Starship
Clinical Research Practitioner

RESEARCH support hub staff are here to help investigators with the identification of relevant resources, connect with experts, and understand processes and best practices for performing research at Starship.

General

The role of the Clinical Research Practitioner is to support researchers in the delivery of their projects through a research operations study support service. The post-holder will support the existing research team in the successful delivery of commercial and academic (investigator led) studies.

The post holder will be responsible for supporting Principal Investigators and their research teams in approaching potential participants and taking informed consent, collecting data and managing the study site file. The post holder will work closely with industry in supporting site visits and monitoring visits. The postholder may be required to engage with clinical aspects of the study that may include phlebotomy, processing/analysis of blood specimens, and clinical observation.

The role requires close liaison with the MDT care teams, data managers, pharmaceutical companies, academic research teams, principal investigators, research department and people accessing care services and their family members.

The post holder will also identify barriers to recruitment and research delivery escalating where necessary to the Starship Research and Innovation Manager.

The post holder working as part of the research operation support hub will:

- Promote equality of access, ensuring that wherever possible, patients have an opportunity to participate in research
- Improve the quality, speed and co-ordination of clinical research by removing barriers to initiation and recruitment
- Work to streamline administrative procedures associated with regulatory approvals and governance
- Meet the research delivery needs of the life sciences industry including pharmaceutical, biotechnology, diagnostic, medical technology and contract research organisations
- Further integrate health research and patient care

Research:

To contribute to the management and administration of the local portfolio of research studies ensuring that research study protocols are adhered to and site files are accurately maintained

To ensure that you and the research delivery team are working in accordance with the Medicines for Human use (Clinical Trials) Regulations 2004, the Principles of GCP, information governance requirements, and other local policies and procedures as applicable for the conduct of research

Build relationships and liaise with relevant care professionals to promote study participation and to identify patients/participants eligible to enter research studies

Facilitate or undertake the informed consent of a participant (appropriate to age and level of understanding) during the recruitment process in accordance with the principles of GCP, ethical and legal requirements

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Evaluate patient/participant eligibility for research study entry in liaison with clinical colleagues, co-ordinating pre-study tests, obtaining results and arranging appropriate appointments according to the study protocol

Ensure patients are randomised and allocated treatment in accordance with the clinical trial protocol

Identify barriers to recruitment into research studies and problem solve or escalate as applicable in a timely manner

Responsible for timely, complete and accurate data recording in patients' medical or participant notes, requesting and tracking the notes, and accurately recording data from the notes into the study case report form (CRF)

Ensure that the Trial Master File (TMF)/ Investigator Site File (ISF) is appropriately maintained and available for monitoring, inspection and audit. And to partake in monitoring visits and audit inspections arranged on behalf of the study Sponsor or care organisation as required

Ensure that clinical trial screening and recruitment records are accurately maintained, and site delegation logs are complete

Responsibility for ascertaining from patients/participants whether adverse or serious or serious adverse events have occurred and reporting these appropriately as part of the risk management process for Research Governance

Responsible for forwarding research data in a timely manner to the trial co-ordinating centre, CRO or Sponsor, including providing responses to data queries as stipulated in the study protocol/ethics application and in line with information governance

To supply study progress data/information as required to the senior management team
To attend meetings relevant to the nature of the job

Administration:

Assist in the governance and approvals process for the initial study documentation and subsequent protocol amendments, acting as a facilitator for study teams

Ensure that study information management records are accurately maintained and complete

Input data into the EDGE clinical trials data management database

Ensure that research study documents are effectively archived as required

Lead on or actively support the set-up of studies at site, site selection visit attendance