (64.3)	188 (62.3)	283 (88.4)	263 (78.5)	33 (14.0)	1 (1.1)
12 months	Start date	17 June 2022	17 June 2022	8 July 2022	4 July 2022	6 Sep 2022	20 Oct 2022
	End date	4 Oct 2022	5 Sep 2022	8 Aug 2022	18 Aug 2022	4 Oct 2022	29 Nov 2022
	Recipient, n	1118	277	308	316	217	72
	Mean (SD) duration from baseline (days)	365.5 (3.9)	364.1 (3.0)	365.6 (2.4)	366.2 (5.7)	366.1 (3.0)	367.0 (5.4)
	Retention rate (%)	44.5	45.3	50.7	51.2	32.1	47.1
	Booster status: n (%)	725 (64.8)	177 (63.9)	269 (87.3)	243 (76.9)	36 (16.6)	0

3.1.3 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of Pfizer, Sinovac, AstraZeneca, CanSino and Pfizer (Adolescent) recipients by follow up

SARS-CoV-2 anti-spike IgG can be detected following COVID-19 vaccination and/or infection.

At baseline, the seropositive rate was different among Pfizer, Sinovac, AstraZeneca and CanSino recipients at 8.2%, 15.5%, 7.5% and 52.8%, respectively (Table 9, Table 10, Table 11, Table 12). After the first dose of vaccination, Pfizer and AstraZeneca seropositive rate was markedly increased as compared to Sinovac. Upon completion of vaccination, the seropositive rate and antibody level of Pfizer, Sinovac and AstraZeneca recipients were seen to peak. Meanwhile, the antibody level of CanSino recipients peaked at 14 days after the single dose vaccination, but the seropositive rate peaked later at 28 days after the vaccination. The seropositive rate and antibody level of Pfizer and AstraZeneca declined subsequent to the peak at completed vaccination and down to 6 months after the first dose, before increasing at 9 months. The same was observed for Sinovac and CanSino, but the increase came earlier at 6 months follow up.

As for self-reported past COVID-19 infection, the cohorts that had been previously infected generally had higher seropositive rate and/or antibody level as compared to those without, especially among Pfizer, Sinovac and AstraZeneca recipients. When stratified by booster status, the groups that received booster generally had higher antibody levels than those without a booster. This was more apparent for Pfizer at 6 months, for Sinovac and AstraZeneca at 6 and 12 months, and for CanSino recipients at 9 and 12 months follow up. The other sociodemographic subgroups including age, sex, ethnicity, nationality and comorbidity demonstrated either comparable or inconsistent differences in seropositive rate and antibody level throughout the 12 months follow up.

Approximately 37.3% (n=57) of adolescent Pfizer recipients at baseline were seropositive, but with low antibody levels of 3.7 (2.0, 8.6), respectively (Table 13). The seropositive rate increased to 100% after the first dose until the 12 months follow up. Non-Malaysians, those who reported past COVID-19 symptoms, those who had past COVID-19 close contact and those who had previous COVID-19 infection appeared to have higher seropositive rate at baseline and higher antibody level after the first dose.

Table 9 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of Pfizer recipients by follow up

VARIABLES	BASELINE (n=612)		SECOND DOSE (n=577)		COMPLETED VACCINATION (n=507)		3 MONTHS (n=441)		6 MONTHS (n=352)		9 MONTHS (n=302)		12 MONTHS (n=277)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	50 (8.2)	2.8 (1.4, 5.9)	543 (94.1)	10.4 (5.3, 23.3)	507 (100.0)	100.0 (100.0, 100.0)	440 (99.8)	50.2 (22.7, 100.0)	343 (97.4)	25.9 (7.5, 100.0)	301 (99.7)	100.0 (100.0, 100.0)	276 (99.6)	100.0 (88.6, 100.0)
Sociodemography														
Age group														
18-39 years	29 (8.8)	2.5 (1.4, 3.9)	315 (99.4)	13.1 (6.9, 25.3)	283 (100.0)	100.0 (100.0, 100.0)	252 (100.0)	57.7 (26.6, 100.0)	199 (100.0)	100.0 (14.7, 100.0)	168 (100.0)	100.0 (100.0, 100.0)	159 (99.4)	100.0 (85.0, 100.0)
40-59 years	8 (8.7)	3.7 (2.6, 10.2)	85 (95.5)	9.6 (4.7, 22.0)	82 (100.0)	100.0 (100.0, 100.0)	74 (100.0)	44.4 (23.5, 70.8)	59 (100.0)	10.3 (5.5, 100.0)	56 (100.0)	100.0 (100.0, 100.0)	46 (100.0)	100.0 (85.6, 100.0)
60 years and above	13 (6.8)	5.7 (1.4, 79.3)	143 (83.6)	6.8 (2.8, 11.6)	142 (100.0)	100.0 (100.0, 100.0)	114 (99.1)	35.2 (14.4, 100.0)	85 (90.4)	8.9 (3.6, 39.3)	77 (98.7)	100.0 (100.0, 100.0)	71 (100.0)	100.0 (100.0, 100.0)
Sex														
Male	19 (5.9)	2.5 (1.3, 2.9)	289 (95.4)	8.5 (4.4, 18.2)	262 (100.0)	100.0 (100.0, 100.0)	215 (99.5)	45.8 (23.6, 100.0)	166 (98.2)	18.4 (6.9, 100.0)	142 (99.3)	100.0 (100.0, 100.0)	131 (100.0)	100.0 (71.0, 100.0)
Female	31 (10.7)	3.8 (2.3, 10.9)	254 (92.7)	13.2 (6.6, 29.7)	245 (100.0)	100.0 (100.0, 100.0)	225 (100.0)	56.8 (22.1, 100.0)	177 (96.7)	57.1 (8.7, 100.0)	159 (100.0)	100.0 (100.0, 100.0)	145 (99.3)	100.0 (100.0, 100.0)
Ethnicity														
Malay	32 (7.5)	2.6 (1.4, 5.4)	388 (96.8)	11.3 (5.8, 23.2)	358 (100.0)	100.0 (100.0, 100.0)	314 (99.7)	48.0 (23.5, 100.0)	244 (97.2)	44.1 (9.1, 100.0)	205 (99.5)	100.0 (100.0, 100.0)	188 (99.5)	100.0 (89.9, 100.0)
Chinese	4 (4.9)	51.3 (1.4, 100.0)	64 (85.3)	6.2 (3.7, 15.5)	62 (100.0)	100.0 (100.0, 100.0)	51 (100.0)	34.4 (13.5, 93.4)	39 (95.1)	8.1 (3.8, 28.4)	37 (100.0)	100.0 (100.0, 100.0)	33 (100.0)	100.0 (50.9, 100.0)
Indian	8 (12.5)	4.7 (2.8, 13.4)	51 (85.0)	8.0 (3.2, 24.4)	49 (100.0)	100.0 (100.0, 100.0)	43 (100.0)	76.6 (32.4, 100.0)	36 (100.0)	13.6 (5.8, 100.0)	34 (100.0)	100.0 (100.0, 100.0)	31 (100.0)	100.0 (100.0, 100.0)
Bumiputera Sabah & Sarawak	5 (14.7)	2.3 (1.1, 3.4)	32 (97.0)	15.0 (5.7, 31.6)	32 (100.0)	100.0 (100.0, 100.0)	27 (100.0)	66.7 (20.0, 100.0)	21 (100.0)	100.0 (26.7, 100.0)	23 (100.0)	100.0 (74.6, 100.0)	21 (100.0)	100.0 (83.9, 100.0)
Others	1 (12.5)	-	8 (100.0)	21.8 (5.9, 34.6)	6 (100.0)	100.0 (98.4, 100.0)	5 (100.0)	63.9 (17.5, 87.2)	3 (100.0)	5.4 (3.1, -)	2 (100.0)	19.1 (10.4, -)	3 (100.0)	10.0 (4.1, -)
Nationality														
Malaysian	49 (8.1)	2.7 (1.4, 5.8)	540 (94.2)	10.3 (5.3, 23.2)	503 (100.0)	100.0 (100.0, 100.0)	437 (99.8)	49.7 (22.6, 100.0)	342 (97.4)	25.9 (7.5, 100.0)	301 (99.7)	100.0 (100.0, 100.0)	275 (99.6)	100.0 (88.3, 100.0)
Non-Malaysian	1 (25.0)	-	3 (75.0)	27.5 (9.4, -)	4 (100.0)	100.0 (100.0, 100.0)	3 (100.0)	82.9 (63.9, -)	1 (100.0)	-	N/A		1 (100.0)	-
Comorbidity status														
No comorbid	29 (7.8)	2.5 (1.3, 4.5)	346 (97.5)	12.9 (5.9, 24.5)	317 (100.0)	100.0 (100.0, 100.0)	276 (100.0)	55.1 (25.8, 100.0)	208 (98.1)	98.1 (11.6, 100.0)	187 (100.0)	100.0 (100.0, 100.0)	171 (99.4)	100.0 (79.3, 100.0)
Any 1 comorbidity	13 (10.9)	4.6 (2.6, 8.5)	103 (92.0)	9.6 (5.4, 21.6)	98 (100.0)	100.0 (100.0, 100.0)	85 (100.0)	61.1 (24.6, 100.0)	73 (98.6)	15.7 (7.6, 100.0)	60 (100.0)	100.0 (100.0, 100.0)	58 (100.0)	100.0 (90.3, 100.0)
2 or more comorbidities	8 (6.6)	3.2 (1.3, 79.1)	94 (85.5)	6.1 (3.1, 11.8)	92 (100.0)	100.0 (100.0, 100.0)	79 (98.8)	31.6 (15.1, 66.3)	62 (93.9)	7.2 (3.9, 22.3)	54 (98.2)	100.0 (100.0, 100.0)	47 (100.0)	100.0 (100.0, 100.0)

VARIABLES	BASELINE (n=612)		SECOND DOSE (n=577)		COMPLETED VACCINATION (n=507)		3 MONTHS (n=441)		6 MONTHS (n=352)		9 MONTHS (n=302)		12 MONTHS (n=277)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	22 (10.6)	2.8 (1.6, 5.3)	175 (92.1)	11.1 (5.0, 23.8)	167 (100.0)	100.0 (100.0, 100.0)	146 (100.0)	58.1 (26.2, 100.0)	117 (96.7)	100.0 (10.0, 100.0)	111 (100.0)	100.0 (100.0, 100.0)	103 (100.0)	100.0 (96.7, 100.0)
Symptomatic	28 (6.9)	2.7 (1.3, 10.4)	368 (95.1)	9.9 (5.5, 23.2)	340 (100.0)	100.0 (100.0, 100.0)	294 (99.7)	47.3 (22.2, 100.0)	226 (97.8)	18.6 (6.4, 100.0)	190 (99.5)	100.0 (100.0, 100.0)	173 (99.4)	100.0 (86.6, 100.0)
Past COVID-19 close contact														
Yes	13 (22.8)	3.6 (2.4, 13.2)	51 (92.7)	19.8 (6.0, 100.0)	51 (100.0)	100.0 (100.0, 100.0)	46 (100.0)	61.1 (24.9, 100.0)	39 (100.0)	100.0 (5.0, 100.0)	35 (100.0)	100.0 (100.0, 100.0)	33 (100.0)	100.0 (90.2, 100.0)
No	37 (6.7)	2.6 (1.3, 5.6)	492 (94.3)	9.8 (5.1, 21.9)	456 (100.0)	100.0 (100.0, 100.0)	394 (99.7)	49.8 (22.5, 100.0)	304 (97.1)	23.8 (7.6, 100.0)	266 (99.6)	100.0 (100.0, 100.0)	243 (99.6)	100.0 (86.6, 100.0)
Past COVID-19 infection														
Yes	11 (68.8)	3.6 (2.5, 10.9)	16 (100.0)	100.0 (100.0,100.0)	16 (100.0)	100.0 (100.0, 100.0)	31 (100.0)	100.0 (95.6, 100.0)	37 (100.0)	100.0 (100.0,100.0)	86 (100.0)	100.0 (100.0, 100.0)	87 (100.0)	100.0 (100.0,100.0)
No	39 (6.5)	2.6 (1.3, 5.7)	527 (93.9)	9.9 (5.2, 22.4)	491 (100.0)	100.0 (100.0, 100.0)	409 (99.8)	47.0 (21.0, 100.0)	306 (97.1)	18.4 (6.9, 100.0)	215 (99.5)	100.0 (100.0, 100.0)	189 (99.5)	100.0 (75.2, 100.0)
Booster Status														
No booster									235 (96.7)	12.0 (5.5, 46.3)	113 (99.1)	100.0 (89.2, 100.0)	99 (99.0)	100.0 (79.3, 100.0)
1 booster				N/A					108 (99.1)	100.0 (100.0,100.0)	188 (100.0)	100.0 (100.0,100.0)	175 (100.0)	100.0 (90.5, 100.0)
2 boosters										N/A			2 (100.0)	100.0 (100.0,100.0)
Lifestyle														
Smoking status														
Not smoking	29 (7.0)	4.2 (1.8, 13.0)	367 (93.1)	10.5 (5.5, 22.7)	347 (100.0)	100.0 (100.0, 100.0)	306 (100.0)	55.8 (24.0, 100.0)	242 (96.8)	26.1 (8.2, 100.0)	213 (99.5)	100.0 (100.0, 100.0)	196 (99.5)	100.0 (99.2, 100.0)
Past smoker	3 (7.9)	2.9 (1.7, -)	30 (88.2)	14.2 (5.9, 29.7)	31 (100.0)	100.0 (100.0, 100.0)	26 (96.3)	58.2 (27.4, 100.0)	21 (100.0)	21.5 (8.7, 100.0)	21 (100.0)	100.0 (100.0, 100.0)	22 (100.0)	100.0 (99.5, 100.0)
Current smoker	18 (11.1)	2.5 (1.3, 2.8)	146 (98.0)	9.5 (4.5, 23.3)	129 (100.0)	100.0 (100.0, 100.0)	108 (100.0)	43.6 (18.2, 89.5)	80 (98.8)	22.7 (6.8, 100.0)	67 (100.0)	100.0 (100.0, 100.0)	58 (100.0)	100.0 (52.1, 100.0)
BMI by WHO 1998														
Underweight	4 (9.5)	4.0 (1.6, 5.8)	38 (100.0)	8.9 (3.5, 18.5)	28 (100.0)	100.0 (100.0, 100.0)	26 (100.0)	55.5 (24.3, 100.0)	18 (100.0)	100.0 (42.1, 100.0)	13 (100.0)	100.0 (71.0, 100.0)	13 (100.0)	81.3 (55.3, 100.0)
Normal	18 (7.1)	2.6 (1.4, 4.4)	219 (92.4)	9.6 (5.6, 23.7)	206 (100.0)	100.0 (100.0, 100.0)	170 (100.0)	54.4 (21.5, 100.0)	131 (98.5)	21.5 (8.4, 100.0)	120 (100.0)	100.0 (100.0, 100.0)	106 (99.1)	100.0 (100.0,100.0)
Overweight	12 (6.0)	1.8 (1.1, 84.0)	179 (94.2)	10.0 (5.0, 19.8)	169 (100.0)	100.0 (100.0, 100.0)	153 (99.4)	50.4 (22.6, 100.0)	122 (96.8)	42.4 (7.2, 100.0)	108 (100.0)	100.0 (100.0, 100.0)	103 (100.0)	100.0 (89.7, 100.0)
Obese	16 (13.7)	3.9 (2.6, 7.5)	107 (95.5)	14.0 (5.4, 29.7)	104 (100.0)	100.0 (100.0, 100.0)	91 (100.0)	47.9 (24.3, 100.0)	72 (96.0)	17.3 (5.7, 100.0)	60 (98.4)	100.0 (100.0, 100.0)	54 (100.0)	100.0 (81.5, 100.0)

Table 10 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of Sinovac recipients by follow up

VARIABLES	BASELINE (n=612)		SECOND DOSE (n=577)		COMPLETED VACCINATION (n=507)		3 MONTHS (n=441)		6 MONTHS (n=352)		9 MONTHS (n=302)		12 MONTHS (n=277)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	94 (15.5)	2.4 (1.5, 6.2)	235 (42.3)	2.6 (1.5, 7.6)	462 (94.9)	13.5 (6.4, 27.1)	347 (82.8)	3.6 (2.0, 8.9)	323 (85.0)	100.0 (6.3, 100.0)	315 (98.4)	100.0 (84.1, 100.0)	304 (98.7)	100.0 (28.0, 100.0)
Sociodemography														
Age group														
18-39 years	66 (19.2)	2.2 (1.5, 4.3)	162 (52.4)	2.8 (1.5, 7.3)	254 (97.3)	16.7 (8.7, 31.9)	187 (89.5)	4.3 (2.2, 9.4)	148 (78.3)	72.5 (2.5, 100.0)	144 (99.3)	100.0 (100.0,100.0)	143 (99.3)	94.3 (28.4, 100.0)
40-59 years	25 (10.6)	3.3 (1.7, 13.7)	67 (30.6)	2.3 (1.4, 6.1)	186 (91.6)	10.6 (4.9, 20.3)	139 (74.3)	2.9 (1.7, 7.2)	155 (91.2)	100.0 (100.0,100.0)	152 (97.4)	100.0 (74.4, 100.0)	140 (97.9)	100.0 (29.0, 100.0)
60 years and above	3 (10.3)	100.0 (1.1, -)	6 (22.2)	14.4 (4.4, 79.8)	22 (95.7)	9.2 (3.9, 22.9)	21 (91.3)	3.9 (2.0, 7.6)	20 (95.2)	100.0 (4.8, 100.0)	19 (100.0)	100.0 (26.8, 100.0)	21 (100.0)	45.6 (18.2, 100.0)
Sex														
Male	51 (15.9)	2.1 (1.5, 3.8)	103 (34.8)	2.7 (1.5, 9.5)	242 (95.3)	11.3 (6.1, 24.3)	180 (80.4)	3.3 (2.0, 7.3)	176 (84.6)	100.0 (10.3, 100.0)	175 (98.3)	100.0 (92.4, 100.0)	172 (98.9)	100.0 (38.8, 100.0)
Female	43 (14.9)	2.9 (1.6, 12.7)	132 (51.0)	2.6 (1.5, 6.9)	220 (94.4)	15.5 (8.0, 30.1)	167 (85.6)	4.0 (1.9, 9.5)	147 (85.5)	100.0 (4.1, 100.0)	140 (98.6)	100.0 (77.1, 100.0)	132 (98.5)	100.0 (24.5, 100.0)
Ethnicity														
Malay	81 (16.9)	2.6 (1.6, 7.2)	195 (44.3)	2.8 (1.6, 9.0)	367 (95.8)	14.2 (7.0, 27.9)	267 (82.2)	3.8 (2.0, 9.4)	247 (83.7)	100.0 (4.3, 100.0)	238 (98.3)	100.0 (100.0,100.0)	229 (98.7)	100.0 (30.2, 100.0)
Chinese	4 (5.7)	1.4 (1.1, 5.6)	18 (28.1)	1.9 (1.4, 4.5)	53 (86.9)	7.5 (5.6, 15.3)	44 (78.6)	2.4 (1.3, 4.6)	50 (92.6)	100.0 (62.5, 100.0)	47 (97.9)	100.0 (20.1, 100.0)	49 (100.0)	100.0 (15.5, 100.0)
Indian	7 (17.9)	1.9 (1.4, 2.4)	15 (41.7)	1.6 (1.3, 4.3)	31 (96.9)	18.6 (8.1, 29.1)	27 (96.4)	4.7 (2.5, 10.1)	21 (87.5)	100.0 (100.0, 100.0)	24 (100.0)	100.0 (95.6, 100.0)	19 (95.0)	100.0 (94.3, 100.0)
Bumiputera Sabah & Sarawak	0	-	3 (37.5)	1.7 (1.7, -)	6 (100.0)	15.5 (4.9, 69.9)	4 (80.0)	51.1 (1.5, 100.0)	1 (50.0)	-	3 (100.0)	100.0 (7.3, -)	3 (100.0)	58.2 (14.9, -)
Others	2 (22.2)	1.3 (1.0, -)	4 (57.1)	2.1 (1.2, 4.7)	5 (100.0)	28.5 (8.4, 100.0)	5 (100.0)	4.2 (1.8, 71.1)	4 (80.0)	68.5 (29.2, 100.0)	3 (100.0)	100.0 (73.9, -)	4 (100.0)	8.8 (3.1, 78.2)
Nationality														
Malaysian	92 (15.4)	2.4 (1.5, 6.5)	232 (42.3)	2.6 (1.5, 7.9)	459 (94.8)	13.5 (6.5, 27.0)	344 (82.7)	3.6 (2.0, 8.9)	320 (84.9)	100.0 (6.3, 100.0)	314 (98.4)	100.0 (84.0, 100.0)	302 (98.7)	100.0 (28.6, 100.0)
Non-Malaysian	2 (22.2)	1.3 (1.0, -)	3 (50.0)	2.8 (1.4, -)	3 (100.0)	28.5 (3.7, -)	3 (100.0)	4.2 (1.3, -)	3 (100.0)	100.0 (26.6, -)	1 (100.0)	-	2 (100.0)	7.7 (2.6, -)
Comorbidity status														
No comorbid	71 (20.3)	2.3 (1.5, 4.1)	145 (46.8)	2.7 (1.5, 8.9)	264 (98.5)	15.3 (8.1, 30.1)	193 (89.4)	3.8 (2.1, 8.9)	156 (81.7)	100.0 (3.1, 100.0)	150 (98.7)	100.0 (100.0,100.0)	148 (98.7)	100.0 (26.9, 100.0)
Any 1 comorbidity	10 (7.8)	9.6 (1.9, 24.0)	47 (39.5)	2.3 (1.5, 5.6)	94 (91.3)	13.9 (6.3, 26.3)	71 (74.7)	3.8 (2.3, 9.0)	78 (91.8)	100.0 (100.0, 100.0)	70 (97.2)	100.0 (67.5, 100.0)	68 (98.6)	94.2 (21.6, 100.0)
2 or more comorbidities	13 (10.0)	2.4 (1.8, 22.0)	43 (34.1)	3.0 (1.8, 6.3)	104 (89.7)	10.3 (4.2, 19.9)	83 (76.9)	2.9 (1.6, 9.1)	89 (85.6)	100.0 (89.8, 100.0)	95 (99.0)	100.0 (83.4, 100.0)	88 (98.9)	100.0 (35.8, 100.0)

VARIABLES	BASELINE (n=608)		SECOND DOSE (n=555)		COMPLETED VACCINATION (n=487)		3 MONTHS (n=419)		6 MONTHS (n=380)		9 MONTHS (n=320)		12 MONTHS (n=308)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History														
Past Covid-19 symptoms														
Asymptomatic	38 (12.7)	1.9 (1.3, 3.3)	104 (39.1)	2.1 (1.4, 4.7)	209 (95.0)	13.6 (6.3, 26.7)	157 (82.2)	3.3 (2.0, 7.0)	141 (82.5)	100.0 (3.4, 100.0)	131 (97.8)	100.0 (100.0,100.0)	133 (100.0)	100.0 (31.0, 100.0)
Symptomatic	56 (18.2)	2.9 (1.7, 12.6)	131 (45.3)	3.7 (1.7, 10.9)	253 (94.8)	13.5 (6.6, 27.9)	190 (83.3)	3.9 (2.0, 9.6)	182 (87.1)	100.0 (13.5, 100.0)	184 (98.9)	100.0 (75.8, 100.0)	171 (97.7)	85.4 (27.6, 100.0)
Past COVID-19 close contact														
Yes	32 (35.6)	5.4 (1.9, 34.3)	49 (62.0)	10.2 (1.9, 46.4)	72 (98.6)	18.8 (7.7, 39.5)	51 (91.1)	4.9 (2.3, 14.4)	37 (75.5)	15.4 (2.7, 100.0)	40 (100.0)	100.0 (100.0,100.0)	38 (97.4)	91.1 (29.3, 100.0)
No	62 (12.0)	2.2 (1.3, 3.7)	186 (39.1)	2.3 (1.5, 5.6)	390 (94.2)	12.8 (6.3, 26.0)	296 (81.5)	3.4 (1.9, 7.9)	286 (86.4)	100.0 (13.8, 100.0)	275 (98.2)	100.0 (83.4, 100.0)	266 (98.9)	100.0 (27.8, 100.0)
Past COVID-19 infection														
Yes	30 (88.2)	7.9 (2.0, 31.7)	29 (90.6)	20.1 (8.0, 92.5)	31 (100.0)	20.2 (9.5, 42.2)	44 (100.0)	14.0 (6.1, 66.4)	49 (96.1)	100.0 (6.4, 100.0)	111 (99.1)	100.0 (100.0,100.0)	113 (99.1)	100.0 (45.2, 100.0)
No	64 (11.1)	2.0 (1.3, 3.2)	206 (39.4)	2.2 (1.4, 5.3)	431 (94.5)	13.0 (6.3, 26.4)	303 (80.8)	3.2 (1.9, 6.4)	274 (83.3)	100.0 (6.0, 100.0)	204 (98.1)	100.0 (46.1, 100.0)	191 (98.5)	86.9 (23.1, 100.0)
Booster Status														
No booster	N/A								90 (64.7)	2.6 (1.5, 6.3)	33 (89.2)	100.0 (11.2, 100.0)	36 (92.3)	63.4 (21.8, 100.0)
1 booster									233 (96.7)	100.0 (100.0, 100.0)	282 (99.6)	100.0 (93.7, 100.0)	268 (99.6)	100.0 (29.2, 100.0)
Lifestyle														
Smoking status														
Not smoking	69 (16.3)	2.7 (1.5, 7.9)	175 (45.8)	2.6 (1.5, 8.2)	323 (95.0)	15.3 (7.0, 28.6)	248 (84.6)	3.9 (2.1, 9.4)	223 (85.4)	100.0 (8.7, 100.0)	215 (98.2)	100.0 (94.1, 100.0)	203 (98.1)	100.0 (27.4, 100.0)
Past smoker	4 (9.8)	1.7 (1.3, 28.8)	14 (35.9)	3.3 (1.6, 14.7)	36 (92.3)	11.6 (5.0, 26.3)	27 (79.4)	5.1 (1.7, 13.2)	29 (85.3)	100.0 (2.1, 100.0)	31 (100.0)	100.0 (100.0,100.0)	32 (100.0)	91.5 (38.8, 100.0)
Current smoker	21 (14.6)	1.9 (1.5, 3.6)	46 (34.3)	2.5 (1.6, 5.0)	103 (95.4)	11.0 (6.1, 21.4)	72 (78.3)	3.0 (1.9, 5.8)	71 (83.5)	100.0 (13.9, 100.0)	69 (98.6)	100.0 (51.6, 100.0)	69 (100.0)	100.0 (25.9, 100.0)
BMI by WHO 1998														
Underweight	6 (18.2)	2.2 (1.3, 7.4)	15 (46.9)	1.6 (1.3, 8.8)	25 (96.2)	13.6 (7.5, 32.5)	17 (100.0)	2.3 (1.9, 7.1)	11 (68.8)	5.4 (1.5, 100.0)	14 (93.3)	100.0 (27.6, 100.0)	12 (100.0)	100.0 (37.2, 100.0)
Normal	34 (20.0)	1.7 (1.3, 3.2)	72 (46.2)	2.7 (1.6, 6.7)	132 (97.8)	13.9 (7.7, 27.3)	102 (87.2)	4.3 (2.2, 9.6)	91 (86.7)	100.0 (4.0, 100.0)	80 (98.8)	100.0 (53.5, 100.0)	78 (97.5)	98.8 (22.0, 100.0)
Overweight	27 (15.6)	2.9 (1.6, 6.9)	66 (41.8)	2.7 (1.5, 10.2)	137 (96.5)	12.8 (6.2, 25.4)	105 (82.7)	3.3 (2.1, 8.1)	94 (83.2)	100.0 (5.0, 100.0)	97 (99.0)	100.0 (100.0,100.0)	93 (98.9)	100.0 (39.9, 100.0)
Obese	27 (11.7)	3.3 (1.9, 22.0)	82 (39.4)	2.5 (1.5, 8.3)	167 (91.3)	12.7 (5.6, 28.4)	122 (77.7)	3.4 (1.7, 9.4)	127 (87.6)	100.0 (55.8, 100.0)	124 (99.2)	100.0 (76.1, 100.0)	121 (100.0)	79.1 (27.7, 100.0)

Table 11 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of AstraZeneca recipients by follow up

VARIABLES	BASELINE (n=617)		SECOND DOSE (n=563)		COMPLETED VACCINATION (n=486)		3 MONTHS (n=N/A)	6 MONTHS (n=394)		9 MONTHS (n=335)		12 MONTHS (n=316)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX		SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	46 (7.5)	3.7 (1.7, 6.0)	518 (92.0)	5.2 (2.9, 11.1)	486 (100.0)	24.8 (12.6, 67.5)		379 (96.2)	7.1 (3.5, 28.0)	328 (97.9)	100.0 (24.2, 100.0)	311 (98.4)	51.1 (17.7, 100.0)
Sociodemography													
Age group													
18-39 years	30 (6.8)	3.2 (1.6, 7.2)	379 (93.6)	5.5 (3.0, 11.8)	337 (100.0)	26.0 (13.8, 70.2)		260 (97.4)	6.1 (3.3, 21.9)	217 (97.7)	100.0 (27.1, 100.0)	200 (98.5)	43.9 (16.4, 100.0)
40-59 years	16 (9.5)	4.2 (1.8, 5.9)	135 (88.2)	4.2 (2.3, 10.9)	144 (100.0)	21.9 (11.1, 63.6)		115 (93.5)	10.0 (4.2, 58.9)	109 (98.2)	100.0 (18.3, 100.0)	107 (98.2)	63.1 (20.7, 100.0)
60 years and above	0	-	4 (80.0)	2.3 (1.3, 8.4)	5 (100.0)	16.9 (8.7, 50.7)		4 (100.0)	100.0 (31.6, 100.0)	2 (100.0)	100.0 (100.0,100.0)	4 (100.0)	83.9 (60.2, 100.0)
Sex													
Male	14 (5.1)	3.4 (1.3, 6.4)	228 (90.8)	4.1 (2.4, 8.6)	213 (100.0)	20.5 (11.2, 41.8)		174 (97.8)	7.8 (3.8, 36.1)	143 (98.6)	100.0 (32.2, 100.0)	141 (100.0)	72.5 (17.7, 100.0)
Female	32 (9.4)	3.7 (1.9, 5.6)	290 (92.9)	6.4 (3.2, 14.5)	273 (100.0)	31.0 (13.9, 87.1)		205 (94.9)	6.4 (3.3, 26.9)	185 (97.4)	100.0 (19.1, 100.0)	170 (97.1)	41.7 (16.9, 100.0)
Ethnicity													
Malay	33 (7.8)	3.7 (1.8, 6.5)	361 (92.6)	5.7 (2.9, 11.9)	331 (100.0)	27.8 (14.6, 82.1)		252 (96.2)	6.7 (3.5, 27.6)	211 (97.7)	100.0 (47.9, 100.0)	204 (98.6)	51.9 (20.7, 100.0)
Chinese	10 (6.9)	3.6 (1.2, 5.6)	118 (90.1)	4.1 (2.9, 9.8)	125 (100.0)	16.7 (9.4, 35.4)		106 (97.2)	6.8 (3.6, 18.3)	95 (97.9)	90.1 (7.0, 100.0)	86 (97.7)	56.3 (10.8, 100.0)
Indian	2 (4.9)	2.9 (1.4, -)	32 (94.1)	4.4 (2.0, 13.9)	26 (100.0)	37.5 (9.2, 100.0)		18 (90.0)	16.9 (2.4, 65.4)	19 (100.0)	100.0 (91.7, 100.0)	20 (100.0)	29.2 (19.8, 100.0)
Bumiputera Sabah & Sarawak	1 (16.7)	-	5 (100.0)	3.8 (2.7, 54.5)	2 (100.0)	20.5 (13.9, -)		2 (100.0)	65.3 (30.5, -)	2 (100.0)	58.5 (17.0, -)	N/A	
Others	0	-	2 (66.7)	6.3 (3.9, -)	2 (100.0)	70.5 (40.9, -)		1 (100.0)	-	1 (100.0)	-	1 (100.0)	-
Nationality													
Malaysian	46 (7.5)	3.7 (1.7, 6.0)	514 (91.9)	5.1 (2.9, 11.2)	483 (100.0)	24.8 (12.6, 66.8)		377 (96.2)	7.1 (3.5, 28.7)	326 (97.9)	100.0 (25.2, 100.0)	310 (98.4)	51.4 (17.8, 100.0)
Non-Malaysian	0	-	4 (100.0)	7.7 (2.5, 27.4)	3 (100.0)	100.0 (35.0, -)		2 (100.0)	9.8 (5.6, -)	2 (100.0)	2.5 (2.1, -)	1 (100.0)	-
Comorbidity status													
No comorbid	36 (7.1)	3.4 (1.6, 5.9)	430 (92.9)	5.3 (2.9, 11.6)	398 (100.0)	25.2 (13.6, 67.5)		316 (97.5)	6.8 (3.5, 26.3)	264 (97.8)	100.0 (19.1, 100.0)	246 (98.0)	43.0 (15.9, 100.0)
Any 1 comorbidity	8 (9.8)	4.7 (1.7, 8.0)	67 (90.5)	4.7 (2.3, 10.3)	67 (100.0)	24.1 (9.6, 61.7)		48 (92.3)	8.3 (3.1, 89.9)	51 (98.1)	100.0 (67.0, 100.0)	50 (100.0)	65.8 (20.5, 100.0)
2 or more comorbidities	2 (6.9)	3.2 (2.7, -)	21 (80.8)	3.7 (1.4, 10.4)	21 (100.0)	16.4 (6.1, 100.0)		15 (83.3)	30.9 (4.2, 100.0)	13 (100.0)	100.0 (17.8, 100.0)	15 (100.0)	72.1 (54.0, 100.0)

VARIABLES	BASELINE (n=617)		SECOND DOSE (n=563)		COMPLETED VACCINATION (n=486)		3 MONTHS (n=N/A)	6 MONTHS (n=394)		9 MONTHS (n=335)		12 MONTHS (n=316)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX		SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History													
Past Covid-19 symptoms													
Asymptomatic	3 (3.1)	2.7 (1.2, -)	81 (96.4)	3.6 (2.4, 9.7)	74 (100.0)	24.5 (11.00, 68.6)		60 (95.2)	6.2 (4.2, 32.4)	58 (98.3)	100.0 (24.0, 100.0)	60 (98.4)	41.6 (14.8, 100.0)
Symptomatic	43 (8.3)	3.7 (1.7, 6.2)	437 (91.2)	5.5 (2.9, 11.8)	412 (100.0)	25.0 (12.9, 67.2)		319 (96.4)	7.1 (3.5, 27.4)	270 (97.8)	100.0 (23.3, 100.0)	251 (98.4)	54.0 (19.3, 100.0)
Past COVID-19 close contact													
Yes	15 (15.5)	5.4 (3.2, 7.9)	82 (92.1)	5.8 (2.6, 15.6)	78 (100.0)	25.2 (12.3, 90.1)		64 (97.0)	8.4 (3.4, 27.2)	49 (100.0)	100.0 (30.8, 100.0)	43 (97.7)	47.3 (19.5, 100.0)
No	31 (6.0)	2.7 (1.4, 5.0)	436 (92.0)	5.0 (2.9, 10.9)	408 (100.0)	24.8 (12.7, 61.7)		315 (96.0)	6.9 (3.5, 30.5)	279 (97.6)	100.0 (19.9, 100.0)	268 (98.5)	51.4 (17.1, 100.0)
Past COVID-19 infection													
Yes	14 (70.0)	5.3 (3.1, 8.0)	18 (100.0)	100.0 (9.2, 100.0)	17 (100.0)	100.0 (54.6, 100.0)		26 (100.0)	100.0 (29.6, 100.0)	128 (100.0)	100.0 (100.0,100.0)	144 (100.0)	100.0 (42.6, 100.0)
No	32 (5.4)	2.6 (1.4, 5.4)	500 (91.7)	5.0 (2.8, 10.6)	469 (100.0)	23.9 (12.4, 60.8)		353 (95.9)	6.3 (3.3, 21.3)	200 (96.6)	72.9 (8.0, 100.0)	167 (97.1)	22.2 (7.3, 78.7)
Booster Status													
No booster								270 (94.7)	5.2 (3.0, 11.2)	66 (91.7)	100.0 (36.6, 100.0)	71 (97.3)	32.2 (17.0, 98.8)
1 booster			N/A					109 (100.0)	32.4 (11.1, 100.0)	262 (99.6)	100.0 (19.1, 100.0)	238 (98.8)	63.2 (17.5, 100.0)
2 boosters									N/A			2 (100.0)	100.0 (100.0, 100.0)
Lifestyle													
Smoking status													
Not smoking	39 (8.1)	3.7 (1.9, 6.9)	409 (92.7)	5.5 (3.0, 11.9)	389 (100.0)	25.9 (13.4, 71.7)		305 (96.2)	6.9 (3.6, 25.8)	269 (97.8)	100.0 (26.1, 100.0)	250 (98.0)	53.4 (19.5, 100.0)
Past smoker	1 (2.7)	-	31 (93.9)	4.4 (2.2, 8.6)	26 (100.0)	14.7 (9.5, 22.1)		20 (95.2)	7.8 (3.2, 73.9)	17 (100.0)	37.2 (9.3, 100.0)	16 (100.0)	30.6 (9.4, 70.0)
Current smoker	6 (6.1)	3.4 (1.3, 6.1)	78 (87.6)	4.3 (2.3, 10.7)	71 (100.0)	23.9 (13.7, 57.9)		54 (96.4)	12.4 (3.4, 46.0)	42 (97.7)	100.0 (52.4, 100.0)	45 (100.0)	49.6 (14.3, 100.0)
BMI by WHO 1998													
Underweight	2 (5.1)	12.7 (2.0, -)	28 (93.3)	8.8 (4.0, 15.8)	27 (100.0)	22.1 (14.9, 54.1)		22 (100.0)	7.1 (3.8, 18.0)	17 (100.0)	100.0 (13.9, 100.0)	18 (100.0)	38.4 (12.5, 100.0)
Normal	15 (6.2)	2.7 (1.4, 4.4)	201 (91.4)	4.4 (2.9, 9.9)	194 (100.0)	19.9 (11.0, 45.0)		148 (94.3)	5.7 (3.0, 21.9)	133 (97.8)	100.0 (18.3, 100.0)	127 (97.7)	54.2 (17.7, 100.0)
Overweight	14 (7.4)	3.9 (1.4, 5.8)	166 (92.2)	5.5 (2.8, 11.0)	145 (100.0)	27.3 (15.4, 82.5)		125 (96.9)	8.9 (4.3, 42.4)	104 (96.3)	100.0 (20.0, 100.0)	99 (98.0)	55.8 (14.5, 100.0)
Obese	15 (10.3)	4.4 (2.6, 7.9)	122 (92.4)	5.1 (2.5, 14.1)	120 (100.0)	31.5 (12.7, 98.6)		84 (97.7)	9.0 (3.5, 58.1)	74 (100.0)	100.0 (39.0, 100.0)	67 (100.0)	42.3 (20.9, 100.0)

Table 12 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of CanSino recipients by follow up

VARIABLES	BASELINE (n=676)		14 DAYS AFTER SINGLE DOSE (n=562)		COMPLETED VACCINATION *28 DAYS AFTER SINGLE DOSE (n=442)		3 MONTHS (n=368)		6 MONTHS (n=270)		9 MONTHS (n=236)		12 MONTHS (n=217)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	357 (52.8)	8.6 (2.9, 38.2)	428 (76.2)	100.0 (25.7, 100.0)	422 (95.5)	53.9 (10.5, 100.0)	298 (81.0)	18.5 (6.1, 50.0)	256 (94.8)	100.0 (40.6, 100.0)	224 (94.9)	33.1 (10.7,100.0)	212 (97.7)	33.2 (9.8,100.0)
Sociodemography														
Age group														
18-39 years	219 (52.4)	5.8 (2.6, 20.6)	270 (78.5)	98.1 (23.9, 100.0)	264 (95.7)	58.3 (12.1, 100.0)	187 (82.0)	17.8 (6.5, 47.1)	157 (94.0)	100.0 (39.0, 100.0)	142 (95.9)	33.1 (10.9, 100.0)	135 (98.5)	31.7 (9.3, 100.0)
40-59 years	123 (53.0)	18.6 (4.1, 86.6)	142 (72.4)	100.0 (25.0, 100.0)	143 (94.7)	47.6 (6.0, 100.0)	98 (78.4)	17.9 (4.4, 55.1)	86 (95.6)	100.0 (41.8, 100.0)	68 (93.2)	33.9 (9.4, 100.0)	64 (95.5)	31.1 (10.2,100.0)
60 years and above	15 (57.7)	12.8 (3.7, 78.9)	16 (72.7)	100.0 (64.0, 100.0)	15 (100.0)	100.0 (36.7, 100.0)	13 (86.7)	29.1 (19.3, 74.5)	13 (100.0)	100.0 (20.2, 100.0)	14 (93.3)	23.0 (7.5, 100.0)	13 (100.0)	100.0 (47.5, 100.0)
Sex														
Male	162 (45.1)	4.5 (2.5, 26.5)	209 (73.3)	92.9 (20.00,100.0)	209 (94.1)	37.7 (6.3, 100.0)	136 (76.4)	13.7 (5.3, 50.3)	110 (93.2)	100.0 (31.9, 100.0)	105 (92.9)	26.4 (8.5, 89.3)	99 (97.1)	33.3 (9.8, 100.0)
Female	195 (61.5)	12.3 (4.0, 48.5)	219 (79.1)	100.0 (38.4, 100.0)	213 (96.8)	65.7 (16.3, 100.0)	162 (85.3)	21.2 (8.7, 49.5)	146 (96.1)	100.0 (42.6, 100.0)	119 (96.7)	36.3 (12.4, 100.0)	113 (98.3)	32.9 (9.6, 100.0)
Ethnicity														
Malay	160 (58.2)	6.9 (2.8, 29.2)	175 (76.8)	100.0 (33.6, 100.0)	167 (94.9)	59.5 (13.9, 100.0)	131 (80.4)	16.9 (5.9, 37.4)	102 (92.7)	100.0 (41.0, 100.0)	92 (93.9)	32.8 (11.3, 80.3)	84 (97.7)	16.7 (6.6, 52.9)
Bumiputera Sabah & Sarawak	28 (51.9)	3.9 (2.4, 100.0)	29 (76.3)	90.0 (24.4, 100.0)	34 (94.4)	51.2 (9.3, 100.0)	27 (84.4)	20.6 (5.4, 20.6)	38 (100.0)	100.0 (34.7, 100.0)	36 (94.7)	22.2 (8.1, 100.0)	38 (97.4)	91.6 (24.4, 100.0)
Others	169 (48.8)	10.6 (3.3, 41.7)	224 (75.7)	100.0 (15.4, 100.0)	221 (96.1)	51.7 (9.6, 100.0)	140 (80.9)	19.4 (7.2, 71.7)	116 (95.1)	100.0 (38.5, 100.0)	96 (96.0)	35.7 (12.2, 100.0)	90 (97.8)	59.5 (15.7, 100.0)
Nationality														
Malaysian	188 (57.1)	6.8 (2.7, 33.6)	205 (76.8)	96.3 (32.1, 100.0)	201 (94.4)	59.5 (13.8, 100.0)	159 (81.5)	18.0 (5.9, 41.0)	140 (95.2)	100.0 (37.8, 100.0)	127 (94.1)	31.1 (9.1, 100.0)	123 (97.6)	28.8 (8.1, 100.0)
Non-Malaysian	169 (48.7)	10.6 (3.5, 42.8)	223 (75.6)	100.0 (14.5, 100.0)	221 (96.5)	48.9 (8.8, 100.0)	139 (80.3)	19.1 (7.0, 69.1)	116 (94.3)	100.0 (41.4, 100.0)	97 (96.0)	35.9 (12.3, 100.0)	89 (97.8)	59.4 (15.1, 100.0)
Comorbidity status														
No comorbid	287 (52.2)	7.2 (2.8, 27.1)	342 (75.8)	100.0 (23.9, 100.0)	340 (95.8)	48.7 (10.4, 100.0)	228 (79.4)	17.8 (6.1, 46.5)	200 (95.2)	100.0 (42.8, 100.0)	175 (95.1)	32.9 (10.7, 100.0)	166 (98.2)	28.8 (8.9, 100.0)
Any 1 comorbidity	48 (52.7)	18.3 (3.8, 77.9)	62 (76.5)	100.0 (31.0, 100.0)	57 (93.4)	77.3 (20.9, 100.0)	48 (87.3)	23.7 (7.5, 79.0)	41 (95.3)	100.0 (20.6, 100.0)	35 (94.6)	31.1 (8.2, 77.6)	35 (97.2)	100.0 (27.3, 100.0)
2 or more comorbidities	22 (62.9)	44.0 (4.6, 100.0)	24 (80.0)	81.5 (40.7, 100.0)	25 (96.2)	51.7 (3.3, 100.0)	22 (84.6)	17.0 (3.4, 37.5)	15 (88.2)	100.0 (9.2, 100.0)	14 (93.3)	36.1 (15.4, 74.1)	11 (91.7)	44.4 (7.5, 100.0)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	108 (47.0)	7.2 (2.8, 39.3)	136 (70.5)	90.4 (7.5, 100.0)	133 (93.7)	42.1 (5.4, 100.0)	80 (72.7)	14.2 (4.5, 45.9)	67 (93.1)	100.0 (22.0, 100.0)	55 (90.2)	33.4 (8.9, 99.2)	53 (94.6)	31.7 (8.6, 100.0)
Symptomatic	249 (55.8)	8.9 (2.9, 37.4)	292 (79.1)	100.0 (34.1, 100.0)	289 (96.3)	60.7 (14.8, 100.0)	218 (84.5)	18.5 (7.5, 51.2)	189 (95.5)	100.0 (41.2, 100.0)	169 (96.6)	32.9 (11.3, 100.0)	159 (98.8)	35.6 (11.2, 100.0)

