

## CLINICAL TRIALS INSURANCE SERVICES

By: Nurfaizah Saibul



### What is clinical trial insurance?

Insurance is a system under individual or business entity or organization, where in exchange for payment (premium) guarantees compensation for losses resulting from certain perils under specified conditions in a contract or policy. Clinical trial insurance is an important section of liability insurance. This insurance plan offers protection against legal liabilities which result from clinical trials. In principle, clinical trial insurance covers the design risk of the protocol.

### Requirements of Clinical Trial Insurance

The requirement for trial insurance was initially featured in the ethical guidelines for biomedical research on human subjects published by the Indian Council of Medical Research in 2000. These guidelines in the "principles of nonexploitation" state that *"Each research shall include an in-built mechanism for compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary."*

According to the **Section 5.8.1 in the Malaysian Guideline for Good Clinical Practice (NPRA, 2018)<sup>2</sup>**, *"If required by the applicable regulatory requirement(s), the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/ the institution against claims arising from the trial except for claims that arise from malpractice and/or negligence."*

There are many insurance companies offering a broad range of coverage, each with its own terms and conditions. This can be confusing and as a result, the process of acquiring coverage can be time-consuming. Whilst Malaysia has no legal act governing clinical trial activities (including clinical trial indemnification and insurance), the Malaysian GCP guideline states that such indemnification and insurance should be provided if required by applicable regulatory requirements.

It is a requirement by the Independent Ethics Committee (IEC)/ Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia that all ethics submissions for clinical trials must include proof of trial indemnification either by insurance certificate or letter of indemnity. These documents should indicate the protocol title and number, period of coverage and list of coverage for Malaysia sites among others. Insurance certificates that are renewed should be duly submitted to the ethics committee on an on-going basis<sup>3</sup>.

Any institution/ center or investigator involved in clinical trial should be indemnified or insured for claims arising from:

- i. Use of investigational medicinal product (IMP)
- ii. Procedures/ activities performed for clinical trial
- iii. Malpractice/ negligence.

Having the appropriate insurance coverage is part of the clinical trial and the needs should be addressed as early as possible. A sponsor/ contract research organization (CRO) needs to consider the product liability, geographical coverage and cost of clinical trial insurance (among others) when choosing insurance providers for a multi-center trial involving various countries. On the other hand, site and investigators must consider coverage for all their clinical trials and negligence activities when choosing insurance providers.

## Clinical Trial Insurance Coverage

The service of providing insurance by insurers in Malaysia is governed by the Financial Service Act 2013. Under this act, the insurers can be a Malaysia company or an international company with license to operate in Malaysia<sup>3</sup>.

Some examples of insurance companies that provide clinical trial insurance in Malaysia are:

- i. Great Eastern (GE)
- ii. Allianz (Az)
- iii. Chubb Malaysia (CM)



*\*The summary of clinical trial insurance services provided by these companies is in Table 1.* The main differences are that GE allows a no-cost master policy under CRU to cover for all future clinical trials. This is not available to CRU from the other 2 companies. Both GE and AZ have a high deductible before a claim is payable from the company. CM has the extra coverage that others do not have.

The common clinical trial insurance policy coverage is:

**i. Agreed Compensation Cover:**

Compensation to patients follows the agreed amount under the applicable clinical trial compensation clauses in the policy. It covers all the team members within the same institution or partner (which can be included with extra payment) including error or omission.

**ii. Legal Liability Cover:**

It covers damages, defense and claimant's costs that are legally liable to be paid.

**Coverage by Endorsement** is another type of clinical trial insurance. Some product liability policy provides clinical trial extension coverage by an endorsement to this policy. It is not covered if a particular trial is not specified and scheduled on the endorsement. Hence, it is important for the investigator to check the policy clause for this rider or extension. This form of insurance premium is usually cheaper. Be careful when an investigator is conducting an out-of-label claim clinical trial/ new indication trial, as this type of policy will be null and void.

Other liability insurance that site/ investigators overlook is equipment/ material/ public liability damage coverage. This insurance must be purchased separately to cover the equipment loaned from the sponsor. For example, spoilt by any human or natural disaster, stolen, or not returned by the patient.

## How to choose a clinical trial insurance provider?

The decision to choose an insurance provider or a policy should be made after considering factors including:

- i. How much insurance/ limit of indemnity to provide (per claim/ per patient/ per occurrence; per aggregate/ all claim) with retention/ deductible/ out of pocket for each claim by investigator/ sponsor?
- ii. At what cost or premium?
- iii. How long to cover the indemnity after the expiration of the insurance or any exclusion of pre-existing disease that will not be covered?

### What information is needed for a clinical trial insurance application?

The required documents are subject to the requirements of the insurers and depend on the type of coverage to be applied for. As part of the clinical trial insurance application process, the applicant must provide an estimate of the number of subjects/ patients participating in the clinical trial to be covered, and the insurers are using this as a basis of premium.

