



**INSTRUCTIONS:
Site and User Tracker (SUT)**

Version: 1.0
Date: 05 OCTOBER 2023

Site and User Tracker (SUT)

The SUT serves as the master record for users and shipment information, and is critical to AiCure operations for the study. The SUT will be utilized by AiCure to execute contracted operations for the study, including but not limited to:

- User accounts - granting, revoking, or access
- Site SIV Dates
- Red alert email distribution list
- Weekly reporting distribution list
- Clinical Site Services outreach and monitoring reports
- Technical support tickets resolution
- Provisioning of initial, resupply, or replacement device requests

This powerpoint outlines the requirements for formatting and submission to AiCure.

Authorized Requestor(s)

As this document captures user access information to the AiCure Platform with study data, and shipment information for study equipment, it is the **SPONSOR/CRO's** responsibility to approve and submit any updates to this document.

For added security, AiCure requires 1-3 individuals from the Sponsor/CRO team to be designated as an **Authorized Requestor**.

Authorized requestors are responsible for....


1. Maintaining the SUT for the study
2. Reviewing/approving any changes to the SUT
3. Submitting the SUT to AiCure for processing

AiCure will not accept SUT updates from a site or person who is not authorized. For updates or changes to the Authorized Requestor, the Sponsor/CRO must email the AiCure Project Manager for approval and processing.

NOTE: The format of the SUT document is not allowed to be edited without written permission from AiCure. Therefore, do not add/remove columns.

Format - High Level Overview

Tab 1: Cover Page



Site and User Tracker (SUT)

Introduction:
 The AiCure *Site and User Tracker (SUT)* is a study level document which is utilized to capture site and user account access information, as well as site equipment shipment information for AiCure. Submission of this document from the Sponsor/CRO to AiCure will trigger user access and shipments of AiCure equipment such as provisioned devices per the contract. The SUT serves as the master record for users and shipment information, and is critical to AiCure operations for the study

Responsibility & Authorized Requestors
 As this document captures user access information to the AiCure Platform with study data, and shipment information for study equipment, it is the SPONSOR/CRO's responsibility to approve and submit any updates to this document. For added security, AiCure requires 1-3 individuals from the Sponsor/CRO team to be designated as an Authorized Requestor. Authorized requestors are responsible for maintaining the SUT for the study, reviewing/approving any changes to the SUT, and submitting the SUT to AiCure for processing. AiCure will not accept SUT updates from a site or person who is not authorized. For updates or changes to the Authorized Requestor, the Sponsor/CRO must email the AiCure Project Manager for approval and processing.

Study Information

Study ID:	Study ID
AiCure Project Manager:	Name

Sponsor/CRO Authorized Requestors

Only authorized persons from the Sponsor/CRO team are permitted to submit updated SUT to AiCure for processing.

Authorized Requestor #1	Name	Role / Affiliation	Email
Authorized Requestor #2	Name	Role / Affiliation	Email
Authorized Requestor #3	Name	Role / Affiliation	Email

Need Help? Please contact your AiCure Project Manager for questions and instructions.

☰
Cover Page ▾
Revision History ▾
Site User Accounts ▾
Site Shipment & CRA Assignment ▾
Country Shipment ▾
SponsorCRO User Accounts ▾
Alpha-2 Codes ▾

- Study ID
- Includes list of Authorized Requestors.
- This tab will be locked for editing, the list of Authorized Requestors will be updated by AiCure after approval and processing.

About 'Column A: Actions'

Utilize the dropdowns in column A to indicate what action is needed.

IMPORTANT Actions from the previous submission **MUST** be cleared prior to re-submission. If you have submitted a user previously, please mark the row as 'NO CHANGE' for any subsequent re-submission.

Action	Description
ADD	New users, grant access
EDIT	Remove user, revoke access
REMOVE	Edit account information (*Required: please also highlight the cell which was edited)
NO CHANGE	Previously submitted users, no change to their account for this submission
ALREADY REMOVED	Previously removed users that are now deactive

Formatting Requirements

If formatting requirements are not followed, your SUT submission will be rejected and not processed.

