
Imaging Core Lab

Data Submission Instructions

Version 1.0

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Pediatric Early Phase Clinical Trial Network



Pediatric Early Phase Clinical Trials Network (PEP-CTN) Imaging Core Lab Data Submission Instructions

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SUMMARY OF REVISIONS

The following are a list of revisions to the PEP-CTN Imaging Core Lab Data Submission Guidelines.

Version Date	Revisions to Document	New Version #
28MAY2024	Original Document	1.0

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LIST OF ABBREVIATIONS

<u>Abbreviations</u>	<u>Definition of Terms</u>
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DICOM	Digital imaging and communications in medicine - data format
PDF	Portable Document Format
QA	Quality assurance
QARC	Quality Assurance Review Center
SFTP	Secure File Transfer Protocol

OVERVIEW

The PEP-CTN Imaging Core Lab will be responsible for the collection of study participant imaging and facilitation of central imaging review for the PEP-CTN. The study committee and study radiologist will determine which imaging must be submitted for central review evaluation based on participant response to treatment. Participants who respond (CR, PR) to therapy or have long term stable disease (SD) (≥ 6 cycles) on protocol therapy will be centrally reviewed. When CR, PR, or SD is reported, the COG Operations Center will notify the PEP-CTN Imaging Core Lab. The Imaging Core Lab will then request that the treating institution submit the pertinent images within one week from receiving the request for central review.

The central image evaluation results will be entered into Rave for review for data analysis. Central imaging review will be performed retrospectively and will not be used to guide individual patient management.

Submission of diagnostic imaging data in digital format is required. Digital files must be in DICOM format. These files can be submitted via QARC Submit (institutions with established SFTP accounts may continue submitting data using this format). Information to obtain an QARC SUBMIT account and submission instructions can be found at www.QARC.org. Follow the forms header tab and scroll to the bottom. Alternatively, if QARC SUBMIT or sFTP is not feasible, the imaging may be burned to a CD and mailed to PEP-CTN Imaging Core Lab. Multiple studies for the same patient may be submitted on one CD; however, please submit only one patient per CD. All CD shipping costs are the responsibility of the sending institution.

Mail CDs to the following address:

PEP-CTN Imaging Core Lab
UMass Chan Medical School
Building B, Suite 201
640 George Washington Highway
Lincoln, Rhode Island 02865
Phone: +1 (401) 753-7600

An email should be sent to PEPCTN@qarc.org containing the Subject Number, Tracking Number, and how many CDs were mailed.

Information and study related forms for the PEP-CTN trials are available on the PEP-CTN Imaging Core Lab website at www.QARC.org under the link labeled PEP-CTN.



SUBMISSION OF DIGITAL DATA

Overview

Submission of diagnostic imaging should be submitted to the PEP-CTN Imaging Core Lab using a web-based data submission portal named QARC SUBMIT. To submit data via QARC SUBMIT, sites must request an account by completing the QARC Submit request form. Once the requested information is received, a site specific QARC SUBMIT username, password, and link will be provided within 3 business days.

Sites with established QARC Secure File Transfer Protocol (SFTP) accounts may continue to submit data using this method. The same username and password may be used for submission via the QARC SUBMIT portal or submission via SFTP.

Upon submission, please send an email notification to PEP-CTN Imaging Core Lab via PEPCTN@qarc.org.

Uploading Digital Data to PEP-CTN Imaging Core Lab via QARC SUBMIT

Logging On

The PEP-CTN Imaging Core Lab data submission portal can be accessed from the QARC SUBMIT link: [QARC SUBMIT](#)

Open the link in an internet browser and a login screen should appear. NOTE: The features and function of our portal work best when using Google Chrome or Firefox. The portal address should be bookmarked or saved to your local drive for easy access.

Login

Username:

Initial Directory:

