CLINICAL RESEARCH AND ACADEMIC CLINICAL TRIALS

MASARYK MEMORIAL CANCER INSTITUTE
DEPARTMENT OF PHARMACOLOGY, FACULTY OF MEDICINE

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Clinical Research Topics: Onco-pharmacology

- **Personalised Clinical Trials** – Stratified Precision Medicine in Oncology
- **Pharmacogenetics, PK/PD modelling of Tki**
- **ATMPs** – development of Personalised Therapeutic Vaccine (GMP lab)
  - Phase I Academic Clinical Trials : EudraCT:2014-003388-39
  - COMBINED ANTITUMOR THERAPY WITH EX VIVO MANIPULATED DENDRITIC CELLS PRODUCING INTERLEUKIN-12 IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH PROGRESSIVE, RECURRENT OR PRIMARILY METASTATIC HIGH-RISK TUMOR
- **Drug-repurposing**
  - Phase I Academic Clinical Trials : EudraCT number 2016-001386-81
  - PHASE II OPEN LABELED TRIAL OF DISULFIRAM WITH COPPER IN METASTATIC BREAST CANCERS)
- **Pediatric Oncology**

CEPOETA

EnprEMA
European network of paediatric research at the European Medicines Agency

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

CZECRIN
CZECH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

The biggest challenges of carrying out academic clinical studies

- Growing **administrative burden** and requirements
  - Increasing demand on skilled and experienced team
- No systematic **funding** for academic trials on national level
  - Not allowing to hire CRO or pay External specialists
- „Different view“ of academic investigators – **national differences**
- Need for **Innovative Clinical Trial Design**
  - **Adaptive Trial Design**
  - **Basket/Umbrella Trials in Oncology**
  - **N- of-1 clinical trials…**

Need for training of regulatory guidelines and processes

- Systematic support of basic trainings to adequately prepare new specialist in CT RA/PhV
  - Basic introductory course – support of local activities, content, available speakers, financial support
  - Basic knowledge about current technical/IT solutions
- Special advanced courses
- Regulatory GCP trainings
- Training in CT Ethics
  - Different approach in members states in practice (ethic committees, etc.)

Training in regulatory science available/attended

- Regular seminars/ trainings organized by **Local RA (SUKL)**
- **Commercial** trainings and courses – mainly available for industry (high price)
- **CZECRIN** – limited capacity of trainings
- **PharmAround**, endowment fund – basic trainings, limited capacity
  - Phases of Drug Life- Cycle – special parts for discovery, pre-clinical, clinical trials, registration, translational research – with regulatory aspects as well
  - Education and knowledge sharing of CT personnel – annual conference, annual National Clinical trials day – different regulatory topics for academia
- **PhD in Regulatory Science – Masaryk University** – since 2019

Experiences on dealing with national RA authorities

- Wide **long-term cooperation** with local RA (State Institute of Drug Control)
- **Scientific Advice** available – no fee for academia
- CTA – **CZECRIN as a part of training** activities for EMA Database
- GCP – consultation, workshops, seminars available for academic centers
- **Well established cooperation on national level**