



National Institutes of Health
National Institute of Allergy
And Infectious Diseases
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MEMORANDUM

DATE: January 25, 2019

FROM: Bariatu Smith, Acting Branch Chief, Monitoring Operations Branch (MOB)/Office of Clinical Site Oversight (OCSO) *B. Smith*

TO: HIV/AIDS Network Clinical Trials Units (CTUs)/Clinical Research Sites (CRSs)

SUBJECT: Clinical Quality Management Plan (CQMP) Quality Assurance (QA) Summary Report and Quality Management (QM) Activities.

This is an update to a previous memo dated February 15, 2018, regarding the timing of submission of the CRS QA Summary Report to DAIDS.

As you know, DAIDS is currently revising its processes related to Sponsor responsibilities for oversight of Quality Management activities at DAIDS sponsored and/or supported sites. We are working closely with certified quality assurance experts to incorporate all elements of our oversight responsibilities as referenced in the FDA Code of Federal Regulations (CFR) and the International Council for Harmonization (ICH) E6 (R2), specifically related to Quality Management.

The current Division of AIDS (DAIDS) CQMP policy requires that DAIDS sponsored and/or supported CRSs provide a summary report of QA activities to DAIDS biannually. However, given that the CQMP policy and CRS QA Summary Report are under revision, the submission of the QA Summary report **will not** be required by the end of January 2019 as DAIDS had previously communicated.

We are committed to fulfilling our Sponsor responsibilities while also ensuring that we provide clear, meaningful guidance to sites, in order to provide assurance of data integrity and human subject protection. We anticipate implementation of the revised policy and tools later in 2019 and will communicate more specific timelines as we get closer to implementation.

Importantly, sites are expected to continue conducting Quality Assurance and Quality Control activities of their operations to ensure the integrity, completeness and quality of data being collected.

Please contact your Program Officer with any questions about the CQMP.