

Investigator-Sponsored Trial Program Overview



Providing support for
clinical research

The objective of our Investigator-Sponsored Trial (IST) program is to provide support for clinical research that advances medical and scientific knowledge about our products or disease states of interest, and to enhance patient care.

The Seattle Genetics IST Program

- Serves to address unmet medical need with new scientific data
- Support pilot studies that explore the feasibility of new study concepts

Seattle Genetics' support is typically provided in the manner of funding and/or study drug. If you are interested in discussing your clinical or translational research questions or ideas, please email us at IST@seagen.com or contact your regional Medical Science Liaison (MSL). Submit your application and complete all sections of the grant application portal, www.seattlegenetics.com/gms. For assistance in identifying the MSL for your territory, please contact IST@seagen.com.

Visit SeattleGenetics.com to see specific areas of interest.

Eligibility

- Sponsor-investigators must have demonstrated relevant clinical trial experience
- Prior experience with investigator-sponsored studies preferred

IST Review Process

Letter of Intent (LOI) submission

IST review begins with sponsor-investigator submission of a Letter of Intent (LOI) using our online application located at www.seattlegenetics.com/gms. Applicants may discuss LOIs with their MSL prior to submission, however sponsor-investigator must exercise full control of the application. The MSL can provide support only regarding the application process.

LOI Review

Applications are screened for completion and sent to the IST Review Committee (ISTRC) for review. ISTRC meetings typically occur every 3 weeks. Proposals are presented to committee by the applicable Medical Science Liaison (MSL) based on region.

Letter of Intent (LOI) review criteria

- Safety
- Statistical endpoints and methods
- Scientific validity
- Potential ethical issues
- Feasibility
- Impact on the development of the compound
- Whether or not trial addresses an unmet scientific need
- Consistency with corporate business strategy
- Budget alignment with fair market value

LOI Approval

Approved LOI applicants are invited to submit a protocol and detailed budget online within 90 days of LOI approval for further consideration. If not already in place, a Non-Disclosure Agreement (NDA) between Seattle Genetics and the investigator's institution will be executed to provide study drug and safety reporting information for inclusion in the protocol. Submitted protocols and budgets go back to the ISTRC for review. Please note that LOI approval does not mean full approval of an application. It is the first step of the review process. Please see IST Review Process map on page 4 of this overview for clarification.

Protocol Approval

Full protocols must include a detailed budget to be reviewed by the ISTRC. Should the committee approve support for a protocol, a research agreement, copy of IND approval from FDA (if applicable) and a copy of IRB approval are required before support can be provided. Additional institutional and collaborator/vendor requirements should also be considered if applicable.

Timeline

It typically takes several months from LOI submission to protocol activation.

LOI Submission Requirements

The following information must be submitted via our online application for LOI consideration:

- Sponsor-Investigator CV
- Study design including: background, targeted enrollment, number of sites, and estimated trial duration
- Inclusion/exclusion criteria, treatment plan, primary and secondary endpoints
- Detailed preliminary budget and estimated drug need
- Correlative study plans (if applicable)
- Statistical analysis

Partnering with Seattle Genetics for ISTs

We work closely with Sponsor-Investigators to provide support for their clinical research, but wish to remind applicants that our role in ISTs is limited. We are available as a resource to assist Sponsor-Investigators throughout the development and implementation of their IST. We have found that the most successful ISTs are conducted by experienced clinicians who understand their responsibilities as a Sponsor-Investigator and enter the process with realistic expectations. Below is a summary of responsibilities for Sponsor-Investigators and Seattle Genetics.

Sponsor-Investigator Responsibilities

Our IST investigators are responsible for all aspects of trial conduct. This includes:

- Design and conduct of the study protocol
- Regulatory authority (such as FDA) approvals/IND filings
- Safety reporting and updates to regulatory authorities and Seattle Genetics
- IRB obligations
- Investigational drug management
- Collaborating site selection and management
- Budgeting and milestone invoicing
- Protocol and informed consent form maintenance
- Trial registration on www.clinicaltrials.gov
- Correlative study conduct including vendor contracting (if needed)
- Data collection and analysis
- Monthly updates to Seattle Genetics regarding enrollment and safety
- Timely updates regarding protocol changes. Changes to target enrollment and/or budget will require a contract revision.
- Publication planning including Seattle Genetics review as outlined in contract
- Overall compliance with Good Clinical Practice (GCP) guidelines

Seattle Genetics Responsibilities

The following tasks will be performed by Seattle Genetics:

- Provision of study drug and safety reporting information for inclusion in study protocol
- Provision of IND cross reference letter for inclusion in the Sponsor-Investigator's regulatory filing
- Timely review of protocol amendments, budget revisions and publications
- Granting permission to vendors to use specimen assays for specific ISTs
- Distribution of new IND safety letters and/or Investigator Brochures to Sponsor-Investigators
- Drug shipment to the primary sites and collaborating sites with IRB approval
- Payment of invoices submitted by the Sponsor-Investigator at the completion of each milestone defined in the research agreement

We look forward to working together to advance medicine with a strong IST program.

For more information, please contact us at IST@seagen.com.

Investigator-Sponsored Trial Review Process

Concept discussion to LOI submission

1-3 months

LOI review & approval

1 month

Protocol development

1-3 months

Protocol review & approval

1 month

IST activation

Budget & contract negotiations

3-6 months

INVESTIGATOR

1. Complete all sections of our IST application at SGEN grants portal (www.seattlegenetics.com/gms)
2. Attach budget and CV to your application

SEATTLE GENETICS

1. Provide regional Medical Science Liaison (MSL) support regarding application process

INVESTIGATOR

1. Provide legal contact(s) for Non-Disclosure Agreement (NDA) if requested

SEATTLE GENETICS

1. Schedule LOI for next IST Review Committee (ISTRC) meeting (meetings typically occur every 3 weeks)
2. Present LOI at ISTRC meeting (MSL)
3. Execute NDA if not present
4. Refer LOI to 2nd company for review if it is a partnered project (such as ADCETRIS)
5. Send committee feedback on LOI and budget
6. Send Investigator Brochure, safety information and reporting requirements if NDA is executed

INVESTIGATOR

1. Submit protocol and budget to portal within 90 days

INVESTIGATOR

1. Provide contact for budget and contract negotiations
2. Start regulatory filings (IRB and FDA)

SEATTLE GENETICS

1. Schedule protocol for next ISTRC meeting (meetings typically occur every 3 weeks)
2. Review budget for Fair Market Value alignment
3. Present LOI at ISTRC meeting (MSL)
4. Send committee feedback on budget and protocol
5. Provide IND cross-reference permission letter (if applicable)

INVESTIGATOR

1. Provide finalized protocol, IRB approval and IND approval (if applicable)
2. Sign Research Agreement
3. Send drug order form if drug is being provided by SGEN
4. Send invoice for start-up milestone payment
5. Provide monthly enrollment updates

SEATTLE GENETICS

1. Send protocol activation notification
2. Add IST site staff to safety letter distribution list
3. Process invoice for start-up milestone payment