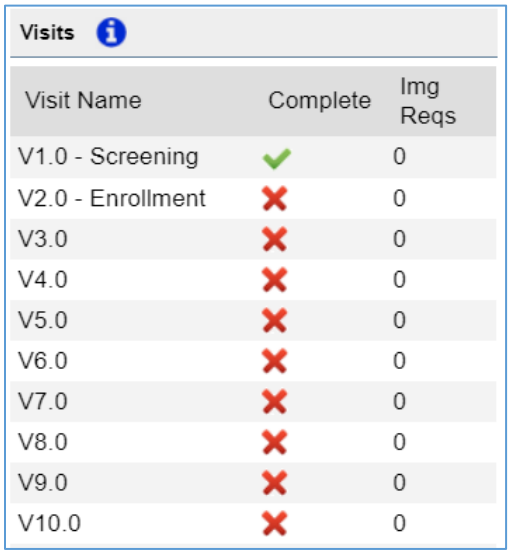
# Frequently Asked Questions (FAQ)

1. **The Medidata eLearning provides information on how to add participants to the system. Do I need to add all of my study participants?**

   No. The RSR module has been configured to automatically add enrolled participants from Rave EDC. Sites should not add participants to the system. If you cannot find a study participant, please contact SCHARP Clinical Data Management for further assistance.

2. **How can I find study visits that align with Rave EDC?**

   When you initially access an individual participant's page, the participant-level view displays by default. The participant-level view contains the following sections: Participant Details, View, Actions, and Visits. Visit names have been preloaded to align with the study visit folders within Medidata Rave.

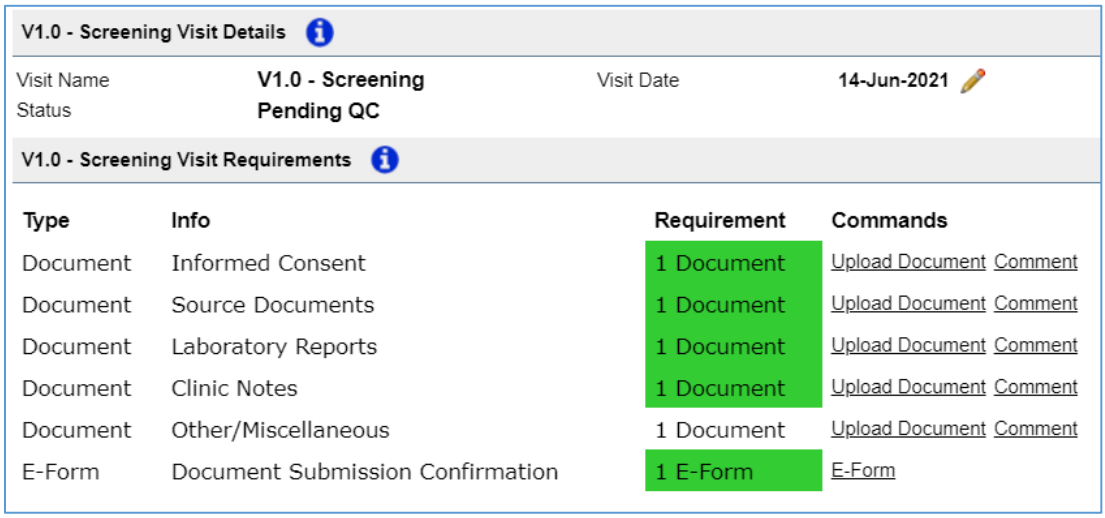


Visits

| Visit Name | Complete | Img Reqs |
|---|---|---|
| V1.0 - Screening | ✔ | 0 |
| V2.0 - Enrollment | ✘ | 0 |
| V3.0 | ✘ | 0 |
| V4.0 | ✘ | 0 |
| V5.0 | ✘ | 0 |
| V6.0 | ✘ | 0 |
| V7.0 | ✘ | 0 |
| V8.0 | ✘ | 0 |
| V9.0 | ✘ | 0 |
| V10.0 | ✘ | 0 |

   **Note**: If there are visit names in RSR that are not in your Rave study, please ignore these visit names and do not upload any requirements into them. DAIDS MOB and SCHARP created RSR templates, instead of customizing the visit names for each study, to expedite RSR implementation.

   Clicking a visit name displays the visit-level view, where you can view details about the visit, complete visit requirements, and submit visits for review.