VARIABLES	BASELINE (n=676)		14 DAYS AFTER SINGLE DOSE (n=562)		COMPLETED VACCINATION *28 DAYS AFTER SINGLE DOSE (n=442)		3 MONTHS (n=368)		6 MONTHS (n=270)		9 MONTHS (n=236)		12 MONTHS (n=217)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Past COVID-19 close contact														
Yes	30 (66.7)	5.1 (2.8, 34.7)	34 (81.0)	100.0 (45.3, 100.0)	34 (97.1)	78.6 (15.6, 100.0)	31 (91.2)	14.8 (5.6, 37.5)	24 (92.3)	100.0 (29.1, 100.0)	20 (90.9)	29.5 (9.6, 95.6)	20 (95.2)	16.3 (7.2, 99.0)
No	327 (51.8)	8.9 (2.9, 39.6)	394 (75.8)	100.0 (23.7, 100.0)	388 (95.3)	51.5 (10.4, 100.0)	267 (79.9)	18.5 (6.2, 53.6)	232 (95.1)	100.0 (41.2, 100.0)	204 (95.3)	33.1 (10.7, 100.0)	192 (98.0)	35.6 (10.6, 100.0)
Past COVID-19 infection														
Yes	29 (96.7)	9.2 (3.6, 44.5)	27 (100.0)	100.0 (100.0,100.0)	24 (100.0)	100.0 (74.5, 100.0)	26 (100.0)	22.1 (11.1,100.0)	24 (100.0)	100.0 (34.0, 100.0)	22 (100.0)	34.7 (18.3, 100.0)	19 (100.0)	35.6 (8.4, 100.0)
No	328 (50.8)	8.5 (2.9, 36.7)	401 (75.0)	96.3 (23.2, 100.0)	398 (95.2)	48.1 (9.3, 100.0)	272 (79.5)	18.0 (6.0, 47.0)	232 (94.3)	100.0 (40.6, 100.0)	202 (94.4)	33.1 (9.8, 100.0)	193 (97.5)	33.1 (9.9, 100.0)
Booster Status														
No booster	N/A								220 (94.0)	100.0 (37.2, 100.0)	191 (94.1)	27.6 (9.1, 80.4)	176 (97.2)	30.0 (8.5, 100.0)
1 booster									36 (100.0)	100.0 (71.3, 100.0)	33 (100.0)	100.0 (28.8, 100.0)	36 (100.0)	84.1 (20.6, 100.0)
Lifestyle														
Smoking status														
Not smoking	218 (60.1)	13.7 (3.9, 52.3)	244 (77.0)	100.0 (39.3, 100.0)	238 (96.4)	69.4 (13.6, 100.0)	174 (83.3)	21.2 (8.9, 51.0)	159 (95.8)	100.0 (41.2, 100.0)	132 (97.1)	33.9 (12.2, 100.0)	125 (99.2)	35.6 (10.9, 100.0)
Past smoker	16 (61.5)	6.9 (2.4, 35.2)	18 (90.0)	100.0 (49.3, 100.0)	15 (100.0)	69.1 (5.0, 100.0)	12 (85.7)	22.3 (6.3, 88.7)	7 (100.0)	100.0 (37.0, 100.0)	9 (100.0)	48.1 (21.5, 82.7)	9 (100.0)	32.3 (12.3, 72.6)
Current smoker	123 (42.9)	3.8 (2.3, 12.3)	166 (73.8)	71.4 (14.0, 100.0)	169 (93.9)	34.5 (7.2, 100.0)	112 (77.2)	12.3 (4.5, 43.8)	90 (92.8)	100.0 (36.0, 100.0)	83 (91.2)	22.5 (8.4, 100.0)	78 (95.1)	32.8 (8.9, 100.0)
BMI by WHO 1998														
Underweight	30 (44.1)	3.0 (2.0, 6.2)	36 (69.2)	100.0 (26.1, 100.0)	39 (95.1)	21.0 (7.5, 100.0)	31 (79.5)	12.8 (5.4, 61.2)	27 (93.1)	100.0 (37.0, 100.0)	25 (92.6)	46.1 (18.9, 100.0)	24 (96.0)	32.4 (10.3, 100.0)
Normal	162 (54.0)	6.0 (2.7, 20.7)	198 (78.6)	100.0 (23.4, 100.0)	185 (95.9)	48.9 (12.7, 100.0)	127 (81.4)	14.9 (5.9, 46.9)	109 (93.2)	100.0 (22.7, 100.0)	95 (94.1)	29.3 (8.4, 90.3)	92 (97.9)	37.1 (8.5, 100.0)
Overweight	98 (51.6)	10.4 (3.4, 66.0)	117 (74.5)	100.0 (27.0, 100.0)	120 (94.5)	69.0 (12.6, 100.0)	79 (79.8)	18.5 (5.9, 45.3)	68 (94.4)	100.0 (47.7, 100.0)	58 (96.7)	31.9 (10.0, 100.0)	52 (96.3)	23.8 (11.9, 100.0)
Obese	67 (56.8)	20.6 (6.5, 82.4)	77 (76.2)	84.2 (30.0, 100.0)	78 (96.3)	54.6 (7.2, 100.0)	61 (82.4)	23.1 (9.4, 67.1)	52 (100.0)	100.0 (45.5, 100.0)	46 (95.8)	39.4 (13.2, 100.0)	44 (100.0)	41.7 (9.5, 100.0)

Table 13 SARS-CoV-2 anti-spike IgG antibody level and seropositive rate of Pfizer (Adolescent) recipients by follow up

VARIABLES	BASELINE (n=153)		SECOND DOSE (n=143)		COMPLETED VACCINATION (n=124)		3 MONTHS (n=110)		6 MONTHS (n=98)		9 MONTHS (n=90)		12 MONTHS (n=72)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	57 (37.3)	3.7 (2.0, 8.6)	143 (100.0)	93.8 (24.0, 100.0)	124 (100.0)	100.0 (100.0, 100.0)	110 (100.0)	100.0 (100.0, 100.0)	98 (100.0)	100.0 (51.8, 100.0)	90 (100.0)	100.0 (48.5, 100.0)	72 (100.0)	100.0 (32.7, 100.0)
Sociodemography														
Sex														
Male	28 (32.9)	4.1 (2.3, 8.7)	78 (100.0)	83.0 (20.0, 100.0)	66 (100.0)	100.0 (100.0, 100.0)	60 (100.0)	100.0 (100.0, 100.0)	49 (100.0)	100.0 (50.9, 100.0)	47 (100.0)	100.0 (36.5, 100.0)	36 (100.0)	100.0 (31.1, 100.0)
Female	29 (42.6)	2.8 (1.6, 10.7)	65 (100.0)	100.0 (26.6, 100.0)	58 (100.0)	100.0 (100.0, 100.0)	50 (100.0)	100.0 (100.0, 100.0)	49 (100.0)	100.0 (52.4, 100.0)	43 (100.0)	100.0 (62.8, 100.0)	36 (100.0)	100.0 (41.9, 100.0)
Nationality														
Malaysian	8 (16.0)	3.7 (1.9, 4.2)	40 (100.0)	47.4 (17.9, 100.0)	31 (100.0)	100.0 (100.0, 100.0)	31 (100.0)	100.0 (100.0, 100.0)	21 (100.0)	100.0 (39.7, 100.0)	20 (100.0)	100.0 (19.7, 100.0)	14 (100.0)	100.0 (44.0, 100.0)
Non-Malaysian	49 (47.6)	3.7 (2.0, 8.9)	103 (100.0)	100.0 (26.9, 100.0)	93 (100.0)	100.0 (100.0, 100.0)	79 (100.0)	100.0 (100.0, 100.0)	77 (100.0)	100.0 (55.3, 100.0)	70 (100.0)	100.0 (50.3, 100.0)	58 (100.0)	100.0 (31.3, 100.0)
Comorbidity status														
No comorbid	53 (38.1)	3.7 (2.0, 8.4)	130 (100.0)	96.9 (24.0, 100.0)	112 (100.0)	100.0 (100.0, 100.0)	101 (100.0)	100.0 (100.0, 100.0)	90 (100.0)	100.0 (49.5, 100.0)	81 (100.0)	100.0 (48.1, 100.0)	64 (100.0)	100.0 (31.3, 100.0)
Comorbid	4 (28.6)	12.5 (1.4, 25.2)	13 (100.0)	58.2 (27.5, 100.0)	12 (100.0)	100.0 (100.0, 100.0)	9 (100.0)	100.0 (100.0, 100.0)	8 (100.0)	100.0 (100.0, 100.0)	9 (100.0)	100.0 (75.5, 100.0)	8 (100.0)	100.0 (55.2, 100.0)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	15 (28.3)	4.2 (1.6, 21.3)	50 (100.0)	56.7 (20.5, 100.0)	43 (100.0)	100.0 (100.0, 100.0)	38 (100.0)	100.0 (100.0, 100.0)	35 (100.0)	100.0 (63.2, 100.0)	26 (100.0)	100.0 (45.5, 100.0)	23 (100.0)	89.2 (40.2, 100.0)
Symptomatic	42 (42.0)	3.6 (2.1, 8.4)	93 (100.0)	100.0 (25.4, 100.0)	81 (100.0)	100.0 (100.0, 100.0)	72 (100.0)	100.0 (100.0, 100.0)	63 (100.0)	100.0 (49.0, 100.0)	64 (100.0)	100.0 (52.6, 100.0)	49 (100.0)	100.0 (30.4, 100.0)
Past COVID-19 close contact														
Yes	11 (50.0)	2.8 (1.6, 4.2)	20 (100.0)	100.0 (48.2, 100.0)	17 (100.0)	100.0 (100.0, 100.0)	17 (100.0)	100.0 (100.0, 100.0)	13 (100.0)	63.2 (38.9, 100.0)	9 (100.0)	100.0 (61.7, 100.0)	8 (100.0)	74.6 (34.5, 100.0)
No	46 (35.1)	3.9 (2.1, 8.8)	123 (100.0)	76.8 (23.9, 100.0)	107 (100.0)	100.0 (100.0, 100.0)	93 (100.0)	100.0 (100.0, 100.0)	85 (100.0)	100.0 (55.3, 100.0)	81 (100.0)	100.0 (48.4, 100.0)	64 (100.0)	100.0 (32.7, 100.0)
Past COVID-19 infection														
Yes	6 (66.7)	2.8 (2.2, 8.0)	8 (100.0)	100.0 (95.4, 100.0)	7 (100.0)	100.0 (100.0, 100.0)	7 (100.0)	100.0 (100.0, 100.0)	14 (100.0)	100.0 (100.0, 100.0)	10 (100.0)	100.0 (90.8, 100.0)	10 (100.0)	100.0 (29.3, 100.0)
No	51 (35.4)	3.8 (1.9, 8.8)	135 (100.0)	76.8 (23.5, 100.0)	117 (100.0)	100.0 (100.0, 100.0)	103 (100.0)	100.0 (100.0, 100.0)	84 (100.0)	100.0 (49.2, 100.0)	80 (100.0)	100.0 (45.1, 100.0)	62 (100.0)	100.0 (35.4, 100.0)

VARIABLES	BASELINE (n=153)		SECOND DOSE (n=143)		COMPLETED VACCINATION (n=124)		3 MONTHS (n=110)		6 MONTHS (n=98)		9 MONTHS (n=90)		12 MONTHS (n=72)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Lifestyle														
Smoking status														
Not smoking	55 (37.2)	3.5 (1.9, 8.4)	138 (100.0)	96.9 (24.5, 100.0)	121 (100.0)	100.0 (100.0, 100.0)	108 (100.0)	100.0 (100.0, 100.0)	96 (100.0)	100.0 (52.6, 100.0)	88 (100.0)	100.0 (48.3, 100.0)	70 (100.0)	100.0 (35.5, 100.0)
Past smoker	2 (50.0)	10.9 (3.7, -)	4 (100.0)	56.9 (8.2, 100.0)	3 (100.0)	100.0 (100.0, 100.0)	2 (100.0)	73.5 (47.0, -)	2 (100.0)	63.5 (27.1, -)	2 (100.0)	100.0 (100.0,100.0)	2 (100.0)	64.4 (28.7, -)
Current smoker	0	-	1 (100.0)	-						N/A				
BMI														
Thinness	6 (46.2)	4.0 (1.9, 8.8)	12 (100.0)	96.9 (27.9, 100.0)	11 (100.0)	100.0 (100.0, 100.0)	12 (100.0)	100.0 (100.0, 100.0)	11 (100.0)	100.0 (28.7, 100.0)	9 (100.0)	100.0 (20.6, 100.0)	9 (100.0)	100.0 (60.5, 100.0)
Normal	32 (33.7)	3.1 (2.2, 8.4)	88 (100.0)	58.5 (19.9, 100.0)	78 (100.0)	100.0 (100.0, 100.0)	65 (100.0)	100.0 (100.0, 100.0)	57 (100.0)	100.0 (63.6, 100.0)	52 (100.0)	100.0 (58.5, 100.0)	41 (100.0)	100.0 (43.6, 100.0)
Overweight	12 (48.0)	4.4 (1.7, 15.0)	24 (100.0)	100.0 (30.6, 100.0)	21 (100.0)	100.0 (100.0, 100.0)	20 (100.0)	100.0 (100.0, 100.0)	18 (100.0)	86.5 (42.9, 100.0)	19 (100.0)	100.0 (32.9, 100.0)	15 (100.0)	100.0 (31.2, 100.0)
Obese	7 (35.0)	4.2 (1.9, 24.8)	19 (100.0)	100.0 (45.2, 100.0)	14 (100.0)	100.0 (100.0, 100.0)	13 (100.0)	100.0 (100.0, 100.0)	12 (100.0)	100.0 (32.1, 100.0)	10 (100.0)	100.0 (47.2, 100.0)	7 (100.0)	36.8 (28.7, 100.0)

3.1.4 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of Pfizer, Sinovac, AstraZeneca, CanSino and Pfizer (Adolescent) recipients by follow up

SARS-CoV-2 anti-nucleocapsid IgG can be detected after infection and/or following Sinovac vaccination

At baseline, the seropositive rate was different for Pfizer, Sinovac, AstraZeneca and CanSino recipients at 6.0%, 8.2%, 5.0% and 57.5%, respectively (Table 14, Table 15, Table 16, Table 17). Subsequently, the seropositive rate of Pfizer and AstraZeneca recipients increased gradually over time with an obvious rise from 6 to 9 months follow up. There was a more gradual increase in the seropositive rate for CanSino recipients from the baseline. Notably, anti-nucleocapsid IgG antibodies following Sinovac vaccination displayed a similar pattern to anti-spike IgG antibodies. The seropositive rate of Sinovac recipients peaked at completed vaccination/3 months and decreased at 6 months, before increasing again at 9 and 12 months follow up. In fact, Sinovac recipients generally had higher antibody levels relative to other vaccine recipients, especially at 9 and 12 months follow up.

As for self-reported past COVID-19 infection, the cohorts with past infection had higher seropositive rate and/or antibody level compared to those without past infection, especially in the first few follow ups. When classified by booster status, the groups with no booster shots being administered appeared to have higher seropositive rate as compared to the boosted groups, except for CanSino recipients. This was more apparent among Pfizer recipients at 9 and 12 months, and at 9 months follow up among Sinovac and AstraZeneca recipients. The other sociodemographic subgroups including age, sex, ethnicity, nationality and comorbidity demonstrated either comparable or inconsistent differences in seropositive rate and antibody level throughout the 12 months follow up.

Approximately 40.5% (n=62) of adolescent Pfizer recipients were seropositive with an antibody level of 53.5 (15.3, 124.5) at baseline (Table 18). The seropositive rate plateaued up to 3 months follow up before doubling to 85.7% at 6 months and gradually increased over time. Non-Malaysian, those who reported past COVID-19 symptoms, past COVID-19 close contact and past COVID-19 infection had higher seropositive rate up to 3 months follow up.

Table 14 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of Pfizer recipients by follow up

VARIABLES	BASELINE (n=612)		SECOND DOSE (n=577)		COMPLETED VACCINATION (n=507)		3 MONTHS (n=441)		6 MONTHS (n=352)		9 MONTHS (n=302)		12 MONTHS (n=277)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	37 (6.0)	29.7 (4.6, 99.6)	44 (7.6)	24.6 (7.7, 81.2)	52 (10.3)	18.8 (4.3, 78.6)	75 (17.0)	21.8 (7.0, 56.2)	90 (25.6)	17.3 (7.7, 59.2)	207 (68.5)	33.0 (15.0, 71.5)	222 (80.1)	26.9 (15.2, 62.8)
Sociodemography														
Age group														
18-39 years	21 (6.4)	16.5 (2.8, 56.3)	24 (7.6)	13.0 (4.4, 40.4)	31 (11.0)	16.0 (3.1, 32.9)	47 (18.7)	16.1 (7.7, 43.8)	61 (30.7)	20.4 (8.0, 48.2)	139 (82.7)	39.2 (16.5, 90.1)	140 (87.5)	26.8 (15.4, 64.1)
40-59 years	6 (6.5)	14.3 (5.3,130.3)	7 (7.9)	23.8 (4.9, 82.0)	7 (8.5)	32.4 (12.3,123.5)	11 (14.9)	33.8 (9.5, 105.6)	14 (23.7)	15.9 (3.3, 107.3)	41 (73.2)	20.6 (15.2, 50.7)	37 (80.4)	23.7 (14.0, 63.1)
60 years and above	10 (5.2)	74.1 (40.1,135.2)	13 (7.6)	47.1 (17.4,135.7)	14 (9.9)	48.3 (2.3, 119.8)	17 (14.8)	54.2 (3.9, 106.7)	15 (16.0)	17.4 (8.1, 80.7)	27 (34.6)	23.8 (2.0, 49.7)	45 (63.4)	31.1 (15.5, 58.9)
Sex														
Male	10 (3.1)	19.9 (2.8, 97.6)	15 (5.0)	14.1 (3.1, 41.8)	22 (8.4)	11.7 (2.6, 50.4)	32 (14.8)	12.2 (6.4, 44.2)	36 (21.3)	16.5 (7.1, 67.1)	87 (60.8)	32.7 (14.3, 63.8)	96 (73.3)	25.4 (11.5, 52.1)
Female	27 (9.3)	34.8 (6.0, 112.3)	29 (10.6)	32.2 (9.2, 89.1)	30 (12.2)	22.3 (7.2, 109.0)	43 (19.1)	33.5 (11.7, 77.3)	54 (29.5)	22.8 (8.0, 55.5)	120 (75.5)	34.6 (15.1, 87.1)	126 (86.3)	27.9 (15.8, 69.8)
Ethnicity														
Malay	21 (5.0)	33.6 (3.1, 118.8)	24 (6.0)	14.2 (7.7, 61.3)	29 (8.1)	16.0 (2.9, 38.4)	44 (14.0)	12.9 (6.4, 43.7)	67 (26.7)	16.5 (7.0, 40.7)	154 (74.8)	33.4 (15.2, 62.3)	163 (86.2)	26.5 (13.9, 51.9)
Chinese	4 (4.9)	28.8 (23.6, 40.5)	4 (5.3)	28.0 (13.0,176.9)	2 (3.2)	127.7 (21.0, -)	6 (11.8)	18.1 (7.1, 110.2)	4 (9.8)	30.2 (12.1, 156.9)	13 (35.1)	19.6 (13.6, 63.1)	16 (48.5)	19.4 (10.3, 36.5)
Indian	8 (12.5)	45.4 (3.8, 119.7)	10 (16.7)	76.7 (20.0,125.7)	12 (24.5)	88.8 (11.1,135.5)	12 (27.9)	98.7 (20.7,147.5)	10 (27.8)	67.1 (3.0, 105.4)	17 (50.0)	32.7 (3.3, 82.4)	21 (67.7)	40.4 (17.1, 65.0)
Bumiputera Sabah & Sarawak	2 (5.9)	10.1 (7.8, -)	4 (12.1)	3.1 (2.1, 32.2)	7 (21.9)	4.5 (2.9, 18.9)	10 (37.0)	43.1 (13.3, 80.6)	7 (33.3)	28.7 (24.8, 54.7)	21 (91.3)	64.1 (15.7, 144.6)	19 (90.5)	35.7 (17.3, 110.3)
Others	2 (25.0)	57.3 (2.3, -)	2 (25.0)	45.5 (8.9, -)	2 (33.3)	103.7 (29.3, -)	3 (60.0)	33.5 (7.7, -)	2 (66.7)	8.5 (6.3, -)	2 (100.0)	189.6 (186.6, -)	3 (100.0)	58.0 (23.6, -)
Nationality														
Malaysian	36 (5.9)	28.8 (3.9, 94.0)	43 (7.5)	23.8 (7.4, 78.9)	51 (10.1)	18.7 (4.2, 74.6)	74 (16.9)	20.8 (6.9, 54.7)	90 (25.6)	17.3 (7.7, 59.2)	207 (68.5)	33.0 (15.0, 71.5)	221 (80.1)	27.0 (15.1, 62.8)
Non-Malaysian	1 (25.0)	-	1 (25.0)	-	1 (25.0)	-	1 (33.3)	-	0	-	N/A		1 (100.0)	-
Comorbidity status														
No comorbid	23 (6.2)	16.5 (2.9, 68.1)	27 (7.6)	14.1 (3.4, 41.8)	35 (11.0)	16.0 (3.1, 32.4)	47 (17.0)	16.1 (7.7, 46.1)	63 (29.7)	16.6 (8.3, 48.6)	150 (80.2)	33.4 (15.6, 67.9)	147 (85.5)	25.5 (15.3, 51.7)
Any 1 comorbidity	9 (7.6)	52.6 (20.0,133.3)	12 (10.7)	41.6 (5.8, 144.9)	12 (12.2)	53.8 (11.1,117.1)	22 (25.9)	39.8 (6.3, 99.1)	20 (27.0)	25.6 (6.0, 77.0)	37 (61.7)	40.7 (10.2, 109.0)	45 (77.6)	35.8 (16.0, 74.9)
2 or more comorbidities	5 (4.1)	44.2 (15.5,145.4)	5 (4.5)	74.6 (20.8,158.8)	5 (5.4)	108.0 (2.2,195.8)	6 (7.5)	113.7 (6.0, 167.6)	7 (10.6)	13.7 (1.9, 89.0)	20 (36.4)	29.7 (5.9, 81.5)	30 (63.8)	36.6 (10.7, 50.1)

VARIABLES	BASELINE (n=612)		SECOND DOSE (n=577)		COMPLETED VACCINATION (n=507)		3 MONTHS (n=441)		6 MONTHS (n=352)		9 MONTHS (n=302)		12 MONTHS (n=277)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	12 (5.8)	38.9 (9.3, 155.7)	14 (7.4)	21.8 (7.9, 103.2)	19 (11.4)	8.3 (2.6, 32.9)	31 (21.2)	29.3 (7.7, 60.5)	36 (29.8)	15.2 (8.1, 69.6)	73 (65.8)	41.5 (15.3, 98.3)	83 (80.6)	28.8 (15.3, 62.7)
Symptomatic	25 (6.2)	22.1 (4.5, 81.9)	30 (7.8)	24.6 (6.8, 79.6)	33 (9.7)	21.0 (6.9, 80.1)	44 (14.9)	16.2 (6.8, 53.9)	54 (23.4)	18.9 (7.5, 50.4)	134 (70.2)	31.8 (14.7, 61.5)	139 (79.9)	25.7 (15.0, 62.9)
Past COVID-19 close contact														
Yes	15 (26.3)	34.8 (6.4, 95.7)	14 (25.5)	40.3 (10.3,118.6)	14 (27.5)	52.0 (15.6,133.5)	14 (30.4)	32.6 (10.5,113.6)	15 (38.5)	22.6 (7.7, 65.9)	28 (80.0)	37.5 (16.1, 122.4)	29 (87.9)	35.8 (19.8, 80.2)
No	22 (4.0)	28.6 (3.1, 116.2)	30 (5.7)	14.2 (3.6, 69.6)	38 (8.3)	11.7 (2.9, 50.4)	61 (15.4)	19.8 (6.8, 49.5)	75 (24.0)	17.3 (8.1, 54.7)	179 (67.0)	33.0 (14.9, 67.3)	193 (79.1)	25.7 (14.0, 58.0)
Past COVID-19 infection														
Yes	14 (87.5)	39.7 (13.2, 90.6)	14 (87.5)	56.8 (13.1,131.2)	14 (87.5)	74.3 (20.3,144.7)	26 (83.9)	16.2 (6.9, 57.8)	31 (83.8)	11.4 (6.0, 37.7)	84 (97.7)	40.7 (17.0, 96.2)	85 (97.7)	33.3 (17.6, 74.9)
No	23 (3.9)	27.5 (3.1, 127.7)	30 (5.3)	13.0 (3.3, 50.0)	38 (7.7)	11.1 (2.7, 32.5)	49 (12.0)	29.3 (7.1, 57.3)	59 (18.7)	24.8 (9.9, 70.9)	123 (56.9)	28.2 (12.8, 61.4)	137 (72.1)	24.6 (13.6, 52.1)
Booster Status														
No booster									65 (26.7)	16.6 (8.3, 66.1)	100 (87.7)	31.8 (14.0, 65.8)	94 (94.0)	24.2 (14.7, 60.0)
1 dose				N/A					25 (22.9)	22.6 (6.9, 51.7)	107 (56.9)	39.7 (16.2, 84.8)	126 (72.0)	28.8 (15.4, 63.3)
2 doses										N/A			2 (100.0)	10.5 (5.0, -)
Lifestyle														
Smoking status														
Not smoking	25 (6.1)	34.8 (4.6, 120.0)	28 (7.1)	24.6 (8.6, 92.7)	32 (9.2)	18.4 (3.8, 105.5)	49 (16.0)	24.4 (8.4, 81.2)	63 (25.2)	21.5 (7.7, 57.9)	144 (67.3)	32.0 (14.9, 67.6)	157 (79.7)	28.2 (15.8, 67.0)
Past smoker	2 (5.3)	81.9 (68.1, -)	2 (5.9)	91.6 (66.5, -)	3 (9.7)	80.3 (11.1, -)	6 (22.2)	26.5 (4.3, 126.4)	6 (28.6)	44.5 (5.9, 91.0)	17 (81.0)	43.9 (32.8, 120.1)	18 (81.8)	48.1 (22.8, 92.8)
Current smoker	10 (6.2)	19.9 (2.8, 51.1)	14 (9.4)	14.2 (3.0, 37.6)	17 (13.2)	18.9 (3.5, 38.4)	20 (18.5)	12.2 (7.8, 35.9)	21 (25.9)	16.5 (8.1, 42.6)	46 (68.7)	31.5 (13.7, 87.0)	47 (81.0)	16.5 (8.9, 38.8)
BMI by WHO 1998														
Underweight	2 (4.8)	14.8 (2.1, -)	2 (5.3)	15.9 (2.4, -)	3 (10.7)	3.1 (1.5, -)	6 (23.1)	7.8 (3.4, 34.5)	9 (50.0)	16.5 (4.6, 66.9)	11 (84.6)	26.8 (14.3, 40.9)	12 (92.3)	17.1 (8.2, 33.6)
Normal	14 (5.6)	25.2 (2.6, 111.1)	19 (8.0)	14.1 (3.4, 66.5)	21 (10.2)	21.9 (5.1, 77.0)	26 (15.3)	15.1 (4.8, 60.2)	27 (20.3)	16.6 (5.5, 70.9)	83 (69.2)	27.7 (12.8, 52.6)	86 (80.4)	26.1 (13.6, 71.5)
Overweight	7 (3.5)	44.2 (22.1, 95.7)	10 (5.3)	24.6 (11.7, 64.5)	13 (7.7)	11.1 (2.5, 22.3)	24 (15.6)	19.6 (10.6, 46.7)	32 (25.4)	15.9 (9.6, 37.0)	70 (64.8)	41.0 (15.5, 67.9)	77 (74.8)	27.6 (15.2, 62.8)
Obese	14 (12.0)	31.6 (5.3, 116.2)	13 (11.6)	74.6 (6.9, 138.0)	15 (14.4)	32.9 (6.0, 130.2)	19 (20.9)	54.2 (13.0,109.7)	22 (29.3)	35.0 (8.2, 71.6)	43 (70.5)	49.0 (18.6, 136.6)	47 (87.0)	29.6 (15.7, 66.1)

Table 15 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of Sinovac recipients by follow up

VARIABLES	BASELINE (n=608)		SECOND DOSE (n=555)		COMPLETED VACCINATION (n=487)		3 MONTHS (n=419)		6 MONTHS (n=380)		9 MONTHS (n=320)		12 MONTHS (n=308)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	50 (8.2)	65.4 (21.4,135.5)	81 (14.6)	60.8 (8.2, 147.7)	305 (62.6)	10.7 (3.3, 49.5)	264 (63.0)	6.0 (2.3, 41.2)	186 (48.9)	7.3 (1.9, 82.6)	225 (70.3)	121.8 (64.8, 172.4)	226 (73.4)	145.5 (76.6, 201.5)
Sociodemography														
Age group														
18-39 years	34 (9.9)	50.4 (9.9, 86.7)	57 (18.4)	50.8 (7.8, 145.1)	193 (73.9)	16.2 (4.0, 58.3)	161 (77.0)	9.0 (2.5, 61.0)	108 (57.1)	6.4 (2.1, 53.6)	109 (75.2)	113.5 (60.0, 167.0)	111 (77.1)	125.1 (53.5, 191.4)
40-59 years	13 (5.5)	123.7 (43.1, 180.6)	20 (9.1)	69.0 (5.5, 163.9)	102 (50.2)	5.8 (2.6, 21.5)	93 (49.7)	4.0 (1.8, 19.2)	66 (38.8)	5.4 (1.7, 112.8)	101 (64.7)	131.7 (83.5, 184.9)	98 (68.5)	154.7 (101.6,210.3)
60 years and above	3 (10.3)	135.9 (118.3, -)	4 (14.8)	114.9 (72.2, 187.2)	10 (43.5)	17.5 (1.8, 134.7)	10 (43.5)	29.7 (1.6, 120.9)	12 (57.1)	76.1 (48.1,180.1)	15 (78.9)	91.4 (34.9, 137.5)	17 (81.0)	127.7 (56.0, 189.1)
Sex														
Male	29 (9.1)	46.1 (11.7, 137.8)	41 (13.9)	70.8 (20.2, 164.3)	145 (57.1)	8.0 (2.9, 44.1)	127 (56.7)	5.9 (2.1, 56.3)	93 (44.7)	18.5 (2.3, 97.4)	122 (68.5)	116.1 (66.2, 176.4)	123 (70.7)	143.1 (67.6, 196.3)
Female	21 (7.3)	85.7 (50.4, 127.0)	40 (15.4)	52.4 (5.4, 114.7)	160 (68.7)	12.0 (4.7, 54.2)	137 (70.3)	6.2 (2.4, 25.3)	93 (54.1)	4.7 (1.9, 67.9)	103 (72.5)	122.3 (61.4, 167.5)	103 (76.9)	149.9 (84.7, 210.7)
Ethnicity														
Malay	43 (9.0)	72.0 (23.1, 135.9)	72 (16.4)	66.1 (8.0, 149.0)	243 (63.4)	10.7 (3.2, 55.0)	207 (63.7)	7.3 (2.4, 55.0)	146 (49.5)	6.6 (2.0, 73.1)	179 (74.0)	123.9 (61.4, 172.0)	170 (73.3)	151.7 (81.4, 201.9)
Chinese	1 (1.4)	-	3 (4.7)	36.5 (1.2, -)	31 (50.8)	6.6 (2.5, 16.5)	27 (48.2)	3.0 (1.5, 4.8)	21 (38.9)	18.5 (1.7, 194.7)	24 (50.0)	112.3 (42.1, 171.2)	32 (65.3)	123.9 (67.6, 196.1)
Indian	4 (10.3)	50.7 (27.6, 194.0)	5 (13.9)	50.3 (26.7, 208.7)	23 (71.9)	16.9 (5.0, 72.2)	22 (78.6)	6.0 (2.3, 52.6)	13 (54.2)	4.3 (1.7, 33.3)	16 (66.7)	97.2 (71.5, 181.2)	17 (85.0)	76.7 (17.2, 182.0)
Bumiputera Sabah & Sarawak	0	-	0	-	3 (50.0)	16.7 (9.9, -)	3 (60.0)	77.6 (15.1, -)	1 (50.0)	-	3 (100.0)	172.7 (92.0, -)	3 (100.0)	125.1 (99.7, -)
Others	2 (22.2)	10.3 (8.7, -)	1 (14.3)	-	5 (100.0)	25.1 (18.0, 102.9)	5 (100.0)	16.4 (9.8, 135.5)	5 (100.0)	81.2 (2.2, 173.5)	3 (100.0)	94.0 (89.2, -)	4 (100.0)	114.5 (49.8, 133.3)
Nationality														
Malaysian	48 (8.0)	66.7 (25.9, 135.8)	80 (14.6)	61.4 (8.0, 149.0)	302 (62.4)	10.7 (3.3, 49.5)	261 (62.7)	5.9 (2.3, 39.4)	183 (48.5)	7.2 (1.9, 78.3)	224 (70.2)	122.1 (64.4, 172.5)	224 (73.2)	147.8 (77.3, 201.6)
Non-Malaysian	2 (22.2)	10.3 (8.7, -)	1 (16.7)	-	3 (100.0)	25.1 (17.8, -)	3 (100.0)	10.6 (8.9, -)	3 (100.0)	81.2 (2.6, -)	1 (100.0)	-	2 (100.0)	72.9 (29.0, -)
Comorbidity status														
No comorbid	35 (10.0)	58.6 (11.9, 120.0)	56 (18.1)	61.2 (8.0, 145.1)	194 (72.4)	11.5 (3.3, 47.6)	153 (70.8)	6.2 (2.5, 29.7)	99 (51.8)	7.2 (1.9, 65.5)	114 (75.0)	116.7 (60.3, 164.7)	116 (77.3)	148.8 (62.7, 203.1)
Any 1 comorbidity	7 (5.4)	28.7 (9.9, 189.4)	13 (10.9)	38.8 (4.9, 107.5)	53 (51.5)	16.3 (4.1, 69.8)	51 (53.7)	6.0 (1.8, 33.2)	35 (41.2)	6.4 (1.9, 135.9)	43 (59.7)	137.7 (88.5, 170.9)	44 (63.8)	124.8 (56.2, 182.2)
2 or more comorbidities	8 (6.2)	127.1 (56.1, 168.2)	12 (9.5)	112.5 (22.5, 162.6)	58 (50.0)	8.0 (2.9, 32.9)	60 (55.6)	5.6 (2.1, 81.2)	52 (50.0)	14.1 (2.0, 99.3)	68 (70.8)	114.2 (57.4, 187.3)	66 (74.2)	152.5 (115.7,200.8)

VARIABLES	BASELINE (n=608)		SECOND DOSE (n=555)		COMPLETED VACCINATION (n=487)		3 MONTHS (n=419)		6 MONTHS (n=380)		9 MONTHS (n=320)		12 MONTHS (n=308)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	16 (5.3)	25.2 (10.3, 78.0)	27 (10.2)	50.3 (4.6, 121.6)	138 (62.7)	9.6 (3.4, 25.2)	122 (63.9)	5.2 (2.3, 21.6)	82 (48.0)	4.5 (1.7, 52.1)	95 (70.9)	123.4 (70.6, 172.7)	99 (74.4)	149.9 (76.7, 198.7)
Symptomatic	34 (11.0)	87.3 (43.2, 157.4)	54 (18.7)	64.3 (8.6, 160.3)	167 (62.5)	14.7 (3.2, 71.5)	142 (62.3)	7.4 (2.3, 66.7)	104 (49.8)	17.4 (2.2, 110.9)	130 (69.9)	120.6 (60.3, 173.1)	127 (72.6)	143.4 (76.4, 201.6)
Past COVID-19 close contact														
Yes	24 (26.7)	78.1 (27.6, 149.0)	31 (39.2)	103.4 (38.8, 171.2)	55 (75.3)	58.5 (7.9, 190.6)	42 (75.0)	44.9 (4.1, 138.7)	32 (65.3)	21.2 (2.5, 63.0)	33 (82.5)	113.2 (24.8, 169.8)	32 (82.1)	127.0 (33.3, 213.4)
No	26 (5.0)	56.6 (11.1, 118.8)	50 (10.5)	49.5 (2.7, 100.8)	250 (60.4)	9.8 (3.1, 31.3)	222 (61.2)	5.2 (2.0, 23.4)	154 (46.5)	6.2 (1.9, 92.0)	192 (68.6)	122.9 (67.2, 174.1)	194 (72.1)	149.3 (81.4, 198.8)
Past COVID-19 infection														
Yes	28 (82.4)	76.7 (33.1, 149.0)	28 (87.5)	126.9 (65.9, 173.5)	29 (93.5)	190.6 (70.7, 216.4)	44 (100.0)	130.9 (46.1, 180.9)	48 (94.1)	105.4 (41.8, 178.0)	108 (96.4)	133.9 (78.0, 176.3)	111 (97.4)	144.5 (79.1, 199.2)
No	22 (3.8)	44.3 (9.6, 122.7)	53 (10.1)	44.6 (2.4, 102.3)	276 (60.5)	9.8 (3.0, 31.3)	220 (58.7)	4.4 (2.0, 12.6)	138 (41.9)	3.2 (1.6, 28.7)	117 (56.3)	110.1 (47.9, 168.0)	115 (59.3)	146.5 (76.4, 201.6)
Booster Status														
No booster	N/A								75 (54.0)	6.4 (1.7, 47.4)	31 (83.8)	113.9 (60.1, 166.5)	35 (89.7)	138.8 (48.0, 174.9)
1 dose									111 (46.1)	9.4 (2.1, 116.9)	194 (68.6)	122.1 (66.9, 175.0)	191 (71.0)	146.5 (81.4, 203.5)
Lifestyle														
Smoking status														
Not smoking	37 (8.7)	72.0 (25.2, 135.0)	60 (15.7)	66.1 (8.0, 153.8)	221 (65.0)	11.9 (3.7, 57.9)	194 (66.2)	5.9 (2.2, 44.5)	136 (52.1)	6.4 (1.9, 73.2)	158 (72.1)	118.3 (66.9, 167.1)	159 (76.8)	143.8 (76.4, 201.6)
Past smoker	2 (4.9)	135.7 (135.4, -)	6 (15.4)	91.2 (42.9, 161.1)	17 (43.6)	10.2 (4.4, 85.1)	16 (47.1)	18.7 (5.4, 194.0)	13 (38.2)	47.0 (4.1, 142.3)	20 (64.5)	149.1 (63.0, 169.8)	20 (62.5)	121.8 (54.8, 183.2)
Current smoker	11 (7.6)	28.8 (11.5, 54.7)	15 (11.2)	48.7 (7.0, 92.8)	67 (62.0)	5.7 (2.7, 29.5)	54 (58.7)	4.5 (2.2, 23.2)	37 (43.5)	9.1 (2.7, 97.4)	47 (67.1)	115.8 (31.4, 186.3)	47 (68.1)	156.1 (79.5, 203.5)
BMI by WHO 1998														
Underweight	2 (6.1)	47.7 (9.8, -)	4 (12.5)	39.5 (2.6, 130.7)	23 (88.5)	6.7 (3.1, 19.5)	13 (76.5)	11.8 (3.2, 18.7)	10 (62.5)	7.0 (2.7, 45.3)	11 (73.3)	102.8 (22.3, 155.5)	9 (75.0)	175.1 (113.8,211.7)
Normal	15 (8.8)	25.5 (6.9, 67.6)	26 (16.7)	40.6 (6.3, 72.0)	95 (70.4)	14.2 (3.8, 58.2)	85 (72.6)	9.5 (3.1, 61.0)	57 (54.3)	9.4 (2.0, 69.4)	62 (76.5)	112.6 (51.9, 169.6)	62 (77.5)	137.7 (51.5, 199.7)
Overweight	16 (9.2)	79.0 (24.1, 135.8)	23 (14.6)	70.8 (7.9, 145.1)	86 (60.6)	16.1 (4.2, 60.5)	77 (60.6)	6.3 (2.5, 68.4)	51 (45.1)	3.5 (1.9, 53.5)	68 (69.4)	119.0 (66.1, 169.9)	70 (74.5)	134.8 (76.6, 207.0)
Obese	17 (7.4)	113.1 (55.2, 157.5)	28 (13.5)	86.7 (19.2, 167.3)	100 (54.6)	7.5 (2.6, 54.4)	89 (56.7)	3.6 (1.7, 23.3)	68 (46.9)	11.0 (2.0, 145.1)	84 (67.2)	128.1 (78.0, 180.5)	85 (70.2)	143.8 (89.4, 194.1)

Table 16 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of AstraZeneca recipients by follow up

VARIABLES	BASELINE (n=617)		SECOND DOSE (n=563)		COMPLETED VACCINATION (n=486)		3 MONTHS (n=N/A)	6 MONTHS (n=394)		9 MONTHS (n=335)		12 MONTHS (n=316)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX		SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	31 (5.0)	64.2 (19.8, 137.5)	53 (9.4)	28.6 (7.5, 71.6)	53 (10.9)	23.1 (9.8, 54.6)		58 (14.7)	24.7 (6.1, 72.6)	203 (60.6)	42.2 (17.4, 88.2)	221 (69.9)	34.2 (14.8, 72.9)
Sociodemography													
Age group													
18-39 years	19 (4.3)	34.5 (10.4, 100.1)	38 (9.4)	18.4 (5.4, 69.0)	35 (10.4)	19.6 (9.2, 48.9)		41 (15.4)	21.8 (6.0, 69.2)	134 (60.4)	41.3 (17.1, 85.6)	141 (69.5)	34.2 (14.8, 71.3)
40-59 years	12 (7.1)	110.4 (28.0, 173.7)	15 (9.8)	58.4 (21.1, 114.4)	18 (12.5)	34.7 (13.3, 101.9)		15 (12.2)	25.2 (11.8, 81.4)	67 (60.4)	42.2 (15.4, 92.1)	77 (70.6)	39.0 (14.9, 78.5)
60 years and above	0	-	0	-	0	-		2 (50.0)	160.6 (124.1, -)	2 (100.0)	127.9 (58.6, -)	3 (75.0)	18.5 (16.3, -)
Sex													
Male	13 (4.7)	41.7 (17.7, 150.8)	21 (8.4)	28.6 (7.4, 119.3)	21 (9.9)	18.8 (6.6, 39.3)		23 (12.9)	18.5 (5.7, 124.1)	91 (62.8)	36.3 (10.8, 82.7)	104 (73.8)	28.7 (11.3, 71.0)
Female	18 (5.3)	69.1 (17.4, 138.9)	32 (10.3)	27.2 (7.3, 69.9)	32 (11.7)	34.7 (11.1, 55.4)		35 (16.2)	25.2 (11.7, 64.5)	112 (58.9)	48.0 (23.2, 93.9)	117 (66.9)	39.4 (17.4, 88.5)
Ethnicity													
Malay	17 (4.0)	93.3 (36.0, 157.5)	37 (9.5)	31.9 (8.6, 80.7)	36 (10.9)	26.7 (11.4, 55.4)		43 (16.4)	27.0 (12.9, 69.5)	152 (70.4)	42.4 (19.0, 87.7)	161 (77.8)	35.4 (16.3, 71.2)
Chinese	10 (6.9)	33.7 (5.6, 139.1)	10 (7.6)	20.8 (4.7, 73.3)	11 (8.8)	14.0 (4.3, 54.0)		12 (11.0)	9.0 (4.2, 115.1)	36 (37.1)	37.8 (13.6, 64.0)	45 (51.1)	28.0 (10.1, 75.4)
Indian	3 (7.3)	33.2 (1.7, -)	4 (11.8)	17.2 (4.1, 60.2)	5 (19.2)	18.9 (10.8, 98.2)		3 (15.0)	6.0 (1.5, -)	14 (73.7)	58.8 (7.0, 159.0)	14 (70.0)	47.7 (10.9, 106.2)
Bumiputera Sabah & Sarawak	1 (16.7)	-	1 (20.0)	-	0	-		0	-	1 (50.0)	-	N/A	
Others	0	-	1 (33.3)	-	1 (50.0)	-		0	-	0	-	1 (100.0)	-
Nationality													
Malaysian	31 (5.1)	64.2 (19.8, 137.5)	51 (9.1)	21.3 (7.1, 73.2)	52 (10.8)	22.2 (9.6, 54.9)		57 (14.5)	24.6 (6.1, 75.5)	202 (60.7)	42.6 (17.4, 88.8)	221 (70.2)	34.2 (14.8, 72.9)
Non-Malaysian	0	-	2 (50.0)	54.9 (39.9, -)	1 (33.3)	-		1 (50.0)	-	1 (50.0)	-	0	-
Comorbidity status													
No comorbid	25 (4.9)	34.5 (9.8, 139.9)	45 (9.7)	21.3 (6.3, 69.8)	44 (11.1)	21.1 (7.5, 52.8)		46 (14.2)	24.7 (6.8, 72.6)	154 (57.0)	40.3 (19.3, 87.2)	166 (66.1)	36.6 (14.8, 78.4)
Any 1 comorbidity	5 (6.1)	87.2 (34.0, 161.6)	7 (9.5)	28.6 (11.6, 102.2)	8 (11.9)	26.9 (15.1, 75.1)		11 (21.2)	15.4 (5.6, 68.9)	40 (76.9)	57.0 (9.9, 99.3)	43 (86.0)	33.6 (13.6, 73.1)
2 or more comorbidities	1 (3.4)	-	1 (3.8)	-	1 (4.8)	-		1 (5.6)	-	9 (69.2)	32.3 (6.9, 66.9)	12 (80.0)	25.0 (16.4, 55.9)

VARIABLES	BASELINE (n=617)		SECOND DOSE (n=563)		COMPLETED VACCINATION (n=486)		3 MONTHS (n=N/A)	6 MONTHS (n=394)		9 MONTHS (n=335)		12 MONTHS (n=316)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX		SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History													
Past COVID-19 symptoms													
Asymptomatic	2 (2.1)	17.0 (1.1, -)	3 (3.6)	16.4 (15.6, -)	6 (8.1)	14.7 (9.5, 26.4)		7 (11.1)	17.9 (6.1, 124.1)	35 (59.3)	53.5 (12.3, 109.6)	40 (65.6)	42.7 (16.3, 79.5)
Symptomatic	29 (5.6)	73.9 (23.0, 140.2)	50 (10.4)	32.5 (6.7, 76.7)	47 (11.4)	29.1 (9.3, 55.5)		51 (15.4)	24.7 (6.1, 69.5)	168 (60.9)	40.2 (17.8, 86.0)	181 (71.0)	33.8 (14.5, 72.3)
Past COVID-19 close contact													
Yes	13 (13.4)	64.2 (28.3, 173.1)	14 (15.7)	21.2 (11.0, 115.3)	15 (19.2)	18.9 (9.3, 93.2)		13 (19.7)	18.5 (5.9, 94.4)	32 (65.3)	28.9 (8.5, 73.9)	33 (75.0)	47.5 (22.2, 99.5)
No	18 (3.5)	57.8 (5.6, 106.9)	39 (8.2)	31.9 (5.6, 70.0)	38 (9.3)	26.7 (10.0, 50.4)		45 (13.7)	25.2 (9.4, 75.5)	171 (59.8)	44.7 (20.6, 92.9)	188 (69.1)	32.4 (14.5, 68.6)
Past COVID-19 infection													
Yes	14 (70.0)	83.7 (32.5, 146.1)	14 (77.8)	55.9 (18.7, 124.4)	13 (76.5)	40.4 (15.0, 117.8)		21 (80.8)	50.5 (13.6, 105.5)	118 (92.2)	48.4 (22.5, 103.0)	134 (93.1)	47.5 (19.5, 85.9)
No	17 (2.8)	33.2 (5.2, 121.5)	39 (7.2)	20.4 (5.4, 59.6)	40 (8.5)	20.2 (7.5, 48.9)		37 (10.1)	17.9 (6.0, 67.0)	85 (41.1)	37.1 (9.5, 76.5)	87 (50.6)	22.4 (10.7, 57.5)
Booster Status													
No booster								46 (16.1)	21.8 (6.1, 72.6)	57 (79.2)	47.4 (14.0, 104.2)	58 (79.5)	33.5 (12.5, 67.8)
1 dose			N/A					12 (11.0)	28.5 (8.2, 82.3)	146 (55.5)	40.6 (18.4, 83.3)	163 (67.6)	36.5 (16.3, 77.4)
2 doses												0	-
Lifestyle													
Smoking status													
Not smoking	23 (4.8)	80.3 (32.9, 137.5)	43 (9.8)	35.1 (7.8, 73.2)	42 (10.8)	32.7 (10.00, 55.7)		44 (13.9)	29.6 (11.7, 69.6)	166 (60.4)	44.2 (21.0, 90.9)	183 (71.8)	36.0 (16.3, 77.3)
Past smoker	2 (5.4)	3.7 (1.3, -)	3 (9.1)	7.1 (5.4, -)	3 (11.5)	17.1 (6.2, -)		4 (19.0)	18.7 (7.9, 99.5)	11 (64.7)	36.0 (17.4, 144.3)	11 (68.8)	28.7 (6.5, 68.6)
Current smoker	6 (6.1)	31.8 (22.0, 192.1)	7 (7.9)	15.6 (9.3, 140.8)	8 (11.3)	13.8 (7.2, 22.0)		10 (17.9)	9.5 (5.6, 143.6)	26 (60.5)	29.0 (6.6, 81.1)	27 (60.0)	32.4 (8.5, 67.6)
BMI by WHO 1998													
Underweight	1 (2.6)	-	5 (16.7)	7.1 (2.3, 23.3)	6 (22.2)	11.9 (3.3, 25.1)		4 (18.2)	14.7 (12.3, 18.0)	10 (58.8)	15.7 (7.5, 92.1)	11 (61.1)	19.1 (6.7, 34.4)
Normal	10 (4.1)	77.1 (15.9, 95.0)	18 (8.2)	32.5 (4.5, 59.1)	16 (8.2)	36.5 (7.5, 52.7)		17 (10.8)	21.8 (4.9, 75.4)	76 (55.9)	44.3 (15.1, 76.9)	89 (68.5)	28.7 (12.4, 61.5)
Overweight	10 (5.3)	33.9 (10.1, 129.9)	19 (10.6)	21.2 (5.6, 91.5)	18 (12.4)	17.1 (6.1, 58.9)		22 (17.1)	26.1 (5.9, 73.2)	69 (63.9)	41.8 (15.5, 112.8)	75 (74.3)	45.6 (16.3, 93.6)
Obese	10 (6.8)	139.9 (32.5, 183.7)	11 (8.3)	68.7 (16.4, 124.1)	13 (10.8)	40.4 (20.2, 117.8)		15 (17.4)	43.2 (14.5, 171.5)	48 (64.9)	57.7 (28.1, 104.5)	46 (68.7)	40.5 (20.0, 89.7)

