Protocol Title: A Multicenter Study of Detection of Low Ventricular Ejection Fraction (LVEF) ≤ 40% Based on Point-of-Care 12-lead ECG Data

Mayo Clinic Co-Principal Investigators: Drs. Peter Noseworthy and Konstantinos Siontis

Date:

Dear Dr.,

You are being considered as a potential Site Investigator for the aforementioned study. This is not a firm commitment to participate but an indication of your site’s interest in the study. The final decision regarding site participation will be made based on recruitment potential, site resources, and the ability to meet protocol requirements.

The following items are being sent with this feasibility form, as applicable:

Protocol Date provided:

Budget draft Date provided:

Other:       Date provided:

Please complete this attached questionnaire and return it to sender.

Thank you for your time and cooperation,

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| 1. **STUDY REQUIREMENTS** | | | |
| Will your site be able to systematically export and provide digital 12-lead, 10-second ECGs in an XML format that have been de-encrypted and de-identified? | | | Yes  No |
| Do you have engineering support for the IT-related requirements of the study? | | | Yes  No |
| Please confirm that your site uses the Simpson method as the standard approach for ejection fraction (EF) determination? | | | Yes  No |
| Is the echo lab at your site IAC accredited? | | | Yes  No |
| Does your site have the capability to distinguish and exclude cases for which EF has been only visually estimated? | | | Yes  No |
| Can your site link ECG and Echo records for each patient? | | | Yes  No |
| Does your site have a central echo database with structured data fields for retrieval of echo data and patient demographics? | | | Yes  No |
| What is the time horizon for your electronic medical record? | | |  |
| Describe your site’s IT capabilities for EHR-based capture of risk factors based on ICD-9 and ICD-10 diagnostic codes | | |  |
| Please confirm your site will be able to provide relevant regulatory documents, including:   * Investigator CVs * Delegation of Authority Log * Confirmation of any site-conducted training * IRB approvals * Notification to study sponsor of any study issues/events/deviations | | | Yes  No |
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| 1. **INVESTIGATOR AND FACILITY INFORMATION** | | | |
| First Name: | | Last Name: | Title: |
| Institution Name: | | Department: | |
| Street Address: | | | |
| Town/City: | | State/County/Province: | |
| Zip/Postcode: | | Country: | |
| Phone: | | Fax: | |
| Email address: | | | |
| Practice Setting *(check all that apply)* | | Hospital  University Hospital  Private Clinic  Specialist Clinic – Specify:  Non-profit Organization  Other – Specify: | |

1. Has an FDA 483 warning letter been issued to your site?

Yes  No

1. Have any of the site staff involved in this research been debarred from practicing or participating in Clinical Research by the FDA?

Yes  No

***If checked “Yes”, please complete the following information:***

|  |  |  |  |
| --- | --- | --- | --- |
| **Staff Member/IRB Name** | **Site Name** | **Reason for debarment**  ***(Why was it issued?)*** | **FDA debarment details attached?** |
|  |  |  | Yes  No |
|  |  |  | Yes  No |
|  |  |  | Yes  No |
|  |  |  | Yes  No |

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| --- | --- | --- | --- |
| 1. Have any sites and/or staff members involved in this research had a history and/or have current issues with non-compliance? (*This most likely would have been captured in monitoring letters/reports, requested or issued Corrective and Preventative Actions (CAPAs), and/or audits.)*   Yes  No  ***If checked “Yes”, please complete the following information:*** | | | |
| **Staff Member/IRB Name** | **Site Name** | **Description of Non-Compliance** | **Documentation of Non-Compliance issues attached?** |
|  |  |  | Yes  No |
|  |  |  | Yes  No |
|  |  |  | Yes  No |
|  |  |  | Yes  No |

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| 1. **PATIENT POPULATION, RECRUITMENT POTENTIAL, AND ACCRUAL** | |
| Do you foresee any challenges/restrictions with any of the patient eligibility criteria? | Yes  No |
| If Yes, please indicate which inclusion/exclusion criterion: | Inclusion criterion:  Exclusion criterion: |
| Based on the inclusion/exclusion criteria provided – anticipate the number of cases your site will be able to provide. |  |
| Please estimate the percentage of non-white patients undergoing echocardiography at your site. |  |
| How many ECGs and transthoracic echocardiograms did your site perform annually on average over the past 5 years? |  |
|  | |
| Thank you for taking the time to complete this questionnaire.  Please include any applicable site policies or procedures, CV (signed and dated within the last 2 years), and a current medical license of the Site Investigator.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Site Representative Signature and Title Date** | |