LIFE SCIENCES ON THE CUTTING EDGE:

How Bespoke Insurance Navigates the Evolving Landscape of Clinical Trials

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Life Sciences

The COVID-19 pandemic was a stark reminder of the critical role clinical trials play in developing vaccines and other life-saving treatments. Countries needed accelerated vaccine development, fostering new era of collaboration between companies, researchers, regulatory bodies, and governments. It led to the COVID-19 vaccines becoming the fastest vaccines ever created, which is attributed to previous endeavors in the development of other vaccines.[1]

As the dust settles and clinical trial activity rebounds, excitement about groundbreaking innovations and new technologies (including gene therapy and artificial intelligence) grows. The demand for such advanced technologies is increasing due to their ability to speed up potential time to market. In 2022, the global clinical trials market was worth more than USD55.5 billion, and it is expected to cross USD96.4 billion in the next ten years.[2]

However, these advancements are accompanied by inherent risks and uncertainties. Insurance carriers are monitoring the latest developments closely as securing comprehensive and compliant insurance coverage for trials has become paramount. In this dynamic environment, it is essential to partner with a specialized insurance broker ("broker") who understands the needs of all stakeholders. By navigating the complexities of the changing landscape, a knowledgeable broker can ensure contract certainty and adherence to applicable regulatory requirements. This should be evaluated and monitored throughout the entire lifecycle of a clinical trial, from inception to its conclusion.

TOP TRENDS SHAPING CLINICAL TRIALS POST-PANDEMIC

Rise of AI and advanced technologies

Machine learning (ML) analyzes vast datasets of medical records and patient demographics. This results in more targeted recruitment, potentially leading to faster and more efficient trial enrollment.

Natural language processing (NLP) and other AI tools are being implemented to automate tasks, such as analyzing clinical trial data and generating reports. The technology is being used to predict patient responses to treatments to help researchers design more effective trials and tailor treatment strategies for individual patients.

New clinical trial models

Hybrid trials combine the elements of traditional, in-clinic visits with telehealth consultations and remote monitoring. Wearable devices and digital platforms are some of the technologies facilitating these new models. Crucially, hybrid trials allow geographically dispersed populations to participate in the trials. This reliance on technology necessitates robust cybersecurity measures to protect sensitive patient data.

In virtual trials, technology is used to conduct the entire trial remotely. Participants enroll, complete assessments, and submit data electronically. Virtual trials have the potential to significantly increase accessibility for patients who are unable to access traditional trial sites due to geographical limitations, mobility issues, or other factors.

In virtual and hybrid trials, it is important to confirm patient identification and protect their sensitive personal data. Implementing robust security measures on the virtual trial platform, including firewalls, intrusion detection systems, and regular security updates, can improve the overall security posture of the trial.

Emerging bioengineering and life science technologies

Gene therapy and cell therapy trials offer promising avenues for treating various diseases by modifying a patient's genes or introducing healthy cells. In addition, 3D printing is changing the personalized medicine landscape. Researchers are using these methods and techniques to create customized drug delivery systems with greater control over medication release and bioprinting tissues for drug testing and potential future transplantation applications.

These trials require careful monitoring and robust ethical considerations to ensure patient safety and address potential societal implications.

Navigating cyber exposures and data privacy

Clinical trials are becoming more reliant on connected devices and digital platforms. The risk of cyberattacks targeting sensitive patient data grows. Implementing robust cybersecurity measures and regular security assessments is crucial to protecting a patient's privacy and maintaining trust.

Researchers should comply with data privacy regulations, such as General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability (HIPAA), to obtain informed consent from patients, encrypt data, and prevent unauthorized access to personal information. Navigating these regulations adds an additional layer of complexity to the trials but is necessary for upholding ethical standards and protecting patient rights.

Evolving regulations

The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are among the regulatory agencies actively adapting their regulations to address the rapidly evolving landscape of clinical trials. Collaboration between regulators, researchers, and industry stakeholders is becoming increasingly important to ensure ethical conduct, data integrity, and the safety of participants.