**V1.0 - Screening Visit Details**

| | | | |
|---|---|---|---|
| Visit Name | **V1.0 - Screening** | Visit Date | **14-Jun-2021** |
| Status | **Pending QC** | | |

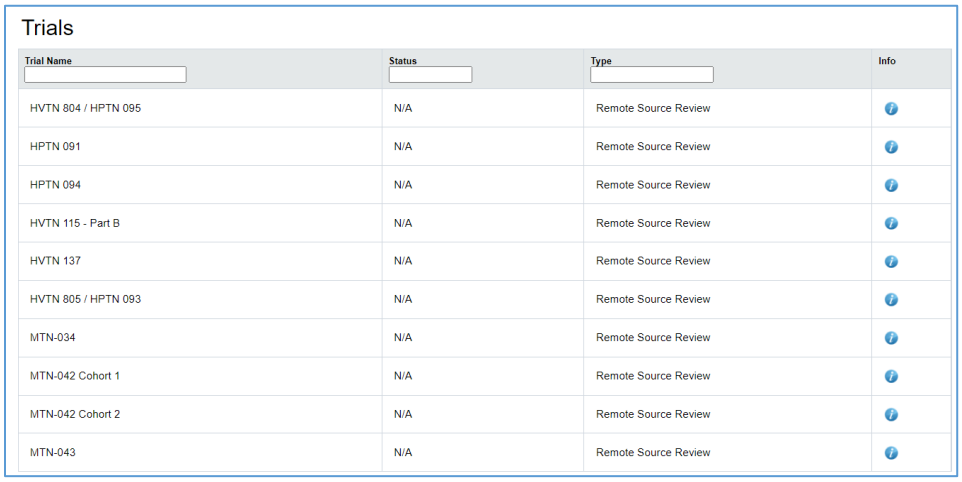
**V1.0 - Screening Visit Requirements**

| Type | Info | Requirement | Commands |
|---|---|---|---|
| Document | Informed Consent | 1 Document | Upload Document Comment |
| Document | Source Documents | 1 Document | Upload Document Comment |
| Document | Laboratory Reports | 1 Document | Upload Document Comment |
| Document | Clinic Notes | 1 Document | Upload Document Comment |
| Document | Other/Miscellaneous | 1 Document | Upload Document Comment |
| E-Form | Document Submission Confirmation | 1 E-Form | E-Form |

### 3. I don’t see the study visit. Can I add an additional visit folder in RSR?

Unscheduled visits, such as Interim visits, may be added in RSR.

a. Access the appropriate study. If your site is participating in multiple studies, you will see all the studies on the RSR dashboard.

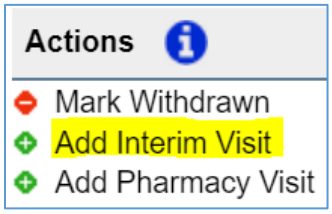


Trials

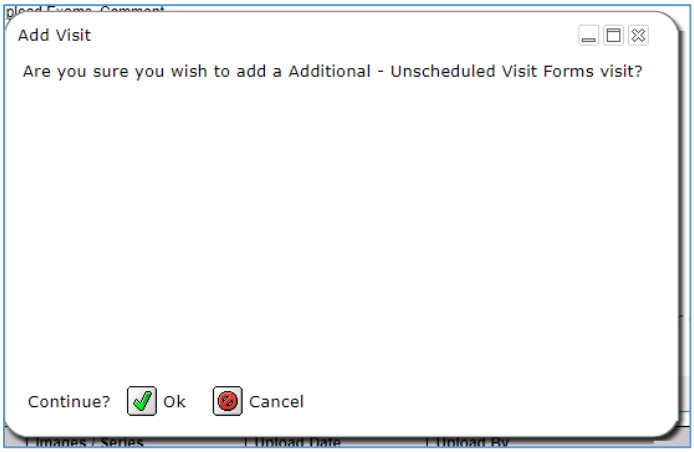
| Trial Name | Status | Type | Info |
|---|---|---|---|
| HVTN 804 / HPTN 095 | N/A | Remote Source Review | |
| HPTN 091 | N/A | Remote Source Review | |
| HPTN 094 | N/A | Remote Source Review | |
| HVTN 115 - Part B | N/A | Remote Source Review | |
| HVTN 137 | N/A | Remote Source Review | |
| HVTN 805 / HPTN 093 | N/A | Remote Source Review | |
| MTN-034 | N/A | Remote Source Review | |
| MTN-042 Cohort 1 | N/A | Remote Source Review | |
| MTN-042 Cohort 2 | N/A | Remote Source Review | |
| MTN-043 | N/A | Remote Source Review | |

b. On the Home page > Subjects list, find and access the participant for whom you want to add an unscheduled visit.

c. On the participant's page > Actions section, click ‘Add Interim Visit’.



d. In the Add Visit dialog, click Ok.




