the CTN
CIHR Canadian
HIV Trials Network

le Réseau
Réseau canadien
pour les essais VIH des IRSC

Data Management Service Milestones for Study Start-up

Protocol #: _____

Title of Study: _____

▢ **Team Input Required**

▨ **Involvement of Qualified Investigator (QI) Required**

Milestones	Team Input Required	Team Member Involved	Timeline
1. Protocol and REB Approved	Y	PM/Study Manager	W 0
2. Determine Data Points to be Captured	Y	QI, DM, Statistician	W 0
3. Schedule of Events and Database Workflow Determined	N	DM	W 0
4. CRFs / Data Collection Worksheet (DCW) Created	N	DM	W1 – W3
5. CRFs / DCW Reviewed and Approved	Y	PM/Study Manager	W4
6.1 Data Management Plan (DMP) Drafted	N	DM	W1 – W4
6.2 DMP Reviewed and Approved	Y	QI, PM/Study Manager	W5 – W6
7.1 Database Entry Screens Built and Validated	N	DM	W4 – W12
7.2 Online Review	Y	QI, PM/Study Manager	W7 – W10
8 Data Validation Plan (DVP) Created	N	DM	W6 – W12
9.1 Edit Checks Programmed and Validated	N	DM	W4 – W14
10. User Acceptance Test (UAT)	Y	PM/Study Manager	W10 – W14
11. Confidentiality Agreements signed and User Access Request forms completed	Y	QI, PM/Study Manager	W14
12. Training and Database Release	Y	DM	W15 – W16

* *Modified from CTN P-Track DM Milestones V0.1 15-Sep-2016 and SOPDM_03_T01_01_Database Set-up Timelines.*