AtRial Cardiopathy and Antithrombotic Drugs In prevention After cryptogenic stroke (ARCADIA)

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ARCADIA Summary

Primary hypothesis: Apixaban is superior to aspirin for prevention of recurrent stroke or death in patients with cryptogenic stroke and atrial cardiopathy

- 1,100 patients to be randomized at 120 sites
- 86 sites have been named to date (cohort 1-3)
- Cohort 4 still to be determined
- Sites are chosen based on feasibility survey (# strokes, % cryptogenic, competing trials and level of enthusiasm)
- If you have added new sites or information has changed let us know!

*ARCADIA listed on StrokeNet website  https://www.nihstrokenet.org/
( click on Clinical Trials/Prevention)
Estimated ARCADIA Timeline

• Protocol Trial Agreements - 3 B information being collected now
  PTA will be sent as soon as sub-award with Columbia is executed
  (approx. 6 weeks) Trial Budgets to be included with this

• Protocol — Amendment 1 will be sent to sites as soon as it is approved by CIRB - June 2017

• Site IRB submissions - August 2017

• Release first site to enroll - September 2017

• Investigator meeting — September 13, 2017
ARCADIA Investigator Meeting
Atlanta September 13th

- Sites need to identify attendees as soon as possible
- ARCADIA will cover the cost for a PI and Coordinator from each site
- Travel arrangements will be coordinated through Columbia University (Linda Busacca)
- DSM Travel will arrange flights to and from Atlanta for ARCADIA
- Atlanta Airport Marriot will be providing a link for participants to reserve a hotel room
- Meeting will be all day, Sept 13th, 8am-4pm with an informal (non-mandatory) welcome reception the evening before (Sept 12th) from 7pm -9pm with appetizers provided and a cash bar available
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<th>Step 1 Document</th>
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<td>Curriculum Vitae</td>
<td>Site Principal Investigator, Sub- Investigator,</td>
<td>WebDCU™ - 🚀</td>
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<tr>
<td>Medical/ Professional License</td>
<td>Site Principal Investigator, Sub- Investigator, Nurse Coordinator, Primary Site Pharmacist</td>
<td>WebDCU™ - 🚀</td>
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<tr>
<td>StrokeNet CIRB Financial Interest Disclosure Form OR VA FCOI form</td>
<td>Site Principal Investigator, Sub- Investigator, Coordinators</td>
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<td>Human Subjects Protection Training Certification</td>
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<td>NIHSS Certification</td>
<td>People who will administer the NIH Stroke Scale</td>
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<td>mRS Certification</td>
<td>People who will administer the modified Rankin Scale.</td>
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<td>Sample Handling and Shipping Certification</td>
<td>People who will ship biologic specimens</td>
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<td>ePAS assurance form</td>
<td>Site PI only</td>
<td>NCC/CIRB 📧 <a href="mailto:Irene.ewing@uc.edu">Irene.ewing@uc.edu</a></td>
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<td>IRB Federal Wide Assurance</td>
<td>Per institution</td>
<td>WebDCU™ - 🚀</td>
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Regulatory Document Collection

Step 1 document collection:

Identify your ARCADIA Team members to be listed on the Delegation of Authority Log

- Site PI and Sub-Investigators
- Primary Site Coordinator and other coordinators
- Primary Pharmacist
- Lab technician/coordinator - someone certified to ship biologic specimens
StrokeNet National Data Management Center (NDMC) – Medical University of South Carolina

The NDMC is the centralized data management center for the NIH StrokeNet. The web-based clinical trials management system is called the WebDCU™ (https://webdcu.musc.edu/login.asp)

Opportunities for training in the WebDCU system include:
• Web-based training
• Webinars
• In person training at the Investigator meeting
Human Subject Protection (HSP) Training

• Participating institutions may require a particular program (e.g., CITI Training) or may choose to develop a program to meet this requirement.

• A certificate of completion of the NIH tutorial “Protecting Human Research Participants” will also meet the requirement (https://phrp.nihtraining.com/users/login.php).

• Frequency of HSP training is institution specific and will be driven by the expiration date stated on the certificate. If no expiration date is listed, the expiration date is 5 years from the certification date.
NIH Stroke Scale (NIHSS) Certification

- All protocol required NIH Stroke Scale (NIHSS) assessments will be completed by a study team member who has a current NIHSS certification and is assigned that responsibility on the Delegation of Authority Log.

- Recertification will be required per the expiration date on the certificate. If no expiration date is specified, recertification will be required every two years.

- A resource link for NIHSS training certification can be found at https://webdcu.musc.edu/campus/).
Modified Rankin Scale Certification

- All protocol required modified Rankin Scale (mRS) assessments will be completed by a study team member who has a current mRS certification and is assigned that responsibility on the Delegation of Authority Log.
- Recertification will be required per the expiration date on the certificate. If no expiration date is specified, recertification will be required every 2.
- mRS training certification can be obtained at https://webdcu.musc.edu/campus/