The unscheduled visit displays as 'Interim 1' at the bottom of the Visits section. You may create as many interim visits as appropriate to match the interim visits in Rave EDC.

**Note:** You cannot rename unscheduled visits.

## 4. How do I upload a document?

You can upload documents that are required for your visit as follows:

a. Access the appropriate study.

b. Select the appropriate participant visit.

c. In the Visit Requirements section, click Upload Document for the associated requirement you want to fulfill.

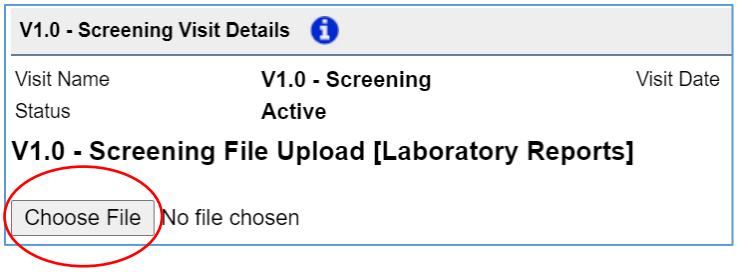
**Tip:** Incomplete requirements that are essential to the visit are highlighted in red; optional requirements are not highlighted. Completed requirements—whether required or optional—are highlighted in green.

**V1.0 - Screening Visit Requirements**

| Type | Info | Requirement | Commands |
|---|---|---|---|
| Document | Informed Consent | 1 Document | Upload Document |
| Document | Source Documents | 1 Document | Upload Document |
| Document | Laboratory Reports | 1 Document | Upload Document |
| Document | Clinic Notes | 1 Document | Upload Document |
| Document | Other-Miscellaneous | 1 Document | Upload Document |
| E-Form | Document Submission Confirmation | 1 E-Form | E-Form |

**Note:** If the requirement you select is the last incomplete requirement, you receive a prompt asking if you wish to automatically send the visit for review after the upload completes. Click Yes to automatically submit the visit for review; otherwise, click No to submit the visit for review manually at another time.

d. Click Choose File and select the file you want to upload. Repeat for each file you need to upload.



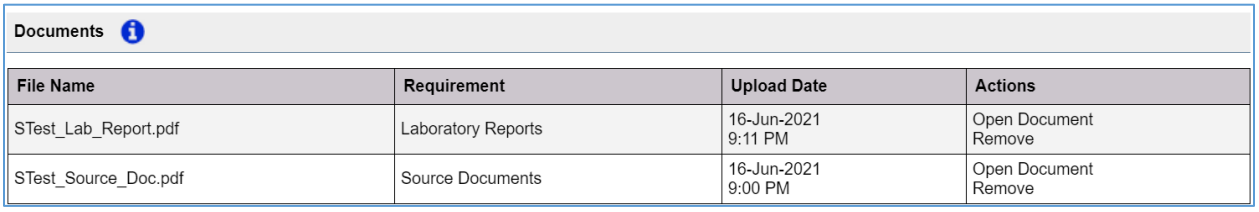

e. Click Save Uploads.

f. The completed requirement now displays in green in the Visit Requirements section.

## 5. My document contains PHI. How do I redact a document in RSR?

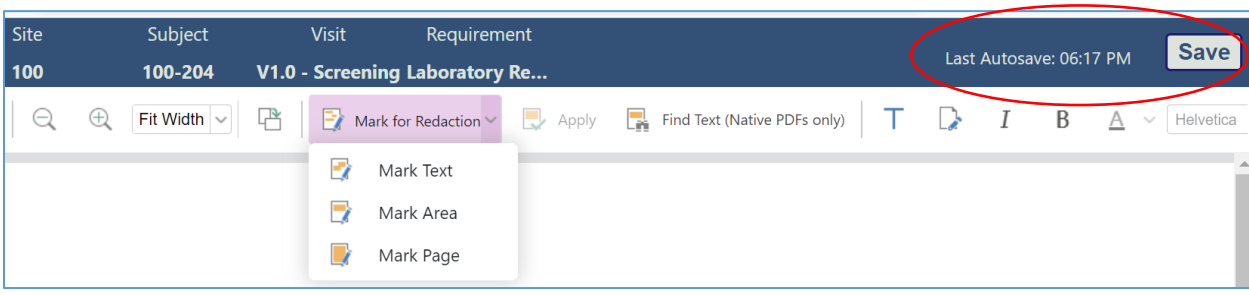
**Note**: DAIDS does not require PHI redaction, however this may be required by institutional policies and/or the IRB/EC.

a. After uploading your document, it will appear in the Documents grid of the participant visit:



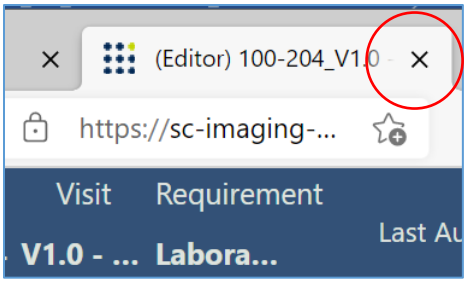

b. Click Open Document under Actions to preview.

c. On the top of the screen, click the Mark for Redaction drop-down and choose redaction option you want.




d. Apply redaction, then click Save. **Important:** Once redaction is applied to a document, it cannot be removed.

e. Leave the PDF viewer by closing the window.




