CTI's Global Regulatory Affairs Team Can Expertly Navigate Pre-IND Meetings for Faster Drug Development

The US Food and Drug Administration (FDA) issued a draft guidance in October 2018 to assist sponsors in drug development for the treatment of rare diseases. This is one of many recent examples of the FDA taking steps to assist companies in accelerating the development and approval process of innovative products. Other international agencies, such as Brazilian Health Authorities (ANVISA), have been providing similar assistance on a global scale.

Early interactions with the FDA allows for careful strategic planning in the design of your program and is especially important for rare disease drug development for the following reasons:

- Limited number of patients available for the study population affects the feasibility of certain studies
- Lack of drug development precedent, e.g., established clinical endpoints, validated biomarkers
- The need to conduct trials in pediatric populations

The guidance describes frequently encountered issues to consider in early drug development. It also provides details of the type of quality, non-clinical., clinical pharmacology, and clinical development information to be included in a Pre-IND meeting information package to guide discussions on specific issues at the Pre-IND meeting. Pre-IND meetings allow the opportunity to engage with the FDA early in the development process, and are encouraged by the agency to help sponsors avoid potential pitfalls leading to costly delays that may arise during early drug development programs.

CTI's global Regulatory & Scientific Affairs team, in conjunction with our expert international Medical Affairs team, has established long-term relationships with many key regulatory officials around the world. These relationships help to facilitate communication, as well as build on expectations of quality products and documents that are scientifically sound and clearly presented. Our team helps our sponsors in the development and review of meeting materials to ensure the agency receives the appropriate information included in the Pre-IND meeting briefing package to coordinate and guide discussions on specific issues of concern at the Pre-IND meeting. Moreover, our team works with our sponsors to develop carefully crafted questions directed to the FDA to ensure important issues are addressed as part of the Pre-IND meeting, which ultimately leads to a quality submission, appropriate review by the FDA, and a timely

approval of the IND.

The guidance also provides insight into pediatric product development study requirements per the Pediatric Research Equity Act (PREA) that requires sponsors to submit an assessment of the safety and effectiveness of the drug at the time of submission of the marketing application, unless the requirement has been deferred or waived.

CTI has a team of dedicated professionals with more than 30 years of global regulatory, clinical, and management experience, including former FDA committee members, that frequently helps our US and international clients navigate and facilitate these important interactions with the FDA, EMA, and other global regulatory agencies, along with determining the feasibility and timing of requesting special designations such as Orphan Drug, Fast-Track, Breakthrough Therapy, Priority Review, Accelerated Approval, PRIME, and Regenerative Medicine Advanced Therapy (RMAT). The team has vast experience in navigating all the various pathways and special designations around the world, leading to more than 100 drug and device approvals that CTI has been a part of.

Additional Highlights from this Month

Join Our Team

We are currently seeking qualified individuals to join our team!

Search Open Positions

CTI Cares

The Alport Syndrome Foundation is a non-profit organization founded in 2007 by a group of families affected by the disease. Alport Syndrome, a rare disease affecting less than 200,000 people in the US, damages blood vessels in the kidneys, leading to kidney disease, kidney failure, hearing loss and vision problems.

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New Hires & Promotions

CTI is thrilled to welcome all of our new employees, and to congratulate our recently promoted employees!

View New Hires and Promotions

CTI in the News:

CTI Clinical Trial and Consulting Services Awarded 2018 Prix-Galien Medstartup Award

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CTI Clinical Trial and Consulting Services Announces Promotion of Günter Stetter to Vice President, Global Regulatory Affairs Study Start-Up

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