

Science

Compliance

Speed



## Optimize LC-MS/MS Method for New Metabolite

### NEED

- For multiple European clinical studies, the generated samples were analyzed using a validated LC-MS/MS method. During sample analysis of a non-European clinical study an unexpected shouldering of the known metabolite peak was observed
- The bioanalytical laboratory demonstrated that this was an additional metabolite, not observed in previous studies

### APPROACH

- Optimized the chromatographic method to solve the tailing, separated the additional metabolite and revalidated the LC-MS/MS method
- Reanalyzed a percentage of study samples generated in previous European clinical studies to demonstrate the additional metabolite was specific to a non-European population

### BENEFITS

- The client was able to document the difference in metabolism of different subject populations at the beginning of the drug development process

### See Other Case Studies

[Mass Balance Study](#)

[Partnering with Biotechnology Companies](#)

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

