

Small but perfectly formed

Don't overlook the value of smaller laboratories for carrying out clinical trials. Bärbel Wilke, CEO of **LKF**, discusses the advantages of working with mid-size central labs compared with the bigger industry players.

Could you please give us some background on the company?

Bärbel Wilke: Laboratorium für Klinische Forschung (LKF) is a medical laboratory established in 1991, which supports multinational clinical trials in phases I–IV. Located in northern Germany, LKF offers a broad range of services covering all aspects of the laboratory part of clinical trials, from planning to completion. Up until now, LKF has supported more than 1,200 clinical trials, with several thousand investigational sites located in Western and Eastern Europe, the Americas, Australia, Asia and South Africa.

What are some of the key challenges faced by sponsors looking to carry out clinical trials?

The planning of clinical trials is a complex process and sponsors expect to get support from the laboratory with regard to certain key aspects:

- **Medicinal and scientific:** the selection of adequate laboratory parameters requires thorough medical knowledge of the respective therapeutic areas. Sound analytical expertise is required to select the ideal analytical methodologies for reliability, clinical sensitivity or comparison of results with previous studies.
- **Regulatory:** analytical methodologies have to comply with the relevant regulatory requirements, whether GCP, GCLP, the EMA reflection paper on guidance for laboratories that perform the analysis or evaluation of clinical trial samples, or the bioanalytical method validation guidelines published by the EMA and the FDA.
- **Pre-analytical:** especially in multicentre trials, the pre-analytical conditions and the shipment procedures should be aimed at keeping the balance between turnaround times, specimen stability, shipment costs and the standardisation of specimen collection and packing procedures.
- **Data management:** individual data management agreements should allow the implementation of electronic data transfer specifications and schedules, from daily uploads into an eCRF to regular incremental or cumulative data transfers. The integrity of the data as well as the encryption of the respective files should be ensured.

What sort of solutions can a smaller, mid-size lab offer to these challenges?

Due to the nature of its size and the lower number of specimens to be analysed, a smaller or mid-size lab will find more individual access to the study and its specific requirements. This may include consideration of tailored assays, new study-specific procedures or the improvement of

communication lines within the facility. With the right procedures in place, laboratory staff are able to connect each sample and test result with the individual background of the study during their daily work. With the specialised, protocol-based LIMS database established at LKF, an additional layer of control exists, which supports the workflow, and therefore increases the quality and reliability of the laboratory data.

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Could you give an example of how LKF provided effective clinical trial support for a sponsor?

LKF developed a method for quantifying menstrual blood loss (MBL) in women with menorrhagia. The blood loss is determined by the extraction and quantification of haemoglobin from used sanitary material. As one can imagine, there are challenges for the central laboratory to overcome: besides the analytical approach to determine the recovery rates of haemoglobin from the variety of sanitary products, it is of high importance to convince patients of their participation by designing a clean, secure and convenient collection and storage procedure for their used sanitary material. Our fully integrative approach comprises the provision of different sanitary products, collection bags and chic handbags for use away from home.

With all the advantages of mid-size labs, why do sponsors still often opt for your huge competitors?

One main reason seems to be the combination of experience and control that is generally assumed to be inherent in a big company. In addition, some of these larger companies offer extra services and may have facilities located in all regions of the world. This allows a substantial analytical capacity and a reduction of shipment costs, thanks to the shipment of specimens to the nearest, 'local' facility. As one can imagine, this advantage requires a high degree of harmonisation in all processes, which goes along with a reduction in flexibility and customer service levels. ■

Further information
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