CHDR
Centre for Human Drug Research

Innovation Services

CHDR's novel approach to providing consultancy support for innovation in the pharmaceutical and biotech industries

Providing team-based consultancy services

CHDR has more than three decades of experience in performing innovative clinical drug research. During this long history, we have advised large and small companies regarding their drug development programmes. In 2018, CHDR established Innovation Services (InnoS), a full-service consultancy group that draws on our vast pharmacological and clinical expertise.

InnoS provides consultancy services both on a case-by-case basis and within the context of strategic partnerships with biotech companies; as needed, we can also supply an interim Chief Medical Officer and/or Chief Scientific Officer. This approach can be used to help develop a complete research strategy or to provide advice regarding an existing programme. At InnoS, we work closely with venture capitalists and investors to support biomedical and scientific due diligence built on CHDR's expertise in drug development, as well as the underlying scientific principles. Knowledge sharing in the form of scientific publications, white papers, and educational programmes is also one of our core activities.

Highlights

- InnoS provides advice to pharmaceutical companies, biotech companies, investors, researchers with a new business plan, governments, and regulatory bodies.
- InnoS provides knowledge, an interim CMO and/or CSO (if needed), and other essential resources to help the company succeed.
- Our consultants have an established track record in the pharmaceutical industry and in the drug development process, contributing to our success in both business and academia.
- InnoS provides a wide range of support services, including finance, administration, knowledge base development, database management, research, and medical writing.
- Because InnoS is a fully independent unit at CHDR, our clients have access to CHDR's Clinical Research Unit and Biomarker Development programme.

InnoS services at a glance

- Establish a sound R&D strategy.
- Develop a question-based drug development plan for optimal cost effectiveness.
- Provide comprehensive analyses of preclinical data using our special data integration tool IB-derisk.
- Optimise and/or revise existing development plans and target profiles, including addressing development issues, identifying indications, and optimising dosage.
- Supply additional technical and/or clinical services and expertise with high-level operational feasibility using our vast network of medical and scientific experts; these services include:
  - Developing innovative new methodologies.
  - Identifying and utilising biomarkers.
  - Developing and applying PK/PD models and simulations.
- Provide regulatory advice and arrange scientific consultation with regulatory bodies.

Keeping pace with the ever-changing world of drug development

InnoS helps biotech companies solve problems commonly associated with drug development. Historically, the strength of most small biotech companies lies in their scientific and technical knowledge. We build upon that strength by adding our expertise in translational and clinical research and regulatory requirements. As needed, we can also help recruit investors and address other challenges associated with starting and maintaining a successful business.

Experience meets synergy: the added value of a team

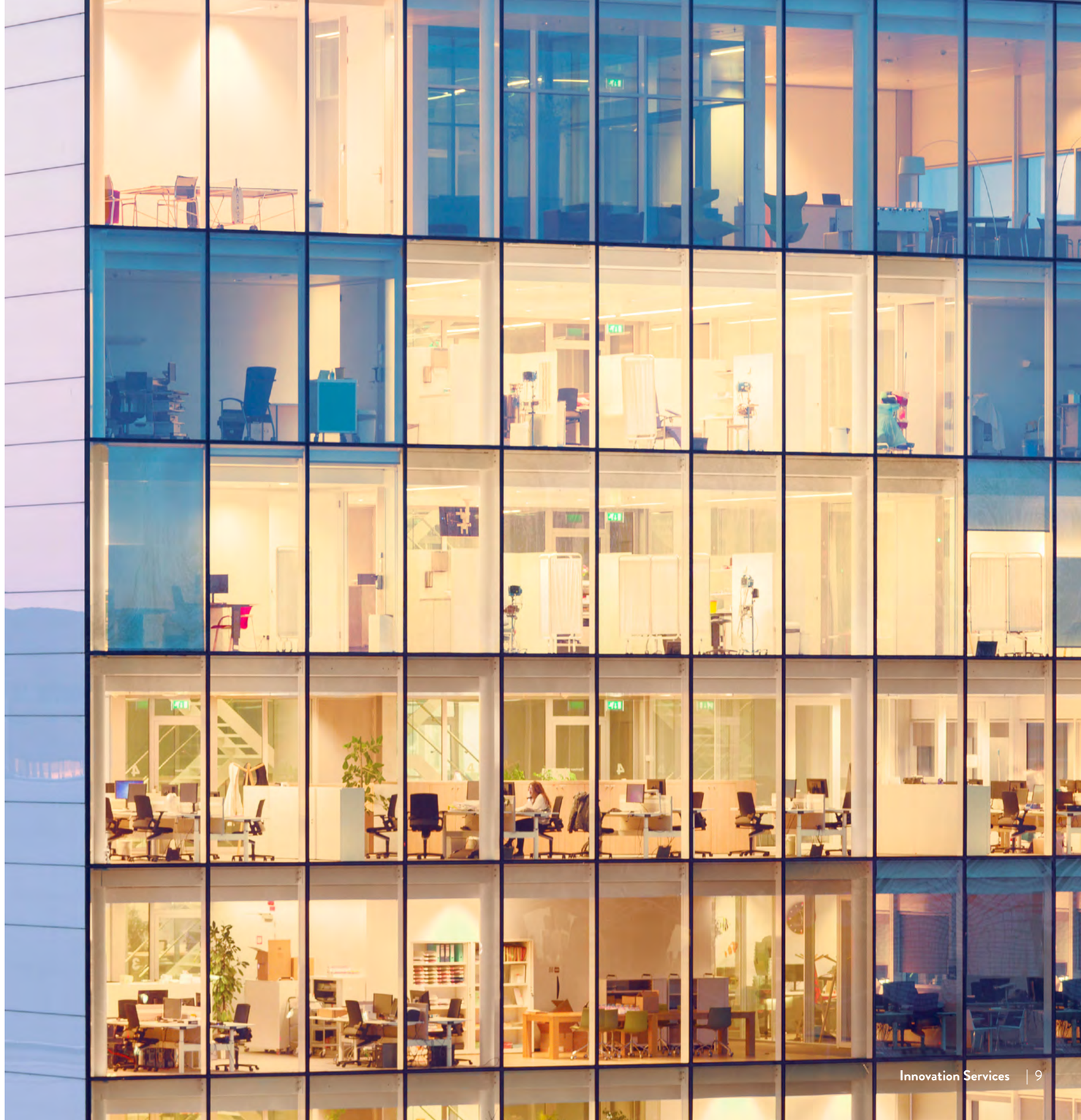
Many technical consultants in the pharmaceutical and biotech industries are relatively small firms without connections to academic institutions. At InnoS, we've created a vast network of consultants who are experts in specific subjects and who work together with talented young researchers and PhD students, ensuring that our knowledge and expertise are always at the forefront.

