

Clinical Trial Policy

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At Insmmed, 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 Insmmed-sponsored trials to support our efforts to bring new treatments to underserved patient populations. This statement applies globally to all Insmmed-sponsored clinical trials, including clinical trial activities that are outsourced to third-party suppliers.

Ethical Considerations

When designing and conducting our clinical trials we seek to follow the ethical standards established by the International Council for Harmonization, the Declaration of Helsinki, and the Belmont Report. We also strive to ensure all regional and local Health Authority requirements are met. In addition, and as required by Health Authorities around the globe, our trial protocols are reviewed and approved by a qualified Institutional Review Board or Ethics Committee 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 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 Insmmed regarding the safety of the investigational medication being studied.

The Clinical Trial Investigative Sites we partner with also play a key role in Trial Participant 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 that 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.

Quality of Clinical Data

The consistent review of Trial Participant level data by Clinical Investigative Site Staff, Clinical Trial Monitors, Medical Monitors, Data Managers, and DMCs help to identify, investigate, and if needed, correct any errors or inconsistencies 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 Insmmed strives to ensure clinical trial data quality.

Training

We ensure all Clinical Trial Investigative Site Staff and Trial Operations Teams have been trained on and adhere to Good Clinical Practice (ICH-GCP), the internationally recognized ethical and scientific quality

standards for conducting clinical trials involving human subjects. These standards prioritize subject welfare, risk-benefit analysis, informed consent, and data integrity.

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.

To the extent we employ third party suppliers to assist us in conduct of our clinical trials we seek to ensure they are trained on the requirements and expectations of the relevant clinical trial protocol and its related assessments, with specific focus given to areas where they are providing support.

Data Privacy

As guardians of our Trial Participant's data, 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 suppliers and the Clinical Trial Investigative Sites to abide by the same data privacy standards. As part of our clinical trials, we seek to collect as little Participant identifier data as is necessary and ensure it is recorded using a code instead of a Participant's name. This process protects against the Participant's personal data from being traced back to the individual, ensuring anonymity

Transparency

We make information about our clinical trials available to the public, in compliance with relevant global and local laws and regulations. We registered our trials and we disclose our trial results on public clinical trial registries in the U.S. (clinicaltrials.gov), Europe (euclinicaltrials.eu) and Japan (jrct.mhlw.go.jp/en-top). In addition, we provide links to the U.S. registry on our Insmmed clinical trial website to aid patients or researchers looking to learn more about our trials, as well as our summary of results, when available. We also create plain language protocol synopses and plain language summaries for our clinical trials and make them available to the public on goodday.health. 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 working to register our clinical trials and communicate our research results, and we work closely with external experts and thought leaders so that our work reflects the latest clinical and scientific advances.

Clinical Trial Participation

Insmmed is committed to helping people from all backgrounds address their unmet medical needs. Our goal is to enroll participants that represent the patient population for a given therapy. We pursue this goal by creating a geographic footprint of the potential patient population using best available scientific data. Then, our cross-functional clinical study teams select Clinical Investigative Sites with the highest probability of access to anticipated patients.

Additionally, Insmmed focuses on reducing the burden on Participants to participate in our clinical trials. We established a cross-functional workstream to address protocol complexity and minimize Participant burden through design elements such as time required at the Clinical Investigative Site and number of procedures.

In addition to our patient-focused efforts, we regularly evaluate health authority guidance (e.g., FDA Guidance Documents for Industry) and legislation to further enhance our practices.