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## Multi-Sponsor Environment

# SAS<sup>®</sup> Clinical Trial Data Transparency Version 2.3 Getting Started

Version 1.0 30 January 2018

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# 1 Overview

This user guide is to be used by **researchers** and **sponsors** who are using the SAS® Clinical Trial Data Transparency system (version 2.3 and higher). A majority of this guide is directed toward researchers, since they will be the main users of the system; however, many parts also show how the sponsor can use/access the system.

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

- **SAS Secure Access Management**

- **How to access:** Enter <https://www.ondemand.sas.com/sam/> from your browser for access through the Internet.
- **Tasks you can perform:**
  - Set up your password.
  - Set up security/challenge questions.
  - Reset your password.

- **Research environment**

- **How to access:** You will need to first set up your Secure Access Management account information before you can log on remotely (see above). Then, follow the instructions on accessing the environment through a remote desktop connection (see Section 3 [[Accessing the Research Environment](#)]).
- **Tasks you can perform:**
  - Perform research work using PC software provided (e.g., PC-SAS, R, PLINK).
  - Collect files for export from the research environment.

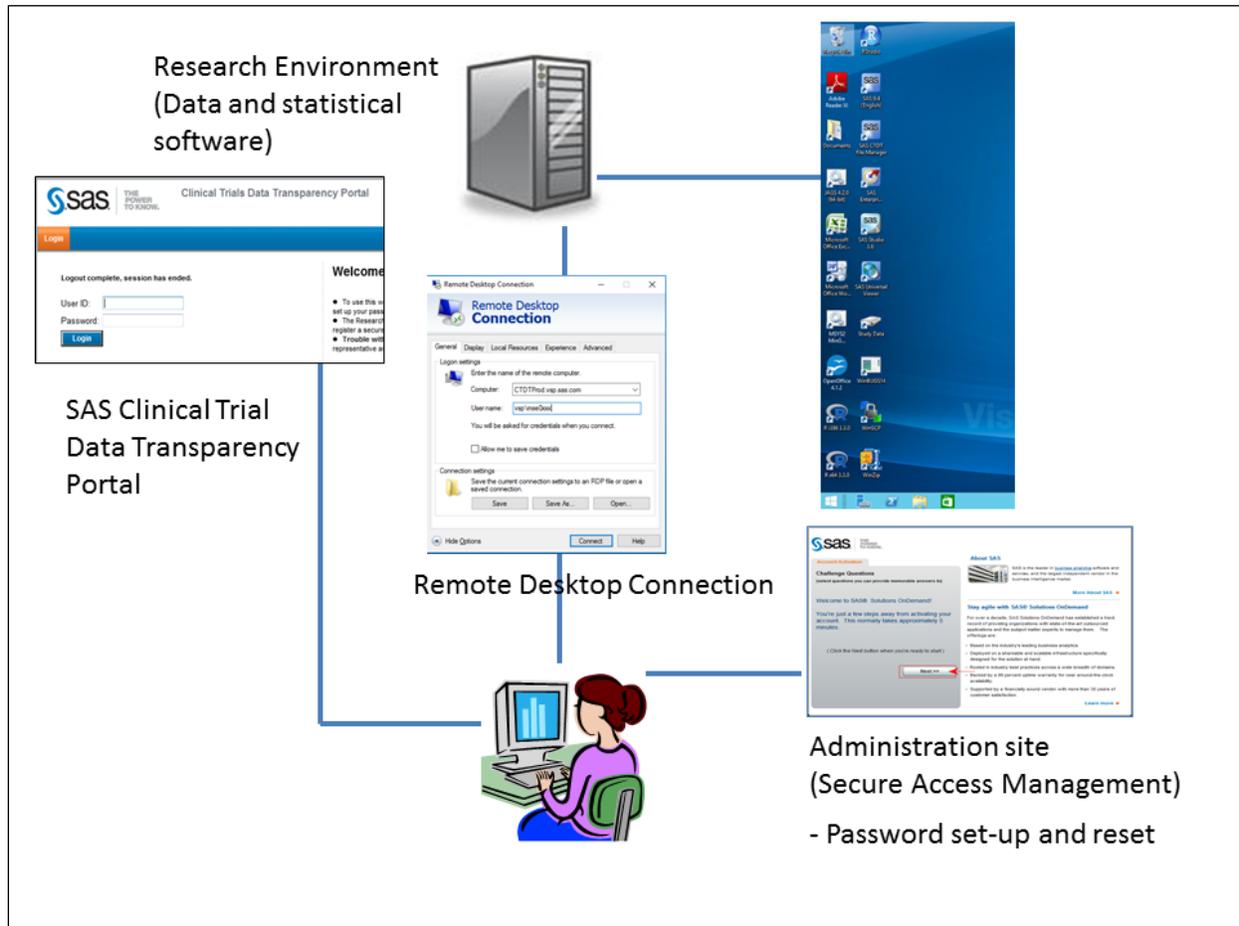
- **SAS Clinical Trial Data Transparency portal**