Table 17 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of CanSino recipients by follow up

VARIABLES	BASELINE (n=676)		14 DAYS AFTER SINGLE DOSE (n=562)		COMPLETED VACCINATION *28 DAYS AFTER SINGLE DOSE (n=442)		3 MONTHS (n=368)		6 MONTHS (n=270)		9 MONTHS (n=236)		12 MONTHS (n=217)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	389 (57.5)	40.0 (12.6, 97.1)	339 (60.3)	39.1 (12.0,104.3)	271 (61.3)	39.3 (12.0, 101.0)	234 (63.6)	24.9 (8.3, 74.0)	232 (85.9)	81.7 (19.0, 146.9)	210 (89.0)	79.4 (21.0, 165.1)	199 (91.7)	38.5 (11.5, 124.6)
Sociodemography														
Age group														
18-39 years	238 (56.9)	34.1 (10.8, 86.8)	211 (61.3)	33.4 (9.8, 94.8)	173 (62.7)	32.4 (10.6, 95.2)	149 (65.4)	21.1 (7.7, 61.7)	142 (85.0)	81.7 (14.9, 144.4)	133 (89.9)	73.1 (21.0, 165.0)	128 (93.4)	33.6 (10.2, 107.7)
40-59 years	135 (58.2)	44.4 (18.7,116.0)	112 (57.1)	51.6 (15.4, 110.8)	86 (57.0)	57.6 (19.1, 123.9)	73 (58.4)	31.7 (12.4, 96.7)	78 (86.7)	80.8 (23.5, 154.0)	64 (87.7)	96.7 (23.8, 169.2)	58 (86.6)	45.9 (14.4, 146.3)
60 years and above	16 (61.5)	52.9 (22.6, 129.5)	16 (72.7)	54.4 (16.1, 156.9)	12 (80.0)	38.4 (18.1, 166.9)	12 (80.0)	25.0 (9.9, 131.4)	12 (92.3)	68.4 (12.4, 112.5)	13 (86.7)	47.6 (12.0, 162.7)	13 (100.0)	41.8 (10.5, 95.5)
Sex														
Male	185 (51.5)	25.4 (7.7, 83.9)	159 (55.8)	22.2 (6.9, 70.0)	126 (56.8)	23.1 (7.9, 95.3)	97 (54.5)	14.4 (4.1, 69.5)	94 (79.7)	71.8 (10.4, 153.6)	97 (85.8)	51.6 (16.1, 164.2)	91 (89.2)	27.8 (9.5, 139.6)
Female	204 (64.4)	54.9 (20.8, 115.1)	180 (65.0)	54.0 (22.8, 115.2)	145 (65.9)	47.4 (19.8, 112.3)	137 (72.1)	30.7 (14.4, 79.0)	138 (90.8)	84.8 (23.1, 142.1)	113 (91.9)	98.8 (24.6, 168.4)	108 (93.9)	53.7 (15.6, 112.4)
Ethnicity														
Malay	161 (58.5)	39.4 (11.3, 83.8)	144 (63.2)	38.2 (10.8, 94.9)	108 (61.4)	38.1 (8.9, 89.0)	106 (65.0)	22.7 (7.7, 77.7)	93 (84.5)	77.3 (21.3, 131.6)	87 (88.8)	83.8 (25.8, 165.3)	82 (95.3)	29.4 (8.9, 100.9)
Bumiputera Sabah & Sarawak	34 (63.0)	33.5 (5.2, 124.3)	25 (65.8)	51.7 (13.8, 143.0)	25 (69.4)	70.1 (11.0, 178.5)	21 (65.6)	45.6 (15.3, 134.4)	36 (94.7)	75.5 (13.4, 154.8)	35 (92.1)	69.3 (20.9, 157.2)	36 (92.3)	48.1 (10.8, 142.6)
Others	194 (56.1)	41.5 (15.1, 109.2)	170 (57.4)	36.2 (13.2, 105.9)	138 (60.0)	35.3 (13.0, 114.6)	107 (61.8)	22.1 (8.9, 45.6)	103 (84.4)	85.6 (17.0, 147.7)	88 (88.0)	78.5 (17.2, 174.3)	81 (88.0)	50.1 (14.1, 138.3)
Nationality														
Malaysian	195 (59.3)	39.4 (10.9, 90.1)	170 (63.7)	41.9 (11.2, 104.2)	134 (62.9)	46.4 (9.8, 99.4)	128 (65.6)	27.2 (8.1, 94.7)	129 (87.8)	75.0 (19.2, 141.6)	122 (90.4)	79.4 (24.6, 165.0)	119 (94.4)	34.2 (10.0, 117.7)
Non-Malaysian	194 (55.9)	40.9 (14.5, 109.2)	169 (57.3)	35.8 (12.6, 106.9)	137 (59.8)	33.9 (12.7, 117.4)	106 (61.3)	20.8 (8.3, 44.6)	103 (83.7)	89.2 (17.0, 151.3)	88 (87.1)	78.5 (17.2, 174.3)	80 (87.9)	52.3 (14.9, 142.1)
Comorbidity status														
No comorbid	313 (56.9)	38.8 (11.7, 91.0)	271 (60.1)	35.8 (11.8, 100.1)	217 (61.1)	39.3 (12.1, 97.3)	182 (63.4)	21.6 (8.3, 61.5)	181 (86.2)	90.6 (19.2, 155.5)	166 (90.2)	75.9 (20.5, 165.0)	157 (92.9)	38.0 (10.6, 127.3)
Any 1 comorbidity	54 (59.3)	49.7 (14.3, 136.6)	49 (60.5)	43.1 (12.3, 134.0)	39 (63.9)	35.9 (10.7, 127.6)	35 (63.6)	42.1 (8.2, 104.1)	37 (86.0)	57.7 (10.8, 120.6)	30 (81.1)	49.6 (20.7, 165.7)	31 (86.1)	39.6 (12.4, 94.6)
2 or more comorbidities	22 (62.9)	59.3 (23.1, 114.5)	19 (63.3)	59.5 (15.5, 103.5)	15 (57.7)	47.1 (20.3, 99.1)	17 (65.4)	45.6 (15.8, 73.6)	14 (82.4)	45.5 (24.7, 101.2)	14 (93.3)	122.4 (61.6, 170.4)	11 (91.7)	95.4 (16.5, 168.8)

VARIABLES	BASELINE (n=676)		14 DAYS AFTER SINGLE DOSE (n=562)		COMPLETED VACCINATION *28 DAYS AFTER SINGLE DOSE (n=442)		3 MONTHS (n=368)		6 MONTHS (n=270)		9 MONTHS (n=236)		12 MONTHS (n=217)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	119 (51.7)	46.7 (14.3, 91.4)	102 (52.8)	41.7 (15.2, 100.4)	76 (53.5)	49.5 (19.0, 114.0)	58 (52.7)	27.3 (7.7, 72.6)	54 (75.0)	53.9 (11.4, 123.7)	52 (85.2)	41.0 (11.6, 159.6)	51 (91.1)	23.6 (8.8, 84.7)
Symptomatic	270 (60.5)	38.2 (11.7, 101.7)	237 (64.2)	38.1 (11.2, 108.2)	195 (65.0)	36.9 (9.9, 97.1)	176 (68.2)	23.4 (8.6, 75.0)	178 (89.9)	89.6 (19.6, 150.3)	158 (90.3)	95.8 (24.9, 165.4)	148 (91.9)	51.6 (13.5, 131.4)
Past COVID-19 close contact														
Yes	31 (68.9)	27.1 (8.9, 81.6)	28 (66.7)	47.4 (10.3, 93.5)	23 (65.7)	51.0 (20.0, 86.0)	24 (70.6)	29.1 (10.0, 73.9)	23 (88.5)	85.2 (34.1, 174.0)	19 (86.4)	70.7 (17.1, 156.4)	19 (90.5)	38.0 (16.2, 130.5)
No	358 (56.7)	40.8 (13.3, 99.6)	311 (59.8)	36.4 (12.2, 106.4)	248 (60.9)	36.7 (11.1, 103.5)	210 (62.9)	24.9 (8.2, 74.5)	209 (85.7)	80.7 (17.2, 145.7)	191 (89.3)	79.8 (21.1, 165.3)	180 (91.8)	39.0 (10.7, 122.3)
Past COVID-19 infection														
Yes	28 (93.3)	46.3 (17.2, 84.2)	26 (96.3)	49.0 (14.1, 86.9)	23 (95.8)	51.2 (17.2, 103.9)	25 (96.2)	44.5 (13.1, 88.2)	23 (95.8)	80.7 (39.8, 143.9)	21 (95.5)	110.5 (25.7, 198.9)	19 (100.0)	59.3 (13.5, 135.9)
No	361 (55.9)	39.7 (12.4, 98.8)	313 (58.5)	36.4 (11.9, 105.7)	248 (59.3)	36.7 (11.7, 100.8)	209 (61.1)	23.2 (8.1, 72.4)	209 (85.0)	82.8 (14.6, 147.4)	189 (88.3)	75.8 (20.2, 164.3)	180 (90.9)	38.2 (11.0, 116.4)
Booster Status														
No booster	N/A								208 (88.9)	79.0 (20.2, 146.9)	182 (89.7)	80.2 (21.7, 166.6)	166 (91.7)	42.4 (10.8, 124.7)
1 dose									24 (66.7)	95.2 (7.0, 150.2)	28 (84.8)	49.6 (17.5, 154.7)	33 (91.7)	34.2 (14.1, 122.1)
Lifestyle														
Smoking status														
Not smoking	231 (63.6)	57.0 (20.9, 118.3)	205 (64.7)	54.7 (19.3, 113.7)	166 (67.2)	52.2 (18.8, 114.6)	152 (72.7)	31.7 (12.6, 82.6)	153 (92.2)	84.4 (23.7, 141.6)	126 (92.6)	98.4 (23.9, 170.4)	122 (96.8)	57.8 (16.3, 124.7)
Past smoker	18 (69.2)	39.0 (18.8, 114.5)	15 (75.0)	32.8 (23.5, 117.9)	10 (66.7)	30.5 (18.3, 139.8)	10 (71.4)	28.3 (11.1, 148.9)	6 (85.7)	44.1 (3.4, 145.6)	8 (88.9)	113.0 (56.6, 165.9)	8 (88.9)	36.3 (20.8, 145.1)
Current smoker	140 (48.8)	17.5 (6.5, 58.5)	119 (52.9)	16.7 (5.3, 47.6)	95 (52.8)	20.0 (5.4, 65.3)	72 (49.7)	11.5 (3.2, 34.6)	73 (75.3)	73.5 (9.5, 165.2)	76 (83.5)	42.7 (14.4, 158.3)	69 (84.1)	16.7 (8.1, 92.1)
BMI by WHO 1998														
Underweight	34 (50.0)	13.3 (3.7, 60.3)	31 (59.6)	16.0 (4.8, 45.6)	24 (58.5)	16.3 (3.8, 35.6)	25 (64.1)	8.0 (2.7, 24.9)	24 (82.8)	86.0 (10.8, 142.4)	25 (92.6)	51.6 (21.1, 150.5)	22 (88.0)	21.2 (9.4, 38.8)
Normal	180 (60.0)	29.4 (11.2, 86.8)	158 (62.7)	27.8 (11.0, 74.6)	122 (63.2)	26.5 (10.1, 87.3)	94 (60.3)	19.6 (6.0, 40.9)	98 (83.8)	67.4 (9.5, 135.3)	84 (83.2)	60.8 (17.7, 164.8)	84 (89.4)	29.5 (8.8, 106.1)
Overweight	103 (54.2)	54.2 (20.8, 116.0)	90 (57.3)	63.4 (23.1, 124.0)	76 (59.8)	47.4 (20.0, 124.9)	62 (62.6)	38.3 (15.1, 94.6)	61 (84.7)	107.8 (24.0, 165.9)	55 (91.7)	76.3 (23.1, 155.2)	49 (90.7)	58.2 (15.8, 143.6)
Obese	72 (61.0)	61.2 (22.5, 127.2)	60 (59.4)	79.0 (25.0, 128.1)	49 (60.5)	78.2 (29.6, 129.3)	53 (71.6)	43.6 (15.8, 119.9)	49 (94.2)	85.2 (31.3, 147.6)	46 (95.8)	112.3 (33.4, 174.0)	44 (100.0)	78.8 (17.0, 138.7)

Table 18 SARS-CoV-2 anti-nucleocapsid IgG antibody level and seropositive rate of Pfizer (Adolescent) recipients by follow up

VARIABLES	BASELINE (n=153)		SECOND DOSE (n=143)		COMPLETED VACCINATION (n=124)		3 MONTHS (n=110)		6 MONTHS (n=98)		9 MONTHS (n=90)		12 MONTHS (n=72)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	62 (40.5)	53.5 (15.3, 124.5)	62 (43.4)	36.8 (10.0, 80.0)	53 (42.7)	29.0 (8.1, 63.3)	44 (40.0)	18.3 (7.6, 44.6)	84 (85.7)	31.5 (7.7, 90.7)	81 (90.0)	63.0 (22.8, 114.1)	68 (94.4)	35.3 (10.8, 84.0)
Sociodemography														
Age														
Below 18 years	62 (40.5)	53.5 (15.3, 124.5)	62 (43.4)	36.8 (10.0, 80.0)	53 (42.7)	29.0 (8.1, 63.3)	44 (40.0)	18.3 (7.6, 44.6)	84 (85.7)	31.5 (7.7, 90.7)	81 (90.0)	63.0 (22.8, 114.1)	68 (94.4)	35.3 (10.8, 84.0)
Sex														
Male	32 (37.6)	71.2 (31.3, 135.8)	32 (41.0)	52.6 (18.6, 92.1)	27 (40.9)	33.5 (9.1, 76.7)	23 (38.3)	20.0 (13.9, 53.0)	41 (83.7)	53.1 (9.2, 126.9)	41 (87.2)	37.9 (24.1, 123.0)	33 (91.7)	33.5 (10.5, 74.5)
Female	30 (44.1)	28.0 (11.5, 100.1)	30 (46.2)	21.7 (6.7, 63.2)	26 (44.8)	22.2 (5.5, 58.6)	21 (42.0)	13.1 (4.7, 38.9)	43 (87.8)	25.3 (4.0, 69.3)	40 (93.0)	67.2 (21.3, 106.0)	35 (97.2)	37.6 (12.3, 90.3)
Nationality														
Malaysian	11 (22.0)	67.0 (28.5, 124.3)	11 (27.5)	48.3 (18.3, 88.5)	8 (25.8)	39.8 (17.7, 58.5)	8 (25.8)	17.9 (9.6, 28.3)	15 (71.4)	11.8 (4.0, 65.8)	16 (80.0)	62.2 (24.8, 95.7)	13 (92.9)	36.4 (15.6, 127.6)
Non-Malaysian	51 (49.5)	53.2 (13.8, 124.9)	51 (49.5)	31.9 (9.1, 77.2)	45 (48.4)	24.7 (7.5, 69.3)	36 (45.6)	18.7 (5.0, 49.9)	69 (89.6)	33.2 (8.7, 103.0)	65 (92.9)	63.0 (21.6, 118.3)	55 (94.8)	35.2 (9.8, 71.0)
Comorbidity status														
No comorbid	58 (41.7)	53.5 (13.9, 126.0)	58 (44.6)	36.8 (9.3, 88.9)	49 (43.8)	29.0 (7.7, 69.3)	41 (40.6)	18.4 (6.3, 46.3)	77 (85.6)	29.4 (7.3, 85.7)	72 (88.9)	44.6 (20.4, 109.6)	60 (93.8)	34.4 (10.4, 76.3)
Comorbid	4 (28.6)	62.5 (31.3, 98.8)	4 (30.8)	39.4 (19.1, 58.7)	4 (33.3)	31.2 (15.8, 46.2)	3 (33.3)	17.5 (8.5, -)	7 (87.5)	135.2 (30.6, 174.2)	8 (100.0)	109.6 (65.6, 140.0)	8 (100.0)	74.2 (18.2, 143.5)
COVID-19 History														
Past COVID-19 symptoms														
Asymptomatic	15 (28.3)	92.7 (27.6, 215.1)	15 (30.0)	53.4 (22.7,110.7)	13 (30.2)	44.2 (13.4,125.9)	9 (23.7)	33.0 (9.0, 78.6)	26 (74.3)	28.3 (9.2, 85.6)	22 (84.6)	52.7 (22.8, 77.6)	20 (87.0)	33.4 (11.3, 70.4)
Symptomatic	47 (47.0)	46.7 (13.9, 100.8)	47 (50.5)	31.8 (9.4, 70.6)	40 (49.4)	22.2 (8.0, 54.7)	35 (48.6)	18.2 (7.5, 43.8)	58 (92.1)	31.7 (6.8, 117.5)	59 (92.2)	68.3 (22.3, 123.2)	48 (98.0)	35.3 (10.6, 90.2)
Past COVID-19 close contact														
Yes	12 (54.5)	30.4 (10.5, 93.3)	12 (60.0)	24.7 (7.0, 68.6)	9 (52.9)	37.5 (9.7, 58.9)	9 (52.9)	13.1 (5.2, 25.8)	10 (76.9)	6.1 (2.9, 27.6)	8 (88.9)	31.6 (8.1, 76.6)	7 (87.5)	116.8 (15.7, 192.2)
No	50 (38.2)	55.4 (15.9, 129.6)	50 (40.7)	43.2 (10.0, 90.8)	44 (41.1)	24.5 (8.0, 71.3)	35 (37.6)	18.9 (7.5, 47.7)	74 (87.1)	33.3 (9.4, 114.8)	73 (90.1)	66.4 (24.1, 121.1)	61 (95.3)	35.2 (10.7, 74.5)
Past COVID-19 infection														
Yes	7 (77.8)	67.0 (10.4, 100.8)	7 (87.5)	38.8 (12.1, 75.4)	6 (85.7)	43.5 (12.1, 57.7)	6 (85.7)	19.3 (6.8, 35.7)	13 (92.9)	18.5 (7.1, 66.3)	10 (100.0)	65.7 (52.6, 116.2)	10 (100.0)	37.4 (15.1, 145.5)
No	55 (38.2)	53.2 (15.8, 129.2)	55 (40.7)	34.8 (9.4, 90.0)	47 (40.2)	24.7 (7.9, 73.4)	38 (36.9)	18.3 (6.9, 45.6)	71 (84.5)	33.2 (7.6, 114.7)	71 (88.8)	44.9 (20.3, 117.6)	58 (93.5)	35.3 (10.2, 79.6)

VARIABLES	BASELINE (n=153)		SECOND DOSE (n=143)		COMPLETED VACCINATION (n=124)		3 MONTHS (n=110)		6 MONTHS (n=98)		9 MONTHS (n=90)		12 MONTHS (n=72)	
	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX	SEROPOSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Lifestyle														
Smoking status														
Not smoking	60 (40.5)	51.7 (14.3, 121.9)	60 (43.5)	33.3 (9.6, 76.7)	51 (42.1)	24.7 (7.9, 61.5)	43 (39.8)	18.2 (7.5, 44.9)	82 (85.4)	32.6 (7.5, 91.4)	79 (89.8)	63.0 (23.4, 110.6)	66 (94.3)	35.3 (10.9, 85.6)
Past smoker	2 (50.0)	149.2 (74.1, -)	2 (50.0)	120.9 (54.8, -)	2 (66.7)	114.8 (33.5, -)	1 (50.0)	-	2 (100.0)	11.6 (10.0, -)	2 (100.0)	89.9 (19.8, -)	2 (100.0)	43.9 (9.8, -)
Current smoker	0	-	0	-						N/A				
BMI														
Thinness	6 (46.2)	119.5 (21.2, 136.3)	6 (50.0)	64.4 (24.5, 89.7)	5 (45.5)	31.6 (17.3, 71.4)	6 (50.0)	32.3 (11.1, 54.6)	8 (72.7)	45.4 (5.0, 159.9)	7 (77.8)	60.9 (29.8, 118.9)	8 (88.9)	35.5 (15.5, 167.0)
Normal	35 (36.8)	40.6 (12.9, 100.8)	35 (39.8)	22.7 (8.4, 75.4)	29 (37.2)	16.9 (5.4, 51.4)	22 (33.8)	16.5 (4.4, 37.2)	47 (82.5)	33.4 (5.6, 114.9)	46 (88.5)	69.7 (24.5, 129.7)	38 (92.7)	35.9 (10.4, 83.7)
Overweight	13 (52.0)	67.0 (12.7, 177.4)	13 (54.2)	38.8 (12.3, 99.5)	12 (57.1)	38.5 (14.5, 73.9)	9 (45.0)	30.7 (14.8, 52.2)	17 (94.4)	28.4 (7.4, 88.9)	18 (94.7)	54.0 (15.2, 92.5)	15 (100.0)	22.4 (10.4, 89.7)
Obese	8 (40.0)	62.1 (33.2, 93.4)	8 (42.1)	44.8 (18.6, 92.8)	7 (50.0)	33.5 (15.5, 113.4)	7 (53.8)	17.7 (8.5, 24.7)	12 (100.0)	12.8 (8.8, 68.7)	10 (100.0)	35.4 (5.2, 103.7)	7 (100.0)	33.5 (8.7, 78.0)

3.2 MODULE B: ADVERSE EVENTS FOLLOWING IMMUNIZATION AND ADVERSE EVENTS OF SPECIAL INTEREST

3.2.1 Adverse events following immunization (AEFI) and adverse events of special interest (AESI) among adults

AEFI and AESI of the first and second doses among adults

During the first follow up, a total of 568 Pfizer recipients, 553 Sinovac recipients, 563 AstraZeneca recipients and 562 CanSino recipients participated in the monitoring of AEFI/AESI (Table 19). This study revealed that the AEFI symptoms after the first and second dose were 31.3% and 40.4% among Pfizer, 28.9% and 27.3% among Sinovac, 59.5% and 29.2% among AstraZeneca and 29.5% among CanSino recipients.

We classified the reported AEFI symptoms based on severity. We also observed that the majority of the recipients had experienced mild symptoms which led to discomfort but could still carry out their daily routines. Based on AEFI severity, mild and slightly uncomfortable symptoms after the first and second dose were 53.9% and 74.1% among Pfizer, 64.4% and 64.7% among Sinovac, 32.8% and 64.1% among AstraZeneca, and 65.1% among CanSino recipients. Moreover, recipients that were uncomfortable but still allowed to carry out their everyday task following the first and second dose were 34.3% and 16.6% among Pfizer, 30.0% and 29.3% among Sinovac, 41.8% and 28.2% among AstraZeneca and 25.9% among CanSino.

The majority of recipients (ranging from 18.1% to 43.4%) reported that they did not require any treatment for the AEFI symptoms following the first and second dose of all vaccines. Among individuals who presented symptoms from all types of vaccines after the first and second dose, about 77.4% to 95.5% were completely recovered, while only 1.2% to 12.0% indicated that the side effects persisted.

In this study, when monitoring for AESI-related hospitalizations, we observed that the percentage was consistently low across all vaccines, with reported rates of below 0.8%. Among individuals who experienced AEFI symptoms from all types of vaccines, about 86.4% did not report their symptoms, 10.4% utilized the MySejahtera platform to report their symptoms and 3.2% opted for the conventional form of reporting at clinics and hospitals.

AEFI and AESI for booster dose among adults

Throughout the 6 to 12 months follow up, a total of 201 Pfizer recipients, 327 Sinovac recipients, 294 AstraZeneca recipients and 50 CanSino recipients participated in the monitoring of AEFI/AESI. It is important to note that the number of total recipients decreased over time due to various reasons including unavailability, retraction from the study and did not-show up (unresponsive). This study revealed that AEFI symptoms after booster were 28.9% for Pfizer, 47.4% for Sinovac, AstraZeneca reported 35.7% for AstraZeneca and 28.0% for CanSino.

After categorizing the reported AEFI symptoms based on their severity, we found that the majority of the recipients experienced mild symptoms, especially slightly uncomfortable. Recipients that were experiencing mild and slightly uncomfortable symptoms were among 53.9% Pfizer, 64.4% Sinovac, 61.0% AstraZeneca and 92.9% CanSino, respectively.

The majority of recipients (ranging from 21.9% to 43.4%) reported that they did not need any treatment for the AEFI symptoms following the booster dose of all vaccines. Among individuals who experienced symptoms from all types of vaccines after receiving the booster dose, a significant percentage ranging from 82.9% to 92.9% reported on being completely recovered. Conversely, only a small proportion ranging from 3.4% to 5.8% mentioned that the side effects persisted.

In this study, when monitoring for AESI-related hospitalizations, we observed that the percentage was consistently low across all vaccines, with reported rates of below 1.0%. Among individuals who experienced AEFI symptoms after receiving the booster dose from all types of vaccines, a majority of 86.5% did not report their symptoms followed by 5.4% that utilized the MySejahtera platform to report their symptoms and 3.9% opted for the conventional method of reporting at clinics and hospitals.

Table 19 Adverse events following immunization (AEFI) and adverse events of special interest (AESI) among adults

AEFI / AESI AMONG ADULTS	AFTER FIRST DOSE n (%)				AFTER SECOND DOSE n (%)				AFTER BOOSTER DOSE n (%)			
	PFIZER (n=568)	SINOVAC (n=553)	ASTRAZENECA (n=563)	CANSINO (n=562)	PFIZER (n=507)	SINOVAC (n=487)	ASTRAZENECA (n=486)	CANSINO (n=NA)	PFIZER (n=201)	SINOVAC (n=327)	ASTRAZENECA (n=294)	CANSINO (n=50)
Symptom												
fever	27	35	249	52	70	29	48		24	37	25	7
chills	1	3	25	5	9	5	4		3	3	2	1
rigors	0	3	0	0	0	0	0		0	0	0	0
myalgia	2	8	3	3	0	5	4		4	18	4	0
headache	48	50	107	69	61	47	55		11	24	19	1
sore throat	3	3	1	1	1	3	4		1	0	0	0
nausea & vomiting	5	10	15	4	2	4	1		3	4	1	0
diarrhoea	2	6	8	2	2	4	3		0	2	0	0
fatigue	20	39	46	14	31	40	36		3	9	17	1
runny nose	3	6	4	0	1	1	0		0	0	0	0
cough	2	3	3	3	3	4	2		2	3	0	0
shortness of breath	5	2	4	5	2	4	1		2	3	2	1
dyspnoea	0	0	0	0	0	0	0		0	2	0	0
anosmia	0	0	0	0	0	0	0		0	0	0	0
ageusia	1	2	2	1	1	1	1		0	0	0	0
muscle/body pain/pain at injection site	111	71	166	65	147	45	57		33	78	49	6
hungry/thirsty	4	6	7	5	1	1	1		1	2	2	0
AEFI symptom												
No	390 (68.7)	393 (71.1)	228 (40.5)	396 (70.5)	302 (59.6)	354 (72.7)	344 (70.8)		143 (71.1)	167 (51.1)	189 (64.3)	36 (72.0)
Yes	178 (31.3)	160 (28.9)	335 (59.5)	166 (29.5)	205 (40.4)	133 (27.3)	142 (29.2)		58 (28.9)	160 (48.9)	105 (35.7)	14 (28.0)
AEFI severity												
Mild and slightly uncomfortable	96 (53.9)	103 (64.4)	110 (32.8)	108 (65.1)	152 (74.1)	86 (64.7)	91 (64.1)		48 (82.8)	104 (65.0)	68 (64.8)	13 (92.9)
Uncomfortable but could carry out daily activities	61 (34.3)	48 (30.0)	140 (41.8)	43 (25.9)	34 (16.6)	39 (29.3)	40 (28.2)		5 (8.6)	34 (21.3)	21 (20.0)	1 (7.1)
Bad and interferes with daily activities	17 (9.6)	8 (5.0)	81 (24.2)	15 (9.0)	17 (8.3)	7 (5.3)	11 (7.7)		5 (8.6)	22 (13.8)	16 (15.2)	0
Had to seek medical advice	4 (2.2)	1 (0.6)	4 (1.2)	0	2 (1.0)	1 (0.8)	0		0	0	0	0
AEFI treatment												
No	119 (66.9)	131 (81.9)	200 (59.7)	94 (56.6)	140 (68.3)	94 (70.7)	112 (78.9)		45 (77.6)	103 (64.4)	82 (78.1)	9 (64.3)
Yes	59 (33.1)	29 (18.1)	135 (40.3)	72 (43.4)	65 (31.7)	39 (29.3)	30 (21.1)		13 (22.4)	57 (35.6)	23 (21.9)	5 (35.7)

AEFI / AESI AMONG ADULTS	AFTER FIRST DOSE n (%)				AFTER SECOND DOSE n (%)				AFTER BOOSTER DOSE n (%)			
	PFIZER (n=568)	SINOVAC (n=553)	ASTRAZENECA (n=563)	CANSINO (n=562)	PFIZER (n=507)	SINOVAC (n=487)	ASTRAZENECA (n=486)	CANSINO (n=NA)	PFIZER (n=201)	SINOVAC (n=327)	ASTRAZENECA (n=294)	CANSINO (n=50)
AEFI current outcome												
Fully recovered	149 (83.7)	141 (88.1)	320 (95.5)	146 (88.0)	188 (91.7)	103 (77.4)	123 (86.6)		53 (91.4)	145 (90.6)	98 (93.3)	13 (92.9)
Getting better	18 (10.1)	13 (8.1)	11 (3.3)	12 (7.2)	11 (5.4)	14 (10.5)	16 (11.3)		3 (5.2)	6 (3.8)	3 (2.9)	1 (7.1)
Side effects continuing	11 (6.2)	6 (3.8)	4 (1.2)	8 (4.8)	6 (2.9)	16 (12.0)	3 (2.1)		2 (3.4)	9 (5.6)	4 (3.8)	0
AEFI medium reporting												
Never report	151 (84.8)	142 (88.8)	253 (75.5)	164 (98.8)	187 (91.2)	123 (92.5)	120 (84.5)		50 (86.2)	148 (92.5)	94 (89.5)	14 (100.0)
MySejahtera (online)	12 (6.7)	12 (7.5)	72 (21.5)	0	14 (6.8)	8 (6.0)	19 (13.4)		2 (3.5)	6 (3.8)	10 (9.5)	0
Conservative form (clinic or hospital)	15 (8.4)	6 (3.8)	10 (3.0)	2 (1.2)	4 (2.0)	2 (1.5)	3 (2.1)		6 (10.3)	6 (3.8)	1 (1.0)	0
AESI hospitalization												
No	566 (99.6)	552 (99.8)	561 (99.6)	562 (100.0)	506 (99.8)	483 (99.2)	486 (100.0)		199 (99.0)	325 (99.4)	293 (99.7)	50 (100.0)
Yes	2 (0.4)	1 (0.2)	2 (0.4)	0	1 (0.2)	4 (0.8)	0		2 (1.0)	2 (0.6)	1 (0.3)	0

* No AEFI questions were asked to CanSino recipients at completed vaccination; 28 days for single dose.

3.2.2 Adverse events following immunization (AEFI) and adverse events of special interest (AESI) among adolescents

AEFI and AESI of the first and second doses among adolescents

During the first follow up, a total of 143 Pfizer (A) recipients participated in the monitoring of AEFI/AESI (Table 20). This study revealed that the AEFI symptoms after the first and second dose for Pfizer (A) were 28.0% and 23.4%, respectively.

We classified the reported AEFI symptoms based on severity and observed that the majority of the recipients who experienced mild symptoms were slightly uncomfortable with 72.5% after the first dose and 62.1% after the second dose. Besides, reported AEFI severity on recipients that were uncomfortable but could still carry out their daily activities were 20.0% after the first dose and 31.0% after the second dose.

The majority of recipients (ranging from 75.0% to 75.9%) reported that they did not require any treatment for the AEFI symptoms following the first and second dose of Pfizer vaccine. About 92.5% and 89.7% of recipients reported being completely recovered after the first and second dose, with only 3.4% indicating that the side effects persisted after the second dose of vaccination.

In this study, when monitoring for AESI-related hospitalizations, no reported hospitalization was observed. Among individuals who experienced AEFI symptoms, a majority of 98.6% and 98.4% did not report their symptoms for the first and second dose. Apart from that, only 1.4% and 1.6% of recipients utilized the MySejahtera platform to report their symptoms for first and second dose, excluding none opted for the conventional form of reporting at clinics and hospitals.

Table 20 Adverse events following immunization (AEFI) and adverse events of special interest (AESI) among adolescents

AEFI / AESI AMONG ADOLESCENTS	AFTER FIRST DOSE n (%)	AFTER SECOND DOSE n (%)
	PFIZER (n=143)	PFIZER (n=124)
Symptom		
fever	17	13
chills	2	0
rigors	0	0
myalgia	0	0
head ache	11	3
sore throat	0	0
nausea & vomiting	0	0
diarrhoea	0	1
fatigue	3	1
runny nose	1	2
cough	2	1
shortness of breath	1	0
dyspnoea	0	0
anosmia	0	0
ageusia	1	0
muscle/body pain/pain at injection site	15	8
AEFI symptom		
No	103 (72.0)	95 (76.6)
Yes	40 (28.0)	29 (23.4)
AEFI severity		
Mild and slightly uncomfortable	29 (72.5)	18 (62.1)
Uncomfortable but could carry out daily activities	8 (20.0)	9 (31.0)
Bad and interferes with daily activities	3 (7.5)	2 (6.9)
Had to seek medical advice	0	0
AEFI treatment		
No	30 (75.0)	22 (75.9)
Yes	10 (25.0)	7 (24.1)
AEFI current outcome		
Fully recovered	37 (92.5)	26 (89.7)
Getting better	3 (7.5)	2 (6.9)
Side effects continuing	0	1 (3.4)
AEFI medium reporting		
Never report	38 (95.0)	27 (93.1)
MySejahtera (online)	2 (5.0)	2 (6.9)
Conservative form (clinic or hospital)	0	0
AESI hospitalization		
No	143 (100.0)	124 (100.0)
Yes	0	0

3.3 MODULE C: HUMORAL AND CELLULAR IMMUNITY

3.3.1 Sociodemography, COVID-19 infection and lifestyle of recipients at baseline based on vaccine type

A total of 26 Pfizer, 26 Sinovac, 23 AstraZeneca, 27 CanSino and 27 Pfizer (A) recipients with age mean±SD of 46.6±17.3, 31.4±7.3, 37.4±13.1, 37.2±11.1 and 14.4±1.8 were recruited in this cohort (Table 21). The majority of Pfizer, Sinovac and CanSino recipients were male, except for AstraZeneca and Pfizer (A). The main ethnicity of Pfizer recipients was Indian while Sinovac and AstraZeneca were Malay, given that they were largely Malaysians. Meanwhile, CanSino and Pfizer (A) recipients consisted of non-Malaysians from others ethnicity. The recruitment of vaccine recipients was 100% equally distributed across Selangor. Almost all of the recipients reported having no comorbidity ranging from 50.0% among Pfizer to 92.6% among Pfizer (A) recipients, while the rest had at least one and two or more comorbidities. Sinovac and AstraZeneca had no prior COVID-19 infection, unlike Pfizer, CanSino and Pfizer (A) recipients with 7.7%, 3.7% and 11.1%, respectively.

Table 21 Sociodemography, COVID-19 infection and lifestyle of recipients at baseline based on vaccine type

CHARACTERISTICS	ADULTS				ADOLESCENTS
	PFIZER n (%)	SINOVAC n (%)	ASTRAZENECA n (%)	CANSINO n (%)	PFIZER n (%)
Overall Participants	**26 (100.0)**	**26 (100.0)**	**23 (100.0)**	**27 (100.0)**	**27 (100.0)**
Age					
Mean age, SD	46.6 (17.3)	31.4 (7.3)	37.4 (13.1)	37.2 (11.1)	14.4 (1.8)
Median age (25, 75 percentiles)	49.0 (28.3, 62.3)	32.0 (26.0, 35.3)	33.0 (26.0, 52.0)	37.0 (29.0, 44.0)	14.0 (13.0, 16.0)
Below 18 years old	-	-	-	-	27 (100.0)
18-39 years old	10 (38.5)	22 (84.6)	14 (60.9)	17 (63.0)	-
40-59 years old	6 (23.1)	4 (15.4)	9 (39.1)	9 (33.3)	-
60 years old and above	10 (38.5)	0	0	1 (3.7)	-
Sex					
Male	14 (53.8)	15 (57.7)	7 (30.4)	19 (70.4)	12 (44.4)
Female	12 (46.2)	11 (42.3)	16 (69.6)	8 (29.6)	15 (55.6)
Ethnicity					
Malay	7 (26.9)	15 (57.7)	15 (65.2)	0	9 (33.3)
Chinese	2 (7.7)	3 (11.5)	6 (26.1)	0	0
Indian	16 (61.5)	4 (15.4)	1 (4.3)	0	2 (7.4)
Bumiputera Sabah & Sarawak	1 (3.8)	3 (11.5)	1 (4.3)	0	0
Others	0	1 (3.8)	0	27 (100.0)	16 (59.3)
Nationality					
Malaysian	26 (100.0)	25 (96.2)	22 (95.7)	1 (3.7)	11 (40.7)
Non-Malaysian	0	1 (3.8)	1 (4.3)	26 (96.3)	16 (59.3)
Location					
Selangor	26 (100.0)	26 (100.0)	23 (100.0)	27 (100.0)	27 (100.0)
Comorbidity status					
No comorbid	13 (50.0)	19 (73.1)	18 (78.3)	22 (81.5)	25 (92.6)
Any 1 comorbidity	9 (34.6)	6 (23.1)	3 (13.0)	4 (14.8)	2 (7.4)
2 or more comorbidities	4 (15.4)	1 (3.8)	2 (8.7)	1 (3.7)	0
Past COVID-19 infection					
Yes	2 (7.7)	0	0	1 (3.7)	3 (11.1)
No	24 (92.3)	26 (100.0)	23 (100.0)	26 (96.3)	24 (88.9)

Approximately 50.0% of CanSino and 93.8% of Pfizer (A) recipients did not receive booster shots, unlike Pfizer (63.6%), Sinovac (70.6%) and AstraZeneca (72.7%) recipients that have received at least 1 dose with none received 2 doses of booster.

Table 22 COVID-19 booster of recipients based on vaccine type

CHARACTERISTICS	ADULTS				ADOLESCENTS
	PFIZER n (%)	SINOVAC n (%)	ASTRAZENECA n (%)	CANSINO n (%)	PFIZER n (%)
COVID-19 booster Status					
No booster	4 (36.4)	5 (29.4)	2 (18.2)	4 (50.0)	15 (93.8)
1 dose	7 (63.6)	12 (70.6)	8 (72.7)	4 (50.0)	1 (6.3)
2 doses	0	0	1 (9.1)	0	0

3.3.2 COVID-19 vaccination, recruitment and follow up

This cohort was conducted at different time points from 21st July 2021 until 26th October 2022: before first dose at baseline, 14 days after first dose, 14 days after completed vaccination of two doses and 28 days of single dose, 3 months, 6 months, 9 months and 12 months from baseline (Table 23).

Baseline

At baseline, a total of 129 recipients were recruited from 21st July 2021 to 26th October 2021 including 26 Pfizer, 26 Sinovac, 23 AstraZeneca, 27 CanSino and 27 Pfizer (A) recipients.

Before the second dose or 14 days after the first dose

After their first vaccine dose, a total of 128 recipients were followed between 11th August 2021 until 23rd November 2021 with a retention rate of 99.2%. Retention rate was shown to be 100% in all vaccine groups including Pfizer, AstraZeneca, CanSino and Pfizer (A), except Sinovac with 96.2%.

Completed vaccination: 14 days after two doses or 28 days after single dose

After completed vaccination, approximately 105 total recipients were followed up between 25th August 2021 to 7th December 2021 with a retention rate of 81.4%. Retention rate was seen the highest among Sinovac recipients with 92.3%, followed by Pfizer (A) (85.2%), Pfizer (84.6%) and AstraZeneca (69.6%). Meanwhile, CanSino recipients were followed up 28 days after they received the single dose of vaccine with a retention rate of 74.1%.

3 months follow up

The 3 months follow up was conducted between 20th October 2021 to 27th January 2022 with an overall retention rate of 48.8% for 63 total recipients. The retention rate was the highest among Sinovac recipients with 73.1%, followed by Pfizer (A) (63.0%), Pfizer (57.7%) and CanSino (44.4%). No follow up was done among AstraZeneca recipients during the 3 months.

6 months follow up

Approximately a total of 58 recipients were later followed up at 6 months from baseline in between 13th January 2022 to 26th April 2022 with a retention rate of 45.0%. The retention rate was highest among Sinovac with 61.5%, followed by Pfizer (A) (55.6%), AstraZeneca (43.5%), Pfizer (42.3%) and CanSino (22.2%). As for the booster status, the majority of recipients who had received at least one dose were among AstraZeneca recipients with 80.0%, followed by Pfizer (63.6%), Sinovac (56.3%) and CanSino (33.3%), while none booster was given for Pfizer (A).

9 months follow up

The 9 months follow up was carried out between 20th April 2022 to 28th July 2022 with an overall retention rate of 38.8% among 50 total recipients. The retention rate was highest among Pfizer (A) with 48.1%, followed by Sinovac (42.3%), AstraZeneca (39.1%), Pfizer (38.5%) and CanSino (22.2%). As for the booster status, the majority of the recipients who had received at least one dose were among Sinovac with 100%, followed by AstraZeneca (88.9%), Pfizer (70.0%), CanSino (33.3%) and Pfizer (A) with only 7.7%, respectively.

12 months follow up

The 12 months follow up was conducted between 20th July 2022 to 28th October 2022 with an overall retention rate of 34.1% among 44 total recipients. The retention rate was highest among Sinovac with 50.0%, followed by Pfizer (A) (44.4%), AstraZeneca (30.4%), Pfizer (26.9%) and CanSino (18.5%). As for booster status, the majority of the recipients who had received at least one dose were among AstraZeneca with 85.7%, followed closely by Sinovac (84.6%), Pfizer (71.4%) and CanSino (60.0%), with none reported for Pfizer (A).

Table 23 COVID-19 vaccination, recruitment, and follow up

RECRUITMENT DATES		OVERALL (n=129)	ADULTS				ADOLESCENTS
			PFIZER (n=26)	SINOVAC (n=26)	ASTRAZENECA (n=23)	CANSINO* (n=27)	PFIZER (n=27)
Baseline (Before first dose)	Start date	21 July 2021	3 Aug 2021	21 July 2021	26 July 2021	29 Sep 2021	21 Oct 2021
	End date	26 Oct 2021	5 Aug 2021	29 July 2021	29 July 2021	30 Sep 2021	21 Oct 2021
	Recipient, n	129	26	26	23	27	27
Second dose *14 days after first dose	Start date	11 Aug 2021	24 Aug 2021	11 Aug 2021	27 Sep 2021	13 Oct 2021	11 Nov 2021
	End date	23 Nov 2021	26 Aug 2021	19 Aug 2021	30 Sep 2021	14 Oct 2021	23 Nov 2021
	Recipient, n	128	26	25	23	27	27
	Mean (SD) duration from baseline, days	28.0 (17.0)	21.0 (0.0)	21.0 (0.0)	63.1 (0.4)	14.0 (0.2)	25.2 (3.5))
	Retention rate (%)	99.2	100.0	96.2	100.0	100.0	100.0
Completed vaccination (14 days after two-dose *28 days after single dose)	Start date	25 Aug 2021	7 Sep 2021	25 Aug 2021	11 Oct 2021	27 Oct 2021	25 Nov 2021
	End date	7 Dec 2021	13 Sep 2021	2 Sep 2021	15 Oct 2021	28 Oct 2021	7 Dec 2021
	Recipient, n	105	22	24	16	20	23
	Mean (SD) duration from baseline (days)	41.0 (15.9)	35.5 (1.2)	35.7 (1.8)	77.4 (0.5)	28.0 (0.2)	39.0 (3.5)
	Retention rate (%)	81.4	84.6	92.3	69.6	74.1	85.2
3 months	Start date	20 Oct 2021	8 Nov 2021	20 Oct 2021	N A	29 Dec 2021	24 Jan 2022
	End date	27 Jan 2022	9 Nov 2021	29 Oct 2021		8 Jan 2022	27 Jan 2022
	Recipient, n	63	15	19		12	17
	Mean (SD) duration from baseline (days)	93.8 (2.8)	96.7 (0.7)	91.9 (1.9)		92.7 (3.5)	94.0 (2.1)
	Retention rate (%)	48.8	57.7	73.1		44.4	63.0
6 months	Start date	13 Jan 2022	31 Jan 2022	19 Jan 2022	13 Jan 2022	29 Mar 2022	21 Apr 2022
	End date	26 Apr 2022	15 Feb 2022	31 Jan 2022	28 Jan 2022	30 Mar 2022	26 Apr 2022
	Recipient, n	58	11	16	10	6	15
	Mean (SD) duration from baseline (days)	183.2 (3.7)	187.6 (4.8)	182.7 (1.5)	180.8 (4.3)	181.0 (0.0)	183.2 (1.8)
	Retention rate (%)	45.0	42.3	61.5	43.5	22.2	55.6
	Booster status: n (%)	26 (44.8)	7 (63.6)	9 (56.3)	8 (80.0)	2 (33.3)	0
9 months	Start date	20 Apr 2022	10 May 2022	20 Apr 2022	22 Apr 2022	29 June 2022	21 July 2022
	End date	28 July 2022	12 May 2022	27 Apr 2022	11 May 2022	30 June 2022	28 July 2022
	Recipient, n	50	10	11	9	6	13
	Mean (SD) duration from baseline (days)	275.4 (4.0)	280.3 (0.8)	273.6 (1.4)	275.4 (6.9)	273.0 (0.9)	274.2 (1.9)
	Retention rate (%)	38.8	38.5	42.3	39.1	22.2	48.1
	Booster status: n (%)	29 (58.0)	7 (70.0)	11 (100.0)	8 (88.9)	2 (33.3)	1 (7.7)

RECRUITMENT DATES		OVERALL (n=129)	ADULTS				ADOLESCENTS
			PFIZER (n=26)	SINOVAC (n=26)	ASTRAZENECA (n=23)	CANSINO* (n=27)	PFIZER (n=27)
12 months	Start date	20 July 2022	3 Aug 2022	20 July 2022	23 July 2022	28 Sep 2022	20 Oct 2022
	End date	28 Oct 2022	3 Aug 2022	5 Aug 2022	28 July 2022	4 Oct 2022	28 Oct 2022
	Recipient, n	44	7	13	7	5	12
	Mean (SD) duration from baseline (days)	365.3 (3.2)	364.3 (0.8)	365.5 (4.6)	363.1 (2.2)	367.6 (3.4)	365.8 (2.2)
	Retention rate (%)	34.1	26.9	50.0	30.4	18.5	44.4
	Booster status: n (%)	25 (56.8)	5 (71.4)	11 (84.6)	6 (85.7)	3 (60.0)	0

3.3.3 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Pfizer recipients by follow up

A total of 2 (7.7%) of Pfizer recipients were positive before receiving the vaccination, with an overall low median (25, 75th percentiles) antibody level or index of 2.7 (1.2, 4.1). The positive rate rose rapidly to 96.2% after the first dose and achieved 100.0% upon completion of two doses of vaccination before declining to 86.7% at 3 months, 63.6% at 6 months, 90.0% at 9 months and 85.7% at 12 months follow up. The highest antibody level was seen at 6 months with 4.9 (2.9, 5.5) and slowly decreased to 2.7 (1.8, 3.8) at 12 months follow up (Table 24).

