CTC

CLINICAL TRIALS CENTRE

Clinical Trials Centre (CTC) is an expert team of the national research infrastructure CZECRIN. It provides comprehensive and partial services, including consultation and training, to implement academic/non-commercial clinical studies and research in drugs, diagnostic methods, and medical devices following Czech legislation and good clinical practice (GCP).

The CTC expert team has extensive experience with clinical trials in many therapeutic areas and offers free assistance and collaboration in the following activities as part of "open access":

Contracting and project management of the study:

- Taking over the role of the contracting authority and ensuring the associated legislative obligations
- Professional management and coordination of the clinical trial/project, ensuring all key points necessary for the smooth running of the clinical trial, including meeting deadlines, budget and addressing critical points occurring from the beginning of the clinical trial to its completion
- Establishing and maintaining up-to-date study documentation (Trial Master File – TMF)

Preparation of study documentation and services Medical writer/Medical consultant:

- Design or complete preparation of documents according to the requirements of the State Institute for Drug Control (SÚKL) and Ethical Commissions (EC) required for the implementation of the study
- Creation or revision of a clinical trial protocol, informed consent, investigational medicinal product dossier

Study processing at the Regulatory Authority (SÚKL) and the Ethics Committee:

- Submission of documents necessary for the clinical trial approval to SÚKL and the EC for the approval process, communication with SÚKL and the EC for the approval process, communication with SÚKL and the EC in case of comments on the submitted documentation
- Submission of substantial/non-essential amendments to the protocol, ICF and other documents during KH, submission of an annual report on the course of KH and a development safety report

Data management and Biostatistics:

- Expertise in the field of planning and design of clinical trials, calculation of patient sample size
- Creation and consultation of a statistical plan and implementation of statistical data processing
- Design and creation of electronic forms for data collection (eCRF), system validation, patient randomization, data query, database, closure

Pharmacovigilance:

- Expertise in a local pharmacovigilance
- Setting up processes for the correct reporting and monitoring of adverse events
- Active involvement in pharmacovigilance processes

Monitoring

(Not included in the free open access services. To cover the costs, we will provide activities related to the supervision of the clinical trial):

- Creating a clinical study monitoring plan
- Ensuring the monitoring of the study – an initial visit to the centre, continuous monitoring of the study and

Consulting and advisory activities

- Quality control and assurance:
  - Creating your quality assurance and control system using standard operating procedures
- Legislation:
  - Legal aspects and regulation of clinical research
  - Liability insurance
  - The contractual provision of a clinical study
  - Documentation required for the application for authorization/notification of a clinical study for regulatory authorities and ethics committees
- Ethical aspects:
  - Ethics of clinical research
  - Compilation of informed consents including involvement of vulnerable subjects (children including new-borns, unconscious patients, psychiatric patients)
- Involvement of foreign centres:
  - Legislative requirements for the implementation of an international clinical study
  - Cooperation with a transnational consortium of pan-European importance within the European Consortium for Research infrastructure ECRIN-ERIC
- Financing:
  - o Identification of available national and international financial resources available to cover the costs of academic/non-commercial clinical research

Educational activity

- Implementation of conferences and seminars with internal and external experts
- Preparation of a training course according to individual requirements

CZECRIN is a key national functional infrastructure facilitating academic clinical research in the Czech Republic. CZECRIN as a national node of the European infrastructure ECRIN-ERIC represents also direct connection with European Research Area, which is crucial for development of the Czech clinical research for the benefit of global public health. CZECRIN has a unique network covering major clinical sites and provides the knowledge, development, production and implementation capacities in the field of medical sciences. Sets the quality of processes and data based on the application of FAIR principles. CZECRIN is also a center for education in the field of clinical trials.

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