argenx

Investigator-Initiated Studies (IIS) Guide

Get started →

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IIS Guide Contents

Investigator-Initiated Studies at argenx

Our Company Commitment

argenx is committed to pioneering innovative solutions to help improve the lives of patients suffering from autoimmune diseases. Inspired by their resilience, we turn breakthroughs into medicines with urgency for patients.

The goal of this program is to support the pursuit of externally driven research that advances the understanding of disease and its treatment.

argenx – Together we are better.

What is an Investigator-Initiated Study?

Overview

An Investigator-Initiated Study (IIS) is an externally sponsored research (ESR) project that is managed by an independent third party (without direct involvement of argenx) who takes on regulatory and legal responsibility for the study's development, conduct, and oversight. argenx supports both interventional and observational types of IIS. The researchers handle the research design and implementation, addressing scientific or medical questions.

IIS has the potential to greatly enhance our understanding and treatment of diseases. argenx is dedicated to fostering discovery processes that provide solutions to patients through innovation, collaboration, and science-driven research.

Key Criteria for IIS Proposals:

- The request is unsolicited and independent
- Research is scientifically valid and relevant
- Research can be ethically conducted by qualified researchers
- Support complies with laws and industry guidelines, as well as investigators institutional guidelines.
- The research is not intended to generate business or promote products
- Financial support covers necessary costs only.

Areas of Primary Research Interest

argenx will consider high-quality proposals for Investigator-Initiated Studies in the following areas.
These areas of interest are subject to change at the sole discretion of argenx. If you're unsure about how your proposal aligns with our current areas of interest, please contact esr@argenx.com. We still want to hear from you.

Generalized Myasthenia Gravis (gMG)

- Efgartigimod's potential to reduce concomitant gMG therapies
- The use of efgartigimod early in gMG
- The effect of efgartigimod in acute presentations of gMG
- Long-term outcomes of gMG
- Development of novel patient assessment tools for assessing Myasthenia Gravis (MG)
- Holistic assessment of patient outcomes during efgartigimod treatment for gMG (eg employment, ability to function)
- The central role of immunoglobulin G (IgG) autoantibodies in the pathophysiology of MG

Chronic Immune Demyelinating Polyneuropathy (CIDP)

- The use of efgartigimod early in CIDP
- The use of efgartigimod in comparison to immunoglobulins
- Efgartigimod's impact on CIDP disease progression
- The switch of CIDP patients from immunoglobulins to efgartigimod
- Development of novel patient assessment tools and treatment goals in CIDP
- The central role of IgG autoantibodies in the pathophysiology of CIDP

Other Areas of Research Interest

argenx will consider high-quality proposals for Investigator-Initiated Studies in the following areas.
These areas of interest are subject to change at the sole discretion of argenx. If you're unsure about how your proposal aligns with our current areas of interest, please contact esr@argenx.com. We still want to hear from you.

Neurology

IgG mediated autoimmune diseases of the central and peripheral nervous system such as:

- Anti-IgLON5 disease
- Autoimmune autonomic ganglionopathy (AAG)
- Autoimmune nodopathies (excluding bridging)
- Guillain Barre Syndrome (GBS)
- Lambert Eaton Myasthenic Syndrome (LEMS)
- Neuromyelitis optica spectrum disorder maintenance (NMOSD)
- Myelin oligodendrocyte glycoprotein antibody disease maintenance (MOGAD)
- Stiff Person Syndrome (SPS)

Rheumatology

Autoimmune diseases with IgG-Autoantibody involvement such as:

- IgG4-related disease
- Minimal Change Disease (MCD)

Dermatology

- Pemphigus vulgaris
- Bullous pemphigoid

Hematology

IgG mediated autoimmune diseases with significant unmet need such as:

- Acquired hemophilia (AHA)
- Catastrophic Anti-Phospholipid Syndrome (APS)

The IIS Study Process

Overview of the **Investigator-Initiated Study Process**

Preparing Your Proposal

Review this guide to prepare to submit your Concept Proposal. Contact us at esr@argenx.com if you have any questions.

Submit a Concept Proposal

Review and provide all of the required information to submit a complete Concept Proposal.

Submit Full Research Proposal

Upon review and acceptance of the Concept Proposal by the IIS Committee, a Full Proposal that includes the final budget and study protocol should be submitted for final approval.

Contracting

After the Full Proposal is accepted, we begin the process of contracting with your institution and setting up the study.

Conducting the Study & Reporting

Ensure that you have a plan for periodic reporting, publication, and other analysis milestones.

Publishing

As part of your research agreement with argenx, you will want to think about a publication strategy, as a publication is anticipated.

The investigator must be knowledgeable about and comply with all local regulations related to the application and execution of the study.

IIS Proposal Process:

Preparing Your Proposal

Overview

The first step in initiating an IIS request is to submit a Concept Proposal. While it is not necessary to contact argenx before submitting a proposal, a member of the argenx Medical Affairs team is available if you have any questions about the process.

What is the IIS Committee?

