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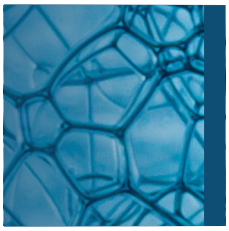
Case Study

Venture Capital Investment
in Novel Bacteriophage Development Space

Objective

Identify and assess both expected and unexpected regulatory risks of an early-stage company engaged in a unique and challenging development space.



Challenge

Venture capital investor conducting diligence on an early-stage biopharmaceutical company engaged in a unique and challenging development space focused on novel natural and engineered phage therapies that target specific pathogenic

Solution

Assembled a team of infectious disease experts, including former reviewers and Center for Biologics and Evaluation (CBER) leadership to provide an assessment of the regulatory history to date, early clinical and non-clinical data, and target company regulatory strategy.

Outcome

Convened multiple meetings with Client and target company to discuss FDA clinical data expectations for phage therapies and the most efficient means of generating required data for regulatory approval.

Developed a detailed assessment of the regulatory risks in the phage therapy space, anticipated FDA reactions to the current regulatory strategy, and a detailed roadmap of recommendations for how to best prioritize and advance the target company's pipeline moving forward.

Client proceeded with the investment and the target company incorporated feedback from the team's diligence into their regulatory strategy.

Due Diligence Solutions

ELIQUENT's expanded due diligence platform leverages the unmatched experience and robust institutional knowledge of the firm's regulatory experts to empower decisions and drive value. Learn more at **ELIQUENT.com**