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by age

At baseline, the older and younger age groups had the same positive rate among those who tested positive. During the second dose, the positive rate reached 100% for older age groups and 90% for the 18-39 years age group. Upon completed vaccination, antibody level was seen the highest among the older age group of 60 years above with 5.1 (4.6, 5.8). The sequence of positive rates decreased in the next four follow ups (3, 6, 9 and 12 months), especially in the younger age groups but still above 50.0%. Generally, antibodies levels were seen higher among older age groups than younger age group on most of the follow ups, except at 9 months.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by sex, ethnicity and nationality

The obvious differences between the positive rate when all recipients seroconverted at completion of two doses of vaccination reached the rate at 100%. At baseline, the positive rate was higher in females with 8.3% compared to males with 7.1%, respectively. During the second dose and throughout subsequent follow ups, the positive rate was generally higher in females, except at 9 and 12 months follow up with 83.3% and 75.0%. The antibody level decreased at 3 months and peaked to the highest level at 6 months before declining again at 9 months subsequently. As for ethnicity, Indians appeared to have a higher positive rate compared to other ethnicities before receiving the first vaccine dose. Upon completed vaccination, the seropositive rate was 100% in Malay, Chinese and Indian, with index median of 2.7 (2.3, 2.8), 4.6 (4.05, 5.1) and 5.1 (3.5, 5.8), respectively. Based on nationality, the positive rate among the Malaysians increased from 7.7% at baseline to 96.2% at the second dose and reached 100% at completed vaccination. Even so, the highest antibody level reported was 4.9 (2.9, 5.5) at 6 months follow up. There was no other consistent difference or observable changes when comparing the seropositive rate and antibody level between different sexes, ethnicities and nationalities.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by comorbidity status

People with no comorbidity and with comorbidity had the same positive rate of 7.7% at baseline. At the second dose, those with comorbidity were 100% positive compared to recipients without comorbid that were 92.3% positive. Upon completed vaccination, all of the recipients regardless of comorbidity status were 100% positive. However, positive rates for those with no comorbidity were the lowest in the subsequent follow ups, as compared to those with comorbidity that remained with 100% positive rate up to 12 months. The Pfizer recipients with comorbidity generally had higher antibody levels after completed vaccination, especially at 6 months with median index of 5.5 (4.3, 6.8).

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by past COVID-19 infection and booster status

At baseline, the positive rate among those with past COVID-19 infection was substantially higher than those without, with an antibody level of 2.7 (1.2, 4.1). However, the antibody level of those without and with past infection increased after completed vaccination and decreased at 3 months before rising again at 6 months follow up. Upon completed vaccination, all recipients were 100.0% positive, but only recipients who had been infected previously remained 100% positive up to 12 months follow up. On the other hand, those who received booster vaccination consistently had higher seropositive rate compared to those without, especially at 6 and 9 months follow up. The number of booster doses was also positively correlated to the level of antibody.

Table 24 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Pfizer recipients by follow up

VARIABLES	BASELINE (n=26)		SECOND DOSE (n=26)		COMPLETED VACCINATION (n=22)		3 MONTHS (n=15)		6 MONTHS (n=11)		9 MONTHS (n=10)		12 MONTHS (n=7)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	2 (7.7)	2.7 (1.2,4.1)	25 (96.2)	1.5 (1.3,2.4)	22 (100.0)	4.0 (2.8,5.2)	13 (86.7)	2.9 (2.0,3.1)	7 (63.6)	4.9 (2.9,5.5)	9 (90.0)	2.2 (1.3,3.1)	6 (85.7)	2.7 (1.8,3.8)
Sociodemography														
Age group														
18-39 years	1 (10.0)	-	9 (90.0)	1.5 (1.4,2.2)	7 (100.0)	2.8 (2.7,3.7)	5 (83.3)	1.8 (1.3,2.5)	4 (80.0)	4.1 (2.2,6.8)	4 (100.0)	1.3 (1.2,1.8)	1 (50.0)	-
40-59 years	0	-	6 (100.0)	1.5 (1.3,2.2)	6 (100.0)	3.3 (2.3,5.1)	4 (80.0)	3.0 (2.5,3.1)	0	-	2 (66.7)	3.5 (3.2,5.8)	2 (100.0)	2.7 (2.3,3.2)
60 years and above	1 (10.0)	-	10 (100.0)	1.9 (1.3,2.6)	9 (100.0)	5.1 (4.6,5.8)	4 (100.0)	3.3 (2.9,4.2)	3 (100.0)	4.9 (4.0,5.2)	3 (100.0)	2.2 (1.9,2.6)	3 (100.0)	3.8 (2.8,4.0)
Sex														
Male	1 (7.1)	-	13 (92.9)	2.2 (1.4,2.5)	12 (100.0)	4.3 (3.1,5.2)	6 (85.7)	2.8 (1.8,3.1)	3 (60.0)	4.9 (3.8,5.2)	4 (100.0)	1.8 (1.3,2.7)	3 (100.0)	1.8 (1.6,2.0)
Female	1 (8.3)	-	12 (100.0)	1.4 (1.3,2.3)	10 (100.0)	3.5 (2.3,5.8)	7 (87.5)	2.9 (2.5,3.3)	4 (66.7)	4.3 (2.4,6.8)	5 (83.3)	2.2 (1.7,3.1)	3 (75.0)	3.8 (3.5,4.0)
Ethnicity														
Malay	0	-	6 (85.7)	1.4 (1.3,1.5)	6 (100.0)	2.7 (2.3,2.8)	5 (100.0)	1.8 (1.3,2.0)	4 (100.0)	2.9 (2.2,4.4)	4 (100.0)	1.3 (1.2,1.5)	2 (66.7)	2.8 (1.4,4.1)
Chinese	0	-	2 (100.0)	1.8 (1.3,2.2)	2 (100.0)	4.6 (4.0,5.1)	0	-			N/A			
Indian	2 (12.5)	2.7 (1.2,4.1)	16 (100.0)	1.9 (1.3,2.6)	13 (100.0)	5.1 (3.5,5.8)	7 (87.5)	3.1 (3.0,3.9)	3 (50.0)	5.5 (5.2,6.8)	5 (83.3)	3.1 (2.2,3.2)	4 (100.0)	2.7 (2.0,3.5)
Bumiputera Sabah & Sarawak	0	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	0	-		N/A		
Nationality														
Malaysian	2 (7.7)	2.7 (1.2,4.1)	25 (96.2)	1.5 (1.3,2.4)	22 (100.0)	4.0 (2.8,5.2)	13 (86.7)	2.9 (2.0,3.1)	7 (63.6)	4.9 (2.9,5.5)	9 (90.0)	2.2 (1.3,3.1)	6 (85.7)	2.7 (1.8,3.8)
Non-Malaysian							N/A							
Comorbidity status														
No comorbid	1 (7.7)	-	12 (92.3)	2.2 (1.4,2.6)	12 (100.0)	4.3 (3.1,5.1)	7 (87.5)	2.9 (2.1,3.0)	3 (75.0)	2.7 (2.2,3.8)	3 (100.0)	1.3 (1.2,1.8)	1 (50.0)	-
Yes	1 (7.7)	-	13 (100.0)	1.4 (1.3,1.6)	10 (100.0)	3.3 (2.7,5.8)	6 (85.7)	3.0 (2.0,3.7)	4 (57.1)	5.5 (4.3,6.8)	6 (85.7)	2.6 (1.7,3.2)	5 (100.0)	3.2 (2.3,3.8)
Past COVID-19 infection														
No	0	-	23 (95.8)	1.5 (1.3,2.3)	20 (100.0)	3.8 (2.8,5.1)	11 (84.6)	2.9 (1.9,3.0)	5 (55.6)	3.2 (2.7,5.5)	7 (87.5)	1.7 (1.3,3.1)	5 (83.3)	3.2 (2.3,3.8)
Yes	2 (100.0)	2.7 (1.2,4.1)	2 (100.0)	5.0 (4.5,5.5)	2 (100.0)	6.5 (6.3,6.7)	2 (100.0)	5.6 (4.7,6.4)	2 (100.0)	6.5 (4.9,8.1)	2 (100.0)	2.2 (2.2,2.2)	1 (100.0)	-
Booster Status														
No booster									0	-	2 (66.7)	4.5 (3.2,5.8)	2 (100.0)	2.7 (2.3,3.2)
1 dose				N/A					7 (100.0)	4.9 (2.9,5.5)	7 (100.0)	1.7 (1.3,2.2)	4 (80.0)	2.8 (1.6,4.0)

3.3.4 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Sinovac recipients by follow up

A total of 1 (3.8%) of Sinovac recipients were positive before receiving the vaccination. The positive rate rose rapidly to 52.0% after the first dose and achieved 87.5% upon completion of vaccination before declining to 76.9% at 12 months follow up. The antibody level was seen highest at 6 months with 5.0 (2.0, 5.4) and slowly decreased to 1.3 (1.3, 1.5) at 12 months follow up (Table 25).

SARS-CoV-2 anti-Spike IgA antibody level and positive rate by age

At baseline, the younger age groups were 4.5% positive among those who tested positive. The positive rate reached 57.1% after the first dose and increased to 90.0% after completed vaccination for the younger age group. There was no other consistent difference or observable changes when comparing the seropositive rate and antibody level between the older and younger age groups. Antibody level was higher among younger age group of 18-39 years, with the highest index median of 5.1 (3.2, 5.3) at 6 months follow up. Generally, antibody level was seen higher among younger age group than older age group on most of the follow ups.

SARS-CoV-2 anti-Spike IgA antibody level and positive rate by sex, ethnicity and nationality

Generally, the positive rate and antibody level among Sinovac recipients of different sexes, ethnicities and nationalities increased from the baseline to after completed vaccination. At baseline, the positive rate was higher among the males with 6.7% compared to females. The positive rate among both males and females increased at the second dose until the completed vaccination. Antibody levels among females were generally higher than males on most of the follow ups, except during the second dose follow up. The highest antibody level among males and females was 3.5 (1.5, 5.2) and 5.2 (3.5, 6.5) at 6 months follow up, but somehow gradually declined in the subsequent months. As for ethnicity, the highest seropositive rate at the baseline were among Malay. All ethnicities' positive rate reached 100.0% after completed vaccination and remained up to 12 months, except for Malay. The highest antibody level was 5.7 (1.2, 10.2) among the Indians at 6 months follow up. Based on nationality, the positive rate among the Malaysians increased from 4.0% at baseline to 54.2% at second dose, followed by 87.0% at completed vaccination. The highest antibody level was 5.0 (2.0, 5.4) at 6 months follow up. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between different sexes, ethnicities and nationalities.

SARS-CoV-2 anti-Spike IgA antibody level and positive rate by comorbidity status

At baseline, the positive rate was seen highest for recipients with comorbid with 14.3% compared to those without comorbidity. At the second dose and completed vaccination, the positive rate increased regardless of their comorbidity status. However, the positive rate markedly decreased at 3 months before increasing again from 6 to 12 months. Generally, the Sinovac recipient without comorbidity had slightly higher antibody levels versus those with comorbidity on most of the follow ups. The highest antibody level among recipients with no comorbid was 5.1 (3.2, 6.5) at 6 months follow up.

SARS-CoV-2 anti-Spike IgA antibody level and positive rate by past COVID-19 infection and booster status

At baseline, recipients without past COVID-19 infection were 3.8% positive. Upon completed vaccination, the positive rate was 87.5% before decreasing to 10.5% at 3 months follow up. The positive rate subsequently increased from 6 to 9 months, but not at 12 months follow up. The antibody level was seen the highest at 6 months follow up with median index of 5.0 (2.0, 5.4). On the other hand, those who received booster vaccination consistently had higher positive rate and antibody level compared to those without, except at 12 months follow up. The number of booster doses was also positively correlated to the level of antibody.

Table 25 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Sinovac recipients by follow up

VARIABLES	BASELINE (n=26)		SECOND DOSE (n=25)		COMPLETED VACCINATION (n=24)		3 MONTHS (n=19)		6 MONTHS (n=16)		9 MONTHS (n=11)		12 MONTHS (n=13)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	1 (3.8)	-	13 (52.0)	1.6 (1.4,1.8)	21 (87.5)	2.1(1.7,2.3)	2 (10.5)	1.8 (1.7,2.0)	10 (62.5)	5.0 (2.0,5.4)	10 (90.9)	2.1 (1.2,2.7)	10 (76.9)	1.3 (1.3,1.5)
Sociodemography														
Age group														
18-39 years	1 (4.5)	-	12(57.1)	1.6 (1.4,1.9)	18 (90.0)	2.1 (1.8,2.4)	2 (13.3)	1.8 (1.7,2.0)	7 (58.3)	5.1 (3.2,5.3)	8 (88.9)	2.2 (1.5,3.0)	8 (80.0)	1.5 (1.3,2.1)
40-59 years	0	-	1 (25.0)	-	3 (75.0)	1.5 (1.4,1.8)	0	-	3 (75.0)	2.1 (2.0,4.9)	2 (100.0)	1.6 (1.1,2.0)	2 (66.7)	1.2 (1.2,1.3)
Sex														
Male	1 (6.7)	-	6 (42.9)	1.7 (1.6,1.8)	12 (92.3)	2.0 (1.7,2.3)	1 (10.0)	-	6 (66.7)	3.5 (1.5,5.2)	6 (100.0)	1.7 (1.1,3.2)	5 (83.3)	1.3 (1.2,1.4)
Female	0	-	7 (63.6)	1.4 (1.3,1.8)	9 (81.8)	2.1 (1.7,2.7)	1 (11.1)	-	4 (57.1)	5.2 (3.5,6.5)	4 (80.0)	2.1 (1.9,2.4)	5 (71.4)	1.5 (1.3,1.5)
Ethnicity														
Malay	1 (6.7)	-	8 (53.3)	1.7 (1.5,2.3)	12 (80.0)	2.2 (1.6,3.0)	2 (15.4)	1.8 (1.7,2.0)	5 (50.0)	5.0 (2.0,5.2)	4 (80.0)	1.9 (1.4,2.1)	5 (62.5)	1.5 (1.3,1.5)
Chinese	0	-	1 (50.0)	-	2 (100.0)	1.8 (1.5,2.1)	0	-	2 (100.0)	3.7 (2.1,5.4)	2 (100.0)	1.9 (1.1,2.7)	2 (100.0)	1.2 (1.2,1.3)
Indian	0	-	3 (75.0)	1.7 (1.6,1.7)	4 (100.0)	2.2 (2.0,2.4)	0	-	2 (100.0)	5.7 (1.2,10.2)	2 (100.0)	3.0 (1.2,4.9)	2 (100.0)	2.1 (1.4,2.7)
Bumiputera Sabah & Sarawak	0	-	1 (33.3)	-	2 (100.0)	1.8 (1.7,1.9)	0	-	0	-	1 (100.0)	-	1 (100.0)	-
Others	0	-	0	-	1 (100.0)	-	0	-	1 (100.0)	-	1 (100.0)	-	N/A	
Nationality														
Malaysian	1 (4.0)	-	13 (54.2)	1.6 (1.4,1.8)	20 (87.0)	2.1 (1.7,2.4)	2 (11.1)	1.8 (1.7,2.0)	9 (60.0)	5.0 (2.0,5.4)	9 (90.0)	2.0 (1.2,2.7)	10 (76.9)	1.3 (1.3,1.5)
Non-Malaysian	0	-	0	-	1 (100.0)	-	0	-	1 (100.0)	-	1 (100.0)	-	N/A	
Comorbidity status														
No comorbid	0	-	10 (55.6)	1.7 (1.4,2.1)	15 (83.3)	2.1 (1.9,2.4)	1 (7.1)	-	7 (58.3)	5.1 (3.2,6.5)	8 (88.9)	2.2 (1.6,3.0)	7 (70.0)	1.4 (1.3,2.1)
Yes	1 (14.3)	-	3 (42.9)	1.6 (1.5,1.6)	6 (100.0)	1.8 (1.2,2.3)	1 (20.0)	-	3 (75.0)	2.1 (2.0,3.7)	2 (100.0)	1.4 (1.1,1.8)	3 (100.0)	1.3 (1.2,1.4)
Past COVID-19 infection														
No	1 (3.8)	-	13 (52.0)	1.6 (1.4,1.8)	21 (87.5)	2.1 (1.7,2.3)	2 (10.5)	1.8 (1.7,2.0)	10 (62.5)	5.0 (2.0,5.4)	10 (90.9)	2.1 (1.2,2.7)	10 (76.9)	1.3 (1.3,1.5)
Yes	N/A													
Booster Status														
No booster	N/A								2 (40.0)	3.6 (2.0,5.2)	N/A		2 (100.0)	1.4 (1.3,1.5)
1 dose									8 (72.7)	5.0 (1.8,6.5)	10 (90.9)	2.1 (1.2,2.7)	8 (72.7)	1.3 (1.2,2.1)

3.3.5 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of AstraZeneca recipients by follow up

A total of 1 (4.3%) of AstraZeneca recipients were positive before receiving the vaccination. The positive rate rose rapidly to 56.5% after the first dose and achieved 93.8% upon completed vaccination before declining to 71.4% at 12 months follow up. The antibody level was seen highest at 9 months with 2.0 (1.2, 3.0), at which later slightly decreased to 1.7 (1.7, 1.7) at 12 months follow up (Table 26).

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by age

At baseline, the younger age group had a higher positive rate with 5.9% among those who tested positive. At second dose follow up, the positive rate reached to 57.1% and increased to 90.0% upon the completion of vaccination in the younger age group. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between the older and younger age groups. Antibody level was seen the highest among younger age group of 18-39 years with 2.7 (1.2, 3.3) at 9 months follow up. Generally, antibody level was higher among younger age group than older age group on most of the follow ups.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by sex, ethnicity and nationality

The highest positive rate was seen among females at the baseline. However, a higher positive rate was seen among males from 57.1% after the first dose to 100% upon completed doses which sustained up to 12 months follow up. The antibody level was comparable in the subsequent follow ups among males and females. The antibody level among the male was highest with the median index of 2.3 (1.3, 3.4) at completed vaccination. As for ethnicity, recipients from Bumiputera Sabah were 100% positive as compared to the other ethnicities that none was positive. At second dose follow up, Indian and Bumiputera Sabah positive rate reached 100.0%, except for Malay (60%) and Chinese (33.3%). The highest antibody level was 2.7 (2.1, 4.7) among the Chinese at 9 months follow up. Based on nationality, the positive rate among the Malaysians increased from 4.5% at baseline to 54.5% at second dose and reached 93.8% after completion of vaccination, with the highest median index of 2.0 (1.2, 3.0) at 9 months follow up. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between different sexes, ethnicities and nationalities.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by comorbidity status

At baseline, the positive rate was seen highest for those without comorbid with 4.3%, respectively. At the second dose and completed vaccination, the positive rate increased regardless of the comorbidity status. However, the positive rate among recipients without comorbid was seen to decrease at 6 months follow up before increasing again at 9 months, with an antibody level of 2.7 (2.5, 3.3). Generally, AstraZeneca recipients without comorbidity had higher antibody levels versus those with comorbidity on most of the follow ups, except at completed vaccination and 6 months follow up.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by past COVID-19 infection and booster status

At baseline, the positive rate among those without past COVID-19 infection was 4.3%. The positive rate increased from 56.5% at second dose to 93.8% upon completed vaccination while the antibody level gradually increased up to 9 months follow up. However, the positive rate of those without past infection decreased to 80.0% at 6 months and rose to 88.9% at 9 months follow up. The highest antibody level was 2.0 (1.2, 3.0) at 9 months follow up. On the other hand, recipients who received two doses of booster consistently had a 100% positive rate compared to those boosted with only one dose.

Table 26 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of AstraZeneca recipients by follow up

VARIABLES	BASELINE (n=23)		SECOND DOSE (n=23)		COMPLETED VACCINATION (n=16)		3 MONTHS (n=N/A)	6 MONTHS (n=10)		9 MONTHS (n=9)		12 MONTHS (n=7)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX		POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	1 (4.3)	-	13 (56.5)	1.3 (1.2,2.0)	15 (93.8)	1.8 (1.5,2.3)		8 (80.0)	1.8 (1.7,2.6)	8 (88.9)	2.0 (1.2,3.0)	5 (71.4)	1.7 (1.7,1.7)
Sociodemography													
Age group													
18-39 years	1 (7.1)	-	8 (57.1)	1.8 (1.3,2.6)	9 (90.0)	2.0 (1.6,2.3)		5 (71.4)	1.9 (1.8,3.1)	5 (83.3)	2.7 (1.2,3.3)	2 (50.0)	1.9 (1.7,2.1)
40-59 years	0	-	5 (55.6)	1.2 (1.2,1.3)	6 (100.0)	1.4 (1.3,1.8)		3 (100.0)	1.7 (1.6,1.9)	3 (100.0)	1.5 (1.3,2.0)	3 (100.0)	1.7 (1.5,1.7)
Sex													
Male	0	-	4 (57.1)	1.2 (1.2,3.3)	2 (100.0)	2.3 (1.3,3.4)		2 (100.0)	1.9 (1.7,2.2)	2 (100.0)	2.0 (1.5,2.5)	2 (100.0)	1.7 (1.7,1.7)
Female	1 (6.3)	-	9 (56.3)	1.3 (1.3,2.0)	13 (92.9)	1.8 (1.5,2.2)		6 (75.0)	1.8 (1.6,3.1)	6 (85.7)	2.0 (1.2,3.3)	3 (60.0)	1.7 (1.5,1.9)
Ethnicity													
Malay	0	-	9 (60.0)	1.3 (1.2,2.2)	9 (90.0)	1.8 (1.5,2.0)		5 (71.4)	1.7 (1.6,1.8)	5 (83.3)	1.2 (1.2,2.5)	2 (50.0)	1.7 (1.7,1.7)
Chinese	0	-	2 (33.3)	1.3 (1.3,1.3)	6 (100.0)	1.9 (1.5,2.3)		3 (100.0)	2.2 (2.0,4.9)	3 (100.0)	2.7 (2.1,4.7)	3 (100.0)	1.7 (1.5,1.9)
Indian	0	-	1 (100.0)	-	N/A			N/A					
Bumiputera Sabah & Sarawak	1 (100.0)	-	1 (100.0)	-									
Nationality													
Malaysian	1 (4.5)	-	12 (54.5)	1.3 (1.3,2.1)	15 (93.8)	1.8 (1.5,2.3)		8 (80.0)	1.8 (1.7,2.6)	8 (88.9)	2.0 (1.2,3.0)	5 (71.4)	1.7 (1.7,1.7)
Non-Malaysian	0	-	1 (100.0)	-	N/A			N/A					
Comorbidity status													
No comorbid	1 (5.6)	-	9 (50.0)	1.3 (1.3,2.0)	12 (92.3)	1.7 (1.5,2.1)		5 (71.4)	1.8 (1.7,1.9)	5 (83.3)	2.7 (2.5,3.3)	4 (80.0)	1.7 (1.5,1.9)
Yes	1 (20.0)	-	4 (80.0)	1.2 (1.2,1.7)	3 (100.0)	2.4 (1.8,2.9)		3 (100.0)	2.2 (1.9,2.6)	3 (100.0)	1.2 (1.2,1.4)	1 (50.0)	-
Past COVID-19 infection													
No	1 (4.3)	-	13 (56.5)	1.3 (1.2,2.0)	15 (93.8)	1.8 (1.5,2.3)		8 (80.0)	1.8 (1.7,2.6)	8 (88.9)	2.0 (1.2,3.0)	5 (71.4)	1.7 (1.7,1.7)
Yes	N/A							N/A					
Booster Status													
No booster	N/A							1 (50.0)	-	1 (100.0)	-	1 (100.0)	-
1 dose								6 (85.7)	1.8 (1.6,3.1)	6 (85.7)	2.0 (1.2,3.3)	3 (60.0)	1.7 (1.5,1.9)
2 doses								1 (100.0)	-	1 (100.0)	-	1 (100.0)	-

3.3.6 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of CanSino recipients by follow up

A total of 10 (37.0%) of CanSino recipients were positive before receiving the vaccination, with an overall low median (25, 75th percentiles) antibody level or index of 1.5 (1.3, 1.8). The positive rate declined from 77.8% after the first dose to 33.3% at 3 months follow up, but rose to 100% at 6 months. Subsequently, the positive rate was sustained before decreasing to 66.7% at 9 months and increasing again to 80.0% at 12 months follow up. The highest antibody level was seen at the second dose with 2.9 (2.5, 3.7), respectively (Table 27).

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by age

At baseline, the older age group had a higher positive rate of 44.4% (44.4%) with an antibody level of 1.6 (1.4,1.8) among those who tested positive. However, the positive rate was higher among the younger age group of 18-39 years after the first dose and in the subsequent follow ups. The younger age group maintained 100.0% positive up until 12 months, meanwhile the older age group showed a decline in their positive rate from 100% at 6 months to 33.3% at 9 months follow up. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between the older and younger age groups. Antibody level was seen the highest among younger age group with 3.3 (2.7, 4.3) at completed vaccination. Generally, antibody level was higher among younger age group than older age group on most of the follow ups, except at baseline.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by sex, ethnicity and nationality

The highest positive rate was seen among females with 62.5% at the baseline. The antibody level among the female was higher than male, except at baseline and completed vaccination. As for ethnicity, recipients from the others ethnicity were 37.0% positive at baseline and 100% positive at 6 months follow up. Based on nationality, the positive rate among the non-Malaysian increased from 34.6% at baseline to 76.9% at second dose, but then declined to 27.3% at 3 months follow up. At 6 months, the positive rate rose to 100.0% and subsequently declined again to 66.7% at 9 months and 75.0% at 12 months follow up. The highest antibody level was 2.9 (2.3, 3.6) during the second dose follow up. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between different sexes, ethnicities and nationalities.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by comorbidity status

At baseline, the positive rate was 100% among recipients with comorbid, with an antibody level of 1.8 (1.4, 1.8), respectively. Meanwhile, the positive rate among recipients with no comorbidity increased rapidly at second dose but decreased earlier at completed vaccination. Generally, the CanSino recipients with comorbidity had higher antibody levels versus those with no comorbidity on most of the follow ups, except at 3 and 9 months follow up. The highest antibody level was 3.6 (3.5, 5.0) among the comorbid group at second dose. There was no other consistent difference or observable changes when comparing the positive rate and antibody level between comorbidity status.

Salivary SARS-CoV-2 anti-Spike IgA antibody level and positive rate by past COVID-19 infection and booster status

At baseline, the positive rate among those without past COVID-19 infection was 34.6% with an antibody level of 1.4 (1.3, 1.8), respectively. The positive rate and antibody level increased at the second dose and decreased after completed vaccination until 3 months follow up. At 6 months follow up, the positive rate rose to 100.0% before decreasing at 9 and 12 months follow up. The highest antibody level was 2.9 (2.2, 3.6) at second dose follow up of recipients that had not been previously infected. On the other hand, recipients that received booster vaccination were consistently 100% positive from 6 until 12 months follow up.

Table 27 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of CanSino recipients by follow up

VARIABLES	BASELINE (n=27)		14 DAYS AFTER FIRST DOSE (n=27)		COMPLETED VACCINATION (n=20)		3 MONTHS (n=12)		6 MONTHS (n=6)		9 MONTHS (n=6)		12 MONTHS (n=5)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	10 (37.0)	1.5 (1.3,1.8)	21 (77.8)	2.9 (2.5,3.7)	14 (70.0)	2.3 (1.5,2.8)	4 (33.3)	1.3 (1.2,1.4)	6 (100.0)	2.3 (1.5,3.9)	4 (66.7)	2.0 (1.5,2.6)	4 (80.0)	2.6 (1.5,4.1)
Sociodemography														
Age group														
18-39 years	6 (35.3)	1.5 (1.3,2.2)	14 (82.4)	3.3 (2.7,4.3)	10 (83.3)	2.3 (1.8,2.8)	3 (42.9)	1.4 (1.3,1.4)	4 (100.0)	2.9 (1.6,4.2)	3 (100.0)	2.3 (2.0,2.6)	3 (100.0)	1.7 (1.5,2.6)
40-59 years	4 (44.4)	1.6 (1.4,1.8)	7 (77.8)	2.5 (1.6,3.1)	4 (57.1)	2.1 (1.3,3.3)	1 (20.0)	-	2 (100.0)	2.2 (1.5,2.8)	1 (33.3)	-	1 (50.0)	-
60 years and above	0	-	0	-	0	-				N/A				
Sex														
Male	5 (26.3)	1.8 (1.4,1.8)	15 (78.9)	2.7 (1.8,4.3)	9 (69.2)	2.7 (1.5,2.8)	2 (28.6)	1.2 (1.1,1.4)	1 (100.0)	-	1 (50.0)	-	1 (100.0)	-
Female	5 (62.5)	1.4 (1.3,1.6)	6 (75.0)	3.2 (2.9,3.5)	5 (71.4)	2.2 (1.8,2.4)	2 (40.0)	1.4 (1.2,1.5)	5 (100.0)	2.8 (1.8,3.9)	3 (75.0)	2.3 (2.0,2.6)	3 (75.0)	1.7 (1.5,2.6)
Ethnicity														
Malay														
Chinese														
Indian								N/A						
Bumiputera Sabah & Sarawak														
Others	10 (37.0)	1.5 (1.3,1.8)	21 (77.8)	2.9 (2.5,3.7)	14 (70.0)	2.3 (1.5,2.8)	4 (33.3)	1.3 (1.2,1.4)	6 (100.0)	2.3 (1.5,3.9)	4 (66.7)	2.0 (1.5,2.6)	4 (80.0)	2.6 (1.5,4.1)
Nationality														
Malaysian	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-		N/A	1 (100.0)	-
Non-Malaysian	9 (34.6)	1.4 (1.3,1.8)	20 (76.9)	2.9 (2.3,3.6)	13 (68.4)	2.2 (1.5,2.7)	3 (27.3)	1.4 (1.3,1.4)	5 (100.0)	2.8 (1.8,3.9)	4 (66.7)	2.0 (1.5,2.6)	3 (75.0)	1.7 (1.5,2.6)
Comorbidity status														
No comorbid	5 (22.7)	1.4 (1.3,1.6)	16 (72.7)	2.8 (1.8,3.6)	10 (62.5)	2.2 (1.5,2.8)	2 (25.0)	1.3 (1.2,1.4)	3 (100.0)	1.8 (1.6,2.9)	2 (66.7)	2.3 (1.7,3.0)	2 (100.0)	2.3 (1.3,3.4)
Yes	5 (100.0)	1.8 (1.4,1.8)	5 (100.0)	3.6 (3.5,5.0)	4 (100.0)	2.4 (1.7,3.3)	2 (50.0)	1.3 (1.1,1.5)	3 (100.0)	2.8 (2.2,3.7)	2 (66.7)	1.8 (1.2,2.3)	2 (66.7)	3.3 (1.7,4.8)
Past COVID-19 infection														
No	9 (34.6)	1.4 (1.3,1.8)	20 (76.9)	2.9 (2.2,3.6)	13 (68.4)	2.2 (1.5,2.7)	3 (27.3)	1.4 (1.3,1.4)	5 (100.0)	2.8 (1.8,3.9)	4 (66.7)	2.0 (1.5,2.6)	3 (75.0)	1.7 (1.5,2.6)
Yes	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-		N/A	1 (100.0)	-
Booster Status														
No booster									2 (100.0)	2.3 (1.8,2.8)	2 (50.0)	2.1 (1.2,3.0)	1 (50.0)	-
1 dose				N/A					4 (100.0)	2.7 (1.4,4.2)	2 (100.0)	2.0 (1.7,2.3)	3 (100.0)	1.7 (1.5,3.3)

3.3.7 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Pfizer (Adolescent) recipients by follow up

A total of 6 (22.2%) of Pfizer (A) recipients were positive before receiving the vaccination, with an overall median (25, 75th percentiles) antibody level or index of 1.3 (1.2, 1.4), respectively. The positive rate increased to 100% at second dose and remained up to 3 months before declining to 50.0% at 12 months follow up. The highest antibody level was seen at completed vaccination with 4.7 (3.4, 5.7) at which later decreased in the subsequent months (Table 28).

Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate by sex and nationality

At baseline, the positive rate was higher among the male (25.0%) with an antibody level of 1.2 (1.2, 1.3), respectively. The positive rate rose to 100% at second dose to 3 months among the male, while remained up to 9 months among the female. The antibody level was seen higher in females compared to male on most follow ups, except at 3 months. Subsequently, the positive rate and antibody level declined in both sex at 12 months follow up. As for the nationality, the positive rate was higher among non-Malaysian throughout the 12 months follow up. The positive rate reached 100% at second dose for 3 months among Malaysians and non-Malaysian, but later gradually decreased up to 12 months follow up.

Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate by comorbidity status

At baseline, the positive rate and antibody level among the recipients with no comorbidity was 24.0% with an antibody level of 1.3 (1.2, 1.3), respectively. The positive rate reached 100% at second dose and remained until 3 months regardless of the comorbidity status. Subsequently, the positive rate among recipients without comorbid declined from 86.7% at 6 months to 50.0% at 12 months follow up. The highest antibody level was seen at completed vaccination in both comorbidity groups.

Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate by past COVID-19 infection

At baseline, the positive rate among those with past COVID-19 infection was 33.3%, higher than those without infection. After the first dose, the positive rate rose to 100% and remained to 3 months among recipients with no past infection whereas remained up to 12 months among recipients with past infection. The highest antibody level was seen at completed vaccination with 4.7 (3.3, 5.4) among those without past infection while 6.9 (6.7, 7.0) among those who had been previously infected.

Table 28 Salivary SARS-CoV-2 anti-spike IgA antibody level and positive rate of Pfizer (Adolescent) vaccine by follow up

VARIABLES	BASELINE (n=27)		SECOND DOSE (n=27)		COMPLETED VACCINATION (n=23)		3 MONTHS (n=17)		6 MONTHS (n=15)		9 MONTHS (n=13)		12 MONTHS (n=12)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	6 (22.2)	1.3 (1.2,1.4)	27 (100.0)	2.6 (1.6,3.7)	23 (100.0)	4.7 (3.4,5.7)	17 (100.0)	1.8 (1.4,2.4)	13 (86.7)	1.7 (1.2,5.1)	10 (76.9)	2.3 (1.5,2.9)	6 (50.0)	1.5 (1.3,1.5)
Sociodemography														
Age group														
Below 18 years	6 (22.2)	1.3 (1.2,1.4)	27 (100.0)	2.6 (1.6,3.7)	23 (100.0)	4.7 (3.4,5.7)	17 (100.0)	1.8 (1.4,2.4)	13 (86.7)	1.7 (1.2,5.1)	10 (76.9)	2.3 (1.5,2.9)	6 (50.0)	1.5 (1.3,1.5)
Sex														
Male	3 (25.0)	1.2 (1.2,1.3)	12 (100.0)	2.3 (1.6,3.8)	10 (100.0)	4.7 (3.6,6.0)	7 (100.0)	1.9 (1.4,3.0)	4 (66.7)	1.2 (1.2,1.5)	2 (40.0)	1.7 (1.5,1.8)	2 (33.3)	1.4 (1.3,1.6)
Female	3 (20.0)	1.4 (1.4,1.4)	15 (100.0)	2.8 (1.4,3.5)	13 (100.0)	4.8 (3.0,5.6)	10 (100.0)	1.6 (1.4,2.4)	9 (100.0)	2.0 (1.7,5.2)	8 (100.0)	2.4 (1.8,3.4)	4 (66.7)	1.5 (1.4,1.5)
Ethnicity														
Malay	0	-	9 (100.0)	2.7 (2.5,3.3)	8 (100.0)	5.4 (4.7,5.7)	7 (100.0)	2.2 (1.4,2.5)	5 (100.0)	5.1 (2.0,5.5)	4 (80.0)	3.1 (1.8,4.3)	1 (33.3)	-
Indian	1 (50.0)	-	2 (100.0)	2.9 (1.6,4.1)	2 (100.0)	5.6 (4.2,7.0)	2 (100.0)	2.7 (1.9,3.5)	1 (50.0)	-	1 (50.0)	-	1 (50.0)	-
Others	5 (31.3)	1.3 (1.2,1.3)	16 (100.0)	2.3 (1.3,3.9)	13 (100.0)	3.6 (2.9,5.4)	8 (100.0)	1.5 (1.2,2.0)	7 (87.5)	1.5 (1.2,1.7)	5 (83.3)	1.8 (1.5,2.4)	4 (57.1)	1.5 (1.3,1.6)
Nationality														
Malaysian	1 (9.1)	-	11 (100.0)	2.7 (2.1,3.3)	10 (100.0)	5.4 (4.7,5.8)	9 (100.0)	2.2 (1.4,2.5)	6 (85.7)	3.6 (1.8,5.5)	5 (71.4)	2.9 (2.2,4.0)	2 (40.0)	1.4 (1.3,1.5)
Non-Malaysian	5 (31.3)	1.3 (1.2,1.3)	16 (100.0)	2.3 (1.3,3.9)	13 (100.0)	3.6 (2.9,5.4)	8 (100.0)	1.5 (1.2,2.0)	7 (87.5)	1.5 (1.2,1.7)	5 (83.3)	1.8 (1.5,2.4)	4 (57.1)	1.5 (1.3,1.6)
Comorbidity status														
No comorbid	6 (24.0)	1.3 (1.2,1.4)	25 (100.0)	2.7 (1.5,3.7)	21 (100.0)	4.7 (3.3,5.8)	16 (100.0)	1.8 (1.4,2.5)	13 (86.7)	1.7 (1.2,5.1)	9 (75.0)	2.4 (1.5,2.9)	6 (50.0)	1.5 (1.3,1.5)
Yes	0	-	2 (100.0)	2.5 (2.5,2.6)	2 (100.0)	4.7 (4.1,5.3)	1 (100.0)	-	N/A		1 (100.0)	-	N/A	
Past COVID-19 infection														
No	5 (20.8)	1.3 (1.2,1.3)	24 (100.0)	2.5 (1.5,3.3)	21 (100.0)	4.7 (3.3,5.4)	15 (100.0)	1.6 (1.3,2.2)	12 (85.7)	1.7 (1.2,5.2)	9 (75.0)	2.2 (1.5,2.5)	5 (45.5)	1.5 (1.4,1.5)
Yes	1 (33.3)	-	3 (100.0)	4.1 (3.9,4.6)	2 (100.0)	6.9 (6.7,7.0)	2 (100.0)	3.6 (3.5,3.7)	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-
Booster Status														
No booster	N/A								13 (86.7)	1.7 (1.2,5.1)	10 (76.9)	2.3 (1.5,2.9)	6 (50.0)	1.5 (1.3,1.5)
1 dose									N/A					

3.3.8 SARS-CoV-2-specific T-cell reactivity of Pfizer recipients by follow up

Positive T cell reactivity against the SARS-CoV-2 SNMO peptide was observed when the reactivity value exceeded 33 SFU/10^6 PBMCs. Among 30 Pfizer recipients, 4 individuals (15.4%) demonstrated positive reactivity values prior to vaccination, with a median (25^{th}, 75^{th} percentiles) of 54 (40, 80) SFU/10^6 PBMCs. The recipients surpassing the positive reactivity threshold consistently reached 100% reactivity from the first dose up to 12 months follow up. Following the initial dose, the positive reactivity value significantly increased, with a median of 220 (128, 320) SFU/10^6 PBMCs and continued to rise after completed vaccination, with a median of 550 (420, 792) SFU/10^6 PBMCs. At 3 months follow up, the median reactivity value declined to 384 (336, 594) SFU/10^6 PBMCs, followed by an increase to 420 (104, 590) SFU/10^6 PBMCs at 6 months. Subsequently, the positive reactivity value declined again between 9 and 12 months follow up (Table 29).

T-cell reactivity of SARS-CoV-2 by age

The age group comprising individuals aged 60 years and above exhibited detectable positive T-cell reactivity, consistent across all age groups before receiving the first dose. At second dose follow up, the positive T-cell reactivity value increased in all age groups, with the age group of 40-59 years demonstrated the highest median positive T-cell reactivity value of 264 (184, 320) SFU/10^6 PBMCs. Subsequently, the positive T-cell reactivity continued to rise after completed vaccination. At 3 months follow up, the positive reactivity value declined in all age groups. At 6 months follow up, the age group of 40-59 years recorded the lowest reactivity value, with a median of 88 (80, 104) SFU/10^6 PBMCs compared to the other age groups. However, the positive reactivity value for the age group of 40-59 years started to increase again at 9 months and remained stable until 12 months follow up. A similar pattern was observed in the age group of 60 years and above. On the other hand, the age group of 18-39 years displayed a declining trend from 6 to 12 months following the first dose.

T-cell reactivity of SARS-CoV-2 by sex

The positive T-cell reactivity values increased from baseline until the completed vaccination in both sexes. The highest median recorded for T-cell reactivity was at completed vaccination with a median of 550 (414, 832) SFU/10^6 PBMCs in males and 542 (420, 756) SFU/10^6 PBMCs in females. However, the positive reactivity value declined for both sexes from 3 until 6 months follow up. Yet, male recipients' positive T-cell response rose again at 9 months but declined at 12 months follow up.

T-cell reactivity of SARS-CoV-2 by ethnicity

The positive T-cell reactivity kept rising until completed two-dose vaccination for all ethnicities, with Indian showed the highest median of 732 (420, 872) SFU/10^6 PBMCs reactivity value. However, the fluctuating trend was observed for Malay as the positive reactivity value started to decline at 3 months, inclined back at 6 months and continuously declined until 12 months. A different trend was observed for Indians, as T-cell reactivity declined after completed vaccination until 6 months before rising again at 9 months and waned at 12 months follow up. As for the Chinese, the positive T-cell reactivity was recorded until completed vaccination. Malay showed the lowest reactivity value with a median of 220 (192, 428) SFU/10^6 PBMCs at 12 months follow up.

T-cell reactivity of SARS-CoV-2 by nationality

Malaysians showed a similar pattern of T-cell reactivity to other variables. The reactivity value was highest with a median of 550 (420, 792) SFU/10^6 PBMCs and decreased after 3 months and remained stable up to 12 months follow up.

T-cell reactivity of SARS-CoV-2 by comorbidity status

The recipients with comorbidities showed higher positive T-cell reactivity up to 3 months follow up than those without comorbidities, with a median of 774 (456, 872) SFU/10^6 PBMCs. After 3 months, the positive reactivity value declined until 12 months in recipients with comorbidities. Yet, the recipients without comorbidities showed a different trend in which the T-cell response increased after 3 months (from the baseline) and waned at 12 months follow up.

T-cell reactivity of SARS-CoV-2 by past COVID-19 infection and booster status

Throughout the 12 months follow up, recipients who were previously infected exhibited a significantly higher positive T-cell reactivity value than those without infections. The most substantial reactivity value was observed following the completed vaccination, with a median of 1442 (1388, 1496) SFU/10^6 PBMCs. Conversely, recipients without past infections maintained a relatively stable reactivity value within the same range for up to 12 months follow up. However, recipients with past infections started to experience a decline in T-cell reactivity at 12 months from the baseline. A different trend was observed for recipients who received boosters, as they exhibited the highest reactivity value after receiving booster shots, with a median of 520 (464, 788) SFU/10^6 PBMCs. Reactivity value started to wane at 9 months and remained stable until 12 months follow up.

Table 29 SARS-CoV-2-specific T-cell reactivity of Pfizer recipients by follow up

VARIABLES	BASELINE (n=26)		SECOND DOSE (n=26)		COMPLETED VACCINATION (n=22)		3 MONTHS (n=15)		6 MONTHS (n=11)		9 MONTHS (n=10)		12 MONTHS (n=7)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	4 (15.4)	54 (40,80)	26 (100.0)	220 (128,320)	22 (100.0)	550 (420,792)	15 (100.0)	384 (336,594)	11 (100.0)	420 (104,590)	10 (100.0)	388 (252,584)	7 (100.0)	352 (260,486)
Sociodemography														
Age group														
18-39 years	1 (10.0)	-	10 (100.0)	172 (124,252)	7 (100.0)	516 (440,710)	6 (100.0)	368 (280,580)	5 (100.0)	520 (344,660)	4 (100.0)	478 (266,612)	2 (100.0)	192 (164,220)
40-59 years	1 (16.7)	-	6 (100.0)	264 (184,320)	6 (100.0)	594 (420,844)	5 (100.0)	508 (360,608)	3 (100.0)	88 (80,104)	3 (100.0)	252 (170,492)	2 (100.0)	326 (300,352)
60 years and above	2 (20.0)	54 (44,64)	10 (100.0)	230 (124,492)	9 (100.0)	584 (408,756)	4 (100.0)	482 (352,782)	3 (100.0)	508 (464,794)	3 (100.0)	384 (356,484)	3 (100.0)	552 (486,594)
Sex														
Male	1 (7.1)	-	14 (100.0)	204 (124,316)	12 (100.0)	550 (414,832)	7 (100.0)	384 (316,590)	5 (100.0)	344 (88,520)	4 (100.0)	488 (266,658)	3 (100.0)	352 (286,452)
Female	3 (25.0)	44 (40,70)	12 (100.0)	250 (162,342)	10 (100.0)	542 (420,756)	8 (100.0)	482 (340,594)	6 (100.0)	464 (120,660)	6 (100.0)	356 (252,564)	4 (100.0)	360 (232,528)
Ethnicity														
Malay	0	-	7 (100.0)	252 (196,308)	6 (100.0)	572 (460,720)	5 (100.0)	384 (300,580)	4 (100.0)	514 (426,590)	4 (100.0)	360 (234,478)	3 (100.0)	220 (192,428)
Chinese	0	-	2 (100.0)	160 (124,196)	2 (100.0)	402 (396,408)	1 (100.0)	-	N/A					
Indian	4 (25.0)	54 (40,80)	16 (100.0)	220 (136,568)	13 (100.0)	732 (420,872)	8 (100.0)	558 (372,828)	6 (100.0)	270 (88,916)	6 (100.0)	484 (252,660)	4 (100.0)	386 (326,486)
Bumiputera Sabah & Sarawak	0	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	N/A			
Nationality														
Malaysian	4 (15.4)	54 (40,80)	26 (100.0)	220 (128,320)	22 (100.0)	550 (420,792)	15 (100.0)	384 (336,594)	11 (100.0)	420 (104,590)	10 (100.0)	388 (252,584)	7 (100.0)	352 (260,486)
Non-Malaysian	N/A													
Comorbidity status														
No comorbid	2 (15.4)	54 (44,64)	13 (100.0)	196 (124,248)	12 (100.0)	440 (414,606)	8 (100.0)	372 (316,626)	4 (100.0)	502 (216,870)	3 (100.0)	564 (352,574)	2 (100.0)	358 (164,552)
Yes	2 (15.4)	66 (36,96)	13 (100.0)	300 (180,492)	10 (100.0)	774 (456,872)	7 (100.0)	508 (352,594)	7 (100.0)	420 (104,514)	7 (100.0)	384 (290,526)	5 (100.0)	352 (300,420)
Past COVID-19 infection														
No	2 (8.3)	40 (36,44)	24 (100.0)	204 (126,308)	20 (100.0)	488 (418,744)	13 (100.0)	384 (320,580)	9 (100.0)	344 (88,508)	8 (100.0)	356 (196,478)	6 (100.0)	326 (220,420)
Yes	2 (100.0)	80 (64,96)	2 (100.0)	676 (648,704)	2 (100.0)	1442 (1388,1496)	2 (100.0)	986 (984,988)	2 (100.0)	998 (916,1080)	2 (100.0)	622 (584,660)	1 (100.0)	-
Booster Status														
No booster	N/A								4 (100.0)	88 (80,104)	3 (100.0)	252 (170,492)	2 (100.0)	326 (300,352)
1 dose									7 (100.0)	520 (464,788)	7 (100.0)	392 (356,574)	5 (100.0)	420 (220,552)

3.3.9 SARS-CoV-2-specific T-cell reactivity of Sinovac recipients by follow up

Positive T-cell reactivity against SARS-CoV-2 SNMO peptide was recorded if the reactivity value was more than 33 SFU/10^6 PBMCs. A total of 5 out of 26 (19.2%) Sinovac recipients showed positive T-cell reactivity value at the baseline with an overall median of 40 (36, 44) SFU/10^6 PBMCs. Positive T-cell reactivity trend started to increase from baseline until the completed two-dose vaccine reached a median with a positive reactivity value of 214 (144, 316) SFU/10^6 PBMCs. However, the T-cell reactivity started to decline at 3 months and rose again at 6 months, with the highest median of 372 (82, 500) SFU/10^6 PBMCs. The T-cell reactivity increment was probably due to the booster vaccination jab they received. Yet, the positive T-cell reactivity started to wane from 9 to 12 months, with a reactivity median of 220 (142, 280) SFU/10^6 PBMCs and 156 (92, 212) SFU/10^6 PBMCs, respectively. However, these values are still above the positivity threshold values for T-cell reactivity (Table 30).

