Multi-Sponsor Environment

SAS® Clinical Trial Data Transparency User Guide

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6.2.5 Starting the Export from the Export Request Detail Screen ........................................ 72

7 Online Help ........................................................................................................................................ 74

8 Troubleshooting ...................................................................................................................................... 76

Information about This Document

Document Control ...................................................................................................................................... 77
Contacts .................................................................................................................................................. 77
Revision History ....................................................................................................................................... 77
Typographical Conventions .................................................................................................................. 78

Figures

Figure 1: Environment Overview ........................................................................................................... 2
Figure 2: Welcome E-Mail .......................................................................................................................... 3
Figure 3: Account Help ................................................................................................................................ 3
Figure 4: SAS Secure Access Management .............................................................................................. 4
Figure 5: Download VIP Access .............................................................................................................. 5
Figure 6: Download and Install VIP Access .............................................................................................. 6
Figure 7: VIP Access Setup ....................................................................................................................... 6
Figure 8: VIP Access – Finish Installation .................................................................................................. 7
Figure 9: VIP Access - Main Screen ......................................................................................................... 7
Figure 10: Self Service Portal - Sign In ...................................................................................................... 8
Figure 11: Confirm Your Identity ............................................................................................................. 9
Figure 12: Temporary VIP Security Code .................................................................................................. 10
Figure 13: Enter Your Temporary Security Code ..................................................................................... 10
Figure 14: VIP Welcome Screen ............................................................................................................. 11
Figure 15: Register Your Credential ....................................................................................................... 12
Figure 16: Create Your PIN ..................................................................................................................... 13
Figure 17: Manage Your PIN ................................................................................................................... 13
Figure 18: SAS® Clinical Trial Data Transparency Portal Logon ................................................................. 14
Figure 19: SAS® Clinical Trial Data Transparency Portal Accept Terms (Start) ....................................... 14
Figure 20: SAS® Clinical Trial Data Transparency Portal Accept Terms (Finish) .................................... 15
Figure 21: SAS® Clinical Trial Data Transparency Portal (Proceed to Home) ......................................... 15
Figure 22: Secure Access Portal - Logon Screen ....................................................................................... 16
Figure 23: Copy Security Code ............................................................................................................... 17
Figure 24: Secure Access Portal – Welcome Screen ............................................................................... 17
Figure 25: Java Update Needed ............................................................................................................. 17
Figure 26: Download Java ........................................................................................................................ 18
Figure 27: Start Java Download ............................................................................................................... 18
Figure 28: Installing Java - Screen 1 ........................................................................................................ 18
Figure 29: Installing Java - Screen 2 ........................................................................................................ 19
Figure 30: Installing Java - Close Programs and Continue .................................................................... 19
Figure 31: Installing Java - Screen 3 ........................................................................................................ 20
Figure 32: Installing Java - Screen 4 ........................................................................................................ 20
Figure 33: Launching Terminal Session .................................................................................................. 21
Figure 34: Install Juniper Terminal Services Client ................................................................................ 21

24-NOV-2015 MSE_Clinical_Trial_Data_Transparency_Users_Guide_4.0.docx Page iii

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Figure 35: Logging on to the Computer that Hosts the Research Environment ........................................ 22
Figure 36: Remote Desktop Session ........................................................................................................ 23
Figure 37: Secure Access Portal - Sign-in Screen .................................................................................. 24
Figure 38: Secure Access Portal - Welcome Screen ............................................................................. 24
Figure 39: Mac – Popup Blockers ........................................................................................................... 25
Figure 40: Mac – Remote Office Dialog .................................................................................................. 25
Figure 41: Mac – Remote Office Dialog (Java not installed) ................................................................. 26
Figure 42: Mac – Remote Office Dialog (Popup) .................................................................................... 27
Figure 43: Mac – Install Java Website .................................................................................................... 27
Figure 44: Mac – JRE DMG File ................................................................................................................ 28
Figure 45: Mac – JRE DMG File .................................. 28
Figure 46: Mac – Java Install – Screen 1 .................................................................................................. 29
Figure 47: Mac – Java Install – Screen 2 ................................................................................................ 29
Figure 48: Mac – Install Admin Screen .................................................................................................. 30
Figure 49: Mac – Install Java Finish ....................................................................................................... 30
Figure 50: Mac – Accept Applet Dialog .................................................................................................. 31
Figure 51: Mac – Allow HOBLink Dialog ................................................................................................ 32
Figure 52: Mac – HOBLink JWT Logon ................................................................................................... 32
Figure 53: Mac – Research Environment Desktop .................................................................................. 33
Figure 54: Logging off the Research Environment ................................................................................. 33
Figure 55: SAS® Clinical Trial Data Transparency Icon ........................................................................... 34
Figure 56: SAS® Clinical Trial Data Transparency Logon Screen ........................................................... 35
Figure 57: SAS® Clinical Trial Data Transparency Main Screen ............................................................. 35
Figure 58: SAS® Clinical Trial Data Transparency Tabs .......................................................................... 36
Figure 59: SAS® Clinical Trial Data Transparency - Preferences -> Views .............................................. 36
Figure 60: SAS® Clinical Trial Data Transparency - Help Tab ................................................................. 37
Figure 61: SAS® Clinical Trial Data Transparency - Repository Tab ......................................................... 38
Figure 62: SAS® Clinical Trial Data Transparency – Study Folders ......................................................... 39
Figure 63: SAS® Clinical Trial Data Transparency – Research Area Folders ........................................... 40
Figure 64: Opening a SAS Data Set .......................................................................................................... 41
Figure 65: Data Set ................................................................................................................................. 42
Figure 66: Sorting Columns .................................................................................................................... 42
Figure 67: Filtering Options ...................................................................................................................... 43
Figure 68: Statistics ............................................................................................................................... 43
Figure 69: Modifying Current Filter ....................................................................................................... 44
Figure 70: Repository and Workspace Tabs ............................................................................................ 44
Figure 71: Get Latest or Specific Version ............................................................................................... 45
Figure 72: Workspace Tab ....................................................................................................................... 46
Figure 73: SAS Session Tab .................................................................................................................... 47
Figure 74: New -> SAS Program ............................................................................................................ 48
Figure 75: Sending Results to Other Locations ....................................................................................... 49
Figure 76: PDF Output ............................................................................................................................ 49
Figure 77: Download .............................................................................................................................. 51
Figure 78: Select Location ....................................................................................................................... 52
Figure 79: Save Location ......................................................................................................................... 52
Figure 80: R Studio List of R Packages ................................................................................................... 53
Figure 81: R LIBPATHS .......................................................................................................................... 54
Figure 82: R Desktop Icon ........................................................................................................55
Figure 83: R Startup Screen .....................................................................................................56
Figure 84: RStudio Desktop Icon ............................................................................................57
Figure 85: RStudio Startup Screen .........................................................................................58
Figure 86: Locally Saved CSV File ..........................................................................................58
Figure 87: RStudio View .........................................................................................................58
Figure 88: Exports Folder .........................................................................................................59
Figure 89: Upload Files ...........................................................................................................60
Figure 90: Contents of Exports Folder .....................................................................................61
Figure 91: SAS® Clinical Trial Data Transparency Portal Logon .............................................62
Figure 92: SAS® Clinical Trial Data Transparency Portal after Logon .....................................62
Figure 93: CTDT Options Tab ..................................................................................................62
Figure 94: Imports Section .......................................................................................................63
Figure 95: Add Import ..............................................................................................................63
Figure 96: Detail View ..............................................................................................................64
Figure 97: Add File(s) ............................................................................................................64
Figure 98: Attached Files ........................................................................................................65
Figure 99: Manage Import Settings Link ................................................................................65
Figure 100: Manage Import Settings Screen .........................................................................65
Figure 101: Modify ..................................................................................................................65
Figure 102: Select Folder .........................................................................................................66
Figure 103: Update ..................................................................................................................66
Figure 104: Copy to All ............................................................................................................66
Figure 105: Start Import Run ..................................................................................................67
Figure 106: Import Summary ..................................................................................................67
Figure 107: Imports / Exports Tab ..........................................................................................68
Figure 108: Exports Section ....................................................................................................68
Figure 109: Add Export Request ............................................................................................68
Figure 110: Export List Screen with Download Icon ...............................................................69
Figure 111: Export Request Detail Screen ...............................................................................70
Figure 112: Export Paths Section ...........................................................................................70
Figure 113: Add / Edit Export Paths .....................................................................................70
Figure 114: Select Folder ........................................................................................................71
Figure 115: Name of Zip File ...................................................................................................71
Figure 116: Current Paths .......................................................................................................71
Figure 117: Status ...................................................................................................................72
Figure 118: Attached Files / Generated Exports ....................................................................72
Figure 119: Export Created / Approved for View ..................................................................72
Figure 120: Export Available to Download ..........................................................................73
Figure 121: Company Approval(s) .......................................................................................73
Figure 122: Help and User Guide Desktop Icon ....................................................................74
Figure 123: Help Link ............................................................................................................74
Figure 124: Help Screen .........................................................................................................74

Tables

Table 1: Guide Sections Related to the full SAS® Clinical Trial Data Transparency Repository User Guide
Table 2: Common issues ........................................................................................................73

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1 Overview

Three environments or websites encompass the SAS® Clinical Trial Data Transparency system:

- **Research Environment**
  - **How to access:** Log on to the SAS Solutions OnDemand Secure Portal ([https://shqaccess.ondemand.sas.com/dana-na/auth/url_3/welcome.cgi](https://shqaccess.ondemand.sas.com/dana-na/auth/url_3/welcome.cgi)). From the landing page, click the Clinical Trial Data Transparency Research Environment link. A remote terminal server session launches, requiring an additional logon (with same account). You then access the Research Environment.
  - **Tasks you can perform:**
    - Perform research work using SAS Clinical Trial Data Transparency or R.
    - Collect files for export from the Research Environment.
    - Review user guides and how-to videos.

