FACET
LIFE SCIENCES

FACET LIFE SCIENCES IDENTIFIES NEED AND FILLS RESOURCING GAPS WITH BIOMETRICS EXPERTISE

EXPERTS PROVIDE VENDOR OVERSIGHT FOR SUBMISSION-CRITICAL ACTIVITIES

BACKGROUND

A small (less than 20 person), innovative pharmaceutical company based in the United States was in late stage (Phase 3) development with a drug-device product that was targeted for a 505(b)(2) submission within 12 months of engagement with the Facet Life Sciences Team.

BUSINESS CHALLENGE

The Sponsor did not have internal expertise in a few key disciplines (i.e., regulatory affairs, biometrics). Like most very small companies, the clinician in the company was responsible for interacting with FDA as well as directing the CROs to keep development activities moving forward. The resource constraints threatened to impact the regulatory submission timeline.

SOLUTION

Facet Life Sciences Regulatory experts assessed the Sponsor's resources and submission content and identified gaps while working with the company to plan the NDA activities. Their findings included the following:

- Data package was not adequately discussed and agreed with FDA
- Clinical datasets and documentation were not compliant with FDA requirements
- Limitations in the human factors components of the application

The Facet Life Sciences team identified the gaps, raised them to the company's core team for discussion, and recommended solutions to mitigate the gaps.

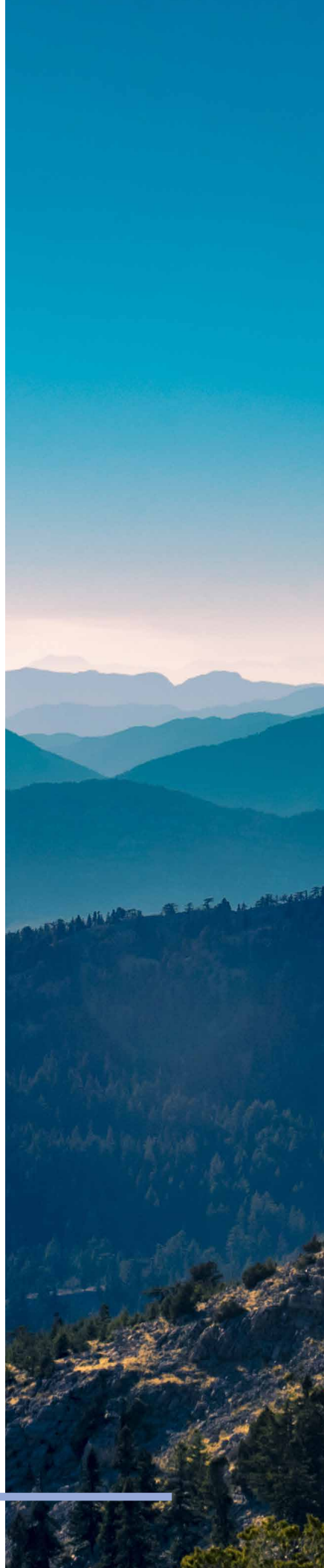
The Facet team connected the Sponsor team with two biometrics vendors and provided leadership and coordination of the vendor activities to achieve a comprehensive, compliant data package for submission.

The Facet team then worked with the company and an external vendor to plan and track the additional human factors components of the submission.

RESULTS

Facet Life Sciences partnered with the Sponsor to rapidly identify gaps in the submission. The team worked closely with the Sponsor and their vendors to close those gaps. Facet experts identified the right vendors and provided oversight to the virtual team to ensure timely delivery. FDA accepted the submission for filing and approval was secured in 2016.

The Facet Life Sciences Team provided guidance and expertise to the Sponsor that led to a fully compliant and content complete FDA submission. Vendor identification, oversight and coordination helped the client address critical gaps to meet their strategic goals.



FACET LIFE SCIENCES
230 SUGARTOWN ROAD
WAYNE, PA 19087

PHONE: +1.610.222.6326
EMAIL: INFO@FACETLS.COM

WWW.FACETLIFESCIENCES.COM