eQA Frequently Asked Questions (FAQ)

1. Q. If a finding in a Field Data Book audit requires a correction to an actual notebook page how is this handled?

A. The pages will still need to be copied, corrected and the originals sent into HQ for inclusion in the FDB.

2. Q. Can the email function of eQA be used to document study related items?

A. eQA system only allows messaging to the last person working on the packet so regular email should be used and if necessary the email can be printed, scanned and attached to the audit in eQA if communication needs to occur between study particpants.

3. Q. How long will FRDs and SDs we have to respond to Field Data Book audit findings in eQA once we go live?

A. We are establishing the due date for FDB audits as 30 days. We will have the ability to change the process if we find the length of time needs to be adjusted up or down. (note: there are currently 15 days allotted for completion of responses for Field Critical Phase Inspections reports.)

4. Q. At what state (step in the process) is an audit closed?

A. Once the SD and TFM signatures are complete and the originating QA has acknowledged receipt of the completed audit, the audit is closed. This is automatically captured by the system.

5. Q. When searching for a packet does capitalization of words affect the search?

A. It doesn't appear to.

6. Q. Who can correct errors in titles of packets/QA reports?

A. The system administrators, Tammy, Jane and Juliet at IR-4 HQ.

7. Q. Does eQA have a mechanism to tell me that a Field Data Book audit is missing/outstanding?

A. No, this can be determined by comparing the master schedule (lists the field trials, laboratory analysis location(s), processing test sites, etc) and any QA statements in contributing scientist's reports against the list of audit/inspection reports maintained in the eQA system. All active FDBs are required to be audited, the field portion of the study must have, at a minimum, one critical phase inspection, the lab portion must have, at a minimum, one critical phase inspection at each location, all raw data must be audited and all contributing scientists reports are also to have been audited. If these criteria have not been met, not all required inspections/audits have either been conducted or reported and you should communicate this to your QA as soon as possible.

8. Q. If the Study Director thinks a QA comment needs to be addressed by the Field Investigator how can they make this happen?

A. The Study Director can copy the comment and paste it into test editor located in section 4 (the response section). They can either reject the packet and explain that there is an additional comment for the FRD to answer or the SD can send the Field Investigator an email asking them to address the comment.

9. Q. Who has e signature capability?

A. Study Director, Quality Assurance and Testing Facility Management.

10. Q. Once the packet is closed can changes be made?

A. No, it can only be viewed. An exception would be if the administrator were to reopen a packet and make changes. Any and all changes are tracked by change control . This will be controlled under SOP.

11. Q. How does the packet go from open to closed?

A. As all steps are completed, the system tracks each step and closes the packet when all steps are completed.

12. Q. Who will receive and email that there is an “activity” for them to complete?

A. The person(s) who needs to answer a QA finding (for field work; the FRD and the SD) will receive an email of activity. Other persons that are to be made aware of the availability to view a packet will receive a notification email.

13. Q. For Field Data Book audits-can a page be attached to the audit via scan (as a pdf, etc)?

A. Yes. Scans, photos, etc. can be attached to the audit (by QA or the responders in their appropriate sections) for clarification. However, all original data and or changed pages will need to be sent into to IR-4 HQ for inclusion in the FDB.

14. Q. Will there be technical support for mobile devices such as I pads, I phones, tablets, etc.

A. No, technical support will be offered only for computers both Windows based PCs and Apple Mac based products.

15. Q. Do I have to copy and paste responses from my Word Document into the text writer in the packet?

A. All responses to QA findings must be captured and saved into the word processor/text editor that is available in section 4 (the Response to QA Findings Section).   You can write/type your responses using the Word Document provided by QA in section 3, but text in attachments is not searchable. Therefore, using a Word Document and attaching it in section 4 is not sufficient for responding to QA findings. Responses written into a Word Document that is attached to section 4 must be copied and pasted into the text editor in the section.

16. Q. How does the system know what goes in the FRD section, the SD section, and the comments section?

A. There is a "pencil" link for each section which acts as the text writer for each section. Text must be added to each section as applicable. All findings are divided into these sections.

17. Q. What happens if you generate a response in a Word Document but forget to cut and paste into the text editor but you close the packet?

A. There are 3 options if this occurs:

i. You can call the system administrator and have them "reset" the packet so that you can go in and correct your error.

ii. If the Study Director has not closed their section he/she can make the correction for you.

iii. The Study Director can "reject" the packet and send it back to you and then you can correct your error.

18. Q. What happens if you attach the Word Document with responses but don't put your responses in the text editor?

A. See the answer to question above. These steps are applicable for this question also.

19. Q. What happens if QA puts their findings in the text editor but not in a Word Document?

A. This may happen periodically. If there are less than three or four findings generated it might be easiest to just write them directly into the text editor and not generate a Word Document. The QAU will be vigilant on making sure that if there are more than three findings the findings will be presented in the text editor and in an attached Word Document for use by the FRD/LRD as they choose.

