MOB CQMP News Blast

Monitoring Ops. Branch

Urgent Bulletin
February 2016

Clinical Quality Management Plan eLearning

The Clinical Quality Management Plan (CQMP): Clinical Research Site (CRS) Quality Management (QM) Activities eLearning training is now available. It is posted on the DAIDS Learning Management System (LMS) and can be accessed via this link HERE.

The training focuses on key QM concepts, conducting Quality Assurance (QA)/Quality Control (QC) activities, simulation exercises and tips for completing the CRS QA Summary Report. Each of the 6 modules provides an in-depth and systematic process for conducting QM specific activities using various tools. The modules are presented in the order seen in the box to the right.

CQMP eLearning Modules

1. **Introduction**
2. **Review of CRS Activities and Tools**
3. **Completion of the Sample QA Participant Chart Review Tool**
4. **Completion of the Sample QA Protocol Regulatory File Review Tool**
5. **Other Supporting QM Resources & Tools**
6. **The CRS QA Summary Report**

Upon completion of this eLearning, you will know how to conduct QM activities using different QA tools. You will also learn how to evaluate findings from the QA process, which can provide the required information for inclusion in the CRS QA Summary Report.

To complete the training you must have a DAIDS LMS account. If you have trouble accessing the LMS or need to create an account please send an email to DAIDS LMS Support team at daidscrss-support@westat.com

CRS QA Summary Report

Your next CRS QA Summary Report is due to your OCSO PO on April 1st, 2016. Upon completion of the eLearning modules, you will be able to effectively complete and provide all the information required in this Report. Please access the Office of Budget Management (OMB) Approved CRS QA Summary Report template (OMB Approval # 0925-0668) HERE. We recognize that the character limitation restricts you from providing a lot of detail, so keep your answers short and concise. You can attach additional PDF pages as an appendix when submitting your CRS QA Summary Report.

While you will continue to use the OMB approved version, please note that for **Section 1; Composition of PIDs Reviewed**, questions **b** and **d** were revised to provide clarity. So when you complete your CRS QA Summary Report please remember that questions b and d should now read as stated below;

Composition of PIDs reviewed;
b. Number of newly enrolled PIDs reviewed during this period (=n)____
d. Total number of PIDs with study visits occurring during this review period (y) ____

Revised CRS QA Summary Report

The CRS QA Summary Report has been revised based on feedback we received from stakeholders, but it cannot be used at this time as it is undergoing OMB approval process. For reference only: The Revised CRS QA Summary Report can be accessed HERE.

PLEASE DO NOT USE THIS VERSION FOR THE APR. 1st SUBMISSION.

When this revised version receives OMB approval you will receive communication at that time indicating that you may now begin using this version.

This revision to the CRS QA Summary Report includes changes to section 1; Composition of PIDs reviewed, examples of QA findings, potential corrective action that can be implemented and increase in the character limit.