- **How to access:** Log on to the SAS Solutions OnDemand secure portal via <https://mseportal.ondemand.sas.com/ctdt/>.
- **Tasks you can perform:**
  - Initially accept the terms of the system.
  - Import files into the research environment.
  - Receive exports from the research environment.
  - Administrators can review reporting and summary reports on activity/access.
  - Review user guides and how-to videos.

**Note:** Once you set up 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.

[Figure 1](#) provides an overview of the system.

**Figure 1: Overview**



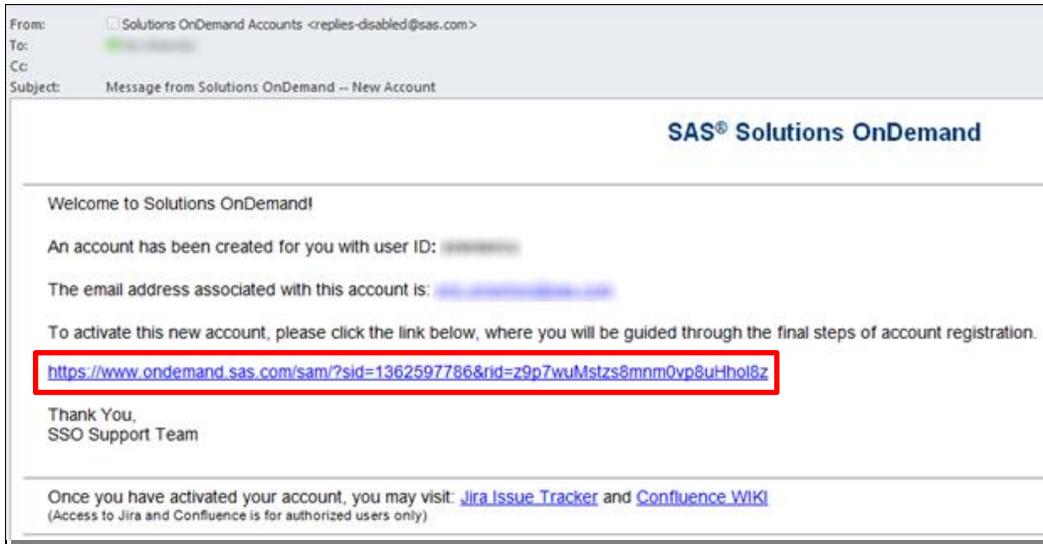
**Note:** Your account information (username [or user ID] and password) enables you to access all the components of the SAS Clinical Trial Data Transparency system.

## 2 Setting Up Your Account

### 2.1 Completing the Initial Email and Password Setup

You will receive an email from SAS Solutions OnDemand with your username (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 email ([Figure 2](#)).

