# Q&A – Support for PK Test in Web LDMS

***Question:*** *Will individual sites be required to perform computer system validation on the web version? If so, will the validation process be a prescribed process for labs from FSTRF since it is hosted by FSTRF and web based?*

**Answer:** Frontier Science performs full developer validation testing on every single release of web LDMS whereby each defined requirement is tested. This would include prior functionality as well as all new functionality being added into the upcoming new release. This is reflected in the Frontier developer validation documentation that we make available on the LDMS website with each release, along with the version release notes (also available on the website). In addition, Frontier performs the IQ (installation qualification) for each release knowing we are hosting the application (something end users do not have to perform).

As end users of web LDMS labs should have a basic change control process in place to ensure that when a new web LDMS version is released that you are reviewing the release notes and verifying (testing) any changes that are applicable to your lab or labs workflows. You would want to run tests for those as needed. You would also want to download the latest developer validation documents showing Frontier's validation steps (referenced in above paragraph).

There is a lot less "work" on our web LDMS users knowing Frontier is hosting the application and database so one big difference vs windows LDMS is that you do not have to complete the installation checklist, DAIDS EIS checklist, etc. for each web LDMS release like you did for windows LDMS.

**********

***Question:*** *I don't think you mentioned it, but this should mean the end to LDMS queries and making clinical site data corrections?*

**Answer:** Unfortunately, the data correction policies and procedures required by laboratories for DMC queries does not change in web LDMS. The primary reason being although Frontier hosts the web LDMS, each lab web database is still separate and unique – data is not "shared" across databases. Also, per GCLP guidelines, I'm not sure we want data to change in an LDMS database (i.e. testing lab) without end users being aware and documenting them appropriately within their local database. This is the primary reason why each lab is responsible for making their own data corrections to their local LDMS database.

**********

***Question:*** *Will FSTRF be performing QA of lab database movement or transfer to web based system?*

**Answer:** Yes, Frontier Science performs a full QA of a labs LDMS database during the migration process, including verification of record counts, etc.

**********

***Question:*** *Data security/access is a big topic now. We have projects with sponsors that now include compliance with GDPR, FISMA, performing firewall penetration tests, IT audits, etc… One of the biggest items is encryption at all times (at rest, in use, and in transit). One of the great features is ability to*

*access the web based system from any cpu or location. Does this impact current data security requirements? Have any other labs run into some of these requirements and if so- how has it been working with University IT infrastructure groups to ensure compliance?*

**Answer:** LDMS is 21 CFR Part 11 compliant. We have worked with laboratories to update their local SOP and procedures to indicate that the database is hosted at Frontier Science on a secure, isolated, environment that meets all FISMA moderate controls. In hosting the database and application, Frontier Science assumes all responsibility in properly maintaining procedures to ensure all data is backed up and stored securely, including having the proper encryption policies in place. Frontier Science has also been asked to complete IT questionnaires from select laboratories in response to their data no longer being hosted/installed locally, which is something we can certainly accommodate for any of our PSL's.

**********

***Question:*** *You mentioned virtual or on-line training. When will this be available?*

**Answer:** Training will be scheduled with all labs in the 3rd/4th quarters this year. We plan to host join sessions with all of our labs, as well as, individual sessions as we work with each lab to schedule their web LDMS migration.

**********

***Question:*** *Do we maintain control of our Admins/Users, or does this now change with the database being centralized?*

**Answer:** Frontier Science, specifically our 24x7 user support team, manages all user accounts and access for our laboratories. Each lab has the ability to view current access for all users via a user access report available in the LDMS (reports module) and changes can be requested via email to our user support team.

**********

***Question:*** *You say we will be able to upload a file to LDMS from our processing software, how will this be that much better than a simple copy/paste from our results window to LDMS?*

**Answer:** The current copy/paste feature supported in windows LDMS requires that the data in the Excel file be formatted in a specific format to ensure that the data is copied in the same format into LDMS. Whereas, the new file upload feature will remove these requirements since web LDMS will auto match results in the file to records in LDMS per specific identifiers (PID, global ID or other specimen ID). This should hopefully alleviate work at the labs in having to properly curate Excel files when copying data into windows LDMS – this will no longer be required in web LDMS.

**********

***Question:*** *We have concerns with uploading too much information to LDMS as we do not just run samples for the ACTG. If we were to upload files, can we restrict it to just the ACTG samples?*

**Answer:** The file upload feature will only match records according to entries in LDMS. So, if a test run includes both network and non-network samples, and the data is uploaded into LDMS via the new file upload feature, LDMS will only auto match the results for the ACTG samples assuming the non-network samples have not been added to the LDMS run. Data results for the non-ACTG samples included in the file would not be available in LDMS and/or stored at Frontier Science.

***Question:*** *For raw file uploads, what types of files will be acceptable for uploading (eg. .wiff, rdb, etc.)? Will instrument data have to be transferred to a .csv or .xls for uploading?*

**Answer:** Our hope and goal is to support various file formats. We encourage labs to send us whatever file type is exported off of the instrument. Our hope would not to have labs transfer the data into another file format, and we simply accept the file format that is exported off the instrument.

***Question:*** *If direct uploading is possible, will matching in LDMS be driven only by the global specimen ID?*

**Answer:** Matching in LDMS is driven by (3) different identifiers (Global specimen ID, PID and Other Specimen ID). Therefore, as long as one of these LDMS identifiers is available in the result file, LDMS will attempt to properly match the result to the correct specimen record on the run in LDMS.

***Question:*** *Will there be any modifications in how we export reports? Sites may need to report data to FSTRF or to other statistical centers (such as SCHARP)?*

**Answer:** At this time, our priority is to support all of the existing reports from Windows LDMS in web LDMS, including how those reports are generated/exported.

***Questions:*** *Will there be increased flexibility/capacity in terms of uploading alternative matrices (fluids, tissue), including the potential assignment specimen-specific lower limits of quantification or a mechanism to normalize a raw result to a weight-normalized result?*

**Answer:** Yes, we are looking at supporting alternative matrices, including having more flexibility in specimen specific lower limits, etc.