As a general guideline, the compulsory documents needed are the **investigator's names, trial protocol, patient consent form, and approval letter by IEC.**

### Claim handling

#### Potential claims include the following<sup>3</sup>:

- i. A subject/ patient reports on injuries that is claimed to be caused by participation in clinical trials, for which cost is not covered within the clinical trial budget and with no other means of cost coverage, especially when the claim amount is more than the access or deductible in the policy.
- ii. A serious side effect or any event that causes bodily injuries during a clinical trial.
- iii. A technical operational staff realizes that he/she has committed some error or missed some step which would cause adverse event/effect.




#### Steps to abide by when the above scenario arise<sup>3</sup>:




- i. To inform the following personnel when such a scenario arises as soon as possible. This shall include the CEO of institution (CRC or CRO), principal investigator, sponsor (depending on SOP of site).
- ii. The person in-charge or any other person involved should not at any point of time, admit liability or settle any claim or incur any costs or expenses in connection therewith.
- iii. The personnel should immediately contact insurance agent within a time limit not exceeding three (3) days. It is advisable to use multiple forms of communications to ensure the agent is informed.




### References:

1. Gooi RB and Divekar D (2014). Insurance in clinical research. Perspectives in Clinical Research.5(4),145-150.
2. Society of Clinical Research Professionals Malaysia (SCRPM) (2016). A guide to conducting clinical trials in Malaysia. First Edition 2016.
3. National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia (2018). Malaysian Guideline for Good Clinical Practice, 4<sup>th</sup> Edition.

**TABLE 1: SUMMARY OF CLINICAL TRIALS INSURANCE SERVICES IN MALAYSIA**

No.	Description			
1.	<b>Policy Coverage</b>	<ul style="list-style-type: none"> <li>➤ Compensates the research subject for bodily injury arising from the use of any pharmaceutical or medical devices in human clinical trials.</li> <li>➤ The claim must be first notified to the insurers in writing during the period of insurance.</li> <li>➤ The cover is on both “No Fault Compensation” and “Legal Liability” forms (dependent upon local licensing and regulatory requirements).</li> </ul>	<ul style="list-style-type: none"> <li>➤ The legal liability imposed by law to pay damages in respect of injury to any research subject caused by or arising out of participation by the research subject in any clinical trial.</li> <li>➤ Claims-made basis i.e. claims first made against an insured and notified to the company during the period of insurance or within an agreed extended reporting period following the expiration date of the policy.</li> <li>➤ The application will be reviewed and evaluated by the regional office.</li> </ul>	<p><b>Clinical Trials Liability</b></p> <ul style="list-style-type: none"> <li>✓ Legal Liability Claims</li> <li>✓ No Fault Compensation Claims (where applicable).</li> </ul> <p><b>Human Clinical Trial Insurance</b></p> <ul style="list-style-type: none"> <li>✓ Indemnifies the insureds (Sponsor, CMO, CRO, investigators) against claims in respect of 3<sup>rd</sup> party bodily injury arising out of or in connecting with the insured trial.</li> </ul> <p><b>Clinical Trials Extras</b></p> <ul style="list-style-type: none"> <li>✓ Clinical trial product recall expenses.</li> <li>✓ Crisis response expenses.</li> <li>✓ Medical expenses.</li> <li>✓ Medical monitoring expenses etc.</li> </ul>
2.	<b>Major Exclusions</b>	<p>The policy does <b>not cover</b>:</p> <ul style="list-style-type: none"> <li>✓ Any liability for injury to employee unless such employee is a research subject in the clinical trial.</li> <li>✓ Penalties, liquidated and punitive damages.</li> <li>✓ Deductible amount specified in the policy.</li> <li>✓ A clinical trial which was not approved by the ethics committee, all required authorization, licensing authority including the Ministry of Health Malaysia.</li> <li>✓ Intended or expected injury.</li> <li>✓ Pre-existing medical conditions.</li> </ul>	<p>The policy does <b>not cover</b>:</p> <ul style="list-style-type: none"> <li>✓ Any injury to any employee unless the employee is a research subject.</li> <li>✓ Any liability in respect of fines, penalties, punitive or exemplary damages.</li> <li>✓ Any liability for clinical trials that have not received approval from authorities.</li> <li>✓ Any liability arising from the departure from the agreed protocol.</li> <li>✓ Any liability arising from the failure to obtain informed consent from the patient.</li> </ul>	<p>The policy is <b>not suitable</b> for:</p> <ul style="list-style-type: none"> <li>✓ Hospital’s roles as both sponsor and investigator involve surgery procedures in the clinical trial.</li> </ul>