The IIS Committee is made up of a cross functional team that includes Medical Affairs, Science, Development, Regulatory, Legal, and Compliance. Their purpose is to evaluate incoming proposals.

argenx considers the following elements when reviewing proposals:

- ❑ Alignment with argenx research objectives and areas of interests
- ❑ Proposed research addresses an unmet patient need or important scientific question
- ❑ The results are expected to be publishable in a peer-reviewed journal
- ❑ Patient safety and privacy plans
- ❑ Clear study design, specific and appropriate objectives and endpoints
- ❑ Appropriate patient populations
- ❑ Overall study feasibility and appropriateness of payment milestones
- ❑ Investigator capable of executing the study and achieving the objectives
- ❑ Requested financial support is limited to the reasonable and necessary costs of carrying out the research

argenx is deeply committed to Investigator-Initiated Study proposals, and will make public its areas of interest for ESR. All proposal will be objectively assessed, but submitting a proposal does not guarantee approval.

IIS Proposal Process:

Submit a Concept Proposal

Overview

A concept proposal gives a simple overview of your planned study. The concept proposal allows argenx to assess interest in supporting without requiring the submitter to prepare a full protocol.

IIS Concept proposals must be sent to esr@argenx.com for review for consideration of advancement to Full Proposal request.

Research proposals will be reviewed and approved based on scientific merit and alignment with our areas of strategic interest. We evaluate all funding requests against local fair market value. Funding requests for expenses not associated with the conduct of the study are strictly prohibited.

AVERAGE ESTIMATED TIMELINE:
Decisions are typically communicated within 45 days of receipt of a complete concept proposal or full proposal.

What to Expect

During the Concept Proposal submission and evaluation period, argenx may ask scientific questions about your proposal. Our IIS Committee might ask you to resubmit your Concept Proposal with clarifications—especially if the proposal is scientifically complex. This helps the committee fully understand your proposed study.

You'll want to be prepared for:

- Requests for explanation of the Concept Proposal to be submitted
- Scientific questions on your proposal
- Discussions with Medical Affairs Team

For proposals to be considered complete they need to include the following…

- ❑ Description of relevance to argenx areas of interest
- ❑ A title and description of the overall research plan
- ❑ Clear hypotheses and study objectives
- ❑ Inclusion and exclusion criteria for recruiting
- ❑ Estimated number of subjects
- ❑ Proposed clinical endpoints
- ❑ Estimated study and publication timeline(s)
- ❑ Type of support request—eg, study drug, funding, or both
- ❑ Name of the principal investigator and the sub investigator
- ❑ Research capabilities and experience

Please reach out to esr@argenx to receive a template for your Concept Proposal if you do not already have one. Note that not all concepts and full proposals will move forward. For more about Concept Proposal requirements, please reach out to esr@argenx.com.

IIS Proposal Process:

Submit Full Research Proposal

Overview

Once the Full Research Proposal is approved, contracting and study startup activities will begin. argenx will provide the necessary research agreements for review and signing.

Documentation of the final details of the study, alongside key budget items, make up the Full Research Proposal.

In addition to everything you've already provided in the Concept Proposal, a Full Research Proposal should also include:

- ❑ Participant population and sample size
- ❑ Interventions and procedures
- ❑ Data collection and analysis plan
- ❑ Complete Site Feasibility Checklist
- ❑ A thorough timeline of the research activities
- ❑ Detailed budget, including direct and indirect costs and publication expenses
- ❑ Compliance and regulation considerations

Contracting

Research agreements will include key study milestones along with the final protocol study-related documents as attachments.

Contracting timelines are contingent upon study specifications and dependent on local procedures.

argenx is committed to timely review and execution for all research agreements. If contracting takes longer than 6 months, we may need to reconsider funding.

Please be sure to obtain approval from your local Internal Review Board (IRB). We will need the final study protocol and informed consent form that was approved by your local IRB in order to move forward into contracting.

IIS Proposal Process:

Reporting and Publishing

Overview

We'll ask that you provide regular updates and reporting on an agreed-upon schedule throughout the process to keep argenx informed of progress and clinical insight along the way.

Reporting

Ensure that you have a plan for periodic reporting, publication, and other analysis milestones.

A typical IIS research agreement with argenx includes a requirement for quarterly progress reports, as well as a final report on the study for the IIS Committee and other potential argenx representatives.

Publishing

As part of your research agreement with argenx, you will want to think about a publication strategy, as a publication is anticipated.

Research agreements with argenx typically include a request for notification of intent to publish prior to initiation and expectation for a courtesy review for medical accuracy, intellectual property (IP), and compliance review at least 60 days prior to the submission date.

Any publications resulting from Investigator-Initiated Studies with argenx must follow recommendations developed by the International Committee of Medical Journal Editors (ICJME) and Good Publication Practice (GPP) 2022 guidelines, as well as any other relevant international medical publishing guidelines.

Contact Information

Still have questions?

Please email us with the following information, tell us how we can help, and we will get in touch with you shortly by email or phone:

- First and last name
- Email address
- Phone Number
- Your specialty or field
- Any comments or questions you may have

CONTACT US
esr@argenx.com

Inquiries about research proposals that are not Investigator-Initiated Studies can be sent to BD@argenx.com