- **SAS Clinical Trial Data Transparency (CTDT) Portal:**
  - **How to access:** Log on to the SAS Solutions OnDemand Secure Portal [https://mseportal.ondemand.sas.com/ctdt/](https://mseportal.ondemand.sas.com/ctdt/)
  - **Tasks you can perform:**
    - Import files into the Research Environment.
    - Receive exports from the Research Environment.
    - Administrators can review reporting.

- **SAS Secure Access Management:**
  - **How to access:** Enter [https://www.ondemand.sas.com/sam/](https://www.ondemand.sas.com/sam/) from your browser for access through the internet.
  - **Tasks you can perform:**
    - Set-up your password for the first time.
    - Reset your password.
    - Administrators can add and update users.

**Note:** Once you setup your password and challenge questions, you are required to accept the Terms of Use Agreement in the SAS Clinical Trial Data Transparency Portal. Accepting these terms unlocks your account in the SAS Clinical Trial Data Transparency Repository system, which is available at the Research Environment desktop.
Figure 1 provides an overview of the environments.

**Figure 1: Environment Overview**

![Diagram showing the environments](image)

**Note:** Your account information (user name (or user ID) and password) enable you to access all the components of the SAS Clinical Trial Data Transparency system. An additional security code is required to access the Research Environment through the secure portal.
2 Setting up Your Account

2.1 Completing the Initial Email and Password Setup

1. Receive an e-mail from SAS Solutions OnDemand with your user name (or user ID) for the SAS Clinical Trial Data Transparency system. To activate the account and set-up a password, click the link in the e-mail (Figure 2).

Figure 2: Welcome E-Mail

![Welcome Email](https://www.ondemand.sas.com/sas?soc=13625977786&icc=x087mlAHzdS9mmn6yq8x4Hn00y)

Note: The link in the e-mail expires after 72 hours. If you do not activate your account within 72 hours, visit the Account Help tab (Figure 3) at the [https://www.ondemand.sas.com/sam/](https://www.ondemand.sas.com/sam/) website. Use the My password expired or I don't know my username options. Otherwise, contact SAS Technical Support as follows:

- Email: CTDTSupport@sas.com
- URL: [http://support.sas.com/ctx/supportform/index.jsp](http://support.sas.com/ctx/supportform/index.jsp)
- North America: Call 919-677-8008

Figure 3: Account Help

![Account Help](https://www.ondemand.sas.com/sas?soc=13625977786&icc=x087mlAHzdS9mmn6yq8x4Hn00y)
2. Click the link to setup a password. The Secure Access Management system guides you through the process of setting up a password (Figure 4).

Figure 4: SAS Secure Access Management

Note: The Secure Access Management system provides password rules when you set a password. Your account’s password expires after 90 days. Beginning eight days prior to your password’s expiration, you receive a daily e-mail reminder to re-set your password.

2.2 Installing and Setting Up the Security Token (One-Time Only)

Access to the Research Environment requires a secure connection. To make this secure connection, you must enter your SAS Clinical Trial Data Transparency system user name (or user ID) and password and use a security token to provide a security code. This section outlines the steps necessary to install and set up the security token provided by Verisign. You only need to perform these steps once.

1. Download the VIP Access application by visiting the website link https://idprotect.verisign.com/desktop/download.v
2. Click Download for Windows or Download for Mac, when appropriate, and follow the instructions provided (Figure 5).

**Figure 5: Download VIP Access**

![VIP Access Desktop](image)

**Note:** The following are instructions for Windows users. Mac users follow similar steps, but use Mac DMG application setup files.
3. To initiate the VIP Access application, select **Run** when prompted (**Figure 6**).

**Figure 6: Download and Install VIP Access**

4. The VIP Access Setup Wizard appears (**Figure 7**). Select **Next** for all screens, accept the terms in the license agreement, as well as all defaults, and select **Install** in the final step of the wizard screens.

**Figure 7: VIP Access Setup**
5. Upon successful completion, the **InstallShield Wizard Completed** screen appears (Figure 8). Select **Finish** to launch the **VIP Access** application.

**Figure 8: VIP Access – Finish Installation**

2.3 **Open VIP Access / How the Token Works**

Launch the **VIP Access** application (Figure 9). You must create a **Credential ID** to identify your computer. Using the **Security Code** identifies you as a registered user.

- **Credential ID**: This ID is machine or device-specific. You need to register this ID. (See 2.4 Registering Your Credential ID.)

- **Security Code**: Use this code to log on to the computer that hosts the Research Environment through a secure portal or connection.
  - The code changes every 30 seconds, with a countdown clock next to the Security Code that shows the time remaining before the code is changed.
  - Selecting the **copy** button next to the code copies the Security Code to the clipboard. This enables you to easily paste it into the required field when logging on to the Research Environment.

**Figure 9: VIP Access - Main Screen**
2.4 Registering Your Credential ID


2. The Welcome to the Symantec® VIP Self Service Portal appears (Figure 10). Enter your SAS Clinical Trial Data Transparency system User Name (or User ID) and Password from section 2.1 Completing the Initial Email and Password Setup and click Sign In.

Figure 10: Self Service Portal - Sign In
3. The **Confirm Your Identity** screen appears, prompting you for a location to send a temporary security code ([Figure 11](#)). Choose an option and click **Continue**.

**Figure 11: Confirm Your Identity**

![Confirm Your Identity](image)

To Complete Your Sign-in
Request a temporary security code to help confirm your identity.

How would you like to receive your security code?
- Email Address: er********@sas.com
- Voice Call:

[Cancel] [Continue]
4. Select **Email Address** (recommended). An e-mail containing a temporary VIP security code ([Figure 12](#)) is sent to the e-mail address you provided previously in the VIP setup process.

**Note:** If you have any questions or need further assistance, contact the SAS Technical Support as follows:

- Email: [CTDTSsupport@sas.com](mailto:CTDTSsupport@sas.com)
- URL: [http://support.sas.com/ctx/supportform/index.jsp](http://support.sas.com/ctx/supportform/index.jsp)
- North America: Call 919-677-8008

![Figure 12: Temporary VIP Security Code](image)

5. The **Enter your Temporary Security Code** screen appears ([Figure 13](#)). Enter your temporary VIP Security Code and select **Sign In**.

![Figure 13: Enter Your Temporary Security Code](image)
6. The **Welcome to VIP Self Service** screen appears (Figure 14) where you can register your **Credential ID** for use. Click **Select** in the **VIP Credential** section.

**Figure 14: VIP Welcome Screen**

![VIP Welcome Screen](image)
7. Register your credentials (Figure 15):
   - Enter a **Credential Name** (for example, *My Work Machine*).
   - Copy the current **Credential ID** number from the **VIP Access** window and paste it into the **Credential ID** field.

   **Note:** If you install the VIP Access application on a smart phone, and the smart phone is upgraded, your smart phone may change this credential ID. You need to log on to [https://vip.sas.com](https://vip.sas.com) and change the Credential ID to the new one.

   - Copy the current **Security Code** number from the **VIP Access** window and paste it into the **Security Code** field.
   - Click **Submit**.

   **Note:** Ensure that enough time remains in the Security Code countdown before you paste the code. If a new Security Code is generated before you attempt to proceed to the next step, you must enter the new Security Code (Figure 15).

Figure 15: Register Your Credential
8. The **Create Your PIN** screen appears (**Figure 16**). Enter and re-enter a PIN that is 6 to 12 numbers and click **Create**.

   **Note:** This PIN is not your security code number. Use it to change any details associated with your registered security code.

**Figure 16: Create Your PIN**

9. When the PIN setup is successfully completed, the Credential Name you entered for your machine appears, along with your Credential ID (**Figure 17**).

