

PRODUCT DISCLOSURE SHEET

Dear Customer,

This Product Disclosure Sheet (PDS) is designed to provide you with some key information on your Clinical Trial Insurance.

Other customers have read this PDS and found it helpful; **you should read it too.**

Date: dd.mm.yyyy

1 What is Clinical Trial Insurance?

Clinical Trial insurance provides protection in respect of claims made against you by clinical trial participants for injury caused by or arising out of their participation in your clinical trials and investigations. This insurance coverage is open to trial sponsors including pharmaceutical companies and clinical research organizers.

2 Know Your Coverage

As an illustration, for RM20,000 , you will receive the following **coverage**:

This policy covers:	This policy excludes:
<ul style="list-style-type: none"> • Compensatory monetary and statutory damages which you are legally liable to pay by operation of law in respect of injury to any trial participant caused by or arising out of the participant's participation in any of your clinical trial:- <ul style="list-style-type: none"> ○ which commences within the period of insurance; ○ which is conducted in Malaysia; ○ which has been notified to and accepted by Allianz in writing; and ○ for which claim is first made against you and is notified to Allianz. 	<p>Any liability:</p> <ul style="list-style-type: none"> • For injury to employees unless such employee is a participant in the clinical trial; • You assume solely under a contract; • In respect of penalties, liquidated and punitive damages; • Arising from a clinical trial which has not received approval from an ethics committee and all required authorisations from the relevant licensing authorities including the Ministry of Health, Malaysia; • Arising from the failure of any medicinal product to have its intended medicinal purpose; • Arising from intended or expected injury; • Arising from any departure from the agreed protocol of the ethics committee and/or licensing authorities; • From failure to obtain informed consent from any participant; • Arising from the continued use of a medicinal product after the completion of the clinical trial; • Arising from pre-existing medical conditions.

This is not a complete list. You should refer to the policy wording for the full details on what is covered and what is not.

Duration of cover depends on the duration of the clinical trial.

If you have any questions or require assistance on our Clinical Trial Insurance , you can:



Call us at
1 300 22 5542



Visit us at
<https://www.allianz.com.my/CT>



Email us at
customer.service@allianz.com.my



Scan the QR
code above

3 Know Your Obligations

The total premium that you have to pay may vary depending on Allianz's underwriting requirements.

For illustration purposes, assuming you (i.e. the insured) are a clinical research organizer with 150 clinical trial participants, and a limit of indemnity of RM1,000,000 for any one occurrence and in the aggregate, the premium payable is as follows:

Base premium	RM20,000.00
Which is inclusive of:	
Commission paid to the insurance intermediaries (if any)	15% of premium or RM3,000.00
You also have to pay the following fees and charges:	
Services Tax	8% of premium or RM1,600.00
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.

To note that the following factors will affect the premium amount:

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

4 Important Information You Should Know

- Pre-contractual duty of disclosure for non-consumer insurance contracts (pursuant to Schedule 9 of the Financial Services Act 2013):
 - o If you are applying for insurance related to your trade, business or profession, you must disclose any matter that you know to be relevant to our decision in accepting the risks and determining the applicable rates and terms and any matter a reasonable person in the circumstances could be expected to know to be relevant.
 - o Otherwise it may result in avoidance of contract, claim denied or reduced, terms changed or varied, or contract terminated.
 - o You must also inform us immediately of any inaccuracies or changes in your information after entering into, varying or renewing your contract of insurance.
- You must provide Allianz with your complete, signed and dated application form for our evaluation.
- Premium Warranty – Premium due must be paid and received by Allianz within sixty (60) days from policy inception. Failing which, the policy is automatically cancelled and Allianz shall be entitled to the 60 days pro-rated premium for the period Allianz provided cover.

? Can I cancel my policy?

You may cancel your policy by giving written notice to Allianz. Upon cancellation, you may be entitled to a refund of the premium which would be between 20%-50% less than the pro-rated refund, as determined by Allianz. The cancellation will be effective even if Allianz has not made or offered any refund.

The benefit(s) payable under eligible product is (are) protected by PIDM up to limits. Please refer to PIDM's TIPS Brochure or contact Allianz General Insurance Company (Malaysia) Berhad or PIDM (visit www.pidm.gov.my).