OFFICE OF NEW ANIMAL PRODUCT EVALUATION REVIEWER'S CHAPTER

ONAPE ELECTRONIC DATA CAPTURE (EDC) SYSTEM REMOTE ACCESS REVIEW PROGRAM

I. PURPOSE

This document describes the procedures for participating in the Electronic Data Capture (EDC) System Remote Access Review Program provided by the Center for Veterinary Medicine (CVM) in the Office of New Animal Product Evaluation (ONAPE).

II. BACKGROUND

As a response to industry feedback regarding the challenges of submitting studies with copies of raw data collected in an EDC system, in 2018, ONAPE initiated a pilot program that would offer sponsors the opportunity to provide CVM with remote read-only access to their EDC systems as an alternative to submitting copies of electronic raw data via eSubmitter. In 2026, CVM adopted the EDC System Remote Access Review Program as a regular review process. The program is available for many types of studies including Target Animal Safety, Tissue Residue (typically conducted per Good Laboratory Practice); and Effectiveness studies (typically conducted under Good Clinical Practice). The Quality Assurance (QA) Branch is the lead for coordinating sponsor participation in the remote access review program. The QA Branch coordinates with the appropriate review division if a sponsor expresses interest in participating in the program.

The EDC System Remote Access Review Program is an alternative way to share study data for CVM's review. CVM's review procedures and timelines are not affected or changed; the only unique aspect of the program is the method by which the copies of raw data are provided to CVM for review.

III. PROGRAM PROCEDURES

A. Initial Discussions

Sponsors interested in participating in the program should contact the QA Branch Chief (BC). When the QA BC is contacted, they will provide the sponsor with a brief overview of the program and answer any general preliminary questions. Based on the information provided by the sponsor regarding the study intended for submission under this program and the EDC system used for the conduct of the study, an initial assessment of eligibility of the sponsor's proposed study will be conducted. The QA

BC will determine if the study appears to meet the general requirements of the program and can progress in the assessment of eligibility in the program[1]. If the proposed study is a reasonable candidate for the program, the QA BC will provide the sponsor with the remote access program questions that have been developed to further assess the eligibility of the study for this program (see Appendix 1 of this document). The questions are also available on the CVM Data Quality Resources Webpage[2].

The sponsor will be directed to provide their responses to the questions in a formal meeting request (Z submission) via eSubmitter to the appropriate INAD file or (A)NADA for the proposed study. The meeting request should be addressed to the QA Branch in the Division of Business Information Science and Management (DBISM). Once CVM receives the Z submission, the QA BC will assign the Z submission AA package to a Quality Assurance Study Reviewer (QASR). The ONAPE policies and procedures (P&P) 1243.3024 Scheduling and Holding Meetings with Outside Parties will be followed to schedule the meeting. Typically, the QASR assigned to this meeting will serve as the lead QASR for all subsequent submissions under the proposed study.

B. Before meeting with the Sponsor

1. After the Z submission is received by CVM and assigned to a QASR, the QA BC or QASR will contact the appropriate division director and/or BC and determine which primary scientific reviewer (PR) should be consulted for the sponsor meeting. Ideally, the consulted PR for the sponsor meeting would be the PR that would be assigned to the data submission when it is submitted to CVM for review. The appropriate project manager (PM) will also be invited to the meeting.

2. The review team should have an internal pre-meeting following P&P 1243.3024 where CVM will discuss the sponsor's meeting agenda and responses to the remote access program questions. Additional questions may arise during CVM's review of the meeting materials. These may need to be addressed during the meeting, delaying CVM's determination regarding eligibility for participation in the program. Appropriate follow-up questions to ask the sponsor can be confirmed at the CVM internal pre-meeting.

C. Meeting with the Sponsor

1. The meeting is used to discuss the sponsor's responses to the questions, gather any additional information needed to determine if the sponsor is eligible to participate and answer any questions the sponsor has about participating in the Remote Access Review Program. As these meetings are focused on the logistics of remote access, certain reminders about the overall Remote Access Review Program are appropriate to provide to the sponsor as follows

    a. The EDC System Remote Access Review Program is an alternative way to allow CVM to access study data needed for CVM's review. CVM's review

[1] If the interested party is considered a contract research organization (CRO) or testing facility, the QA BC will direct the interested party to work through the sponsor of the proposed study to determine participation in the program.
[2] https://www.fda.gov/animal-veterinary/new-animal-drug-applications/data-quality-resources

procedures and timelines are not affected or changed; the only difference is how the copies of raw data are provided to CVM for review.

b. If a sponsor is participating in the Remote Access Review Program, any necessary submission material that cannot be accessed via remote access should be submitted as usual. For example, statistical and final value files and all other study material should be submitted in eSubmitter.

2. Obtaining access to the EDC system is discussed at the sponsor meeting. Based on the information provided, a decision regarding the acceptability of the study into the EDC System Remote Access Program may be made by the review team prior to the meeting with the sponsor.

