UNIVERSITÄT BERN

# Central Data Monitor

60 – 80 %

CTU Bern is the clinical trials unit of the Faculty of Medicine of the University of Bern and works closely with the affiliated university hospital. It functions as a service unit to support and coordinate investigator-initiated clinical studies in any clinical field.

As Central Data Monitor at CTU Bern, you will be part of the Monitoring & Regulatory Affairs division. The purpose of central data monitoring is to ensure that the data entered in the study databases meets the highest quality standards, and that the study is run in compliance with the approved protocol, the principles of Good Clinical Practice (GCP), and the governing laws and regulations. To achieve this, centralized checks of accumulating data are performed regularly throughout the duration of the study, and the identified issues will be communicated to the study personnel and followed-up until resolution. In this position, you will collaborate closely with the Statistics & Methodology and Data Management divisions at CTU Bern. Furthermore, you will be working with clinical researchers and study personnel of collaborating institutions and external partners.

**Duties and responsibilities**

- Responsible for all data review activities of the assigned studies
- Planning of the central data monitoring activities for clinical trials and observational studies, including the creation of supporting documents, such as the central data monitoring plan
- Liaise with the data management and the statistics divisions to define the checks required for the conduct of central data monitoring, and ensure that data discrepancy reports are programmed by the Data management/Statistics divisions
- Perform ongoing data validation, including checks for completeness, plausibility, and consistency, and raise queries as required in the study database
- Monitor the data regularly for identification of data trends across study sites, protocol and reporting incompliance, and other risks occurring during study conduct, and report the identified issues to the study sponsor and all stakeholders in a timely manner
- Regularly report the progress of central data monitoring, issues or risks identified, and recommendations for corrective actions to the Sponsor
- Participation in GCP-teaching courses for clinical research professionals

**Qualifications and skills**

- University degree (minimum Masters degree, M.Sc) in life sciences or a related field
- Interest in handling, understanding, and interpreting clinical trial data
- Experience in performing central data monitoring activities would be an asset
- Experience with Clinical Trial Management Systems (CTMS) or in IT would be an asset
- Good knowledge of GCP rules
- Good knowledge of MS Word and Excel. Basic knowledge of STATA is an asset, but not a must
- Attention to detail, quality, and record keeping
- High sense of responsibility, very good organizational skills, and willingness to learn
- Excellent communication skills. Fluency in English (written and oral) is a must, German and French would be an asset
- Ability to work cooperatively in a team as well as independently

We are offering an interesting position with diverse activities in a growing clinical trials unit with the chance to contribute to the successful further development of CTU Bern. CTU Bern is dedicated to high quality research. It provides a multicultural international academic environment and operates with interdisciplinary teams.
Salary depends on qualification and experience and the salary scale of the cantonal administration of Bern.

We are looking to have the successful candidate in place on **01.01.2021** or as negotiated.
If you need further information on the post, you can contact Dr. Felix Rintelen, Head of the Monitoring & Regulatory Affairs Division: Tel: +41 31 631 59 17, felix.rintelen@ctu.unibe.ch

If you are looking for an exciting position in a highly motivated team please send your CV with motivation letter to Andrea Flükiger: hr@ctu.unibe.ch