

# Request for Proposals: Research Studies Incorporating BiImage Study Assets Aimed at the Better Understanding of Atherothrombosis and its Clinical Manifestations

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**Issued by: BG Medicine on behalf of the HRP Initiative**

The HRP Initiative is a precompetitive industry alliance launched in 2006 to advance the knowledge of atherothrombosis, the underlying disease process that may lead to heart attack or stroke. The HRP Initiative is sponsored by Abbott Pharmaceuticals, AstraZeneca, Merck & Co., Philips Medical Systems, and Takeda Pharmaceuticals. Work conducted under the Initiative included the completion of the BiImage Study, a large observational study enrolling approximately 7,000 healthy individuals presumed to be at high risk for cardiovascular disease. The BiImage Study created a wealth of research assets including biological specimens, imaging results, and rich clinical data sets. The HRP Initiative would like to make these assets available for use in research studies aimed to support the original objective of improving detection of those at near-term risk for atherothrombotic events, or which contribute to the understanding of atherothrombosis and its risk factors.

The results of these efforts, which are under the auspices of the HRP Initiative, will be shared openly with the member companies and the HRP Scientific Advisory Board. Certain intellectual property and data sharing conditions apply.

This Request for Proposals (RFP) is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of BG Medicine or the HRP Initiative. BG Medicine or the HRP Initiative does not intend to make any awards based on responses to this RFP or to otherwise pay for the preparation of any information submitted or for the use of such information.

## **Purpose**

The purpose of this RFP is to solicit ideas regarding the design and execution of research studies directed at advancing the knowledge of atherothrombosis and the underlying disease process that may lead to heart attack or stroke. The HRP Initiative is offering the use of its BiImage Study assets to help facilitate important research aimed at understanding this major health problem.

Proposals that support the original BiImage Study objective of improving detection of those at near-term risk for atherothrombotic events, or which contribute to the understanding of atherothrombosis and its risk factors are eligible.

Proposals will be reviewed by a committee consisting of members from the Joint Steering Committee and the Scientific Program Board of the HRP Initiative.



Some of the scientific resources that are being offered for further scientific study include:

- i) Biological specimens: plasma, serum, RNA, and DNA, obtained from the participants at baseline
- ii) Baseline imaging studies (~6,000) include:
  - a. Coronary Artery Calcium Score (CACS) by CT
  - b. Measurement of carotid Intima-Media Thickness (IMT)
  - c. Presence of carotid atherosclerotic plaques and Abdominal Aortic Aneurysm (AAA) by ultrasound
  - d. Ankle Brachial Index (ABI)
- iii) Advanced imaging (~1,000) studies include:
  - a. Contrast-enhanced or non-contrast MRI of carotid arteries and aorta
  - b. Contrast enhanced carotid CT angiography for non-calcified plaques and stenoses
  - c. PET-CT for carotid and aortic inflammation
- iv) Clinical measurements, including blood pressure, weight, height, and waste/hip circumference
- v) Health questionnaire

For further information about the BioImage Study please visit:

<http://www.hrpinitiative.com/hrpinit/bioimage>

### Feedback is sought from

- Members of the academic scientific community
- Biotechnology and pharmaceutical industries
- Relevant professional societies or organizations

### Background

Atherosclerosis is a major cause of death and disability in both industrialized and developing countries. The vast majority of patients with atherosclerosis are asymptomatic. In a significant proportion, the first clinical manifestation of atherosclerosis is an acute myocardial infarction or stroke. Primary prevention with risk factor modification has been shown to be effective in reducing overall risk. However, assessments of clinical risk factors and traditional biomarkers have limited accuracy in detecting the presence and severity of subclinical disease and predicting major cardiovascular events.

### Goals and Objectives

To make new discoveries and develop tools which will enable one to identify subjects at higher risk of Major Adverse Cardiac and Cerebrovascular Events (MACCE) beyond the estimate provided by current risk engines.

Studies of interest include those aimed at the identification of imaging markers and/or circulating biomarkers and their association with each other or with cardiovascular outcomes.



It is the intention of the RFP to seek proposals defining a research strategy utilizing the BiImage Study assets with specific aims and research goals which align with the original BiImage Study objectives. Proposals should state the broad goals of the project and describe the research approach and rationale, the measurable outcomes and tangible deliverables, as well as estimated timelines for the proposed research. Proposals should be submitted electronically using the BiImage RFP Application which can be found at <http://www.hrpinitiative.com/hrpinit/bioimagerfp>

### **How to Respond**

Responses should be submitted using the BiImage RFP Application and be limited to ten pages. Proposed research must be funded by the entity submitting the proposal or funded by appropriate third-party grants or funds that are solicited and secured by the entity submitting the proposal or the Principal Investigator. Certain intellectual property and data sharing conditions apply.

Responses should be submitted electronically by email to the following email address: [bioimagerfp@bg-medicine.com](mailto:bioimagerfp@bg-medicine.com)

Respondents will receive an email confirmation acknowledging receipt of their response, but may not receive immediate or individualized feedback.

Responses to this RFP are voluntary. All responses will remain confidential. Nonetheless, no proprietary information should be submitted.

### **Questions or Feedback**

Contact Rene Myers, [rmyers@bg-medicine.com](mailto:rmyers@bg-medicine.com), (781) 890-1199.