3. If the review team determines the proposed study is acceptable for participation in the program, next steps (described below) may be discussed at the meeting. Typically, this will include the sponsor providing their target date for submitting the study and the QASR providing their contact information for communication prior to submission of the study. The sponsor will be informed that if any issues arise and cannot be resolved in preparation for submission of the study, CVM may determine that participation in the program is no longer possible for that study.

4. If the sponsor confirms their interest in participating in the program, CVM can confirm participation at the end of the meeting. Alternatively, if additional internal discussion is necessary to determine if the study meets the criteria for participation, the sponsor will be informed that the final determination will be provided in the acknowledgement letter accompanying the Memorandum of Conference for the meeting. If earlier notification is requested, informal communication prior to the issuance of the acknowledgement letter is at the discretion of the review team. As each study and EDC system are different, the process for the CVM review team to make a final decision may vary.

5. The meeting will be closed out per normal process.

D. Preparation to access data when the study is submitted

1. Testing access to the EDC system will need to occur after the meeting and prior to submission of the study for review. The assigned QASR should be the individual testing access.

2. Based on the information provided in the meeting, the QASR may need to contact FDA IT to determine if the FDA computers meet the minimum requirements to access the EDC system. The minimum requirements include personal computer operating system versions, compatible internet browsers and their versions, compatibility with Microsoft Office software versions when downloading documents, and if any IP addresses must be whitelisted.

   If the EDC system has not previously been used and reviewed by FDA IT, FDA IT can be contacted and provided the minimum requirements to access the EDC system, and they can inform the lead QASR if FDA computers can access the EDC system.

3. Testing EDC System Access

   The process for testing EDC system access discussed at the sponsor meeting will be followed and documented either in a Q submission to the file, or in the review for the data submission. The tester should be the lead QASR for the Remote Access Review Program submission. For example, if the EDC system needs a name and email address to create an account, the name and the FDA email of the lead QASR will be provided to the sponsor. Once access to the EDC system is deemed successful or unsuccessful, the lead QASR will document the results in a Q submission or in the data submission.

   The electronic data accessed during the test may be from the study intended for submission but may also be a study intended only for testing purposes. If the sponsor provides test access to the study intended for submission, CVM's review of the study should not occur during this test access. This period is to determine that the EDC system can be accessed by CVM personnel.

   When testing access to the EDC system, the QASR should confirm they can access the EDC system and any modules or features that were used for study data collection and ensure they can access the necessary modules for CVM's review. The QASR may also confirm access to the audit trails, PDF scan uploads (if used), the export and search functions, and any other pertinent functions.

   The QASR should set up a meeting with the PR to confirm that the necessary modules they may need for their review can be accessed as well.

   The QASR should also confirm that the testing access is read only. The user should not be able to make any changes to the data.

4. If testing is successful, the sponsor will be notified that accessing and navigating the EDC system was successful, and they can proceed to submit their study data as part of the Remote Access Review Program. If accessing the EDC system is unsuccessful, the possible technical issues will be communicated to the sponsor and/or to FDA's IT team for troubleshooting. Any issues should be communicated to the QA BC and the Director of the DBISM prior to notifying the sponsor or IT team.

5. The review team and their management will be contacted to coordinate and confirm the additional members of the review team. For example, if a statistician and/or pharmacologist will be part of the review team, the QASR will work with the PR to contact the appropriate BC or division director(s) to determine the individuals the data submission will be assigned to once submitted to CVM.

6. Once the review team is determined, the appropriate information to create EDC system accounts for the review team can be provided to the sponsor. The process for creating accounts should be the same process that was used for establishing the test account for testing access on FDA computers. Reviewers with access to an EDC system account should document that in their review of the data submission.

7. When the QASR provides the sponsor with the review team's information to create EDC system accounts, it should also be communicated that the personnel

comprising the review team may change if the sponsor is unable to submit the data by the date discussed at the meeting.

IV. SUBMISSION PROCEDURES

A. Orientation to the EDC system

After the review team's accounts have been created, the sponsor will be asked to schedule an EDC system orientation meeting for the CVM review team. The purpose of the orientation is to help the review team understand how to navigate the sponsor's version of the EDC system and how information is organized. Ideally, the orientation would mimic what the sponsor provided to their quality assurance personnel. The orientation session should be scheduled to occur approximately two weeks before or after receipt of the submission. The QASR is responsible for scheduling the orientation between the review team and the sponsor.

B. Refuse to File (RTF)/Refuse to Review (RTR) Assessment

The lead QASR for the submission will perform the RTF or RTR assessment as part of the QASR screen portion of the QASR review. The QASR will communicate to the review team when the RTF or RTR will be completed by using P&P 1243.2050 Refuse to File and Refuse to Review. The RTF or RTR can be performed under the QASR consult. The final QASR review should document the RTF or RTR and QASR review appropriately.

