The Positive Impact of a Study Coordinator to Streamline Research Delivery

Situation

The study coordinator position was created with the formation of the Clinical Research Facility's Infectious Disease research team. The COVID-19 pandemic highlighted the need for faster implementation of complex studies, and the coordinator was to support their smooth operation.

Prior to the creation of the role, studies within the Clinical Research Facility were primarily led by nursing staff with support from Trial Administrators. In a shift of responsibility, the Coordinator would be expected to take ownership of the studies they are allocated.

Originally the Study Coordinator was responsible for the ENSEMBLE-2 study, including:

- Managing supplies, kits and IMP
- Management of documents, logs and the Investigator Site File
- Data entry and handling of data queries
- Liaising with Clinical Research Associates and Central data managers
- Handling updates and queries from participants
- Working to ensure delegated staff meet mandatory training compliance
- Coordinating and assisting with study visits and the reconsenting of participants

The role has recently expanded to include the non-clinical elements of the Rapid Protection Study:

- Producing and managing study logs
- Coordinating study visits and ensuring suitable staffing
- Working closely with the study sponsor and research team to ensure the study's delivery.

The role is expected to expand and develop over time, with further studies planned.

The Role

A study coordinator is integrated into a research team, and is responsible for coordinating a small number of studies throughout their life cycle. They will likely be the primary liaison to the principal investigator, Sponsor/Clinical Research Associate, clinical staff and participants.

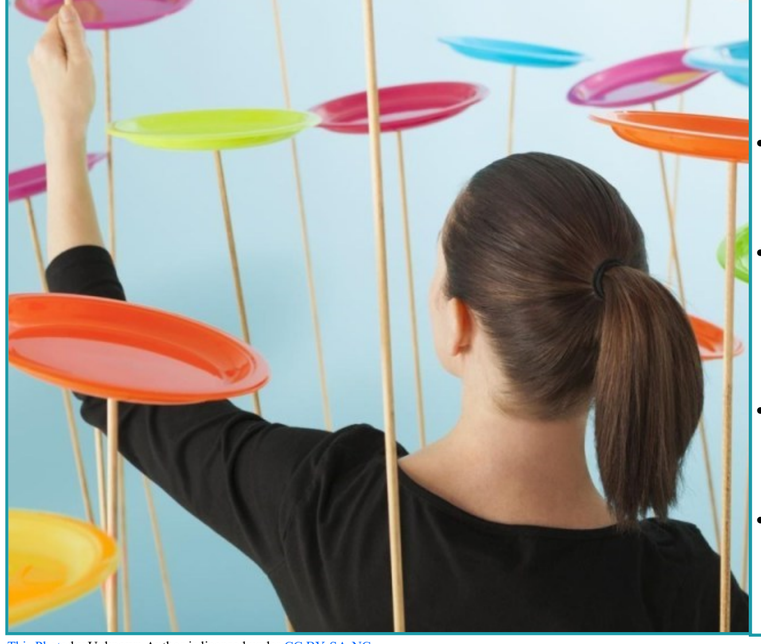
The coordinator will closely monitor the study, relaying updates to the research team when appropriate, and acting as a resource on the particulars of the study. They will ensure that the study progresses on site, handling issues and queries as they arise and delegating tasks to the research nurses as appropriate. The role will vary considerably day to day, and includes the responsibilities held by Trial Administrators.

The role is predominantly non-clinical, although the development of the role has led to some clinical duties such as re-consenting participants, liaising face to face with participants to discuss study interventions and future visits.

Skills Required

- Experience of working in a healthcare environment
- An strong understanding of research and a clinical trial's life cycle.
- Good general IT skills, particularly MS office suite
- Adaptability, working flexibly according to the needs of the role
- Attention to detail and ability to concentrate for prolonged periods
- An understanding of medical terminology and the ability to manage complex information.
- Organisation and time management skills
- A pro-active approach, acting on ones own initiative to identify tasks, opportunities and solutions
- Effective and tactful communication with a range of people, including healthcare providers, research participants and the public

Benefits to the Research Team



- A Study Coordinator takes much of the burden of managing a study from the Research Nurses, allowing them to focus on recruitment and clinical responsibilities.
- Close oversight of complex studies reduces the risk that important events will be missed.
- The role of study coordinator provides an opportunity for career progression for administrative staff, potentially improving staff retention.
- An individual dedicated to resolving any issues that arise
- A source of administrative and technical support and guidance to the research team

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