**DRUG X CLINICAL TRIAL REPORT – SUBJECT ENROLLMENT/DROPOUT**

**20130101 – Mayca Roig**

**Requested by: Markus McKein**

**Request Date: 12/28/2012**

**Due Date: 01/02/2013**

Create a file/report/list providing subject enrollment and dropout information for Drug X protocol as follows:

* Use as input data the REGISTRY from EDC after data lock.
* Include only enrolled subjects (as defined in QSPS-Drug\_X).
* Each ‘subject’ occurrence is unique and the list is subject-exhaustive.
* Each entry will reflect the very last OCCURRED visit (see QSPS-Drug\_X for assessment of ‘occurrence’ in this case) of each subject, including following information:
  + Subject identification (as known by the site).
  + For scheduled visits (scheduled visit really occurred as described in QSPS-Drug\_X), value of the scheduled visit.
  + For implicit termination visits (see QSPS-Drug\_X), termination value plus value of corresponding scheduled visit.
  + For explicit termination visits (see QSPS-Drug\_X), termination value plus matching scheduled visit (\*).
  + The file/report/list has to have complete information to allow identifying each subject as belonging to one of four groups indicated below.
  + The grouping criteria is group-exclusive and subject-exhaustive:

**Group M18/TV-M18/M21/TV-M21 includes subjects whose last visit is either:**

* M18 or M21.
* Implicit or explicit (\*) termination visit at either M18 or M21.

**Group M12/M15 includes subjects whose last visit is either:**

* M12 or M15.

**Group TV-M12/TV-M15 includes subjects whose last visit is either:**

* Implicit or explicit (\*) termination visit at either M12 or M15.

**Group WK1/TV-WK1/M01/TV-M01/M03/TV-M03/M06/TV-M06/M09/TV-M09 includes subjects whose last visit is either:**

* WK1, M01, M03, M06, or M09.
* Implicit or explicit (\*) termination visit at either WK1, M01, M03, M06, or M09.

*(\*)* For explicit termination visits, the corresponding scheduled visit needs to be inferred as follows:

1. Find its immediately preceding OCCURRED (IPO) scheduled visit.
2. Based on order of scheduled visits reflected in QSPS-DRUG\_X, find (theoretically) following visit (FV) to the IPO visit.
3. Explicit termination visit will be matched with this FV visit as its corresponding scheduled visit.

I.e., if the IPO scheduled visit to the explicit termination visit is M09, the explicit termination visit will be matched with M12.

NOTE: If IPO scheduled visit is an implicit termination visit, its corresponding scheduled visit value will be used as the IPO value.