**Figure 17: Manage Your Credentials**
2.5 Accepting Terms in the Portal

Before you can access files and study data in the Research Environment, you must first accept the Terms of Use Agreement at the SAS Clinical Trial Data Transparency Portal.

1. Access the SAS Clinical Trial Data Transparency Portal at https://mseportal.ondemand.sas.com/ctdt/

2. On the logon screen, enter your SAS Clinical Trial Data Transparency system User ID (or user name) and Password (Figure 18).

![Figure 18: SAS® Clinical Trial Data Transparency Portal Logon](image)

3. After logon is complete, Accept Terms is the only option that displays (Figure 19). Select the Click and review this information link.

![Figure 19: SAS® Clinical Trial Data Transparency Portal Accept Terms (Start)](image)

4. A PDF of terms appears. Review the text of the PDF.

5. Once the review is complete, select the Next button.
6. A statement appears enabling you to accept the terms (Figure 20). Select the **Yes, I agree** radio button and then click the **Finish** button.

**Figure 20: SAS® Clinical Trial Data Transparency Portal Accept Terms (Finish)**

![Accept Terms](image)

7. Once the statement is accepted, a confirmation appears (Figure 21). Click the **Proceed to Home** link to open the Home tab.

   **Note:** A copy of the terms accepted is available on your research access request for reference.

**Figure 21: SAS® Clinical Trial Data Transparency Portal (Proceed to Home)**

![Proceed to Home](image)
3  Accessing the Research Environment

Note: If you have not accepted the terms at the SAS Clinical Trial Data Transparency Portal, you must follow those steps first. See section 2.5 Accepting Terms in the Portal.

Accessing the Research Environment involves two steps:

- Connect to the SAS Solutions OnDemand Secure Portal using your user name (or user ID), password, and security code.
- Log on to a remote terminal server session. (This is the computer that hosts the Research Environment.)

Note: The Research Environment is not accessible from tablet computers (for example, an iPad) or other devices.

3.1  Windows Users

3.1.1  Connecting to the Secure Access Portal

1. Visit the website: https://shqaccess.ondemand.sas.com and access the welcome screen (Figure 22).

Figure 22: Secure Access Portal - Logon Screen

2. For Username, enter your SAS Clinical Trial Data Transparency system user name (or user ID).
3. For Password, enter your SAS Clinical Trial Data Transparency system password.
4. For Security Code:
   a. Open your VIP Access application.
   b. Copy the Security Code by using the copy icon.
   c. Paste the Security Code into the field.
**Note:** The VIP Access application provides a 30-second countdown to copy the Security Code. Make sure you have at least 15 seconds left in the countdown before copying the VIP Security Code ([Figure 23]).

**Figure 23: Copy Security Code**

![VIP Access](image)

5. Click **Sign In**.

6. The **Welcome to the SAS Solutions OnDemand Secure Portal** page appears. Click the **Clinical Trial Data Transparency Research Environment** link listed under **Terminal Sessions** ([Figure 24]).

   **Note:** If your account has rights to the Test/UAT system, you might see multiple choices on the landing page.

**Figure 24: Secure Access Portal – Welcome Screen**

![Clinical Trial Data Transparency Research Environment](image)

### 3.1.1.1 Installing or Updating Java for Windows

If Java is not installed on your computer or your Java version is old, a dialog appears ([Figure 25]).

1. Click **Update**.

**Figure 25: Java Update Needed**

![Java Update Needed](image)
2. A web site launches in a separate tab or window of your internet browser (Figure 26). Click *Free Java Download*.

*Figure 26: Download Java*

```
Free Java Download
Download Java for your desktop computer now!
Version 7 Update 25

Free Java Download

» What is Java? » Do I have Java? » Need Help?
```

3. The screen changes (Figure 27). Click *Agree and Start Free Download*.

*Figure 27: Start Java Download*

```
Download Java for Windows
Recommended Version 7 Update 25 (filesize: 882 KB)

Agree and Start Free Download
```

4. The Java installer appears (Figure 28). Click *Install*.

*Figure 28: Installing Java - Screen 1*
5. Uncheck the boxes (Figure 29). Click Next.

Figure 29: Installing Java - Screen 2

6. If certain programs are running, a dialog appears asking you to close them before continuing (Figure 30). Save your work and click Close Programs and Continue. If a confirmation dialog appears, click OK.

Figure 30: Installing Java - Close Programs and Continue
7. The installer begins installing Java (Figure 31).

Figure 31: Installing Java - Screen 3

8. When the installer is finished, click Close (Figure 32).

Figure 32: Installing Java - Screen 4
3.1.1.2 **Launching Terminal Server Session**

A terminal server session launches.

1. If the **Java(TM) needs your permission to run** message appears, click **Always run on this site** *(Figure 33)*.

2. The **Welcome to the SAS Solutions OnDemand Secure Portal** page appears again. Click the **Clinical Trial Data Transparency Research Environment** link listed under **Terminal Sessions** *(Figure 24)*.

   **Figure 33: Launching Terminal Session**

   ![Launching Terminal Session](image)

   **Please wait...**

   Launching Terminal Services Session. This may take from a few seconds to a couple of minutes, depending on your bandwidth.

   **Note:** You might be required to accept the installation of **Juniper Terminal Services Client**, as part of accessing the Research Environment *(Figure 34)*. Click **Yes**.

   **Figure 34: Install Juniper Terminal Services Client**

   ![Install Juniper Terminal Services Client](image)
3.1.2 Logging on to the Research Environment (Terminal Session)

The logon screen for the computer that hosts the Research Environment (terminal server) appears (Figure 35).

1. Select the icon with your User ID.

Figure 35: Logging on to the Computer that Hosts the Research Environment
2. Enter your SAS Clinical Trial Data Transparency **user name** (or **user ID**) and **password**, and click the arrow icon. The Research Environment appears (**Figure 36**).

**Figure 36: Remote Desktop Session**
3.2 Mac Users

3.2.1 Connecting to the Secure Access Portal

Note: The screens in this section show the use of Safari on a Mac. The screens for other browsers can vary.

1. Visit the website: https://shgaccess.ondemand.sas.com. The sign-in screen appears (Figure 37).

Figure 37: Secure Access Portal - Sign-in Screen

2. For Username, enter your SAS Clinical Trial Data Transparency system Username (or User ID).

3. For Password, enter your SAS Clinical Trial Data Transparency system Password.

4. For Security Code:
   - Open your VIP Access application.
   - Copy the Security Code by using the copy icon.
   - Paste the Security Code into the field.
   - Click Sign In.

Note: The VIP Access application provides a 30-second countdown to copy the Security Code. Make sure you have at least 15 seconds left in the countdown before copying the VIP Security Code.

5. The Welcome to the SAS Solutions OnDemand Secure Portal page appears. Select the Clinical Trial Data Transparency Research Environment link listed under Terminal Sessions (Figure 38).

Figure 38: Secure Access Portal - Welcome Screen
6. If... | Then...
--- | ---
A Remote Office dialog appears ([Figure 40](#)). | Proceed to step 7.
A Remote Office dialog is not displayed and you see a message about pop-ups being blocked ([Figure 39](#)). | • Use Safari Preferences to allow pop-ups.  
• Once complete, return to the Welcome Screen ([Figure 38](#)) and click the **Clinical Trial Data Transparency Research Environment** link again.

**Figure 39: Mac – Popup Blockers**

![Terminal Sessions](https://shqaccess.ondemand.sas.com/data/term/winlaunchterm.cpp?row=byes.resource_13779818296:251846.36/index=0&perm=yes)

*Please wait...*  
Launching Terminal Services Session. This may take a few moments depending on your bandwidth.

![Terminal Services window failed to open because your Web browser is configured to block pop-ups.](https://shqaccess.ondemand.sas.com)

*OK*

**Figure 40: Mac – Remote Office Dialog**

![Remote Office](#)
7. You see **Missing Plug-in** or **Inactive Plug-in** in the lower-right corner of the screen (Figure 40) 
   | **If...** | **Then...** |
   | You see **Missing Plug-in** or **Inactive Plug-in** in the lower-right corner of the screen (Figure 40) | Install Java. (See section 3.2.1 Java Installation on Mac.) |
   | You see **Active Plug-in**. | Log on to the Research Environment (See section 3.2.2 Logging into the Research Environment (Terminal Session)). |

### 3.2.1.1 Java Installation on Mac

This section is only applicable if the Remote Office dialog indicates a Java plug-in is not available (Figure 41).

1. From the dialog, click the link in the lower right corner of the dialog (**Missing Plug-in** or **Inactive Plugin**).

   **Figure 41: Mac – Remote Office Dialog (Java not installed)**

   ![Remote Office Dialog](image)

   - **Remote Office**
   - **Missing Plug-in**
2. A dialog appears, as shown in Figure 42. Click More info.

