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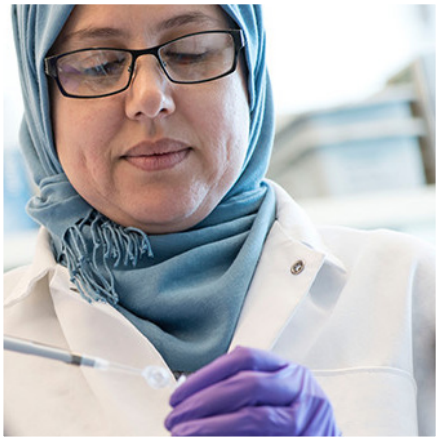
Investigator Sponsored Studies

Program Overview



Types of Research Eligible for Support

Funding and/or drug support may be available for the following categories of research:

- Interventional clinical studies
- Observational studies that support research into disease states, e.g., epidemiological and outcomes studies
- Non-clinical studies using Vertex compounds for in vitro assays or in vivo models
  - Compound only requests for nonclinical studies should be submitted directly to compoundrequests@vrtx.com

CF Areas of Interest

- Disease modification with CFTR modulators
- Treatment with CFTR modulators early in disease course
- Addressing unmet need (e.g., rare CFTR mutations)
- Non-pulmonary effects of CFTR modulators
- Health resource utilization (e.g., medication burden) associated with CFTR modulator use

Applications are being considered for the following:

- CF disease state
- Studies involving approved Vertex drugs

Applications are NOT being accepted for the following programs:

Acute Spinal Cord Injury: VX-210
Influenza: VX-787

Pain: VX-150
Oncology: VX-803, VX-970, VX-984

Cystic Fibrosis: VX-152, VX-371, VX-440, VX-445, VX-561, VX-659

Choose a box below to learn more and apply:

Review Criteria | Submission Process | Contracting and Study Initiation

Regulatory and Safety Reporting Requirements | Active Study | Apply

Vertex Pharmaceuticals Incorporated | Boston, MA, USA | 617.341.6100 | www.vrtx.com

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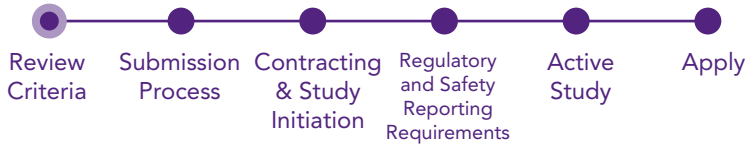
Review Criteria



The following areas are taken into consideration during the proposal review:

- Availability of support
- Innovation
- Rationale and scientific rigor
- Ethical considerations
- Institution and PI qualifications
- Reasonableness of support
- Alignment with Vertex's overall research and development strategies

To be eligible for support, you must accept full responsibility for designing, conducting and monitoring your own studies.

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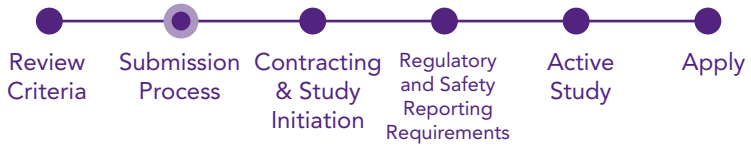
Proposal Submission Process

Applications can be submitted at www.vrtxissgrants.com



Non-clinical Research

Non-clinical research applications require a single proposal submission. This proposal is a comprehensive summary of your research plan.

At this time you will submit a comprehensive study budget. The budget should include any study supplies, statistical analysis, animal costs and any other 1-time costs. Any required institutional overhead must be included in the budget.

Concept reviews are usually completed within 8 to 12 weeks. You will be notified of review decisions via email.

Clinical Research

Clinical research applications require a 2-step process involving a preliminary concept proposal submission that, if accepted, is followed by a more detailed protocol submission.

Concept Submission:

A concept proposal is a brief, high level outline of your study. It is not intended to be a complete abstract or protocol. At this time you will also submit a detailed estimate of the study budget.

Concept reviews are usually completed within 8 to 12 weeks. You will be notified of review decisions via email.

Protocol Submission:

If a clinical concept is approved, the next step is to submit a full protocol. A protocol is significantly more detailed and well developed than a clinical concept submission, and is required only for clinical research applications.

At this time you will also submit a comprehensive line-item study budget. Include any start-up costs, personnel costs, patient costs, laboratory fees, and any other requirements. In an effort to ensure this can be done efficiently, we recommend using the budget template provided to the left of the protocol submission tab in the portal.

Protocol reviews are usually completed within 60 days. You will be notified of review decisions via email.

Study Budgets

All budgets will be reviewed for accuracy, inclusion of covered costs, and for alignment with fair market value.

