Fact Sheet

Assay Development for Large-Scale Clinical Studies

Bringing a candidate drug to market — and ensuring it reaches the patients who need it — requires supporting data from high-volume, regulated clinical studies. At IQVIA Laboratories, we lead with science and understand the importance of delivering qualified clinical sample data throughout every stage of the drug development cycle.

IQVIA Laboratories' bioanalytical experts are ready to partner with you to develop assays that incorporate state-of-the-art instrumentation, rigorous quality control, and a comprehensive logistics infrastructure to support large-scale international studies.

We can support your large-scale clinical projects by leveraging:

Expertise in developing assays for human samples

IQVIA Laboratories has built a strong reputation for excellence in method development through our 30+ years' experience with assaying human samples. Transitioning from animal studies to human trials requires assays capable of measuring novel metabolites and accommodating low-level dosing. We collaborate with you to create automated small molecule LC-MS assays, large molecule ligand binding assays, and hybrid LC-MS assays including high-resolution mass spectrometry (HRMS), to support all phases of your clinical trial.

An end-to-end assay development process

Understanding that clinical assays must maintain reliability over time, IQVIA Laboratories has implemented a rigorous process to ensure quality and reduce risk. Prior to validation, each assay undergoes a formal pre-qualification process where our scientists review preliminary data and identify necessary modifications to support validation.

Project managers with scientific expertise

All IQVIA Laboratories' project managers are scientists with hands-on experience in analytical methodologies. They understand the science behind the assays, ensuring data quality and smooth operation throughout the project. With weekly or bi-weekly updates, our project managers address any concerns or questions as they arise and actively collaborators in decision-making.

>1 MILLION
bioanalytical and ADME tests performed yearly

A global presence to support international studies

IQVIA Laboratories combines local expertise with a global logistics network to support sample processing for international clinical studies. With state-of-the-art facilities in the United States and China, we adhere to global bioanalytical regulatory guidance and Good Laboratory Practice (GLP) regulations.

Flexibility with transparency

At our laboratories, all assays are conducted under a unified set of Standard Operating Procedures (SOPs), ensuring consistent data quality. Our bioanalytical and clinical project managers maintain regular communication across internal teams to quickly resolve any sample processing issues. This integration allows us to adapt flexibly to changing analytical demands and customer timelines, delivering a seamless experience for our clients.

30+ years regulated and discovery bioanalytical experience

>150 unique, customized bioanalytical assays developed and validated per year

Translating a large-scale, long-term study into a successful outcome requires reliable, qualified measurements at a clinical scale. IQVIA Laboratories bioanalytical experts can help you design and carry out validated assays that will support all stages of your clinical study. To learn more, call us today or visit us at **labs.iqvia.com**

IQVIA LABORATORIES

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