CHDR
Centre for Human Drug Research

# Data Management Services


# Data Management Services

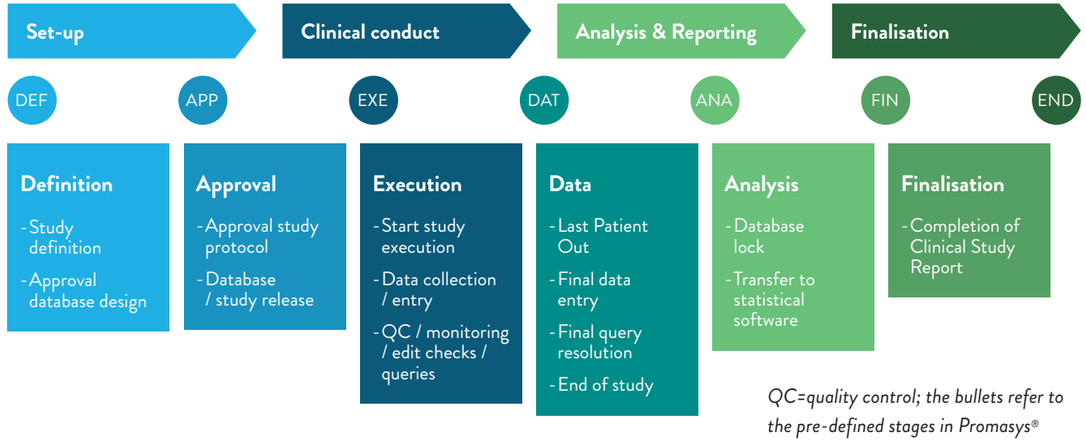
**With three decades of experience in innovative, early-stage clinical drug research, our data management service is known for excellent planning and organisation. Our data managers engage seamlessly with both internal and external operational teams from the start of a study until database lock, ensuring timely, high quality deliverables.**

## Data Management Plan

A Data Management Plan (DMP) forms the starting point for every CHDR study. The DMP provides an overview of data-related requirements and activities used in a study, thereby ensuring the blinding, accuracy, integrity, consistency, reliability, and completeness of the data collected. Data programmers, data officers, project leaders and sponsors co-ordinate to create and execute a DMP that is in accordance with ICH-GCP.

## Study Life Cycle

We use the Study Life Cycle, a structure that embodies the various stages of phase I/II studies, as a blueprint for our data management services (figure 1). From set-up to clinical conduct, through analysis and reporting to finalisation, each stage is paralleled by the pre-defined study phases in our clinical data management system.




*QC=quality control; the bullets refer to the pre-defined stages in Promasys®*

Figure 1: The Study Life Cycle paralleled by pre-defined study phases in Promasys®

## Data Validation and Discrepancy Management

Our data managers ensure clean, consistent and unambiguous data by following a stringent data validation and discrepancy management strategy, outlined in a Data Management Plan. Programmed checks and live feedback mechanisms in our database help to ensure adequate completion of data.

## Safe and certified

We strive to uphold the pillars of Good Clinical Practice (GDP): database quality, standardisation and integrity. Along with being GCP compliant, our services abide by the Dutch GDPR Implementation Act and European regulations. Data is protected by our secure backup system that includes incremental and full backups, with zero downtime. Our team includes certified medical coders who can encode your data to the applicable dictionaries (e.g. MedDRA, WHO Drug / WHO-DDE, WHOCC). Maintaining these standards across all our work ensures that collaboration runs as smoothly and efficiently as possible, optimising the Study Life Cycle.

## Well-structured

Our standard is well-structured, clean and consistent data that is perfectly presented to support the claims in your Clinical Study Report. CHDR's own Standard Operation Procedures (SOPs) lead throughout the execution of the study, unless otherwise agreed. We encourage the sharing of structured data across different information systems through the implementation of data exchange standards (e.g. CDISC).

## Customised

Our data management service aims to provide clients with customised data management solutions for clinical trials. Our clinical data managers are all-rounders: with medical and life science backgrounds as well as targeted clinical data management experience, they communicate effectively with all kinds of professionals in the field of early drug development.

## State of the art

We understand the importance of accurate, timely data management for clinical trials. To achieve this, we seek to leverage the best that recent technologies have to offer. We work with different industry-leading database software providers. Promasys® is our clinical data management system and is (CDMS) validated with IQ/OQ/PQ in accordance with GAMP 5 and compliant with 21 CFR part 11. Promasys® not only allows direct bedside data entry using iPads, but also connects to various information systems, such as the MUSE™ Cardiology Information System for integrating, managing, and streamlining the flow of cardiac information.

## Innovative

We are passionate about breaking new ground. With our in-house Method Development team and Innovation Services (InnoS™) consultancy, we are driving cutting-edge developments in clinical data management, such as the implementation and validation of mobile devices for remote monitoring of trial participants. We invite our clients to explore new possibilities with us.

# 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.**

## Why choose CHDR?

Research at CHDR covers a wide range of fields, including the central nervous system (CNS) and pain, the cardiovascular system, haemostasis, immunology, 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, or a new monoclonal antibody designed to treat rheumatoid arthritis, 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

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