ctn+ CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research | Réseau pancanadien pour des essais cliniques sur le VIH et autres ITSS

Data Management Service Milestones for Study Start-up

Protocol #: _____

Title of Study: _____

	ACTIVITY	ROLES INVOLVED	TIME RANGE
STUDY START-UP			
1.	Study Start/Kick-off Meeting	Sponsor* /Study Team/PM/DM	W0
2.	Protocol Development	Sponsor/Study Team/PM/DM	W0
3.	Protocol Finalized	Sponsor	W0
Other than consultation and assistance with protocol development, Data Management work cannot begin until contracts are signed and a protocol is finalized. Arrows indicate where activities may be repeated until the work is approved and finalized. Time ranges may increase as necessary.			
4.	Data Management Plan (DMP) Drafted	DM	W0 + 4 weeks
5.	Critical Database Workflow Determined, e.g., Arms, Blinding	DM, Sponsor, PM	W0 + 3 weeks
6.	CRFs / Data Collection Worksheets (DCWS) Created, if required	DM, Sponsor	W0 + 3 weeks
7.	CRFs / DCWS Reviewed and Approved	DM/PM/SM/Stats	W0 + 4 weeks
8.	DMP Reviewed and Approved	DM, Sponsor, PM/SM	W0 + 6 weeks
9.	Database Development	DM	W0 + 12 weeks
10.	Stats Review of Data Dictionary or Annotated Study Book	DM/Stats	W0 + 12 weeks
11.	Data Validation Plan (DVP) Created	DM/Stats/PM	W0 + 12 weeks
12.	Edit Checks Programmed	DM	W0 + 14
13.	Online Review (1 session with DM regarding navigation, basic functionality, additional requirements)	DM, Sponsor, PM/SM	W0 + 12 weeks
14.	Validation – test cases and results	DM	W0 + 14 weeks
15.	Data Entry Guidelines	DM/PM	W0 + 14 weeks
16.	User Acceptance Test (UAT) (no major revisions or additions are expected at this stage)	PM/SM	W0 + 14 weeks
17.	Confidentiality Agreements signed and User Access Request forms completed	QI, PM/SM	W0 + 14 weeks
18.	Training	DM	W0 + 16 weeks
19.	Database Release (user account creation and release of login credentials)	DM	W0 + 16 weeks
ENROLLMENT			
20.	First Participant Enrolled	Sponsor Representative or Sponsor, SM	

21.	Last Participant Enrolled	Sponsor Representative or Sponsor, SM	
STUDY CLOSE-OUT			
22.	Last Participant Last Visit	Sponsor Representative or Sponsor, SM	LPFV + follow-up duration
23.	Last (e)CRF entered in database	Sponsor Representative or Sponsor, SM	LPLV + 2 weeks
24.	Last Query Resolved	DM	LPLV + 4 weeks
25.	Review of Dry Run Listings (by study team)	Sponsor Representative or Sponsor, SM, Stats	LPLV + 6 weeks
26.	Final Database Lock	DM	LPLV + 8 weeks
27.	Locked datasets exported and delivered	DM	LPLV + 9 weeks

*Sponsor representative or Sponsor-Investigator

Definitions and Acronyms

ACRONYM	DEFINITION
CRF	Case Report Form
DCWS	Data Collection Worksheets
DM	Data Management
DMP	Data Management Plan
DVP	Data Validation Edit Check Plan
LPLV	Last Participant Last Visit
PM	Project Manager
QI	Qualified Investigator
Sponsor	Sponsor-Investigator
SM	Study Manager