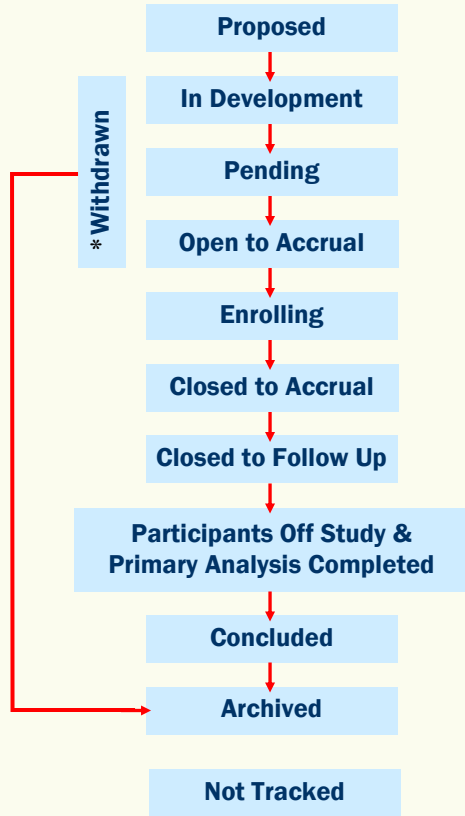


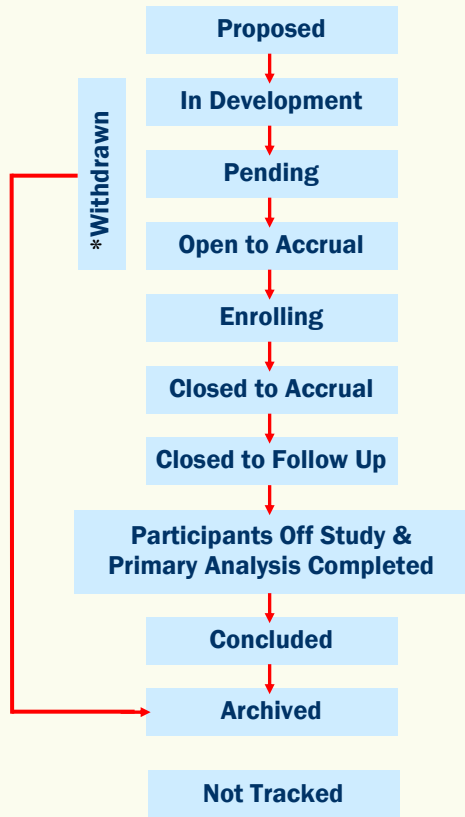
# Study Statuses

## 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"> <li>Study Agents/Products available.</li> <li>Regulatory requirements met.</li> <li>All data management requirements met.</li> <li>All other requirements to "Open to Accrual" met.</li> </ul>		
MILESTONE	<b>Proposal Approved for Protocol Development</b> Proposal is approved for protocol development.	<b>Protocol Received at DAIDS</b> The Protocol has been received at DAIDS for the first time on this date. This is the initial draft of the protocol.  <b>Team Sign-Off</b> The Protocol Team has signed off on the team sign-off version of the protocol before SRC Full Review on this date.  <b>DAIDS SRC Full Review</b> CSRC or PSRC Full Review has occurred on this date.  <b>Final Team Sign-Off</b> The Protocol Team has signed off on the final team sign-off version of the protocol on this date.  <b>Full Regulatory Review</b> The Regulatory Review version comments are completed and sent to the Protocol Team by RCC on this date.  <b>MO Sign-Off</b> The MO has signed off on the MO version of the protocol on this date.  <b>RAB Sign-Off</b> RAB has signed off on the final version of the protocol on this date.  <b>Protocol Distributed to Field</b> The RAB signed off final version of the protocol was distributed to sites on this date.	<b>Requirements Met to Open to Accrual</b> 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.	<b>First Participant Enrolled</b> The first enrollment to the study has occurred on this date.	<b>Temporarily Closed (Paused) to Study Agents/Products</b> 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.  <b>Re-opened to Study Agents/Products</b> The study has been re-opened to study agents/products administration after a temporary closure on this date.  <b>Temporarily Closed (Paused) to Accrual and Study Agents/Products</b> 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.  <b>Temporarily Closed (Paused) to Accrual</b> The study has been temporarily closed to accrual on this date.  <b>Re-Opened</b> The study has been re-opened after a temporary closure on this date.  <b>Enrollment Closed</b> No longer able to enroll participants on study.
<b>* Withdrawn</b> 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	<b>Closed to Accrual</b> The study is closed to accrual and no more participants are enrolled on the study.	<b>Closed to Follow Up</b> The study has been permanently closed to accrual, all participants have completed Study Agents/Products and all follow up visits have been completed.	<b>Participants Off Study &amp; Primary Analysis Completed</b> All participants are off study and primary analysis is completed.	<b>Concluded</b> The study is ended and no further activity or resource expenditure on the study is expected.	<b>Archived</b> The study is archived.	<b>Not Tracked</b> 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"> <li>Primary analysis is completed or it has been determined no primary analysis can be done.</li> </ul>	<ul style="list-style-type: none"> <li>All protocol-required data analyses are finished or it has been determined no analysis can be done.</li> <li>Primary manuscript has been accepted for publication or determined to be "not publishable" in any journal.</li> <li>Primary manuscript is published if primary manuscript has been accepted for publication.</li> <li>Other manuscripts from study's original plan have been accepted for publication or it has been determined that the analyses are "not publishable."</li> <li>Final Report or Executive Summary is submitted to DAIDS.</li> </ul>	<ul style="list-style-type: none"> <li>SMDC dataset archived.</li> <li>Site CRFs archival permission.</li> <li>Public dataset released.</li> </ul>		
MILESTONE	<b>Temporarily Closed (Paused) to Study Agents/Products</b> 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.	<b>Requirements Met for all Participants Off Study and Primary Analysis Completion (POS-PAC)</b> The study is "Closed to Follow Up" and the primary analysis is completed or it has been determined no primary analysis can be done.	<b>Requirements Met for Concluding</b> All requirements are met for concluding the study.	<b>Requirements Met for Archival</b> All requirements are met for archiving the study.		
	<b>Re-opened to Study Agents/Products</b> The study has been re-opened to study agents/products administration after a temporary closure on this date.					
	<b>Closed to Study Agents/Products</b> The study has been permanently closed to accrual and all participants have completed Study Agents/Products on this date.					
	<b>Last Participant Off Study</b> All participants have completed follow up visits and are off study.					