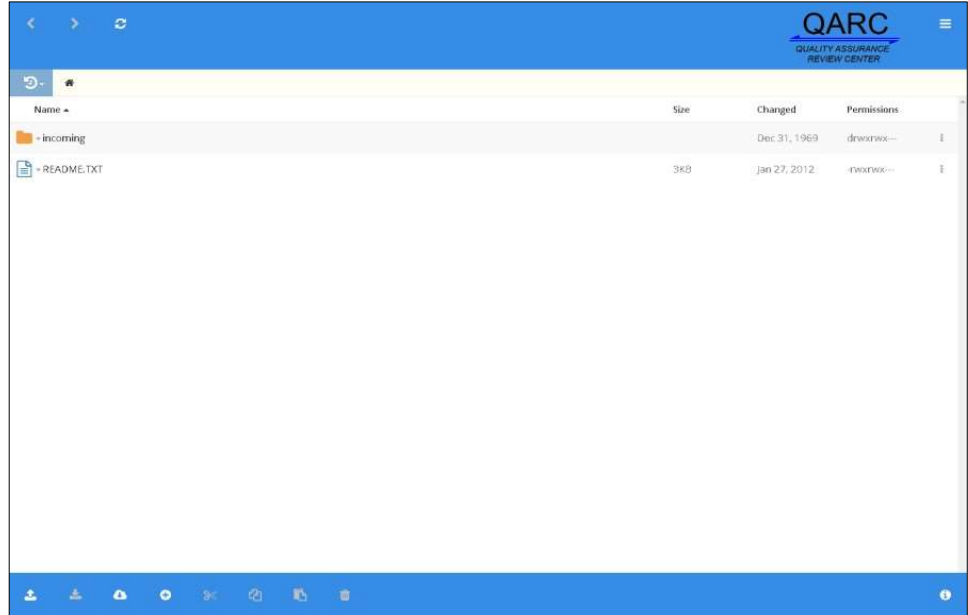
Authentication Type:
Password

Password:



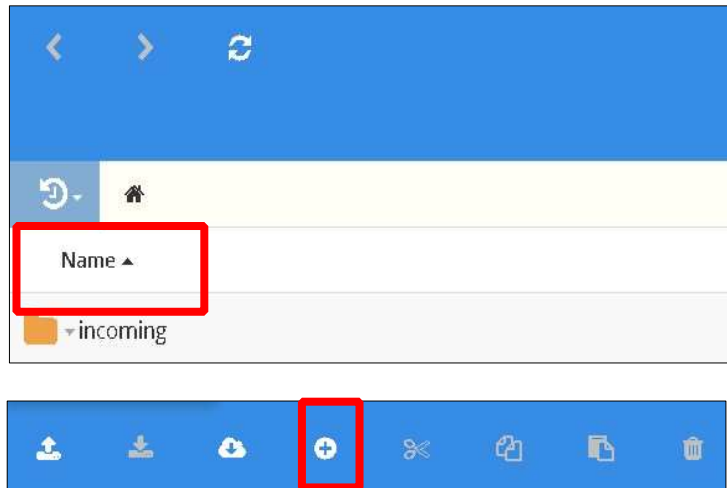
- Enter your site's QARC SUBMIT username (begins with "qarc-") into the "Username:" text field.
- Skip over "Initial Directory:" and leave the field blank.
- Click on the drop-down menu under "Authentication Type:" and select password.
- Enter the assigned QARC SUBMIT password into the text field and click [connect].

When successfully logged into the portal you will see the home page, as displayed on the right. An incoming folder and a "README.TXT" should be present.



Uploading Files to the PEP-CTN Imaging Core Lab

- **Double click on the incoming folder.**
- Once inside, create a new folder by clicking the [plus] symbol at the bottom of the page.
- Enter a descriptive name for the data being uploaded to QARC as shown in the examples below. (Please use only alphanumeric characters, underscore, hyphen, and dashes. Avoid using spaces when creating the folder).



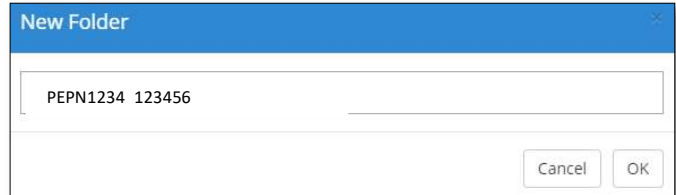
- **Subject Related Data Submissions:**

Study Name_COG subject identifier

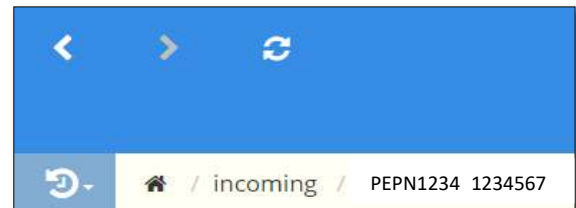
Example of initial submission: PEPNXXXX_123456

Example of revised data submission: PEPNXXXX_Revised_123456

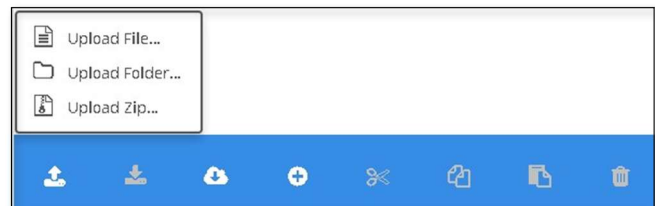
After typing the name click on [ok]. The newly created folder should now display on the web page. A separate folder must be created for each participant.



Enter the newly created folder by double clicking on it. The folder will then be displayed at the top of the page. Data related only to the benchmark or participant should be uploaded into the newly created folder.



