

MOST...In Brief

Why the wait?

Due to supply chain issues with glassware and commercially available drug, manufacturing of MOST study drug has been delayed. This will push our go-live date to July 2019.

Between the Investigator Meeting and the time study drug becomes available, sites should solidify their local logistics, train their teams, and complete Readiness Calls. Please continue to push forward with study approvals and preparations. We need to have as many sites as possible ready to enroll when study drug is available in order to adhere to our recruitment timelines.

Investigator Meeting

The MOST Investigator Meeting in Philadelphia is 6 weeks away!

Flights should be purchased by **Friday, March 29**. Please purchase your flight first, then complete the online registration form with your travel details: <u>MOST Investigator Meeting Registration</u>. **Everyone attending should complete this form**, even if you do not need reimbursement, so we can get an accurate headcount.

MOST is paying for Renaissance Philadelphia Airport Hotel rooms on the back end and will be booking the rooms as well. Individuals *do not need* to make hotel reservations, just indicate on the registration form which night(s) you will be staying. Upon check in, you will give your name and present a credit card for incidentals.

Please reach out to Iris Deeds, <u>deedsss@uc.edu</u>, with questions.

FDA Form 3455

It was recently determined that the FDA Form 3455 is not a requirement for the MOST trial. These documents no longer need to be collected.

FAQS

Will a serum pregnancy test be allowed in place of a urine pregnancy test?

Yes. Both serum and urine pregnancy tests are acceptable.

Is MOST subject to the Common Rule changes?

The University of Cincinnati Institutional Review Board will continue to follow the pre-2018 requirements for all StrokeNet protocols that were approved prior to January 21, 2019. The addition of sites to these protocols are considered amendments to the Prime Award Protocol and will also be maintained and approved with pre-2018 requirements.

When do COIs expire?

When entering COI expiration dates in WebDCU[™], please enter 27Jan2020. This is the study expiration date at which time all approved sites will need to renew their COI forms.

Congratulations to our first 50 sites with completed CTAs!

Thank you to all the sites who have executed their Clinical Trials Agreement and are working through CIRB approval. We are receiving more approvals each day and are on pace to have most sites ready to open enrollment by July. Please see the chart below for site readiness progress.

Sending E-mails

Please continue to reach out to the MOST leadership teams with your questions. It is very helpful to provide your RCC and site name in all email correspondence. This helps us solve issues more easily and quickly.

Example subject line: MOST - University of Cincinnati - UCMC - topic of email

Site Start-up Progress

