# Investigator-Sponsored Trial

## Program Overview

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 Seagen IST Program

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

Seagen's 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. For assistance in identifying the MSL for your territory, please contact IST@seagen.com.

## Eligibility

- Sponsor-investigators must have demonstrated relevant clinical trial experience
- Prior experience with Investigator-Sponsored studies preferred Sponsor-investigators must have demonstrated relevant clinical trial experience

## IST Review Process

### Concept Submission

IST review begins with sponsor-investigator submission of a concept using our online application. Applicants may discuss the concept 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.

### Concept Review

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

### Concept 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

### Concept Approval

Approved concept applicants are invited to submit a protocol and detailed budget online within 90 days of concept approval for further consideration. If not already in place, a Non-Disclosure Agreement (NDA) between Seagen and the investigator's institution will be executed in order 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 concept approval does not mean full approval of an application. It is the first step of the review process. Please see IST Proposal Timeline for clarification.

### Protocol Approval

Full protocols must include a detailed budget in order to be reviewed by the ISTRC. Should the committee approve support for a protocol, a research agreement, copy of regulatory application (e.g. IND, CTA) approval from the Regional Health Authority (if applicable) and a copy of ethics committee 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 concept submission to protocol activation.

## Concept Submission Requirements

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

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

## Partnering with Seagen for ISTs

We work closely with Sponsor-Investigators to provide support for their clinical research, but we 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 Seagen.

## Sponsor-Investigator Responsibilities

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

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

## Seagen Responsibilities

The following tasks will be performed by Seagen:

- Provision of study drug and safety reporting information for inclusion in study protocol
- Provision of regulatory application 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 safety letters and/or Investigator Brochures to Sponsor-Investigators
- Drug shipment to the primary sites and collaborating sites with ethics committee 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.

# IST Review Process


## 1. Concept Discussion to Submission

**INVESTIGATOR**

- Complete all sections of our IST application at Seagen grants portal
- Attach budget and CV to your application
- Provide legal contact(s) for NDA if requested

**SEAGEN**

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

## 2. Review and Approval

**SEAGEN**

- Schedule concept for next IST Review Committee (ISTRC) meeting
- Present concept at ISTRC meeting (MSL)
- Execute Non-Disclosure Agreement (NDA) if not present
- Refer concept to partner company for review if it is a partnered-product
- Send committee feedback on concept and budget
- Send Investigator Brochure, safety information and reporting requirements if NDA is executed

## 3. Protocol Development

INVESTIGATOR

- Submit protocol and budget to portal within 90 days

## 4a. Protocol Review and Approval

INVESTIGATOR

- Provide contact for budget and contract negotiations
- Start regulatory filings (ex. IRB and FDA)

**SEAGEN**

- Schedule protocol for next ISTRC meeting
- Review budget for Fair Market Value alignment
- Present concept at ISTRC meeting (MSL)
- Send committee feedback on budget and protocol
- Provide cross reference permission letter (if applicable)

## 4b. Budget and Contract Negotiations

INVESTIGATOR

- Provide finalized protocol, regulatory approvals
- Execute Research Agreement
- Send drug order form if drug is being provided by Seagen
- Send invoice for startup milestone payment
- Provide monthly enrollment updates

**SEAGEN**

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