## 6. I uploaded the wrong document. How do I delete a document in RSR?

a. Uploaded documents will appear in the Documents grid of the participant visit:

**Documents**

| File Name | Requirement | Upload Date | Actions |
|---|---|---|---|
| STest_Lab_Report.pdf | Laboratory Reports | 16-Jun-2021 9:11 PM | Open Document Remove |
| STest_Source_Doc.pdf | Source Documents | 16-Jun-2021 9:00 PM | Open Document Remove |

b. Click Remove under Actions to remove a document.

## 7. The status of the visit is "Locked", and I need to upload additional documents. How should I proceed?

If the visit is locked and you have additional documents to upload for review, please contact SCHARP Clinical Data Management to have the visit reset, sc.medidata.rsr@scharp.org. In your email provide the study name, the participant ID and the visit folder.

## 8. I am a Pharmacy site user. Where do I upload Pharmacy documents?

**Important**: Pharmacy visits in RSR are ONLY visible to a Pharmacy site user (and monitors) and not to other site users.

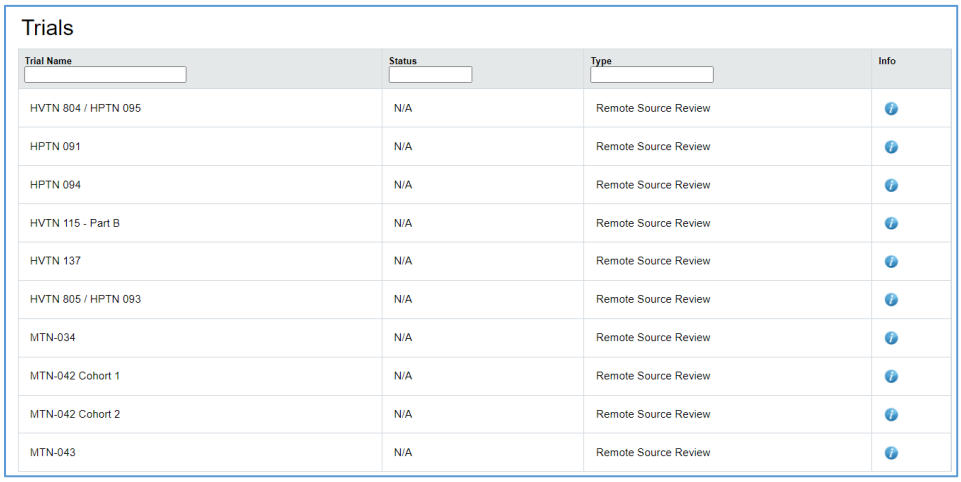
**Note**: Each site has a study-level participant named "SITE NUMBER – Study Documents" (e.g., 123-Study Documents). To create an additional study-level participant, please contact SCHARP Clinical Data Management, sc.medidata.rsr@scharp.org, to add a folder with a label such as "SITE NUMBER – Pharmacy – MONITORING VISIT DATE" for your site (e.g., 123-Pharmacy-23Sep2021). In your email provide the study name and the site ID/name.

Pharmacy visits are handled differently depending on when RSR was implemented for your study:

- If RSR was implemented for your study prior to September 2023, the Pharmacy site user will create a Pharmacy visit. Please see section 8.1 below.
- If RSR was implemented for your study in September 2023 or later, the Pharmacy visit is located in the study-level participant. Please see section 8.2 below.

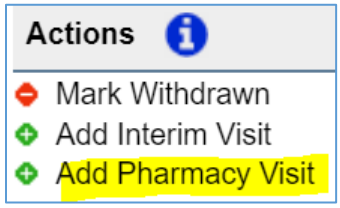
### 8.1 To create a Pharmacy visit folder at the participant level:

a. Access the appropriate study. If your site is participating in multiple studies, you will see all the studies on the RSR dashboard.