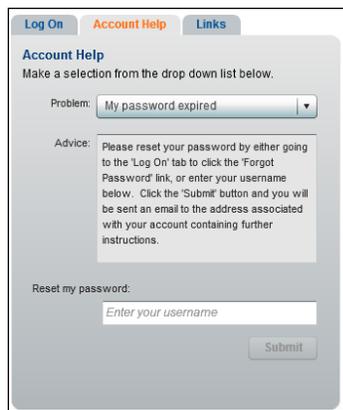
**Figure 2: Welcome Email**



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

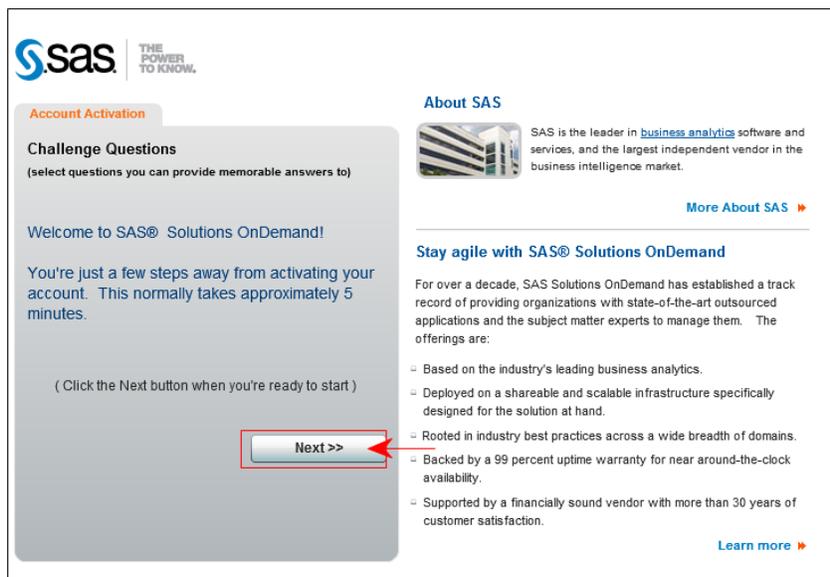
- Email: [CTDTsupport@sas.com](mailto:CTDTsupport@sas.com)
- URL: <http://support.sas.com/ctx/supportform/index.jsp>
- North America: Call 919-677-8008

**Figure 3: Account Help**



Click the link to set up 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**



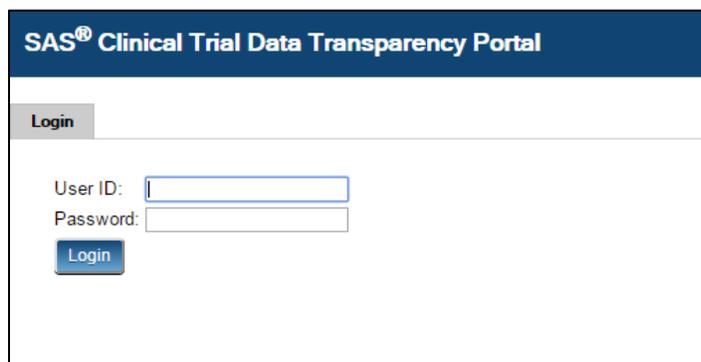
**Note:** The Secure Access Management system provides password rules when you set a password. Your account's password expires after 90 days. Beginning eight days prior to your password's expiration, you receive a daily email reminder to reset your password.