T-cell reactivity of SARS-CoV-2 by age

The age group of 40-59 years old showed higher T-cell reactivity value after the first dose compared to the 18-39 years old age group, with a median of 108 (80, 160) and 84 (64, 108) SFU/10^6 PBMCs, respectively. The positive reactivity value increased two-fold after a completed two-dose vaccine for both age groups, with medians of 214 (140, 310) SFU/10^6 PBMCs among 18-39 years old and 248 (172, 368) SFU/10^6 PBMCs among 40-59 years old age group. However, the T-cell reactivity value started to decline at 3 months for both age groups and doubled at 6 months due to administration of booster dose. It was also observed that T-cells reactivity declined from 9 until 12 months for both age groups.

T-cell reactivity of SARS-CoV-2 by sex

Both males and females for Sinovac recipients showed a positive T-cell reactivity value after the first vaccine, with a median of 90 (60, 120) and 84 (68, 104) SFU/10^6 PBMCs. However, females showed a slightly higher reactivity value after completed two doses of vaccine, with a median of 284 (154, 316) SFU/10^6 PBMCs as compared to males with the median of 208 (144, 284) SFU/10^6 PBMCs. Nevertheless, the T-cell reactivity value started to decline at 3 months in both sexes, with the lowest median of 108 (92, 168) SFU/10^6 PBMCs in females, whereas 133 (96, 160) SFU/10^6 PBMCs in males. At 6 months, the T-cell reactivity value for males started to increase again and gradually waned at 9 to 12 months after the first dose. A similar trend was observed in female recipients as the T-cell reactivity value doubled at 6 months and declined at 9 to 12 months follow up. Both observations were obtained due to the subjects' booster vaccination dose at 6 months follow up.

T-cell reactivity of SARS-CoV-2 by ethnicity and nationality

As for the ethnicity, Indians showed the highest T-cell reactivity value, with a median of 128 (84, 208) SFU/10^6 PBMCs after the first vaccine dose, compared to other ethnicities, and remained the highest after completed vaccination. After completing two doses, Indian, Malay and Chinese showed a comparable T-cell reactivity with the median of 264 (178, 318), 256 (166, 316) and 232 (180, 284), respectively. On the other hand, Bumiputera Sabah ethnicity showed the lowest T-cell reactivity upon completion of two vaccine doses with a median of 114 (92, 136). At 3 months follow up, a decreased trend in T-cell reactivity was observed in all ethnicities, except for Bumiputera Sabah. Yet, Chinese and Indian started to rise again at 6 months but declined at 9 until 12 months follow up. Notably, a different pattern was observed in Malay, as T-cell reactivity value increased at 6 months with a median of 148 (79, 770) SFU/10^6 PBMCs and almost doubled at 9 months with a median of 308 (120, 470) SFU/10^6 PBMCs, but waned at 12 months with the median of 100 (64, 304) SFU/10^6 PBMCs. Generally, all Sinovac recipients were Malaysian. Therefore, the same trend was recorded, in which the T-cell reactivity started to rise after the first dose until the completed vaccination. The trend started to decline at 3 months but doubled at 6 months with a median of 120 (92, 160) SFU/10^6 PBMCs and 290 (81, 624) SFU/10^6 PBMCs, respectively. However, the T-cell reactivity decreased to 230 (120, 308) SFU/10^6 PBMCs at 9 months and 156 (92, 212) SFU/10^6 PBMCs at 12 months follow up.

T-cell reactivity of SARS-CoV-2 by comorbidity status

The recipient with comorbidities showed a higher positive T-cell reactivity value until 3 months after the first dose than the recipient without comorbidities. The changes in positive T-cell reactivity among Sinovac recipients with comorbidities were generally similar to the overall trend mentioned above, as the positive reactivity value for both recipients with or without comorbidities started to increase after the first vaccine shot, reached its peak after completed vaccination, and then declined. The highest positive reactivity value was observed for recipients without comorbidities at 6 months, with a median of 380 (82, 748) SFU/10^6 PBMCs. The observation is probably due to their booster vaccination at 6 months follow up.

T-cell reactivity of SARS-CoV-2 by past COVID-19 infection and booster status

All Sinovac recipients did not have a history of COVID-19 before receiving the vaccine. The positive T-cell reactivity value started to increase after the first vaccine dose, with a median of 84 (64, 116) SFU/10^6 PBMCs followed by 214 (144, 316) SFU/10^6 PBMCs after completed vaccination. The positive T-cell reactivity value decreased at 3 months and later increased at 6 months, reaching the highest

median of 372 (82, 500) SFU/10^6 PBMCs. However, the positive T-cell reactivity value waned after 9 until 12 months after the first dose. The positive T-cell reactivity value for the recipients who received the booster showed a significant increase, with the highest median of 408 (372, 748) SFU/10^6 PBMCs at 6 months, compared to those without a booster shot. Yet, the positive T-cell reactivity value trend for recipients with one booster dose started to decline from 9 to 12 months with a median of 220 (142, 280) and 168 (120, 214) SFU/10^6 PBMCs, respectively.

Table 30 SARS-CoV-2-specific T-cell reactivity of Sinovac recipients by follow up

VARIABLES	BASELINE (n=26)		SECOND DOSE (n=25)		COMPLETED VACCINATION (n=24)		3 MONTHS (n=19)		6 MONTHS (n=16)		9 MONTHS (n=11)		12 MONTHS (n=13)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	5 (19.2)	40 (36, 44)	25 (100.0)	84 (64, 116)	24 (100.0)	214 (144, 316)	19 (100.0)	132 (94, 160)	13 (81.3)	372 (82, 500)	11 (100.0)	220 (142, 280)	13 (100.0)	156 (92, 212)
Sociodemography														
Age group														
18-39 years	5 (22.7)	40 (36, 44)	21 (100.0)	84 (64, 108)	20 (100.0)	214 (140, 310)	15 (100.0)	108 (94, 148)	9 (75.0)	372 (82, 408)	9 (100.0)	196 (120, 252)	10 (100.0)	144 (92, 196)
40-59 years	0	-	4 (100.0)	108 (80, 160)	4 (100.0)	248 (172, 368)	4 (100.0)	150 (106, 164)	4 (100.0)	354 (128, 646)	2 (100.0)	355 (240, 470)	3 (100.0)	216 (144, 306)
Sex														
Male	3 (20.0)	40 (38, 42)	14 (100.0)	90 (60, 120)	13 (100.0)	208 (144, 284)	10 (100.0)	133 (96, 160)	7 (77.8)	408 (84, 624)	6 (100.0)	230 (196, 308)	6 (100.0)	190 (156, 216)
Female	2 (18.2)	44 (36, 52)	11 (100.0)	84 (68, 104)	11 (100.0)	284 (154, 316)	9 (100.0)	108 (92, 168)	6 (85.7)	290 (82, 380)	5 (100.0)	164 (120, 252)	7 (100.0)	92 (64, 152)
Ethnicity														
Malay	4 (26.7)	42 (38, 48)	15 (100.0)	84 (76, 118)	15 (100.0)	256 (166, 316)	13 (100.0)	108 (92, 140)	8 (80.0)	148 (79, 770)	5 (100.0)	308 (120, 470)	8 (100.0)	100 (64, 304)
Chinese	0	-	2 (100.0)	84 (72, 96)	2 (100.0)	232 (180, 284)	2 (100.0)	132 (104, 160)	2 (100.0)	436 (372, 500)	2 (100.0)	246 (240, 252)	2 (100.0)	206 (196, 216)
Indian	1 (25.0)	-	4 (100.0)	128 (84, 208)	4 (100.0)	264 (178, 318)	2 (100.0)	164 (160, 168)	2(100.0)	244 (80, 408)	2(100.0)	130 (64, 196)	2(100.0)	162 (156, 168)
Bumiputera Sabah & Sarawak	0	-	3 (100.0)	60 (58, 76)	2 (100.0)	114 (92, 136)	1 (100.0)	-	0	-	1 (100.0)	-	1 (100.0)	-
Others	0	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	N/A	
Nationality														
Malaysian	5 (20.0)	40 (36, 44)	24 (100.0)	88 (68, 118)	23 (100.0)	216 (154, 316)	18 (100.0)	120 (92, 160)	12 (80.0)	290 (81, 624)	10 (100.0)	230 (120, 308)	13 (100.0)	156 (92, 212)
Non-Malaysian	0	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	N/A	
Comorbidity status														
No comorbid	3 (15.8)	36 (36,40)	18 (100.0)	84 (64,108)	18 (100.0)	214 (144,304)	14 (100.0)	106 (72,136)	9 (75.0)	380 (82,748)	9 (100.0)	220 (164,308)	10 (100.0)	162 (92, 212)
Yes	2 (28.6)	46 (40, 52)	7 (100.0)	96 (76, 118)	6 (100.0)	262 (180, 320)	5 (100.0)	160 (140, 168)	4 (100.0)	148 (68, 354)	2 (100.0)	180 (120, 240)	3 (100.0)	108 (90, 162)
Past COVID-19 infection														
No	5 (19.2)	40 (36, 44)	25 (100.0)	84 (64, 116)	24 (100.0)	214 (144, 316)	19 (100.0)	132 (94, 160)	13 (81.3)	372 (82, 500)	11 (100.0)	220 (142, 280)	13 (100.0)	156 (92, 212)
Yes	N/A													
Booster Status														
No booster	N/A								4 (80.0)	82 (62, 148)	N/A		2 (100.0)	64 (56, 72)
1 dose									9 (81.8)	408 (372, 748)	11 (100.0)	220 (142, 280)	11 (100.0)	168 (120, 214)

3.3.10 SARS-CoV-2-specific T-cell reactivity of AstraZeneca recipients by follow up

After receiving the first vaccination dose, the T-cell reactivity values experienced a rapid rise, reaching 100% positivity with a median of 160 (124, 188) SFU/10^6 PBMCs. The positivity rate remained 100% until 12 months follow up among the recipients. Upon completing the vaccination regimen, the median T-cell reactivity value increased to 341 (294, 390) SFU/10^6 PBMCs. However, at 6 months, there was a decline to 280 (220, 368) SFU/10^6 PBMCs, reaching its lowest point at 9 months with a median of 144 (100, 360) SFU/10^6 PBMCs (Table 31).

T-cell reactivity of SARS-CoV-2 by age

All age groups who received the first dose of AstraZeneca had 100% T-cell reactivity and remained consistent above the positivity threshold for up to 12 months follow up. However, after 6 months, the median T-cell reactivity value was higher in the older group than the younger group. The T-cell reactivity value for younger age groups increased after completing the second vaccination dose but decreased gradually to 138 (48, 336) SFU/10^6 PBMCs at 12 months follow up. Meanwhile, the median T-cell reactivity value increased to 616 (402, 654) SFU/10^6 PBMCs at 6 months and declined to 148 (127, 484) SFU/10^6 PBMCs at 9 months in older age groups.

T-cell reactivity of SARS-CoV-2 by sex, ethnicity, and nationality

T-cell reactivity values varied among males and females during the second dose and throughout the follow up. Median T-cell values were higher among males than females on most follow ups. A rapid increase was seen among males from 305 (248, 362) SFU/10^6 PBMCs at completed vaccination to 654 (616, 692) SFU/10^6 PBMCs at 6 months follow up. Then, the median gradually decreased to 484 (148, 820) SFU/10^6 PBMCs and 352 (192, 512) SFU/10^6 PBMCs at 9 and 12 months, respectively. Contrary, the median of T-cell reactivity of female recipients peaked at completed vaccination with a median of 341 (304, 396) SFU/10^6 PBMCs and declined gradually to 106 (92, 252) SFU/10^6 PBMCs at 9 months before rising again at 12 months follow up. In addition, the changes in T-cell reactivity values among AstraZeneca recipients of different ethnicities were similar over time. Malay and Chinese appeared to have the highest median T-cell reactivity at completed vaccination of 320 (304, 364) SFU/10^6 PBMCs and 379 (240, 424) SFU/10^6 PBMCs, respectively. Nevertheless, T-cell reactivity values continuously decreased from 6 to 9 months and slightly increased at 12 months follow up. All the AstraZeneca recipients were Malaysian. Generally, the T-cell reactivity values changes among AstraZeneca recipients followed the overall trend mentioned above.

T-cell reactivity of SARS-CoV-2 by comorbidity status

All recipients with comorbidity status were at maximum T-cell reactivity values at completed vaccination. After completing two doses of AstraZeneca, recipients with comorbidities recorded the highest T-cell reactivity value compared to those without comorbidities, with a median of 362 (341, 363) SFU/10^6 PBMCs, but decreased rapidly at 6 until 12 months follow up. Nevertheless, those without comorbidities appeared to have higher T-cell reactivity values across the follow ups, even though they demonstrated a decline pattern in the last three months.

T-cell reactivity of SARS-CoV-2 by past COVID-19 infection and booster status

None of the recipients of AstraZeneca had a previous history of COVID-19 infection, with the changes observed in T-cell reactivity values following the overall trend. On the other hand, all recipients including those who received booster shots and those who did not, exhibited reactivity of 100.0%. Among those who received booster vaccination, the T-cell reactivity value initially decreased from 272 (234, 322) SFU/10^6 PBMCs to 106 (92, 252) SFU/10^6 PBMCs between 6 and 9 months follow up. However, it subsequently rose again at 12 months, with a median value of 152 (60, 216) SFU/10^6 PBMCs.

Table 31 SARS-CoV-2-specific T-cell reactivity of AstraZeneca recipients by follow up

VARIABLES	BASELINE (n=23)		SECOND DOSE (n=23)		COMPLETED VACCINATION (n=16)		3 MONTHS (n=N/A)	6 MONTHS (n=10)		9 MONTHS (n=9)		12 MONTHS (n=7)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX		POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)		n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	1 (4.3)	-	23 (100.0)	160 (124,188)	16 (100.0)	341 (294,390)		10 (100.0)	280 (220,368)	9 (100.0)	144 (100,360)	7 (100.0)	192 (106,336)
Sociodemography													
Age group													
18-39 years	1 (7.1)	-	14 (100.0)	160 (124,200)	10 (100.0)	318 (284,384)		7 (100.0)	272 (234,322)	6 (100.0)	122 (84,360)	4 (100.0)	138 (48,336)
40-59 years	0	-	9 (100.0)	160 (120,164)	6 (100.0)	363 (320,424)		3 (100.0)	616 (402,654)	3 (100.0)	148 (127,484)	3 (100.0)	192 (172,352)
Sex													
Male	0	-	7 (100.0)	144 (122,174)	2 (100.0)	305 (248,362)		2 (100.0)	654 (616,692)	2 (100.0)	484 (148,820)	2 (100.0)	352 (192,512)
Female	1 (6.3)	-	16 (100.0)	162 (126,202)	14 (100.0)	341 (304,396)		8 (100.0)	260 (204,322)	7 (100.0)	106 (92,252)	5 (100.0)	152 (60,216)
Ethnicity													
Malay	0	-	15 (100.0)	164 (126,176)	10 (100.0)	320 (304,364)		7 (100.0)	272 (218,322)	6 (100.0)	103 (84,360)	4 (100.0)	138 (48,364)
Chinese	0	-	6 (100.0)	152 (124,204)	6 (100.0)	379 (240,424)		3 (100.0)	368 (294,492)	3 (100.0)	148 (146,446)	3 (100.0)	192 (172,324)
Indian	0	-	1 (100.0)	-	N/A			N/A					
Bumiputera Sabah & Sarawak	1 (100.0)	-	1 (100.0)	-									
Nationality													
Malaysian	1 (4.5)	-	22 (100.0)	162 (124,192)	16 (100.0)	341 (294,390)		10 (100.0)	280 (220,368)	9 (100.0)	144 (100,360)	7 (100.0)	192 (106,336)
Non-Malaysian	0	-	1 (100.0)		N/A			N/A					
Comorbidity status													
No comorbid	1 (5.6)	-	18 (100.0)	156 (124,200)	13 (100.0)	320 (284,396)		7 (100.0)	288 (234,362)	6 (100.0)	252 (100,744)	5 (100.0)	216 (152,456)
Yes	0	-	5 (100.0)	164 (144,168)	3 (100.0)	362 (341,363)		3 (100.0)	272 (230,444)	3 (100.0)	106 (93,127)	2 (100.0)	114 (36,192)
Past COVID-19 infection													
No	1 (4.3)	-	23 (100.0)	160 (124,188)	16 (100.0)	341 (294,390)		10 (100.0)	280 (220,368)	9 (100.0)	144 (100,360)	7 (100.0)	192 (106,336)
Yes			N/A					N/A					
Booster Status													
No booster								2 (100.0)	368 (44,692)	1 (100.0)	-	1 (100.0)	-
1 dose			N/A					7 (100.0)	272 (234,322)	7 (100.0)	106 (92,252)	5 (100.0)	152 (60,216)
2 doses								1 (100.0)	-	1 (100.0)	-	1 (100.0)	-

3.3.11 SARS-CoV-2-specific T-cell reactivity of CanSino recipients by follow up

A total of 13 out of 27 (48.1%) of CanSino recipients were positive before receiving the vaccination, with a median of 50 (40, 84) SFU/10^6 PBMCs. Subsequent months after receiving the vaccination showed a 100% positivity of T-cell reactivity in CanSino recipients, except during 3 months follow up. The positive T-cell reactivity value rose rapidly to 180 (105, 322) SFU/10^6 PBMCs at 14 days after vaccination but bottomed at 3 months follow up with a median of 70 (56, 83) SFU/10^6 PBMCs. However, it gradually increased at 6 until 12 months follow up with a median of 308 (268, 390) SFU/10^6 PBMCs (Table 32).

T-cell reactivity of SARS-CoV-2 by age

At baseline, older age group (40-59 years old) had higher positive T-cell reactivity values compared to younger age group (18-39 years old) with a median of 76 (59, 90) and 48 (36, 56) SFU/10^6 PBMCs, respectively. After 14 days of vaccination, T-cell reactivity increased to 200 (124, 328) and 148 (104, 320) for the older age group and younger age group, respectively. For both age groups, the positive reactivity values gradually declined and bottomed at 3 months follow up before rising again for 6 to 12 months follow up. The highest T-cell reactivity in younger age group was at 9 months follow up with a median of 360 (242, 396) SFU/10^6 PBMCs, while in older age group was at 12 months follow up with a median of 262 (68, 456) SFU/10^6 PBMCs.

T-cell reactivity of SARS-CoV-2 by sex, ethnicity, and nationality

The highest T-cell reactivity value was females after 14 days of vaccination with a median of 312 (190, 326) SFU/10^6 PBMCs. At 3 months follow up, the median value in males was 62 (48, 72) SFU/10^6 PBMCs with 85.7% reactivity, whereas in females was 78 (66, 84) SFU/10^6 PBMCs with 80.0% reactivity, respectively. Then, positive T-cell reactivity reached 100% from 6 to 12 months follow up for both sexes. Since all the recipients of CanSino were non-Malaysian, a single trend was observed in ethnicity and nationality. The changes in positive recipients and T-cell reactivity values among CanSino recipients of different statuses followed the trend mentioned above.

T-cell reactivity of SARS-CoV-2 by comorbidity status

Participants with comorbidities had higher T-cell reactivity than those without comorbidities in every follow up except at 12 months. The T-cell reactivity was seen the highest at 14 days after the vaccination for those with comorbidities with a median of 416 (320, 416) SFU/10^6 PBMCs. After receiving the vaccination, all recipients with or without comorbidities showed 100% of T-cell reactivity. At baseline, T-cell reactivity was highest among those with comorbid with a median of 84 (68, 96) SFU/10^6 PBMCs. Recipients with no comorbidities declined at 3 and 6 months, but sharply increased again at 9 to 12 months follow up. Among recipients with comorbidities, a decrease in T-cell reactivity was observed at 28 days after the vaccination and 3 months with median of 238 (138, 288) and 84 (78, 98) SFU/10^6 PBMCs, but rose again at 6 to 12 months follow up.

T-cell reactivity of SARS-CoV-2 by past COVID-19 infection and booster status

The majority of CanSino recipients did not experience COVID-19 infection previously, with the pattern of T-cell reactivity following the overall trend mentioned above. T-cell reactivity showed higher values among boosted individuals with a median of 308 (288, 382) SFU/10^6 PBMCs compared to non-boosted individuals with a median of 229 (68, 390) SFU/10^6 PBMCs at 12 months follow up. This trend indicated that T-cell reactivity was more prevalent among booster recipients than those without a booster.

Table 32 SARS-CoV-2-specific T-cell reactivity of CanSino recipients by follow up

Variables	Baseline (n=27)		14 days after first dose (n=27)		Completed Vaccination (n=20)		3 months (n=12)		6 months (n=6)		9 months (n=6)		12 months (n=5)	
	Positive	Index	Positive	Index	Positive	Index	Positive	Index	Positive	Index	Positive	Index	Positive	Index
	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)	n (%)	Median (25th, 75th percentile)
Total	13 (48.1)	50 (40,84)	27 (100.0)	180 (105,322)	20 (100.0)	86 (50,192)	10 (83.3)	70 (56,83)	6 (100.0)	116 (40,272)	6 (100.0)	182 (120,360)	5 (100.0)	308 (268,390)
Sociodemography														
Age group														
18-39 years	9 (52.9)	48 (36,56)	17 (100.0)	148 (104,320)	12 (100.0)	94 (52,192)	6 (85.7)	66 (56,83)	4 (100.0)	156 (38,372)	3 (100.0)	360 (242,396)	3 (100.0)	308 (288,349)
40-59 years	4 (44.4)	76 (59,90)	9 (100.0)	200 (124,328)	7 (100.0)	80 (64,196)	4 (80.0)	70 (52,92)	2 (100.0)	116 (84,148)	3 (100.0)	120 (94,180)	2 (100.0)	262 (68,456)
60 years and above	0	-	1 (100.0)	-	1 (100.0)	-				N/A				
Sex														
Male	7 (36.8)	56 (45,90)	19 (100.0)	124 (100,306)	13 (100.0)	76 (48,96)	6 (85.7)	62 (48,72)	1 (100.0)	-	2 (100.0)	154 (68,240)	1 (100.0)	-
Female	6 (75.0)	48 (36,68)	8 (100.0)	312 (190,326)	7 (100.0)	188 (96,200)	4 (80.0)	78 (66,84)	5 (100.0)	148 (40,272)	4 (100.0)	242 (122,396)	4 (100.0)	288 (168,349)
Ethnicity														
Malay														
Chinese														
Indian							N/A							
Bumiputera Sabah & Sarawak														
Others	13 (48.1)	50 (40,84)	27 (100.0)	180 (105,322)	20 (100.0)	86 (50,192)	10 (83.3)	70 (56,83)	6 (100.0)	116 (40,272)	6 (100.0)	182 (120,360)	5 (100.0)	308 (268,390)
Nationality														
Malaysian	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-		N/A	1 (100.0)	-
Non-Malaysian	12 (46.2)	49 (38,82)	26 (100.0)	164 (104,320)	19 (100.0)	80 (50,174)	9 (81.8)	68 (56,72)	5 (100.0)	148 (40,272)	6 (100.0)	182 (120,360)	4 (100.0)	288 (168,349)
Comorbidity status														
No comorbid	8 (36.4)	44 (36,53)	22 (100.0)	134 (96,312)	16 (100.0)	78 (48,136)	7 (87.5)	60 (52,70)	3 (100.0)	40 (38,156)	3 (100.0)	124 (96,278)	2 (100.0)	349 (308,390)
Yes	5 (100.0)	84 (68,96)	5 (100.0)	416 (320,416)	4 (100.0)	238 (138,288)	3 (75.0)	84 (78,98)	3 (100.0)	148 (116,310)	3 (100.0)	240 (180,300)	3 (100.0)	268 (168,362)
Past COVID-19 infection														
No	12 (46.2)	49 (38,82)	26 (100.0)	164 (104,320)	19 (100.0)	80 (50,174)	9 (81.8)	68 (56,72)	5 (100.0)	148 (40,272)	6 (100.0)	182 (120,360)	4 (100.0)	288 (168,349)
Yes	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-		N/A	1 (100.0)	-
Booster Status														
No booster									2 (100.0)	94 (40,148)	4 (100.0)	180 (94,336)	2 (100.0)	229 (68,390)
1 dose				N/A					4 (100.0)	178 (60,372)	2 (100.0)	242 (124,360)	3 (100.0)	308 (288,382)

3.3.12 SARS-CoV-2-specific T-cell reactivity of Pfizer (Adolescent) recipients by follow up

A total of eight out of 27 (29.6%) Pfizer adolescent recipients were reactive before receiving the vaccination, with an overall low median T-cell reactivity value of 43 (39, 60) SFU/10^6 PBMCs. After receiving the first dose, the T-cell reactivity rate surged to 100% and remained up to 12 months follow up. Upon completed vaccination, the reactivity value peaked with a median of 748 (612, 1112) SFU/10^6 PBMCs, but declined in the subsequent follow ups with the lowest reactivity value of 185 (115, 280) SFU/10^6 PBMCs at 3 months (Table 33).

T-cell reactivity of SARS-CoV-2 by age

Generally, the T-cell reactivity value trend among Pfizer adolescent recipients by age was comparable to the overall trend across follow ups. The changes in T-cell reactivity value were contributed by a similar age group of Pfizer (A) recipients, comprising those below 18 years old. At baseline, the reactive T-cell recorded was 29.6% with a median of 43 (39, 60) SFU/10^6 PBMCs and reached 100% after receiving the first dose for 12 months. The median among the Pfizer (A) by age was the highest with a reactivity value of 748 (612, 1112) SFU/10^6 PBMCs after two doses of vaccine, but significantly dropped from 3 to 12 months follow up with a value of 185 (115, 280) SFU/10^6 PBMCs.

T-cell reactivity of SARS-CoV-2 by sex, ethnicity, and nationality

The changes in T-cell reactivity value among Pfizer adolescent recipients of different sexes, ethnicities and nationalities across the follow ups were generally similar to the total T-cell reactivity trend mentioned above. At baseline, the T-cell positive reactivity value was seen to be less than 30% before rising to 100% after receiving the first dose and maintained for up to 12 months. The majority of recipients had high T-cell reactivity values after completed vaccination, with a reactivity value of 766 (508, 1292) SFU/10^6 PBMCs in males, whereas 728 (616, 1056) SFU/10^6 PBMCs in females. However, a rapid decline in those values was observed for both sexes from 3 to 12 months follow up. As for the ethnicity, Malay, Indian and others were 100% reactive after receiving the first dose, together with an upsurge in their T-cell reactivity median value of 316 (208, 376), 450 (204, 696) and 340 (222, 510) SFU/10^6 PBMCs, respectively. At 3 months follow up, Indian recipients showed the highest median of 784 (464, 1104) SFU/10^6 PBMCs, followed by others and Malay with the median of 656 (502, 908) and 628 (392, 688) SFU/10^6 PBMCs, respectively. While Indian and others ethnicity demonstrated a consistent reduction in the T-cell reactivity values over time, there was a slight increase in the median of Malay recipients at 6 months before declining at 9 months with a median of 172 (124, 228) SFU/10^6 PBMCs. To conclude, the T-cell reactivity values were comparable between ethnicities across follow ups. After receiving the first dose of vaccine, both Malaysian and non-Malaysians achieved 100% T-cell reactivity positivity. The T-cell reactivity was at maximum after second dose of vaccine with a median of 756 (508, 832) SFU/10^6 PBMCs in Malaysian, whereas 748 (616, 1292) SFU/10^6 PBMCs in non-Malaysian. Regardless, Malaysian and non-Malaysians demonstrated a consistent drop in their T-cell reactivity values from 3 months to subsequent months.

T-cell reactivity of SARS-CoV-2 by comorbidity status

At the baseline, about 32.0% (8/27) of Pfizer recipients with no comorbidities were reactive with a median of 43 (39, 60) SFU/10^6 PBMCs. In contrast, recipients with comorbidities were seen to be non-reactive. After receiving the first dose, the T-cell reactivity increased to 100% in recipients with and without comorbidities with a median of 316 (216, 484) and 264 (208, 320) SFU/10^6 PBMCs, respectively. Both comorbidity status was at their maximum value upon completed vaccination: 748 (612, 1168) SFU/10^6 PBMCs in recipients with no comorbidities and 698 (612, 784) SFU/10^6 PBMCs in those with comorbidities. The median in those without comorbidities status declined at 3 to 12 months follow up, even though the T-cell reactivity value remained above the T-cell reactivity threshold throughout the follow ups.

T-cell reactivity of SARS-CoV-2 by past COVID-19 infection and booster status

At baseline, those with past COVID-19 infection have higher T-cell reactivity values than those without a history of infection, with a median of 69 (42, 96) and 42 (38, 60) SFU/10^6 PBMCs, respectively. Upon completed vaccination, recipients that were positive for T-cell response surged to 100% together with a median of 728 (612, 1056) SFU/10^6 PBMCs in those without past COVID-19 infection and 1178 (916, 1440) SFU/10^6 PBMCs in those with past COVID-19 infection. However, the T-cell reactive values decreased at 3 months and over time while the recipients remained 100% reactive. As no booster was administered among the adolescent, no increment in T-cell reactivity was observed at 6 months compared with adults who received booster vaccination at 6 months follow up.

Table 33 SARS-CoV-2-specific T-cell reactivity of Pfizer (Adolescent) recipients by follow up

VARIABLES	BASELINE (n=27)		SECOND DOSE (n=27)		COMPLETED VACCINATION (n=23)		3 MONTHS (n=17)		6 MONTHS (n=15)		9 MONTHS (n=13)		12 MONTHS (n=12)	
	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX	POSITIVE	INDEX
	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)	n (%)	MEDIAN (25TH, 75TH PERCENTILE)
Total	8 (29.6)	43 (39,60)	27 (100.0)	316 (212,476)	23 (100.0)	748 (612,1112)	17 (100.0)	628 (436,736)	15 (100.0)	496 (297,688)	13 (100.0)	228 (124,482)	12 (100.0)	185 (115,280)
Sociodemography														
Age group														
Below 18 years	8 (29.6)	43 (39,60)	27 (100.0)	316 (212,476)	23 (100.0)	748 (612,1112)	17 (100.0)	628 (436,736)	15 (100.0)	496 (297,688)	13 (100.0)	228 (124,482)	12 (100.0)	185 (115,280)
Sex														
Male	3 (25.0)	60 (52,60)	12 (100.0)	366 (216,510)	10 (100.0)	766 (508,1292)	7 (100.0)	584 (416,824)	6 (100.0)	394 (116,552)	5 (100.0)	228 (80,264)	6 (100.0)	159 (90,260)
Female	5 (33.3)	40 (38,42)	15 (100.0)	300 (212,416)	13 (100.0)	728 (616,1056)	10 (100.0)	654 (436,716)	9 (100.0)	656 (316,876)	8 (100.0)	324 (148,649)	6 (100.0)	230 (140,296)
Ethnicity														
Malay	0	-	9 (100.0)	316 (208,376)	8 (100.0)	756 (536,822)	7 (100.0)	628 (392,688)	5 (100.0)	656 (288,940)	5 (100.0)	172 (124,228)	3 (100.0)	140 (115,218)
Indian	1 (50.0)	-	2 (100.0)	450 (204,696)	2 (100.0)	974 (508,1440)	2 (100.0)	784 (464,1104)	2 (100.0)	506 (292,720)	2 (100.0)	434 (52,816)	2 (100.0)	302 (60,544)
Others	7 (43.8)	44 (39,60)	16 (100.0)	340 (222,510)	13 (100.0)	748 (616,1292)	8 (100.0)	656 (502,908)	8 (100.0)	408 (309,584)	6 (100.0)	342 (228,482)	7 (100.0)	196 (159,262)
Nationality														
Malaysian	1 (9.1)	-	11 (100.0)	316 (206,394)	10 (100.0)	756 (508,832)	9 (100.0)	628 (436,696)	7 (100.0)	656 (290,830)	7 (100.0)	172 (102,522)	5 (100.0)	140 (90,296)
Non-Malaysian	7 (43.8)	44 (39,60)	16 (100.0)	340 (222,510)	13 (100.0)	748 (616,1292)	8 (100.0)	656 (502,908)	8 (100.0)	408 (309,584)	6 (100.0)	342 (228,482)	7 (100.0)	196 (159,262)
Comorbidity status														
No comorbid	8 (32.0)	43 (39,60)	25 (100.0)	316 (216,484)	21 (100.0)	748 (612,1168)	16 (100.0)	654 (442,820)	15 (100.0)	496 (297,688)	12 (100.0)	246 (110,521)	12 (100.0)	185 (115,280)
Yes	0	-	2 (100.0)	264 (208,320)	2 (100.0)	698 (612,784)	1 (100.0)	-	N/A		1 (100.0)	-	N/A	
Past COVID-19 infection														
No	6 (21.4)	42 (38,60)	24 (100.0)	292 (206,432)	21 (100.0)	728 (612,1056)	15 (100.0)	596 (428,706)	14 (100.0)	408 (292,656)	12 (100.0)	228 (110,451)	11 (100.0)	174 (115,262)
Yes	2 (66.7)	69 (42,96)	3 (100.0)	552 (518,624)	2 (100.0)	1178 (916,1440)	2 (100.0)	920 (736,1104)	1 (100.0)	-	1 (100.0)	-	1 (100.0)	-
Booster Status														
No booster	N/A								15 (100.0)	496 (297,688)	13 (100.0)	228 (124,482)	12 (100.0)	185 (115,280)
1 dose									N/A					

CONCLUSION

4.0 CONCLUSION

The level of immunoglobulin G against SARS-CoV-2 spike protein and its changes varied slightly across different groups. It generally peaked at 14 days after the last vaccine dose, decreased and bottomed at three or six months from the first vaccine dose, and increased at six to nine months, especially among those who were boosted and/or infected. The level of IgG against SARS-CoV-2 nucleocapsid that indicates infection was generally lower and stable among all vaccine recipients (except for inactivated vaccine – Sinovac, where changes in the anti-nucleocapsid IgG level were similar to the anti-spike IgG) until six or nine months, when it increased sharply. Majority of the vaccine recipients did not report any AEFI or AESI, or experienced mild AEFI not requiring treatment that were improving or had fully recovered.

Almost all vaccine recipients tested positive for salivary IgA and T-cell reactivity after the first vaccine dose onward. However, the level of salivary IgA remained low throughout when compared to the baseline, while the increase in T-cell reactivity was more obvious.

In conclusion, the immune response against SARS-CoV-2 and COVID-19 vaccine safety were demonstrated among different vaccine recipients in Malaysia.

SUPPLEMENTS

ANNEX A: QUESTIONNAIRES

MODUL A: SOSIODEMOGRAFI ***MODULE A: SOCIODEMOGRAPHY***		
Pilih **SATU** jawapan sahaja/ Choose **ONE** answer only		
BAHAGIAN 1/ ***SECTION 1***		
A1000a	Nama responden: *Name of the respondent:*	
A1000b	No. barkod: (sila scan) *Barcode Number: (please scan)*	
A1000c	Nama penemuramah *Interviewer's name*	
A1000d	Tarikh temuramah *Interview date*	
A1000e	Tempat menerima vaksin *Vaccination place:*	
A1001	Apakah jenis tanda pengenalan diri anda? *What is your identification card?*	1. No. Kad Pengenalan Baru/MyKid *New Identification Card/ My Kid* 2. No. Passport/ *Passport No.* 3. No. Kad Pengenalan lain (Tentera/ Polis/ Sijil lahir/ Lain-lain) *Other identification card no. (Army/Police/Birth cert/Others)*
A1002	Apakah nombor kad pengenalan diri anda? (tanpa "-") *What is your identification card number? (without "-")*	☐☐☐☐☐☐☐☐☐☐☐☐
A1003	Bila tarikh lahir anda? *When is your birth date?*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
A1004	Berapa umur anda? *How old are you?*	☐☐☐☐ Tahun Genap
A1005	Apakah jantina anda? *What is your gender?*	1. Lelaki *Male* 2. Female *Female*
A1006	Apakah bangsa anda? *What is your ethnicity?*	1. Melayu *Malay* 2. Cina *Chinese* 3. India *Indian* 4. Bumiputera Sabah 5. Bumiputera Sarawak 6. Lain-lain *Others* Sila nyatakan: *Please specify:*
A1006a	Apakah kerakyatan anda? *What is your citizenship?*	1. Warganegara *Malaysian* 2. Bukan warganegara *Non-Malaysian*
A1007	Alamat kediaman: *Home address:*	

A1008	No. telefon peribadi (tanpa "-") : *Personal telephone number (without "-"):*	
A1008a	Alamat emel *Email address*	
A1009	No. telefon waris 1 *Relative 1 phone number*	
A1010	Hubungan dengan waris 1 *Relationship with relative 1*	1. Anak *Children* 2. Ibu/Bapa *Mother/Father* 3. Pasangan *Spouse* 4. Adik-beradik *Siblings* 5. Menantu *In-laws* 6. Datuk/Nenek *Grandfather/Grandmother* 7. Tidak berkenaan *Not Applicable* 8. Lain-lain *Others* Sila nyatakan: *Please specify:*
A1011	No. telefon waris 2 *Relative 2 phone number*	
A1012	Hubungan dengan waris 2 *Relationship with relative 2*	1. Anak *Children* 2. Ibu/Bapa *Mother/Father* 3. Pasangan *Spouse* 4. Adik-beradik *Siblings* 5. Menantu *In-laws* 6. Datuk/Nenek *Grandfather/Grandmother* 7. Tidak berkenaan *Not Applicable* 8. Lain-lain *Others* Sila nyatakan: *Please specify:*
A1013	Adakah anda bekerja? *Are you working?*	1. Ya *Yes* 2. Tidak *No* **(teruskan ke A1014/ *skip to A1014*)**
A1013a	Adakah anda… *Are you a…* Pilih satu jawapan **UTAMA** sahaja. *Choose only **one MAIN** answer?*	1. Pekerja kerajaan *Government employee* 2. Pekerja separa kerajaan *Semi-government employee* 3. Pekerja swasta *Private employee* 4. Bekerja sendiri *Self-employed* 5. Pekerja tanpa gaji *Unpaid worker* 6. Pekerja keluarga tanpa gaji *Unpaid family worker*
A1013b	Alamat tempat kerja: *Office address:*	
A1013c	No. telefon tempat kerja (tanpa "-") : *Office phone number (without "-") :*	
A1014	Berat: *Weight:*	kg

A1015	Tinggi: *Height:*	☐☐☐☐ cm
A1016	Ukur lilit pinggang: *Waist circumference:*	☐☐☐☐ cm
A1017	Jenis vaksin: *Vaccine Type:*	1. Pfizer *Pfizer* 2. Sinovac *Sinovac* 3. Astra Zeneca *Astra Zeneca* 4. Gamaleya *Gamaleya* 5. CanSino *CanSino* 6. Johnson & Johnson *Johnson & Johnson*
A1018	Tarikh dos pertama vaksin: *First vaccine dose date:*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
A1019	Tarikh jangkaan dos kedua vaksin: *Expected second vaccine dose date:*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
Bahagian 2 (Faktor Risiko) ***Section 2 (Risk Factors)***		
COVID-19		
B1001	Pernahkah anda mengalami sebarang gejala di bawah dalam 12 bulan yang lepas? *Have you had any symptom below in the past 12 months?*	
B1001a	Demam *Fever*	1. Ya *Yes* 2. Tidak *No*
B1001b	Merasa sejuk *Chills*	1. Ya *Yes* 2. Tidak *No*
B1001c	Menggigil *Rigors*	1. Ya *Yes* 2. Tidak *No*
B1001d	Sakit otot *Myalgia*	1. Ya *Yes* 2. Tidak *No*
B1001e	Sakit kepala *Headache*	1. Ya *Yes* 2. Tidak *No*
B1001f	Sakit tekak *Sore throat*	1. Ya *Yes* 2. Tidak *No*
B1001g	Loya dan muntah *Nausea and vomiting*	1. Ya *Yes* 2. Tidak *No*
B1001h	Cirit- birit *Diarrhea*	1. Ya *Yes* 2. Tidak *No*
B1001i	Kelesuan *Fatigue*	1. Ya *Yes* 2. Tidak *No*
B1001j	Hidung tersumbat atau selesema *Acute onset nasal congestion or running nose*	1. Ya *Yes* 2. Tidak *No*
B1001k	Batuk *Cough*	1. Ya *Yes* 2. Tidak *No*
B1001l	Sesak nafas *Shortness of breath*	1. Ya *Yes* 2. Tidak *No*

B1001m	Sukar bernafas *Difficulty in breathing*	1. Ya *Yes* 2. Tidak *No*
B1001n	Hilang deria bau secara tiba- tiba *Sudden loss of smell*	1. Ya *Yes* 2. Tidak *No*
B1001o	Hilang deria rasa secara tiba- tiba *Sudden loss of taste*	1. Ya *Yes* 2. Tidak *No*
B1001p	Tiada gejala *No Symptoms*	1. Ya *Yes* 2. Tidak *No*
B1002	Pernahkah anda mempunyai kontak rapat dengan pesakit COVID-19 sebelum ini? *Have you ever been in close contact with COVID-19 patient?*	1. Ya *Yes* 2. Tidak *No*
B1003	Pernahkah anda menjalani ujian swab untuk COVID-19 sebelum ini? *Have you ever gotten a swab test for COVID-19 in the past 12 months?*	1. Ya *Yes* 2. Tidak *No*
B1004	Pernahkah anda didiagnosa sebagai pesakit COVID-19 oleh pengamal perubatan? *Have you ever been diagnosed as a COVID-19 patient by a medical practitioner?*	1. Ya *Yes* 2. Tidak *No*
B1004a	Bilakah anda didiagnosa sebagai pesakit COVID-19? *When were you diagnosed as COVID-19 patient?*	1. Ya *Yes* 2. Tidak *No*
Komorbiditi ***Comorbidities***		
B1005	Adakah anda pernah diberitahu oleh pengamal perubatan bahawa anda mempunyai penyakit seperti dibawah? *Have you ever been told by medical practitioner to have any of these diseases?*	
B1005a	Kencing Manis *Diabetes Mellitus*	1. Ya *Yes* 2. Tidak *No*
B1005b	Tekanan darah tinggi *Hypertension*	1. Ya *Yes* 2. Tidak *No*
B1005c	Sakit jantung *Heart Disease*	1. Ya *Yes* 2. Tidak *No*
B1005d	Asma *Asthma*	1. Ya *Yes* 2. Tidak *No*
B1005e	Penyakit paru-paru kronik *Chronic pulmonary diseases*	1. Ya *Yes* 2. Tidak *No*
B1005f	Penyakit Hati *Liver disease*	1. Ya *Yes* 2. Tidak *No*

B1005g	Kanser *Cancer*	1. Ya *Yes* 2. Tidak *No*
B1005h	Penyakit radang sendi rheumatoid *Rheumatoid Arthritis*	1. Ya *Yes* 2. Tidak *No*
B1005i	Lupus Eritematosus Sistemic (SLE) *Systemic Lupus Erythematosus (SLE)*	1. Ya *Yes* 2. Tidak *No*
B1005j	Sindrom Down *Down Syndrome*	1. Ya *Yes* 2. Tidak *No*
B1005k	Penyakit buah pinggang *Kidney disease*	1. Ya *Yes* 2. Tidak *No*
B1005l	Gagal buah pinggang dan memerlukan Hemodialisis *Kidney failure on hemodialysis*	1. Ya *Yes* 2. Tidak *No*
Merokok ***Smoking***		
B1006	Pernahkah anda merokok/ vape/ e-rokok (seperti dalam senarai buku kod)? *Have you ever smoked cigarette/ vape/ e-cigarette? (refer code book)*	1. Ya *Yes* 2. Tidak *No*
B1006a	Adakah anda masih merokok dalam masa sebulan yang lepas? *Do you currently smoke in the past one month?*	1. Ya *Yes* 2. Tidak *No*
Pengambilan buah-buahan dan sayur- sayuran ***Fruits and vegetable intake***		
B1007	Kebiasaannya, dalam seminggu berapa hari anda makan buah? *In a typical week, how many days did you consume fruits?*	1. 0 hari *0 day* **(teruskan ke B1009/ *skip to B1009*)** 2. 1 hari *1 day* 3. 2 hari *2 days* 4. 3 hari *3 days* 5. 4 hari *4 days* 6. 5 hari *5 days* 7. 6 hari *6 days* 8. 7 hari *7 days*
B1007a	Biasanya pada hari yang anda makan buah (epal, oren, pisang dan sebagainya) berapa sajian yang anda makan? *Usually on the day that you eat fruits (e.g apple, orange, banana and so on), how many servings did you take?*	_____ bil. sajian *no. of serving* ***sila rujuk kad untuk anggaran hidangan** ****please refer to the card given for serving size estimation***

B1008	Kebiasaannya, dalam seminggu berapa hari anda makan sayuran dimasak dan/ atau ulam-ulaman? *In a typical week, how many days did you eat cooked and/ or raw vagetables?*	1. 0 hari *0 day* **(teruskan ke B1010/ *skip to B1010*)** 2. 1 hari *1 day* 3. 2 hari *2 days* 4. 3 hari *3 days* 5. 4 hari *4 days* 6. 5 hari *5 days* 7. 6 hari *6 days* 8. 7 hari *7 days*
B1008a	Biasanya pada hari yang anda makan sayuran dimasak dan/atau ulam-ulaman, berapa sajian yang anda makan? *Usually on the day that you eat cooked and/ or raw vegetables, how many servings did you take?*	_____ bil. sajian *no. of serving* ***sila rujuk kad untuk anggaran hidangan** ****please refer to the card given for serving size estimation***
Aktiviti Fizikal ***Physical Activity***		
B1009	Dalam tempoh 7 hari yang lepas, berapakah hari yang anda telah melakukan aktiviti fizikal lasak (contohnya: mengangkat barang berat, mencangkul, senaman aerobic atau berbasikal laju dan lain-lain) sekurang-kurangnya 10 minit pada suatu masa? *In the past 7 days, how many days have you done vigorous physical activity (e.g: carry heavy weights, till the earth, aerobic exerciseor fast cycling and others) for at least 10 minutes per session*	1. 0 hari *0 day* **(teruskan ke B1010/ *skip to B1010*)** 2. 1 hari *1 day* 3. 2 hari *2 days* 4. 3 hari *3 days* 5. 4 hari *4 days* 6. 5 hari *5 days* 7. 6 hari *6 days* 8. 7 hari *7 days*
B1009a	Pada hari yang anda melakukan aktiviti fizikal lasak, berapa lamakah anda melakukannya? *On the day you carry out the vigorous physical activity, how long do you do this activity?*	_____ minit *minutes*

