

How Are Completeness, Timeliness and Quality Calculated?

1. Completeness Report

The completeness report is based upon the current date. If you run the report on July 15th, the report looks at all study item placeholders whose due date is < the current date.

Completed study items, from that total set of study items, is based upon any of those that have an activation date (this handles either fulfilled by reason or a document).

1.1. Example:

If you have the following placeholders:

Placeholder	Due Date	Activation Date
1	05-Jun-2013	12-Jun-2013
2	05-Jun-2013	
3	12-Jul-2013	
4	12-Jul-2013	05-Jul-2013
5	23-Jul-2013	
6		
7		12-Jun-2013
8	23-Jun-2013	08-Jul-2013

They are evaluated as follows:

- Placeholder 1 is included in the calculation and is

considered complete.

- Placeholder 2 is included in the calculation and is considered NOT complete.
- Placeholder 3 is included in the calculation and is considered NOT complete.
- Placeholder 4 is included in the calculation and is considered complete.
- Placeholder 5 is not included in the calculation because the due date is not before the current date.
- Placeholder 6 is not included in the calculation because it does not have a due date.
- Placeholder 7 is not included in the calculation because it does not have a due date.
- Placeholder 8 is included in the calculation and is considered complete.

The calculation for the completeness report is: 3 completed / 5 total = 60%

1.2. Historical Completeness

For the historical completeness metric, the evaluation for a month is based upon the completeness as of the first of the next month. So for the calculation for a month like Jun 2013, it is based upon looking at completeness as of July 1. The total set of study items are those whose due date is < the date (July 1st). The completed set of study items are taken from that set which have an activation date < the date (July 1st).

If we evaluate the same set of placeholders for the historical month of June, they are evaluated as follows:

- Placeholder 1 is included in the calculation and is considered complete.
- Placeholder 2 is included in the calculation and is considered NOT complete.

- Placeholder 3 is not included in the calculation because the due date is not before July 1st.
- Placeholder 4 is not included in the calculation because the due date is not before July 1st.
- Placeholder 5 is not included in the calculation because the due date is not before July 1st.
- Placeholder 6 is not included in the calculation because it does not have a due date.
- Placeholder 7 is not included in the calculation because it does not have a due date.
- Placeholder 8 is included in the calculation and is considered NOT complete because the activation date is not before July 1st.

So the historical completeness percent for June is: 1 completed / 3 total = 33.33%

Note 1: Remember that Due Dates can change for a study item.

So let's say you looked at the historical completeness above based upon the above data, and then the milestone date associated with Placeholder 8 is changed (or an actual date is provided which is different from the planned date). This change to the milestone changes the due date for Placeholder 8 to be 02-Jul-2013. If you go after that and look at the historical completeness – placeholder 8 is no longer included in the calculation and the historical completeness calculation for June changes to: 1 completed / 2 total = 50%.

Note 2: Remember that a study item can be deactivated and re-activated at a later date. So let's say you take the original historical data above and you deactivate Placeholder 1 and you re-activate the placeholder on 03-Jul-2013. If you go back and look at the historical completeness for June, Placeholder 1 is still included in the completeness, but is no longer considered complete as of 01-Jul-2013. Therefore the historical completeness for June changes to: 0 completed / 3 total = 0%

2. Quality Report

Data for the Quality Report comes from **the first time** a document was processed through QC during the specified timeframe. Quality is based on the percentage of QC tasks resulting in documents being activated, as opposed to returning for QC rework.

Documents that are Finalized on the first time they go through QC count as "Passed".

Documents that are sent for rework the first time they go through QC count as "Failed".

The Document Quality metric is the percentage of documents that did not fail the QC task out of the total number of documents that were processed through the QC task for the first time in the given time frame.

As of eTMF 2.2, the Quality Report excludes documents authored within the eTMF.

3. Timeliness Report

Timeliness Report is based on the percentage of documents that have been processed within a specified number of days after receipt. The Timeliness report is useful for understanding how long it is taking to process documents through the QC Workflow.

A business administrator can configure the number of days that a document can take from Receipt to Finalization and be counted as "On Time". Changing this configuration after documents are finalized has no effect on the timeliness of those documents.

The value shown in Timeliness Report is the number of documents finalized "On Time", divided by the number of

documents finalized during the reporting timeframe.