GenMark

Investigator Initiated Study Form

GenMark Dx™

Areas of Interest

- Patient outcomes
- Clinical utility with Antimicrobial Stewardship
- Health economic impact

What is a GenMark Dx Investigator-Initiated Study?

An Investigator-Initiated Study (IIS) is a research effort in which the investigator designs and implements the study in collaboration with GenMark Dx and the investigator or the institution acts as the study sponsor, not GenMark Dx. As the sponsor, the Investigator assumes all responsibilities for complying with applicable regulatory requirements. GenMark Dx may offer a level of support for the IIS in the form of instrumentation, test panels, funding, and/or technical input and support. While all studies can provide meaningful outcomes, prioritization will be given to studies that fit within the long-term goals and objectives of GenMark Dx.

Investigator Responsibilities

- Designing and conducting the scientific investigation
- Complying with institutional requirements where the study will be conducted and all relevant laws, regulations and guidelines for clinical and pre-clinical research
- Providing GenMark with interim and final research summary reports, a proposed publication plan and draft abstracts, posters, or manuscript for review, as applicable.

Application Materials

- A completed Application Form (See below)
- A study protocol or proposal that includes, at a minimum, the study objectives, background and rationale, clinical population description and size, study plan, projected study timeline, and amount of product/funding requested
- Investigator Curriculum Vitae (signed and dated)
- Itemized budget for any requested funding

Application Submission

GenMark accepts applications on a rolling basis until all funding for the fiscal year has been exhausted. Then the acceptance window will close until budgets for the following year have been allocated.

Once the Application Package has been completed, it should be submitted to GenMark Dx Scientific and Medical Affairs at ScientificAffairs@genmarkdx.com for review. Please contact Scientific Affairs for questions or additional instructions. Review of application packages takes approximately 1 month.

Review Process

All submissions will first be reviewed by Scientific and Medical Affairs to gauge interest in support. All applications of interest will then be reviewed by a cross-functional team for additional review/approval. A decision is based on criteria in the areas of strategic fit with the areas of interest (*above),* long-term goals and objectives of GenMark Dx, investigator research experience, and scientific merit. Scientific Affairs will notify the applicant of the committee's decision regarding the study proposal.

What Happens After My Study Proposal is Approved?

Notification will be by e-mail and if additional study documents are required for final review they will be requested.

These documents may include:

- IIS Research Agreement, provided by GenMark Dx for signature
- Full Protocol
    - IRB-approved Full Protocol, if applicable
- IRB Approval Letter, if applicable
- IRB-approved Informed Consent, if applicable

Once these documents have been reviewed and approved, agreed-upon funding, product, and/or technical input will be released according to the terms and milestones in the funding agreement. The study cannot commence until final approval is provided by GenMark Dx.
On completion of the study, you will provide GenMark Dx with the deliverable and an associated timeframe for the deliverable that is noted in the IIS Research Agreement (e.g. final study report, draft manuscript, abstract, poster, etc.)

Investigator Initiated Study (IIS) Application Form

GenMark representative: **Date:**

Study site and Principal Investigator:

Site demographics:

Hospital bed size:

Proposal (*2 pages max*):

1) Study Aim (e.g. comparison study, performance) and summary. Please provide details on the study proposal overview including goals/aims, assay, and comparator method.

2) Data or endpoints to be collected:

3) Projected study timeline:

4) Number of kits and instrumentation requested or other anticipated GenMark support:

5) Deliverables and timeframe for the study, including any potential poster, publication, speaking engagement etc.:

Investigator (signature*): _____(date)_____

*if you are not able to electronically sign the document, please confirm this in the emailed submission

Submit to ScientificAffairs@genmarkdx.com

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