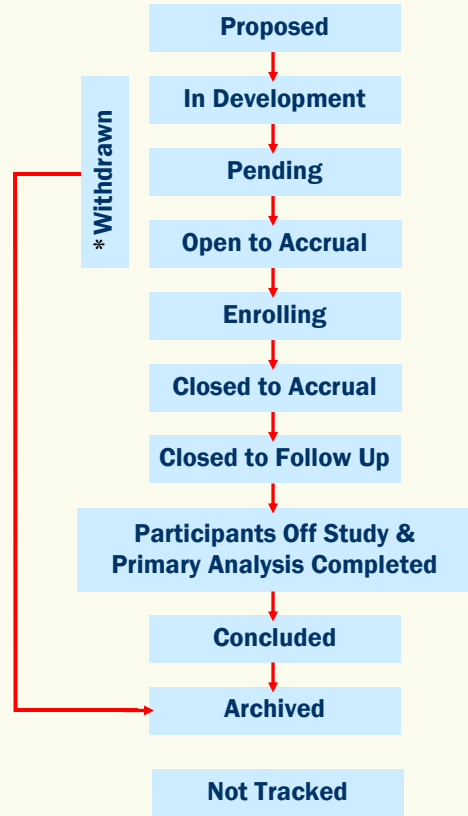


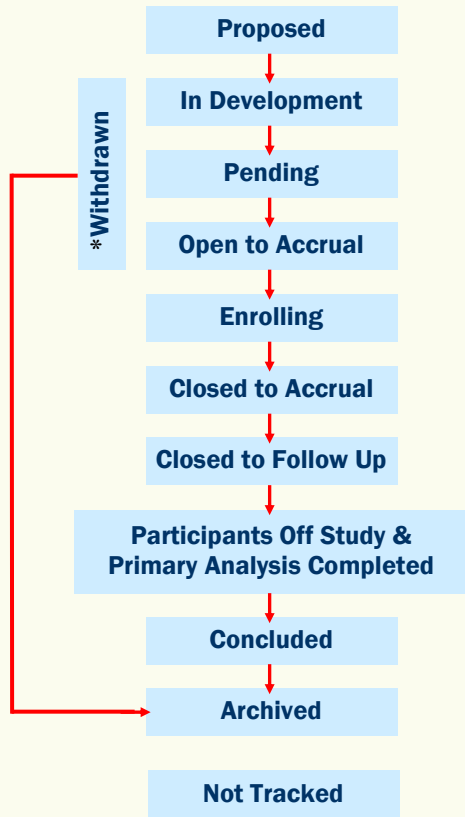
Study Statuses

Protocol Management

September 14, 2015



STATUS	Proposed 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.
EVENT			<ul style="list-style-type: none"> Study Agents/Products available. Regulatory requirements met. All data management requirements met. All other requirements to "Open to Accrual" met. 		
MILESTONE	Proposal Approved for Protocol Development Proposal is approved for protocol development.	Protocol Received at DAIDS The Protocol has been received at DAIDS for the first time on this date. This is the initial 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 data management requirements, all the regulatory, and any other requirements 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

STATUS	Closed to Accrual The study is closed to accrual and no more participants are enrolled on the study.	Closed to Follow Up The study has been permanently closed to accrual, all participants have completed Study Agents/Products and all follow up visits have been completed.	Participants Off Study & Primary Analysis Completed All participants are off study and primary analysis is completed.	Concluded The study is ended and no further activity or resource expenditure on the study is expected.	Archived The study is archived.	Not Tracked The study activities are not tracked in Protocol Management (e.g., for some DOD protocols only courtesy review is performed by DAIDS).
EVENT		<ul style="list-style-type: none"> Primary analysis is completed or it has been determined no primary analysis can be done. 	<ul style="list-style-type: none"> All protocol-required data analyses are finished or it has been determined no analysis can be done. 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. 	<ul style="list-style-type: none"> SMDC dataset archived. Site CRFs archival permission. Public dataset released. 		
MILESTONE	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.	Requirements Met for all Participants Off Study and Primary Analysis Completion (POS-PAC) The study is "Closed to Follow Up" and the primary analysis is completed or it has been determined no primary analysis can be done.	Requirements Met for Concluding All requirements are met for concluding the study.	Requirements Met for Archival All requirements are met for archiving the study.		
	Re-opened to Study Agents/Products The study has been re-opened to study agents/products administration after a temporary closure on this date.					
	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.					