Life Sciences Claims

Important Notice: These are examples only. You should read them only as a guide. They do not form part of any policy. Every claim is different. We always determine indemnity decisions and claim payments on an individual basis, after we have assessed the claim. Information provided is general only and has been prepared without taking into account any person's particular objectives, financial situation or needs. Insurance cover and whether a policy responds to a claim is subject to the terms, conditions, limits and exclusions of the policy. When making a decision to buy or continue to hold a financial product, you should review the relevant policy documents.

Contract Research Organisation (CRO)

A pharmaceutical company (sponsor) hired a CRO to manage the distribution of drugs for a double-blind clinical trial. Due to a distribution error, the CRO allegedly caused too many participants to receive the placebo instead of the active ingredient under investigation. The regulatory authority deemed the trial's resulting data flawed. This prevented the sponsor from obtaining market approval for the drug. The sponsor was also required to incur additional unexpected costs as the trial had to be re-run.

Contract Manufacturing Organisation (CMO)

A pharmaceutical firm hired a CMO to manufacture epinephrine mist. A Class III product recall resulted from the CMO's alleged failure to test the mist for all microbial specifications. The pharmaceutical firm sought damages for breach of contract and negligent misrepresentation.

University Conducted Clinical Trial

A dental device company retained a university to conduct a dental implant clinical trial. The university allegedly breached the clinical trial contract by failing to provide information required, such as the implantation date, the date the patient was examined, and a description of the implant tissue quality and the amount of bone growth. Additionally, the university allegedly failed to follow the protocol: one patient exceeded the age limit, one implant was too close to the patient's sinus cavity, and in one instance the wrong cement was used.

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Bodily Injury to a Clinical Trial Participant

A biotechnology company sponsors a Phase II clinical trial for an investigational oncology drug being conducted at multiple hospitals. The protocol has been approved by the relevant ethics committee and regulatory authorities.

A 52-year-old participant enrols in the study after signing an informed consent form and passing all screening requirements. During the third treatment cycle, the participant develops a severe and unexpected immune-mediated reaction that was not identified in earlier studies.

The participant is hospitalised with acute respiratory distress syndrome (ARDS), requiring intensive care treatment for 10 days. Although the participant survives, they suffer permanent impairment to lung function and are unable to return to their previous employment.

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