ANTICIPATED “Primary Completion Date” & “Study Completion Date”
Anticipated dates can be updated at any point.

ACTUAL “Primary Completion Date”
The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome(s).
Equivalent to CTRP “Closed to Accrual and Intervention” & ClinicalTrials.gov “Active, not recruiting”.

ACTUAL “Study Completion Date”
(Last participant’s last visit)
The date that the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events, whether the clinical study concluded according to the pre-specified protocol or was terminated. Equivalent to CTRP “Complete” or “Administratively Complete” & ClinicalTrials.gov “Completed” or “Terminated”.

OnCore Data Entry
Registration
Study treatment/data collection for primary outcome measure(s)
12 months
Study treatment/data collection for secondary outcome measure(s)
12 months
IRB Closure

Start CTRP & ClinicalTrials.gov registrations
Trial registrations completed in CTRP & ClinicalTrials.gov
Submit accruals to CTPR quarterly
Enter subject information in OnCore
Enter protocol information in OnCore
SRC Approval (for interventional trials)
IRB Approval or Open to Accrual
Closed to Accrual

IRB Final Closure

All research activities and data analyses completed.

Initial Results/AE reporting completed in ClinicalTrials.gov
For any NIH-funded or FDAAA “Applicable Clinical Trial”

Final Results/AE reporting completed in ClinicalTrials.gov
For any NIH-funded or FDAAA “Applicable Clinical Trial”

Government Registry Actions
OnCore Actions

Submit accruals to CTRP quarterly
Prior to enrollment of first participant.

The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome(s).
Equivalent to CTRP “Closed to Accrual and Intervention” & ClinicalTrials.gov “Active, not recruiting”.

Equivalent to CTRP “Complete” or “Administratively Complete” & ClinicalTrials.gov “Completed” or “Terminated”.

This time frame lasts until a trial closes to accrual AND participants have completed therapy/interventions related to the primary outcome(s).
Only the investigator and study staff will know when this collection period actually ends.

Long-term follow-up may continue after the Actual Primary Completion Date (if data is not being collected for the primary outcome measures).

Protocol completed normally or prematurely. Participants are no longer being examined, treated, or followed up.
The study does not need to be closed in IRB to be considered complete in government registries.