No.	Description			
2.	<b>Major Exclusions</b>	<p>The policy does <b>not cover</b>:</p> <ul style="list-style-type: none"> <li>✓ War.</li> <li>✓ Nuclear, radioactive contamination.</li> <li>✓ Any claim arising from Hepatitis, Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants derivatives or variations thereof, related to Acquired Immune Deficiency Syndrome.</li> <li>✓ Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).</li> <li>✓ Liability arising from any Occurrence happening prior to the retroactive date.</li> <li>✓ Known circumstances by Insured prior to the inception of the policy.</li> <li>✓ Cyber liability exclusion.</li> </ul> <p>Communicable disease exclusion.</p>	<p>The policy does <b>not cover</b>:</p> <ul style="list-style-type: none"> <li>✓ Any liability arising from the deterioration of existing health conditions, which would have occurred whether the patient had participated in the study or otherwise.</li> <li>✓ Any liability arising from the failure of any Medicinal Product to have its intended medicinal purpose.</li> <li>✓ Any liability arising from an injury that was intended or expected by the Insured.</li> </ul>	
3.	<b>Required information to get indication/ quotation</b>	<ol style="list-style-type: none"> <li>1. A copy of duly completed of clinical trial insurance proposal form.</li> <li>2. A copy of protocol.</li> <li>3. Patient's consent form.</li> <li>4. Confirmation of no serious adverse events being reported.</li> <li>5. Past experience from similar trials.</li> </ol>	<ol style="list-style-type: none"> <li>1. Trial protocol.</li> <li>2. Informed consent form.</li> <li>3. Clinical trial proposal form.</li> </ol>	<ol style="list-style-type: none"> <li>1. Clinical trial protocol (full version or synopsis or draft).</li> <li>2. ICF (Informed Consent Form) or PIS (Patient Information Sheet)-prefer draft.</li> <li>3. Chubb HCT application form.</li> </ol>

No.	Description	 <small>A member of the OCBC Group</small>		
4.	<b>Product information /contact information</b>	<p><a href="http://www.greasterngeneral.com">www.greasterngeneral.com</a>.</p> <p><b>Contact info:</b> Great Eastern General Insurance (Malaysia) Berhad Level 18, Menara Great Eastern 303 Jalan Ampang 50450 Kuala Lumpur Tel: 1300-1300 88</p> <p><i><b>Important Note:</b> This information is issued as a matter of information only and please refer to the policy wording for more comprehensive terms and conditions.</i></p>	<p><a href="https://www.allianz.com.my/corporate/liabilities-operations-and-asset-protections/liabilities/clinical-trial-insurance.html">https://www.allianz.com.my/corporate/liabilities-operations-and-asset-protections/liabilities/clinical-trial-insurance.html</a></p> <p><b>For product disclosure sheet:</b> <a href="https://www.allianz.com.my/content/dam/onemarketing/azmb/wwwallianzcommy/corporate/liabilities-operations-and-asset-protection/liabilities/clinical-trial-insurance/ClinicalTrialInsuranceDisclosureSheet_EN.pdf">https://www.allianz.com.my/content/dam/onemarketing/azmb/wwwallianzcommy/corporate/liabilities-operations-and-asset-protection/liabilities/clinical-trial-insurance/ClinicalTrialInsuranceDisclosureSheet_EN.pdf</a></p> <p><b>Contact info:</b> Allianz Malaysia Berhad Allianz Arena, Ground Floor, Block 2A, Plaza Sentral, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur. <a href="tel:1-300-22-5542">Tel: 1-300-22-5542</a> customer.service@allianz.com.my</p>	<p><a href="https://www.chubb.com/sg-en/business/clinical-trials-liability-insurance.html">https://www.chubb.com/sg-en/business/clinical-trials-liability-insurance.html</a></p> <p><a href="https://www.chubb.com/content/dam/chubb-sites/chubb-com/pl-pl/products/life-science/OWU-LIFE-SCIENCE-ENG-III-2020.pdf">https://www.chubb.com/content/dam/chubb-sites/chubb-com/pl-pl/products/life-science/OWU-LIFE-SCIENCE-ENG-III-2020.pdf</a></p> <p><b>Clinical Trials Fact Sheet:</b> <a href="https://www.chubb.com/content/dam/chubb-sites/chubb-com/sg-en/business/clinical-trials-liability-insurance/documents/pdf/chubb-clinical-trials-factsheet--sg.pdf">https://www.chubb.com/content/dam/chubb-sites/chubb-com/sg-en/business/clinical-trials-liability-insurance/documents/pdf/chubb-clinical-trials-factsheet--sg.pdf</a></p> <p><b>Clinical Trials Liability Policy Case Study Infographic:</b> <a href="https://www.chubb.com/content/dam/chubb-sites/chubb-com/sg-en/business/clinical-trials-liability-insurance/documents/pdf/clinical-trials-liability-policy-case-study-infographic--sg.pdf">https://www.chubb.com/content/dam/chubb-sites/chubb-com/sg-en/business/clinical-trials-liability-insurance/documents/pdf/clinical-trials-liability-policy-case-study-infographic--sg.pdf</a></p> <p><b>Contact info:</b> Chubb Insurance Malaysia Berhad Wisma Chubb Jalan Sultan Ismail 50250 Kuala Lumpur Tel: 03 2058 3000 Fax: 03 2058 3333 <a href="http://www.chubb.com/my">www.chubb.com/my</a></p>
5.	<b>How to apply?</b>	<p>Contact CRU, HPUPM at 03-97699763 or email to <a href="mailto:clu_hpupm@upm.edu.my">clu_hpupm@upm.edu.my</a> for further information.</p>		