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# Insurance Task and Finish Group Glossary of terms



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# Insurance Task and Finish Group

## Glossary of terms

### Introduction

This document is intended to provide simple definitions of insurance terminology. It is aimed at individuals that are not insurance experts but that may be required to understand insurance terminology as part of Trial or Site set-up or contract negotiations.

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| <b>Claims Made Basis</b>               | <p><a href="#">Insurance policy</a> that only pays claims that arise from an event that occurs during the period covered by the policy and where the claim is filed within the same period. Also see 'Extended Reporting Period'.</p> <p>e.g. A University insures a trial that takes place between 2010 and 2013. Their insurance is on a claims made basis and is maintained by the University on an ongoing basis. In 2015 the University is sued by someone for an event that took place during the trial in 2012. The University is able to make a claim on their insurance to respond to the claim because the University has maintained ongoing insurance cover with the same provider.</p> <p>Example 2: A university changes insurer, the new insurer takes on the university's existing clinical trial portfolio, including past trials, on a claims made basis. If there is a claim on one of those trials the new insurer will respond.</p> |
| <b>Claims Occurring Basis</b>          | <p>A type of insurance policy that pays claims that arise from an event that occurs during the policy period regardless of when the claim is actually filed (i.e. the claim may be made after the policy has expired).</p> <p>e.g. A University insures a trial that takes place between 2010 and 2013. Their insurance covers the trial period 2010-2013 and is on a claims occurring basis. In 2015 the University is sued by someone for an event that took place during the trial in 2012. The University is able to make a claim on their insurance in place at that time to respond to the claim.</p>   |
| <b>Co-Insured</b>                      | <p>Type of insurance where cover is provided by two or more insurers (to off-set large risks); or, insurance policy where the insured party pays a fixed amount of any loss claimed. See also 'Deductible' and 'Excess'.</p>  |
| <b>Deductible</b>                      | <p>The amount of an insurance claim that must be paid by the insured party and that the insurer therefore 'deducts' from any payment to made to the insured party. See also 'Excess'.</p>   |
| <b>Excess</b>                          | <p>The amount that the insured party has to pay towards any claim.</p>  |
| <b>Extended Reporting Period (ERP)</b> | <p>A specific time frame after an insurance policy has expired (see also 'Claims made basis') during which a claim may still be made as if the claim had been made during the policy period.</p> <p>e.g. A university takes out insurance for a clinical trial for the period of the trial. If a claim is made the day after the trial finishes, the</p>  |

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|                                      | policy will not respond. If they had taken out a policy with an extended reporting period the policy would have responded, as long as the claim is made within that extended reporting period.   |
| <b>Indemnity</b>                     | <p>An obligation by one party (the indemnitor) to pay for any anticipated loss or damage incurred by another party (the indemnitee).</p> <p>e.g. A clinical trial sponsor delegates duties to a clinical research organisation (CRO). In the contract the CRO provides an indemnity to the Sponsor for any costs to the Sponsor that arises out of the CRO's negligence. During the course of the trial a mistake by the CRO results in a claim against the Sponsor. The CRO (or their insurers) pay the costs of responding to the claim.</p> |
| <b>Insurance</b>                     | <p>A type of protection from financial loss. Different type of insurance in this context are:</p> <ul style="list-style-type: none"> <li>• Clinical Trials Insurance</li> <li>• Medical Malpractice Insurance</li> <li>• Public Liability Insurance (often known Overseas as General or Civil Liability)</li> <li>• Professional Indemnity / Negligence Insurance</li> </ul>   |
| <b>Insured (as in 'the insured')</b> | The organisation or party who will be compensated for loss by an insurer under the terms of an insurance policy.   |
| <b>In the Aggregate</b>              | <p>The total amount that is covered by an insurance policy during the policy period. It may be described as a total amount for any one claim, or an aggregate total amount that will be paid for several claims of a similar nature.</p> <p>e.g. A clinical trials insurance policy is taken out with a limit of £1.5 million in the aggregate. The trial goes catastrophically wrong and two participants each successfully sue for £1 million each. The insurance only pays £1.5 million.</p>  |
| <b>Legal liability</b>               | Legal liability concerns both <a href="#">civil law</a> and <a href="#">criminal law</a> . Legal liability can arise from various areas of law, including <a href="#">contracts</a> . Liabilities may be covered by <a href="#">insurance</a> , although typically insurance does not cover intentional wrongdoings or <a href="#">breach of contract</a> .  |
| <b>Liability</b>                     | Having legal responsibility (i.e. being obliged to) to do, pay or make good something.   |
| <b>Liability cap</b>                 | <p>This would normally be in the form of a maximum amount a party is potentially liable for. However, liability may also be limited by other non-financial methods.</p> <p>A Sponsor hires a CRO. In their contract, the CRO caps their liabilities to £500,000. Due to a mistake made by the CRO in drug distribution, the Sponsor loses £1million. The CRO only has to pay £500,000. Note: liability arising from negligence for personal injury cannot be capped.</p>   |
| <b>Long-Tail</b>                     | Where a claim is made a long time after the event has occurred. For example, where 'harm' is not immediately apparent, or where there is a lengthy period of legal limitation [for example, if a   |

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|                                 | research subject is a minor or lacks legal capacity] a Clinical Trial participant may make a claim months or years after being involved in a trial.   |
| <b>Negligent</b>                | Failure by action, behavior, or response, willful or not, to maintain the expected care required from a reasonable, prudent person under the circumstances.   |
| <b>Negligent harm cover</b>     | The person alleging injury must prove that the other party has been negligent in undertaking their legal responsibilities in order for the cover to respond   |
| <b>Non-negligent harm cover</b> | This is also referred to as 'no-fault compensation'. In this scenario, the injured party does not have to prove negligence in order to be compensated. For example, a clinical trial participant bringing a claim would only need to show that their health had deteriorated and that this was due to the trial. They would not need to show that anyone had been negligent or that someone had done something wrong. |
| <b>Stop Loss</b>                | The point at which the losses of the insurer are stopped. Insurers may take out a stop-loss insurance policy to protect themselves against large claims. Stop-loss policies take effect after a certain threshold has been exceeded in claims.  |
| <b>Subrogation</b>              | The assuming of legal rights of another party for whom expenses or a debt has been paid. For example, Subrogation is the legal right normally reserved by insurers to pursue a third party that caused an insurance loss to the insured. So if a trial Sponsor was sued because of negligence at a clinical trial site, the Sponsor's insurer would seek to subrogate their losses from the site.                     |

## References

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