Clinical Trial Policy
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At Insmed, our commitment to run patient-focused, ethically conducted clinical trials is at the center of what we do. Included in our commitment is the delivery of high-quality trial data from Insmed-sponsored trials to support our efforts to bring new treatments to underserved patient populations. This statement applies globally to all Insmed-sponsored clinical trials, including clinical trial activities that are outsourced to third party suppliers.

Ethical Considerations

When designing and conducting our clinical trials we follow the ethical standards established by the International Council for Harmonization (ICH), the Declaration of Helsinki, and the Belmont Report. We also ensure all regional and local Health Authority requirements are followed. In addition, and as required by Health Authorities around the globe, we ensure our trial protocols are reviewed and approved by a qualified Institutional Review Board (IRB) or Ethics Committee (EC) prior to trial initiation.

Patient Safety

Trial Participants are monitored throughout our clinical trials to ensure their safety. From a data perspective, we use experienced Clinical Trial Monitors to verify safety data collected at Clinical Trial Investigative Sites and leverage medically-trained Medical Monitors to review blinded, patient-level data across all patients and all investigational sites to identify medically-relevant trends.

We also ensure that, when appropriate for the trial, independent Data Monitoring Committees (DMCs) are formed to review clinical trial data at agreed-upon intervals throughout the trial. All DMCs are established according to regional and local Health Authority requirements and are charged with providing an independent opinion to Insmed regarding the safety of the investigational medication being studied.

The Clinical Trial Investigative Sites we partner with also play a key role in ensuring patient safety. We work closely with them to ensure any adverse events (AEs) experienced by Trial Participants are recorded, assessed, and reported as required by applicable Health Authorities. We also ensure Clinical Investigators update Trial Participants, as appropriate, of any new risks associated with the use of the investigational product that arise during a clinical trial.

Ensuring Quality

The consistent review of patient-level data by Clinical Investigative Site Staff, Clinical Trial Monitors, Medical Monitors, Data Managers, and DMCs helps to ensure any errors or inconsistencies are identified, investigated, and if needed, corrected in a timely manner. These reviews contribute to the

level of confidence we have regarding the accuracy and quality of our clinical trial-related data and ultimately our clinical trial results.

Our Clinical Operations Team also partners with Clinical Quality Assurance (cQA) to establish annual audit plans for each of our clinical trials. cQA serving as an independent function and using a risk-based approach to identify and select Clinical Trial Investigative Sites for audit is another way Insmed strives to ensure quality clinical trial data.

Training

We ensure all Clinical Trial Investigative Site Staff and Trial Operations Teams have been trained on Good Clinical Practice (ICH-GCP).

We also ensure the Clinical Trial Investigative Site Staff are trained on requirements and expectations regarding adherence to the clinical trial protocol, including completion of required trial assessments.

If we employ third party vendors to assist us in conduct of the clinical trial, we ensure they are trained on the requirements and expectations of the clinical trial protocol and its related assessments as well, with specific focus given to areas where they are providing support.

Data Privacy

As guardians of data about the patients who use our medicines and participate in our clinical trials, as well as their caregivers and the healthcare professionals who serve them, we are committed to handling personal data in accordance with global laws and regulations that govern data protection and privacy and require our third party vendors to abide by the same data privacy standards. As part of our trials, we collect as little Participant identifier data as possible so that Participants' data cannot be traced back to an individual.

Transparency

Insmed makes information about our clinical trials available to the public, in compliance with relevant global and local laws and regulations. We ensure our trials are registered and trial results disclosed on public clinical trial registries in the U.S. (clinicaltrials.gov), Europe (clinicaltrialsregister.eu) and Japan (rctportal.niph.go.jp//en). In addition, we provide links to these registries on our corporate website to aid patients or researchers looking to learn more about our trials, including a summary of results, when available. We also create plain language summaries for our clinical trials and make them available to the public. These summaries allow the results of our clinical trials to be reported using terminology more easily understood by patients and others not involved in the conduct of research.

We are proud to have dedicated and trained staff to ensure timely registration of clinical trials and communication of our research results, and we work closely with external experts and thought leaders to ensure our work reflects the latest clinical and scientific advances.

Diversity

Insmed is committed to helping people from all backgrounds address their unmet medical needs and ensuring our research reflects the populations we aim to serve. Our efforts to achieve diverse representation in our clinical trials substantiate this commitment.

We have established a cross-functional Clinical Trial Diversity Task Force to ensure we are developing strategies to enhance diversity in our clinical trials. The Task Force aims to:

- Enhance outreach to underrepresented communities by partnering with patient advocacy groups and community organizations to facilitate and ensure the inclusion of these populations in Insmed's clinical trials.
- Better understand the patient journey, diagnosis, and participation in clinical studies to better address gaps in health care access.

We also seek to achieve clinical trial diversity by ensuring conversations about diversity occur early in the clinical trial planning process. These conversations include topics regarding identification and removal of barriers to diversity in clinical trials such as socioeconomic, cultural, and language barriers. At the beginning of the clinical trial planning process, we look at the epidemiology of the disease state we are studying with the goal of enrolling participants representative of the patient population the therapy is intended to treat. Clinical Teams set the geographic footprint for where we run our trials, as well as select clinical investigative sites with diversity in mind.

We also partner with experienced vendors specialized in improving diverse representation in clinical trials across the pharmaceutical and biotechnology industry. These partners support us in minority community outreach efforts to ensure we raise awareness of the disease and the opportunity to participate in clinical trials. In addition, they review our clinical trial site list and offer feedback regarding the sites' ability to contribute to a diverse population. They also help us review and determine the effectiveness of our current recruitment practices and identify gaps and areas requiring improvement.

In addition to our patient-focused efforts, we continually evaluate Health Authority guidance (e.g., FDA Guidance Documents for Industry) and legislation to ensure alignment as we further enhance our practices regarding diversity and inclusion in clinical trials.

These internal and external efforts support Insmed's goal of enhancing access to our clinical trials and that clinical trial participants reflect the patient populations our medications intend to treat.