## 2.2 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 on the SAS Clinical Trial Data Transparency portal.

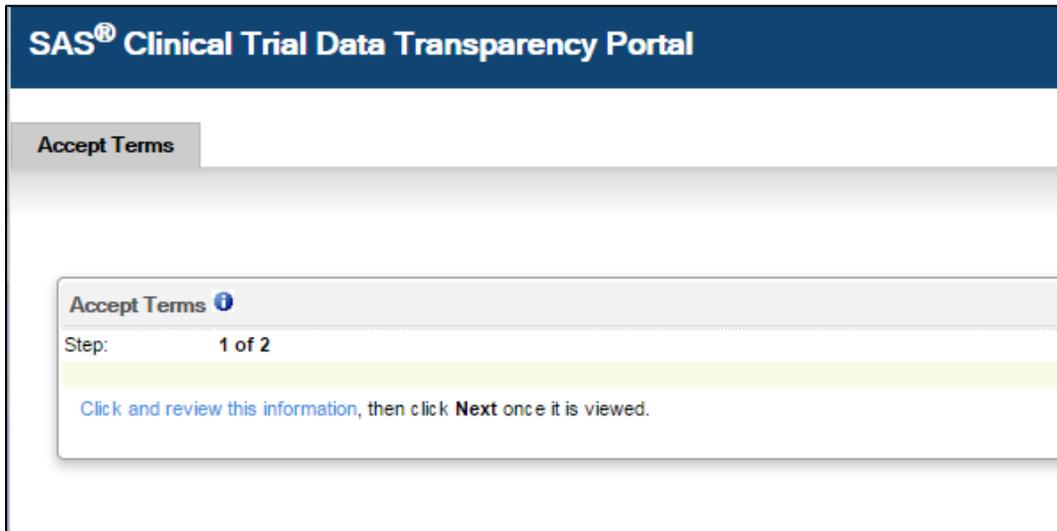
1. Access the SAS Clinical Trial Data Transparency portal at <https://mseportal.ondemand.sas.com/ctdt/>.
2. On the logon screen, enter your SAS Clinical Trial Data Transparency system user ID (or username) and password ([Figure 5](#)).

**Figure 5: SAS Clinical Trial Data Transparency Portal Logon**



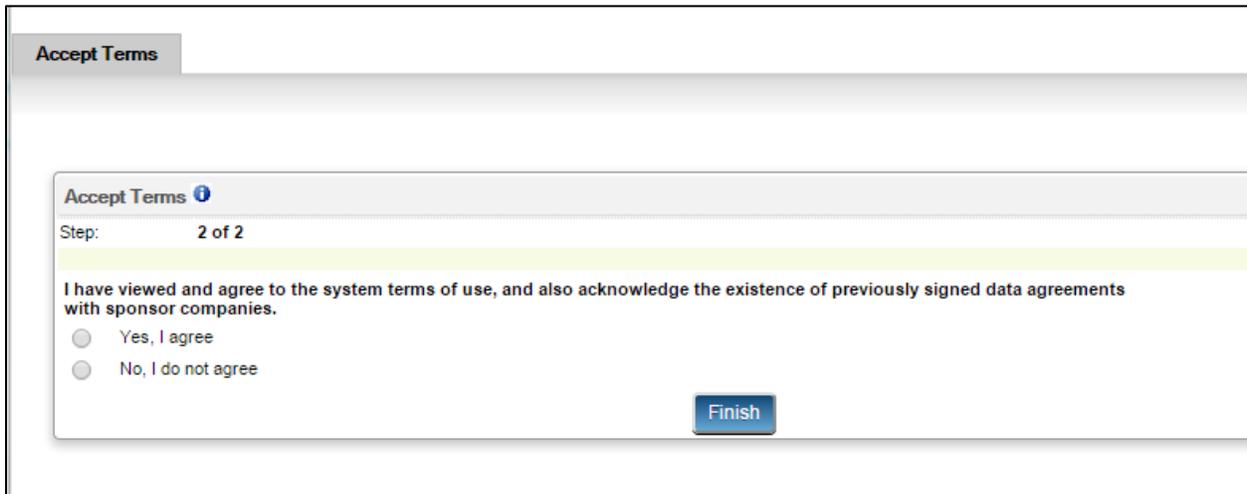
3. After logon is complete, Accept Terms is the only option that displays ([Figure 6](#)). Click the **Click and review this information** link.

Figure 6: SAS Clinical Trial Data Transparency Portal Accept Terms (Start)



4. A PDF of terms displays. Review the text of the PDF. Once the review is complete, click **Next**.
5. A statement displays enabling you to accept the terms ([Figure 7](#)). Click **Yes, I agree**, and then click **Finish**.

