



# 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)



ARCADIA

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## 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 13<sup>th</sup>**

- 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 13<sup>th</sup> , 8am-4pm with an informal (non-mandatory) welcome reception the evening before (Sept 12<sup>th</sup> ) from 7pm -9pm with appetizers provided and a cash bar available



ARCADIA

Step 1 Document	Required for:	Document Repository
Curriculum Vitae	Site Principal Investigator, Sub- Investigator,	WebDCU™
Medical/ Professional License	Site Principal Investigator, Sub- Investigator, Nurse Coordinator, Primary Site Pharmacist	WebDCU™
StrokeNet CIRB Financial Interest Disclosure Form OR VA fCOI form	Site Principal Investigator, Sub- Investigator, Coordinators	WebDCU™
Human Subjects Protection Training Certification	Site Principal Investigator, Sub- Investigator, Coordinators	WebDCU™
NIHSS Certification	People who will administer the NIH Stroke Scale	WebDCU™
mRS Certification	People who will administer the modified Rankin Scale.	WebDCU™
Sample Handling and Shipping Certification	People who will ship biologic specimens	WebDCU™
ePAS assurance form	Site PI only	NCC/CIRB Irene.ewing@uc.edu
IRB Federal Wide Assurance	Per institution	WebDCU™



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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

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## 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.





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## **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://webdca.musc.edu/campus/>