Celyad is looking for a **Clinical Data Manager (M/F)**. The successful candidate will be based in Belgium and will report into the Head of Clinical Operations.

Role:

The Clinical Data Manager:

- is responsible for leading all aspects of the global clinical study data management process from start-up to database lock and regulatory submission support.
- ensures that clean and valid clinical study data are used for deliveries to Clinical Development and Medical Affairs team.
- works in **crossed partnerships and in transversality** with the Contract Research Organizations (CRO), other external vendors, and the Clinical Development & Operations and Medical Affairs team members to define and implement data management requirements.

Responsibilities:

- Functional Lead on project and program teams including multi-disciplinary interactions by participating in/leading project meetings to ensure clear overview of progress, risks and mitigation strategies by all participants for all data management related deliverables.
- **Leading the development** of Case Report Forms (CRFs) in coordination with all team members and ensure **consistency** across all studies.
- CRO oversight:
    - **Responsible of the review and approval** of all essential data management documents developed by the CROs, including but not limited to: Data Management Plans, CRF and Electronic Data Capture (EDC) Specifications, CRF Completion Guidelines, Data Review Plans, and External Data Handling Specifications (data transfers and reconciliations).
    - Perform User Acceptance Tests (UAT) of EDC systems.
    - Ensure that clinical databases and external data files are designed in a consistent format to produce datasets that are conducive to analysis.
    - Surveillance of CRO and third-party vendor activities regarding the quality and timeliness of the deliverables.
    - Ensure that databases are ready for lock.
- **Lead DM budget reviews:**
    - provide justification for and perform direct negotiations with CROs and third-party vendors for data management activities.
    - **Endorse DM section of final budgets**.
- Observe and recommend opportunities for improvement and optimization of all DM processes.
- Provide feedback on draft protocols, CSRs, SAPs, and other documents as required.
- **Design, program, and generate** standard and custom-built listings and reports for medical reviews, data cleaning, and data analyses and dissemination (e.g. EDC data cleaning and monitoring dashboards, reports to authorities and steering committees, conference posters).

- **TREP Database Oversight: elaborate internal storage options** for the handling of correlative analyses data. **Lead and participate in the design, development, and maintenance** of the TREP database.
- Maintain all data management internal files, ensuring preparedness for regulatory inspections.
- Responsible for tracking individual project tasks and overall data management timelines.
- Develop and maintain data management SOP's and related control documentation.

Qualifications & Experience

- A minimum of Bachelor's degree or equivalent in a health-related field preferred.
- 7+ years' experience in clinical data management in the pharmaceutical/biotechnology industry covering early phase oncology trials.
- Proven experience managing efficiently third-party vendors.
- Extensive experience in eCRF design, especially for Oncology trials.
- Extensive experience with clinical data collection, cleaning and analysis.
- In depth knowledge of at least one EDC system, preferably Medidata Rave.
- Good understanding of medical terminology.
- Good understanding of ICH and regulatory environment as it pertains to data management.
- Experience with SDTM/C-DASH is desirable.
- Good knowledge of SAS programming is an asset.

Skills & Competencies

- Outstanding written and verbal communication skills, including excellent attention to details.
- Good team player, used to working in multifunctional environments. The ability to build and maintain excellent working relations at all levels with a high regard for honesty, integrity, and professional ethics.
- The ability to take the initiative and work autonomously on selected topics.
- Proven ability to manage complex projects and to organize heavy workloads effectively.
- Flexibility to re-prioritize workload to meet changing timelines, adaptability.
- Ability to work in cross-functional team-oriented environments.

For more information about this position or about the Company, please contact us by email at **job@celyad.com**

About Celyad Oncology

Celyad Oncology is a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer. The Company is developing a pipeline of allogeneic (off-the-shelf) and autologous (personalized) CAR T cell therapy candidates for the treatment of both hematological malignancies and solid tumors. Celyad Oncology was founded in 2007 and is based in Mont-Saint-Guibert, Belgium and New York, NY. The Company has received funding from the Walloon Region (Belgium) to support the advancement of its CAR T cell therapy programs. For more information, please visit **www.celyad.com**.