Additional information on ISS budgets is available in the ISS Budget Guidelines document on the ISS portal (vrtxissgrants.com)

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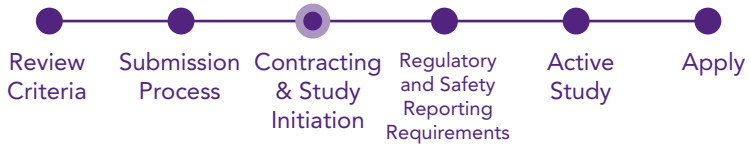
Contracting



Once all Vertex approvals are in place, Vertex will work with the legal department or contracts office at your institution to begin negotiating a grant agreement.

The research agreement will cover such things as regulatory responsibilities, safety reporting requirements, indemnification, intellectual property and publications.

Studies may not be initiated until a mutually acceptable grant agreement has been executed.

Initiation Requirements

Non-clinical studies:

Vertex requires a fully executed research agreement and documentation of Institutional Animal Care and Use (IUCAC) approval, if appropriate, prior to study initiation.

Clinical Studies:

Vertex requires documentation of Institutional Review Board (IRB)/Ethics Committee (EC) approval, a copy of the IRB/EC approved final protocol, confirmation of Regulatory Authority approval (if applicable), and a fully executed grant agreement prior to study initiation.

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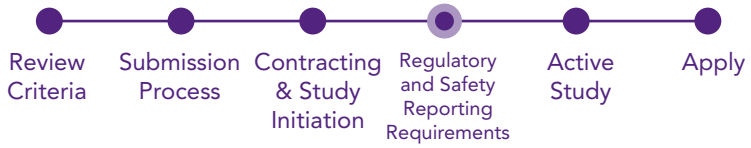
Regulatory Responsibilities (Clinical Research)



As the study sponsor, you must ensure that the study is conducted in accordance with all applicable regulatory requirements, including adherence to International Conference on Harmonisation (ICH) and Good Clinical Practice (GCP) guidelines.

You must assume all regulatory responsibilities including but not limited to, IRB/EC approvals, regulatory authority approvals, and any associated reporting obligations to regulatory authorities.

If a study utilizes a product in a way that is not consistent with the approved product label, you, as the study sponsor, must file any required application with the relevant regulatory authority, e.g., an Investigational New Drug (IND) application to the FDA or a Clinical Trial Application (CTA) to Health Canada. Vertex will provide necessary supporting documentation for IND/CTA filings in the form of a cross-reference letter.

Safety Reporting Requirements (Clinical Research)

If your study involves the use of a Vertex product, you will be required to follow Vertex's safety reporting requirements.

All safety reporting requirements will also be set forth in the contract between Vertex and your institution. Reporting to Vertex does not relieve you of your reporting obligations to your IRB/EC or Regulatory Authority. Vertex will not report AEs/SAEs to your Regulatory Authority on your behalf.

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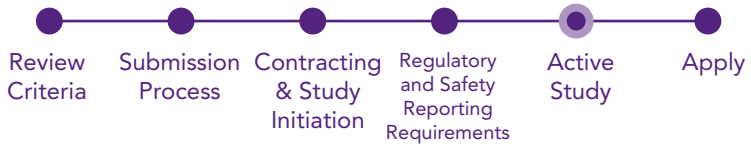
Study Updates



All investigators will be contractually required to submit quarterly study progress updates. This will require that the investigator describe, in specific and quantifiable ways, the current status of the protocol and report any planned publications, updated study approvals or proposed study amendments.

Payment Information

Payments are linked to the achievement of study milestones and are outlined in the grant agreement.

Drug Supply

Vertex will supply study drug or drug compound in accordance with the terms of the grant agreement. These must be used solely in the study and may not be made available to any other party. Drug or compound remaining at the completion of the study must be destroyed according to institutional policy and documentation of its destruction must be provided to Vertex.

For clinical studies, unless otherwise specified, study drug will be supplied in the approved commercial packaging. Any study-specific labeling is the responsibility of you, as the study sponsor. Secured storage, drug accountability, etc, are also your responsibility as study sponsor.

Closeout Requirements

Vertex requires a final written report documenting study results at the conclusion of each investigator sponsored study. At the conclusion of the study, it will also be necessary to provide Vertex with a financial reconciliation of funds provided and documentation of the destruction of any remaining study drug or compound.

Publications

Vertex is committed to transparency of study data and encourages the publication of all study results. As such, we expect all investigators to review the guiding principles set forth by the International Committee of Medical Journal Editors and comply with their registration and publication requirements, which can be found here: http://www.icmje.org

As noted above, we require in our contracts that manuscripts, abstracts and presentations first be submitted to Vertex, in advance of their submission, for courtesy review and to allow for protection of intellectual property rights.

Registration of Studies on Public Web Sites

Vertex encourages investigators, or their institution, to post applicable studies to the FDA's ClinicalTrials.gov database (www.ClinicalTrials.gov) or a trial registry web site in your country.

Financial Disclosure

Vertex may publicly disclose funding associated with ISS support.

Application Assistance

For questions regarding the Vertex ISS Program, please contact: vrtx_iss@vrtx.com.

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