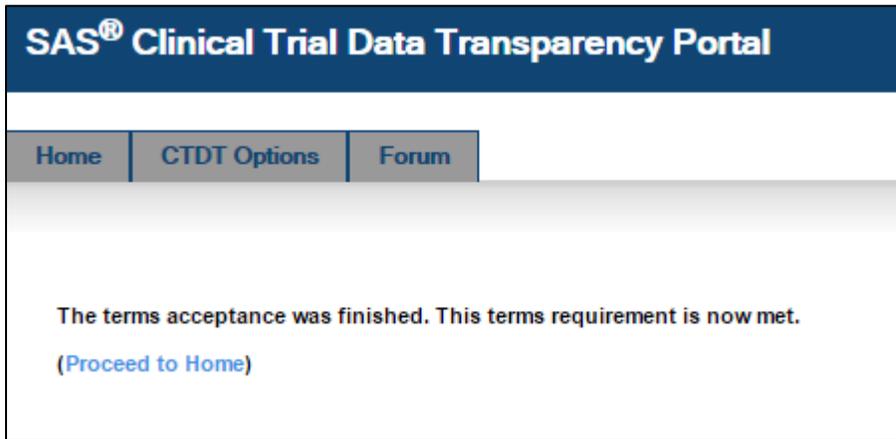
Figure 7: SAS Clinical Trial Data Transparency Portal Accept Terms (Finish)



6. Once the statement is accepted, a confirmation displays ([Figure 8](#)). 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 8: SAS Clinical Trial Data Transparency Portal (Proceed to Home)



## 3 Accessing the Research Environment

**Note:** If you have not accepted the terms on the SAS Clinical Trial Data Transparency portal, you must follow those steps first. See Section 2.2 ([Accepting Terms in the Portal](#)).

The research environment is accessed via a remote desktop connection session. For Windows users, a remote desktop should be available for any version. Mac users can download the application via the Mac App Store. Once you have accessed the Mac App Store, use the search bar at the top right of the screen to search for “Microsoft Remote Desktop.” The first search result should be the one you need. To begin the download, click **Get** ([Figure 9](#)). This app is free, so no price will be listed.

**Figure 9: Microsoft Remote Desktop Download—“Get” Button**

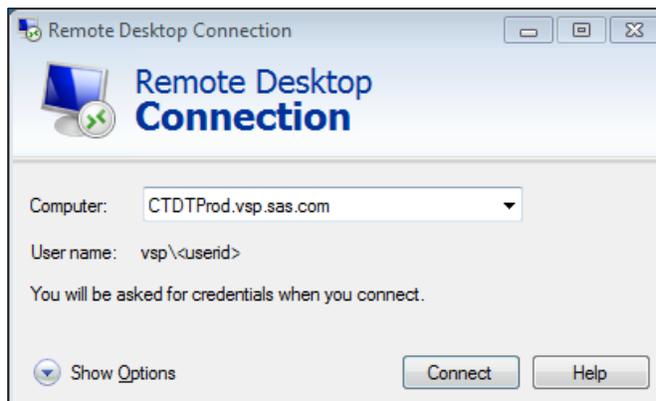


### 3.1 Manually Configure Remote Desktop Session Settings

#### 3.1.1 Windows Users

1. Access Remote Desktop from **Start > All Programs > Accessories > Remote Desktop Connection**. You can also type “Remote Desktop Connection” in the dialog box after you click the **Start** icon.
2. For Computer, enter the value `CTDTProd.vsp.sas.com` ([Figure 10](#)).

**Figure 10: Remote Desktop Configuration—Computer Name**



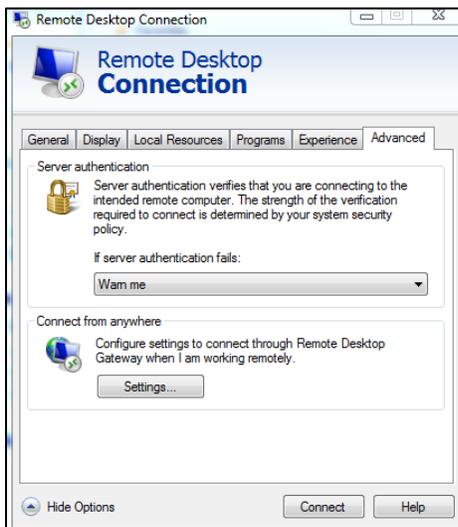
**Note:** Depending on your version of Windows, the following instructions/screenshots may not match exactly in tab/field name, although they should be very similar in intent. Any questions can be directed to SAS Technical Support.

