CHDR
Centre for Human Drug Research

Infectious diseases

What CHDR offers:

- Leading expertise combined with cutting-edge clinical facilities to test vaccines and treatments in healthy volunteers and patients
- CHDR's beReady protocol: a unique fast-track protocol for vaccine research that drastically reduces start-up times for first-in-human vaccine trials
- An in-house state-of-the-art immunological research laboratory to test effects of a compound on fresh human samples, such as whole blood or isolated peripheral blood cells
- Close partnerships with infectious diseases experts encompassing a range of themes in vaccine development, including respiratory syncytial virus (RSV), influenza, SARS-CoV-2, malaria, yellow fever and rabies

Infectious diseases

Infectious diseases represent a rapidly developing therapeutic area, both at CHDR and in the world at large. With a focus on fast-track vaccine research and controlled human infection models, we aim to accelerate the development pipeline and make new treatments more rapidly available.

Expert partnerships

CHDR enjoys a long-standing collaboration with the Department of Infectious Diseases at the Leiden University Medical Center, enabling us to leverage the combined expertise of infectious disease specialists and clinical pharmacologists. As leaders in the implementation of first-in-human drug trials and human challenge studies, we provide clients with the perfect setting to effectively test the safety, pharmacokinetics and immunogenicity of new treatments and vaccine candidates. Our experience includes testing vaccine candidates for RSV, influenza and SARS-CoV-2, and investigating the pharmacokinetics of a new anti-malaria agent in combination with a controlled human malaria infection model. Upcoming and running studies include clinical trials investigating novel RSV, influenza and SARS-CoV-2 vaccines/treatments and the development of controlled human infection models for RSV and influenza, in collaboration with the Leiden University Medical Center and the Leiden Controlled Human Infection Center (L-CHIC), headed by infectiologist Prof. Meta Roestenberg, professor in vaccinology.

CHDR is proud to participate in the INCENTIVE and INNO4VACC consortium, both funded by the European Commission's Horizon 2020 Framework Programme for Research and Innovation. The INCENTIVE consortium addresses the economic and global health challenges posed by influenza infections, and aims to reduce the worldwide burden resulting from outbreaks. INNO4VAC is an interdisciplinary project with the goal to accelerate the development of new vaccines.

Environmental clearance

We have a demonstrable track record in executing and obtaining environmental permits for studies involving genetically modified organisms (GMOs) and gene therapy products. Previous work with GMOs includes the testing of a genetically modified RSV vaccine candidate on behalf of Intravacc, a Netherlands-based non-profit R&D organisation specialising in innovative translational vaccinology. Following the appointment of a dedicated biosafety officer at CHDR, all relevant clinical operational procedures have been brought into alignment with safe working procedures laid down in national environmental regulations.

The controlled human infection model

In the controlled human infection model (CHIM), healthy volunteers are inoculated with a wild-type (GMP produced) viral strain, such as RSV or influenza. Subjects are administered an investigational therapeutic either before inoculation (prophylactic vaccine) or after inoculation (anti-viral treatment). The CHIM is an efficient approach that can provide proof-of-concept at an early stage of development for novel vaccines, monoclonal antibodies and antivirals. Compared with traditional development approaches, this controlled human infection model offers the means to make much-needed vaccines and therapeutics more rapidly available.

beReady: the fast track to vaccine research

The recent COVID-19 pandemic and the MERS, SARS and Ebola outbreaks of the last decade have highlighted the need for speed in the development of vaccines for emerging infectious diseases. In response to this need, we have joined forces with the Dutch regulators (CCMO), expert immunology laboratories and academic partners to develop and maintain beReady, CHDR's unique fast-track protocol for vaccine research.

beReady includes a general protocol and a consent procedure that are approved by the regulatory authority. The beReady protocol allows us to maintain a pre-screened pool of eligible healthy volunteers, ready at a moment's notice to be enrolled and dosed in a clinical study with a new vaccine. Thanks to our partnerships with expert laboratories, we are also able to ensure rapid setup and turnaround times for viral screens. Overall, this approach promises significant reductions in the time needed to test vaccines for emerging infectious diseases, meaning that a vaccine trial can start in as little as four weeks.

Accelerating the pipeline

Data-rich early-phase studies are a hallmark of CHDR's approach, and vaccine studies are no exception. By collecting as much information as possible on a vaccine or anti-viral candidate in the early phases of clinical development, we help you to make informed decisions regarding the course of clinical development for your compound. In collaboration with key partners, we are engaged in developing controlled human infection models to enable early selection of promising compounds and vaccines, thereby accelerating the product development pipeline for novel compound for infectious diseases.

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.

+31(0)71 524 64 00

info@chdr.nl

www.chdr.nl

For more information on CHDR's Infectious Diseases research, contact Dr. Ingrid de Visser-Kamerling, Associate Director CHDR:

+31(0)71 524 64 57

IdVisser@chdr.nl