**Figure 42: Mac – Remote Office Dialog (Popup)**

3. A website launches in a separate tab or window of Safari (Figure 43). Click Agree and Start Free Download.

   **Note:** Depending on your Mac Operating System (OS), you might see a different page, and the version of Java might be a later version.

**Figure 43: Mac – Install Java Website**
4. A Mac DMG install file is downloaded to your machine. Find and open the DMG file. Figure 44 shows an example, jre-7u25-macosx-x64.dmg.

**Figure 44: Mac – JRE DMG File**

![Mac - JRE DMG File](image)

5. When you open the DMG file, a dialog similar to the one below appears (Figure 45). Double-click the icon to start the installation.

**Figure 45: Mac – JRE DMG File**

![Mac - JRE DMG File](image)
6. The installation screens might differ depending on your OS and the Java version being installed. Click Continue (Figure 46).

Figure 46: Mac – Java Install – Screen 1

7. Click Install (Figure 47).

Figure 47: Mac – Java Install – Screen 2
8. You are prompted to enter for your machine’s administrator account (Figure 48). Enter this information and click **Install Software**.

Figure 48: Mac – Install Admin Screen

![Figure 48: Mac – Install Admin Screen](image)

9. **Figure 49** shows the final screen of the installation process. Click **Close**.

Figure 49: Mac – Install Java Finish

![Figure 49: Mac – Install Java Finish](image)
3.2.1.2 **Launching Terminal Server Session**

1. Close all dialogs and browser tabs or windows.
2. Repeat the steps for signing in as described in section 3.1.2 **Logging on to the Research Environment (Terminal Session)**, which includes:
   - After logging in, select the **Clinical Trial Data Transparency Research Environment** link on the welcome screen.
   - The Remote Office dialog appears. Continue to section 3.2.2 **Logging into the Research Environment (Terminal Session)**.

3.2.2 **Logging into the Research Environment (Terminal Session)**

1. When the Remote Office dialog appears, an additional message is also displayed (Figure 50). Click **Allow**.

   **Note:** If you do not have Java installed on your Mac, you need to download it to proceed further (see 3.2.1.1 **Java Installation on Mac**).

Figure 50: Mac – Accept Applet Dialog
2. An additional security warning appears. Check the box I accept...application and click Run (Figure 51).

Figure 51: Mac – Allow HOBLink Dialog

![Security Warning]

Running this application may be a security risk

Risk: This application will run with unrestricted access which may put your computer and personal information at risk. The information provided is unreliable or unknown so it is recommended not to run this application unless you are familiar with its source.

Select the box below, then click Run to start the application

- [ ] I accept the risk and want to run this application.

3. A HOBLink JVT dialog appears (Figure 52).

- For Username, enter your SAS Clinical Trial Data Transparency system Username (or User ID).
- For Password, enter your SAS Clinical Trial Data Transparency system Password.
- For Domain, enter VSP.

Figure 52: Mac – HOBLink JWT Logon

![HOBLink JWT Logon]
4. The Research Environment appears (Figure 53).

Figure 53: Mac – Research Environment Desktop

3.3 Logging off
To log off the Research Environment, navigate to Start Menu -> Log off (Figure 54).

Note: If you close the session window without logging off, you can return to the session in the same state as you left it. However, sessions do expire after a specified time period; therefore, you should always save your work and log off.

Figure 54: Logging off the Research Environment
4  SAS® Clinical Trial Data Transparency Repository

The SAS Clinical Trial Data Transparency Repository provides access to the data for your project, whether you plan to perform your analyses with SAS software or with R.

4.1  Logging on

1. In the Research Environment, double-click the SAS Clinical Trial Data Transparency Repository icon (Figure 55).

Figure 55: SAS® Clinical Trial Data Transparency Icon
2. Internet Explorer opens and the **SAS Clinical Trial Data Transparency Logon** screen appears (Figure 56). Enter your SAS Clinical Trial Data Transparency system **Username** (or User ID) and **Password**. Click **Log On**.

Figure 56: SAS® Clinical Trial Data Transparency Logon Screen

3. The SAS Clinical Trial Data Transparency main screen appears (Figure 57).

Figure 57: SAS® Clinical Trial Data Transparency Main Screen
4.2 Organizing Tabs

SAS Clinical Trial Data Transparency uses a tab-based interface. The tabs include:

- **Dashboard**: This summarizes parts of the system. (Navigate to View -> Preferences to order this as the last tab as described below.)

- **Repository**: This is the location of the study data for your research and the location of your research project area where you save your work and make files available for export.

- **Workspace**: This is where you run SAS code on the study data.

When you log on for the first time, the Dashboard view is automatically displayed (Figure 58).

**Figure 58: SAS® Clinical Trial Data Transparency Tabs**

Because the Dashboard tab is not heavily used for the solution, you can move it to the third position. To change the order of the View of tabs, you can drag and drop them into a new order, or:

1. Navigate to View -> Preferences -> Views.
2. Move the Dashboard tab to third position (Figure 59).

**Figure 59: SAS® Clinical Trial Data Transparency - Preferences -> Views**
3. Click OK. The first two tabs are now Repository (your data access) and Workspace. The next time you log on, the Repository tab appears automatically.

4.3 Accessing the SAS® Clinical Trial Data Transparency Repository User Guide

The Help menu (Figure 60) provides a link to the comprehensive SAS Clinical Trial Data Transparency User Guide. This is also available from the SAS Clinical Trial Data Transparency Portal Help page, and from the desktop of the Research Environment.

**Note:** Not all functionality described in this guide applies to SAS Clinical Trial Data Transparency.

**Figure 60: SAS® Clinical Trial Data Transparency - Help Tab**

![SAS® Clinical Trial Data Transparency - Help Tab](image)

**Note:** The SAS on the Web link does not work from the Research Environment because the research server provides very limited internet access.

The following sections provide examples of approaches to using SAS Clinical Trial Data Transparency Repository for browsing data and programming in SAS. Table 1 references relevant sections within this document and the corresponding sections within the full SAS Clinical Trial Data Transparency Repository User Guide.

**Table 1: Guide Sections Related to the full SAS® Clinical Trial Data Transparency Repository User Guide**

<table>
<thead>
<tr>
<th>Section in this Guide</th>
<th>SAS Clinical Trial Data Transparency Repository User Guide Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4 Data Access</td>
<td>Chapter 2: Getting Started</td>
</tr>
<tr>
<td>4.5 Browsing Data</td>
<td>Chapter 2: The Data Explorer</td>
</tr>
<tr>
<td>4.6 Copying Files from the Repository to the Workspace</td>
<td>Chapter 2: Repository and Your Workspace</td>
</tr>
<tr>
<td>4.7 Running SAS</td>
<td>Chapter 19: SAS Sessions</td>
</tr>
<tr>
<td></td>
<td>Chapter 20: Developing SAS Programs</td>
</tr>
<tr>
<td>4.8 Producing Graphical Results</td>
<td>Chapter 20: Developing SAS Programs</td>
</tr>
</tbody>
</table>
4.4 Data Access

In the Repository view (Figure 61), the CTDT folder contains your research project area and studies you can access:

- **Research Project**
  - If you are assigned **Lead Researcher** or **Researcher** permissions on the project, you can add, modify, and delete files.
  - If you plan to run SAS, copy files from this area to the Workspace tab to run SAS programs and view results. (See section 4.6 Copying Files from the Repository to the Workspace.)
  - To export files from the Research Environment, you must add them to the exports folder of your research project.

- **Studies**
  - These are the clinical studies available for use, according to your Data Sharing Agreement.
  - You have read-only permissions. You cannot add, modify, or delete files or folders from a study.
  - If you plan to run SAS, copy files from here to the Workspace tab for inclusion into SAS programs you write within your research area. (See section 4.6 Copying Files from the Repository to the Workspace.)
  - If you plan to run R, download R-ready CSV files from the study to a folder (in My Documents) in the Research Environment (outside SAS Clinical Trial Data Transparency).

Figure 61: SAS® Clinical Trial Data Transparency - Repository Tab

![SAS® Clinical Trial Data Transparency - Repository Tab](image)

**Note:** To expand the folders, click the Expand icon.
Under a study, a number of folders (Figure 62) are available with information on that study, for example:

- **SAS_analysis** and **SAS_raw** folders contain study data in SAS format.
- **R_analysis** and **R_raw** folders contain study data in R-ready format (comma delimited). There is also an additional file for each CSV file that includes metadata describing the columns from the source SAS data set.
- Other folders contain supporting information to help you understand and navigate the data sets. Figure 62 shows an example of a folder structure.

Figure 62: SAS® Clinical Trial Data Transparency – Study Folders
Figure 63 shows three sample studies (ACME-12345, ABCP-65890, and ACME-12987), as well as an expanded view of an example research project area (CTDT RP-12345). Users assigned the Researcher or Lead Researcher role have full permissions to create, modify, and delete folders and files within the research project area.