B1010	Dalam tempoh 7 hari yang lepas, berapakah hari yang anda telah melakukan aktiviti fizikal sederhana (contohnya: mengangkat muatan ringan, mengelap lantai, berbasikal pada kelajuan biasa dan lain-lain) sekurang-kurangnya 10 minit pada suatu masa tidak termasuk berjalan kaki? *In the past 7 days, how many days you have done moderate physical activity (e.g: carry light weights, mop the floor, or normal rate of cycling and others) for at least 10 minutes per session? This does not include walking.*	1. 0 hari *0 day* **(teruskan ke B1011/ *skip to B1011*)** 2. 1 hari *1 day* 3. 2 hari *2 days* 4. 3 hari *3 days* 5. 4 hari *4 days* 6. 5 hari *5 days* 7. 6 hari *6 days* 8. 7 hari *7 days*
B1010a	Pada hari yang anda melakukan aktiviti fizikal sederhana, berapa lamakah anda melakukannya? *On the day you carry out the moderate physical activity, how long do you do this activity?*	_____ minit *minutes*
B1011	Dalam tempoh 7 hari yang lepas, berapa harikah yang anda telah berjalan kaki selama sekurang-kurangnya 10 minit pada suatu masa? *In the past 7 days, how many days have you walked for at least 10 minutes per session?*	1. 0 hari *0 day* **(teruskan ke B1012/ *skip to B1012*)** 2. 1 hari *1 day* 3. 2 hari *2 days* 4. 3 hari *3 days* 5. 4 hari *4 days* 6. 5 hari *5 days* 7. 6 hari *6 days* 8. 7 hari *7 days*
B1011a	Pada salah satu daripada hari berkenaan, berapakah masa yang anda gunakan untuk berjalan kaki? *On one of these days that you walked, how long do you spend walking?*	_____ minit *minutes*
B1012	Biasanya dalam sehari, berapa jamkah yang anda gunakan untuk duduk atau berbaring termasuk di tempat kerja, di rumah, di waktu lapang dan semasa perjalanan, TETAPI TIDAK TERMASUK waktu tidur? *Normally in a day, how many hours do you spend on sitting or lying down including the workplace, in the house, in your free time and while travelling, BUT NOT INCLUDING the time spent sleeping?*	_____ jam *hours* _____ minit *minutes*

SELF-ADMINISTERED QUESTIONNAIRE (SAQ)		
SOSIODEMOGRAFI ***SOCIODEMOGRAPHY***		
C1001	No. Barkod: (sila scan) *Barcode number: (please scan)*	
C1002	Apakah nombor kad pengenalan diri anda? (tanpa "-") *What is your identification card number? (without "-")*	☐☐☐☐☐☐☐☐☐☐☐☐
C1003	Adakah anda merupakan pesakit HIV? *Are you an HIV patient?*	1. Ya *Yes* 2. Tidak *No* **(teruskan ke C1004/ *skip to C1004*)**
C1003a	Adakah anda mendapat rawatan HAART? *Are you on HAART treatment?*	1. Ya *Yes* 2. Tidak *No*
Alkohol ***Alcohol***		
C1004	Dalam tempoh 12 bulan yang lepas, berapa kerap anda mengambil minuman beralkohol/ arak/ minuman keras? *How often do you have a drink containing alcohol?*	1. Tidak pernah *Never* **(teruskan ke C1007/ *skip to C1007*)** 2. Sebulan sekali atau kurang *Once a month or less* 3. 2 - 4 kali sebulan *2 - 4 times a month* 4. 2 - 3 kali seminggu *2- 3 times a week* 5. > 3 kali seminggu *> 3 days a week*
C1005	Kebiasaannya, pada hari yang anda minum, berapa banyakkah anda minum minuman beralkohol/ arak/ minuman keras? (rujuk gambarajah) *How many standard drinks containing alcohol do you have on a typical day? (refer pictures)*	1. 1 atau 2 *1 or 2* 2. 3 atau 4 *3 or 4* 3. 5 atau 6 *5 or 6* 4. 7 atau 8 atau 9 *7 or 8 or 9* 5. 10 atau lebih *10 or more*
C1006	Berapa kerap anda minum 6 unit atau lebih minuman beralkohol pada sesuatu masa? *How often do you have six or more drinks on one occasion?*	1. Tidak pernah *Never* 2. Kurang dari sebulan sekali *Less than monthly* 3. Setiap bulan *Monthly* 4. Setiap minggu *Weekly* 5. Setiap hari atau hamper setiap hari *Daily or almost daily*
Tahap Stress ***Stress Level***		
C1007	Pada sebulan yang lepas, berapa kali anda merasa kecewa kerana sesuatu yang terjadi diluar jangkaan anda? *In the last month, how often have you been upset because of something that happened unexpectedly?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*

C1008	Pada sebulan yang lepas, berapa kerap anda merasakan anda tidak mampu mengawal perkara penting didalam hidup anda? *In the last month, how often have you felt that you were unable to control the important things in your life?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1009	Pada sebulan yang lepas, berapa kali anda berasa resah dan tertekan? *In the last month, how often have you felt nervous and stressed?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1010	Pada sebulan yang lepas, berapa kerap anda merasa yakin tentang kemampuan anda untuk menghadapi masalah peribadi anda? *In the last month, how often have you felt confident about your ability to handle your personal problems?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1011	Pada sebulan yang lepas, berapa kerap anda merasakan perkara yang berlaku adalah mengikut rancangan anda? *In the last month, how often have you felt that things were going your way?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1012	Pada sebulan yang lepas, berapa kerap anda mendapati anda tidak mampu mengatasi perkara-perkara yang perlu anda lakukan? *In the last month, how often have you found that you could not cope with all the things that you had to do?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1013	Pada sebulan yang lepas, berapa kerap anda mampu mengawal perasaan marah dalam hidup anda? *In the last month, how often have you been able to control irritations in your life?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1014	Pada sebulan yang lepas, berapa kerap anda merasakan anda berjaya diatas segala sesuatu? *In the last month, how often have you felt that you were on top of things?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*

C1015	Pada sebulan yang lepas, berapa kerap anda menjadi marah kerana halhal yang berada diluar kawalan anda? *In the last month, how often have you been angered because of things that happened that were outside of your control?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
C1016	Pada sebulan yang lepas, berapa kerap anda merasakan kesulitan yang menimbun tinggi sehingga anda tidak mampu menanganinya? *In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?*	1. Tidak pernah *Never* 2. Hampir tidak pernah *Almost never* 3. Jarang-jarang *Sometimes* 4. Kadang-kadang *Fairly often* 5. Sering *Very often*
SELF-ADMINISTERED QUESTIONNAIRE (SAQ)		
MODUL 1A: AEFI (ADVERSE EVENTS FOLLOWING IMMUNIZATION)		
1A1000	No. Barkod: (sila imbas) *Barcode Number: (please scan)*	
1A1000a	Nama responden: *Name of the respondent:*	
1A1000b	Apakah nombor kad pengenalan diri anda? (tanpa "-") *What is your identification card number? (without "-")*	☐☐☐☐☐☐☐☐☐☐☐☐
1A1001	Adakah anda mengalami sebarang kesan sampingan setelah mendapat suntikan vaksin COVID-19? *Have you experienced any side effects after vaccination?*	1. Ya *Yes* 2. Tidak *No* **(teruskan ke 1B1001/ *skip to 1B1001*)**
1A1001a	Adakah anda melaporkan kesan sampingan tersebut? *Have you reported the side effects experienced after vaccination?*	1. Ya *Yes* 2. Tidak *No* **(teruskan ke 1A1001d / *skip to 1A1001d*)**
1A1001b	Bilakah anda melaporkannya? *When did you report it?*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
1A1001c	Bagaimanakah anda melaporkannya? *How did you report it?*	1. MySejahtera (atas talian) / *MySejahtera (online)* 2. Borang(klinik atau hospital) / *Conservative form (clinic or hospital)*

1A1001d	Apakah kesan sampingan yang anda alami? *What side effect(s) did you experience?*	Nyatakan: Specify;
1A1001e	Bilakah anda mengalaminya? *When did you experienced it?*	D D M M Y Y Y Y
1A1001f	Adakah kesan sampingan tersebut berkurangan? *Did the side effect(s) subside?*	1. Ya *Yes* 2. Tidak *No*
1A1001g	Bilakah kesan sampingan tersebut berkurang? *When did the side effect(s) subsided?*	D D M M Y Y Y Y
1A1001h	Berapa serius kesan sampingan tersebut? *How serious was the side effect(s)?*	1. Ringan dan sedikit tidak selesa *Mild and slightly uncomfortable* 2. Tidak selesa tetapi masih boleh melakukan aktiviti harian *Uncomfortable but could carry out daily activities* 3. Berat dan mengganggu aktiviti harian *Bad and interferes with daily activities* 4. Perlu mendapatkan rawatan *Had to seek medical advice*
1A1001i	Adakah anda menerima sebarang rawatan? *Was there any treatment(s) given?*	1. Ya *Yes* 2. Tidak *No*
1A1001j	Apakah keadaan terkini kesan sampingan tersebut? *What is the current outcome of the side effect(s)?*	1. Sembuh sepenuhnya *Fully recover* 2. Semakin sembuh *Getting better* 3. Masih berterusan *Side effects continuing*
MODUL 1B: AESI (ADVERSE EVENTS OF SPECIAL INTEREST)		
1B1001	Sejak hari terakhir vaksinasi (COVID19), pernahkah anda dimasukkan ke hospital? *Since the last vaccination dose, have you ever been hospitalized?*	1. Ya/ *Yes* **(teruskan ke 1B1001a sehingga selesai/ *continue to 1B1001a until the end of questions*)** 2. Tidak/ *No* **(soalan selesai/ *end module*)**
1B1001a	Mengapakah anda dimasukkan ke hospital? *Why were you hospitalized?*	Nyatakan: *Specify:* ***Jika jawapan adalah seperti senarai AESI di lampiran atau hampir seperti itu, teruskan menjawab soalan sehingga selesai. Jika tidak, modul selesai*** *If the answer as same as AESI on the list in the annex or similarly like it, proceed answer the question until the end. If not, end module.
1B1001b	Apakah diagnosis terakhir doctor? *What was the final diagnosis by doctor?*	Nyatakan: *Specify:*
1B1001c	Bilakah tarikh anda dimasukkan ke hospital? *What is the date of admission?*	D D M M Y Y Y Y

1B1001d	Bilakah tarikh anda dibenarkan keluar hospital? *What was the date of discharge?*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y
1B1001e	Berapa harikah anda berada di wad? *How many days were you admitted to the ward?*	_____ hari *days*
1B1001f	Pernahkah anda mengalami masalah yang sama sebelum ini? *Have you encountered the same problem before?*	1. Ya *Yes* 2. Tidak *No* **(soalan selesai/ *end of module*)**
1B1001g	Bilakah kejadian (1B1001f) berlaku? *When did the event (1B1001f) happen?*	☐☐ ☐☐ ☐☐☐☐ D D M M Y Y Y Y

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MODUL TINDAK SUSUL TEMUJANJI/FOLLOW-UP IMSURE (6 BULAN SELEPAS DOS PERTAMA)

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KEMENTERIAN KESIHATAN MALAYSIA

MODUL A: STATUS KEHADIRAN TEMUJANJI/ FOLLOW-UP		
A6001	Nombor kad pengenalan diri	1. No. kad pengenalan baru 2. No. pasport 3. No. kad pengenalan lain (tentera/ polis/ sijil lahir/ lain-lain)
A6002	No. kad pengenalan	Nyatakan: _____
A6003	Tarikh temujanji/ *follow-up*	HH/BB/TT
A6004	Status peserta yang telah hadir mengikut jadual temujanji/ *follow-up*	1. Hadir (mengikut jadual temujanji) dan biospesimen diambil. 2. Hadir (*reschedule*) dan biospesimen diambil 3. Hadir namun terlepas (*missed*) pengambilan darah, tiada darah diambil 4. Tidak hadir temujanji, namun masih berminat menyertai survelan ini 5. Tidak hadir kerana enggan menyertai survelan ini
A6005	Untuk hadir dan *rescheduled*, sebab-sebab *rescheduled*	Nyatakan:
A6006	Untuk tidak hadir kerana enggan, nyatakan sebab enggan menyertai	1. Tidak berminat **(Tamat)** 2. Kesukaran untuk menghadiri *follow-up* **(Tamat)** 3. Mengidap penyakit yang perlu pemantauan rapi/ dimasukkan ke hospital **(Tamat)** 4. Perlu kuarantin kerana mendapat jangkitan COVID-19 atau kontak rapat **(Tamat)** 5. Berpindah **(Tamat)** 6. Tukar tempat vaksinasi **(Tamat)** 7. Tidak dapat dikesan **(Tamat)** 8. Dimaklumkan oleh ahli keluarga telah meninggal **(Tamat)** 9. Lain-lain **(Tamat)**
MODUL B: BIOMARKER		
B6001	Adakah sampel darah virologi (*gel tube*) diambil?	1. Ya 2. Tidak
B6002	Adakah sampel *cell response* bagi darah diambil?	1. Ya 2. Tidak
B6003	Adakah sampel *cell response* bagi *saliva* diambil?	1. Ya 2. Tidak

MODUL C: DOS PENGGALAK DAN JANGKITAN COVID-19		
C6001	Sudahkah anda menerima dos penggalak?	1. Ya 2. Tidak 3. Enggan jawab 4. Tidak tahu
C6002	Jika **YA**, bilakah anda menerimanya?	HH/BB/TT
C6003	Apakah jenis dos penggalak yang diambil?	1. Pfizer 2. Sinovac 3. AstraZeneca 4. Lain-lain
C6004	Sejak dari *follow-up* terakhir sehingga kini, Adakah anda telah dijangkiti COVID-19?	1. Ya 2. Tidak
C6004b	Adakan responden menerima dos penggalak?	1. Ya 2. Tidak
C6005	Jika **YA**, adakah anda dijangkiti COVID-19 sebelum atau selepas mendapat dos penggalak?	1. Sebelum 2. Selepas 3. Tidak tahu 4. Enggan jawab
C6006	Bilakah tarikh jangkitan tersebut?	HH/BB/TT
C6007	Apakah kategori jangkitan COVID-19 anda?	1. Positif, tidak bergejala 2. Positif, mempunyai gejala ringan (demam, batuk, sakit tekak, hilang deria bau dan rasa) 3. Positif, alami jangkitan atau radang paru-paru (*pneumonia*). Tidak memerlukan bantuan oksigen 4. Positif, alami radang paru-paru dan memerlukan bantuan oksigen 5. Pesakit kritikal melibatkan simptom sesak nafas kegagalan multi organ dan perlukan bantuan pernafasan melalui v*entilator*.
MODUL D: AEFI (ADVERSE EVENTS FOLLOWING IMMUNIZATION)		
D6001	Adakah anda mengalami sebarang kesan sampingan setelah mendapat suntikan vaksin COVID-19?	1. Ya 2. Tidak 3. Tidak berkenaan (Tidak menerima dos penggalak)
D6A001a	Adakah anda melaporkan kesan sampingan tersebut?	1. Ya 2. Tidak
D6A001b	Bilakah anda melaporkannya?	HH/BB/TT
D6A001c	Bagaimanakah anda melaporkannya?	1. MySejahtera (atas talian) 2. Borang (klinik atau hospital)
D6A001d	Apakah kesan sampingan yang anda alami?	Nyatakan:
D6A001e	Bilakah anda mengalaminya?	HH/BB/TT

D6A001f	Adakah kesan sampingan tersebut berkurangan?	1. Ya 2. Tidak
D6A001g	Bilakah kesan sampingan tersebut berkurangan?	HH/BB/TT
D6A001h	Berapa serius kesan sampingan tersebut?	1. Ringan dan sedikit tidak selesa 2. Tidak selesa tetapi masih boleh melakukan aktiviti harian 3. Berat dan mengganggu aktiviti harian 4. Perlu mendapatkan rawatan
D6A001i	Adakah anda menerima sebarang rawatan?	1. Ya 2. Tidak
D6A001j	Apakah keadaan terkini kesan sampingan tersebut?	1. Sembuh sepenuhnya 2. Semakin sembuh 3. Masih berterusan
AESI (ADVERSE EVENTS OF SPECIAL INTEREST)		
D6B001	Sejak hari terakhir vaksinasi (COVID-19), pernahkah anda dimasukkan ke hospital?	1. Ya 2. Tidak
D6B001a	Mengapakah anda dimasukkan ke hospital?	Nyatakan:
D6B001b	Apakah diagnosis terakhir doktor?	Nyatakan:
D6B001c	Bilakah anda dimasukkan ke hospital?	HH/BB/TT
D6B001d	Bilakah tarikh anda dibenarkan keluar hospital?	HH/BB/TT
D6B001e	Berapa harikah anda berada di wad?	Nyatakan:
D6B001f	Pernahkan anda mengalami masalah sama sebelum ini?	1. Ya 2. Tidak
D6B001g	Bilakah kejadian itu berlaku?	HH/BB/TT

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MODUL A: STATUS KEHADIRAN TEMUJANJI/ FOLLOW-UP		
F6A001	Nombor kad pengenalan diri	1. No. kad pengenalan baru 2. No. pasport 3. No. kad pengenalan lain (tentera/ polis/ sijil lahir/ lain-lain)
F6A002	No. kad pengenalan	Nyatakan:
F6A003	Tarikh temujanji/ *follow-up*	HH/BB/TT
F6A004	Status peserta yang telah hadir mengikut jadual temujanji/ *follow-up*	1. Hadir (mengikut jadual temujanji) dan biospesimen diambil. 2. Hadir (*reschedule*) dan biospesimen diambil 3. Hadir namun terlepas (*missed*) pengambilan darah, tiada darah diambil 4. Tidak hadir temujanji, namun masih berminat menyertai survelan ini 5. Tidak hadir kerana enggan menyertai survelan ini
F6A005	Untuk hadir dan *rescheduled*, sebab-sebab *rescheduled*	Nyatakan:
F6A006	Untuk tidak hadir kerana enggan, nyatakan sebab enggan menyertai	1. Tidak berminat 2. Kesukaran untuk menghadiri *follow-up* **(Tamat)** 3. Mengidap penyakit yang perlu pemantauan rapi/ dimasukkan ke hospital **(Tamat)** 4. Perlu kuarantin kerana mendapat jangkitan COVID-19 atau kontak rapat **(Tamat)** 5. Berpindah **(Tamat)** 6. Tukar tempat vaksinasi **(Tamat)** 7. Tidak dapat dikesan **(Tamat)** 8. Dimaklumkan oleh ahli keluarga telah meninggal **(Tamat)** 9. Lain-lain **(Tamat)**
MODUL B: BIOMARKER		
F6B001	Adakah sampel darah virologi (*gel tube*) diambil?	1. Ya 2. Tidak
F6B002	Adakah sampel *cell response* bagi darah diambil?	1. Ya 2. Tidak

F6B003	Adakah sampel *cell response* bagi *saliva* diambil?	1. Ya 2. Tidak
MODUL C: DOS PENGGALAK DAN JANGKITAN COVID-19		
F6C001	Sudahkah anda menerima dos penggalak?	1. Ya 2. Tidak 3. Enggan jawab 4. Tidak tahu
F6C002	Jika **YA**, bilakah anda menerimanya?	HH/BB/TT
F6C003	Apakah jenis dos penggalak yang diambil?	1. Pfizer 2. Sinovac 3. AstraZeneca 4. Lain-lain
F6C004	Sejak dari *follow-up* terakhir sehingga kini, Adakah anda telah dijangkiti COVID-19?	1. Ya 2. Tidak
F6C005	Jika **YA**, adakah anda dijangkiti COVID-19 sebelum atau selepas mendapat dos penggalak?	1. Sebelum 2. Selepas 3. Tidak tahu 4. Enggan jawab
F6C006	Bilakah tarikh jangkitan tersebut?	HH/BB/TT
F6C007	Apakah kategori jangkitan COVID-19 anda?	1. Positif, tidak bergejala 2. Positif, mempunyai gejala ringan (demam, batuk, sakit tekak, hilang deria bau dan rasa) 3. Positif, alami jangkitan atau radang paru-paru (*pneumonia*). Tidak memerlukan bantuan oksigen 4. Positif, alami radang paru-paru dan memerlukan bantuan oksigen 5. Pesakit kritikal melibatkan simptom sesak nafas kegagalan multi organ dan perlukan bantuan pernafasan melalui *ventilator*.
MODUL D: AEFI (ADVERSE EVENTS FOLLOWING IMMUNIZATION)		
F6D001	Adakah anda mengalami sebarang kesan sampingan setelah mendapat suntikan vaksin COVID-19?	1. Ya 2. Tidak 3. Tidak berkenaan (Tidak menerima dos penggalak)
F6D001a	Adakah anda melaporkan kesan sampingan tersebut?	1. Ya 2. Tidak
F6D001b	Bilakah anda melaporkannya?	HH/BB/TT
F6D001c	Bagaimanakah anda melaporkannya?	1. MySejahtera (atas talian) 2. Borang (Klinik atau hospital)
F6D001d	Apakah kesan sampingan yang anda alami?	Nyatakan:
F6D001e	Bilakah anda mengalaminya?	HH/BB/TT

F6D001f	Adakah kesan sampingan tersebut berkurangan?	1. Ya 2. Tidak
F6D001g	Bilakah kesan sampingan tersebut berkurangan?	HH/BB/TT
F6D001h	Berapa serius kesan sampingan tersebut?	1. Ringan dan sedikit tidak selesa 2. Tidak selesa tetapi masih boleh melakukan aktiviti harian 3. Berat dan mengganggu aktiviti harian 4. Perlu mendapatkan rawatan
F6D001i	Adakah anda menerima sebarang rawatan?	1. Ya 2. Tidak
F6D001j	Apakah keadaan terkini kesan sampingan tersebut?	1. Sembuh sepenuhnya 2. Semakin sembuh 3. Masih berterusan
AESI (ADVERSE EVENTS OF SPECIAL INTEREST)		
F6D002	Sejak hari terakhir vaksinasi (COVID-19), pernahkah anda dimasukkan ke hospital?	1. Ya 2. Tidak
F6D002a	Mengapakah anda dimasukkan ke hospital?	Nyatakan:
F6D002b	Apakah diagnosis terakhir doktor?	Nyatakan:
F6D002c	Bilakah anda dimasukkan ke hospital?	HH/BB/TT
F6D002d	Bilakah tarikh anda dibenarkan keluar hospital?	HH/BB/TT
F6D002e	Berapa harikah anda berada di wad?	Nyatakan:
F6D002f	Pernahkan anda mengalami masalah sama sebelum ini?	1. Ya 2. Tidak
F6D002g	Bilakah kejadian itu berlaku?	HH/BB/TT

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MODUL TINDAK SUSUL TEMUJANJI/FOLLOW-UP IMSURE (12 BULAN SELEPAS DOS PERTAMA)

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MODUL A: STATUS KEHADIRAN TEMUJANJI/ FOLLOW-UP		
F7A001	Nombor kad pengenalan diri	1. No. kad pengenalan baru 2. No. pasport 3. No. kad pengenalan lain (tentera/ polis/ sijil lahir/ lain-lain)
F7A002	No. kad pengenalan	Nyatakan:
F7A003	Tarikh temujanji/ *follow-up*	HH/BB/TT
F7A004	Status peserta yang telah hadir mengikut jadual temujanji/ *follow-up*	1. Hadir (mengikut jadual temujanji) dan biospesimen diambil. 2. Hadir (*reschedule*) dan biospesimen diambil 3. Hadir namun terlepas (*missed*) pengambilan darah, tiada darah diambil 4. Tidak hadir temujanji, namun masih berminat menyertai survelan ini 5. Tidak hadir kerana enggan menyertai survelan ini
F7A005	Untuk hadir dan *rescheduled*, sebab-sebab *rescheduled*	Nyatakan:
F7A006	Untuk tidak hadir kerana enggan, nyatakan sebab enggan menyertai	1. Tidak berminat **(Tamat)** 2. Kesukaran untuk menghadiri *follow-up* **(Tamat)** 3. Mengidap penyakit yang perlu pemantauan rapi/ dimasukkan ke hospital **(Tamat)** 4. Perlu kuarantin kerana mendapat jangkitan COVID-19 atau kontak rapat **(Tamat)** 5. Berpindah **(Tamat)** 6. Tukar tempat vaksinasi **(Tamat)** 7. Tidak dapat dikesan **(Tamat)** 8. Dimaklumkan oleh ahli keluarga telah meninggal **(Tamat)** 9. Lain-lain **(Tamat)**
MODUL B: BIOMARKER		
F7B001	Adakah sampel darah virologi (*gel tube*) diambil?	1. Ya 2. Tidak
F7B002	Adakah sampel *cell response* bagi darah diambil?	1. Ya 2. Tidak
F7B003	Adakah sampel *cell response* bagi *saliva* diambil?	1. Ya 2. Tidak

MODUL C: DOS PENGGALAK DAN JANGKITAN COVID-19		
F7C001	Sudahkah anda menerima dos penggalak?	1. Ya 2. Tidak 3. Enggan jawab 4. Tidak tahu
F7C002	Jika **YA**, bilakah anda menerimanya?	HH/BB/TT
F7C003	Apakah jenis dos penggalak yang diambil?	1. Pfizer 2. Sinovac 3. AstraZeneca 4. Lain-lain
F7C004	Sejak dari *follow-up* terakhir sehingga kini, Adakah anda telah dijangkiti COVID-19?	1. Ya 2. Tidak
F7C005	Jika **YA**, adakah anda dijangkiti COVID-19 sebelum atau selepas mendapat dos penggalak?	1. Sebelum 2. Selepas 3. Tidak tahu 4. Enggan jawab
F7C006	Bilakah tarikh jangkitan tersebut?	HH/BB/TT
F7C007	Apakah kategori jangkitan COVID-19 anda?	1. Positif, tidak bergejala 2. Positif, mempunyai gejala ringan (demam, batuk, sakit tekak, hilang deria bau dan rasa) 3. Positif, alami jangkitan atau radang paru-paru (*pneumonia*). Tidak memerlukan bantuan oksigen 4. Positif, alami radang paru-paru dan memerlukan bantuan oksigen 5. Pesakit kritikal melibatkan simptom sesak nafas kegagalan multi organ dan perlukan bantuan pernafasan melalui *ventilator*.
MODUL D: AEFI (ADVERSE EVENTS FOLLOWING IMMUNIZATION)		
F7D001	Adakah anda mengalami sebarang kesan sampingan setelah mendapat suntikan vaksin COVID-19?	1. Ya 2. Tidak 3. Tidak berkenaan (tidak menerima dos penggalak)
F7D001a	Adakah anda melaporkan kesan sampingan tersebut?	1. Ya 2. Tidak
F7D001b	Bilakah anda melaporkannya?	HH/BB/TT
F7D001c	Bagaimanakah anda melaporkannya?	1. MySejahtera (atas talian) 2. Borang (Klinik atau hospital)
F7D001d	Apakah kesan sampingan yang anda alami?	Nyatakan: _____
F7D001e	Bilakah anda mengalaminya?	HH/BB/TT
F7D001f	Adakah kesan sampingan tersebut berkurangan?	1. Ya 2. Tidak

F7D001g	Bilakah kesan sampingan tersebut berkurangan?	HH/BB/TT
F7D001h	Berapa serius kesan sampingan tersebut?	1. Ringan dan sedikit tidak selesa 2. Tidak selesa tetapi masih boleh melakukan aktiviti harian 3. Berat dan mengganggu aktiviti harian 4. Perlu mendapatkan rawatan
F7D001i	Adakah anda menerima sebarang rawatan?	1. Ya 2. Tidak
F7D001j	Apakah keadaan terkini kesan sampingan tersebut?	1. Sembuh sepenuhnya 2. Semakin sembuh 3. Masih berterusan
AESI (ADVERSE EVENTS OF SPECIAL INTEREST)		
F7D002	Sejak hari terakhir vaksinasi (COVID-19), pernahkah anda dimasukkan ke hospital?	1. Ya 2. Tidak
F7D002a	Mengapakah anda dimasukkan ke hospital?	Nyatakan:
F7D002b	Apakah diagnosis terakhir doktor?	Nyatakan:
F7D002c	Bilakah anda dimasukkan ke hospital?	HH/BB/TT
F7D002d	Bilakah tarikh anda dibenarkan keluar hospital?	HH/BB/TT
F7D002e	Berapa harikah anda berada di wad?	Nyatakan:
F7D002f	Pernahkan anda mengalami masalah sama sebelum ini?	1. Ya 2. Tidak
F7D002g	Bilakah kejadian itu berlaku?	HH/BB/TT
MODUL E: CADANGAN		
F7E001	Jika kami meneruskan *survey*, berapa lamakah anda dapat meneruskan *survey* ini?	1. Selama 12 bulan 2. Selama 9 bulan 3. Selama 6 bulan 4. Selama 3 bulan 5. Saya tidak berminat untuk meneruskannya lagi
F7E001a	Jika jawapan diatas **BUKAN (a)**, sila nyatakan sebab (boleh pilih lebih dari 1 jawapan)	1. Saya tidak mahu 2. Saya tidak nampak kepentingan *survey* ini 3. Saya akan berpindah ke tempat lain 4. Temujanji ini membebankan saya 5. Terlalu banyak percubaan yang gagal semasa pengambilan darah 6. Nilai token yang tidak mencukupi untuk menampung kos pengangkutan untuk menghadiri temujanji 7. Lain-lain
F7E002	Apakah cadangan yang boleh kami lakukan untuk menggalakkan anda kekal sehingga akhir *survey*?	Nyatakan:

F7F001	Sudahkah anda menerima dos penggalak kedua?	1. Ya 2. Tidak
F7F001a	Bilakah anda menerima dos penggalak kedua?	HH/BB/TT
F7F001b	Apakah jenis dos penggalak kedua yang diterima?	1. Pfizer 2. Sinovac 3. AstraZeneca 4. CanSino 5. Lain-lain

ANNEX B: STUDY INFORMATION SHEET

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

1. **Title**: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

2. **Name of investigator and institution:** Dr Chong Zhuo Lin, Institute for Public Health, National Institutes of Health, Ministry of Health Malaysia

3. **Name of funder**: The Government of Malaysia

4. **Introduction:**
   You are invited to participate in a surveillance because you are a COVID-19 vaccine recipient. The details of the surveillance are described in this document. It is important that you understand why the surveillance is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the surveillance investigator if anything is unclear or if you like more information. After you are properly satisfied that you understand this surveillance, and that you wish to participate, you must sign this informed consent form. To participate in this surveillance, you may be required to provide information on your health history.

   Your participation in this surveillance is voluntary. You do not have to be in this surveillance if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this surveillance, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the surveillance. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

   This surveillance study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the surveillance?**
   The purpose of this surveillance is to examine the response of your immune system, side effects, and the occurrence of COVID-19 after you receive COVID-19 vaccination. This surveillance is necessary because different people have different degree of immune response and side effects towards vaccination. The duration of immune response following vaccination also differs from individual to individual. In addition, while most COVID-19 vaccines protect recipients from death and severe disease requiring hospitalization, mild disease can still occur occasionally. The occurrence of COVID-19 post-vaccination needs to be monitored and reported. Information collected through this surveillance will help the Ministry of Health Malaysia understand the proportion of vaccine recipients with immunity after vaccination, the duration this immunity lasts, and the level of protection it provides. It will help us decide if the residents in Malaysia need a booster dose in the time to come, and when it is needed.

   Up to 7400 vaccine recipients like you from across Malaysia will be participating in this surveillance. The whole surveillance will include six to nine (6 - 9) data collection and last about one (1) or two (2) years. Your participation will be about only 5-15 minutes each time.

6. **What kind of surveillance will I receive?**
   If you agree to participate in the surveillance, the surveillance investigator may need to screen you to determine if you are suitable for the surveillance. If you are deemed suitable, your blood samples will be tested in the Institute for Medical Research, Setia Alam, for your immune response (antibodies level) before you receive your first dose of vaccine, before you receive your second dose of vaccine (if any), and 14 days after completion of the vaccination (additional follow-up at 28 days after completion of single dose vaccine). Subsequently, you will also be followed-up every three (3) months for the first year after your first dose of vaccine (at month 3, 6, 9, and 12). If necessary, follow-up might continue into the second year, but the gap will be every six (6) months (at month 18 and 24). (For some of you who live very close to our laboratory, we will also additionally test the activity of your immune cells and the antibodies level in your saliva)

   In addition, we will contact you through telephone prior to each follow-up to remind you, and to find out if you have been diagnosed with COVID-19 from the last time we meet you.

7. What will happen if I decide to take part?

If you decide to take part in this surveillance, the following will happen:

A) Consent and registration: You will sign the consent form and fill in registration form.

B) Blood sample collection: Subsequently, blood sample will be taken from you following aseptic principles to ensure cleanliness and prevent cross-infection. The blood sample will be drawn from a vein using a needle. Around 10 ml (2 teaspoons) of venous blood will be obtained from you for the purpose of this surveillance. (If you are also selected to test the activity of your immune cells and the antibodies in your saliva, an additional 20 ml (4 teaspoons) of venous blood and 5 ml of saliva will also be obtained from you.)

For underaged participants, the amount of blood sampled will be determined according to weight. For those involved only with antibody tests, the blood volume sampled are: <10 kg: 2.0 ml (0.4 teaspoon), 10-19.9 kg: 2.5 ml (half teaspoon), 20-29.9 kg: 4.0 ml (0.8 teaspoon), 30-39.9 kg: 6.0 ml (1.2 teaspoon), >40 kg: 8.0 ml (1.6 teaspoon). For those also involved with immune cell tests, the additional blood volume needed are: <10 kg: 4.0 ml (0.8 teaspoon), 10-19.9 kg: 5.0 ml (1 teaspoon), 20-29.9 kg: 8.0 ml (1.6 teaspoon), 30-39.9 kg: 12.0 ml (0.8 tablespoon), >40 kg: 16.0 ml (around 1 tablespoon).

C) Vaccination and observation: After that, you will proceed to receive your vaccine shot and then to the observation bay like other vaccine recipients.

D) Interview: You will be interviewed by a surveillance investigator for some important basic personal information, COVID-19 related questions, and risk factors for COVID-19. Your height, weight, and abdominal circumference will also be measured. You will also be given a list of questions to answer on your own.

E) Follow-up appointment setting and token: Finally, you will be given your surveillance follow-up card with next appointment date and a token for your time and contribution.
Prior to the next follow-up, a surveillance investigator will call to remind you about the coming follow-up.

If your vaccine has a second dose, your next follow-up will coincide with the date of the second dose of vaccination. Once you arrive at the vaccination centre, only steps B, C, D, and E mentioned above will happen.

Once you have completed your vaccination, during the subsequent follow-ups, only steps B and E mentioned above will happen. Step D will only happen during certain follow-ups. Additionally, if the result of your immune response is ready, you will also be given a copy with its interpretation.

8. When will I receive the trial product and how should it be kept?

Not applicable as this is a surveillance. No trial product will be used on you. Only laboratory results will be given to the participants.

9. What are my responsibilities when taking part in this surveillance?

It is important that you commit with us for the all the follow-ups across one (1) or two (2) years. Important information of the changes in your immune response will be missing if you miss any follow-up. Otherwise, it is also important that you answer all the questions asked by the surveillance investigator honestly and completely.

10. What kind of treatment will I receive after my participation in the surveillance?

Not applicable as this is a surveillance. No treatment product is tested here. Whether you complete the surveillance or withdraw early, you will still receive and would have already received your COVID-19 vaccines. If you happen to get COVID-19 after the vaccination at any point of time, you will be managed and treated according to the latest management and treatment guidelines at that point of time.

11. What are the potential risks and side effects of being in this surveillance?

The only risk you are exposed to in this surveillance is the risks associated with blood-sampling, such as profuse bleeding and blood-borne infection. Rest assure that the blood sampling procedure will be performed by an experience healthcare professional following strict aseptic principle to avoid any chance of complication. However, there is no escape to the major side effect of blood-sampling – the painful sensation. If you are not comfortable with it, you may choose not to participate in this surveillance. Please ask the surveillance investigator if you need more information on risks and side effects.

12. What are the benefits of being in this surveillance?

Personally, participation in this surveillance provides you information regarding your body immune response following vaccination. Beyond that, your contribution to the society and its member is far greater. Information collected through this surveillance will help the Ministry of Health Malaysia understand the proportion of vaccine recipients with immunity after vaccination, the duration this immunity lasts, and the level of protection it provides. It will help us decide if the residents in Malaysia need a booster dose in the time to come, and when it is needed. In essence, you will contribute to the policy of COVID-19 vaccination, which will protect the residents of Malaysia from future COVID-19 outbreaks, and every subsequent event following these outbreaks such as quarantine, isolation, loss of health, and loss of lives.

13. What if I am injured during this surveillance?

In the event of a bodily injury or illness directly resulting from a medical procedure (blood sample collection) required for this surveillance, the surveillance investigator will arrange for reasonable and necessary treatment. The funder is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your vaccinator or the vaccination site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

14. What are my alternatives if I do not participate in this surveillance?

You do not have to participate in this surveillance to get the vaccination. The surveillance investigator will discuss in more details the benefits and risks of this surveillance with you.

15. Who is funding the surveillance?

This surveillance is funded by the Government of Malaysia. The funder will pay for all diagnostic procedures under the surveillance. All other drugs and procedures that are not required by the surveillance but are part of your routine medical care will have to be paid by you or your insurance. The sponsor will financially compensate the time spent by the surveillance investigator for including you in the surveillance. You will also be reimbursed for your time spent for this surveillance.

16. Can the surveillance or my participation be terminated early?

The surveillance investigators or the funder may, due to concerns for your safety, stop the surveillance or your participation at any time. If the surveillance is stopped early for any reason, you will be informed.

17. Will my medical information be kept private?

All your information obtained in this surveillance will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the surveillance results, your identity will not be revealed without your expressed consent. Individuals involved in this surveillance and in your medical care, qualified monitors and auditors, the funder or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Some of your excess biospecimens, if any, may be stored in the laboratories of Institute for Medical Research for future coronavirus-related testing until they are exhausted. No genetic testing will be conducted. The researcher may share those biospecimens with other researchers. Your biospecimens may be sent to laboratories in other countries for testing. In any situation, your biospecimens will be coded and information that can identify you will be removed. Only the researcher will be able to link the code with you with the help of a confidential linking document.

You can withdraw your consent and request for the specimen to be destroyed during the conduct of the surveillance. The surveillance investigator will still use any information obtained from the biospecimens up until the time you withdraw consent.

Data from the surveillance will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

18. Who should I call if I have questions?

If you have any questions about the surveillance or if you think you have a surveillance-related injury and you want information about treatment, please contact the IMSURE secretariat, Institute for Public Health at telephone number 03-3362 8791.

If you have any questions about your rights as a participant in this surveillance, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8888/8205 or email to mrecsec@moh.gov.my.

INFORMED CONSENT FORM

19. Title: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

By signing below, I confirm the following:

- I have been given oral and written information for the above surveillance and have read and understood the information given.
- I have had sufficient time to consider my participation in the surveillance and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at any time withdraw from the surveillance without giving a reason and this will in no way affect my vaccination/future treatment. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the investigator's instructions related to my participation in the surveillance.
- I understand that surveillance investigator, qualified monitors and auditors, the funder or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the surveillance is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

Subject:

Signature:		I/C number:	
Name:		Date:	

Investigator conducting informed consent:

Signature:		I/C number:	
Name:		Date:	

Impartial witness: (Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)

Signature:		I/C number:	
Name:		Date:	

YOUNG PARTICIPANT INFORMATION SHEET AND ASSENT FORM

1. **Title**: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

2. **Name of investigator and institution:** Dr Chong Zhuo Lin, Institute for Public Health, National Institutes of Health, Ministry of Health Malaysia

3. **Name of funder**: The Government of Malaysia

4. **Introduction:**
   You are invited to participate in this surveillance because you are receiving a COVID-19 vaccine. The details of the surveillance are described in this document. It is important that you understand what this surveillance is about and why is it being done.

   Please read through and consider carefully before you decide if you are willing to participate. Ask the surveillance investigator if you need more information. After you understand this surveillance, and you wish to participate, you must sign this assent form.
   You can decide if you want to participate in this surveillance or not. Your participation surveillance is voluntary, nobody can force you, even your parents/guardian. You do not have to be in this surveillance if you do not want to. You may also refuse to answer any questions you do not want to answer.

   If you volunteer to participate, you may stop at any time. If you stop, any data collected from you before will still be used for the surveillance. Even if you refuse or stop participating, the medical or health benefits you should receive will not be affected.

   This surveillance study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the surveillance?**
   The purpose of this surveillance is to examine how much and how long your immune response is, and whether there is any side effect or COVID-19 infection, after you receive COVID-19 vaccination.

   This surveillance is necessary because different people have different immune response and side effects towards vaccination and receive different degree of protection against the virus that causes COVID-19.

   Information collected through this surveillance will help the Ministry of Health Malaysia decide what to do, to make sure most people in this country maintain high level of immunity against COVID-19.

   Up to 7400 vaccine recipients like you from across Malaysia will be participating in this surveillance. The whole surveillance will include six to nine (6 - 9) meeting with us over one (1) or two (2) years. Each meeting will only spend 5-15 minutes of your time.

6. **What kind of surveillance will I receive?**
   If you agree to participate in the surveillance, the surveillance investigator may need to see if you are suitable for the surveillance. If you are suitable, we will take your blood sample and test it in the Institute for Medical Research, Setia Alam.

   The laboratory test will tell us your antibody level before you receive your first dose of vaccine, before you receive your second dose of vaccine (if any), and 14 days after completion of the vaccination (additional meeting at 28 days after receiving vaccine that comes only in a single dose). Subsequently, you will also meet us every three (3) months for the first year after your first dose of vaccine (at month 3, 6, 9, and 12). If necessary, we might continue to meet into the second year, but the gap will be every six (6) months (at month 18 and 24). (For some of you who live very close to our laboratory, where we can maintain the freshness of the samples, we might also additionally test the activity of your immune cells and the antibody level in your saliva)

   In addition, we will contact you through telephone prior to each follow-up to remind you, and to find out if you have been diagnosed with COVID-19 from the last time we meet you.

7. What will happen if I decide to take part?

If you decide to take part in this surveillance, the following will happen:

A) Consent, assent and registration: Your parents/guardian must allow you to participate first, by signing an informed consent form. Then, you will sign the assent form and fill in registration form.

B) Blood sample collection: Subsequently, blood sample will be taken from you. We will ensure cleanliness to prevent any infection. The blood sample will be taken from a vein using a needle.

The amount of blood sampled will be determined according to your weight. For those involved only with antibody tests, the blood volume sampled are: <10 kg: 2.0 ml (0.4 teaspoon), 10-19.9 kg: 2.5 ml (half teaspoon), 20-29.9 kg: 4.0 ml (0.8 teaspoon), 30-39.9 kg: 6.0 ml (1.2 teaspoon), >40 kg: 8.0 ml (1.6 teaspoon).

For those also involved with immune cell tests, the additional blood volume needed are: <10 kg: 4.0 ml (0.8 teaspoon), 10-19.9 kg: 5.0 ml (1 teaspoon), 20-29.9 kg: 8.0 ml (1.6 teaspoon), 30-39.9 kg: 12.0 ml (0.8 tablespoon), >40 kg: 16.0 ml (around 1 tablespoon).

C) Vaccination and observation: After that, you will receive your vaccine shot and go to the observation bay like other vaccine recipients.

D) Interview: You will be interviewed by a surveillance investigator for some important basic personal information and information related to COVID-19. Your height, weight, and belly circumference will also be measured. You will also be given a list of questions to answer on your own.

E) Follow-up appointment setting and token: Finally, you will be given your surveillance appointment card with next meeting date and a token for your time and contribution.

Prior to the next meeting, a surveillance investigator will call to remind you about it.

If your vaccine has a second dose, our next meeting is the date of the second dose of vaccination. Once you arrive at the vaccination centre, only steps B, C, D, and E mentioned above will happen.

Once you have completed your vaccination, during the meetings that follow, only steps B and E mentioned above will happen. Step D will only happen during certain meetings. Additionally, if the result of your immune response is ready, you will also be given a copy with explanation.

8. When will I receive the trial product and how should it be kept?

There is no trial product that will be used on you. Only laboratory results will be given to the participants.

9. What are my responsibilities when taking part in this surveillance?

It is important that you meet us for the all the appointments across one (1) or two (2) years. Important information of the changes in your immune response will be missing if you miss any meeting. It is also important that you answer all the questions asked by the surveillance investigator honestly and completely.

10. What kind of treatment will I receive after my participation in the surveillance?

No treatment product is tested here. Whether you complete the surveillance or stop early, you would have received your COVID-19 vaccines. If you happen to get COVID-19 after the vaccination at any point in time, you will be treated accordingly.

11. What are the potential risks and side effects of being in this surveillance?

The only risk you are exposed to in this surveillance is the risks that come with blood-sampling, such as bleeding and infection. But do not worry, the blood sampling procedure will be performed by an experience healthcare worker in a clean way to make it safe. You might feel slight pain initially from the needle. If you are not comfortable with it, you may choose not to participate in this surveillance. Please ask the surveillance investigator if you need more information on risks and side effects.

12. What are the benefits of being in this surveillance?

Personally, participation in this surveillance tells you how much and how long your immune response is. Beyond that, your contribution to the society and other people is far greater. Information collected through this surveillance will help the Ministry of Health Malaysia decide if the residents in Malaysia need any additional vaccine dose in the future, and when it is needed. In essence, you will contribute to the policy of COVID-19 vaccination, which will protect the

people in Malaysia from future COVID-19 outbreaks, and all the inconveniences they bring, including sickness, and death.

13. What if I am injured during this surveillance?

If injury or illness happen as a direct result of the blood sample collection, the surveillance investigator will arrange for reasonable and necessary treatment. The funder will not pay for medical expenses due to known or unknown sickness you might have, any ongoing treatment, your carelessness or neglect, or of the vaccinator or the vaccination site or any third parties. However, you can still seek compensation even after signing this form.

14. What are my alternatives if I do not participate in this surveillance?

You do not have to participate in this surveillance to get the vaccination. The surveillance investigator will discuss in more details the benefits and risks of this surveillance with you.

15. Who is funding the surveillance?

This surveillance is funded by the Government of Malaysia, who pays for all laboratory tests. All other drugs and procedures that are not required by the surveillance but are part of your routine treatment will have to be paid by your parents/guardian or your insurance. You will be given a token for your time spent for this surveillance.

16. Can the surveillance or my participation be terminated early?

If there is any safety concern, the surveillance investigators or the funder may stop the surveillance or your participation at any time. If the surveillance is stopped early for any reason, you will be informed.

17. Will my medical information be kept private?

All your information obtained in this surveillance will be kept and handled confidentially, according to laws and regulations. When publishing or presenting the results, we will not tell who you are unless your give your permission. Individuals involved in this surveillance and in your medical care, and qualified people with authority may inspect and copy your medical records, where appropriate and necessary.

Some of your extra blood (and saliva) samples, if any, may be stored in the laboratories of Institute for Medical Research for future coronavirus tests until there is none left. We will not do any genetic testing. The investigators may share your samples with other investigators or send them to laboratories in other countries for testing. In any situation, your samples will be given a code and information that can identify you will be removed. Only the investigators will be able to link the code with your personal information with the help of a confidential linking document.

You can change your mind and request for the samples to be destroyed during the conduct of the surveillance. The surveillance investigator will still use any information obtained from the sample up until the time you change your mind.

Data from the surveillance will be kept and may be transmitted outside the country for examination, but your information will be kept secret at all times.

