Advanced Clinical

CASE STUDY

CTIS SUBMISSION IN SUPPORT OF A CAR T-CELL THERAPY PHASE I/II STUDY IN AUTOIMMUNE DISEASES

Client Profile

- Clinical-stage biotechnology company located on the East Coast in the U.S.
- Therapeutic focus on therapies for autoimmune diseases

Project Details

- Phase I/II, open-label, first-in-human study to evaluate safety, tolerability and efficacy of a CAR T-cell therapy for subjects with lupus nephritis and/or active non-renal systemic lupus erythematosus

BUSINESS CHALLENGE

A U.S. East Coast-based biotechnology company was seeking support to make a Clinical Trials Information System (CTIS) submission for the first time. Completing a CTIS submission in Europe was crucial to the study's success, given the new clinical trial regulations and the complexities of stand-alone Advanced Therapy Medicinal Product (ATMP) submissions. In addition to the CTIS submission, each country has its own separate ATMP submission, which can prove challenging.

The sponsor needed a clinical research partner with local and global experience to complete these submissions for their clinical study while also having the knowledge to navigate regulations and different processes in Europe.

SOLUTION

Advanced Clinical had been working with this sponsor on multiple studies and had the global experience to help the sponsor expand into Europe for the first time. At the time of submission, very few ATMP CTIS submissions had been made, industry wide. Because of this, the sponsor sought a partner with strong operational, therapeutic and regional expertise to ensure successful execution. The sponsor worked with the Advanced Clinical team, who had the global/local experience to ensure the submissions were made and handled any challenges that arose. By leveraging a pre-developed process and knowledge library to expedite submissions across all regions, Advanced Clinical ensured submissions were made successfully.

Advanced Clinical led the preparation of the specific ATMP section of the protocol, which was required for the submission. The team also developed a new portal for France for this ATMP requirement of the study, while also ensuring that the general submission for Europe was prepared and that the correct documents were used in all parallel submissions. The Advanced Clinical global study startup lead on

Provided successful submissions in France and Spain

the supported document review to standardize connections between the supply management process and labels/manuals. The Advanced Clinical team worked hand in hand with the sponsor to stay ahead of the required components in order to provide a better clinical experience and complete these global submissions for this study.

RESULTS

With the support of the Advanced Clinical team, the ATMP-specific approvals were delivered to each participating European country within two months. The CTIS submission was within a month of the final core document being provided.

Advanced Clinical guided this sponsor through a successful CTIS submission in Europe. The Advanced Clinical team also provided the sponsor with additional country-specific and CTIS presentations so that the sponsor could learn about the process with the assurance that everything would be successfully conducted in collaboration with the Advanced Clinical team.

ABOUT ADVANCED CLINICAL

Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research – approaching each opportunity with foresight, character, resilience and innovation. Based on decades of experience, we help our clients achieve better outcomes by conducting candid conversations and anticipating potential issues through our customized solutions.

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