CVM's EDC Remote Access Pilot Program Information

Thank you for your interest in the Center for Veterinary Medicine's (CVM) EDC (Electronic Data Capture) Remote Access Pilot Program. If you choose to participate in the pilot, you will be granting CVM reviewers "read only" access to the locked electronic raw data (*in lieu* of submitting copies of the electronic raw data in XML format) for the entire length of CVM's review of a submitted study (typically 180 days).

Please review the following questions and provide CVM with the responses via a Z submission.

1. State the INAD or JINAD file number for which you are considering for the EDC Remote Access Pilot Program. Please include the type of study and the study number you wish to be part of the pilot.

2. Describe the EDC system(s) used for your study. For each EDC system:
   a. Identify each EDC system by name, server location, and study phase.
   b. Confirm the EDC system has been appropriately validated by you as the sponsor.
   c. Confirm that the EDC system can be accessed using a computer running Microsoft Windows 10 Operating System. Identify any minimal requirements needed for Microsoft Windows 10 to access and navigate the EDC system.
   d. Identify whether any software, cookies, etc. are needed on CVM's end to navigate within the system.
   e. If your EDC system can be accessed by a web browser, confirm that either Microsoft Edge Version 129.0.2792.79 or Google Chrome Version 129.0.6668.101 can access and be used to navigate the EDC system.
   f. If your EDC system is compatible with Microsoft Office software, confirm that Microsoft Office 365 Version 2402 is compatible with your EDC system,
   g. Identify and list, if any, IP addresses that must be whitelisted to permit access to the EDC system.

3. Provide a brief description of how the raw data are captured within the system and what controls are in place that ensure the raw data captured meet the principles of ALCOA: Attributable, Legible, Contemporaneous, Original and Accurate. Include a description of when (and if) the audit trails begin relative to initial data entry.

4. Describe how data may be exported from the EDC system and what file format(s) are available in that export that can be used for review purposes. Please also describe how the audit trail information is exported from the EDC system.

5. Explain if the exported data files are human readable once exported using readily available software (Web browser, MS Excel, etc.) or if they must be manipulated prior to viewing or viewed using special software.

6. Describe any perceived "gaps" in the system (mainly gaps in data integrity) and what you plan to do or have done to mitigate those gaps. For example, if your EDC system relies on a secure internet connection and the internet connection becomes unavailable, what procedures are in place to ensure the raw data collected meets ALCOA.

7. Identify which EDC systems used CVM will be able to access for the study. For the EDC systems CVM won't have remote read only access to, describe how you plan to provide copies of electronic raw data to CVM for review.

8. Describe the process by which CVM personnel would access the EDC system.
   a. Will individual user identifications and passwords be provided for each CVM review team member, and can multiple individuals review data simultaneously?
   b. Can you confirm that the data are "read only" and locked so that it is only viewable by CVM reviewers and no inadvertent changes can be made.
   c. How much time is needed to create an account(s)? CVM will work the sponsor to create the accounts for the CVM review team members.

9. Describe in detail what information would be available for CVM to view remotely for each EDC system.
   a. How will you assure CVM that the data that are viewable by CVM remotely are the identical data that are viewable to the sponsor? This could be either be a statement from the sponsor or the EDC vendor.
   b. What modules or permission structure would be viewable by CVM?
   c. Can you provide example screenshots of the electronic data capture forms? If the electronic data capture forms have previously been submitted to CVM in another submission such as a protocol submission (E), you can refer to the submission number if the forms have not changed.
   d. Do data have to be unarchived to be viewed? If the data don't have to be unarchived, will CVM be reviewing archived data? Would all audit trails be viewable?
   e. How can data be filtered while viewing?

10. Describe the system support available to the CVM reviewers during their access (EDC system vendor resources, training manuals, sponsor personnel, etc.).

11. Include a discussion of the contents of the submission and what data will be available through the EDC system and what data will be included in the submission that won't be available through the EDC. Please provide a description of raw data that may be collected manually[1], other automated collection systems(s), or instruments(s) and then transcribed into an EDC system.

12. If available, please provide an example of the table of contents (TOC) or organizational structure for the data files within the submission.

13. Provide a list of questions for CVM to address at our meeting with you.

[1] Manually collected data could be either:
   1. Data planned per protocol to be only collected manually or
   2. Data collected manually due to a failure in the EDC system at the time of observation
   3. Data collected manually but entered retrospectively in the EDC system