*Note:* The folder structure pictured below might be different from your research project area.

*Note:* Do not change the folder names **imports** or **exports**. If you change these names, you can no longer import files into or export files from the SAS Clinical Trial Data Transparency Repository.

**Figure 63: SAS® Clinical Trial Data Transparency – Research Area Folders**

SAS programs are typically stored in the **programs** (or similarly named) folder.

- The **imports** folder is important. To bring files and supporting programs into the Research Environment, you must import them to this location. See section 6 Importing and Exporting for details on importing.

- The **exports** folder is also important. To download files from the Research Environment, you must collect them here. See section 6 Importing and Exporting for details on exporting.
4.5 Browsing Data

As part of your research, you might want to browse and filter data even if you intend to use R for your statistical programming. The SAS Clinical Trial Data Transparency Explorer can be used for this purpose.

**Note:** For full details, refer to Chapter 2: Getting Started -> Data Explorer within the SAS Clinical Trial Data Transparency Repository User Guide.

An abbreviated example is described below:

1. From within a folder, double-click the desired SAS data set (Figure 64).

**Figure 64: Opening a SAS Data Set**

![Figure 64: Opening a SAS Data Set](image)
2. A view of the data set appears (Figure 65). Review the data set:
   - The columns of the data set appear on the left-hand side.
   - Below the columns pane, attributes display for the currently selected column.
   - The rest of the view displays the data contained within the data set.

Figure 65: Data Set

![Data Set Diagram]

3. To sort, click a column heading. Figure 66 shows the filter SUBJID sorted in ascending order.

Figure 66: Sorting Columns

![Sorting Columns Diagram]
4. For more filtering options, right-click the column (Figure 67).

   **Note:** Different options may be displayed for different columns.

Figure 67: Filtering Options

![Filtering Options Diagram]

<table>
<thead>
<tr>
<th>Obs</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>SUBJID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NIC001</td>
<td>DM</td>
<td>011-001</td>
<td>011001</td>
</tr>
<tr>
<td>2</td>
<td>NIC001</td>
<td>DM</td>
<td>011-002</td>
<td>011002</td>
</tr>
<tr>
<td>3</td>
<td>NIC001</td>
<td>DM</td>
<td>011-003</td>
<td>011003</td>
</tr>
<tr>
<td>4</td>
<td>NIC001</td>
<td>DM</td>
<td>011-004</td>
<td>011004</td>
</tr>
<tr>
<td>5</td>
<td>NIC001</td>
<td>DM</td>
<td>011-005</td>
<td>011005</td>
</tr>
<tr>
<td>6</td>
<td>NIC001</td>
<td>DM</td>
<td>011-006</td>
<td>011006</td>
</tr>
<tr>
<td>7</td>
<td>NIC001</td>
<td>DM</td>
<td>011-007</td>
<td>011007</td>
</tr>
<tr>
<td>8</td>
<td>NIC001</td>
<td>DM</td>
<td>011-008</td>
<td>011008</td>
</tr>
</tbody>
</table>

a. Select **Statistics** for a quick view of statistics that describe the currently selected column within the currently filtered view (Figure 68).

Figure 68: Statistics

![Statistics Diagram]

- Column: SUBJID
- Minimum: 011001
- Maximum: 461032

<table>
<thead>
<tr>
<th>Value</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>011001</td>
<td>1</td>
</tr>
<tr>
<td>011002</td>
<td>1</td>
</tr>
<tr>
<td>011003</td>
<td>1</td>
</tr>
<tr>
<td>011004</td>
<td>1</td>
</tr>
<tr>
<td>011005</td>
<td>1</td>
</tr>
<tr>
<td>011006</td>
<td>1</td>
</tr>
<tr>
<td>011007</td>
<td>1</td>
</tr>
<tr>
<td>011008</td>
<td>1</td>
</tr>
<tr>
<td>011009</td>
<td>1</td>
</tr>
<tr>
<td>011010</td>
<td>1</td>
</tr>
<tr>
<td>011011</td>
<td>1</td>
</tr>
<tr>
<td>011012</td>
<td>1</td>
</tr>
</tbody>
</table>
b. Select Filter to customize the filter. Figure 69 shows a filter for AGE < 35 AND Sex=M.
  o The filter syntax appears above the data.
  o The total number of rows and number of filtered rows appears below the data.
  o To modify the current filter, select the Filter icon.

Figure 69: Modifying Current Filter

4.6 Copying Files from the Repository to the Workspace

The SAS Clinical Trial Data Transparency application consists of two primary locations for files (tabs) (Figure 70):

- **Repository**: This is where master copies of files and programs are stored.
- **Workspace**: This is where you store working copies of files, programs, and results.

*Note*: Files and SAS data sets must be present in the Workspace to enable programs to read them.

Figure 70: Repository and Workspace Tabs
1. To copy files from the repository to your workspace, locate the folder(s) in the repository tree, right-click on it (them), and select Get Latest Version (Figure 71).

Figure 71: Get Latest or Specific Version
2. The folders and files are copied to your personal workspace. Navigate to the **Workspace** tab (Figure 72).

**Figure 72: Workspace Tab**

3. Within Workspace, you can:
   a. Create new files.
   b. Save SAS programs.
   c. Review results.
   d. Check in (add) files to your research project area in the Repository when you complete your work.
   e. Copy files to the **exports** folder for your research project, for removal from the application. For details on exports, see section 6.2 **Exports**.

### 4.7 Running SAS

This section provides information to enable you to run SAS within the SAS Clinical Trial Data Transparency Repository. SAS programs are run within a SAS Session.

Use one of the following methods to open a SAS Session:

- From the Menu Bar, click **Tools -> SAS Session** to open a SAS session with an empty Editor window.
- Or

- Right-click and select **Open**, or double-click on an existing SAS program in the **Workspace** tab.

*Note*: SAS is not executed from the **Repository** tab.

Write a new SAS program in an empty Editor window, or modify an existing SAS program that you opened. Click the **Submit** icon on the tool bar to run the program in the active Editor window and review the log within the Log window. A section of code can be run by highlighting it first and clicking the **Submit** icon.
Important Workspace Concept: If you have not already done so, copy the files needed in your program from the Repository to the Workspace. (See section 4.6 Copying Files from the Repository to the Workspace.) These files must be referenced in your program by prepending all paths with the special SAS macro variable &_SASWS_ (Figure 73). This provides SAS with the physical location of your personal Workspace.

Tip: To ensure the correct path, click the Workspace tab and navigate to the file needed in your program. Highlight the full path displayed just under the tool bar, and then copy and paste it into your program. Insert the special macro variable &_SASWS_ in front of the path.

Figure 73: SAS Session Tab

SAS sessions support multiple Editor windows. This enables you to have more than one program open at a time. Use one of the following techniques to open additional Editor windows in your SAS Session:

- Click the Open icon on the tool bar to open an existing SAS program from the Workspace.
- Click the New icon on the tool bar to open an empty Editor window.
- Create an empty new program in the Workspace and then open it in a SAS Session.
  - From the Workspace tab, navigate to the folder in which you want to create a new program.
  - Click the New icon.
  - Select SAS Program from the folder where you want the program to be saved (Figure 74).
  - Open the new empty program in a SAS session.
The additional items in the left-hand pane of the SAS Session window provide the following functionality:

- Inputs
- Outputs
- Listing: Displays output produced by your program.
- Libraries: Lists all libraries defined in your SAS Session. You can navigate them to open and view SAS data sets available to your program.

Once you have your program running to your satisfaction, save it by following these steps:

1. Click the Save or Save As icon on the tool bar
2. Navigate to the location in your Workspace where you want to save your program.
3. Supply a name for your program.
4. Click Save.

**Note:** If you eventually plan to check your program into your research area in the Repository, save the program to a corresponding directory in your Workspace. For example, perform a Get Version on the programs directory of your research area. This places the necessary folder structure in your Workspace. Then, save your program to the programs directory in your Workspace. It is now in the correct location for use with the Check In feature. (See the SAS Clinical Trial Data Transparency Repository User Guide for more details.) The log and listing windows can be saved in the same manner.

**Note:** Refer to the Chapter 20 of the SAS Clinical Trial Data Transparency Repository User Guide for more details.
4.8 Producing Graphical Results

Using SAS Output Delivery System (ODS), you can produce graphical results.

**Note:** Refer to Chapter 20 of the SAS Clinical Trial Data Transparency Repository User Guide for SAS programming details.

Using the same sample program, Figure 75 shows an example of sending your results to both the Listing tab of the SAS Session and to a PDF file.

