ARDELIS HEALTH

Pathways to Product Approval: Determining the Best Route

Case

A preclinical start-up company in process of moving forward with the filing of its Investigational New Drug application (IND) for a potentially groundbreaking treatment for an acute life-threatening illness

Challenge

Company was seeking means to speed preclinical studies and had little experience with IND application elements

Guidance for Industry

Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products

Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 1995

Strategy

Analyze the current regulations underlying statutory law and FDA guidance to industry on necessary elements of IND application and associated process/procedures

Solution

Ardelis Health developed a primer memorandum to guide company in its negotiations to obtain the necessary documentation, data, and authorizations to efficiently move forward with this crucial step in the drug development process

obviously be ideal. That said, the following is a basic overview of some of the initial IND submission requirements generally reflected in the guidance issued by the FDA and related to the information you may want to seek to obtain from . Note that the information summarized in this memo is not necessarily a complete checklist of information that would be required for a complete IND submission. Also, additional information and updates would also be provided throughout the phase 2 and phase 3 (if necessary) development processes.

Letter of Cross-Reference Authorization (LOA)

As an initial matter, as you will likely be referencing data in your IND related to which were the subject of and already included in existing INDs, you should seek a letter of cross-reference