QBE Insurance

Clinical trials

Life sciences risks vary significantly, and as a leading insurance provider, QBE recognizes the importance of staying informed about the industry's complexities. Through educational resources like this one, QBE aims to empower brokers to ask meaningful questions that address their clients' concerns.

Clinical trials are essential for evaluating new medical treatments and ensuring their safety and efficacy. This checklist guides our broker partners through the clinical trial process, covering study purpose, sponsor roles, patient enrollment, protocol approval, informed consent, and procedural documentation, ensuring compliance and smooth operation of trials.

General questions

- What is the purpose of the clinical trial/study?
- What is the potential client's role?
- What kind of tests and/or treatments are involved?

Sponsor/CRO

- Who is the sponsor?
- Who is running the trial?
- Are there contracts in place governing these relationships?

Study enrollment

- How many subjects are needed for the trial?
- How are patients being sourced?
- Does the study involve a sensitive patient population (i.e., pediatrics or pregnant women)?
- Are the inclusion/exclusion criteria reasonable to meet enrollment needs?
- Will the sponsor provide resources and/or a plan of action for recruitment?

Protocol

- Is there currently an approved study protocol?
- Is the study facility in the U.S.?
- Is the study conducted under the FDA's Investigational New Drug Application?
- Does the study involve a drug, biological or device product that is manufactured in and exported from the U.S. for study outside the U.S.?

Informed consent

- Is the reading level of the Informed Consent appropriate given the patient population?
- Have the Informed Consent forms been approved?
- Is consent documented in video form as well as writing?
- Is there a Consent Revision Log?

Procedures

- IRB documentation
- Complete applications and documentation for review of new protocols
- Are contracts in place outlining expectations of involved entities?

Clinical trials

What is a clinical trial?

- Clinical trials are structured research studies involving human participants aimed at assessing new medical interventions including drugs, cells and other biological products, surgical and radiological procedures, treatments, devices and preventive care.
- Their main purpose is to test potential treatments in human volunteers to see whether they should be approved for wider use in the general population and to evaluate the safety and efficacy of new drugs, devices, and treatments for patients.
- They are not always required to bring a product to market.

Government agencies involved

- **Federal Drug Administration (FDA)** oversees the approval processes for new drugs and treatments and ensures trials are conducted ethically.
- **National Institutes of Health (NIH)** supports clinical research through funding and oversight. It plays a vital role in advancing medical knowledge and developing new treatment.
- **Centers for Disease Control (CDC)** engages in clinical trials primarily related to public health issues. It works to implement and evaluate interventions designed to improve community health outcomes.
- **European Medicines Agency (EMA)** is involved in harmonizing clinical trials processes throughout the EU. Clinical trials are authorized at a national level and the Committee for Medicinal Products for Human Use (CHMP) is responsible for assessing the clinical trial data after an EU-wide marketing authorization is made.

Clinical trial phases

- Phase I tests safety and dosage.
- Phase II evaluates effectiveness and monitors for side effects.
- Phase III compares the new intervention to existing treatments and trial is on a larger population.
- Phase IV occurs after approval to monitor long-term effects.

Regulations & guidelines

- **Institutional Review Boards (IRBs)** ensure that trials meet ethical standards and regulatory requirements and monitor clinical trials to safeguard the rights and welfare of participants.
- **Good Clinical Practices (GCP)** guidelines are international ethical and scientific quality standards for designing, conducting and reporting clinical trials, ensuring participant safety and data integrity.
- **Current Goods Manufacturing Practices (cGMP)** are a set of regulations established by the FDA to ensure the quality, safety, and efficacy of products manufactured for human and animal use. They apply to a wide range of products, including drugs, biologics, medical devices, food, and dietary supplements.
- Informed consent is necessary and vital for protecting participant rights.

Building on our extensive industry knowledge, the QBE Life Sciences team specializes in offering customized insurance solutions that address the distinct risks and challenges associated with clinical trials and other life sciences activities. We take pride in providing a wide range of comprehensive coverage options across the life sciences sector.

We understand the importance of safeguarding your endeavors, and our products are crafted to provide peace of mind as you navigate the complexities of the industry.

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