18. Who should I call if I have questions?

If you have any questions about the surveillance or if you think you have an injury due to the surveillance and you want information about its treatment, please contact the IMSURE secretariat, Institute for Public Health at telephone number 03-3362 8791.

If you have any questions about your choices as a participant in this surveillance, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8888/8205 or email to mrecsec@moh.gov.my.

INFORMED CONSENT FORM

19. Title: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

By signing below, I confirm the following:

- I have heard and read information for the above surveillance and understood the information.
- I have had enough time to consider my participation in the surveillance and have had the opportunity to ask questions and I am satisfied with the answers.
- I understand that my participation is voluntary and I can at any time stop participating in the surveillance without giving a reason and this will not affect my vaccination/future treatment. I understand the risks and benefits, and I freely give my assent to participate under the conditions stated. I understand that I must follow the investigator's instructions related to my participation in the surveillance.
- I understand that surveillance investigator and qualified people with authority can read my medical record in order to make sure that the surveillance is conducted correctly, and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL.
- I will receive a copy of this information sheet/assent form with signatures and dates.

Young participant:

Signature:		I/C number:	
Name:		Date:	

Investigator conducting assent:

Signature:		I/C number:	
Name:		Date:	

Impartial witness: (Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)

Signature:		I/C number:	
Name:		Date:	

PARENTAL OR GUARDIAN PARTICIPANT INFORMATION SHEET

1. **Title**: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

2. **Name of investigator and institution:** Dr Chong Zhuo Lin, Institute for Public Health, National Institutes of Health, Ministry of Health Malaysia

3. **Name of funder**: The Government of Malaysia

4. **Introduction:**
   Your child is invited to participate in a surveillance because your child is a COVID-19 vaccine recipient. The details of the surveillance are described in this document. It is important that you understand why the surveillance is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to allow your child to participate. Ask the surveillance investigator if anything is unclear or if you like more information. After you are properly satisfied that you understand this surveillance, and that you wish to allow your child to participate, you must sign this parental/guardian informed consent form. To participate in this surveillance, you may be required to provide information on your child's health history.

   Your child's participation in this surveillance is voluntary. Your child does not have to be in this surveillance if you do not want your child to. You/your child may also refuse to answer any questions you/your child do not want to answer. If you volunteer your child to be in this surveillance, you/your child may withdraw from it at any time. If you/your child withdraw, any data collected from you/your child up to your withdrawal will still be used for the surveillance. Your/your child refusal to participate or withdrawal will not affect any medical or health benefits to which your child is otherwise entitled.

   This surveillance study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the surveillance?**
   The purpose of this surveillance is to examine the response of your child's immune system, side effects, and the occurrence of COVID-19 after your child receives COVID-19 vaccination. This surveillance is necessary because different people have different degree of immune response and side effects towards vaccination. The duration of immune response following vaccination also differs from individual to individual. In addition, while most COVID-19 vaccines protect recipients from death and severe disease requiring hospitalization, mild disease can still occur occasionally. The occurrence of COVID-19 post-vaccination needs to be monitored and reported. Information collected through this surveillance will help the Ministry of Health Malaysia understand the proportion of vaccine recipients with immunity after vaccination, the duration this immunity lasts, and the level of protection it provides. It will help us decide if the residents in Malaysia need a booster dose in the time to come, and when it is needed.

   Up to 7400 vaccine recipients like your child from across Malaysia will be participating in this surveillance. The whole surveillance will include six to nine (6 - 9) data collection and last about one (1) or two (2) years. Your child's participation will be about only 5-15 minutes each time.

6. **What kind of surveillance will my child receive?**
   If you agree to allow your child to participate in the surveillance, the surveillance investigator may need to screen your child to determine if your child is suitable for the surveillance. If your child is deemed suitable, your child's blood samples will be tested in the Institute for Medical Research, Setia Alam, for your child's immune response (antibodies level) before your child receive the first dose of vaccine, before your child receive the second dose of vaccine (if any), and 14 days after completion of the vaccination (additional follow-up at 28 days after completion of single dose vaccine). Subsequently, your child will also be followed-up every three (3) months for the first year after your child's first dose of vaccine (at month 3, 6, 9, and 12). If necessary, follow-up might continue into the second year, but the gap will be every six (6) months (at month 18 and 24). (For some of you who live very close to our laboratory, we will also additionally test the activity of your child's immune cells and the antibodies level in your child's saliva)

   In addition, we will contact you/your child through telephone prior to each follow-up to remind you/your child, and to find out if your child has been diagnosed with COVID-19 from the last time we meet you.

7. What will happen if I decide to allow my child to take part?

If you decide to allow your child to take part in this surveillance, the following will happen:

A) Consent and registration: You will sign the consent form and fill in registration form.

B) Blood sample collection: Subsequently, blood sample will be taken from your child following aseptic principles to ensure cleanliness and prevent cross-infection. The blood sample will be drawn from a vein using a needle.

The amount of blood sampled will be determined according to weight of your child. For those involved only with antibody tests, the blood volume sampled are: <10 kg: 2.0 ml (0.4 teaspoon), 10-19.9 kg: 2.5 ml (half teaspoon), 20-29.9 kg: 4.0 ml (0.8 teaspoon), 30-39.9 kg: 6.0 ml (1.2 teaspoon), >40 kg: 8.0 ml (1.6 teaspoon). For those also involved with immune cell tests, the additional blood volume needed are: <10 kg: 4.0 ml (0.8 teaspoon), 10-19.9 kg: 5.0 ml (1 teaspoon), 20-29.9 kg: 8.0 ml (1.6 teaspoon), 30-39.9 kg: 12.0 ml (0.8 tablespoon), >40 kg: 16.0 ml (around 1 tablespoon).

C) Vaccination and observation: After that, your child will proceed to receive the vaccine shot and then to the observation bay like other vaccine recipients.

D) Interview: You/your child will be interviewed by a surveillance investigator for some important basic personal information, COVID-19 related questions, and risk factors for COVID-19. Your child's height, weight, and abdominal circumference will also be measured. You/your child will also be given a list of questions to answer on your/his/her own.

E) Follow-up appointment setting and token: Finally, your child will be given a surveillance follow-up card with next appointment date and a token for your/your child's time and contribution.

Prior to the next follow-up, a surveillance investigator will call to remind you/your child about the coming follow-up.

If your child's vaccine has a second dose, your child's next follow-up will coincide with the date of the second dose of vaccination. Once your child arrives at the vaccination centre, only steps B, C, D, and E mentioned above will happen.

Once your child has completed the vaccination, during the subsequent follow-ups, only steps B and E mentioned above will happen. Step D will only happen during certain follow-ups. Additionally, if the result of your child's immune response is ready, you/your child will also be given a copy with its interpretation.

8. When will my child receive the trial product and how should it be kept?

Not applicable as this is a surveillance. No trial product will be used on your child. Only laboratory results will be given to the participants.

9. What are my child's responsibilities when taking part in this surveillance?

It is important that you/your child commit with us for the all the follow-ups across one (1) or two (2) years. Important information of the changes in your child's immune response will be missing if your child misses any follow-up. Otherwise, it is also important that you/your child answer all the questions asked by the surveillance investigator honestly and completely.

10. What kind of treatment will my child receive after participation in the surveillance?

Not applicable as this is a surveillance. No treatment product is tested here. Whether you/your child complete the surveillance or withdraw early, your child will still receive and would have already received the COVID-19 vaccines. If your child happens to get COVID-19 after the vaccination at any point of time, your child will be managed and treated according to the latest management and treatment guidelines at that point of time.

11. What are the potential risks and side effects of being in this surveillance?

The only risk your child is exposed to in this surveillance is the risks associated with blood-sampling, such as profuse bleeding and blood-borne infection. Rest assure that the blood sampling procedure will be performed by an experience healthcare professional following strict aseptic principle to avoid any chance of complication. However, there is no escape to the major side effect of blood-sampling – the painful sensation. If you/your child are not comfortable with it, you/your child may choose not to participate in this surveillance. Please ask the surveillance investigator if you/your child need more information on risks and side effects.

12. What are the benefits of being in this surveillance?

Personally, participation in this surveillance provides you/your child information regarding your child's body immune response following vaccination. Beyond that, your child's contribution to the society and its member is far greater. Information collected through this surveillance will help the Ministry of Health Malaysia understand the proportion of vaccine recipients with immunity after vaccination, the duration this immunity lasts, and the level of protection it provides. It will help us decide if the residents in Malaysia need a booster dose in the time to come, and when it is needed. In essence, your child will contribute to the policy of COVID-19 vaccination, which will protect the residents of Malaysia from future COVID-19 outbreaks, and every subsequent event following these outbreaks such as quarantine, isolation, loss of health, and loss of lives.

13. What if my child is injured during this surveillance?

In the event of a bodily injury or illness directly resulting from a medical procedure (blood sample collection) required for this surveillance, the surveillance investigator will arrange for reasonable and necessary treatment. The funder is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, you/your child's negligence or willful misconduct, the negligence or willful misconduct of your child's vaccinator or the vaccination site or any third parties. You do not lose any of your/your child's legal rights to seek compensation by signing this form.

14. What are my child's alternatives if my child does not participate in this surveillance?

Your child does not have to participate in this surveillance to get the vaccination. The surveillance investigator will discuss in more details the benefits and risks of this surveillance with you/your child.

15. Who is funding the surveillance?

This surveillance is funded by the Government of Malaysia. The funder will pay for all diagnostic procedures under the surveillance. All other drugs and procedures that are not required by the surveillance but are part of your child's routine medical care will have to be paid by you or your/your child's insurance. The funder will financially compensate the time spent by the surveillance investigator for including your child in the surveillance. Your child will also be reimbursed for time spent for this surveillance.

16. Can the surveillance or my child's participation be terminated early?

The surveillance investigators or the funder may, due to concerns for your child's safety, stop the surveillance or your child's participation at any time. If the surveillance is stopped early for any reason, you/your child will be informed.

17. Will my child's medical information be kept private?

All your information obtained in this surveillance will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the surveillance results, your child's identity will not be revealed without your/your child's expressed consent. Individuals involved in this surveillance and in your child's medical care, qualified monitors and auditors, the funder or its affiliates and governmental or regulatory authorities may inspect and copy your child's medical records, where appropriate and necessary.

Some of your child's excess biospecimens, if any, may be stored in the laboratories of Institute for Medical Research for future coronavirus-related testing until they are exhausted. No genetic testing will be conducted. The researcher may share those biospecimens with other researchers. Your child's biospecimens may be sent to laboratories in other countries for testing. In any situation, your child's biospecimens will be coded and information that can identify your child will be removed. Only the researcher will be able to link the code with your child with the help of a confidential linking document.

You can withdraw your consent and request for the specimen to be destroyed during the conduct of the surveillance. The surveillance investigator will still use any information obtained from the biospecimens up until the time you withdraw consent.

Data from the surveillance will be archived and may be transmitted outside the country for the purpose of analysis, but your child's identity will not be revealed at any time.

18. Who should I/my child call if I/my child have questions?

If you/your child have any questions about the surveillance or if you/your child think your child has a surveillance-related injury and you want information about treatment, please contact the IMSURE secretariat, Institute for Public Health at telephone number 03-3362 8791.

If you/your child have any questions about your child's rights as a participant in this surveillance, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8888/8205 or email to mrecsec@moh.gov.my.

INFORMED CONSENT FORM

19. Title: Post-vaccination COVID-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

By signing below, I confirm the following:

- I have been given oral and written information for the above surveillance and have read and understood the information given.
- I have had sufficient time to consider my child's participation in the surveillance and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my child's participation is voluntary and I/my child can at any time withdraw from the surveillance without giving a reason and this will in no way affect my child's vaccination/future treatment. I understand the risks and benefits, and I freely give on behalf of my child, informed consent to participate under the conditions stated. I understand that I/my child must follow the investigator's instructions related to my child's participation in the surveillance.
- I understand that surveillance investigator, qualified monitors and auditors, the funder or its affiliates, and governmental or regulatory authorities, have direct access to my child's medical record in order to make sure that the surveillance is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

Parent or Legal Guardian:

Signature:		I/C number:	
Name:		Date:	

Investigator conducting informed consent:

Signature:		I/C number:	
Name:		Date:	

Impartial witness: (Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)

Signature:		I/C number:	
Name:		Date:	

ANNEX C: BIOSPECIMEN MANAGEMENT MANUAL

MANUAL PENGURUSAN BIOSPESIMEN

Kajian *Post-vaccination Covid-19 Immunity and Disease Surveillance in Malaysia (IMSURE)*

PENGURUSAN BIOSPESIMEN

PROSEDUR	PERKARA
MANUAL	PENGURUSAN SPESIMEN DAN UJIAN MAKMAL DI LAPANGAN
SOP 1	PROSEDUR PENGAMBILAN SPESIMEN DARAH DI LAPANGAN
SOP 2	PROSEDUR PENGAMBILAN SPESIMEN AIR LIUR DI LAPANGAN
SOP 3	PROSEDUR PENGURUSAN SISA KLINIKAL DI LAPANGAN
SOP 4	PROSEDUR PENGURUSAN *NEEDLE-STICK INJURY*
SOP 5	PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN.
SOP 6	PROSEDUR PENGEMPARAN SAMPEL DARAH DI LAPANGAN
SOP 7	PROSEDUR PENGGUNAAN *PORTABLE CHILLER* DAN PENYIMPANAN SPESIMEN DI LAPANGAN.
SOP 8	PROSEDUR PENGGUNAAN *THERMOLOGGER*

MANUAL: PENGURUSAN SPESIMEN DAN UJIAN MAKMAL DI LAPANGAN

1. Modul ini bertujuan untuk menerangkan prosedur dan garispanduan bagi pengambilan, pemprosesan dan analisis sampel darah bagi ujian *SARS-CoV-2 Antibodies* dan *Cellular Immunity to SARS-CoV-2* serta sampel air liur bagi ujian *Anti-SARS-CoV-2 IgA and IgG in saliva.*
2. Prosedur ini digunakan untuk analisis ujian seperti di bawah bagi Kajian *Post-vaccination Covid-19 Immunity and Disease Surveillance in Malaysia (IMSURE)*. Semua sampel darah dan sampel air liur akan diambil di lapangan, diproses dan dianalisa di makmal yang ditetapkan.
3. Bahasa Singkatan atau definisi:

PSH	-	Pegawai Sambilan Harian
JT	-	Jururawat Terlatih
IKU	-	Institut Kesihatan Umum
FS	-	Penyelia Lapangan
LO	-	Pegawai Perhubungan Negeri
OSHC	-	Sekretariat Komuniti Kesihatan dan Keselamatan
Pekerja SOHU	-	Unit Kesihatan Pekerjaan Negeri
PKD	-	Pejabat Kesihatan Daerah
PPP	-	Penolong Pegawai Perubatan

4. Persediaan perkakasan dan bahan-bahan seperti yang berikut mesti disediakan untuk prosedur pegambilan spesimen:

    1. *Consent Form*
    2. Borang Permohonan Makmal **(Borang Makmal 1)**
    3. Tiub untuk sampel darah *(Gel tube and Heparin Tube)*
    4. Bekas sampel air liur
    5. *Barcode sticker*
    6. *Venipuncture kits* (*syringe & needle*, *alcohol swab*, *tourniquet*, *gloves*, *cotton*, *plaster*, *sample rack*).
    7. *Biohazard Specimen Bag* (untuk meletakkan spesimen dan borang)
    8. *Cold box/portable chiller*
    9. *Ice pack*
    10. *Thermologger*
    11. *Hand sanitizer*
    12. *Disposable gown*
    13. Borang Penghantaran Spesimen **(Borang Makmal 2)**

5. Prosedur:

PROSEDUR	TANGGUNGJAWAB
A. PRA PENGAMBILAN SPESIMEN DARAH	
1. Sediakan perkakasan untuk mengambil darah. Berikut adalah senarai perkakasan yang digunakan untuk pengambilan darah: • Consent form • Borang Permohonan Ujian Makmal **(Borang Makmal 1)** • Tiub untuk sampel darah (Gel tube dan Heparin tube) • Bekas sampel air liur • Barcode sticker/Label sticker • Venipuncture kits (vacutainer/ syringe & needle, alcohol swab, tourniquet, gloves, cotton, plaster) • Biohazard specimen bag (sample and form) • Sharp Bin/Clinical Waste • Cold Box/Portable chiller • Dry ice/ice pack • Thermologger • Hand sanitizer • Disposable gown • Borang Sampel	JT / PPP / PSH

	PROSEDUR	TANGGUNGJAWAB
2.	Dapatkan consent dari responden dengan melengkapkan maklumat di borang persetujuan (Consent form). Pastikan semua perkakasan yang diperlukan dalam proses pengambilan sampel darah telah disediakan dan dalam keadaan baik.	JT / PPP / PSH
3.	Pasukan pengumpul data hendaklah melengkapkan maklumat nama dan no. kad pengenalan di tiub darah dan bekas sampel air liur. Lengkapkan Borang Permohonan Makmal **(Borang Makmal 1)**. Seterusnya tampal barcode sticker pada kedudukan yang menegak pada semua tiub darah yang diambil, pada bekas sampel air liur dan Borang Permohonan Ujian Makmal. Pastikan barcode yang sama/sepadan ditampalkan pada semua tiub darah, bekas air liur dan Borang Permohonan Makmal **(Gambarajah 1).**  **Gambarajah 1:** Contoh kedudukan tampalan (*barcode sticker)* pada tiub darah dan bekas sampel air liur.	JT / PPP / PSH
B.	**PENGAMBILAN SPESIMEN DARAH**	
1.	Kenal pasti responden dan terangkan prosedur pengambilan spesimen darah kepada responden.	JT / PPP
2.	Semak semula identifikasi responden dengan nama dan maklumat yang telah dilengkapkan pada borang dan tiub darah.	JT / PPP
3.	Lakukan prosedur pengambilan darah **(SOP 1: PROSEDUR PENGAMBILAN SPESIMEN DARAH DI LAPANGAN).**	JT / PPP
4.	Setelah selesai pengambilan darah, biarkan tiub darah (*gel tube*) selama 30 minit – 1 jam (tidak lebih dari 2 jam). Seterusnya empar spesimen darah **(SOP 6: PROSEDUR PENGEMPARAN SPESIMEN DARAH DI LAPANGAN).** Bagi *heparin tube*, tiub tidak perlu dilakukan proses pengemparan dilapangan. *Heparin tube* perlu dihantar ke makmal rujukan seberapa segera yang mungkin (kurang daripada 4 jam).	JT / PPP / PSH
5.	Spesimen darah yang telah tersedia perlu diletakkan di dalam *cold box/portable chiller*. **(SOP 7: PROSEDUR PENGGUNAAN PORTABLE CHILLER UNTUK PENYIMPANAN SPESIMEN DI LAPANGAN).**	JT / PPP / PSH
6.	Sila lengkapkan Borang Penghantaran Spesimen **(Borang Makmal 2)** dan tampal *barcode sticker* di bahagian yang telah ditetapkan.	JT / PPP / PSH
C.	**PENGAMBILAN SPESIMEN AIR LIUR**	
1.	Kenal pasti responden dan terangkan prosedur pengambilan spesimen air liur kepada responden.	PSH
2.	Semak semula identifikasi responden dengan nama dan maklumat yang telah dilengkapkan pada borang dan bekas sampel air liur.	PSH
3.	Terangkan prosedur pengambilan air liur kepada responden **(SOP 2: PROSEDUR PENGAMBILAN SPESIMEN AIR LIUR DI LAPANGAN).**	PSH

	PROSEDUR	TANGGUNGJAWAB
4.	Spesimen air liur yang telah diambil perlu disimpan pada suhu 2-8 °C **(SOP 7: PROSEDUR PENGGUNAAN *PORTABLE CHILLER* UNTUK PENYIMPANAN SPESIMEN DI LAPANGAN)** dan perlu dihantar ke makmal rujukan secepat mungkin (kurang daripada 4 jam).	PSH
5.	Sila lengkapkan Borang Penghantaran Spesimen **(Borang Makmal 2)** dan tampal *barcode sticker* di bahagian yang telah ditetapkan.	PSH
D.	**PROSEDUR PENGUMPULAN DAN PENGHANTARAN SPESIMEN DARAH**	
1.	Pastikan *cold box/portable chiller* telah dilengkapi dengan perkakasan yang diperlukan dan disusun dengan baik. Perkakasan di dalam *cold box/ portable chiller* adalah: • *Ice pack* – 4 – 6 unit (mengikut saiz) • *Thermologger* – 1 unit **(SOP 8: PROSEDUR PENGGUNAAN *THERMOLOGGER)***	PSH
2.	Masukkan spesimen darah dan sampel air liur ke dalam *cold box/Portable chiller*. (**SOP 7: PROSEDUR PENGGUNAAN *PORTABLE CHILLER* DAN PENYIMPANAN SPESIMEN DI LAPANGAN).**	PSH
3.	Spesimen darah dan air liur mesti sentiasa disimpan pada suhu 2 – 8 °C sepanjang berada di dalam *cold box/portable chiller*. Spesimen juga mesti dihantar ke lokasi pengumpulan sampel yang telah ditetapkan (diserahkan kepada petugas logistik/ *runner*) dalam tempoh 24 jam dari masa pengambilan sampel darah.	JT / PPP / PSH
4.	Hubungi pegawai yang bertanggungjawab di lokasi yang dipilih untuk pengumpulan specimen bagi membuat temujanji.	JT / PPP / PSH
5.	Hari penghantaran sampel darah ke makmal analisa adalah pada hari **Isnin hingga Jumaat.** Spesimen darah perlu tiba di pusat pengumpulan **sebelum jam 4.30 petang** setiap hari.	PSH
6.	Walaubagaimanapun adalah digalakkan untuk merancang pengurusan penghantaran pada **hari-hari yang tertentu** sahaja untuk **menjimatkan masa, tenaga dan kos**.	PSH
E.	**PENGHANTARAN SPESIMEN DARAH DARI LOKASI PENGUMPULAN KE MAKMAL ANALISA**	
1.	Pasukan pengumpul data perlu menyerahkan spesimen darah yang tidak diempar (*heparin tube*), spesimen darah yang diempar (*gel tube*) dan spesimen air liur (bekas sampel air liur) kepada petugas logistik (*runner*) dalam masa 4 jam setelah spesimen diambil. Pasukan juga perlu melengkapkan maklumat di borang penghantaran spesimen (**Borang Makmal 2**). Borang tersebut seterusnya disimpan (difailkan) untuk rujukan dari semasa ke semasa.	PSH
2.	Petugas logistik akan membawa spesimen ke makmal analisa (spesimen perlu disimpan pada suhu 2 - 8 °C). Spesimen darah dan air liur perlu tiba di makmal analisa dalam masa 4 jam dari sampel diambil.	Petugas Logistik
3.	Sampel darah dalam *tube heparin* dan sampel air liur perlu dihantar ke Makmal Immunologi, IMR. Sampel darah dalam *gel tube* perlu dihantar ke Makmal Virologi, IMR.	Petugas Logistik

	PROSEDUR	TANGGUNGJAWAB
	SPESIMEN DARI KAWASAN SEMENANJUNG MALAYSIA SELAIN LEMBAH KLANG	
1.	Pasukan pengumpul data perlu menyerahkan spesimen darah yang telah diempar (*gel tube*) kepada petugas logistik (*runner*) serta melengkapkan maklumat di borang penghantaran spesimen (**Borang Makmal 2**). Borang tersebut seterusnya disimpan (difailkan) untuk rujukan dari semasa ke semasa.	Petugas Logistik
2.	Petugas logistik akan membawa spesimen darah ke Makmal Virologi, IMR bagi tujuan analisa (spesimen perlu disimpan pada suhu 2 - 8 °C). Spesimen darah mesti tiba di makmal analisa dalam masa 72 jam dari masa spesimen diambil.	Petugas Logistik
	SPESIMEN DARI KAWASAN SABAH DAN SARAWAK	
1.	Penyelia lapangan perlu mengumpulkan spesimen darah yang telah diempar (*gel tube*) dan melengkapkan maklumat di borang penghantaran spesimen (**Borang Makmal 2**) dari kawasan masing-masing. Borang tersebut seterusnya disimpan (difailkan) untuk rujukan dari semasa ke semasa. Kemudian, sampel akan diserahkan kepada petugas logistik yang telah dilantik di tempat yang telah ditetapkan.	Petugas Logistik
2.	Syarikat logistik yang telah dilantik akan menguruskan proses penghantaran sampel ke semenanjung termasuklah pembungkusan sampel mengikut prosedur, penghantaran menggunakan perkhidmatan kargo kapal terbang dan lain-lain urusan.	Petugas Logistik
3.	Setelah sampel tiba di KLIA, petugas logistik dari syarikat yang sama akan menguruskan penghantaran sampel ke Makmal Virologi di IMR bagi tujuan analisa.	
F.	**PENGANALISAAN SPESIMEN DAN PENGURUSAN KEPUTUSAN SPESIMEN DARAH DI MAKMAL RUJUKAN.**	
1.	Di makmal analisa, spesimen diterima dan diuruskan untuk penganalisaan ujian seperti yang dinyatakan di Borang Permohonan Ujian Makmal.	Petugas Makmal
2.	Keputusan ujian disediakan dalam tempoh 7 hari dari sampel darah diambil.	Petugas Makmal
3.	Keputusan ujian diberi dalam format MS Excell (*soft copy*) dan salinan keras (hard copy). Maklumat di dalam keputusan ujian adalah merangkumi ID responden, No. Kad Pengenalan, *barcode*, nama ujian dan keputusan ujian.	Petugas Makmal
4.	Semua keputusan ujian akan diberi kepada Institut Kesihatan Umum oleh makmal analisa.	Petugas Makmal

CARTA ALIR PENGURUSAN SAMPEL DAN UJIAN MAKMAL DI LAPANGAN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
JT / PPP		Pengambilan spesimen	SOP 1 & Borang 1
JT / PPP / PSH		Lakukan pengemparan tiub darah	SOP 6
JT / PPP / PSH		Masuk sampel ke dalam *cold box* atau *portable chiller*	SOP 7
JT / PPP / PSH		Letakkan *temperature logger* dalam *cold box* atau *portable chiller*	SOP 8
JT / PPP / PSH		Penghantaran Specimen ke lokasi pengumpulan sampel.	

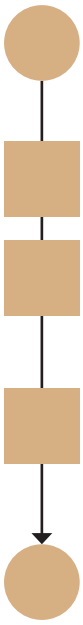
SOP 1: PROSEDUR PENGAMBILAN SPESIMEN DARAH DI LAPANGAN

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
1.	Perkenalkan diri anda kepada responden yang akan diambil darahnya. Maklumkan kepada responden bahawa tugas anda adalah untuk mengambil darahnya bagi ujian makmal. *Tips: Jika tempat yang sesuai untuk pengambilan darah belum dikenalpasti, anda boleh berbuat demikian selepas pengenalan diri. Biasanya, meja dan kerusi di ruang makan adalah tempat yang lebih sesuai berbanding dengan ruang tamu kerana permukaannya yang lebih luas dan ketinggiannya yang *ergonomic* untuk anda.	JT / PPP
2.	Lakukan pengesahan dengan responden berkaitan nama dan nombor kad pengenalan. Pastikan responden adalah orang yang terpilih untuk pengambilan darah. * Tips: Seelok-eloknya, elakkan diri anda dari membaca nama dan nombor kad pengenalan responden untuk pengesahan. Adalah lebih baik untuk anda tanya siapakah nama dan nombor kad pengenalan responden, supaya dia boleh jawab sendiri soalan anda. Kaedah pertama lebih cenderung untuk kesilapan berbanding dengan kaedah kedua.	JT / PPP
3.	Isikan maklumat responden yang diperlukan seperti nama, nombor kad pengenalan, nombor siri tinjauan, *barcode* dan maklumat-maklumat berkaitan dengan responden ke dalam tablet, borang dan tiub darah (*gel tube* dan *heparin tube*). Pastikan maklumat-maklumat tersebut berpadanan dan betul.	JT / PPP
4.	Selepas semua dokumentasi dilengkapkan, sediakan barang-barang yang diperlukan untuk pengambilan darah seperti tourniquet, sarung tangan pakai-buang, *swab* beralkohol, picagari, jarum (saiz 21G atau 23G bergantung kepada saiz urat vena responden), bebola kapas, plaster, beg kuning *biohazard* dan *sharp bin*. *Tips: Anda perlukan rak tiub darah untuk menegakkan tiub darah kosong yang bakal diisi. Pastikan tiub darah kosong tersebut diletakkan di bahagian penjuru rak yang lapang dan jauh dari tiub darah lain yang telah diisi. Pastikan penjuru tersebut dekat dengan anda dan senang dicapai.	JT / PPP
5.	Pastikan barang keperluan tersebut berdekatan dengan anda di atas meja. Beg kuning *biohazard* dan *sharp bin* boleh diletakkan di atas lantai/meja di sisi anda berjauhan dari responden. Rujuk **SOP 3: PROSEDUR PENGURUSAN SISA KLINIKAL DI LAPANGAN.** ***PENTING!!** Pastikan semua barang, terutamanya beg kuning *biohazard* dan *sharp bin*, berada di luar capaian kanak-kanak atau haiwan.	JT / PPP
6.	Pastikan responden duduk pada kedudukan yang bersesuaian bagi memudahkan pengambilan darah dilakukan mengikut kesesuaian sama ada pengambil darah dominan dengan tangan kanan atau kiri. Mohon responden lipatkan lengan baju jika ia panjang, pastikan tangan responden diletak dalam keadaan lurus di atas meja. *Tips: Jika perlu, selitkan sesuatu di bawah siku responden supaya tangannya lurus sepenuhnya.	JT / PPP

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
7.	Lilitkan tourniquet di bahagian lengan. Ketatkan supaya urat vena timbul di bahagian pelipat siku. Pilih urat vena yang tebal, lurus, tidak bergerak-gerak dan pilih urat vena yang memberi keyakinan yang paling tinggi kepada anda untuk melakukan pengambilan darah. *Tips: Urat halus yang terletak pada permukaan kulit tidak sesuai untuk pengambilan darah.	JT / PPP
8.	Disinfeksi tangan dengan cecair alkohol dan pakai sarung tangan. Gosok urat vena yang terpilih dengan *alcohol swab* beberapa kali untuk tujuan aseptik. Sementara cecair alkohol menjadi kering, buang pembalut picagari dan buka pembalut jarum di bahagian sambungannya. Pasangkan jarum dengan picagari. *Tips: Boleh juga pasang picagari dan jarum sebelum prosedur aseptik. Cuma pastikan cecair alkohol kering sepenuhnya sebelum urat vena dicucuk.	JT / PPP
9.	Buka penutup jarum dan dekatkannya ke urat vena. Pastikan pembukaannya menghala ke atas dan jarum tersebut selari dengan permukaan urat vena. Pada masa yang sama, dengan menggunakan tangan tidak dominan, tekan urat vena di bahagian distalnya dan tarik ke arah anda untuk mengekalkan posisinya. ***PENTING!!** Kebanyakan kegagalan pengambilan darah berpunca dari urat vena yang tidak ditetapkan posisinya. Urat vena menjadi bengkok dan koyak sekiranya bergerak ke belakang apabila dicucuk.	JT / PPP
10.	Cucuk jarum ke dalam urat vena 1-2 cm dari sasaran sehingga pembukaan jarum terletak di tengah-tengah ruang urat vena yang disasarkan. Lakukan pengambilan darah sebanyak 10 ml untuk *gel tube* dan 18 ml untuk *Heparin tube* (Jika perlu gunakan *butterfly needle*). *Tips: Pastikan jarum hampir selari dengan permukaan urat vena sebelum cucuk, supaya 1-2 cm jarum boleh memasuki urat vena tersebut. Jarum akan menjadi lebih stabil dan darah akan keluar dengan lebih lancar. Yang paling penting, responden tidak akan rasa sakit jika jarum stabil.	JT / PPP
11.	Pegang bebola kapas dengan tangan tidak dominan anda, letakkan di atas tempat cucukan jarum. Cabut jarum dari urat vena. Sebaik sahaja jarum keluar dari urat vena, tekan luka tersebut dengan bebola kapas. Minta responden tekan bebola kapas tersebut sebelum anda tampalkan plaster luka. ***PENTING!!** Jangan tekan sebelum jarum keluar sepenuhnya dari urat vena.	JT / PPP
12.	Tanpa keluarkan tiub darah milik responden dari rak, pegang rak darah di hujung yang bertentangan untuk stabilkannya, cucukkaan jarum ke dalam botol darah responden. ***PENTING!!** Elakkan memegang tiub darah apabila anda mencucukan jarum ke dalam untuk mencegah *needle-stick injury*. Rujuk **SOP 4: PROSEDUR PENGURUSAN *NEEDLE-STICK INJURY*.** jika berlaku *needle-stick injury.*	JT / PPP

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
13.	Keluarkan tiub darah (*gel tube* dan *heparin tube*) yang diisi dari rak. Cabut jarum dari tiub darah tersebut dekat dengan kedudukan *sharp bin*. Buang jarum dan picagari ke dalam *sharp bin* dengan segera. Larutkan '*clot activator*' dengan spesimen sebanyak 5-8 kali inversi secara perlahan dan biarkan darah membeku menegak selama 25-30 minit (sehingga pembekuan selesai) sebelum pengemparan spesimen dilakukan. *Heparin tube* tidak perlu diemparkan. ***PENTING!!** Jangan *re-cap* jarum yang dipakai dengan penutupnya!	JT / PPP
14.	Kemaskan meja dengan membuang semua sisa klinikal kumpulan A yang telah tercemar ke dalam beg kuning *biohazard*. Selepas semua dibuang, tanggalkan sarung tangan dan buang ke dalam beg kuning *biohazard.* ***PENTING!!** Pastikan sarung tangan disalin untuk pengambilan darah responden seterusnya untuk mencegah jangkitan silang.	JT / PPP
15.	Jika terdapat pertumpahan sisa klinikal seperti darah di rumah responden atau dimana-mana sewaktu pengumpulan data, rujuk **SOP 5: PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN.**	JT / PPP

CARTA ALIR PROSEDUR PENGAMBILAN DARAH RESPONDEN DI LAPANGAN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
JT / PPP		Perkenalkan diri kepada responden dan lakukan pengesahan dengan responden serta lengkapkan maklumat responden di dalam tablet, borang dan tiub darah.	1. Borang kebenaran responden 2. Borang permohonan ujian darah
JT / PPP		Sediakan semua peralatan yang berkaitan untuk pengambilan darah.	SOP 1
JT / PPP		Lakukan prosedur pengambilan darah responden.	SOP 1
JT / PPP		Lakukan 5-8 kali inversi secara perlahan dan biarkan darah membeku menegak selama 25-30 minit (sehingga pembekuan selesai) sebelum pengemparan spesimen dilakukan. Hanya untuk sampel dengan *gel tube*.	SOP 1
JT / PPP		Kemaskan kawasan pengambilan darah dengan membuang semua sisa klinikal ke dalam beg kuning biohazard.	SOP 3

SOP 2: PROSEDUR PENGAMBILAN SPESIMEN AIR LIUR DI LAPANGAN

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
1.	Perkenalkan diri anda kepada responden yang akan diambil sampel air liurnya. Maklumkan kepada responden bahawa tugas anda adalah untuk mengambil air liurnya bagi ujian makmal.	PSH
2.	Lakukan pengesahan dengan responden berkaitan nama dan nombor kad pengenalan. Pastikan responden adalah orang yang terpilih untuk pengambilan sampel air liur. * Tips: Seelok-eloknya, elakkan diri anda dari membaca nama dan nombor kad pengenalan responden untuk pengesahan. Adalah lebih baik untuk anda tanya siapakah nama dan nombor kad pengenalan responden, supaya dia boleh jawab sendiri soalan anda. Kaedah pertama lebih cenderung untuk kesilapan berbanding dengan kaedah kedua.	PSH
3.	Isikan maklumat responden yang diperlukan seperti nama, nombor kad pengenalan, nombor *barcode* dan maklumat- maklumat berkaitan dengan responden ke dalam tablet, borang dan bekas sampel air liur. Pastikan maklumat-maklumat tersebut berpadanan dan betul.	PSH
4.	Selepas semua dokumentasi dilengkapkan, sediakan bekas sampel air liur. Minta responden untuk berkumur menggunakan air kosong (cth. air minuman, air mineral, air masak, air paip). Elakkan dari menggunakan ubat kumur. Responden juga mesti tidak minum, merokok dan mengunyah gula-gula getah dalam masa 30 minit sebelum proses persampelan.	PSH
5.	Responden diminta untuk memenuhkan bekas sampel air liur pada paras yang telah ditetapkan (4 mL). Putar dah ketatkan penutup bekas sampel air liur dan lap bahagian luar bekas spesimen air liur menggunakan *alcohol wipes* bagi tujuan disinfeksi. Simpan pada suhu 2-8 °C. Bawa sampel ke makmal dalam masa 4 jam.	PSH

CARTA ALIR PROSEDUR PENGAMBILAN SPESIMEN AIR LIUR DI LAPANGAN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
PSH		Perkenalkan diri kepada responden dan lakukan pengesahan dengan responden serta lengkapkan maklumat responden di dalam tablet, borang dan bekas sampel air liur.	Borang permohonan ujian
PSH		Sediakan peralatan yang berkaitan pengambilan sampel air liur.	SOP 2
PSH		Lakukan prosedur pengambilan sampel air liur responden.	SOP 2
PSH		Penghantaran spesimen ke lokasi pengumpulan sampel.	

SOP 3: PROSEDUR PENGURUSAN SISA KLINIKAL DI LAPANGAN

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
1.	Kenalpasti kategori sisa klinikal yang hendak dilupuskan. Sila rujuk **Jadual A.**	FS / JT / PPP / PSH
2.	Lupuskan sisa klinikal mengikut bekas sisa klinikal yang telah ditetapkan. • **Sisa klinikal kumpulan A**: Perlu dibuang ke dalam beg plastik berwarna kuning yang berlabel *Biohazard.* Rujuk **Rajah A**. • **Sisa klinikal kumpulan B**: Perlu dibuang di dalam tong yang berwarna kuning dan bertutup merah yang berlabel *Biohazard* (*Sharp bin*). Rujuk **Rajah B**. - Plastik kuning dan *sharp bin* perlu dilabelkan dengan tarikh dah masa permulaan penggunaan.	FS / JT / PPP / PSH
3.	Pastikan kuantiti sisa klinikal di dalam bekas sisa klinikal tidak lebih daripada sukatan 3/4 dari saiz bekas. Plastik kuning hendaklah diikat dengan menggunakan strip pengikat dan penutup bukaan *sharp bin* perlu ditutup rapat.	FS / JT / PPP / PSH
4.	Hantar bekas sisa klinikal yang telah mencapai kuantiti maksimum yang telah ditetapkan ke klinik kesihatan yang berdekatan untuk dilupuskan oleh pihak konsesi yang berdaftar.	FS / JT / PPP / PSH

KATEGORI SISA KLINIKAL	JENIS SISA KLINIKAL DILAPANGAN
Kumpulan A	Sisa daripada kawasan pengambilan darah yang terkena cecair badan (darah) seperti plaster luka, kapas, sarung tangan, *Gauze,* apron plastik dan penutup mulut.
Kumpulan B	Sisa yang terdiri daripada peralatan yang tajam seperti *syringes & needles* atau sebarang peralatan tajam yang boleh menyebabkan luka atau kecedaraan.

Jadual A: Kategori sisa klinikal yang terlibat sewaktu pengambilan spesimen di lapangan.

Rajah A: Beg plastik kuning *Biohazard*

Rajah B: Tong kuning *Biohazard (Sharp bin)*

CARTA ALIR PROSEDUR PENGURUSAN SISA KLINIKAL DI LAPANGAN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
FS / JT / PPP / PSH		Kenalpasti kategori sisa klinikal yang hendak dilupuskan	SOP 3
FS / JT / PPP / PSH		Lupuskan sisa klinikal mengikut bekas sisa klinikal yang telah ditetapkan.	SOP 3
FS / JT / PPP / PSH		Hantar bekas sisa klinikal yang telah mencapai maksimum kuantiti ke klinik kesihatan yang berdekatan untuk dilupuskan oleh pihak konsesi yang berdaftar.	SOP 3

SOP 4: PROSEDUR PENGURUSAN *NEEDLE-STICK INJURY* DI LAPANGAN

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
1.	Jika *needle-stick injury* berlaku semasa bertugas dilapangan, individu yg terlibat perlu melaporkan kejadian kepada penyelia lapangan serta merta.	Individu Terlibat / FS
2.	Penyelia lapangan perlu merujuk individu terlibat kepada pegawai yang bertanggungjawab untuk prosedur pengurusan *shrap injury* (dalam masa 24 jam).	FS / LO
3.	Dalam masa yang sama, penyelia lapangan perlu mengisi borang WEHU A1 dan WEHU A2. Borang yang telah lengkap hendaklah diserahkan kepada sekretariat komuniti kesihatan dan keselamatan pekerja (OSHC) di Pejabat Kesihatan Daerah (PKD).	FS / OSHC
4.	OSHC di PKD perlu menyemak borang WEHU A1 dan WEHU A2, melakukan penyiasatan insiden dan mengisi borang OHU/SIS-1 (bahagian epidemiologi). Hantar ke semua borang ke Unit Kesihatan Pekerjaan Negeri (SOHU). Perkara ini perlu diselesaikan dalam masa satu minggu selepas notifikasi.	Sekreteriat OSHC
5.	OSHC perlu untuk menyemak kembali borang OHU/SIS-1 dan memasukkan data yang relevan ke dalam sistem pendaftaran (registry). Hantar borang OHU/SIS-1 dan maklumat sistem pendaftaran (completed registry) yang lengkap ke SOHU dalam masa 1 dan 6 bulan selepas insiden berlaku.	Sekreteriat OSHC
6.	SOHU perlu menghantar kesemua insiden dalam sistem pendaftaran ke Unit Kesihatan Pekerjaan (OHU), Bahagian Kawalan Penyakit, Kementerian Kesihatan Malaysia secara tahunan sebelum 31 januari setiap tahun.	SOHU
7.	Borang OHU/SIS-2a dan OHU/SIS-2b perlu disimpan di PKD.	Sekreteriat OSHC

CARTA ALIR PROSEDUR PENGURUSAN *NEEDLE-STICK INJURY* DI LAPANGAN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
Individu Terlibat		*Needle-stick injury* berlaku semasa bertugas dilapangan	
FS		Laporkan kejadian kepada penyelia lapangan serta merta	
FS / LO		Penyelia lapangan perlu merujuk individu terlibat kepada FMS atau pegawai yang bertanggungjawab untuk prosedur pengurusan *sharp injury* (dalam masa 24 jam).	
FS		Penyelia lapangan perlu mengisi boring.	WEHU A1 dan WEHU A2
Sekreteriat OSHC		Borang yang lengkap diserahkan kepada sekretariat komuniti kesihatan dan keselamatan pekerja (OSHC) di Pejabat Kesihatan Daerah (PKD).	
Sekreteriat OSHC		OSHC di PKD perlu: * Semak borang WEHU A1 dan WEHU A2 * Lakukan penyiasatan insiden dan mengisi borang OHU/SIS-1 (bahagian epidemiologi). * Lakukan verifikasi maklumat.	WEHU A1, WEHU A2 dan OHU/SIS-1
Sekreteriat OSHC		Hantar ke semua borang ke Unit Kesihatan Pekerjaan Negeri (SOHU). Perkara ini perlu diselesaikan dalam masa satu minggu selepas notifikasi.	
Sekreteriat OSHC		OSHC perlu memasukan maklumat data yang releven (OHU/SIS-1) ke dalam sistem pendaftaran (registry) dan hantar SOHU dalam masa 1 dan 6 bulan selepas insiden berlaku.	OHU/SIS-1
Sekreteriat SOHU		SOHU perlu menghantar kesemua insiden dalam sistem pendaftaran ke Unit Kesihatan Pekerjaan (OHU), Bahagian Kawalan Penyakit, Kementerian Kesihatan Malaysia sebelum 31 januari setiap tahun.	
Sekreteriat OSHC		Borang OHU/SIS-2a dan OHU/SIS- 2b perlu disimpan di PKD	OHU/SIS-2a dan OHU/SIS-2b

SOP 5: PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN

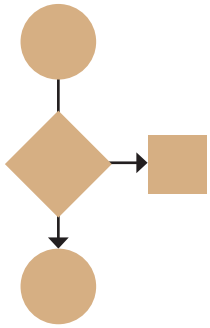
BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
1.	Pastikan kandungan yang terdapat di dalam *spillage kit* lengkap. Rujuk **Jadual 1: Kandungan peralatan *spillage kit.***	FS / JT / PPP / PSH
2.	Jika kuantiti tumpahan darah dalam jumlah yang sedikit; a. Pakai sarung tangan, bersihkan tumpahan menggunakan tuala basah dengan 0.5% larutan *chlorine*. b. Kemudian, lap bersih dengan cecair disinfeksi.	FS / JT / PPP / PSH
3.	Jika kuantiti tumpahan darah dalam jumlah yang banyak; a. Pakai sarung tangan, taburkan serbuk debu atau serbuk kayu ke atas tumpahan cecair darah dari arah sekeliling tumpahan menuju ke tengah. b. Biarkan seketika sehingga kesemua cecair tumpahan diserap oleh serbuk debu atau serbuk kayu. c. Dengan menggunakan penyedok kecil dan berus, masuk keseluruhan tumpahan yang telah menjadi pepejal ke dalam beg plastik kuning *biohazard* dan buang untuk pelupusan. d. Kemudian bersihkan tempat tumpahan dengan cecair disinfeksi.	FS / JT / PPP / PSH

Peralatan yang terdapat di dalam *spillage kit*

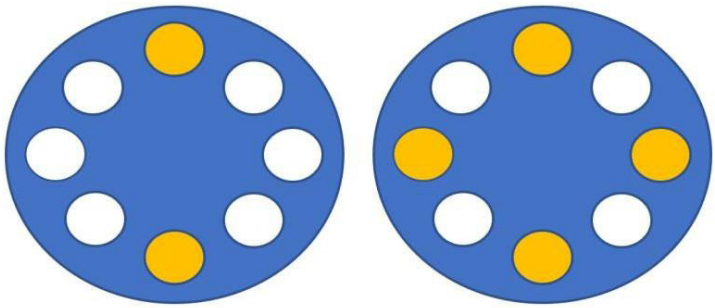
- Sarung tangan
- Penutup mulut
- Penyedok kecil dan berus
- *Absorbent pads*
- Serbuk debu atau serbuk kayu
- Tuala kertas
- Cecair disinfeksi (1:10 Chlorine)
- *Gemicidal wipes*
- *Infectious waste bag*
- Apron plastic

Jadual 1: Kandungan peralatan *spillage kit.*

CARTA ALIR PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN

TANGGUNGJAWAB	CARTA ALIR	AKTIVITI	RUJUKAN
FS / JT / PPP / PSH		Pastikan kandungan yang terdapat di dalam *spillage kit* lengkap	Jadual 1
FS / JT / PPP / PSH		Kenalpasti kuantiti tumpahan specimen sama ada sedikit atau banyak.	
FS / JT / PPP / PSH		Lakukan pembersihan berdasarkan kuantiti tumpahan.	