C. Review of the Submission

Once the study has been submitted to CVM and the CVM review team orientation is complete, the submission can be reviewed per office standard policies and procedures, as applicable. However, instead of copies of electronic data files provided in the submission, raw data captured in the EDC system will be reviewable directly in the EDC system. The sponsor may have scanned copies of manually recorded data that were uploaded into the EDC system and are viewable directly in the EDC system. If this is applicable, these copies of manually recorded data will not need to be provided as separate PDF files in eSubmitter. This will be discussed with the sponsor prior to the submission of the study to CVM for review.

It is important to remember that the copies of raw data for a study will not automatically be part of CVM's administrative record when sponsors participate in this program. Additionally, complete exports of data files from the EDC system will not be retained in CVM's administrative record. Screenshots of raw data, and portions of EDC system exports may need to be taken and included in team members' reviews as access to the raw data reviewed in the EDC system will not be accessible after the submission letter is sent to the sponsor. The sponsor should be contacted if there is an issue navigating or accessing the EDC system. There should not be check-in meetings with the sponsor during CVM's review period. Once CVM's review is complete, and depending on the outcome of CVM's review, the following wording in Section IV.D will be transmitted to the sponsor in the submission letter. If needed, the wording can be revised to better reflect the situation.

D. Closing out the submission

1. In general, the submission should be closed out per normal office procedures.

2. If the submission was acceptable, additional wording regarding remote access may not be needed for the letter; however, it should be reiterated to the sponsor that review team member access to the EDC system should be revoked upon the receipt of this letter. For example:

   "This submission was received through the EDC System Remote Access Review Program and upon the receipt of this letter, the CVM review team members' read only access can be revoked."

3. If the submission was not complete and further information is needed from the sponsor prior to the final determination of the submission, the following wording is an example of wording for the PR to include in the letter:

   "As further information is needed prior to the acceptability of this submission, the review team members access to the EDC system should remain active until CVM completes its review of the additional requested information."

V. POST-REVIEW PROCEDURES

Once CVM's review is complete, a lessons learned meeting with the sponsor may be scheduled, as appropriate. If a lessons learned meeting is requested by the sponsor, the QASR is responsible for organizing and hosting the lessons learned meeting if the content of the meeting is solely regarding the Remote Access Review Program.

The procedures for the lessons learned meeting will follow the office policies and procedures outlined in P&P 1243.3023 Lessons Learned Meetings for New Animal Drug Application Projects.

At a minimum, the scientific reviewer (PR for the data submission) will be invited to attend the lessons learned meeting outside of the QA branch. Other review team members can be invited as well. The appropriate PM, if applicable, will also be notified of the meeting and given the option to attend.

VI. REFERENCES

CVM Policies and Procedures Manual – Office of New Animal Product Evaluation (ONAPE) and Office of Generic Animal Drugs (OGAD) Reviewer's Chapter

1243.2050 Refuse to File and Refuse to Review

1243.3023. Lessons Learned Meetings for New Animal Drug Application Projects

1243.3024 Scheduling and Holding Meetings with Outside Parties

1243.3215 Requesting a Quality Assurance Study Review from the Quality Assurance Team

1243.3250 Q Submissions Agency-Initiated Actions

VII. VERSION HISTORY

March 20, 2026 – Original version.

June 2, 2026 - Minor revisions were made throughout.

APPENDIX 1. REMOTE ACCESS PROGRAM QUESTIONS FOR SPONSOR TO ANSWER FOR PARTICIPATION

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 with 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 either be a statement from the sponsor or the EDC system 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 doesn’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 system. Please provide a description of raw data that may be collected manually[3], other automated collection system(s), or instrument(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.

[3] 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

APPENDIX 2. FREQUENTLY ASKED QUESTIONS

1. Will CVM look at data they would not have had access to otherwise?

   No. CVM only reviews the relevant study data submitted under an associated data (P) submission. Additionally, sponsors control the permissions that CVM has to view data.

2. Will CVM review data in the EDC system differently than data submitted in XML files?

   No. CVM's review process does not change for submissions participating in the EDC System Remote Access Review Program. The only difference is the presentation of the raw data.

3. Are there additional requirements to participate?

   No. The participation procedure is stated in this P&P.

4. What do I need to submit in the data submission if I am approved to submit my study as part of the EDC Remote Access Review Program?

   Your data submission should contain information and files you already intended to submit except the copies of electronically captured raw data and any documentation that can be viewed directly in the EDC system.

   Typically, these copies of electronically captured raw data are exported directly from the EDC system along with the audit trail for all electronically captured raw data and provided to CVM in XML, or other appropriate submissible format. If you are approved to submit your study as part of the EDC System Remote Access Review Program, you will not need to provide these electronic files.

   All other files such as all files for statistical analysis will need to be submitted to CVM.

5. If my study is approved to be submitted as part of the EDC System Remote Access Review Program now but in the future this study needs to be referenced in a future submission, what should I do?

   If the study data needs to be referenced or reviewed by CVM in the future submission, either access to the EDC system for the new review team will need to be granted or the copies of electronically captured raw data will need to be submitted to CVM.

   What will, or may, be needed for the future submission should be discussed with the appropriate target animal division.