Using ‘concurrent engineering’ to optimise drug development

A good example is our ‘concurrent engineering’ approach, which we developed in collaboration with the European Space Agency (ESA) in order to solve problems that can arise in the drug development process. Concurrent engineering differs from the classic step-by-step sequential process in which there is little or no communication between the professionals in charge of each step, which slows down the process. When designing a complex piece of engineering such as a new satellite, the initial design may have problems that manifest only at a later stage. For example, an on-board instrument may require more power than was indicated in the original design, necessitating the installation of a larger solar panel that may not physically fit the satellite. Someone with the necessary knowledge and expertise can anticipate this problem, thereby providing a working solution earlier in the design phase. In drug development, we sometimes experience the same type of problem. For example, we may have to modify our inclusion or exclusion criteria for a study because the patients specified in the original protocol are difficult to find or are simply not available; thus, anticipating this problem can save both valuable time and money.

That’s where concurrent engineering comes in. The basic concept is simple: you establish a system of open communication between everyone who has – or may have at a later stage – relevant input regarding the design, the product itself, and its possible applications. Concurrent engineering – and similar approaches – is commonly used by many industries such as the auto industry, computer systems design, banking, and the air and space industry. Up until now, however, drug development has remained a largely sequential process in which researchers proceed to the next step only after the previous step is completed.

Using our own facilities and the facilities at the ESA, our goal is to open a dialogue between preclinical researchers, clinical pharmacologists, physicians, patients, marketing and financial experts, and other relevant stakeholders as the basis for advice.



New tools for innovative drug development

At CHDR, we've always provided consultancy services – in one form or another – to our clients and sponsors. Thus, it is only natural that the specific products and tools that we've developed through the years are now included in the services offered by InnoS. One such tool is innovative question-based approach to drug development. Another example is our new IB-Derisk analyser, which helps researchers create a colour-coded database of all of the preclinical data contained in the Investigator's Brochure. By helping the investigator visualise the relationship between the test compound's dose and the pharmacological effects, the IB-Derisk analyser can help reveal any possible risks that may arise in first-in-human studies.

Yet another example is the introduction of so-called 'micro-milestones', in which we define the most relevant practical questions that will likely reveal whether a new compound satisfies a series of basic requirements. For example, when developing a new drug for treating Alzheimer's disease, one of the first key questions is whether the compound crosses the blood-brain barrier and enters the central nervous system, thereby reaching its expected target; thus, one key micro-milestone would be to measure the level of the compound in the cerebrospinal fluid. Based on the results of each micro-milestone, the researcher can determine whether or not it is feasible to continue development.

Working closely with other groups at CHDR

Clients who work with InnoS will benefit from CHDR's extensive expertise in drug development and biomarker science, as well as other CHDR initiatives and projects such as Paul Janssen Futurelab Leiden (https://www.pauljanssenfuturelab.eu), where ambitious students and researchers learn the principles of drug development and gain the tools they need to bring their ideas to the market.

Contact

To learn more about InnoS, contact us today.

+31(0)71 524 64 00

chdrinnos@chdr.nl

www.chdr.nl