PHARPOINT RESEARCH

BEST PRACTICES:

Conducting Critical Care Clinical Trials

Introduction

Critical care trials are complex and fast paced, typically with high mortality rates, high patient diversity, and unpredictability. Clinical research in the critical care setting also involves numerous ethical and regulatory requirements, especially as severely ill patients may be unable to consent.

Planning, executing, managing, and analyzing critical care trials requires a nimble and experienced team.

Site Selection, Enrollment, & Recruitment

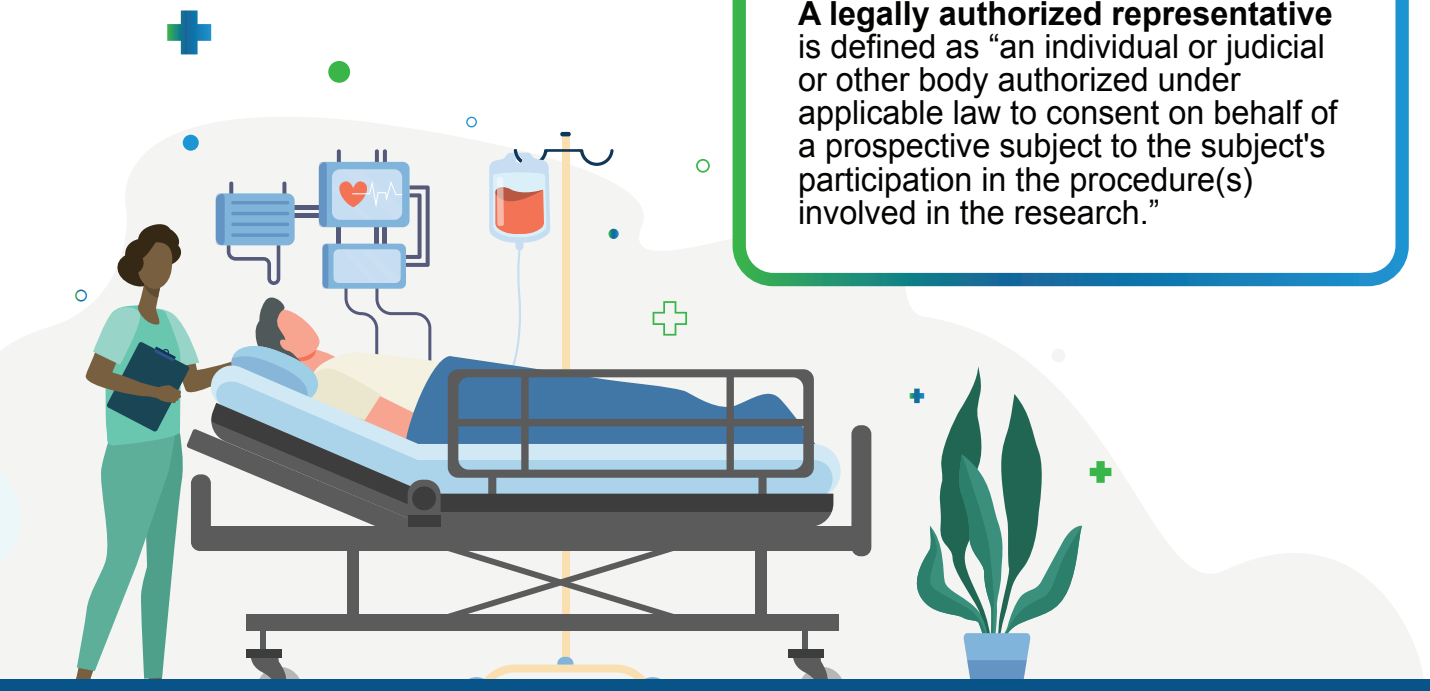
The policies and procedures for conducting trials in critical care environments must be closely analyzed prior to bringing on any sites. Critical care patients often require fast decision-making, and there can be no surprises when it comes to physician collaboration/unit processes.

Additionally, it's important to ensure every site has their own internal process in place for obtaining informed consent from legally authorized representatives (LARs).

Predicting enrollment rates in critical care trials is especially difficult, as it's hard to determine which kind of patients may arrive at sites. Principal Investigators (PIs) drive recruitment within critical care. Good experience and a positive working relationship with these investigators is essential to keeping a study top of mind at the site level.

21 CFR 50.3(l)

A legally authorized representative is defined as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."



Training

The rate of misdiagnoses within the fast-paced critical care environment may be estimated at somewhere between 10-12%. This may have an impact on enrollment rates, and additional precautions may be taken to mitigate the risk of misdiagnosis.

This may include an emphasis on thorough training for site staff along with an evaluation of site protocol during the selection process to learn how definitive diagnoses are determined.

Obtaining Informed Consent

The process of obtaining informed consent in a critical care trial often looks different than other areas due to the nature of subjects involved. In some instances, subjects may be incapable of providing their consent personally if they are unconscious or otherwise incapacitated (which in critical care, they often are).

In these situations, subjects may be enrolled with the consent of the LAR, which is typically a guardian, family member, or spouse. In the United States, individual state laws must be taken into consideration to ensure all requirements for surrogate consent are followed at each site.

In all research, informed consent is an ongoing process, and applicable criteria triggers re-consenting a subject.

Site Management and Monitoring

Studies which target hospitalized subjects are more challenging to monitor, and CRAs for these studies must possess the right skills for the job. This includes a strong knowledge of medical terminology and familiarity with pharmacology and critical care nursing. Medical records can be very complex and dense, and adequate time must be planned to properly review records.

Additionally, it's important that study teams can facilitate communication between site staff and the study's medical monitor. Patient care is 24/7, and questions may arise during non-business hours. A medical monitor, either provided by the Sponsor or through the use of a third party such as a CRO, must be on call 24/7.

CASE STUDY

Thrombosis in Critical Care

In this full service, Phase 1 rescue, the PharPoint team took over a neonatal cardiovascular study from an underperforming CRO.

Our team recreated 7+ study plans and an additional 20+ site documents, allowing the study to get back on track and successful enroll 22 patients aged 1-28 days old.

STUDY DETAILS:

- Patient population required continuous critical care support
- Study required partnership with Investigators/Institutions to identify potential subjects
- Very short, time sensitive screening windows required strict schedule adherence
- Multi-stage consent process involved parents and legally authorized represenatives

KEY TAKEAWAYS:

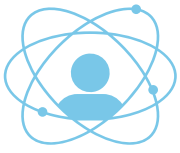
- Met enrollment goals
- Supported DMC/Safety Review
- Completed monitoring in complex critical care environment

PharPoint Research is a full-service CRO with the right experience to successfully support a critical care trial.

PharPoint's **on-team MD** has experience within critical care

Team focuses on a predictive study startup, ensuring **study processes and logistics are clear** and all study partners are equipped to handle potential challenges

Positive working relationships with site staff **keep your study top-of-mind**



Monitors have **strong knowledge** of medical terminology and familiarity with pharmacology and critical care nursing

Industry-leading biometrics timelines, so Sponsors **get results 31 days faster**

Learn more about how PharPoint can support your upcoming study.

PharPoint Research is an award-winning and client-focused contract research organization (CRO) that offers clinical operations, data management, biostatistics, statistical programming, and strategic clinical trial consulting services to clients of all sizes.

Founded in 2007, PharPoint's team has participated in over 1,000 clinical trials with a high business repeat rate.

Speak with our team: pharpoint.com/contact