SOP 6: PROSEDUR PENGEMPARAN SPESIMEN DARAH DI LAPANGAN

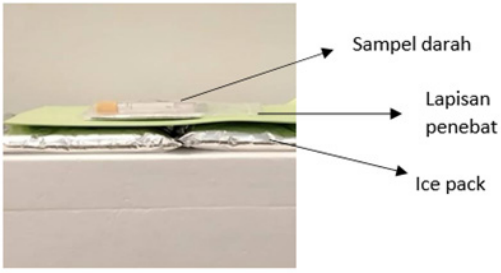
BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
	Pra-pengemparan spesimen	
1.	Letakkan pengempar di atas permukaan yang kukuh dan rata. Pastikan ruangan tiub di dalam mesin pengempar kosong dan bersih. Tutup penutup mesin pengempar.	JT / PPP / PSH
2.	Pastikan suis kuasa berada dalam posisi "*OFF*".	JT / PPP / PSH
3.	Pastikan enjin kenderaan sudah dihidupkan sebelum memasang plug 12V kord pada punca kuasa di dalam kereta (bagi mengelakkan nyahcas bateri). **JANGAN MASUKKAN SEBARANG SPESIMEN PADA WAKTU INI.**	JT / PPP / PSH
4.	Laraskan tombol masa di 5 minit, kemudian tekan suis "ON". Pastikan mesin pengempar berfungsi selama 5 minit. Jika terdapat bunyi halus, serta mesin pengempar beroperasi dengan sedikit atau tiada gegaran, bermakna mesin pengempar sedia untuk digunakan untuk pengemparan spesimen. Rekodkan sebarang ketidak-normalan (bunyi kuat dan gegaran yang berlebihan) pada mesin pengempar kepada FS yang bertugas dan hentikan operasi pengemparan.	JT / PPP / PSH
	Pengemparan spesimen	
1.	Buka penutup mesin pengempar, dan masukkan tiub spesimen ke dalam pemegang tiub di dalam mesin pengempar. Pastikan kesemua tiub spesimen ditutup dengan rapi bagi mengelakkan tumpahan spesimen semasa pengemparan. **PASTIKAN KESEMUA TIUB SPESIMEN DILETAKKAN DENGAN KEDUDUKAN BERTENTANGAN**. Sekiranya tambahan tiub diperlukan untuk mencapai keseimbangan berat, isikan tiub tersebut dengan air sehingga sama aras dengan spesimen di dalam tiub yang diletakkan bertentangan.  Kedudukan untuk 2 tiub Kedudukan untuk 4 tiub ***__peringatan__: mesin pengempar yang beroperasi secara tidak seimbang akan mengakibatkan kerosakan pada mesin dan boleh mendatangkan kecederaan kepada operator.	JT / PPP / PSH
2.	Tutup penutup mesin pengempar. Laraskan tombol masa kepada 10 minit kemudian tekan suis "ON". **JANGAN BUKA PENUTUP KETIKA PENGEMPARAN.**	JT / PPP / PSH
3.	Buka penutup mesin pengempar setelah selesai proses pengemparan. Ambil keluar tiub spesimen.	JT / PPP / PSH

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
	Pasca pengemparan spesimen	
1.	Bersihkan permukaan dalam dan luar mesin pengempar dengan menggunakan kain / tisu lembap dan lembut.	JT / PPP / PSH
2.	Sekiranya tiub spesimen pecah, atau terdapat bocoran sampel, alihkan tiub tersebut secara berhati-hati dan disinfeksi permukaan yang terkena tumpahan spesimen. **(RUJUK SOP 5: PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN)**.	JT / PPP / PSH
3.	Pastikan mesin pengempar disimpan di tempat yang sesuai (teduh dan di atas permukaan rata) sekiranya tidak digunakan.	JT / PPP / PSH

SOP 7: PROSEDUR PENGGUNAAN *PORTABLE CHILLER* DAN PENYIMPANAN SPESIMEN DI LAPANGAN

BIL	PERKARA	PEGAWAI YANG BERTANGGUNGJAWAB
	Cara Penggunaan "*Portable Chiller*"	
1.	Letakkan *portable chiller* di atas permukaan yang rata. Bersihkan ruangan di dalam *portable chiller* dengan cara mengelap dengan tisu yang beralkohol.	JT / PSH
2.	Pastikan suis kuasa berada di sisi *portable chiller* dalam posisi **"OFF".**	JT / PSH
3.	Pastikan enjin kenderaan sudah dihidupkan sebelum memasang plug 12V kord pada punca kuasa di dalam kereta (bagi mengelakkan nyahcas bateri). **JANGAN MASUKKAN SEBARANG SPESIMEN PADA WAKTU INI.**	JT / PSH
4.	Hidupkan dan laraskan suis kuasa pada posisi **"COOLING".** Indikator berwarna hijau akan menyala di "cooling mode" iaitu bermaksud *portable chiller* berada dalam *mode* penyejukan. *Pastikan *portable chiller* telah dihidupkan sekurang-kurangnya selama 30 minit sebelum di gunakan untuk menyimpan sampel.	JT / PSH
5.	Ambil bacaan suhu pada *portable chiller* 3 kali sehari (pagi, tengahari dan petang) dan catat pada borang pemantauan suhu (Borang Makmal 3). Plot bacaan suhu hendaklah dilukis dengan menggunakan pen berwarna yang telah ditetapkan mengikut masa bacaan suhu diambil. • Pagi: pen dakwat hitam • Tengahari: pen dakwat merah • Petang: pen dakwat biru	JT / PSH
	Penyimpanan spesimen	
1.	Buka penutup *portable chiller*, dan masukkan spesimen ke dalamnya mengikut sususan yang kemas (sila rujuk Gambarajah 1: Contoh susunan spesimen darah dan perkakasan yang berkaitan di dalam *cold box/portable chiller*)	JT / PSH
2.	Sekiranya spesimen tertumpah, atau terdapat bocoran sampel, alihkan spesimen tersebut secara berhati-hati dan disinfeksi permukaan yang terkena tumpahan spesimen. **(RUJUK SOP 5: PROSEDUR PENGURUSAN TUMPAHAN SPESIMEN)**.	JT / PSH
3.	Pastikan *portable chiller* disimpan di tempat yang sesuai (teduh dan di atas permukaan rata) sekiranya tidak digunakan.	JT / PSH

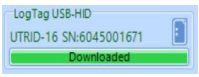
Rajah A: Kedudukan sampel darah di dalam *cold box / portable chiller* dari pandangan atas.



Rajah B : Kedudukan sampel darah di dalam *cold box / portable chiller* dari pandangan tepi.

Gambarajah 3 : Contoh susunan spesimen darah dan perkakasan yang berkaitan di dalam *cold box/portable chiller*

SOP 8: PROSEDUR PENGGUNAAN *THERMOLOGGER* (*LogTag*)

BIL	PERKARA	PEGAWAI YANG BERTANGGUNG JAWAB
	Tetapan Alat	
1.	*** Tetapan *LogTag* telah dilakukan oleh Pegawai Kawalan Kualiti. Sebarang perubahan tetapan *LogTag* perlu berhubung dengan Pegawai Kawalan Kualiti terlebih dahulu. *** Setiap *LogTag* mempunyai Nombor S/N yang tersendiri dan diberikan khusus kepada setiap Penyelia Lapangan untuk pemantauan dan perekodan suhu harian semasa di lapangan.	Pegawai Kawalan Kualiti
	Pra Pengambilan Data Suhu (dilakukan sebelum aktiviti pengumpulan data / pagi)	
1.	Pastikan komputer riba dilengkapi dengan *'Software LogTag ANALYZER 3 VERSION 3.1.9'* yang boleh dimuat turun secara percuma dalam carian internet.	FS
2.	Cucuh USB *LogTag* pada komputer. Akses perisian dengan klik kepada ikon  pada paparan komputer.	
3.	Klik pada ikon  keluar. Tunggu sehingga status  keluar.	
4.	Klik pada ikon  sebanyak 2 kali.	
5.	Klik pada ikon  untuk menutup perisian.	
6.	Cabut keluar USB *LogTag* dari komputer. Pastikan status **READY** terdapat pada paparan *LogTag.* Serahkan *LogTag* kepada PSH.	
	Pengambilan Data Suhu	
1.	Pastikan *LogTag* ditempatkan di dalam *portable chiller* sekurang-kurangnya 15 minit sebelum memulakan proses merakam suhu.	PSH
2.	**Tekan dan tahan** punat START/Mark (lebih kurang 4 saat) sehingga simbol **REC** berhenti berkelip dan kekal **REC**. Simbol ✓ dan paparan suhu semasa akan muncul. *jika melepaskan tekanan terlalu awal, status **READY** masih muncul dan *LogTag* tidak akan merakam suhu.	
3.	Masukkan *LogTag* bersama-sama dengan bekasnya ke dalam *portable chiller* dan lekatkannya pada tempat yang telah ditetapkan. Pastikan *LogTag* berada dalam keadaan yang boleh dilihat dan tidak diletakkan secara terbalik.	PSH
4.	Setelah proses pengumpulan data tamat, **tekan dan tahan** punat STOP/ Review (lebih kurang 4 saat) sehingga simbol **STOPPED** berhenti berkelip dan kekal **STOPPED**. Paparan suhu semasa akan hilang. *jika melepaskan tekanan terlalu awal, status **REC** masih muncul dan LogTag tidak akan berhenti merakam suhu.	
5.	Bawa keluar *LogTag* dan serahkan kepada Penyelia Lapangan.	

BIL	PERKARA	PEGAWAI YANG BERTANGGUNG JAWAB
	Penghantaran Laporan (penghujung hari)	
1.	Cucuh USB *LogTag* pada komputer. Akses perisian dengan klik kepada ikon  pada paparan computer.	
2.	Klik pada ikon  . Tunggu  sehingga status keluar.	
3.	Carta suhu akan muncul secara automatik. Klik  pada ikon sebelah bawah kiri paparan carta suhu	
4.	Paparan laporan penuh suhu akan muncul. Klik pada ikon  dan simpan laporan dalam format PDF. Format untuk penamaan fail adalah seperti berikut: **Tarikh Zon Kumpulan #** (contoh – 05.10.2020 Selatan Kumpulan 3)	FS
5.	Laporan suhu perlu dihantar melalui e-mel kepada Pegawai Kawalan Kualiti (tlogger.IMSURE@gmail.com) untuk disimpan dan direkodkan bagi tujuan tinjauan kualiti. Padam perisian dan data suhu akan tersimpan di dalam fail secara automatik. Klik pada ikon  jika ingin mencari fail laporan suhu.	
6.	Cabut keluar USB *LogTag* dari komputer dan simpan *LogTag* di tempat yang selamat. Pastikan status **STOPPED** pada paparan *LogTag* muncul.	

Borang Makmal 1

BORANG PERMOHONAN UJIAN MAKMAL

Post-vaccination Covid-19 Immunity and Disease Surveillance in Malaysia (IMSURE).

Fasiliti: ……

Jenis vaksin yang diterima: ……..

Sila tampal barkod di sini	No. Kad Pengenalan Responden	
	Masa & Tarikh Pengambilan Spesimen	
	Jenis Sampel	
	Ujian	SARS-CoV-2 Antibodies / Cellular Immunity to SARS-CoV-2 / Anti-SARS-CoV-2 ELISA IgA
	Pegawai yang bertanggungjawab	

BORANG PENGHANTARAN SPESIMEN

Borang Makmal 2

Post-vaccination Covid-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

Fasiliti: .....

BARKOD	PENGAMBILAN		PUNGUTAN					
	TARIKH	MASA	TARIKH	MASA	LOKASI	SUHU	T/TGN (Penerima)	CATATAN
Sila tampal barkod di sini								
Sila tampal barkod di sini								
Sila tampal barkod di sini								
Sila tampal barkod di sini								
Sila tampal barkod di sini								

Ketua Pasukan :

Tandatangan :

Penyelia Lapangan :

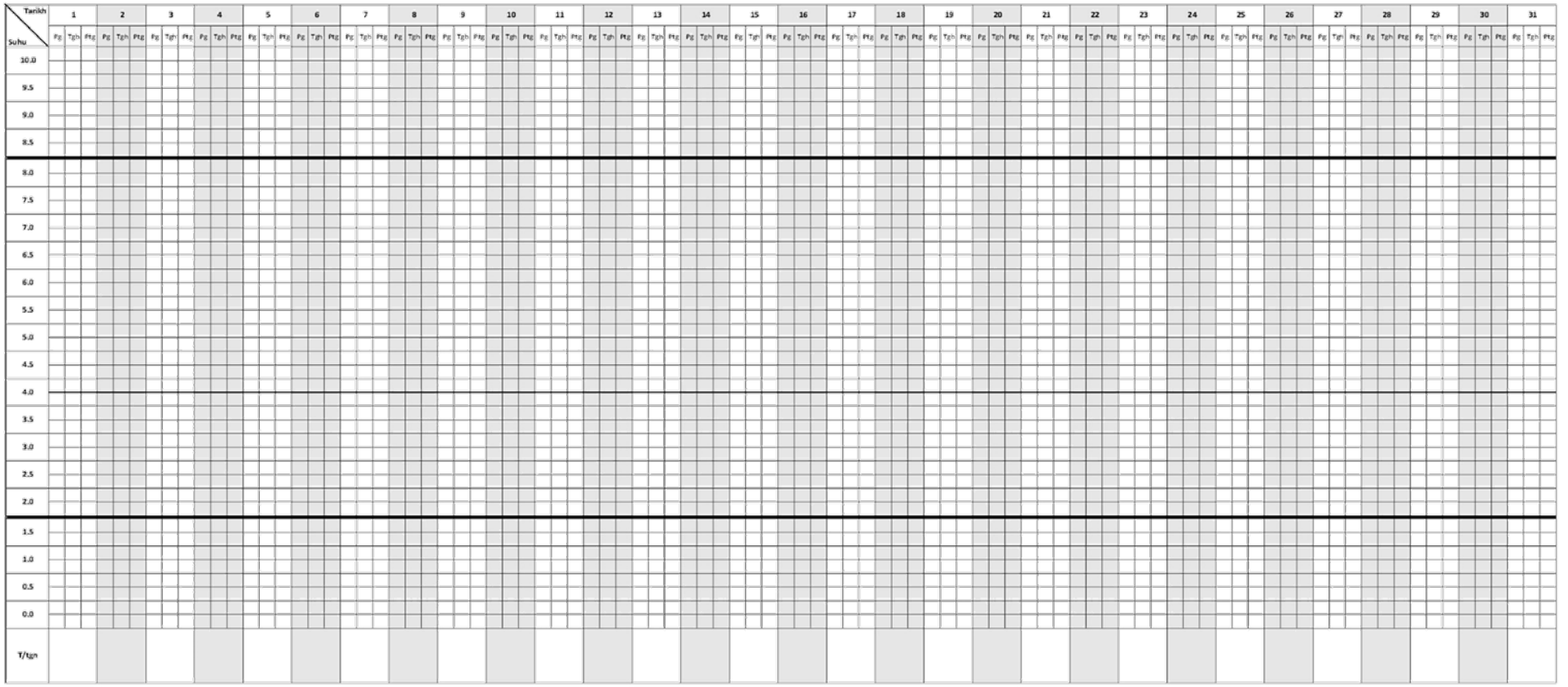
Tandatangan :

BORANG PEMANTAUAN SUHU

Borang Makmal 3

Post-vaccination Covid-19 Immunity and Disease Surveillance in Malaysia (IMSURE)

Fasiliti: ..... **Tarikh :** .....



*** Catatan suhu perlu dilakukan pada **SETIAP HARI** sepanjang tempoh pengumpulan data.

*** Catatan suhu adalah mengikut kod warna : Pagi (Hijau), Tengahari (**Merah**) dan Petang (**Biru**).

*** Sekiranya catatan suhu **TIDAK** memasuki julat suhu, sila maklumkan kepada Penyelia Lapangan dengan segera untuk proses '*troubleshoot*'.

Nama PSH Q41 :

Tandatangan :

Nama Penyelia Lapangan :

Tandatangan dan Cop :

WEHU - A1

(JKKP 6)

NOTIFICATION OF OCCUPATIONAL ACCIDENT AND DANGEROUS OCCURRENCE

Location of accident/incident

Date of accident/incident

Time of accident/incident occur

Send to:

Pengarah Kesihatan Negeri

Jabatan Kesihatan Negeri _____

Part A - Detail of Notifier

Name

Designation

Contact no.

Part B - Affected person (If more than one person please list the name in Part C)

Name

Date of birth / / DD M YY

New IC/Passport no.

Gender Male Female

Occupation

Name and address of organization

District

State

Duration of current job

Date of first informing DOSH

Part C - Description of accident or dangerous occurrence

a) What were the activities involved prior to the accident?

b) What actually happened during the accident (agent involved and effect to the person involved)?

c) Why did the accident happen?

d) What were the actions taken following the accident?

Signature of Notifier

WEHU - A2

Date of Notification ☐

Part I : Particulars of reporting unit	Part II : Particulars of patient
Name of facility ☐	Date seen/treated/admitted ☐
Unit / Department / Ward ☐	Medical certificate (MC) given ☐ No ☐ Yes
	Duration of MC ☐ days

Part III : Classification of accident

(Tick √ more than one if relevant)

1. Nature of injury

- ☐ Abrasions
- ☐ Amputation
- ☐ Asphyxia
- ☐ Burns (heat)
- ☐ Burns (chemical)
- ☐ Bruises and contusions
- ☐ Concussions
- ☐ Cuts
- ☐ Dislocation
- ☐ Effect of electric currents
- ☐ Effect of radiation
- ☐ Fracture
- ☐ Drown
- ☐ Laceration
- ☐ Sharp injuries
- ☐ Sprain & strain
- ☐ Internal injuries
- ☐ Splash of blood/body fluid
- ☐ Splash of chemicals
- ☐ Other (please specify) _____

2. Part of Body Injured *For R/L : Please circle*

Head and Neck		Upper Limbs		Torso		Lower Limbs	
☐ Scalp		☐ Upper arms	R/L	☐ Back		☐ Hip	R/L
☐ Skull		☐ Elbow	R/L	☐ Chest		☐ Thigh	R/L
☐ Eyes	R/L	☐ Forearm	R/L	☐ Abdomen		☐ Leg	R/L
☐ Ears	R/L	☐ Wrist	R/L	☐ Pelvis		☐ Knee	R/L
☐ Nose		☐ Hand	R/L	☐ Groin		☐ Ankle	R/L
☐ Mouth		☐ Palm	R/L			☐ Feet	R/L
☐ Teeth		☐ Fingers	R/L			☐ Toes	R/L
☐ Face		☐ Other specify: _____					
☐ Neck							

3. Mechanism of accident

- ☐ Struck against object
- ☐ Struck by sliding, falling, flying or other moving object
- ☐ motor vehicle accident
- ☐ Caught in/or between object
- ☐ Fall or slip on same level
- ☐ Fall from height
- ☐ Injured while handling, lifting or carrying
- ☐ Contact with extreme temperature
- ☐ Others (please specify): _____
- ☐ Exposure to/or contact with harmful substances/radiation
- ☐ Exposure to/or contact with electric currents
- ☐ Exposure to explosion
- ☐ Drowning
- ☐ Crush by moving/sliding object
- ☐ Needle stick/Needle prick
- ☐ Physical assault

WEHU - A2 (cont'd)

4. Agent involved in accident

- ☐ Machine/Electrical equipment
- ☐ Lifting equipment
- ☐ Transport equipment/Vehicle
- ☐ Needles
- ☐ Medical/Surgical/Dental instruments (other than needles)
- ☐ Lab instruments
- ☐ Pressure Vessels
- ☐ Blood/Body fluids
- ☐ Chemicals/Gases
- ☐ Floors/Levels
- ☐ Ladders
- ☐ Stairs/steps
- ☐ Others (please specify) _____

5. Existing control measure at workplace

- ☐ Engineering Control
- ☐ Standard Operating Procedure (SOP)
- ☐ Training/Education/Work Schedule/Rotation
- ☐ Personal Protective Equipment (PPE)
- ☐ Other (please specify) _____

ANNEX D: LIST OF VACCINATION CENTRES / FOLLOW UP SITES

Kedah
1. Kompleks Sukan Lembaga Pembangunan Langkawi (LADA), Langkawi
2. Kampung Bukit Malut, Langkawi, Kedah

Pulau Pinang
1. Arena Setia Penang International Convention & Exhibition Centre (SPICE), Bayan Lepas
2. Klinik Kesihatan Pusat Transformasi Bandar (UTC) Kompleks Tun Abdul Razak (KOMTAR)
3. Klinik Kesihatan Seberang Jaya

Selangor
1. Dewan Kilat, Tenaga Nasional Berhad (TNB) Kapar, Klang
2. Ideal Convention Center, (IDCC) Shah Alam
3. Universiti Teknologi MARA (UiTM) Kampus Puncak Alam, Kuala Selangor
4. National Institutes of Health (NIH), Setia Alam
5. KPJ Klang Medical Center, Klang
6. El-Shaddai Centre Bhd, Klang
7. Gospel Hall, Klang
8. St. Barnabas Church, Klang

Melaka
1. Dewan Majlis Pembandaran Jasin (MPJ) Seri Umbai, Jasin
2. Klinik Kesihatan Ayer Keroh, Melaka Tengah
3. Klinik Kesihatan Alor Gajah, Alor Gajah

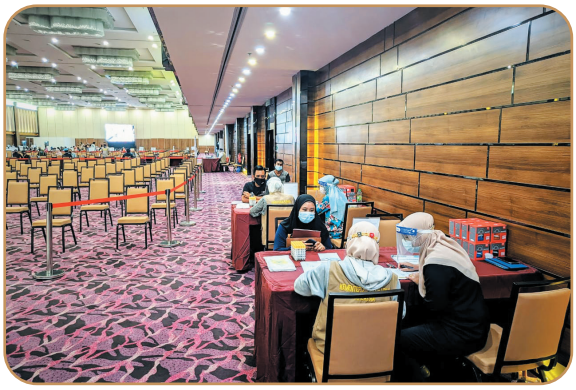
Terengganu
1. Klinik Kesihatan Chendering, Kuala Terengganu

Sarawak
1. Klinik Kesihatan Petrajaya, Kuching

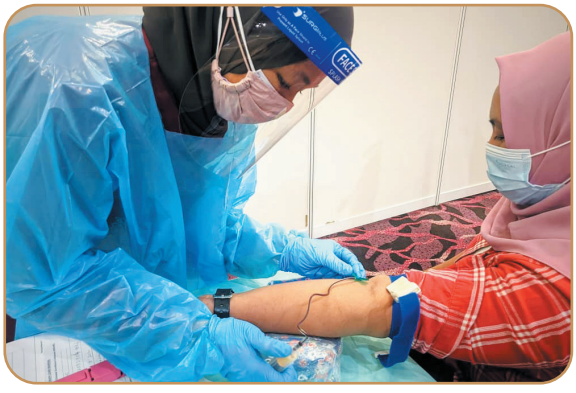
Sabah
1. Pulau Gaya, Kota Kinabalu
2. Kampung Numbak, Kota Kinabalu
3. Skim Penempatan Telipok, Kota Kinabalu

ACTIVITIES AT VACCINATION CENTRE

1. Briefing and getting consent or assent from the recipients



2. Blood collection from the recipients



Biospecimens Management

3. COVID-19 vaccination of recipients

Screening

Registration

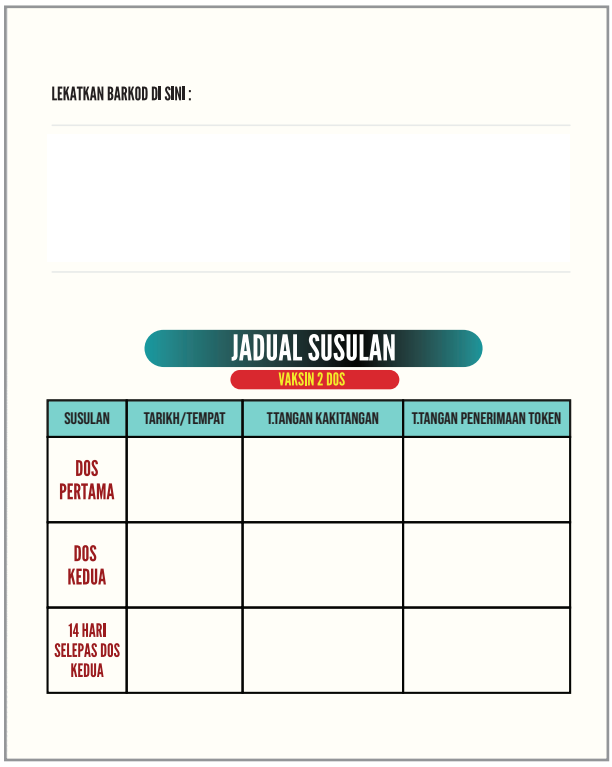
Consent

Injection

Observation

4. Participants answering the questionnaire provided

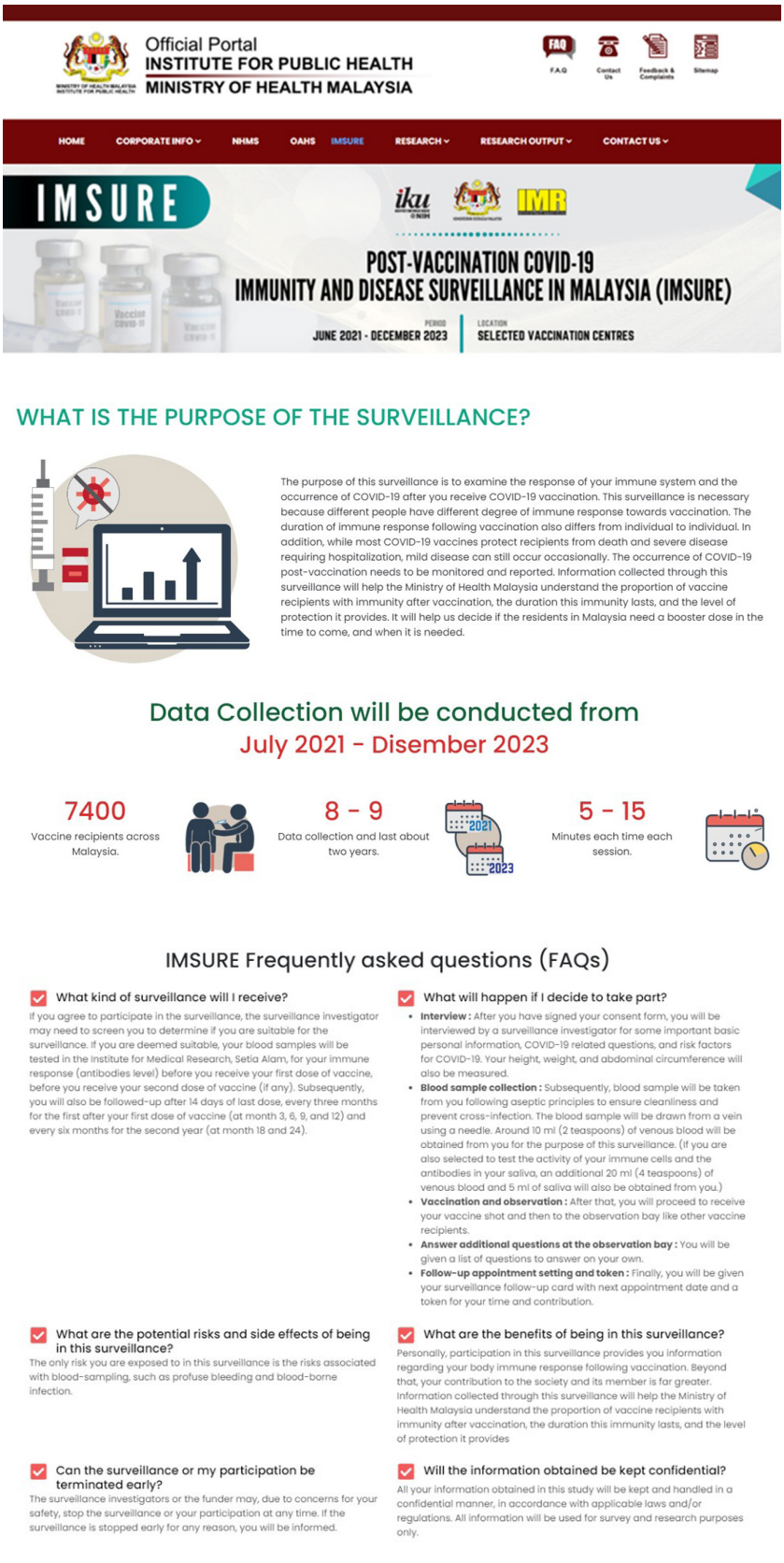
5. Scheduling the date for follow up appointment



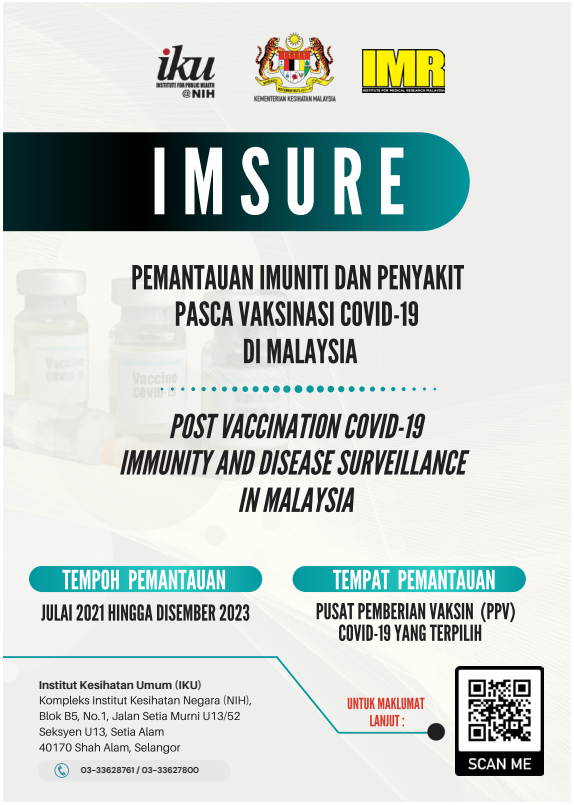
IMSURE Follow-up Book

IMSURE Respondent File

ANNEX E: PUBLICITY MATERIALS AND MEDIA COVERAGE

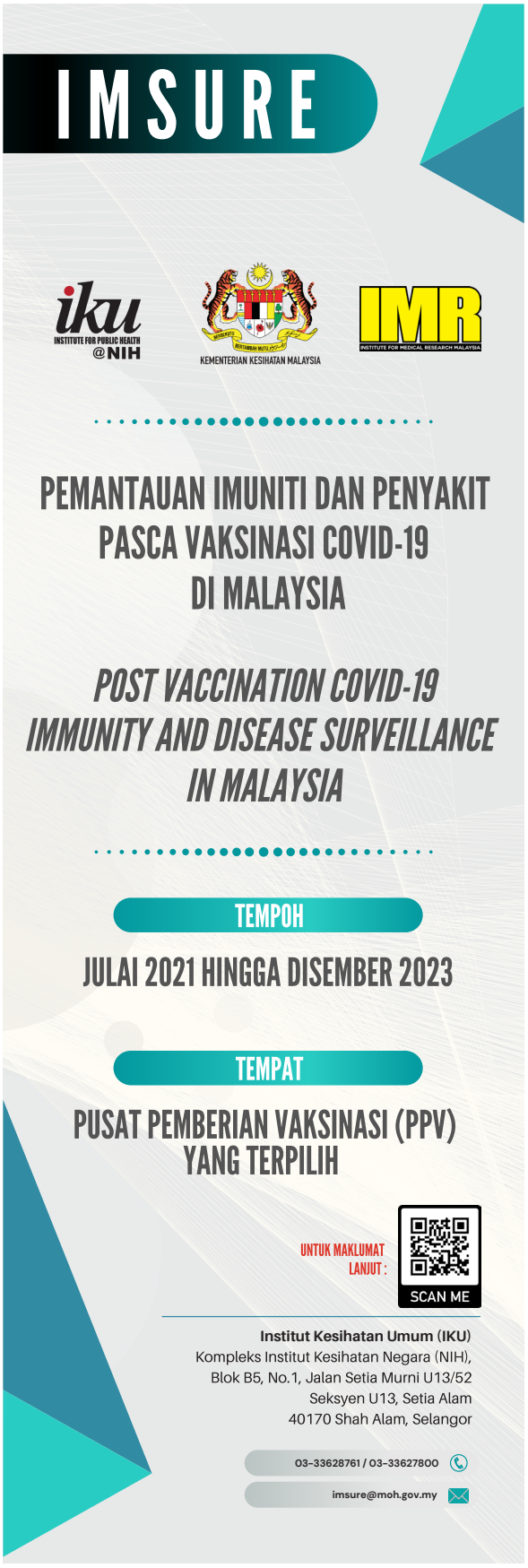


Official Website for IMSURE



Poster

Facebook Page



Bunting

ANNEX F: MEMBERS OF CENTRAL COORDINATING TEAM AND TERMS OF REFERENCE

1. **Dr. Noor Ani Ahmad**
   Director, Institute for Public Health
2. **Dr. Tahir Aris**
   Director, Institute for Medical Research
3. **Dr. Muhammad Fadhli Mohd Yusoff**
   Advisor, Methodology and Statistics
4. **Dr. Shubash Sander Ganapathy**
   Advisor, Data Processing and Quality
5. **Dr. Chong Zhuo Lin**
   IMSURE Principal Investigator
6. **Rafidah Ali**
   Project Manager & DPQ System Development
7. **Dr. Noor Aliza Lodz**
   Questionnaire Design and Development & DPQ System Development
8. **Dr. Fazila Haryati Ahmad**
   Questionnaire Design and Development
9. **Mohd Hatta Abd Mutalip**
   Questionnaire Design and Development
10. **Faizul Akmal Abd Rahim**
    Procurement
11. **Mohd Farihan Md Yatim**
    Logistic and Transportation
12. **Mohd Hazrin Hasim @ Hashim**
    Logistic and Transportation
13. **Eida Nurhadzira Muhammad**
    Laboratory Manager
14. **Mohd Faiz Mohd Hisham**
    Laboratory Management & Data Manager
15. **Hasmah binti Mohamed Haris**
    Laboratory Management
16. **Mohd Amierul Fikri Mahmud**
    Public Relation
17. **Norzawati Yoep**
    Public Relation
18. **Dr. Halizah Mat Riffin**
    DPQ System Development
19. **Mohamad Aznuddin Abd Razak**
    DPQ System Development & Data Monitoring
20. **Dr Muhammad Solihin Rezali**
    DPQ System Development
21. **Norhafizah Sahril**
    Data Manager
21. **Suhainita Md Pazil**
    Secretariat

Central Coordinating Team (CCT)

A working committee within the Institute for Public Health was established to coordinate the implementation of the surveillance according to scheduled Gantt-Chart. This CCT was coordinating and monitoring the progress of the surveillace.

Terms of reference for CCT

1. Principal Investigator
   a. Prepare the study proposal and present it to the Research Evaluation Committee (JPP) Institute for Public Health (IKU) or National Institutes of Health (NIH).
   b. Apply for the research fund.
   c. Provide the study design.
   d. Monitoring the surveillance activities according to scheduled Gantt-Chart.
   e. Planning for the data collection.
   f. Prepare the schedule for field supervisor and data collector.
   g. Monitoring the fieldwork activities.
   h. Report the progress of data collection.
   i. Provide the list of matrices in selection of respondents based on vaccine type.

2. Project Manager
   a. Prepare the letter, meeting minutes and engagement with the research team members, stakeholder and liaison officers related to surveillance activities.
   b. Arrange the employment and prepare materials of recruitment for the temporary Research Assistant under Malaysian Short-Term Employment Programme (MySTEP).
   c. Arrange the meeting including meeting room reservation and other meeting requirements.
   d. Arrange the training related to surveillance activities.

3. Questionnaire Design and Development
   a. Design and formatting the questionnaire based on the surveillance objectives.
   b. Search the reading materials and aid materials related to surveillance.
   c. Conduct the back-to-back translation, suitability validation and pre-test of the questionnaire.
   d. Provide the aid materials for data collection (manual, flowchart, etc.).
   e. Provide the list of variables in dummy tables for the study framework.

4. Procurement
   a. Provide the document or specification for procurement.
   b. Receive and verify the specification document of procurement.
   c. Conduct the market survey and summary.
   d. Manage and involve in the procurement process.
   e. Monitor the process or progress of procurement and follow-up with the Procurement Unit.
   f. Monitor the payment to the supplier.

5. Logistic and Transportation
   a. Provide, maintain and monitor the stock of goods and aid materials for fieldwork.
   b. Manage the stock of goods and aid materials for fieldwork distribution.
   c. Manage the transportation biospecimen from the vaccination centre (PPV).
   d. Provide the standard operating procedure (SOP), checklist and flowchart for fieldwork activities.

6. Laboratory Management
   a. Provide the specification document for reagent and laboratory instruments procurement.
   b. Provide the manual and SOP for laboratory management.
   c. Manage the logistics for the laboratory biospecimens.
   d. Monitor the specimen collection and cold chains by thermologger.
   e. Manage and monitor the laboratory data.
   f. Communicate with IMR for data verification.

7. Public Relation
   a. Provide the SOP, flowchart and reminder script for respondent's follow-up.
   b. Provide the respondent kit including the follow-up card, flyers, etc.
   c. Monitor the token for the respondent.
   d. Design, conduct and distribute the promotion materials.

8. DPQ System Development
   a. Develop the questionnaire survey system by using the SCS software and Optical Character Recognition (OCR) or Optical Mark Reader (OMR).
   b. Conduct the test for the survey system by using the SCS software and Optical Character Recognition (OCR) or Optical Mark Reader (OMR).
   c. Ensure the SCS software is functioning while the interview is conducted.
   d. Responsible for solving the problems or complaints regarding the questionnaire survey system.

9. Data Management
   a. Monitor the data received from the conducted interview.
   b. Conduct the cleaning, combining and verifying data before submitting to the Data Manager.

10. Data Manager
    a. Verify the data received from the DPQ data management team.
    b. Conduct the suitable data analysis.

11. Secretariat
    a. Assist the Principal Investigator and Project Manager in administration related to surveillance activities.
    b. Organizing and distributing letters, memos, notes, messages and other written communications.

ANNEX G: RESEARCH TEAM MEMBERS

STATE LIAISON OFFICER

1. **Dr. Qidran Asyraf Ayob**
   Kedah State Health Department
2. **Dr. Siti Hasnah Nasarudin**
   Pulau Pinang State Health Department
3. **Dr. Intan Azura Mhd Din**
   Melaka State Health Department
4. **Dr Norhana Yazid**
   Terengganu State Health Department
5. **Dr Prabakaran Solomon A//L Dhanaraj**
   Sabah State Health Department
6. **Dr. Ho Ai Chia**
   Sarawak State Health Department

State Liaison Officer

A State Liaison Officer acts as a liaison person between the Institute for Public Health (IKU) and the state in planning and implementation of data collection activities during the survey.

Term of references for State Liaison Officer

a. Communicate with the field supervisor and data collector.
b. Identify the vaccination centres (PPV) that are suitable for surveillance activities and connect the communication between field supervisor and PPV supervisor.
c. Identify the Klinik Kesihatan that is able to conduct the surveillance follow-up and connect the communication between field supervisor and clinic's person in charge or officer.
d. Conduct the training for the staff involved in the surveillance.
e. Ensure the good communication between the state liaison officer, field supervisor and research team members.

CENTRAL TEAM

DPQ SYSTEM

Data Management

1. Norhafizah Sahril

Data Analysis

1. Norhasima Shawal
2. Nurdiyana Farhana Mat Tamizi

LABORATORY

Biospecimen Management

1. Ahmad Haziq Zulasri
2. Daniel Sia Pong Chai
3. Krishnaveni a/p Arumugam
4. Muhammad Asyraf Mohd Sarif
5. Muhammad Zakir Shah Nasaruddin
6. Noorshahrizman sahiar
7. Nor Rafizawati Ab Rashid
8. Nuralina Suhaili

Immunology Laboratory, Institute for Medical Research

1. Azwin Farhin Yaakob
2. Mastura Md Sani
3. Najwa Syahirah Roslan
4. Noramirah Bukhari @ Albukhri
5. Nur Aina Adlan Mustafa
6. Nur Izzatie Zulkiflee
7. Nurain Nadiah Mohd Jaafar
8. Nurul Najwa Ainaa Alias
9. Nurzahidati Azman
10. Siti Mardhiah Mustafha
11. Vivek Prasad Jana Money
12. Yundzir Furqan Yurnalis

Virology Laboratory, Institute for Medical Research

1. Anis Ilyani Kamarruddin
2. Fatin Alwani Mohamad Uzir
3. Irfan Haniff Abdolah
4. Muhamad Zaidi Mohamed Zain
5. Najihah Mohd Noor
6. Nur Syafiqah Muhammad Yunus
7. Nur Umisha Zainuddin
8. Nursyafiqah Azira Norazaman
9. Siti Hajar Azwani Azizan

Laboratory Data Management

1. Ahmad Haziq Mohd Zulasri
2. Krishnaveni Arumugam
3. Nur Syahirah Aina Azmi

ADMINISTRATION

Finance
1. Nazatul Nadia Binti Azman

Logisitic and Transportation
1. Aidah Binti Abd Hamid
2. Muhammad Zakir Shah Nasaruddin

Administration
1. Nurhaziqah Saimin
2. Rabi'atul 'Adawiyah Mohammad

Research Assistants
Research assistant is responsible in assisting officers in Institute for Public Health (IKU) (Central Core Team) for managing matters related to the operational and management of IMSURE.

Terms of reference for Central Team Research Assistants

Research Assistants working at the IKU will assist officers in all matters related to IMSURE, including in term of:

a. Administration and finance.
b. Logistic and transportation.
c. Data collection through DPQ system.
d. Data analysis and management.
e. Laboratory management.

DATA COLLECTION TEAM

KEDAH

Field Supervisor
1. Azli Baharudin@Shaharuddin
2. Dr. Nik Adilah Shahein
3. Dr. Noor Aliza Lodz
4. Faizul Akmal Abdul Rahim
5. Mohd Amierul Fikri Mahmud
6. Mohd Farihan Md Yatim
7. Muhammad Faiz Mohd Hisham
8. Rafidah Ali
9. Siti Balkhis Shafie

Phlebotomist
1. Fazila Haryati Ahmad

Research Assistant
1. Amalina Mohamad
2. Amirun Izzuddin Azmi
3. Azmarhani Abd Rahman
4. Daniel Sia Pong Chai
5. Muhamad Fateh Mustafa
6. Muhammad Asyraf Mohd Sarif
7. Nabihah Mohd Zainuddin
8. Noorshahrizman Sahiar
9. Noraini Hamid
10. Nur Adilla Abdurahman
11. Nur Aliesa Azmi
12. Nur Amirah Ahmad
13. Nur Minhalina Mat Isa
14. Nur Syahirah Aina Azmi
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8. Hamizatul Akmal Abd Hamid
9. Hasmah Mohamed Haris
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17. Noor Syaqilah Shawaluddin
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21. Syafinaz Mohd Sallehuddin
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8. Dr. Muhd Hafizuddin Taufik Ramli
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11. Dr. Nur Liana Ab Majid
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24. Nur Adilla Abdurahman
25. Nur Aliesa Azmi
26. Nur Amalina Ahmad
27. Nur Amirah Ahmad
28. Nur Faraeein Zainal Abidin
29. Nur Farah Hasanah Mohd Zarmi
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31. Nur Fatehah Mohd Zaid
32. Nur Haziqah Mohd Rosli
33. Nur Hidayah Mohd Rosli
34. Nur Minhalina Mat Isa
35. Nur Rabia'tula Dawiyah Rahim
36. Nur Syahirah Aina Azmi
37. Nur Syamim Abd Rahim
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10. Nur Amirah Yahya
11. Nur Faraeein Zainal Abidin
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14. Siti Zulaikha Mohd Zaki
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6. Nur Faraeein Zainal Abidin

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2. Jaidi Duming
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5. Noorshahrizman Sahiar
6. Nor Syafawati Ahmad Sukhairi
7. Nur Rabia'tula Dawiyah Rahim
8. Siti Nursakinah Mohd Saberi

STATE DATA COLLECTION TEAMS

There were a total of seven data collection teams for IMSURE. The teams were distributed throughout seven states to collect the data.

Term of reference for State Data Collection Teams

1. Field Supervisor
   a) Connect with the central teams and data collector and responsible for achievement and quality of data collected from the fieldwork.
   b) Plan before the data collection at vaccination centre (PPV) including:
      i. Plan the data collector movement at the field with State Liaison Officer.
      ii. Verify the accommodations with related officers or personnel.
      iii. Ensure the stock of goods, instruments and aid materials for fieldwork are adequate.
   c) Make the preparation before the data collection by manage the data collector requirements and needs including:
      i. Check the documents such as follow-up cards, questionnaire, personal protective equipment (PPE) and blood tuber are adequate.
      ii. Check all the equipment required through the checklist and take care the asset brought to the field.
   d) During the data collection:
      i. Identify the respondents based on the prepared selection matrix referring to standard operating procedure (SOP).
      ii. Make the appointment with the respondent and manage the data collection schedule.
      iii. Ensure the data collection follow the daily schedule and comply the SOP.
      iv. Monitor and review the interview activities conducted by data collector at the field.
      v. Inform the Central Core Team regarding to technical problems related to data collection, DPQ System and other issues.
      vi. Conduct the quality check on the tablet and SAQ form.
      vii. Ensure the data collected submitted to data manager follow the schedule. All the complete data must be submitted to the server through tablet.
      viii. Manage and coordinate the log and forms compilation used at the field.
      ix. Monitor the usage of equipment on the field and manage the stock of goods.
      x. Manage and monitor the field financial of data collector including the budget, token (giving money), health promotion aid materials, accommodations allowance and food.
      xi. Ensure the surveillance activities is well-conducted and supervise the data collector discipline, appearance and attitude that not affect the integrity of public servant and IKU staff.
   e) Monitor the quality of medical devices and biospecimen based on the SOP including:
      i. Ensure the biospecimen are labelled with correct test.
      ii. Ensure all the medical devices such as centrifuge machine, thermometer logger and freezer in ad good condition.
      iii. Monitor the biospecimen temperature by downloading the thermometer logger data to make sure their quality always in the range between 20° to 80°C.
      iv. Monitor the biospecimen movement by ensuring they are sent to reference lab according to the specified time.
   f) After the data collection:
      i. Gather the feedback on the problems or issues raised on the field for future improvement.
      ii. Check all the asset that has been used at the field are in good condition and return them back to IMSURE's Logistic Officer.
      iii. Submit all the form that has been used at the field to IMSURE's Technical Officer.

2. Phlebotomist
   a) Responsible to the Field Supervisor.
   b) Responsible to review the checklist of daily requirement and needs before conducting the daily task.
   c) Assist the team for carrying all the equipment during the data collection.
   d) Ensure all the blood taking equipment are adequate before conducting the procedure.
   e) Perform the 10 ml blood taking from the adult respondents through venepuncture procedure by using the complete PPE.
   f) Conduct the daily task as best as possible.
   g) Take care the equipment and data at the field.
   h) Responsible to maintain the good image of the Ministry of Health and public services at the field.

3. Research assistant
   a) Conduct the face-to-face interview with respondent.
   b) Ensure the quality of the collected data from the interview.
   c) Ensure all the biospecimens (blood samples) were registered.
   d) Centrifuge the blood samples at the field.
   e) Ensure the respondent received the follow-up card, appointment date and token.
   f) Receive the answered OMR for SAQ module and check for every single time.
   g) Bring the blood samples, answered OMR for SAQ module and other equipment back to the IMR.
   h) Ensure all the equipment are adequate and request it before the sampling.
   i) Assist in taking care and conducting the review project's store inventory.
   j) Communicate with the respondent through the phone call for each date appointment to ensure they attend the follow-up session.
   k) Communicate with the respondent through Call Assisted Telephone Interview (CATI) for the COVID-19 personal health information.
   l) Conduct the scanning for the answered OMR for SAQ module.
   m) Verify all the scanned data from the answered OMR for SAQ module.
   n) Follow-up with the respondent through the phone call to complete the SAQ module.
   o) Assist the Field Supervisor and carry out the tasks given from time to time.

RESEARCH TEAM MEMBERS AT VACCINATION CENTRE


Setia WELCOME TO SPICE ARENA

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INSTITUTE FOR PUBLIC HEALTH

ISBN 978-967-5340-94-9