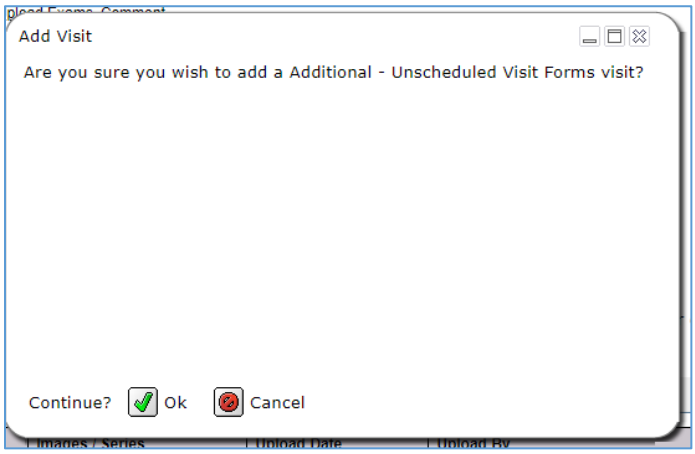



b. On the Home page > Subjects list, find and access the participant for whom you want to add a Pharmacy visit.

c. On the participant's page > Actions section, click ‘Add Pharmacy Visit’.



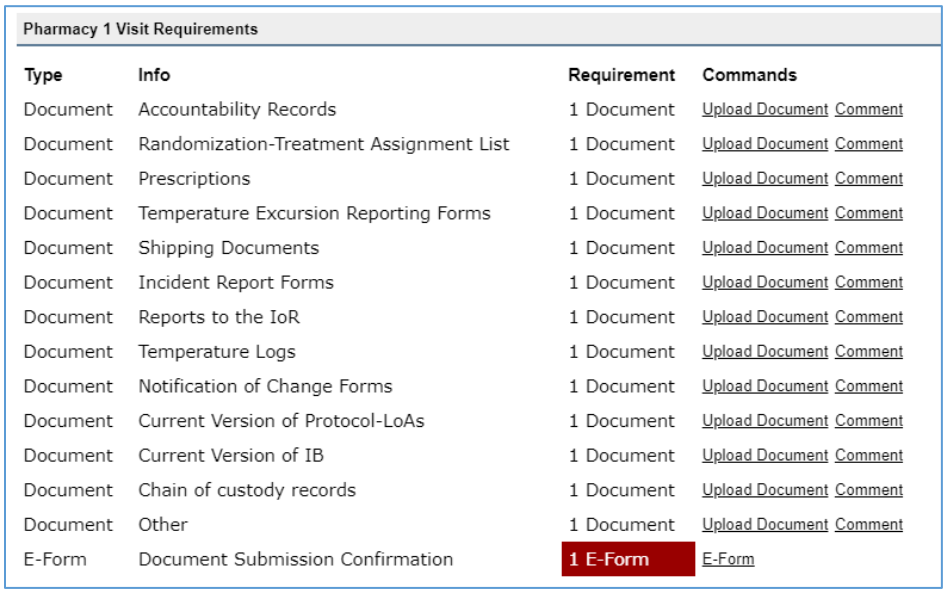

d. In the Add Visit dialog, click Ok.



The added visit displays as 'Pharmacy 1' at the bottom of the Visits section. You may append as many Pharmacy visits as needed.

**Note:** You cannot rename Pharmacy visits.

e. Select the Pharmacy 1 visit folder and the following screen displays. Note that all the requirements of type 'Document' are optional since none are highlighted in red like the Document Submission Confirmation E-Form:



