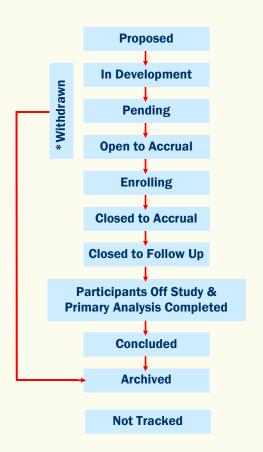
Study Statuses

Protocol Management

September 14, 2015



Proposed
The network le commit resou The network leadership has decided to commit resources on the proposal. For non-network initiatives, DAIDS has decided to commit resources on the proposal.

*In Development

Protocol is being developed.

*Pending

Final protocol version has been approved by DAIDS and distributed to field, but has not yet met all conditions for opening to accrual.

*Open to Accrual

The study has met all conditions for opening and is awaiting the first enrollment.

Enrolling

The study has enrolled the first participant.

· Study Agents/Products available.

· Regulatory requirements met.

· All data management requirements met.

 All other requirements to "Open to Accrual" met.

Proposal Approved for Protocol Development

Proposal is approved for protocol development.

Protocol Received at DAIDS

for the first time on this date. This is the all the regulatory, and any other requireinitial draft of the protocol.

Team Sign-Off

The Protocol Team has signed off on the team sign-off version of the protocol before SRC Full Review on this date.

DAIDS SRC Full Review

CSRC or PSRC Full Review has occurred on this date.

Final Team Sign-Off

The Protocol Team has signed off on the final team sign-off version of the protocol on this date.

Full Regulatory Review

The Regulatory Review version comments are completed and sent to the Protocol Team by RCC on this date.

MO Sign-Off

The MO has signed off on the MO version of the protocol on this date.

RAB Sign-Off

RAB has signed off on the final version of the protocol on this date.

Protocol Distributed to Field

The RAB signed off final version of the protocol was distributed to sites on this date.

Requirements Met to Open to Accrual

The Protocol has been received at DAIDS The data management requirements, ments that need to be fulfilled are met prior to indicating that a study is allowed to open to accrual.

First Participant Enrolled

The first enrollment to the study has occurred on this date.

Temporarily Closed (Paused) to Study Agents/Products

Administration of Study Agents/ Products is temporarily stopped (paused) on this date. This refers to the entire study and not pause on one arm or one product.

Re-opened to Study Agents/Products

The study has been re-opened to study agents/products administration after a temporary closure on this date.

Temporarily Closed (Paused) to **Accrual and Study Agents/Products**

The study has been temporarily closed to accrual and further administration of Study Agents/Products is stopped (paused) on this date. This refers to the entire study and not pause on one arm or one product.

Temporarily Closed (Paused) to Accrual

The study has been temporarily closed to accrual on this date.

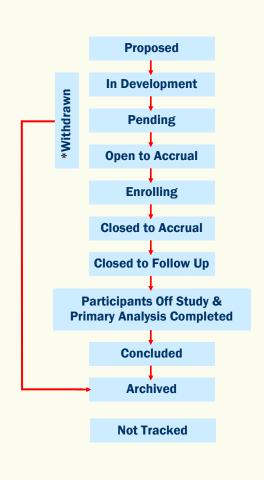
Re-Opened

The study has been re-opened after a temporary closure on this date.

Enrollment Closed

No longer able to enroll participants on study.

* Withdrawn The study is withdrawn prior to achieving "Enrolling" status.



NIAID CRMS Support Information

8:30 a.m. to 5:30 p.m. EST (M-F)

☎ 1 (240) 778—2517 ☑ CRMSsupport@niaid.nih.gov

Closed to Accrual Participants Off Study & **Archived Closed to Follow Up** Concluded **Not Tracked Primary Analysis** The study is closed to accrual and no The study has been permanently The study is ended and no further The study is archived. The study activities are not tracked in Completed Protocol Management (e.g., for some more participants are enrolled on the closed to accrual, all participants have activity or resource expenditure on completed Study Agents/Products and study. All participants are off study and the study is expected. DOD protocols only courtesy review is all follow up visits have been primary analysis is completed. performed by DAIDS). completed. EVENT · Primary analysis is completed or it · All protocol-required data analyses · SMDC dataset archived. has been determined no primary are finished or it has been deter-· Site CRFs archival permission. analysis can be done. mined no analysis can be done. · Public dataset released. · Primary manuscript has been accepted for publication or determined to be "not publishable" in any journal. · Primary manuscript is published if primary manuscript has been accepted for publication. · Other manuscripts from study's original plan have been accepted for publication or it has been determined that the analyses are "not publishable." • Final Report or Executive Summary is submitted to DAIDS. Temporarily Closed (Paused) to **Requirements Met for all Partici-Requirements Met for Concluding Requirements Met for Archival** Study Agents/Products pants Off Study and Primary Analy-All requirements are met for conclud-All requirements are met for archiv-Administration of Study Agents/ sis Completion (POS-PAC) ing the study. ing the study. The study is "Closed to Follow Up" Products is temporarily stopped (paused) on this date. This refers to and the primary analysis is completthe entire study and not pause on ed or it has been determined no one arm or one product. primary analysis can be done. Re-opened to Study Agents/ **Products** The study has been re-opened to study agents/products administration after a temporary closure on this Closed to Study Agents/Products The study has been permanently closed to accrual and all participants have completed Study Agents/ Products on this date. **Last Participant Off Study** All participants have completed follow up visits and are off study.