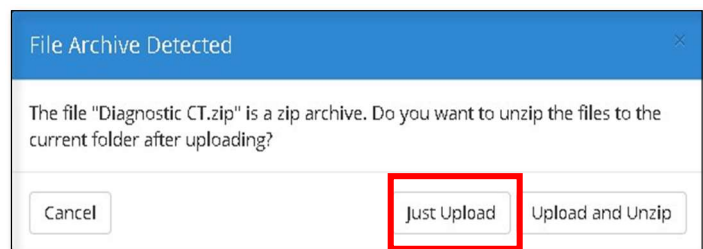
Click on the upload icon at the bottom left-hand side of the web page and select one of the following data transfer methods. A single file, a whole folder, or a zip file can be transferred to QARC.



Please be aware that zip files will transfer the fastest.

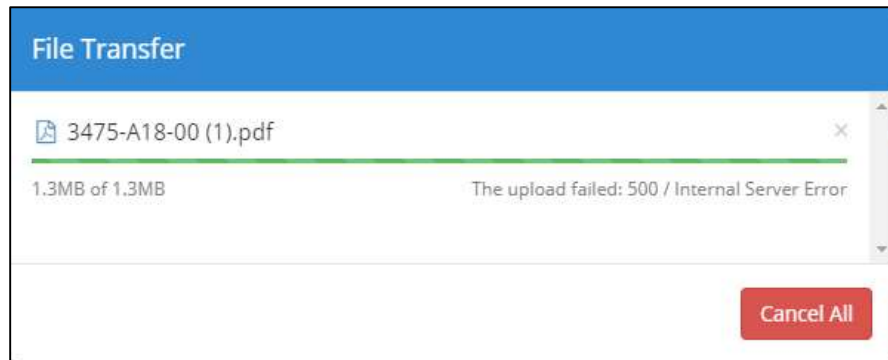
After selecting the upload type, navigate to the benchmark or participant files and/or folders on your local system/server, select the data you want to transfer, and hit [ok].

NOTE: Google Chrome and Firefox users have the option of transferring multiple files at the same time or dragging and dropping the files into the web browser. Files may be compressed into a zip file prior to uploading. This significantly shortens the data transfer process and time. When asked “Do you want to unzip the files to the current folder after uploading?” please select [Just upload].




The files will then start to transfer from your system drive to the PEP-CTN Imaging Core Lab at QARC (Core Lab). Progress will be displayed as each file and/or folder is being transferred. When the file is transferred to the Core Lab, it will display in the web browser. Check the transfer to make sure all files were successfully uploaded to the Core Lab.

NOTE: Uploading data to the QARC SUBMIT home page without double clicking the incoming folder first, will result in a failed transfer and the following message will be displayed: “The upload failed 500 / Internal




Server Error.” Simply click [cancel all], double click the incoming folder, create new folders as previously described and re-upload.

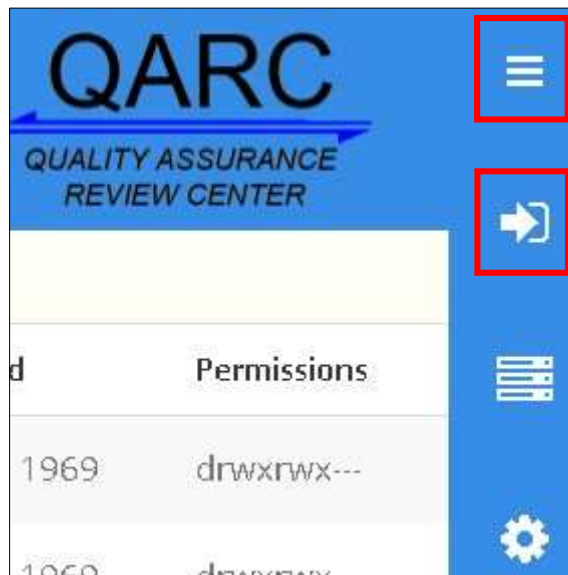
After the data have been checked, exit the folder.

by clicking the upward orange arrow  until the incoming folder is displayed.

If you are submitting data for multiple participants, create a new folder for each and repeat the above steps.

Once all files and folders have been submitted to the PEP-CTN Imaging Core Lab, log off the system by clicking the three lines at the top right,

followed by the  icon.



Please remember to send an email notification to PEPCTN@garc.org containing the protocol and subject number. This will inform our group of whom to contact if the submission is not successfully received or data are not clearly labeled.

Reporting Data Transfer Issues

Users who experience difficulties uploading data or receive an error message while transferring files, should contact the PEP-CTN Imaging Core Lab directly at PEPCTN@garc.org. A screen capture and a brief description of the issue and/or error should be provided to the Imaging Core Lab. We will work with each user and site to resolve the issue.