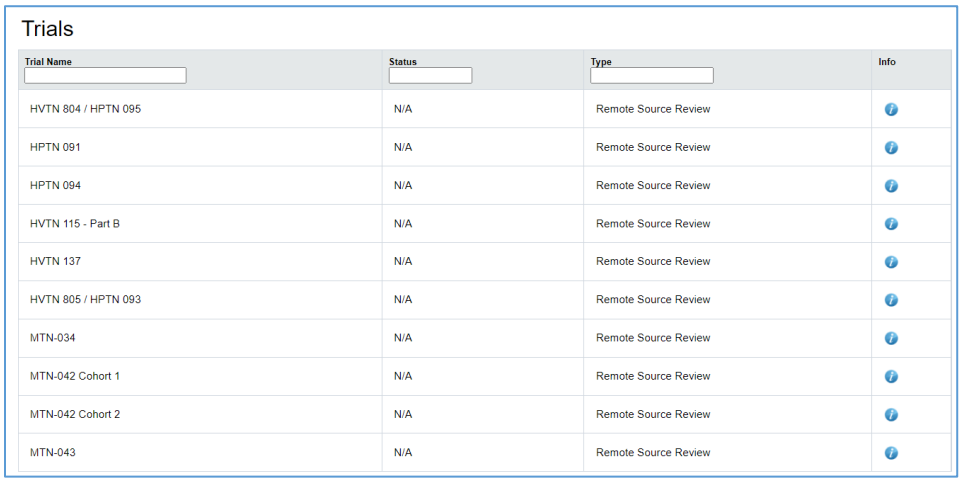
Pharmacy 1 Visit Requirements

| Type | Info | Requirement | Commands |
|---|---|---|---|
| Document | Accountability Records | 1 Document | Upload Document Comment |
| Document | Randomization-Treatment Assignment List | 1 Document | Upload Document Comment |
| Document | Prescriptions | 1 Document | Upload Document Comment |
| Document | Temperature Excursion Reporting Forms | 1 Document | Upload Document Comment |
| Document | Shipping Documents | 1 Document | Upload Document Comment |
| Document | Incident Report Forms | 1 Document | Upload Document Comment |
| Document | Reports to the IoR | 1 Document | Upload Document Comment |
| Document | Temperature Logs | 1 Document | Upload Document Comment |
| Document | Notification of Change Forms | 1 Document | Upload Document Comment |
| Document | Current Version of Protocol-LoAs | 1 Document | Upload Document Comment |
| Document | Current Version of IB | 1 Document | Upload Document Comment |
| Document | Chain of custody records | 1 Document | Upload Document Comment |
| Document | Other | 1 Document | Upload Document Comment |
| E-Form | Document Submission Confirmation | 1 E-Form | E-Form |

f. Upload documents as described in the FAQ under Question #4.

### 8.2 To navigate to the Pharmacy folder:

a. Access the appropriate study. If your site is participating in multiple studies, you will see all the studies on the RSR dashboard.

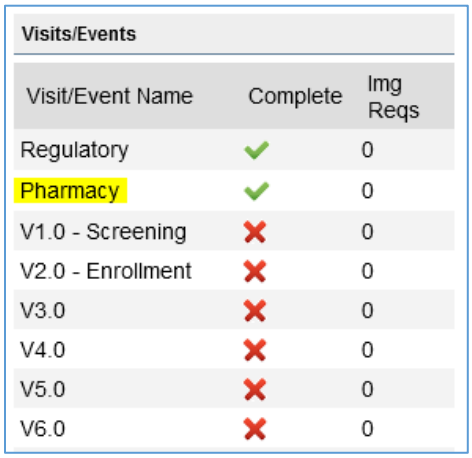


Trials

| Trial Name | Status | Type | Info |
|---|---|---|---|
| HVTN 804 / HPTN 095 | N/A | Remote Source Review | |
| HPTN 091 | N/A | Remote Source Review | |
| HPTN 094 | N/A | Remote Source Review | |
| HVTN 115 - Part B | N/A | Remote Source Review | |
| HVTN 137 | N/A | Remote Source Review | |
| HVTN 805 / HPTN 093 | N/A | Remote Source Review | |
| MTN-034 | N/A | Remote Source Review | |
| MTN-042 Cohort 1 | N/A | Remote Source Review | |
| MTN-042 Cohort 2 | N/A | Remote Source Review | |
| MTN-043 | N/A | Remote Source Review | |

b. On the Home page > Subjects list, find and access the study-level participant by searching for "Study Documents".

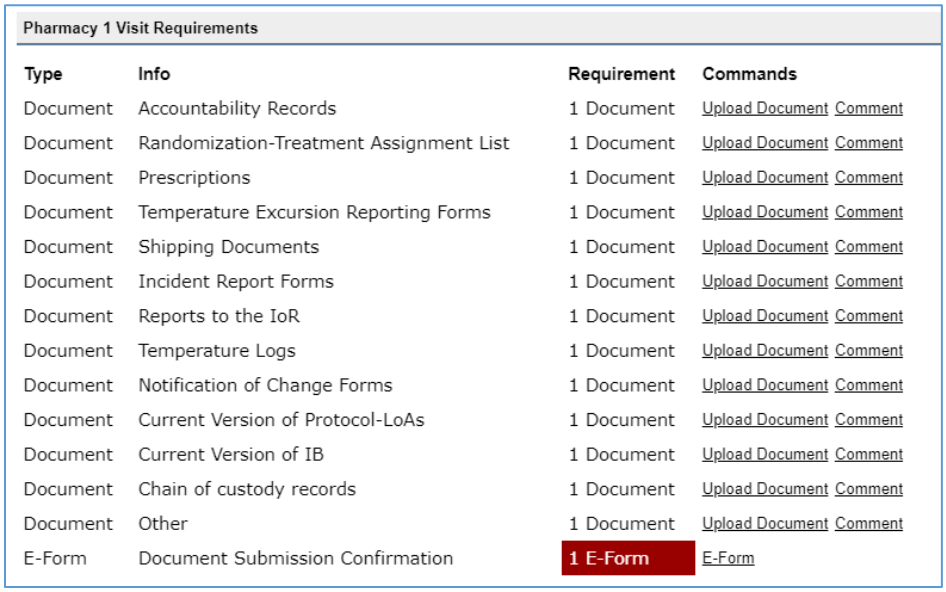
c. The Pharmacy folder is located at the top of the visit list on the right-hand side. Please ignore any scheduled visits (e.g., V1.0 – Screening, V2.0 – Enrollment) in the study-level participant and do not upload any requirements into them.



