

How to Configure Settings for Study Start-Up

TI version 10.8

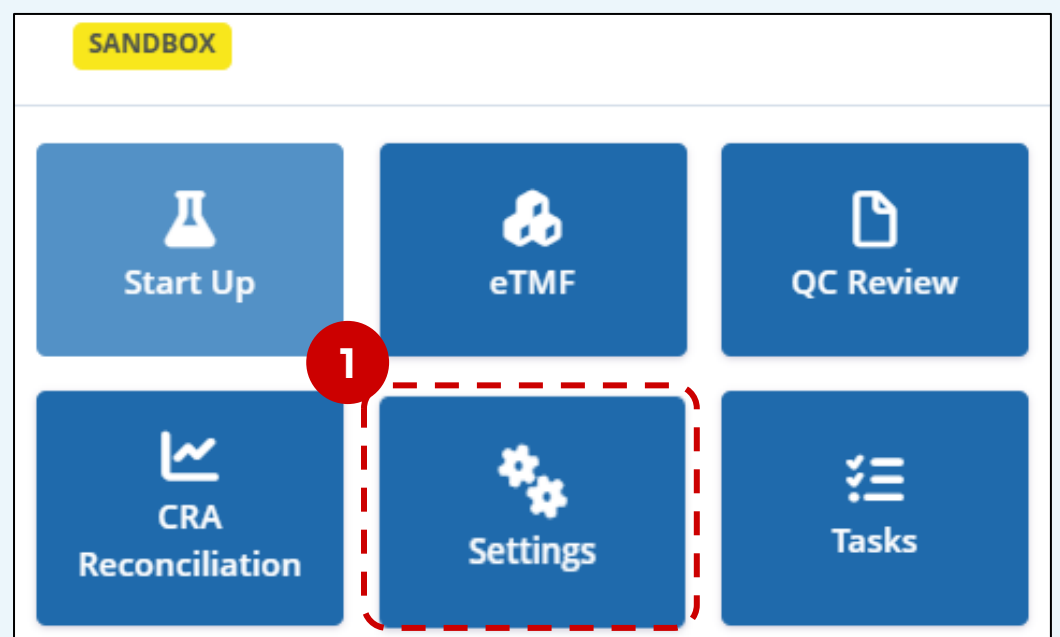
APPLICABLE TO:

- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

This guide is intended for Study Start-up Room Admins and provides oversight and direction on how to utilize SSU specific settings and configuration options.

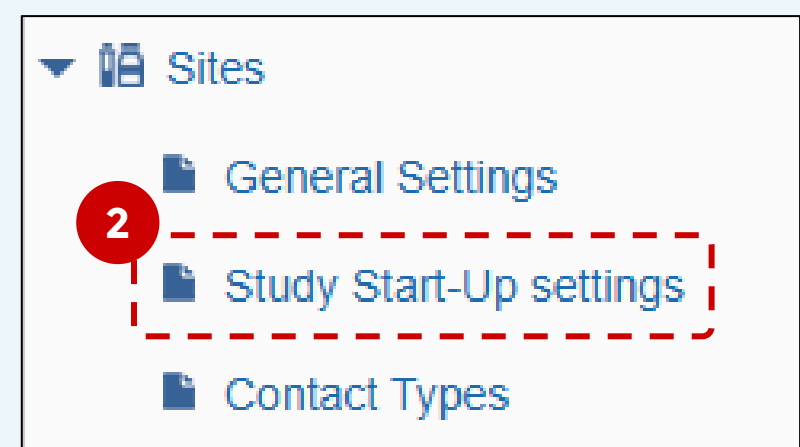
Any and All changes/updates made within the Settings Menu should be documented in the Change Log.

- 1 Enter a room and navigate to the **Settings** area.



Submenu: SSU Settings

- 2 Expand the Sites group of menus and select **Study Start-Up settings**.



- 3 This menu contains most of the basic SSU settings:

- Approval Workflow: 1-step or 2-step
- Enable additional review: Sponsor Review
- Enable manually sending documents to eTMF ('Allow users to select the documents...')
- Prevent auto-publish when conditions met ('Do not publish the documents on eTMF...')



3 [CONTINUED] List of Study Start-Up Settings:

- Required Documents QC (in eTMF) switch (select Publish to Index to skip QC, Publish to eTMF Workflow to maintain)
- Non-Required Documents QC selection (choose from review in SSU or review in eTMF)

Required Documents: Publish to eTMF Workflow Publish to Index without the eTMF Workflow

Non-Required Documents: Publish to eTMF Workflow Workflow in Study Start-Up



Did you know? Most settings entries have a tooltip containing a description of their effects. Look for the icon.

