

# OnCore Communication Memo

## Memo #: 24 – PC Console>Accrual Information Section Updated Definitions

**To:** All CCCTO Research Managers, Non CCCTO Managers, Regulatory Coordinators, Regulatory Manager, SRC Coordinator, CTO-AD

**From:** System Administrator

**Effective Date:** May 3, 2016

**Purpose:** To clear up confusion, to ensure consistent and quality data, and in order to utilize more OnCore functionality, the definitions and usage of the Accrual Information Section has been revisited and updated for MCW Cancer use.

The screenshot shows a web form with two main sections. The top section is titled "Accrual Information" and has a "Not Applicable" checkbox. It contains five input fields: "Protocol Target Accrual\*", "RC Total Accrual Goal (Lower)", "RC Total Accrual Goal (Upper)\*", "RC Annual Accrual Goal", "Affiliate Accrual Goal", and "Accrual Duration (Months)\*". The bottom section is titled "Completion Dates" and contains two rows. The first row is "Primary Completion Date\*" with a date picker and radio buttons for "Actual" and "Anticipated". The second row is "Study Completion Date" with a date picker and radio buttons for "Actual" and "Anticipated".

**Protocol Target Accrual:** The overall accrual goal for the protocol, or if an IIT, total planned accrual for all sites (MCW + affiliates)

**RC Total Accrual Goal (Lower):** This is the 'real' enrollment goal, which should be reflected in the New Trial Submission Form. This is the number of accruals the PI thinks they can realistically enroll for the trial. This number should be the total 'real' goal for enrollment at FMLH, St. Joe's and CMH combined. This number is listed on the DT4 report. When this number is reached the system will send out a Lower Accrual Goal has been met notification.

**RC Total Accrual Goal (Upper):** This is the IRB enrollment goal, or the accrual goal listed in the consent. This number should be the total enrollment listed in the consent for FMLH, St. Joe's and CMH combined. When this number is reached the system will automatically close the study to accrual.

**RC Annual Accrual Goal:** This is only completed for IIT studies, and should be equal to the upper Accrual Goal divided by the Accrual Duration (in years).

**Affiliate Accrual Goal:** For IIT's where we are the coordinating center, this number represents the total number of accruals that will take place at the outside affiliate sites. For example, a study needs to enroll 50 subjects, 12 of them will be enrolled at MCW. When this is the case, the RC Total Accrual Goal (Upper) would be 12 but the Affiliate Accrual Goal would be 38, for a total of 50. The RC Total Accrual Goal (Lower) would be 12. For all other protocols, use the same number entered in the RC Total Accrual Goal (Lower) field (do not leave this field blank). This number is listed on the Reviews>Team Console.

**Accrual Duration (Months):** This is the number of months of planned enrollment. For IIT's, use the number of months written in the protocol. For all other protocols, refer to clinicaltrials.gov webpage. To calculate the number of months, start with the Estimated Primary Completion Date listed on ct.gov (November

2017 in this example), then take the date the study opened at MCW (May 2016 in this example). Subtracting the MCW Study Opening Date (5/1/16) from the Estimated Primary Completion Date of (11/1/17) , and the number of months of Accrual Duration would be 18. If we had opened the study at the same time national accrual opened, then the Accrual Duration would have been 30 months.

Estimated Enrollment:	200
Study Start Date:	June 2015
Estimated Study Completion Date:	March 2018
Estimated Primary Completion Date:	November 2017 (Final data collection date for primary outcome measure)

**Primary Completion Date:** For IIT's, use the date the study opened plus the enrollment months to get the estimated date. For all other studies, use the Estimated Primary Completion Date listed in clinicaltrials.gov (November 2017 in this example). The definition is: the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. This is the date of the last subject, last visit. This date should be marked as Anticipated until the actual date is known. When the date is known, the date can be changed to the real date, and should be marked as Actual.

**Study Completion Date:** For IIT's the date may be entered later, for all other studies use the Estimated Study Completion Date listed in clinicaltrials.gov (March 2018 in this example). This is the final date on which data was or is expected to be collected. If an IIT study, it is the date the study's database was locked at MCW. If any other study, use the date of the sponsor's database lock. This date should be marked as Anticipated until the actual date is known. When the date is known, the date can be changed to the real date, and should be marked as Actual.