

Prepared for: _____

Print Date: _____

PRODUCT DISCLOSURE SHEET

(Read this Product Disclosure Sheet before you decide to take up the Clinical Trial Insurance. Be sure to also read the general terms and conditions)

Financial Service Provider : Allianz General Insurance Company (Malaysia) Berhad
("Insurer"/"We"/"Our"/"Us")
Product Name : Clinical Trial

1. What is this product about?

This policy will provide protection for the Insured who conduct clinical trials and investigations, in respect of claims made against them by the trial participants.

2. What are the covers / benefits provided?

This policy will indemnify Insured such as trial sponsor, including pharmaceutical companies and contract research organisation up to limit of indemnity, against legal liability imposed by operation of law to pay Damages in respect of injury to any trial participant caused by or arising out of participation by the participant in any Clinical trial

- Which commencing within the period of insurance
- Which is conducted in Malaysia
- Which has been notified to an accepted by the Insurer in writing; and
- For which claim is first made against the Insured

3. How much premium do Insured have to pay?

The total premium that Insured have to pay may vary depending on the underwriting requirements of the Insurer. The following factors will affect the premium:-

- Trial phase
- Product
- Drug experience
- Drug profile
- Method factor
- Limit
- Retention
- Territorial
- Number of patient
- Type of patient
- Trial duration

4. What are fees and charges that Insured have to pay?

Type	%/Amount
• Commission paid to the insurance intermediaries (If any)	• 15% of premium/RM XX
• Services Tax	• 8% of premium
• Stamp Duty	• RM10.00

The Service Tax ("ST") amount herein may be subject to change as the ST rate applied shall be based on the prevailing rate(s) in accordance with the laws of Malaysia.

5. What are some of the key terms and conditions that I should be aware of?

- Importance of disclosure

Non-Consumer Insurance Contract

Pursuant to Paragraph 4 (1) of Schedule 9 of the Financial Services Act 2013, if you are applying for this Insurance for purposes related to your trade, business or profession, you have a duty to disclose any matter that you know to be relevant to our decision in accepting the risks and determining the rates and terms to be applied and any matter a reasonable person in the circumstances could be expected to know to be relevant, otherwise it may result in avoidance of contract, claim denied or reduced, terms changed or varied, or contract terminated.

This duty of disclosure for Non-Consumer Insurance Contract shall continue until the time the contract is entered into, varied or renewed. You also have a duty to tell us immediately if at any time after your contract of insurance has been entered into, varied or renewed with us, any of the information given is inaccurate or has changed.

- An appropriate limit of indemnity is taken up.
- Retention – being the amount which is to be borne by the Insured in the event of a claim
- This insurance is subjected to 60 days Premium Warranty, i.e. premium due must be paid and received by Insurer within sixty (60) days from inception. Failing which, policy is automatically cancelled and 60 days pro rate premium shall be entitled to Insurer.

6. What are the major exclusions under this policy?

This policy does not cover :-

- a. Any liability for Injury to employee unless such Employee is a Research Subject in the Clinical Trial
- b. Contractual Liability
- c. Penalties, liquidated and punitive damages
- d. Deductible amount specified in the policy
- e. Clinical trial which was not approved by Ethics committee, all required authorisation, licensing authority including Ministry of Health Malaysia
- f. Failure of intended medicinal purpose
- g. Intended or expected injury
- h. Departure from protocol
- i. Failure to obtain informed consent
- j. Continued use of medicinal products
- k. Pre-existing medical conditions

Note: This list is non-exhaustive. Please refer to the sample policy contract for the full list of exclusions under this policy.

7. Can Insured cancel my policy?

Insured may cancel policy by giving written notice to the Insurer. Upon cancellation, Insured will receive refund premium between 20% to 50% less than the pro rated amount, as may be determined at the absolute discretion of the Insurer. The cancellation will be effective even if the Insurer has not made or offered a refund.

8. What do Insured need to do if there are changes to the contact details?

It is important that Insured to inform Insurer of any change in contact details to ensure that all correspondences reaches Insured in a timely manner.

9. Where can Insured get further information?

Should Insured have any enquiries or require additional information, please refer to our agent or our nearest branch or contact our Customer Service Department at;

Allianz Customer Service Center

Allianz Arena


Ground Floor, Block 2A, Plaza Sentral

Jalan Stesen Sentral 5, Kuala Lumpur Sentral

50470 Kuala Lumpur.

Allianz Contact Center: 1 300 22 5542

Email: customer.service@allianz.com.my

 [@AllianzMalaysia](#)

 allianz.com.my

IMPORTANT NOTE:

YOU MUST ENSURE THAT YOUR LIABILITY IS INSURED AT THE APPROPRIATE AMOUNT. YOU SHOULD READ AND UNDERSTAND THE INSURANCE POLICY AND DISCUSS WITH THE AGENT OR CONTACT THE INSURANCE COMPANY DIRECTLY FOR MORE INFORMATION.

The information provided in this disclosure sheet is valid as at 01/03/2024.