**Figure 75: Sending Results to Other Locations**

```
ods PDF file="&_SASWS_/CTDT/CTDT RP-12345/Files/output"
proc means data=testlib.AE);
run;
ods PDF close;
```

The SAS Output Delivery System (ODS) provides instructions to SAS for producing a variety of different formats of output, such as PDF, RTF, and HTML. In this example, all output produced by steps up to the `ods PDF close;` statement are sent to a PDF file (Figure 76).


**Figure 76: PDF Output**
5 Using R

5.1 Overview

This section provides information on transferring (or downloading) files from the SAS Clinical Trial Data Transparency Repository to your working area on the Research Environment so you can use them in R. It also describes the R packages that are available and how additional R packages can be imported and used.

The general concept is:

- Retrieve files from the SAS Clinical Trial Data Transparency Repository and copy them to your My Documents folder.
- Run R programs on the relevant files. A number of R packages are provided. (See Figure 80).
- Import and use other R packages by saving them to a folder in your My Documents folder. (See Figure 80).
- Upload files and results back to your SAS Clinical Trial Data Transparency research area.
- Move files to the exports folder in your research area to export them from the Research Environment (see section 5.4 Transferring Results for Export).

5.2 Retrieving Files for Use

1. Once in the Research Environment, use your SAS Clinical Trial Data Transparency system account to access the data in the SAS Clinical Trial Data Transparency Repository (see section 4.1 Logging on).
2. Navigate to the R files you wish to use.
3. Right-click the folder(s) and select Download (Figure 77).
Figure 77: Download

![SAS Clinical Trial Data Transparency Dashboard with Download highlighted.](image-url)
4. Navigate to your **My Documents** folder (in the Research Environment) and select the desired folder within this area *(Figure 78)*.

**Figure 78: Select Location**

![Select location for download by sddglass.ondemand.sas.com](image)

5. Select **Save**. The files are now saved to the location specified.

**Note:** If folders (rather than files) are selected in SAS Clinical Trial Data Transparency for download *(Figure 79)*, a ZIP file containing the files from the selected folders is downloaded. Expand the ZIP file to begin using them with R.

**Figure 79: Save Location**

![Select location for download by sddglass.ondemand.sas.com](image)

6. Note the path to these files in order to use them in **R** and **RStudio**.
5.3 Using R and RStudio

5.3.1 Overview

Using R and RStudio in the Research Environment is very similar to using R on your local PC. R (console) 32-bit and 64-bit versions (version 2.15.2) and RStudio 64-bit (version 2.15.2) are provided. Figure 80 shows an example of the package list from R Studio within SAS Clinical Trial Data Transparency.

Note: Your installation may include later versions of packages and/or additional base packages. Additional R packages can be imported as described in section 5.3.2 Importing Additional R Packages. Also, some packages do not run without additional software on the Research Environment server. Contact SAS Technical Support with any software issues as follows:

- Email: CTDTsupport@sas.com
- URL: http://support.sas.com/ctx/supportform/index.jsp
- North America: Call 919-677-8008

Figure 80: R Studio List of R Packages

<table>
<thead>
<tr>
<th>Files</th>
<th>Plots</th>
<th>Packages</th>
<th>Help</th>
<th>Viewer</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="arrow" alt="Install Packages" /></td>
<td><img src="arrow" alt="Check for Updates" /></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>bind</td>
<td>Combine multi-dimensional arrays</td>
<td>1.4-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>arm</td>
<td>Data Analysis Using Regression and Multilevel/Hierarchical Models</td>
<td>1.7-03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>asympow</td>
<td>Calculate Power Utilizing Asymptotic Likelihood Ratio Methods</td>
<td>2013.9-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>base64enc</td>
<td>Tools for base64 encoding</td>
<td>0.1-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BatchExperiments</td>
<td>Statistical experiments on batch computing clusters.</td>
<td>1.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Batchlols</td>
<td>Batch computing with R.</td>
<td>1.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bayesm</td>
<td>Bayesian Inference for Marketing/Micro-econometric</td>
<td>2.2-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bayesSurv</td>
<td>Bayesian Survival Regression with Flexible Error and Random Effects Distributions</td>
<td>2.1-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BBmisc</td>
<td>Miscellaneous helper functions for B. Bischl.</td>
<td>1.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bbmle</td>
<td>Tools for general maximum likelihood estimation</td>
<td>1.0.16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bitops</td>
<td>Bitwise Operations</td>
<td>1.0-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>boot</td>
<td>Bootstrap Functions (originally by D. Brown)</td>
<td>1.3-9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.3.2 Importing Additional R Packages

Follow the steps below to add R packages that are not provided to the Research Environment.

1. In the Research Environment, open **Windows Explorer** and confirm that the **Library** folder exists in your **My Documents** folder. If the folder does not exist, create the folder.
   
   - The library path can be confirmed using the `.libPaths()` command in the R console. The paths should include the user’s local library directory and the shared system level library as in **Figure 81**.

   **Figure 81: R LIBPATHS**

   ```
   > .libPaths()
   [1] "D:/Users/mse0txr/Documents/library"
   >
   ```

2. Import R packages to SAS Clinical Trial Data Transparency using the Import function (see **6.1 Imports**).

3. Download the package from the SAS Clinical Trial Data Transparency **imports** folder using the following steps:
   
a. Navigate to the **imports** folder in the SAS Clinical Trial Data Transparency Repository and download the appropriate file(s) to a folder in your **My Documents** folder in the Research Environment. (For example, you could name this folder **newpackages**).
   
b. Open R from the Research Environment desktop and execute the following command:

   ```r
   install.packages("[local file reference]", repos=NULL, lib=.libPaths()[1])
   ```

   This command installs the package(s) in the referenced ZIP file in the local path.

   The following example installs the survival package when the package has been placed in the **My Documents/newpackages** folder:

   ```r
   install.packages("d:/users/user ID/documents/newpackages/survival_2.37-4.zip", repos=NULL, lib=.libPaths()[1])
   ```

   c. The installation of the module can be confirmed by using the commands:

   ```r
   installed.packages() and/or require (packagename).
   ```
5.3.3 Accessing R

To access R, double-click the R icon on the desktop of the Research Environment (Figure 82).

Figure 82: R Desktop Icon
The R startup screen appears (Figure 83).

**Figure 83: R Startup Screen**

![R Startup Screen](image)

> R version 3.0.2 (2013-09-26) -- "Frisbee Sailing"
> Copyright (C) 2013 The R Foundation for Statistical Computing
> Platform: x86_64-w64-mingw32/x64 (64-bit)

R is free software and comes with ABSOLUTELY NO WARRANTY.
You are welcome to redistribute it under certain conditions.
Type 'license()' or 'licence()' for distribution details.

Natural language support but running in an English locale

R is a collaborative project with many contributors.
Type 'contributors()' for more information and
'citation()' on how to cite R or R packages in publications.

Type 'demo()' for some demos, 'help()' for on-line help, or
'help.start()' for an HTML browser interface to help.
Type 'q()' to quit R.

>
5.3.4 Accessing RStudio

To access RStudio, double-click the RStudio icon in the Research Environment (Figure 84).

Figure 84: RStudio Desktop Icon
The **RStudio** startup screen appears (Figure 85).

**Figure 85: RStudio Startup Screen**

![RStudio Startup Screen](image)

R version 3.0.2 (2013-09-25) -- "Crusoe Sailing"
Copyright (C) 2013 The R Foundation for Statistical Computing
Platforms: x86_64-w64-mingw32/x64 (64-bit)

R is free software and comes with ABSOLUTELY NO WARRANTY.
You are welcome to redistribute it under certain conditions.
Type 'contributors()' for more information and 'citation()' on how to cite R or R packages in publications.

Type 'demo()', 'help()' for on-line help, or 'help.start()' for an HTML browser interface to help.
Type 'q()' to quit R.

Figure 86 shows an example of reading in a CSV file saved locally:

**Figure 86: Locally Saved CSV File**

```r
> AE <- read.table("C:/Users/[username]/Documents/r_analysis_dataset/ae_small.csv", sep="", header=TRUE)
```

This opens the **RStudio** view with browsing ability (Figure 87).

**Figure 87: RStudio View**

![RStudio View](image)
5.4 Transferring Results for Export

Results or files saved to your My Documents folder are not immediately available to export from the Research Environment. You must upload the files into the SAS Clinical Trial Data Transparency Repository and then queue them for export.

1. Consider zipping the files before transferring them to SAS Clinical Trial Data Transparency.

2. Open the SAS Clinical Trial Data Transparency Repository and navigate to the desired exports folder. (See section 4.1 Logging on.) Figure 88 shows the exports folder of a research area named CTDT RP-12345.

Figure 88: Exports Folder

![Exports Folder](image-url)
3. Click the **Upload toolbar** icon and select **Upload Files**.

4. Select the file(s) from the location where they are saved.

5. A screen appears to transfer the files to the SAS Clinical Trial Data Transparency Repository (Figure 89). Select **Upload**.

