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Pedimacs STS Audit Instruction Sheet

The HMS DocuLink Submission Portal is an SSL-encrypted site for Participants in the STS National Database Audit to respond to data requests from the HMS Review Team. This portal is distinct from other document submission procedures for STS and should only be used for the specific request. The URL provided in the document request email is unique to the request and to the organization for which the request was made.

Accessing the document submission portal

1. To access the DocuLink Submission Portal, click on the URL in the Data Request email. You will be directed to the HMS DocuLink Submission Portal.

Note: This link may be forwarded for file upload by someone other than the original recipient.

Downloading sample of cases

- To download the sample file the DocuLink Submission Portal, click on the URL in the Data Request email. Note that the HMS DocuLink portal uses two-factor authentication to download files and only the primary contact with access to the email listed in the Document Request Letter (DRL) may be able to retrieve this list. Email sts@hcmsllc.com if assistance is needed.
- 2. Click on the "Request Passcode" box. A unique passcode will be emailed to the point of contact email address identified at the top of this notice. (**Figure 1**)

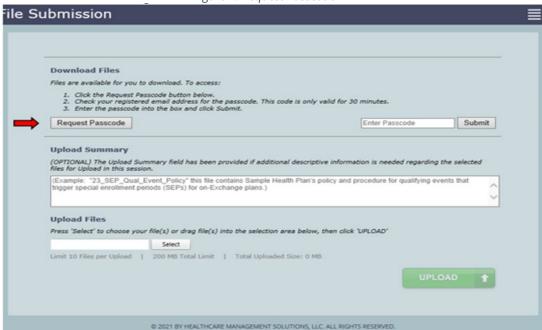
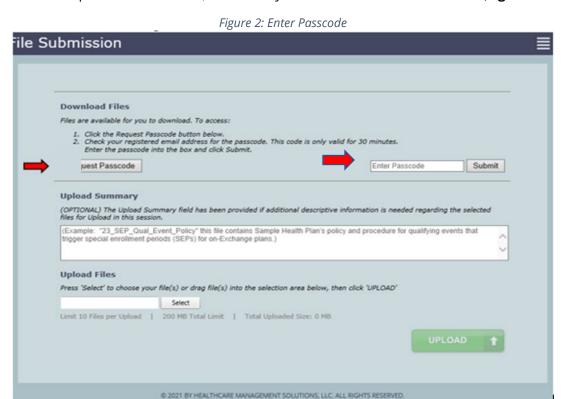
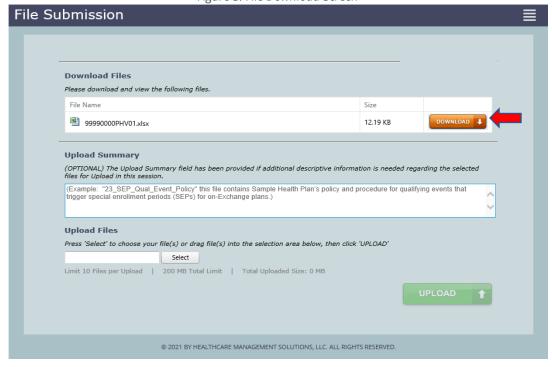


Figure 1: Request Passcode

- 3. The passcode email will only go to the original recipient of the notification email. If forwarded, that user will not receive the passcode email.
- 4. This passcode will expire after its first use within 15 minutes. Subsequent attempts to download this file will require the point of contact identified in the DRL to request an additional passcode.
- 5. Once the passcode is entered, the file may be downloaded to a local drive. (Figures 2 and 3)







6. **IMPORTANT:** This file contains PHI.

Preparing documentation for submission

- 1. Once the sample file has been received, please use the following process to organize the submission.
 - a. Selected variables for review are found in **Appendix A**.
 - b. Contact your Medical Records and IT department to assist with obtaining the required documents from your vendor software. To facilitate an accurate audit, HMS requests that PDF documentation is bookmarked to identify each data collection form where the selected variables (e.g., variable names in Appendix A) may be found in the supporting documentation. Note that this may require the use of PDF editing software such as AdobePro or NitroPro.

