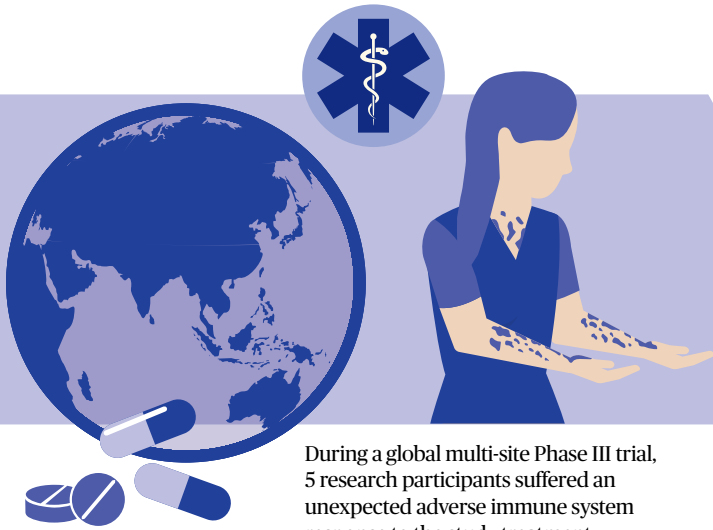
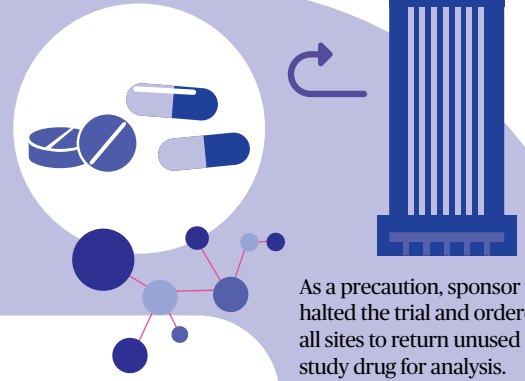


Clinical Trials Liability Policy Case Study



During a global multi-site Phase III trial, 5 research participants suffered an unexpected adverse immune system response to the study treatment.



As a precaution, sponsor halted the trial and ordered all sites to return unused study drug for analysis.

It was discovered there was a higher than expected level of active ingredient in the drug. All recalled product were destroyed.



A global news network ran the story of the injured research subjects and halted trial, and speculated that poor manufacturing controls were to blame for the incident. Several key investors indicated they were considering withdrawing funding on the back of the negative press. Sponsor engaged a public relations company to help with communicating work done to investigate and correct manufacturing process to the investment community.



As a precaution, a further 20 research subjects who had been treated with the contaminated batch but showed no side effects were monitored with monthly testing for 12 months by their study doctor.



A lawyer representing affected research participants issued writ against the sponsor seeking compensation for their clients.

Sponsor incurred costs for:

- Recalling and destroying unused study drugs.
- Engaging public relations company to communicate with investment community

Uninjured research subjects made claims for medical monitoring expenses.



Injured research subjects made claims via their lawyers for:

- medical expenses for additional treatment
- lost income from time off work
- general damages for pain, suffering and emotional distress.

Coverage Response



Loss: Sponsor's costs from recalling and destroying unused study drugs.

Section 5C - Clinical Trials, Product Recall Expenses extension would cover costs associated with transportation and destruction of unused study drugs.



Loss: Sponsor's costs from hiring a public relations company.

Section 5, Special Extension, Crisis Response Expenses would cover the insureds costs of engaging the public relations company.



Loss: Medical expenses incurred by uninjured research subjects exposed to contaminated drug for monitoring tests.

Section 5C - Clinical Trials, Medical Monitoring Expenses, would cover the costs of the medical testing performed on these research subjects.



Loss: Compensation claims brought by research subjects who had suffered adverse immune system response.

Section 5C - Clinical Trials Liability coverage would respond to cover costs associated with investigating claims and negotiating settlement of these claims. Would also cover the settlement amounts agreed to with the injured research subjects. Claim investigation expenses would not reduce policy limits, leaving full amount of those limits available for compensating injured research subjects.

Additional Benefits with Chubb's Clinical Trials Liability Wording



No fault reimbursement of up to €10,000 for Medical Expenses paid by the Insured to treat a Research Subject injured by the medical product being tested in an insured Clinical Trial.



Legal costs to attend coronial inquests or regulatory inquiries connected with injuries to Research Subjects happening during an insured Clinical Trial.



Automatic Extended Reporting Periods for claims made by a Research Subject after policy has expired.



Indemnity for third parties such as Clinical Trial Contractors, Contract Research Organisations, Ethics Committees and independent Data Safety Monitoring Boards.



Extended Use providing expanded access and compassionate use of clinical trial product after the participation in the trial has ended.



Cover for Privacy Injury or Reputational Injury to third parties caused by an Act in connection with an insured Clinical Trial.



Cover for expenses incurred by insured following a Privacy Data Breach in connection with an insured Clinical Trial.

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