*Note:* You do not need to version the files.

**Figure 89: Upload Files**
6. The file or files are displayed in the **exports** folder (Figure 90). At this point, you are ready to queue an export from the Research Environment. For more details, see section 6 Importing and Exporting.

**Figure 90: Contents of Exports Folder**

![Contents of Exports Folder](image)

**Note:** There are several rules regulating what can and cannot be exported from the Research Environment. If any files for export do not meet these rules or criteria, your export request requires approval before downloading to your computer. For details, see section 6 Importing and Exporting. Every sponsor company involved in your research is required to grant approval.
6 Importing and Exporting

To import or export files to or from your research project, you must use the SAS Clinical Trial Data Transparency system.

1. If not already connected, access the SAS Clinical Trial Data Transparency Portal at [https://mseportal.ondemand.sas.com/ctdt/](https://mseportal.ondemand.sas.com/ctdt/)

2. On the logon screen, enter your SAS Clinical Trial Data Transparency system User ID (or user name) and Password (Figure 91).

Figure 91: SAS® Clinical Trial Data Transparency Portal Logon

3. The SAS Clinical Trial Data Transparency Portal opens (Figure 92).

Figure 92: SAS® Clinical Trial Data Transparency Portal after Logon

6.1 Imports

6.1.1 Adding / Starting a Request

1. After logging on to the SAS® Clinical Trial Data Transparency Portal, select the CTDT Options tab (Figure 93).

Figure 93: CTDT Options Tab
2. Select **Imports: Show List**.

   *Note:* The **Home -> Options** dropdown also allows direct access to options.

3. To initiate an import, do one of the following:

   - Click the **Add** button on the far-right hand side of the screen.
   - Or
   - From the **Home tab > Options** dropdown menu (**Figure 94**), select **Imports: Add Request**.

**Figure 94: Imports Section**

```
<table>
<thead>
<tr>
<th>Sections: Imports</th>
<th>Options</th>
</tr>
</thead>
</table>
```

4. Enter a description (required) of the import request. To import files you have previously imported, choose the **Overwrite / Version Existing** option to ensure the files replace existing ones in the **Research Environment** (specifically the relevant SAS Clinical Trial Data Transparency imports folder) (**Figure 95**).

**Figure 95: Add Import**

5. Click **Add** (**Figure 95**).

6. The detail view appears (**Figure 96**) with the following options, allowing you to make required updates:

   - **The Import Request** pane on the left-hand side of the screen displays the following:
     - The details entered on the previous screen including **ID**, **User**, and **Summary / Details**.
     - The **Status** field shows your import request is automatically approved to start.
     - The **Deleted?** check box is blank. This field is used for mistakenly added requests. Check this box to delete the request. The request then appears with the strikethrough text in your SAS Clinical Trial Data Transparency imports list.
   - **The History** of the import appears at the bottom of the screen.
   - **The Attached Files** pane on the right-hand side of the screen displays a list of the files you intend to import with two links at the top:
     - **Add Files:** allows you to add files to your Import Request.
     - **Manage Import Settings:** allow you to define specific settings related to the import of your files. *(Note: As shown in Figure 96, settings can be copied and applied to multiple files.)*
7. Select **Attach File(s)** (Figure 96).

**Figure 96: Detail View**

8. A dialog appears for browsing and selecting a file and the target location for the imported file in SAS Clinical Trial Data Transparency (Figure 97).

- Select **Browse** and navigate to the desired file.
- Select the file and click the **Open** button.
- The file name appears in the **File:** text box. Select a target location from the drop-down list of research areas to which you have access.
- If you have defined settings for another file in this import request (using the **Manage Import Settings** selection), you can select **Copy Import Settings From:** to apply the same settings to the current file.
- Click **Attach** to add the selected file to the import request. The **File:** text box is cleared when the upload is complete.
- Click **Browse:** again to add an additional file.

**Figure 97: Add File(s)**
9. Click **Back to Import Request**. The files you selected are listed (Figure 98).

**Figure 98: Attached Files**

![Attached Files](image)

*Note:* Your files have **not** been imported to the relevant SAS Clinical Trial Data Transparency **imports** folder at this point. They have only been attached to the **Import Request**. The next two sections cover the final steps in the import process.

### 6.1.2 Managing Import Settings

The default settings for imported files are to enable versioning when the files are imported into SAS Clinical Trial Data Transparency, and if importing a ZIP file, not to unzip it. If these settings are acceptable, **skip** to section **6.1.3 Starting the Import** to start your import. Otherwise, to change these settings, or alter other previous settings, do the following:

1. Select the **Manage Import Settings** link (Figure 99).

**Figure 99: Manage Import Settings Link**

![Manage Import Settings Link](image)

2. A list of files and their import settings are displayed (Figure 100). Select the **Modify** link.

**Figure 100: Manage Import Settings Screen**

![Manage Import Settings Screen](image)

3. The **Modify** screen appears (Figure 101). Select a research area from the drop-down menu and select **Continue**.

*Note:* Make sure you select a research area and not a study. Files can only be imported into the **imports** folder of a research area.

**Figure 101: Modify**

![Modify](image)
4. Select a folder from the dropdown menu and select **Continue** *(Figure 102)*.

**Figure 102: Select Folder**

![Select Folder](image)

**Note:** Only the imports folder of the selected research area is available. You can move files to other locations in the research area after this import is complete.

5. Final confirmation appears for the settings *(Figure 103)*. Select one, both, or neither of the following options:

   - **Unzip** – If selected, the uploaded file is a ZIP file that expands (unzips) as part of the import process. The files are placed in the imports folder. If the ZIP file contains a folder structure, that structure is created under the imports folder.
   - **Version It** – If selected, and the file uploaded already exists in the imports folder, a new version of the file is created. If the file does not exist in the imports folder, the file is indicated as a 1.0 version in SAS Clinical Trial Data Transparency.

6. Select **Update** *(Figure 103)*.

**Figure 103: Update**

![Update](image)

7. Your settings are displayed in the summary table. If you have multiple files and want the same settings to be used for all of them, use **Copy to All** to copy settings for all files *(Figure 104)*.

**Figure 104: Copy to All**

![Copy to All](image)
8. Select the previous item in the breadcrumb trail at the upper right to return to the Import Request Screen.

6.1.3 Starting the Import

1. From the Import Request screen, go to the bottom of the Import Request box
2. Select the Start Import Run button (Figure 105).

**Figure 105: Start Import Run**

3. A confirmation appears. Select Yes to place your import in the queue to run.

4. Once the import completes (within a few minutes), a refresh of the screen (Figure 106) shows that:
   - The Import Request status has changed to **Import Processed**.
   - An import summary file is attached to the request.
   - An import summary appears in the History panel.

**Figure 106: Import Summary**

5. Your files are now available in the SAS Clinical Trial Data Transparency Repository (in the imports folder of the location specified). Log on to the Research Environment to work with them.

   **Note:** Once an import request is run, no more files can be added to the request. A new request must be created to import more files.
6.2 Exports

6.2.1 Adding a Request

1. After logging on to the SAS Clinical Trial Data Transparency Portal, select the CTDT Options tab (Figure 107).

Figure 107: Imports / Exports Tab

2. Select Exports.

3. To initiate an export request, do one of the following:
   - Select the Add button on the far right hand side of the screen.
   - Or
   - From the Home tab > Options dropdown menu (Figure 108), select Exports: Add Request.

Figure 108: Exports Section

4. Enter the details for the Export Request (all fields are required) (Figure 109).

Figure 109: Add Export Request

**Note:** The Mode selection enables you to export only the most current version of a file or to export all versions. (See the SAS Clinical Trial Data Transparency Repository User Guide for more information on file versions.) Generally, selecting Full – All File Versions is appropriate.

<table>
<thead>
<tr>
<th>If...</th>
<th>Then...</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Start Run Now option is available to run the export, and you do not need to modify the settings for the export.</td>
<td>Go to section 6.2.2 Starting the Export from the Add Export Request Screen to start the export processing.</td>
</tr>
</tbody>
</table>
### If...  
You need to review or modify the Export Detail Screen or the **Start Run Now** option is not available.  

| Then... |
|---------|---|
| 1. Uncheck the **Start Run Now** box if it is available.  
2. Click **Add**.  
3. Go to section [6.2.3 Export Detail Screen](#) to make the necessary modifications. |

---

### 6.2.2 Starting the Export from the Add Export Request Screen

1. Leave the **Start Run Now** check box selected and click the **Add** button (Figure 109). The Export List appears, showing the status of export request run as *in progress*.

2. If the export has a status of **Approved for View**, a download icon appears next to the export list when the export run finishes (Figure 110). Select the **download** icon.

