

News

July / August 2007

Phase One at Charité Research Organisation

Our ability to perform early clinical development work in patients is frequently seen as one of our key strengths. But what of more traditional Phase I work in healthy volunteers? Does Charité Research Organisation undertake First-in-Man studies?

Our status as a 100% daughter company of Germany's largest university hospital underpins our ability to implement complex studies that explore efficacy in addition to safety and tolerability in early clinical development. But do we also perform the type of healthy volunteer studies that traditional Phase I CROs undertake?

The simple answer is... YES

We perform a full range of Phase I study types, including First-in-Man studies, single and multiple ascending dose studies, drug/drug interaction studies, challenge studies, QTc thorough studies, PK/PD studies. The relative operational efficiency of such studies

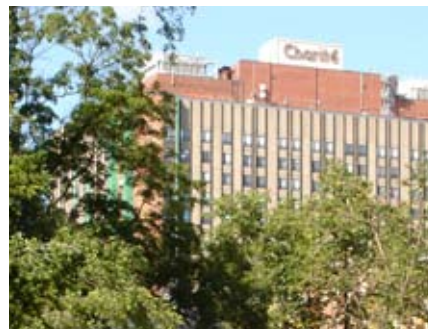
At a Glance

- Well equipped Phase I unit
- Direct access to hospital emergency facilities
- Experienced and highly qualified team
- Access to a wide range of diagnostic technologies on unit and via clinics
- Healthy volunteer and patient studies

and our "differential pricing" approach allow us to offer attractive pricing in these areas.

Appropriate facilities

Our Phase I unit offers 26 beds, of which 10 presently support continual intensive monitoring of subjects. We have fully documented and qualified our medical and laboratory



equipment. We are able to handle practically all forms of administration, including I.V. infusions, subcutaneous injections, intramuscular injections, transdermal applications and of course oral administration. We employ only a dedicated and experienced team of study physicians, study assistants and laboratory technicians - with a high staff to bed ratio.

Located on the 20th floor of the central Charité tower in Berlin Mitte, our unit has

We proudly present

Priv.-Doz. Dr. med. Frank Wagner
CEO & Chief Scientific Officer



Dr. Frank Wagner is board certified in both internal medicine and clinical pharmacology. He has previously

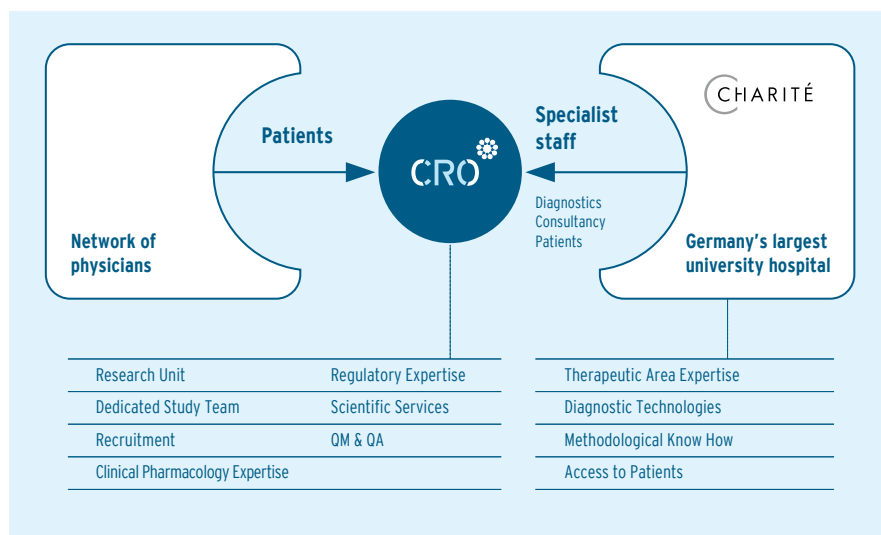
served as the head of intensive care medicine at the world renowned German Heart Institute. Prior to establishing Charité Research Organisation, Dr. Wagner held the position of Chief Scientific Officer with another well known Berlin based contract research organisation.

In founding Charité Research Organisation on behalf of Charité - Universitätsmedizin Berlin, Dr. Wagner has sought to create a new kind of CRO. An organisation that is equally capable of taking care of traditional Phase I programs, while being ready to apply the resources of a leading university hospital to address new aspirations and questions in early clinical development.

direct access to the emergency facilities of the hospital. Our medical emergency procedures were developed in conjunction with the emergency departments, and our medical team undergoes regular training

cytokine tests may allow us to check for the earliest biological signs of cytokine release and allow immediate intervention in First-in-Man studies. When appropriate, we can also support the establishment of Safety

patients - that seek to explore efficacy in addition to safety and tolerability, helping to better shape future development.



Centers of Excellence	
Cardiology Dermatology Gastroenterology Nephrology Psychiatry Rheumatology	Clinical Immunology Endocrinology Infectious Diseases Neurology Pulmonology Urology

Unit Facilities

We are continually expanding the range of assessments that can be physically offered on the unit. For example, recent studies have included implementation of continual gastric pH monitoring, with expert evalu-

with them. This ensures that a high degree of familiarity and consistency of approach exists between our team and the hospital emergency teams.

Monitoring Boards, with input from relevant clinical disciplines, to address and monitor perceived risks.

Expertise within the team

Our level of preparedness to deal with emergencies on the unit is greatly enhanced by the presence of experienced anaesthetologists and intensive medicine specialists within our own team. While we - as you - take every precaution to avoid such events, we think it very important to have the experience and facilities on board to cope with such eventualities. Our team also includes not one but three board certified clinical pharmacologists.

Early detection and monitoring of potential issues

By utilising hospital collaborations, such as cooperation with the Institute for Clinical Immunology, we can try to evaluate and reduce risk in early studies still further. For instance, inclusion of a range of bedside



Centers of Excellence

We offer experience and capabilities across a wide range of therapeutic disciplines. By collaborating with Charité clinics and institutes we are able to complement our dedicated Phase I/IIa facilities and team with access to specific expertise, diagnostic technologies and clinical competence. This enables us to undertake studies in early development - in healthy volunteers and



ation of data supported via our Centers of Excellence model. We have also implemented an extensive respiratory research lab, including spirometry and body plethysmography in addition to routine spirometry.

Contact

Contact us to learn more, discuss feasibility or place a RFP:

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