Uploading the documentation

1. Once the requested data is collected and prepared according to the initial request, the Participant or its designee accesses the portal using the link in the initial request email. The participant begins the file upload process by clicking on the "Select" button in the *Upload Files* section of the portal. (Figure 4)

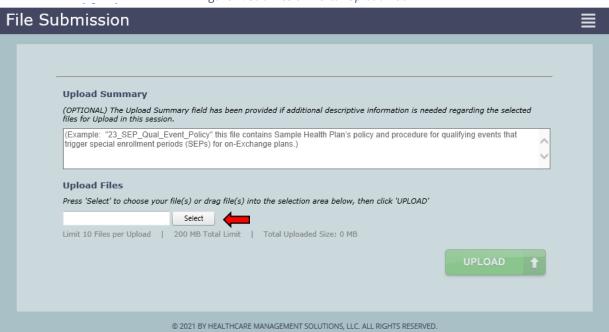
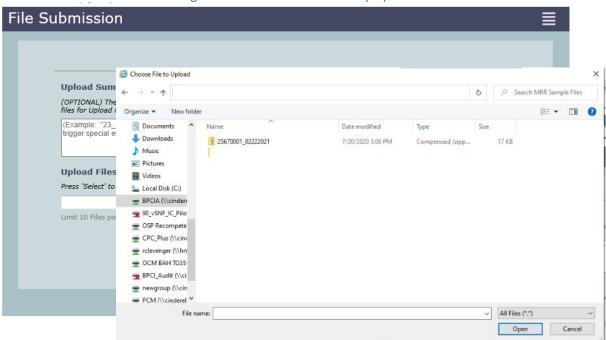


Figure 4: Submission Portal Upload Tool

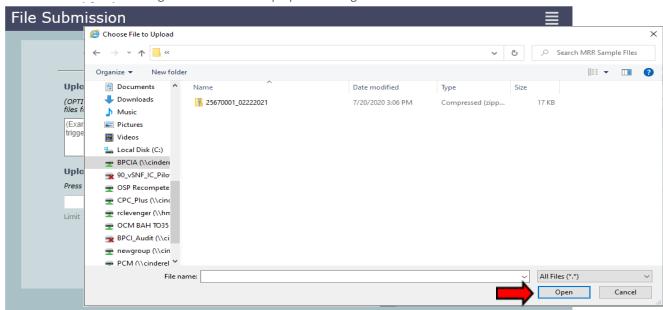
2. A pop-up window appears where the participant locates prepared files saved to their local drive. **(Figure 5)**

Figure 5: Portal with Local Drive Pop-up



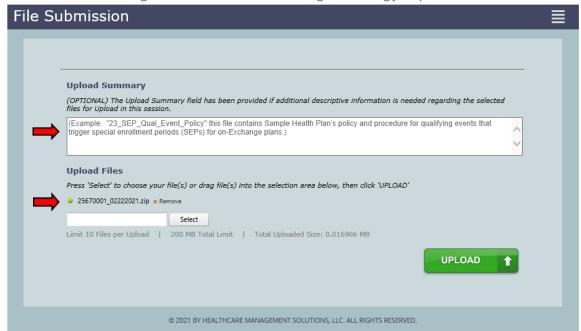
3. Multiple files may be selected by highlighting one file, then holding the Ctrl key while selecting up to nine more files. Once the applicable files are highlighted, click "Open." (Figure 6)

Figure 6: Portal with Pop-up Containing Selected Files



4. Once files for upload are selected from the Participant's local drive, each file is displayed in the *Upload Files* area with a green circle next to it. This indicates the selected file(s) are valid and are pending for upload (**Figure 7**). Enter a brief summary or description of the file(s) being uploaded in the *Upload Summary* field.

Figure 7: Submission Portal Showing File Pending for Upload



5. Once selected data files are ready for upload, click the green *Upload* button (**Figure 8**) to transfer files to the audit contractor site. A confirmation page appears if upload is successful (**Figure 9**).

