



Athersys, Inc. | B01-04 | September 2020

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

As the situation with the COVID-19 pandemic evolves, we will continue to follow up with you for current institutional policies and site status updates. Please notify us promptly if LARs are no longer permitted on site and remote consenting has not been implemented.

Welcome to our newly activated site!

Site
111/Dr. Auchus, Lauren Lovato, and team – University of Mississippi Medical Center

Recruitment

- Patients randomized = 52

Site	Enrolled
101/Dr. Chiu, Jason Lee, and team – Methodist Hospital Research Institute	17
102/Dr. Clark, Megan Pattle, and team – Oregon Health & Science University	28
103/Dr. Switzer, Keith McCalman, and team – Augusta University	1
104/Dr. Uchino, Laura Sweeney, and team – Cleveland Clinic	4
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 hard work with recruitment!

COVID-19 Update Reminders

- Please continue to stay up to date on pre-screening logs and submit to your blinded CRA.
- If COVID-19 is impacting your site's capability to enroll patients into the sub-studies, please inform your CRA.

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- 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 continue to communicate to your CRA any updated consenting policies for your site.
- Reminder: SARS-CoV-2 PCR positive patients should be excluded from randomization on the basis of Exclusion Criteria 15 (Concurrent systemic infection or severe local infection).

ClinTrak Password Reminders

- Your password to ClinTrak and all related ClinTrak systems (IRT, IVRS, EDC) expires after 90 days.
- Your CRA will receive monthly listings of users with upcoming password expirations and will reach out if your password is nearing expiration.
- Please ensure that you have set up your “challenge question,” which enables you to reset your own password within a few weeks of password expiry.
- If you are in need of IRT/IVRS assistance, please contact your CRA or call 1-800-730-5779. We are striving towards improvements in our after-hours assistance, and any future updates will be communicated in subsequent E-Blasts.

Telemedicine and Telephone Assessment Reminders

- 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. Please remember that the NIHSS **can not** be performed via telephone, so a telephone visit may result in a protocol deviation if any assessments are missed.
- Patients should be encouraged to explore all options to make telemedicine possible if an in-person visit is not feasible.
- If the situation with COVID-19 has been resolved at your site, telephone assessment will no longer be permitted.
- **Every attempt** should be made to collect labs at the Day 30 visit as this is important for safety assessments.

Start Up Item Reminders

- Two site personnel must have EDC and IRT access for site activation. Please be sure to submit your EDC and IRT ARM requests as soon as possible; contact your CRA if you have questions.
- Please re-confirm the appropriate shipping address(es) for lab supplies and the Welcome Pack with your CRA.
- Documentation of mRS and NIHSS certification is required for the PI and primary CRC in order to activate your site. Please provide these in a timely manner to your CRA or e.ross@medpace.com.

Investigational Product (IP) Updates

- Team members should ensure they have reviewed in IRT the updated Standard Operating Procedures (SOPs) related to IP handling, preparation, and distribution.
- Please ensure that your site has submitted the new Investigator’s Brochure V7.3 to the IRB and documented approval has been sent to 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.
- 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 notify your CRA if COVID-19 is impacting the unblinded team's hours and capabilities for IP preparation.
- 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 90 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

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