20. Q. How are you to handle a scenario when there are separate response sections in an eQA packet but findings can be answered by the FRD or SD. If the FRD and SD discuss a response that the SD will document on behalf of the FRD, do communication documents need to be provided?

A. In this scenario, the SD will want to explain in the response in section 4 (the response section) that the response is added "as per discussion with the FRD on xx/xx/xxxx the following addition to the documentation was added" or similar wording.

21. Q. How can Regional Coordinators, managers, regional QA personnel and other persons with the appropriate permissions create summaries?

A. There will be special training on creating summaries, generating sorts and using some of the reporting functions in eQA.

22. What can an FRD do if QA fails to attach attachment?

A. Contact the originating QA and ask them to work with one of the administrators on getting the needed document appropriately attached.

23. Q. How do you correct something such as a missing direction designation on a map in the field data?

A. You make the correction on the hard copy, scan the hard copy and attach the scan to the response section to show the correction. Your response to the finding should reference the "attached corrected page". Following the previous step, place the corrected hard copy of the data and mail it to IR-4 Headquarters, or place into the data file for archiving as appropriate.

24. Q. How do I change local Intranet security settings?

A. If pop ups and certain functionality isn't working in eQA you may have to reset a certain security function. This applies only to those working in Internet Explorer. These are the needed steps to follow:

i. Open Internet Explorer (IE) and logon to the eQA system
ii. Select **Tools** from the menu bar in IE at left top of the screen
iii. Select **Internet Options** (it's all the way at the bottom)
iv. Click the Security tab
v. Highlight **Local Intranet** and select sites button
vi. Click **Advanced** button
vii. The site should show up the box "Add this website to the zone". (if it doesn't display a web link that means the site is already there)
viii. Click the **Add** button.

25. Q. When are you planning for eQA to "go live".

A. The end of April or early May.

26. Q. If the FRD makes a response to a QA finding how does the study director know a response has been made?

A. Each response must be initialed and dated by the responder.

27. Q. If besides yourself you want a technician to be able to add responses to the same packet can this be done?

A. Not directly in eQA. A technician can have viewing capability granted but a joint response function cannot be done. The person "Assigned the Activity" can share the findings document with others at their site and have them "respond" using a Word document. Their identity will be tracked by them providing their initials and date to each response they make. The "Assigned" person will then be responsible for copying an pasting the completed responses into the text editor in section 4 and is responsible for any and all content.

28. Q. How do you contact the system administrators via email?

A. The email addresses will be posted on the website or you can go to the IR-4 website and look up how to contact Tammy Barkalow, Jane Forder or Juliet Thompson.

29. Q. Do responses have to be done in a Word document?

A. No, the responses have to be in the text editor. Attachment of the responses captured in a Word document are suggested, but not mandatory.

30. Q. If I use the email link to go to eQA it opens an additional tab on the browser. How can I stop this?

A. This is part of the browser function. BE CAREFUL; if you are logged in to eQA do not use the email link to enter into the packet. Instead, note the packet number and proceed to your "My Activities" page (use the link in the left side menu). If you note that you have multiple tabs open in your browser that are all in eQA, close all but one of the tabs down.

31. Q. I searched for a packet using the main menu link to the forms module, then used the "Field Data Book Audit link" to get to the "Packet List". When I searched for and found the packet I was interested in and navigated to section 4, "Response to QA Findings" there was no pencil. Why did this happen?

A. The system recognizes that a person has an activity if they open the packet through either the email link or if they enter the packet from their "My Activities" page. Using the search function from the "Packet List" page will only allow read only access.

32. Q. I have received activity alert emails for packets I've been working on. But when I use the link I'm told it's no longer available. Why?

A. This occurs when you are faster than the email system. When one activity is completed an email goes out to the next "person" in the workflow. When you have several activities in a row you may complete them faster than you receive the next email.

33. Q. Can you stop and restart answering findings in eQA?

A. Yes, but you have to save your responses so that you can restart at a later date.

32. Q. Will the in life inspections for the 2013 Canadian studies be written in eQA?

A. No, but the Field Data Book audits might be.

For the Study Director

33. Q. When finalizing a Field Data Book audit how do you keep it open until corrected pages are received by the Study Director?

A. As the Study Director you can keep the packet open until the corrected pages are received and the corrections deemed adequate.

34. Q. Can you do a search for all audits for a protocol number?

A. You can if you have permissions to do this. You can search by the protocol number as your “keyword” using the “Document/Packet Search” function located under the “Main Menu” prompt on the left hand menu column in eQA. This is only available to those users with report generating permissions to the system.

35. Q. Will the system alert you to a missing audit (a needed audit that was never conducted and /or not sent in) such as a critical phase inspection that was to be done, but not in the system?

A. No. The system does not schedule required inspections. It generates, communicates and records audit/inspection report’s findings and responses there to within a fully electronic web based system.