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

3. Click **Show Options** to show all options for remote desktop connections.

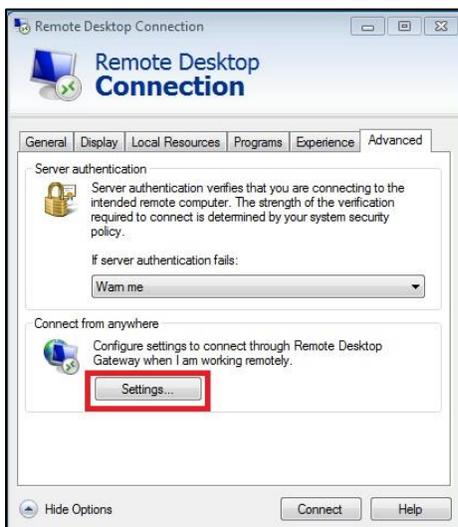
4. Click the **Advanced** tab ([Figure 11](#)).

**Figure 11: Remote Desktop Configuration—Advanced Tab**



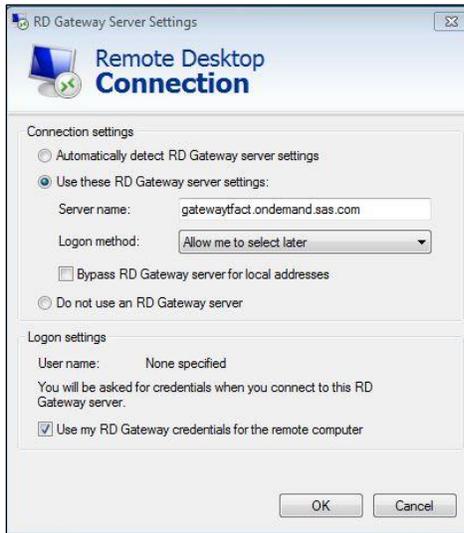
5. Click **Settings...** to display the connection settings ([Figure 12](#)).

**Figure 12: Remote Desktop Configuration—Connection Settings**



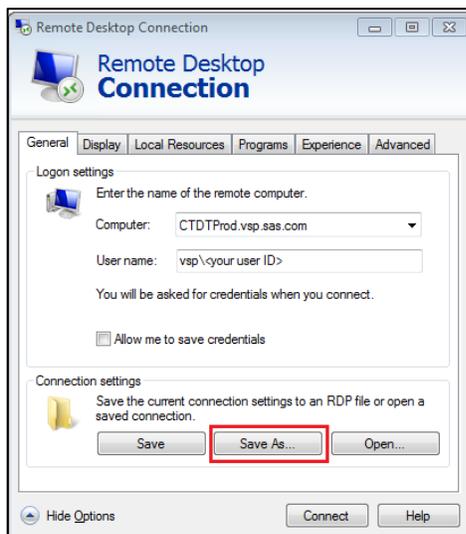
6. Select the **Use these RD Gateway server settings** radio button. For the server name, enter “gatewayfact.ondemand.sas.com”. Check the **Use my RD Gateway credentials for the remote computer** checkbox (see [Figure 13](#)).