Figure 8: Upload Screen in Portal

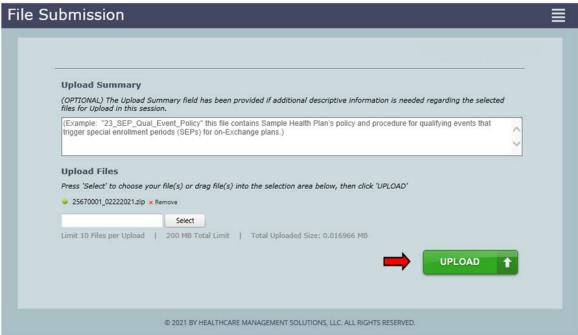
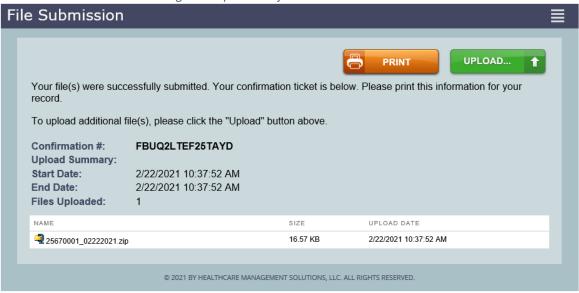


Figure 9: Upload Confirmation Screen in Portal



The Confirmation page provides a list of uploaded files, the date and time of upload, and a confirmation number. Print this page or document the confirmation number as a receipt and evidence of the documents uploaded.

Thank you for your efforts. If you experience any technical difficulties during this process, please reach out to the HMS Review Team at sts@hcmsllc.com.

Appendix A: 2022 Pedimacs Audited Variables List

| Date of BirthDemographicsPre-implant Total BiliPre-Implant FormPre-Implant QOL surveys completed?Pre-Implant FormPre-implant CreatininePre-Implant FormPre-implant AGT/ASTPre-Implant FormNYHA at pre-implantPre-Implant Form6-minute walkPre-Implant FormPrimary Cardiac DiagnosisPre-Implant FormPedimacs Patient Profile-Primary DevicePre-Implant FormImplant Date-Primary DeviceImplant FormDevice Type-Primary DeviceImplant FormImplant Discharge Date completed on Implant Discharge Form (This may also be a transplant date, explant for recovery date or exchange date) but a date must be entered. Primary DeviceImplant Discharge FormQOL Survey at 3-month follow up3 Month Follow-up3 Month Follow-up3 Month Follow-up6-minute walk3 Month Follow-upPost implant Major Bleeding adverse events reported correctly (maybe episodes) Lower GI Bleeding, closest to 3-month follow upAdverse Events - BleedingDevice Malfunction Closest to 3-month follow upAdverse Events - Device MalfunctionHemolysis Post Implant Closest to 3-month follow upAdverse Events - HemolysisMajor Infection adverse events reported and verified Driveline Infection (verify date and location)Adverse Events - Infection |
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| infections only, if applicable. Closest to 3-month follow up (verify date and location) |
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| Re-hospitalization reason completed closest to 3-month follow up Adverse Events - |
| Re-hospitalization discharge date complete closest to 3-month follow Adverse Events - |
| up Rehospitalization |
| Post Implant Respiratory Failure Adverse Events - |
| Rehospitalization |
| Hepatic Dysfunction Post Implant closest to 3-month follow up Adverse Events - |
| Rehospitalization |
| CVA, TIA reported post implant closest to 3-month follow up Adverse Events - |
| Rehospitalization Renal Dysfunction Post Implant classes to 2 month following Adverse Events - Renal |
| Renal Dysfunction Post Implant closest to 3-month follow up Adverse Events - Renal Dysfunction |
| RHF Post Implant closest to 3-month follow up Adverse Events - Right Heart |
| Failure |
| Death Form* If available at 3 months |

^{*}Verification of post-procedure status is required to be submitted to the audit company. This includes any tracking logs or documentation used to code the 3-Month Follow-Up Form and Death Form. Sites who fail to submit all (100%) verification information will be required to undergo a follow-up audit within one to two years. STS will inform the site when the re-audit occurs.