Formatting Requirements

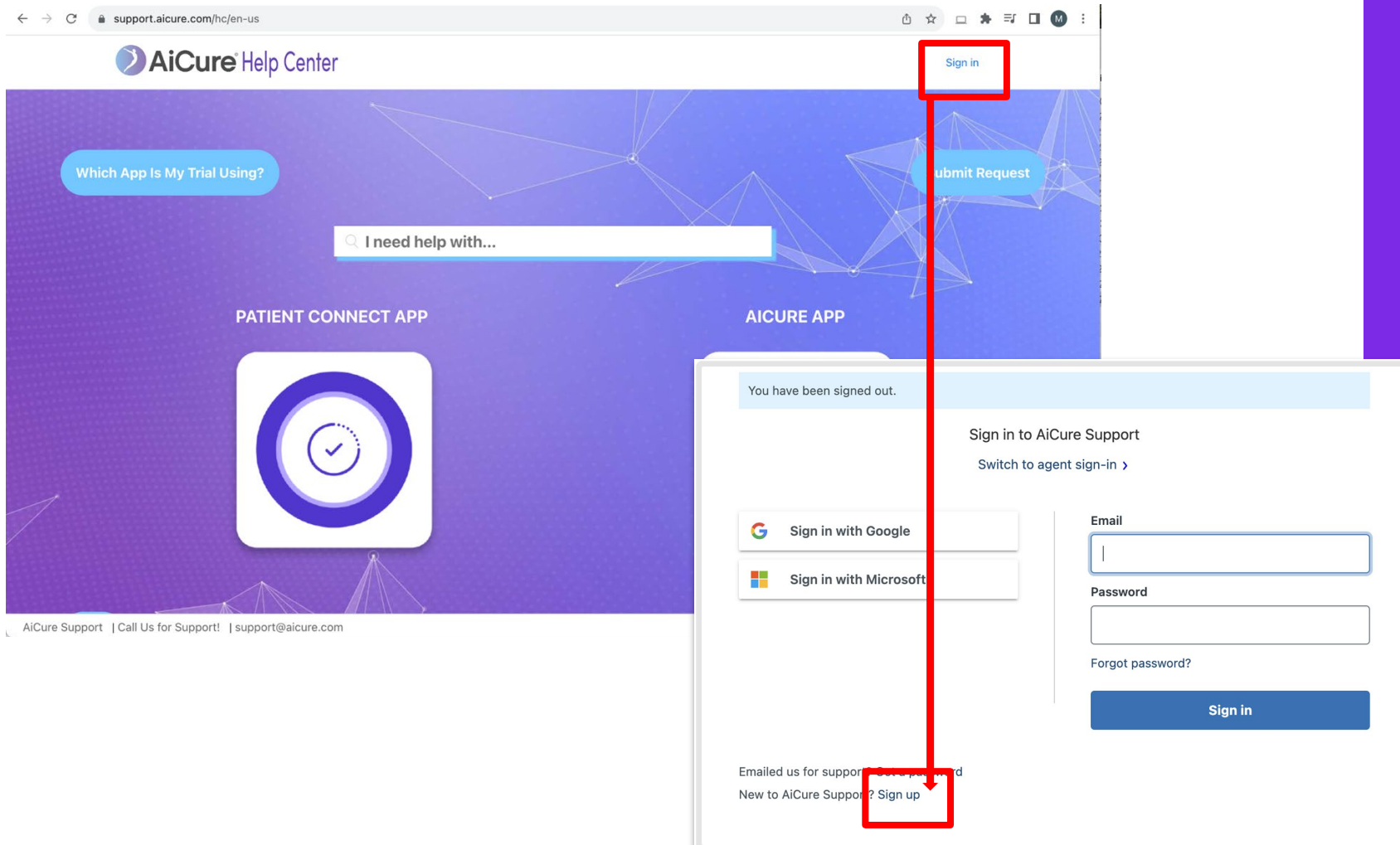
1. Maintain one master SUT per study. Any and all updates should be made to the most recent SUT, and saved with a new date and new version number. Therefore, it is NOT permissible to submit one SUT per country, or create a single SUT per site or per request.
1. Save the SUT according to the following nomenclature, updating the date and the version number for each new submission.
File Name:
FORM-OPS-012-03 AiCure Site & User Tracker_(STUDY ID)_(DATE OF SUBMISSION)
1. All fields on the SUT are required, and must be completed for each user at time of submission. The SUT Template may not be modified without written permission from AiCure; meaning addition or removal of columns is not permitted.
1. For all users on any tab, use the dropdown's in 'Column A: Action' to indicate what change is needed for each entry. A detailed description of the dropdowns & corresponding required actions are on slide 8.
IMPORTANT Actions from the previous submission **MUST** be cleared prior to re-submission. If you have submitted a user previously, please mark the row as 'NO CHANGE' for any subsequent re-submission.
1. For updates regarding site shipment information
 - a. If the exact SIV date is not known, it is permissible to use the best estimate of the SIV date, if the exact date is not known.
 - b. The shipping address must include street address, city, state, and zip code.
1. Duplicate entries are not permitted. Please search for the user and update the existing entry instead of adding a duplicative row.
1. AiCure highly recommends the SUT is updated **weekly**, and requires at minimum an update each **month**.

