



“

...there is nothing without poisonous qualities...it is only the dose which makes a thing a poison.

*Paracelsus
16th century Swiss alchemist and physician*

”

Preview Kendle's capabilities with high-risk molecules

Regulatory

- Excellent regulatory environment (at our Utrecht, The Netherlands, facility) with no additional review for high-risk molecules
- Ethics committee experienced in dealing with high-risk molecules

Safety

- Clinic on academic hospital site
- All beds medium intensive care and centrally monitored
- Staff includes 10 full-time physicians
- Comprehensively trained nurses and physician in the unit 24/7
- All permanent and part-time physicians fully ACLS trained
- Specialists available from the university hospital (e.g. cardiologists and anesthetists)

Expertise

- Access to experts in many clinical specialties (e.g. immunology, pain and rheumatology)

Extensive experience

- Monoclonal antibodies, biologics and high-risk molecules

Highest medical safety standards and expertise

The rapid progress of molecular biology has produced exciting new targets. Drugs targeting new biochemical pathways, never before modulated in humans, can present major challenges for a First-in-Human study. These novel pathways are often not fully understood and the effects of a new molecule in humans can be unpredictable. At Kendle, safety is the highest priority. We provide the expertise and infrastructure, in accordance with exacting and evolving regulations, for First-in-Human studies including high-risk molecules.



High-risk molecules

The Kendle difference

Our Clinical Pharmacology Research Unit in Utrecht, The Netherlands, has extensive experience in conducting First-in-Human studies with high-risk designated molecules. The clinic is situated on the campus of the University Medical Center, Utrecht. All beds are medium intensive care and centrally monitored. There are 10 physicians and more than 30 nurses on staff and a physician is present in the facility 24/7. Experts from the university hospital are consulted regularly for scientific and medical guidance, both before and during the study.

Anesthetists, cardiologists and other specialists from the medical center can be present in the clinic, as required, to further support Kendle's clinical pharmacologists and research physicians during the conduct of your studies.

A key factor in establishing a safe starting dose for First-in-Human studies is the expert evaluation of pre-clinical data. The initial doses for First-in-Human studies are selected using either NOAEL, NOEL and/or MABEL. For high-risk designated molecules, Kendle's Early Stage team will provide you with guidance in dose selection and dose escalation/modification during the ongoing study. We have the expertise, infrastructure and experience to guide you through this entire experience.

“

It is the clinical trial design that leads to acceptable or unacceptable risk to human subjects in First-in-Human trials.

European Federation of Pharmaceutical Industries and Associations

”

For more information

about Kendle's capabilities in First-in-Human studies with high-risk molecules, please contact us at info@kendle.com or one of the telephone numbers listed below:

Canada Toronto, ON. Tel: +1 416 963 9338 Ext. 541

The Netherlands Utrecht. Tel: +31 30 258 45 00

United States Cincinnati, OH. Tel: +1 513 381 5550

