



Accelerated Cross-functional Briefing Book In Preparation for Scientific Advice



Challenge

With the absence of a complete package of biological data, 2 Bridge was brought on board to deliver a comprehensive briefing book in a 3-week time frame for Scientific Advice with the regulatory authority.



Approach

2 Bridge Tiger Team (see the graphic below) with experts from different domains was set up tailored to the client's needs. Thanks to our agile Tiger Team approach, we efficiently blended in with our client organization to ensure a sustainable and seamless collaboration.

Throughout the project, 2 Bridge Tiger Team was:

- Experienced to provide a non-clinical and CMC strategy
- Highly engaged with the KOLs for strategic thinking on the clinical strategy & invited to participate to the Scientific Advice meeting
- Adaptable to the time constraints and client requirements
- Proactive in project management
- Efficient, the briefing book was delivered in 14 days



Outcome

The briefing book was submitted on time for the Scientific Advice. It contains all the necessary information for assessors to provide the client with answers to the questions and clear the path.

One year later, the program's first patient has been treated in a Phase 1b/2 global clinical study.

Experienced cross-functional project management
professional for both pre-clinical and clinical projects

Experienced cross-functional R&D
manager for both pre-clinical and
CMC with medical writing expertise

Seasoned CMC expert with over 25 years
of experience in pharmaceutical
development, registration, and production