#### Figure 110: Export List Screen with Download Icon

3. Enter your **user ID** (or **username**) and **password** to download the resulting export file.

### 6.2.3 Updating the Export Detail Screen

1. Access the Export Detail Screen using one of these two methods:

   - Click **Add** on a new request after deselecting the **Start Run Now** check box.
   - Or

   - Click the **Reason for Export** hyperlink from the Export List screen line for the desired export request.

2. The Export Request detail screen appears. Make any necessary updates to the following options before starting the export process (Figure 111):

   - The **Export** pane on the left-hand side of the screen displays the details entered on the **Add Export Request** screen.
     - The **Status** is automatically assigned as **Approved to Start**.
     - The **Deleted?** check box is blank. This field is used for mistakenly added requests. Check this box to delete the request. The request then appears with the strikethrough text in your SAS Clinical Trial Data Transparency exports list.

   - **A History** of the export appears at the bottom of the page.

   - The **Export Paths** panel enables you to update or add folders from which to export within the SAS Clinical Trial Data Transparency Repository.

   - **Comments** allows you to enter comments about the export request (for example, during approval steps by sponsor companies).

   - **Generated Exports** displays your exports.
3. | If... | Then...
--- | ---
You want to modify one of fields in the **Export Request** panel. | Make the desired modifications, then click **Update Request**.
You are exporting files from only the location selected when creating the request. | Skip to section **6.2.5 Starting the Export** to start the export processing.
You want to modify your export path(s) or settings. | Go to section **6.2.4 Updating Export Path(s) and Settings**.

### 6.2.4 Updating Export Path(s) and Settings

1. In the **Export Source Locations** panel select **Update / Add** (*Figure 112*).

*Figure 112: Export Paths Section*

2. A list of folders and their export settings are displayed (*Figure 113*). To replace an existing folder from which files are to be exported, first delete the existing folder by selecting the **X**.

*Figure 113: Add / Edit Export Paths*
3. Add a new folder (Figure 114):
   a. Select a research area from the Project dropdown menu and click Continue.
   b. Select a folder and click Continue.

   **Note:** In the Research Environment, exports can only include files from research area exports folders in the SAS Clinical Trial Data Transparency Repository. You must move all files desired for export to a research area exports folder before running the export request.

   Figure 114: Select Folder

4. You can also enter a name for the resulting export file in the Name of Zip File field (Figure 115).

   **Note:** The resulting export is a ZIP file. You can enter text for the file in the Name of Zip File field. This text appears at the start of the resulting ZIP file name. If you do not include text in this field, the name of the folder (exports) is used to name the file. The ZIP file name also includes the date and time of the export, regardless of whether you have entered text into the Name of Zip File field.

   Figure 115: Name of Zip File

5. Select Add (Figure 116).

6. The added or modified location appears in Current Paths (Figure 116).

   Figure 116: Current Paths
7. Click the previous link in the breadcrumbs trail in the upper-right corner to return to the Export Request Details screen.

6.2.5 Starting the Export from the Export Request Detail Screen

1. If you did not choose to start the export run from the Add Export Request screen, go to the bottom of the Export Request box located on the Export Request Detail screen.

2. Select the Start Export Run button (Figure 117).

Figure 117: Status

3. When the verification screen appears, select Yes to place your export request in the queue for processing.

   • When the export finishes, the resulting ZIP file appears when the screen is refreshed. (Figure 118).

Figure 118: Attached Files / Generated Exports

   • If your export request meets preset rules for export, the Status appears as Export Created / Approved for View (Figure 119).

Figure 119: Export Created / Approved for View
4. Download the file by clicking the file link in the Generated Exports section (Figure 120). You are required to re-enter your user ID and password to download the file.

**Figure 120: Export Available to Download**

![Generated Exports](image)

**Note:** If you receive an error message about needing approval to download after clicking the file hyperlink, then your export request must go through an approval process. If your export request does not meet the preset rules for export, a system representative reviews your request and updates the **Status** based on the outcome. You are notified of **Status** changes through email. When the **Status** is modified to **Export Created/Approved for View**, you can download the export. If your request is in review, an additional section appears that tracks each company's approval or denial (Figure 121):

**Figure 121: Company Approval(s)**

<table>
<thead>
<tr>
<th>Company</th>
<th>Approval Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharma</td>
<td>Approved</td>
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<td>ACME</td>
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</table>
7 Online Help

Online help is available in the terminal server and in the SAS Clinical Trial Data Transparency Portal.

2. From the Research Environment desktop, open the Help and User Guide folder (Figure 122).

   Figure 122: Help and User Guide Desktop Icon

   - Or

   From the SAS Clinical Trial Data Transparency Portal, click Help at the top of the screen (Figure 123).

   Figure 123: Help Link

3. The Help screen displays guides and how-to videos (Figure 124). To access them, click View.

   Note: QuickTime is the recommended media player to use when viewing the SAS Clinical Trials Data Transparency how-to videos. Using the Windows Media Player to view the videos hosted on the Clinical Trials Data Transparency Portal can sometimes result in short (one second or less) distortions in the visual display during the playback of some of the videos.

   Figure 124: Help Screen
**Note:** For help related to the SAS Clinical Trial Data Transparency system, you can also contact SAS Technical Support as follows:

- Email: CTDTsupport@sas.com
- URL: [http://support.sas.com/ctx/supportform/index.jsp](http://support.sas.com/ctx/supportform/index.jsp)
- North America: Call 919-677-8008
### 8 Troubleshooting

**Table 2** provides a quick reference for troubleshooting the most common issues.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Steps to Remedy</th>
</tr>
</thead>
</table>
| Trouble connecting to the Research Environment (Terminal Server Session) | - Verify that you have performed all steps of the one-time setup of your SAM Access Credential ID.  
- Verify that your account is not locked out, by selecting **My account is locked** in the problem menu under the Account Help tab at: [https://www.ondemand.sas.com/sam](https://www.ondemand.sas.com/sam). |
| Lost password or account information | - Visit [https://www.ondemand.sas.com/sam](https://www.ondemand.sas.com/sam).  
- Select **Account Help**.  
- Select an appropriate problem in the menu under the Account Help tab |
| Account is locked | Contact SAS Technical Support as follows:  
- Email: CTDTsupport@sas.com  
- URL: [http://support.sas.com/ctx/supportform/index.jsp](http://support.sas.com/ctx/supportform/index.jsp)  
- North America: Call 919-677-8008 |
| Trouble viewing how-to videos in the Windows Media Player | QuickTime is the recommended media player to use when viewing the SAS Clinical Trials Data Transparency how-to videos. Using the Windows Media Player to view the videos hosted on the Clinical Trials Data Transparency Portal can sometimes result in short (one second or less) distortions in the visual display during the playback of some of the videos. Distortions in the visual display do not occur when the videos are viewed with QuickTime. If Windows Media Player is the user’s default media player, the user may download the video and play it locally on their computer using a different media player. The videos might start and stop intermittently if the user is attempting to view them while using a slow internet connection. If the user experiences viewing problems to the point that the video is unwatchable, the user may download the video and play it locally on their computer. To download the how-to video to their local computer, the user should right click on the “View” link and select “Save target as...“ The user will then be prompted for a location to save the video. After downloading the video, the user may use any media player they have installed on their local computer to view the video. QuickTime is available for download at: [https://www.apple.com/quicktime/download/](https://www.apple.com/quicktime/download/) |
Document Information

Document Control

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Contacts

If you have questions regarding this document, contact one of the following individuals.

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<th>E-mail: <a href="mailto:Sara.Vosinakis@sas.com">Sara.Vosinakis@sas.com</a></th>
</tr>
</thead>
<tbody>
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<td>Document Owner: Eric Emerton</td>
<td>Project Manager: Sara Vosinakis</td>
</tr>
<tr>
<td>Office Phone: (919) 531 6832</td>
<td>Office Phone: (919) 531 3073</td>
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Revision History

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### Typographical Conventions

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<th>Style</th>
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<tr>
<td>Blue Underline</td>
<td>Hypertext link. Control + Click to open hyperlink target.</td>
</tr>
<tr>
<td>Calibri</td>
<td>Standard type style used for most text.</td>
</tr>
<tr>
<td>UPPERCASE</td>
<td>Names of variables and data sets, programming statements, options, and other language elements when they appear in the text. <strong>Within specific operating environments, these elements may be case-sensitive.</strong></td>
</tr>
<tr>
<td>UPPERCASE BOLD</td>
<td>Keywords such as the names of procedures, statements, and options.</td>
</tr>
<tr>
<td><strong>bold</strong></td>
<td>Window names, selectable items.</td>
</tr>
<tr>
<td><code>&lt;italics&gt;</code></td>
<td>User-supplied values, shown within angle brackets in statements where substitution should occur.</td>
</tr>
<tr>
<td>Monospace</td>
<td>Examples of programming statements in text, SAS code, and values of variables.</td>
</tr>
</tbody>
</table>