Dear ACTG and IMPAACT Network Laboratories,

I wanted to inform all laboratories that your LDMS end user validation efforts are going well. My goal is to ensure that each laboratory is ready for regulatory inspection as far as any required validation for the LDMS. This includes performing an initial end user validation as well as having a change control process in place for subsequent releases.

**As a reminder, Frontier Science is currently providing assistance to all ACTG and IMPAACT laboratories in their end user validation of the LDMS.** Please contact them if you have not already performed end user validation on the LDMS at validationservices@fstrf.org or visit the LDMS website (https://www.ldms.org/resources/validation/). Once you are at the website you will be able to download a power point presentation that describes the end user validation process, and submit a request to access developer validation documents. This suite of templates includes an SOP and various deliverables that cover the spectrum of a typical commercial off the shelf (COTS) validation effort-including change control.

**If you have already performed end user validation on your own**, please inform the Validation Team at Frontier Science so that they can ensure you have done so in accordance with the applicable regulations. They can review your validation materials, even if already completed for another network, to ensure that the documentation is sufficient for regulatory inspection. They can even review validation you may have done for a computer system other than the LDMS.

**All network labs need to obtain copies of Frontier Science's LDMS developer validation records that should be kept on file and made readily available during an inspection.**

**For those of you still needing assistance**, the Frontier Science validation team can assist you by email, phone or on-site visits. Likewise, if you currently have your own SOPs that cover validation, but have not validated the LDMS, the team can help you customize your efforts to the processes and/or templates you already have in place.

Systems validation is a complex issue, and so I urge you again to take advantage of this collaborative resource. This will ensure that all of our labs are performing validation activities consistently, correctly, and in a fashion that withstand impending audit visits.

If you have any specific questions regarding LDMS end user validation, please contact Howard Gutzman, Frontier's LDMS Program Director, or Frontier's Compliance Officer, Colleen Woodworth.

Feel free to email me directly as well.

Sincerely,

Dr. Grace Aldrovandi

ACTG/IMPAACT Laboratory Center, PI