CHDR – Oncology

The rapidly changing field and the increasing complexity of early phase clinical trials in oncology call for an expert approach. CHDR together with its partners moves your drug development program for oncologic diseases forward into the clinical phase.

For oncology, our unique approach in early phase drug development includes comprehensive packages for FIH/Phase I-IIa clinical trials and specific methodology, which will facilitate the rapid and efficient translation of novel compounds into the clinic. We operate at the interface of industry and academia, and closely work with your teams facilitating the design of a tailor-made, value-based study for the unique properties of your therapeutic approach.

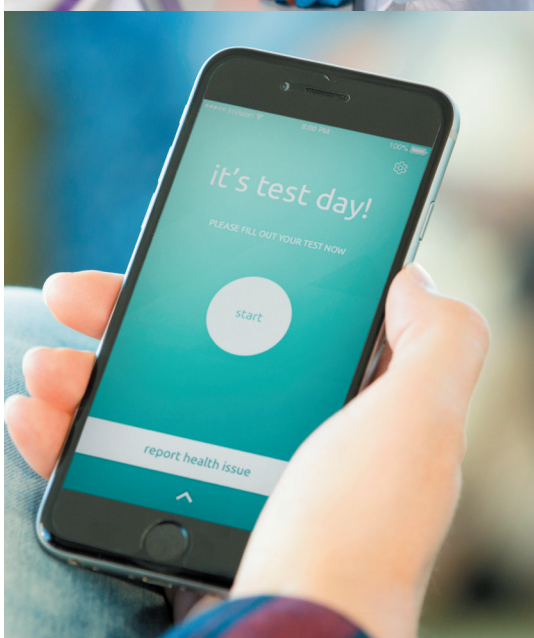
Early phase clinical trials (FIH, Phases I-IIa)

- Clinical trials within the wide indication spectrum of oncology, including medical and hematological oncology, as well as specific niche indications, such as ocular oncology.
- In multicenter trials within our collaborative hospital networks.
- Rapid feasibility, efficient start-up and trial execution process conducted by a specialized early phase clinical team.
- Specific focus on small molecule-based targeted and immunological compounds.
- Novel trial designs with integrative protocols for healthy volunteers and cancer patients and applying CHDR's unique Monocentre™ Approach.

Biomarker and trial methodology

- ✓ Biomarkers, including tumor markers, cell-based assays, assessment in special compartments (bone marrow, CSF) and on-demand biomarker discovery.
- ✓ Imaging techniques for disease and drug effects: ultrasonography, endoscopic and radiologic imaging (CT, MRI, PET) as well as microscopy.
- ✓ CHDR Cardiology Services® offers an array of cardiac electrophysiology services, including comprehensive QT analyses and functional assays to assess the drug effect on cardiac rhythm and/or function, including cardiotoxicity assessment.
- ✓ Trial@Home: a platform using a combination of electronic patient-reported outcomes (ePRO), biometric data from wearables and smartphone usage data for remote monitoring of cancer patients in clinical trials and development of novel digital biomarkers.
- ✓ Image-guided surgery is an emerging multidisciplinary technique for improving cancer diagnostics and the success of surgical treatment of cancer.

CHDR
Centre for Human Drug Research



Why choose CHDR?

The Centre for Human Drug Research specialises in early-phase clinical drug research. CHDR's overall mission is to improve the drug development process by collecting as much information as possible regarding the candidate drug in the early phases of development. This information helps sponsors make informed decisions regarding the course of clinical development for their product.

Research at CHDR covers a wide range of fields, including the central nervous system (CNS) and pain, the cardiovascular system, haemostasis, immunology, oncology and dermatology. In addition, CHDR is at the forefront in developing novel biomarkers and methods for measuring drug-related effects in all of these research areas.

Pharmacology matters

Whether studying a new cognitive-enhancing drug, a next-generation painkiller, a new monoclonal antibody, or a targeted molecular therapy, the goal is to determine how the compound's effects correlate with both the dose and blood concentration at any given moment. In addition, understanding which biological systems are activated is an essential first step towards quantifying this relationship. At CHDR, our focus on pharmacology is reflected clearly in what we call question-based drug development.

Question-based drug development

CHDR actively uses question-based drug development - or QBD - as a more rational approach to drug development compared to conventional approaches. QBD can be best described as a series of questions that are addressed throughout the process. These questions often seem simple enough, but failing to answer even one question - or even addressing the questions in the wrong order - can have dire consequences. Thus, using this approach can potentially save companies millions of dollars by helping predict a catastrophic issue early in the development process, before the more expensive latter stages (for example, large-scale clinical trials or the marketing phase).

From a general perspective, the most important questions are:

1. Does the biologically active compound and/or active metabolite(s) reach the intended site of action?
2. Does the compound cause its intended pharmacological and/or functional effect(s)?
3. Does the compound cause any unintended pharmacological and/or functional effect(s)?
4. Does the compound have a beneficial effect on the disease and/or clinical pathophysiology?
5. What is the compound's therapeutic window?
6. How does any variability with respect to the drug response in the target population affect the product's development?

Contact us

To learn about CHDR's full range of services, contact us today.

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