Administering a clinical trial insurance program: No off-the-shelf solutions

The world of clinical trials, particularly those venturing into uncharted territories like gene and cell therapies, 3D printing, and fetal injury research, necessitates a paradigm shift in the insurance sector. Generic solutions are being replaced by bespoke insurance programs tailored to the specific trial exposure for the sponsor and addressing the unique risks posed by each trial.

The life sciences insurance market boasts healthy competition, with carriers demonstrating a solid appetite for these types of risks. In general, this translates to favorable terms and competitive rates for many traditional clinical trials.

However, specific trials remain more difficult to navigate. Their exposure poses a higher risk for insurers, making them more challenging to place. Trials involving cutting-edge technologies, such as gene and cell therapies, or socially sensitive topics like opioid use disorder drugs often present unique challenges in terms of securing adequate coverage.

Leveraging the expertise of a specialized broker with a deep understanding of the market and established carrier relationships can be invaluable in obtaining the necessary coverage.

Ensuring comprehensive coverage from the outset is paramount throughout the clinical trial lifecycle. Compliance considerations make the process more complex, as regulations in certain jurisdictions require separate "admitted" policies. This highlights the need for tailored policies and a granular approach to insurance planning.

Client-centricity is key. A skilled broker should work alongside the insured to recognize the dynamic and geographically diverse nature of clinical trials and create a master program. Furthermore, staying ahead of the curve is crucial. As the industry evolves, brokers should proactively incorporate coverage for emerging risks, such as cyber threats, data breaches, and intellectual property infringement.

Clients can cultivate a resilient and adaptable risk management strategy by partnering with the right broker and insurer. This proactive approach ensures that even in the event of a claim, the crucial progress of clinical trials is not hampered by costly delays or unforeseen disruptions.

Ecosystem of a clinical trial

In addition to the scientific innovation, a successful clinical trial is a complex undertaking involving a dynamic ecosystem of interconnected players and processes. Leaning on industry expert relationships also offers the opportunity to stress-test potential scenarios to see how policies will respond to real-life claims.

Here is a glimpse into this collaborative network:

Key stakeholders

Stakeholders are individuals or organizations interested in conducting a clinical study with the end goal of achieving a commercialized product to improve one's quality of life or provide a lifesaving treatment. This can include volunteers or patients, sponsors, regulatory agencies, clinical research organizations (CROs), healthcare providers, or patient advocacy groups. Every stakeholder has a crucial role in maximizing the trial's effectiveness and making it a success.

Clinical trial process

Clinical trials follow a methodical process from conceptualization the lab to the end, when results are to be published. Here is a step-by-step breakdown of a typical trial process:

1

Conceptualization

This is the initial stage where researchers develop the research question, design the trial protocol, and define the inclusion/exclusion criteria for participants.

2

Review and approval

The protocol undergoes rigorous review by an Institutional Review Board or an Ethics Committee.

3

Participant recruitment

Eligible participants are recruited, and informed consent is obtained, ensuring they understand the risks and benefits.

4

Conducting the trial

Participants are divided into groups, treatments are administered, and the patient's health and response are carefully monitored.

5

Data analysis

Collected data is analyzed to assess the effectiveness and safety of the treatment.

6

Reporting results

A comprehensive report summarizing the study findings is prepared and submitted for peer review.

Timeline

The journey from a novel concept to a new treatment reaching patients through clinical trials is a multi-year endeavor characterized by rigorous stages and meticulous procedures. According to a survey from the Biotechnology Innovation Organization (BIO), it takes nearly 10.53 years on average for a drug to go from conception to regulatory approval. While the exact duration for every trial differs, understanding the typical timeline for each stage can provide an overall picture:

Preclinical research (1–3 years)

This stage lays the groundwork and is used to determine the efficacy of a drug. It involves laboratory research, animal studies, and drug testing in different ways

Phase 1 trials (6 months–2 years)

These initial trials involve small groups, usually between 20–100, of healthy volunteers or very sick patients for whom treatment options are lacking. It is done to assess the safety and basic tolerability of the intervention.

Phase 2 trials (1–3 years)

These trials involve a larger group of patients, usually between 100–300. This phase further evaluates the safety and efficacy of the treatment while exploring different dosage levels or treatment schedules. This phase is the largest hurdle in drug development, with only 28.9%[4] of candidates being able to complete this phase successfully.

