

**Global Approach**

**Flexibility**

**Speed**



## High Throughput Bioanalytical Analysis

### NEED

- For multiple international Phase I and III studies over a one-year period, more than 140,000 samples required PK and/or ADA sample analysis
- Database log date was two weeks after last sample arrival, additionally PK samples of each subject had to be analyzed within the same analytical run

### APPROACH

- Developed a flexible, global scheduling approach within the client's respective time window to ensure the availability of scientists to perform the required assays
- Effective communication with associated Central Laboratory was implemented, especially at study ends for efficient scheduling
- Weekly meetings with all parties involved that included Central Laboratory, client's team and key Celerion resources (data management, clinical research team, clinical pharmacologists)

### BENEFITS

- All database log dates were successfully achieved for all clinical studies and final data transferred to the client ahead of their expected timelines
- The client successfully met their regulatory submission deadlines without delay

#### See Other Case Studies

[Mass Balance Study](#)

[Partnering with Biotechnology Companies](#)

[EU Biotech Needs First-in-Human FDA Support](#)