

Mitigating Risks Through Clinical Trial Funding Insurance



Insurance | Risk Management | Consulting





Introduction

The critical role of clinical trials in healthcare innovation

Clinical trials are the backbone of healthcare innovation. They are crucial for developing and approving new therapies and treatments — the gateway to validating the efficacy and safety of new drugs, devices and procedures.

In recent years, the biotech and life sciences sectors have experienced a surge in the number and complexity of clinical trials. The rush to find breakthroughs in oncology, neurology and rare diseases fuels this growth. However, this expansion comes with heightened financial and reputational stakes for sponsors and biotech firms. There is a new insurance product available in the market to address these challenges, providing tailored coverage to mitigate risks and protect investments in clinical trials.

From 2018 to 2023, the clinical trial success rate stood around 10%. In 2023, it rose to 10.8%, the highest in five years.¹

The risk landscape in clinical trials

Navigating the risk landscape in clinical trials is no small feat. Here are some of the challenges:

- **Regulatory hurdles:** Navigating complex regulatory requirements is a major challenge, with non-compliance potentially leading to costly litigation.
- **Operational risks:** Patient recruitment, protocol deviations and supply chain disruptions can all impact trial outcomes.
- **Financial risks:** Hefty research and development (R&D) costs, investor pressure and timeline overruns pose significant financial threats.
- **Lost investments and opportunity cost:** Failed trials can result in substantial financial losses and missed investment opportunities.
- **Damaged investor confidence:** Unsuccessful trials can erode investor trust and harm brand reputation.
- **Delayed time-to-market:** Setbacks can delay the introduction of new therapies, resulting in a potential loss of first-mover advantage.
- **Impact on future funding:** Trial failures can affect future funding rounds or readiness for an initial public offering (IPO).



Clinical trial funding insurance

Designed to mitigate the financial risks associated with the potential failure of clinical trials, this specialized insurance provides a safety net for biotech firms, sponsors and investors, ensuring protection from the financial fallout of unsuccessful trials.²

Clinical trial funding insurance typically covers a range of costs related to trial failures. These include sunk R&D expenses, operational disruptions and legal liabilities arising from regulatory non-compliance or adverse events. By transferring these risks to an insurance provider, companies can safeguard their financial stability and continue their pursuit of innovation without the ongoing fear of catastrophic losses.

Enabling innovation through risk transfer

Clinical trial funding insurance also plays a crucial role in enabling innovation by providing a mechanism for risk transfer. This insurance offers several key benefits that contribute to the sustainability and success of clinical trials.

- **Financial protection:** Clinical trial funding insurance provides financial protection for biotech firms, investors and contract research organizations (CROs) against the economic impact of trial failures, allowing them to maintain operations and concentrate on developing new therapies.
- **Investor confidence:** Insurance security enhances investor confidence, making it easier for companies to attract funding. Investors are more inclined to support trials that offer a safety net, with the assurance that their investments are protected against potential failures.
- **Increased focus on risk management:** By offering financial protection, requiring rigorous risk assessments, enforcing adherence to industry standards and providing access to expert guidance, clinical trial funding insurance motivates companies to enhance their risk management practices. This proactive approach to risk mitigation enhances the overall sustainability of trials and increases the likelihood of successful outcomes.
- **R&D acceleration:** With the mitigation of financial risks, companies can pursue more ambitious and faster-paced research and development initiatives. This acceleration of R&D efforts can lead to quicker breakthroughs and the timely introduction of new therapies.

Eligibility: What types of trials qualify for clinical trial funding insurance?

- Phase 1 and Phase 2 trials
- Trial budgets from \$3 million to \$20 million
- Drug asset type — small molecules, monoclonal and conjugated antibody therapies, some biologics**
- Trials with an estimated duration of less than three years
- Companies that have already engaged with a CRO
- Trials that have their clinical trial protocol already written and approved by the relevant regulator
- Companies domiciled in the US, UK and Canada

**Currently unable to support gene therapies

How Gallagher can help

Gallagher is a trusted leader in clinical trial risk management, with over 25 years of experience serving more than 3,000 life sciences companies globally. Leveraging strong relationships with specialized underwriters and carriers, we craft tailored insurance policies that address the unique risk profiles of biotech and pharmaceutical companies. This expertise ensures comprehensive coverage that meets regulatory requirements and aligns with the needs of clinical trials.

In addition to offering bespoke coverage, we provide ongoing advisory support throughout the trial lifecycle. This includes quick policy certificate issuance and a straightforward claims process managed in-house with dedicated claims handlers. By delivering customized solutions and continuous support, our team empowers clients to confidently navigate the complexities of clinical trials.



For any questions, get in touch with your Gallagher client executive or reach out to me directly.

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Citations

¹Vrijens, Bernard. "Clinical Trial Failures: Are We Counting the Cost of Poor Adherence?" *Aardex Group*, 19 Jul 2024.

²"Clinical Trial Insurance Made for Your Business," *The Hartford*, 08 Apr 2025.

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