AMERICAN REGENT™

Investigator-Initiated Studies (IIS) Overview

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AMERICAN REGENT™

Introduction to American Regent

American Regent, Inc. is committed to supporting Investigator Initiated-Studies (IIS) to address medically and scientifically sound research for the management of Iron Deficiency Anemia, related to Injectafer® (ferric carboxymaltose injection). American Regent, Inc. also offers opportunities for outside qualified health care professionals and scientists interested in conducting their own research to submit a research proposal, which is subsequently reviewed by an internal multi-disciplinary committee.

Areas of Interest

- Clinical studies of approved and unapproved uses of Injectafer® (ferric carboxymaltose injection) for the treatment of Iron Deficiency Anemia
- Interventional or observational studies, such as epidemiology studies and certain outcomes research studies for the treatment of Iron Deficiency Anemia
- Societal and health-economic benefits of the treatment of Iron Deficiency Anemia

American Regent may provide support in the form of funding, study drug or both.

Please review the following guidelines and requirements for IIS submission. This information will provide you with an understanding of the requirements for an investigators interested in submitting a proposal.

Investigator-Initiated Study (IIS) Proposal Submission Process

Requirements for initial submission through the IIS portal:

- A completed IIS Proposal Synopsis Form
    - Please click the following link to download the form and complete all of the information to be considered for review: http://americanregent.com/Investigator_Sponsored_Study_Info.aspx
- Investigator Curriculum Vitae (signed and dated)
- Itemized Budget

Please note: IIS applications will only be accepted during the dates listed below:

- For 2018 Support – submissions are now closed
- For 2019 Support – open submissions window from October 01, 2018-December 14, 2018, with review of applications finalized by January 2018.

Review Process

American Regent will confirm receipt of all correctly completed Proposal Synopses submissions. Once American Regent, Inc. receives the completed proposal and supportive documentation, the proposal synopsis will be reviewed by our IIS committee in accordance with company policy. The investigator will be informed of the decision once the review has been completed.

If a study proposal is approved, the investigator will be contacted via e-mail with a Proposal Synopsis approval letter. The investigator is then required to submit the documents noted below for final review:

- Final Submission Form and relevant documentation (provided to the investigator)
- IRB Approval
- IRB-Approved Full Protocol

Upon review and approval of these materials by American Regent, an IIS agreement will be drafted for signature by both parties. Once a fully executed agreement has been achieved, the study can begin.

If all information listed above is not submitted within the given time frame, American Regent reserves the right to deny support for the IIS.

Once the study is completed, all materials discussed in the IIS Agreement (study reports, abstracts, publications, etc.) must be provided to American Regent

Proposal Synopsis Form

Please complete the Proposal Synopsis form on the IIS portal and ensure all of the relevant information is provided. Correctly completing the form will ensure American Regent is able to conduct a full evaluation and determine if we are interested in receiving a Final Submission. Please include supplemental literature, if applicable.

American Regent will contact you regarding a Final Submission Form if the IIS proposal is found to be of interest.

Final Submission Form

The Final Submission form contains detailed information about the investigator, study and budget in order for American Regent to render a comprehensive review and final decision. Once the investigator receives the IIS Proposal Approval letter, please ensure all of the following information is provided with the Final Submission form along with an IRB-approved protocol:

• **Principal Investigator and Institution Name**
o Contact information of all relevant investigators and contracting personnel
o NPI Number and Medical License and State (if applicable)
• **Preliminary Title**
• **Investigational Drug and Dose/Regimen**
• **Number of Subjects**
• **Number of Planned Sites (US or ex-US)**
• **Type of support (drug product, financial, or both)**
• **Total Budget Request**
o Direct Study Costs
o Indirect Study Cost
• **Non-American Regent drugs (if applicable)**
• **Projected study milestones/timeline**
o List the date in the left-hand column with the corresponding suggested milestone payment amount ($) in the right-hand column
o Edit Milestone Titles as applicable
• **Study Rationale**
• **Primary Endpoints**
• **Statistical Methods**
• **Inclusion/Exclusion Criteria**
• **Study design (control, number of treatment arms, inclusion/exclusion criteria, dose administered, treatment duration, endpoints, patient population**)
• **Publication Plans**
• **Itemized Budget**
• **IRS Form W-9**
o American Regent requires all IIS research proposals to submit a completed copy of the payee IRS W-9 Form available at: www.irs.gov
• **Provide Sunshine Act Reporting Information (if applicable)**
o Teaching Hospital and Tax ID
• **Relevant Conflicts of Interest**

Please note: American Regent will not provide support for the following:

- Request for support for ongoing or new research without an associated protocol or synopsis
- Hiring of staff that are not dedicated to the study
- Feasibility costs not considered in the initially approved agreement

American Regent and Investigator Responsibilities

American Regent Responsibilities

- Review and Approval of Proposal and Final Submission
- Review of Protocol Amendments

Investigator-Sponsor Responsibilities

- Research Protocol Development
- Submission of protocol to IRB and assurance of adequate adherence to protocol
- Registry of IIS in a database such as clinicaltrials.gov
- Submission of IND application (*if applicable*)
- Conduct Research
- Submission of Protocol Amendments
- Report Safety Data to American Regent and all relevant authorities
- Analysis of final study data
- Authorship and publication of study results

Safety Reporting Requirements

Timely and accurate reporting of safety data is of upmost importance to investigators and American Regent. American Regent requires that any adverse event must be reported within 24 hours to all relevant authorities and to American Regent via email to IST@americanregent.com and PV@luitpold.com or via facsimile to 610-650-0170.

Additionally, American Regent will conduct quarterly reviews with the investigators for study updates.

IIS Completion

As per the IIS agreement, the investigator is required to provide the final report of the IIS study results as well as any relevant publications to American Regent. Once received, American Regent will send the investigator a letter confirming fulfillment of all agreed upon IIS requirements.

Publications

American Regent is committed to publishing research regarding our products and encourages principal investigators to publish study results from the IIS. Prior to Journal or Conference submission, any publications, including abstracts, must be submitted to American Regent 30 days in advance for internal review.