Submission Process

Submit SUT to the AiCure Help Center

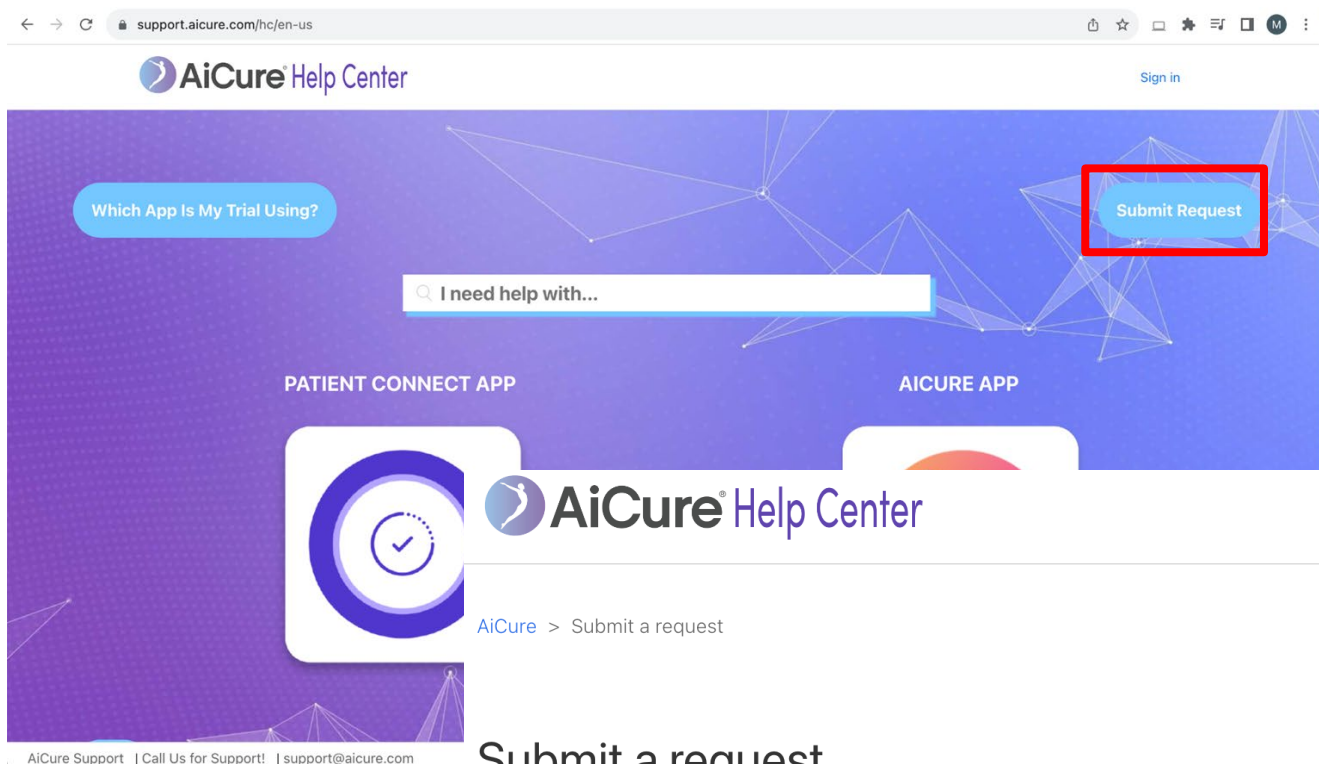
Access & Log In

- Navigate to the **AiCure Help Center** (support.aicure.com) and Login.
- Authorized Requestors must login.
- If you do not have a login, you can sign up with your email.



The screenshot shows the AiCure Help Center website at support.aicure.com/hc/en-us. The page features a search bar with the placeholder text "I need help with...", a "Submit Request" button, and sections for "PATIENT CONNECT APP" and "AICURE APP". A sign-in modal is overlaid on the page, displaying the message "You have been signed out." and "Sign in to AiCure Support". The modal includes options for "Sign in with Google" and "Sign in with Microsoft", as well as input fields for "Email" and "Password". A "Sign in" button is located at the bottom of the modal. A "Forgot password?" link is also present. At the bottom of the modal, there is a "Sign up" link for new users. A red box highlights the "Sign in" link in the top right corner of the page, and another red box highlights the "Sign up" link at the bottom of the modal. A red arrow points from the top "Sign in" link to the bottom "Sign up" link.

Submit SUT to the AiCure Help Center



Submit a request

What would you like to get help with? (If you are a study participant, please do not use this form. Reach out to your site if you are experiencing issues.)

-
Technical Support
(Authorized Requestors ONLY) SUT Submission
Data Change Request Form
Supply Request
Video Review Requests

SUT Submission Form

- After you've logged in, select the 'Submit Request' button in the upper right hand corner.
- From the dropdown menu, select '**SUT Submission (Authorized Requestor Only)**'

NOTE: Only authorized requestors will have access to this dropdown. If you (1 - 3 requestors permitted per study). If you have questions, please contact your AiCure Project Manager.

Submit SUT to the AiCure Help Center

[AiCure](#) > [Submit a request](#)

Submit a request

What would you like to get help with? (If you are a study participant, please do not use this form. Reach out to your site if you are experiencing issues.)

CC

Your name *

Sponsor *

Sponsor organization

Trial (Study ID) *

Ticket Subject

Brief description of issue

Details *

Please enter the details of your request or the issue you are experiencing providing as much detail as you are able. A member of our support staff will respond as soon as possible.

Attachments

If formatting requirements are not followed, your SUT submission will be rejected and not processed.

Fill out the SUT Submission Form

- Fill out the required fields, attach the updated SUT, and press Submit.
- Your AiCure Project Manager will automatically be notified of the new submission.
- You can track the status of your request under your AiCure Help Center account.
- The AiCure Technical Support team will email you once your request has been processed (typically within X business days)

Questions?
Email your AiCure Project Manager