**Visits/Events**

| Visit/Event Name | Complete | Img Reqs |
|---|---|---|
| Regulatory | ✔ | 0 |
| Pharmacy | ✔ | 0 |
| V1.0 - Screening | ✘ | 0 |
| V2.0 - Enrollment | ✘ | 0 |
| V3.0 | ✘ | 0 |
| V4.0 | ✘ | 0 |
| V5.0 | ✘ | 0 |
| V6.0 | ✘ | 0 |

d. Select the Pharmacy folder and the following screen displays. Note that all the requirements of type 'Document' are optional since none are highlighted in red like the Document Submission Confirmation E-Form:



**Pharmacy 1 Visit Requirements**

| Type | Info | Requirement | Commands |
|---|---|---|---|
| Document | Accountability Records | 1 Document | Upload Document Comment |
| Document | Randomization-Treatment Assignment List | 1 Document | Upload Document Comment |
| Document | Prescriptions | 1 Document | Upload Document Comment |
| Document | Temperature Excursion Reporting Forms | 1 Document | Upload Document Comment |
| Document | Shipping Documents | 1 Document | Upload Document Comment |
| Document | Incident Report Forms | 1 Document | Upload Document Comment |
| Document | Reports to the IoR | 1 Document | Upload Document Comment |
| Document | Temperature Logs | 1 Document | Upload Document Comment |
| Document | Notification of Change Forms | 1 Document | Upload Document Comment |
| Document | Current Version of Protocol-LoAs | 1 Document | Upload Document Comment |
| Document | Current Version of IB | 1 Document | Upload Document Comment |
| Document | Chain of custody records | 1 Document | Upload Document Comment |
| Document | Other | 1 Document | Upload Document Comment |
| E-Form | Document Submission Confirmation | 1 E-Form | E-Form |

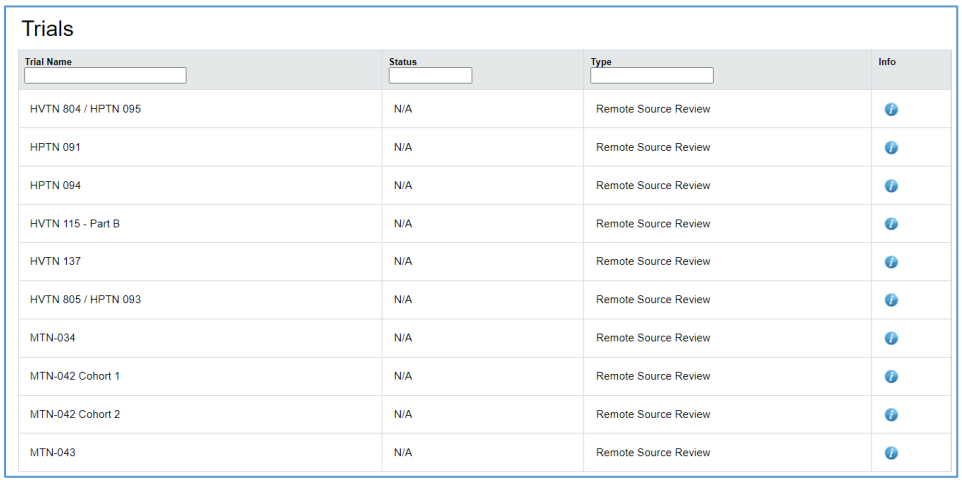
e. Upload documents as described in the FAQ under Question #4.

## 9. I have Regulatory documents that need to be reviewed. Where do I upload them?

The Regulatory folder is located in a study-level participant. Study-level participants are named "SITE NUMBER – Study Documents" (e.g., 123-Study Documents).

To navigate to the Regulatory folder:

f. Access the appropriate study. If your site is participating in multiple studies, you will see all the studies on the RSR dashboard.

