COSMOS CTMS Subject Login:

URD:

CTMS-URD-SUBL-01: Subject should be able to login to CTMS using their username /pw. System should allow them to complete the portal training, view and complete the inform consent.

CTMS-URD-SUBL-02: Subject should be able to complete the health history, able to download the preview and download the completed ICF.

SRS:

CTMS-URD-SUBL-01 – CTMS\_SRS\_SUBL\_01

DES:

**CTMS\_SRS\_SUBL\_01:**

Once the subject is pre-qualified for a study, the study recruiter schedules a screening visit. When we send the visit confirmation email, we can include the portal registration URL and Username. The subject needs to use this URL to create their login and password. Upon logging in, they need to see the Terms & Conditions page, acknowledge it, and save those details.

The next step is for them to complete the portal training, which can be in document or video form. We need to record these details in the subject's audit trail. The subject should not have access to these audit trails. Without completing these two steps, they should not be allowed to enter the system.

Once they enter the system, they can preview the ICF (Informed Consent Form), etc. Depending on the site, the site can share the ICF as READONLY in the subject portal. Once the subject arrives for a screening visit, the study team can assign the ICF process. The subject can start the ICF process by logging into the portal. Once all parties have completed the signing, a copy of the ICF for that subject is saved as their version.

We can also show them their appointment schedule.

**CTMS-URD-SUBL-02:**

Once all parties have completed the signing, a copy of the ICF for that subject is saved for them to download. We allow them to update their health history portion.