DAIDS RSC Regulatory Support Center

Protocol Development Lifecycle

Click on any **Study Status** to link to more information. Roll over any underlined Term, **Milestone**, and **Entity** in order to reveal more detailed information. Additional hyperlinks links are underlined and blue. Click on the FAQ icon as well, for more information.

Study Status	Milestone	Entity and Key Points
Proposed	**Proposal Approved for Protocol Development**	**Network Ops Center/Protocol Team** sends proposal for protocol to **DAIDS**. **DAIDS** approves proposal for development.
In Development	**Clinical Trial Agreement (CTA) Initiation**	**DAIDS CTAT** and **DAIDS RSC CTA Team** initiate and negotiate CTAs between **DAIDS** and **Industry Collaborators** (study product manufacturers).
	Protocol Reviewed by DAIDS Clinical/ Prevention Scientific Review Committee (C/PSRC)	**Protocol Team** signs-off on protocol draft and sends the protocol to **DAIDS**. **CSRC** or **PSRC** reviews the protocol to assess its scientific merit, and to ensure participant safety, and regulatory compliance. **DAIDS RSC SRC** prepares the Consensus Review, which is then sent to the **Protocol Team**. **Protocol Team** addresses the major comments of the committee and submits a revised protocol to **DAIDS RSC**. FAQ
	Regulatory Review	**DAIDS RSC Regulatory** and **DAIDS RSC HSP** work with **DAIDS RAB** and **DAIDS ProPEP**, respectively, to carry out a full regulatory review of a new protocol or an amendment regulatory review for a protocol amendment and send their comments to the **Protocol Team**. **Protocol Team** addresses regulatory comments and sends revised protocol to **DAIDS RSC** who reviews the updates and then sends the protocol to the **DAIDS Medical Officer (MO)**.
	DAIDS Medical Officer (MO) Review and Sign-off	**DAIDS MO** reviews the protocol and either provides sign-off or sends comments that need to be addressed to **DAIDS RSC Regulatory** who forwards the comments to the **Protocol Team**. **Protocol Team** addresses MO comments and if necessary sends revised protocol to **DAIDS RSC Regulatory** who, along with **DAIDS RSC HSP**, reviews the updates and then sends the protocol to **DAIDS RAB**.
	Final DAIDS RAB Review and Sign-off	**DAIDS RAB** reviews the revised protocol and provides sign-off. **DAIDS RSC Regulatory** submits the finalized protocol to the FDA (for IND studies) and sends it to **Network Ops Center** for distribution to **Sites**.

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Study Status	Milestone	Entity and Key Points
Pending	Regulatory Activities	**DAIDS CTAT** and **DAIDS RSC CTA Team** finalize CTAs with collaborators. **DAIDS RSC Safety Information Center (RIC)** distributes IB/PIs (and other DAIDS Safety Information Types) to the Networks and Sites as requested. **Protocol Team** replies to any FDA requests for information. Team also ensures study agents/products are ready, data management requirements met, and any protocol specific requirements are met. FAQ
	Ethical Review	**Sites** submit materials to their **IRB/EC.** FAQ
	Protocol Registration	Using the PRO Manual, **Sites** submit protocol registration materials (e.g., Site Informed Consent forms, IRB/EC/RE approval letters, FDA 1572 forms, IOR forms, CVs, etc.) to **DAIDS RSC PRO** via the DAIDS Protocol Registration System (DPRS). **DAIDS PRO** collects registration materials from Sites and when all documents have been received, they work with **DAIDS PRT** to review and approve the Site's registration. FAQ
Open to Accrual		Study has met all conditions for opening and is officially open and awaiting the first enrollment.
Enrolling		The study has enrolled the first participant and is continuing to accrue more subjects. **Sites** continue to submit required materials (e.g., new/updated FDA 1572 forms, CVs, to **DAIDS RSC PRO**). During this time, the study may be temporarily closed (paused) to study agents/products, temporarily closed (paused) to accrual and study agents/products, or temporarily closed to accrual and then the protocol can reopen, or enrollment can be closed.

A **Study Status** is the current stage of development or implementation of a protocol.

A **Milestone** is an event that occurs within a Study Status. Please note that some Milestones are triggering events for a change in Study Status.