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TO: ACTG and IMPAACT Laboratories

FROM: Dr. Grace Aldrovandi, ACTG & IMPAACT Network Laboratory Principal Investigator

ACTG Laboratory Science Group IMPAACT Laboratory Center

Cc: ACTG Laboratory Science Group

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Dr. Kathleen Eisenach Dr. Anne-Marie Demers

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Re: IMPAACT/ACTG Memo: Mycobacteriology Laboratory Sourcebook for Harmonization and

Support of Tuberculosis (TB) Clinical Trials

**Please forward this information to the relevant clinic and laboratory personnel at your site

ACTG Laboratory Science Group and the IMPAACT Laboratory Center are pleased to announce the availability of a new resource titled "The Mycobacteriology Laboratory Sourcebook for Harmonization and Support of Tuberculosis (TB) Clinical Trials".

This TB Sourcebook document provides TB laboratories and laboratory personnel participating in TB clinical studies information and guidance on technical aspects of TB methods and procedures that can affect microbiology endpoints, comparability and quality of laboratory results, and participant safety. Essential components of these methods and procedures, previously realized in 2016, have been updated and summarized in the TB Sourcebook, and are described as Key Elements. These Key Elements can be used to guide the assessment of quality measures within the TB laboratory. Therefore, we strongly recommend that this document is read by all TB laboratory staff participating in ACTG and IMPAACT protocols.

The recommendations contained in the TB Sourcebook do not indicate an exclusive course of action or serve as a standard of laboratory practice. As a reminder, for DAIDS Network protocols, protocol specific information and documents (e.g. Protocol Appendices, Manual of Procedures, and Laboratory Processing Chart) supersede the TB Sourcebook document.

The Mycobacteriology Laboratory Sourcebook for Harmonization and Support of Tuberculosis (TB) Clinical Trials is available for download from any of the following webpages:

The "ACTG/IMPAACT Laboratory Manual" on the HIV/AIDS Network Coordination (HANC) website: https://www.hanc.info/labs/labresources/procedures/Pages/default.aspx

pSMILE website: http://resources.psmile.org/resources/process-control/section-specific-information/microbiology/mycobacteriology-tb-source-book

ACTG website (login required):

https://member.actgnetwork.org/cms/dl/29696/Mycobacteriology+Laboratory+Sourcebook_Version+1.0_20180307_final2





If you have questions regarding either the TB Sourcebook or the Key Elements please contact:

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