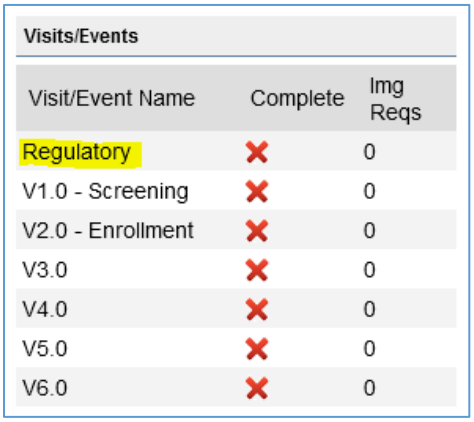


Trials

| Trial Name | Status | Type | Info |
|---|---|---|---|
| HVTN 804 / HPTN 095 | N/A | Remote Source Review | |
| HPTN 091 | N/A | Remote Source Review | |
| HPTN 094 | N/A | Remote Source Review | |
| HVTN 115 - Part B | N/A | Remote Source Review | |
| HVTN 137 | N/A | Remote Source Review | |
| HVTN 805 / HPTN 093 | N/A | Remote Source Review | |
| MTN-034 | N/A | Remote Source Review | |
| MTN-042 Cohort 1 | N/A | Remote Source Review | |
| MTN-042 Cohort 2 | N/A | Remote Source Review | |
| MTN-043 | N/A | Remote Source Review | |

g. On the Home page > Subjects list, find and access the study-level participant by searching for "Study Documents".

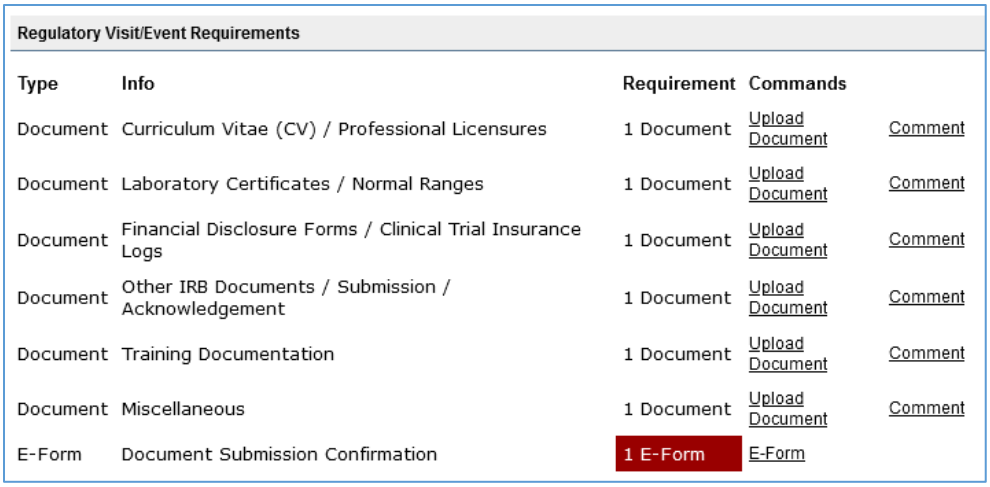
h. The Regulatory folder is located at the top of the visit list on the right-hand side. Please ignore any scheduled visits (e.g., V1.0 – Screening, V2.0 – Enrollment) in the study-level participant and do not upload any requirements into them.



Visits/Events

| Visit/Event Name | Complete | Img Reqs |
|---|---|---|
| Regulatory | ✗ | 0 |
| V1.0 - Screening | ✗ | 0 |
| V2.0 - Enrollment | ✗ | 0 |
| V3.0 | ✗ | 0 |
| V4.0 | ✗ | 0 |
| V5.0 | ✗ | 0 |
| V6.0 | ✗ | 0 |

i. Select the Regulatory folder and the following screen displays. Note that all the requirements of type 'Document' are optional since none are highlighted in red like the Document Submission Confirmation E-Form:



**Regulatory Visit/Event Requirements**

| Type | Info | Requirement | Commands | |
|---|---|---|---|---|
| Document | Curriculum Vitae (CV) / Professional Licensures | 1 Document | Upload Document | Comment |
| Document | Laboratory Certificates / Normal Ranges | 1 Document | Upload Document | Comment |
| Document | Financial Disclosure Forms / Clinical Trial Insurance Logs | 1 Document | Upload Document | Comment |
| Document | Other IRB Documents / Submission / Acknowledgement | 1 Document | Upload Document | Comment |
| Document | Training Documentation | 1 Document | Upload Document | Comment |
| Document | Miscellaneous | 1 Document | Upload Document | Comment |
| E-Form | Document Submission Confirmation | 1 E-Form | E-Form | |

j. Upload documents as described in the FAQ under Question #4.