

# Investigator Sponsored Research (ISR)



**BaudaX BIO®**

## The Baudax Bio® ISR Program

Investigator Sponsored Research is an important part of our commitment to increasing understanding and knowledge of the acute pain management landscape. We believe that ISR offers unique perspectives based on the expertise and clinical experience of investigators. The Baudax Bio ISR program is dedicated to supporting informative research that addresses meaningful clinical objectives.

### Current Areas of Interest

Baudax Bio will evaluate ISR proposals from qualified\* US clinicians and researchers that align with Baudax Bio research areas, which include, but are not limited to:

Use of IV meloxicam across varied treatment areas

Management of moderate to severe pain with IV meloxicam

\*Qualifications are dependent on the type of research proposed. A curriculum vitae will be required.

### Overview of the ISR Application Process



Concept reviews and full ISR proposal reviews are conducted by the Baudax Bio Grant Review Committee (GRC), a multidisciplinary team composed of US-based medical, scientific, regulatory, legal, and operations experts. This committee will review the initial concept proposal for a variety of criteria, including:



Clinical value



Scientific validity



Originality



Rigor of the proposed research



Patient safety



Compliance



Feasibility of timelines

Please visit [BaudaxBio.com](https://www.baudaxbio.com) to access and learn how to submit the Concept Proposal Form.

Within 30-45 days after receipt of the concept proposal form, the potential Grant Recipient will be notified by e-mail of concept approval or denial. If the concept proposal is accepted, the potential Grant Recipient will be provided with the appropriate steps needed for completion of a full ISR proposal with protocol.

**IMPORTANT: The Baudax Bio GRC will approve only select proposals and provides no guarantee that any single proposal will receive support.**

## Helpful Resources

For complete information about how to submit a research proposal, helpful resources for your team can be downloaded at [BaudaxBio.com](https://www.baudaxbio.com):

- The ISR Reference Guide answers questions and provides detailed instructions to guide the application process, including the concept proposal and development of the full ISR proposal
- A link to the US Food and Drug Administration (FDA) website provides access to the principles and required procedures for conducting independent investigator-sponsored research

## FDA Requirements and Resources

Grant Recipients are responsible for adhering to current FDA regulatory and ethical requirements. This includes the submission of an IND, if applicable, as well as fulfilling all necessary safety reports for the FDA.

Although not a comprehensive list, key resources to consult include:

### Good Clinical Practice (GCP)

<https://www.fda.gov/media/93884/download>

### Good Pharmacovigilance Practices (GVP)

<https://www.fda.gov/media/71546/download>

### Safety Reporting Requirements

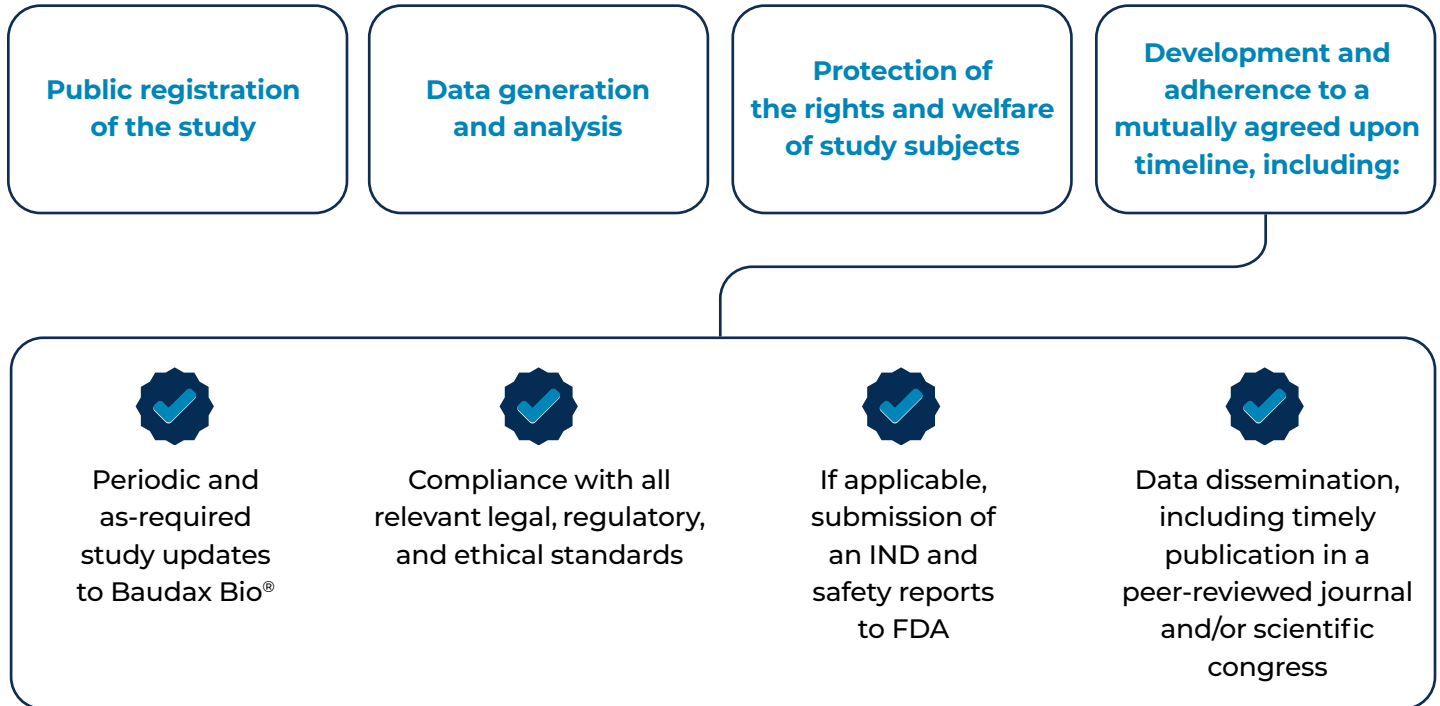
<https://www.fda.gov/media/79394/download>

### Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators

<https://www.fda.gov/media/92604/download>

## Independent Investigator Responsibilities

If Baudax Bio accepts a full ISR proposal, the Grant Recipient may receive financial support and/or medicinal product(s) from Baudax Bio. However, the Grant Recipient will retain full responsibility and control of the design, initiation, management, data analysis, monitoring, and reporting of the trial and its results. A Research Grant Agreement will clearly define the terms for the research, as well as delineate the roles of Baudax Bio and the Grant Recipient. The Grant Recipient's responsibilities include but are not limited to:



**Thank you for your interest in ISR.**

**To submit an ISR Concept Proposal or for more information,  
please visit [BaudaxBio.com](https://BaudaxBio.com).**

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