INVESTIGATOR SPONSORED TRIAL SUBMISSION FORM

Instructions:

Applicants may choose to submit either a **Concept** (Section 1 Only) and/or a **Full Proposal** (Sections 1 and 2 must be completed) for evaluation of Investigator Sponsored Trial (IST) grant support. Please note, your submission must be in English.

- A **Concept** requires limited information which can be used to gauge Verastem Oncology's interest in the research study. If Concept is approved, the investigator may proceed in submitting a "full" study proposal for further review and consideration. Approval of the Concept submission does not guarantee approval of the subsequent full proposal.

- A **Full Proposal** requires detailed additional study information and detailed budget. See Section 2 for required study details. Funding/product support decisions can only be made upon Verastem Oncology's review of a full proposal.

Verastem Oncology will review all concepts and full proposals received; the company does not have a preference for one type of submission. Below is an overview of your submission options for consideration.

Option 1- Concept Proposal as Initial Submission

- For Concept submission, please complete and sign section 1. If the investigator chooses this option, Verastem Oncology will review the submission for strategic alignment. If the IST Concept is deemed of strategic interest, the investigator will be informed via a written approval letter and, at that time, Verastem Oncology will request completion of **Section 2 (Full Proposal).**

Option 2- Full Proposal as Initial Submission

- **If you choose to forgo submitting a Concept and would like to submit a Full Proposal** as your initial submission, please complete **Sections 1 and 2** and ensure the below documents are attached.

    1. Completed Full Proposal Application
    2. Completed Detailed Budget Template
    3. Curriculum Vitae (CV)
    4. Relevant references and other documentation as necessary.

Once the Full Proposal is submitted, Verastem Oncology IST Review Committee will review and confirm if Full Proposal aligns to our research priorities, feasibility, and scientific merits.

All completed applications **must** be submitted to the following mailbox: verastem-IST@verastem.com. Please copy your Medical Science Liaison (MSL) when submitting. We will email you confirmation of receipt within 48 hours.

For any questions about the application process, please contact your assigned Medical Science Liaison or send an email to: verastem-IST@verastem.com. If you are unaware of a MSL in your area, please contact us.

Section 1- Concept/Overview of Research Study

Internal Use Only **Concept Decision:** **Approved** **Not Approved** **Deferred** **Comments:**			
Verastem Oncology will review all submissions through our IST Review Committee. Decisions are made based upon medical and scientific merit as well as available resources. A formal notification of the decision will be communicated to you. PLEASE NOTE ALL FIELDS ARE REQUIRED.			
Submission Date:			
Study Title:			
Principal Investigator (PI) Contact Information:	Institution Name:		
	PI Full Name:		
	Title:		
	Medical License #:		
	Address:		
	City:		
	State/Province:		Post/Zip Code:
	Country:		
	Phone Number:		
	Fax:		
	Email:		
Support Type:	Funding	Funding and Product	Product Only
Product:			
Estimated Cost: *(Choose One)*	Overall Project Cost:	Cost per Patient:	
Disease State(s)/Tumor Type(s):			

Study Detail and Design In this section, please provide a background about the disease, the study population, and the rationale for the proposed study and outcomes. PLEASE NOTE ALL FIELDS ARE REQUIRED.	
Rationale/Background: Provide brief study synopsis. Provide justification why this study has scientific merit.	
Primary Objectives:	

Secondary Objectives:	
Primary Endpoints:	
Secondary Endpoints:	
Line of Therapy:	
Treatment Schedule:	
Approximate Number of Patients:	
Approximate Enrollment Duration:	
Number of Participating Site(s):	Single Center- Study Multi-Center-Study, (please list planned centers): Multi-National Study, countries (please list):

Section 1- Certification Page

Note: Bypass this page if you are completing a Full Proposal. Please proceed to Section 2 of the form.

Please read and acknowledge the following statements:

- I understand that Investigator Sponsored Trial studies supported by Verastem Oncology must follow all relevant Local, International, and National laws, as well as applicable ethical and scientific guidelines, (e.g., ICH E6, GCP Compliance Guideline).
- I have provided supportive literature citations as an attachment.

Certification Statement	By checking the box and entering my name below, I hereby certify that I have read and acknowledge the above statements; and the information in my submission is true and accurate to the best of my knowledge. Please check box as part of certification. Name and Title: _____ Date: _____

*Section 2 is required for **Full Proposals** and is only required:*

- *If Concept is approved by Verastem Oncology and requires a Full Proposal; or*
- *If you intend to forgo submitting a Concept and choose to complete a Full Proposal as your initial submission.*

Section 2- Full Proposal Details

PLEASE NOTE ALL FIELDS ARE REQUIRED EXCEPT WHERE INDIDCATED.

Please Select: My **Concept** application was approved by Verastem Oncology and I received approval to submit a Full Proposal. I am planning to submit a Full Proposal as my initial submission.		
Submission Date:		
Study Title:		
Principal Investigator (PI) Contact Information:	Institution Name:	
	PI Full Name:	
Additional Funding Sources and Relevant Grant Deadlines: (if applicable)		
Full Study Design: Please provide detailed rationale, background, dosage, schedule, and number of patients.		

Inclusion Criteria:	
Exclusion Criteria:	
Statistical Plan: • Statistical approach • Primary study population • Interim analysis (if applicable) All planned primary analyses and key secondary analyses should be discussed in this section. If other secondary and tertiary analyses are planned, then a statement should be included in this section as to what these analyses are. Describe in detail the statistical methods that will be used for the primary hypotheses or estimation. State the statistical tests which will be used along with other important considerations.	

Translational Research: (if applicable provide details)	
Approximate Enrollment Duration:	
Target Start and End Date:	
Number of Participating Site(s):	
Provide Details on Publication Plan: (Please provide abstract submission timeframe and congress, and manuscript submission timeframe.)	
Budget Directions:	Please remember to complete the downloadable budget template. It must be submitted with your Full Proposal. **Please download the template from our site:** https://www.verastem.com/patients-caregivers/our-clinical-trials/.

Section 2 (Full Proposal)- Certification Page

Please read and acknowledge the following statements:

- I understand that Investigator Sponsored Trial studies supported by Verastem Oncology must follow all relevant Local, International, and National laws, as well as applicable ethical and scientific guidelines, (e.g., ICH E6, GCP Compliance Guideline).
- I have attached an updated CV and included an overview of my research experience (no more than 5 pages total).
- I have provided supportive literature citations as an attachment.
- I have **downloaded** and attached the **Detailed Budget Template** to my Full Proposal Submission.

Certification Statement	By checking the box and entering my name below, I hereby certify that I have read and acknowledge the above statements; and the information in my submission is true and accurate to the best of my knowledge. **Please check box as part of certification.** **Name and Title:** _____ **Date:** _____