(Sr) TRIAL SET-UP MANAGER

WHO WE ARE

Cerba Research provides the highest quality specialized laboratory and diagnostic solutions while leveraging patient data and scientific insight to shape and advance clinical trials. With our global footprint and access to leading regional labs, data, patients, technology, and partnered resources, we support global biotech, pharma, and IVD organizations to improve the lives of patients around the world.

From the translation of preclinical to clinical, through commercialization, our expert scientists collaborate with you to optimize your therapeutic development and obtain critical insights earlier. We help accelerate your therapies through the development of highly specialized custom assays, deep biomarker expertise, and a passion for scientific innovation across complex therapeutic areas. Our global network of leading, specialty laboratories ensures you have access to quality data and can reach your patients. Together, we’ll improve patients’ lives around the globe.

WHO YOU ARE

The (Sr) Trial Setup Manager performs day-to-day operational tasks during the setup of a trial.

RESPONSIBILITIES

- Documentation of the complete setup in a Trial Master File part Set-Up (creation, maintenance and archiving)
- Preparation of sponsor study documentation:
  - Preparation of the Laboratory Specifications, describing the services foreseen in a specific project, based on the Trial Notification Form, clinical study protocol, study budget and communication with the sponsor
  - Preparation of Central Laboratory Study Documentation
- Preparation of site study documentation:
  - Preparation of Central Laboratory manuals and the English instruction leaflet
  - Coordinate the translation of leaflets if required
  - Preparation of the study specific requisition forms
• Preparation of other site documentation (e.g., Sampling Material Request form, Request for dry ice form, Sample log form)
• Upload of site study documentation on Cerba Trova

• Preparation of internal study documentation:
  • Local trial set-up (NWHL, Cerba, Histalim, subcontracted labs, ...)  
  • Preparation of the internal study start-up document to provide all departments with trial specific directives as established in agreement with the sponsor (MIPS trials only)

• Technical preparation of the study database:
  • Follow-up on test code creation in Master Test Catalogue
  • Initiation and finalization of study-specific reference ranges
  • Preparation of CTMS Study Set-up configuration

• Perform other tasks deemed necessary to assure good quality work according to standard operating procedures and agreements made with the sponsors

Only applicable for Sr. TSM role
• Cross-review (upper layer QC) sponsor/site/internal study documentation and technical database
• Mentor and training of new employees
• Assist in making sure Standard Operation Procedures, process flows, and templates are in place to achieve local and global transparency and quality
• CTMS set-up superuser (assist in change and issue management, UAT and training of users)

QUALIFICATIONS
• Bachelor’s degree (office management/medical or science oriented)
• Accurate administrator
• Flexible in dealing with problems (related to e.g. project scope or deadlines)
• Good communication skills
• Thorough knowledge of standard computer and office applications
• Fluent in Dutch and English, notions French

CONTACT
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