



Athersys, Inc. | B01-04 | May 2020

Thank you for your continued commitment to the MASTERS-2 study!

We understand that as the situation with the COVID-19 pandemic evolves, the status of your site may continue to change and clinical care may remain a priority. We greatly appreciate your dedication to the MASTERS-2 study and your ability to adapt to these challenging circumstances.

Recruitment

- Patients randomized = 45

| Site | Enrolled |
|--|----------|
| 101/Dr. Chiu, Jason Lee, and team – Methodist Hospital Research Institute | 15 |
| 102/Dr. Clark, Megan Pattle, and team – Oregon Health & Science University | 24 |
| 103/Dr. Switzer, Keith McCalman, and team – Augusta University, Georgia Regents University | 1 |
| 104/Dr. Uchino, Lori Strozniak, and team – Cleveland Clinic | 3 |
| 105/Dr. Savitz, Dorothea Parker, and team – The University of Texas Health Science Center | 1 |
| 115/Dr. Devlin, Katrina Barton, and team – Chattanooga Center for Neurologic Research | 1 |

Thank you for all your recruitment efforts!

COVID-19 Update Reminders

- Please be sure to notify your CRA once screening and/or on-site monitoring is permitted and can resume.
- As LARs may not be allowed on site due to institutional COVID-19 regulations, methods for remote consenting may need to be updated on a site-by-site basis. Please communicate to your CRA any updated consenting policies for your site.
- Reminder: SARS-CoV-2 PCR positive patients should be excluded from participation on the basis of Exclusion Criteria 15 (Concurrent systemic infection or severe local infection).

Protocol Amendment v3.0 Reminders

- Please confirm the Protocol Amendment v3.0 and the Administrative Letter have been submitted to the IRB.
- Athersys approval **must** be obtained to perform any assessment via telemedicine or telephone.
- Telephone assessments should only be utilized as a last resort if in-person and telemedicine are not possible.

EDC Blinded Site Source Portal

- New Blinded Site Source portal is now live; sites can securely upload source documents for CRA remote verification. For more information, please contact your CRA.

Important reminder about trainings

- As a reminder, if your NIHSS or mRS certification is out of date, you will not be permitted to perform those assessments for the study until an updated certificate has been received. Please notify the Medpace team if you anticipate delays due to COVID-19.
- Although the initial mRS certification can be performed via a platform other than BlueCloud, re-certification upon expiration **must** be completed through BlueCloud.
- Please email Janae Fitzpatrick at j.fitzpatrick@medpace.com if a link to BlueCloud training is needed.

Unblinded team reminders:

- Please remember to upload your freezer temperature summary reports to the site source portal **every month** at <https://clintrakedc.medpace.com/>. If you have any questions on how to do this, please review the quick reference guide and/or reach out to your unblinded CRA.
- When uploading the subject batch records to the site source portal, please ensure you include **all** the required documents such as IP Prep Form, IRT transaction, Supply Kit Inventory form, and Chain of Custody form.
- Inform your unblinded CRA **immediately** in the event of a LN2 freezer temperature excursion: storage temp > -140°C or LN2 submersion
- Contact your unblinded CRA if you have added study staff or made changes to your unblinded study team.

Helpful links:

- BlueCloud
 - Website: <https://secure.trainingcampus.net/uas/modules/trees/windex.aspx?rx=medpace-masters-2.trainingcampus.net&>
 - Reminder: IP Training videos and mRS/NIHSS training can be viewed at this website.
- EDC
 - Website: <https://clintrakedc.medpace.com/>
 - Reminder: Data should be entered into EDC within 5 business days of subject visits.
- IRT
 - Website: <https://clintrakirt.medpace.com>
 - Reminder: ClinTrak IRT passwords expire every 60 days
 - SOPs, forms, and instructions for receipt, storage, and preparation of IP can be found here.
- Safety Contact
 - Medpace SAE hotline: 1-866-336-0930 | medpace-safetynotification@medpace.com
 - Medpace fax: 1-866-336-5320

This email is considered confidential study correspondence and must be retained in the Investigator Study File (ISF) binder.

Thank you,
Medpace Study Team

M E D P A C E