3 [CONTINUED] List of Study Start-Up Settings:

- Site Activation prevents document upload Y/N
- Allow paper documents Y/N (permits creation of entries that have no attachment, and can be reviewed as-is)
- Regulatory approvers selection (used to define users that can perform the second review step in SSU)
- SSU processing time (delays the activation date of a Site counting from when the Activate Site button is pressed)
- Email recipients selection: Site Activation and Amendment Completion notifications
- Text for Site Activation (customizable header)

Do not allow addition of new documents to a Site after activation

Allow paper documents

Regulatory approvers: 0 user(s) selected

Start-Up processing time (days):

Site activation email recipients: 2 user(s) selected, 0 contact type(s) selected

Complete amendment email recipients: 0 user(s) selected, 0 contact type(s) selected

Site activation title: *

Submenu: Submission Profile Status

- 4 Select the **Submission Profile Status** menu to review and edit the statuses that apply to submission packages.

Only the Display name of statuses can be changed.

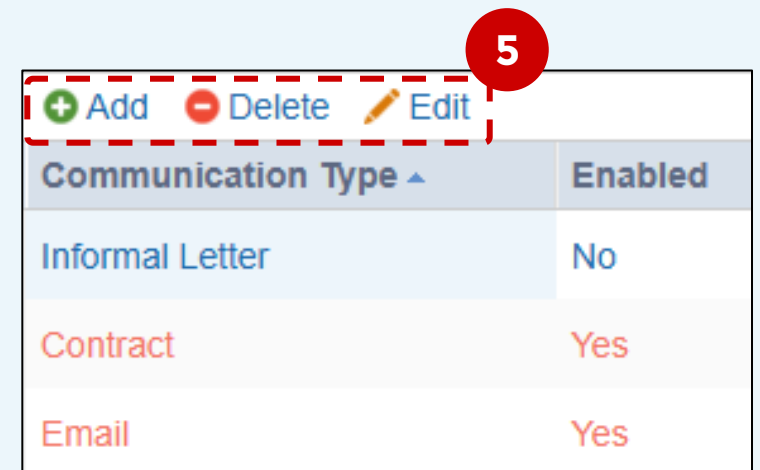
Edit

Display Name	System Status
Awaiting Processing	Pending



Submenu: Communication Types

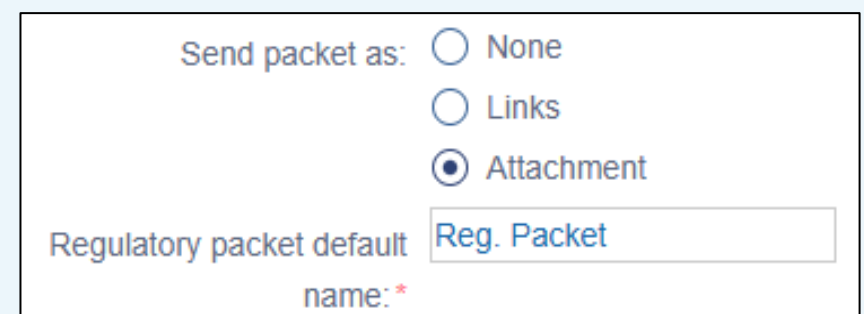
- 5 Select the **Communication Types** menu to manage the labels that can be used when adding entries to the Communications Log. Users can add or delete labels, or temporarily disable existing ones (some default labels cannot be disabled).



Communication Type ^	Enabled
Informal Letter	No
Contract	Yes
Email	Yes

Submenu: Regulatory Packet Options

- 6 Select **Regulatory Packet Options** to manage how packets are issued by the system: as a container of documents (attachments), a container of links, or neither. You can additionally set the default name for a packet.



Send packet as: None
 Links
 Attachment

Regulatory packet default name:



Packet name should never be changed without also addressing the form settings that relate to packets. We recommend contacting your CSM whenever such a change is required.

Other important settings

- 7 To leverage the features of TI's SSU module fully, other system settings require setup. These include Country, IRB, and Site Settings; Required Document Settings; and user role settings. Rather than try and address all of them in one document, a number of dedicated Job Aids are offered.

Please refer to the following documents in the TI Online Guide: **How to Add a Country, How to Create an IRB, How to Create a Site in eTMF Rooms, How to Add Required Documents (Settings Menu), How to Assign a SSU Specialist, How to Assign a Regulatory Reviewer.**