Phase 3 trials (3–5 years)

These large-scale trials involve hundreds or even thousands of patients across diverse populations to confirm the effectiveness and compare the intervention to existing treatments or a placebo.

Regulatory review and approval (1–2 years):

After Phase 3 trials are completed, the sponsor submits a new drug application to regulatory agencies for review and to further ensure safety and efficacy before market release.

Post-marketing surveillance:

Even after approval, new drugs are continuously monitored to evaluate their long-term safety and effectiveness in real-world settings.

Finding the right partner to commercialize your product

With the stakes of successful clinical trials ever-increasing and timelines often tightening, it is essential to have the proper insurance program in place. Collaborating with a skilled and experienced broker who comprehends your specific risk profile and can support you, you can concentrate on innovative research with the assurance that your trial is safeguarded throughout every phase.

Gallagher's extensive expertise in the life sciences industry, insurance, and risk management means it is ideally positioned to guide you through this process. For over 40 years we have worked closely insurance programs catering to the specific nuances clinical trial. We ensure our clients have access to comprehensive coverage and are empowered to mitigate potential risks associated with emerging technologies, complex regulations, and geographical considerations.

[1]Cohen, Sandy "The fastest vaccine in history," *UCLA Health,* 10 Dec. 2020

[2]"Clinical Trials Market Global Market Insights," Apr. 2023, PDF file

[3]Thomas, David, "Clinical development success rates and contributing factors 2011–2020," Biotechnology Innovation Organization, PDF file

[4]Thomas, "David, Clinical development success rates and contributing factors 2011–2020," Biotechnology Innovation Organization, PDF file

ABOUT THE AUTHORS

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Amy Sinclair is an accomplished professional with a remarkable track record advising Life Sciences clients on managing exposures while prioritizing client satisfaction. With over 30 years of experience and possessing a keen focus on leadership and developing efficiencies for clinical trials placements, Amy has garnered extensive expertise in negotiating, implementing, and managing comprehensive insurance programs for a wide range of clients in all phases of development, from venture-backed startups to commercialized companies. Amy's specialization lies in areas such as Products Liability, Professional Liability, Directors' & Officers' Liability and Supply Chain, with a particular emphasis on establishing international clinical trials insurance programs. Amy excels in navigating the complex regulations surrounding patient rights in foreign countries, ensuring compliance while effectively protecting her clients' interests. Amy has achieved favorable outcomes for clients with difficult product portfolios, including those with international exposures. Beyond her client-facing responsibilities, Amy actively serves as a mentor to new and younger employees at Gallagher, sharing her knowledge and fostering their professional growth. Her commitment to developing talent within the organization underscores her exceptional leadership qualities and dedication to building a cohesive and high-performing team.

Amy is an esteemed member of influential industry organizations such as the Biotechnology Industry Organization (BIO), the Massachusetts Biotechnology Council (MBC), and the Massachusetts Medical Device Industry Council (MassMEDIC). Additionally, she contributes her expertise as a member of the advisory panels of several insurers specializing in the Life Sciences sector and frequently shares her insights on topics including product liability and domestic and international clinical trials. Amy's outstanding contributions have been recognized within the industry, as evidenced by her inclusion as a "Power Broker" for Life Sciences by Risk & Insurance Magazine. Her expertise, client-focused approach, and exceptional leadership capabilities make her an invaluable asset in guiding Life Sciences clients towards effective risk management solutions while prioritizing their satisfaction.

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Ceiry Fox is an insurance industry professional, working with clients in the technology and life sciences sectors. In her current role as an Area Senior Vice President with Arthur J. Gallagher & Co., she focuses on life sciences companies. Ceiry maintains solid market relationships and has been involved with providing feedback on policy form development for insurers either entering the market or introducing an admitted option to policyholders. She is responsible for executing a variety of projects and initiatives in support of the growth of the Life Sciences Practice. Before joining William Gallagher Associates (WGA) in 2009 (which merged with Gallagher in 2015), Ceiry worked at Marsh, primarily focusing on accessing Casualty exposures for companies that ranged from start-ups to high-profile Risk Management clients. Ceiry earned a B.A. in Business Management with a double minor in International Business and Communications from Bryant College.

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