**Figure 13: Remote Desktop Configuration—Gateway Credentials**

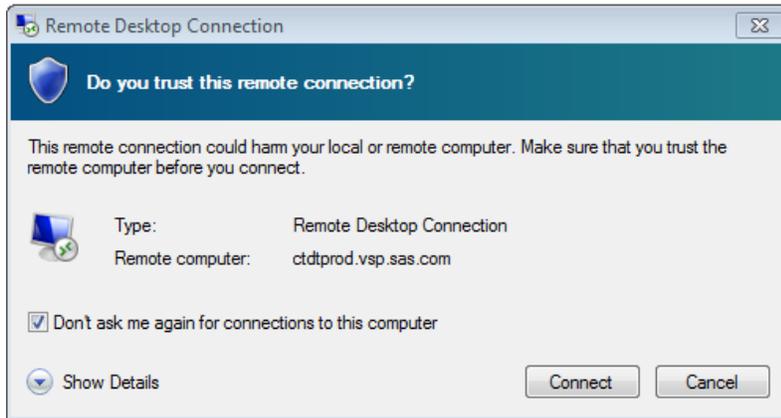


7. Click **OK**, and return to the **General** tab.
8. Enter VSP\Save As and save the settings to an “xxx.rdp” file for later use ([Figure 14](#)).

**Figure 14: Remote Desktop—Save Profile**



9. At this point, you should be able to click **Connect** to establish a connection to the terminal server. When using a newly saved rdp file, an additional logon window ([Figure 15](#)) may display prior to the remote desktop session window. In this window, be sure to check the **Don't ask me again for connections to this computer** checkbox, and then click **Connect**.

**Figure 15: Remote Desktop—Additional Screen and Logon Window**

10. You will be prompted for a username and password. Complete the sign-in process by entering the password on the subsequent screen ([Figure 16](#)).

**Figure 16: Credentials Window—Password**

11. You may be asked about the remote computer's security certificate. This certificate comes from SAS and should be trusted. SAS recommends checking the **Don't ask me again for connections to this computer** box ([Figure 17](#)).

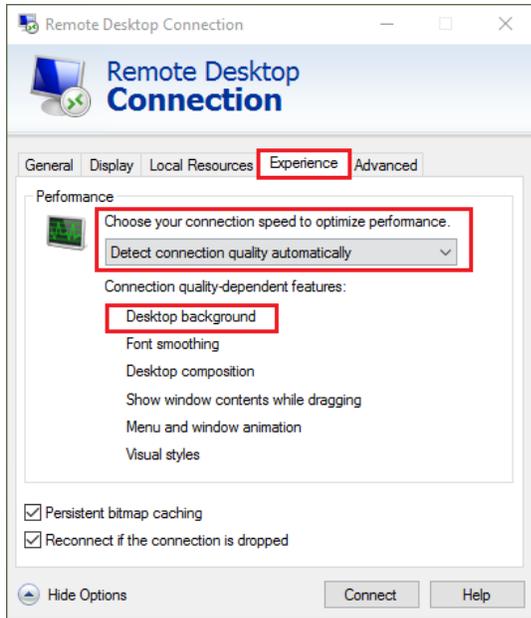
**Figure 17: Remote Desktop Connection Security Certificate Authentication**

12. At this point, you should be at the main terminal server screen ([Figure 18](#)).

**Figure 18: Main Terminal Server Screen**

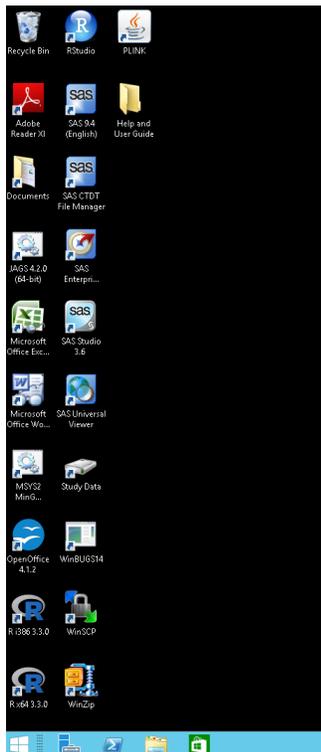
You may not have the blue background shown in the screenshots above. This is usually due to an extra setting you may need to set. Typically, under the **Experience** tab, the **Choose your connection speed to optimize performance** option will be set to **Detect connection quality automatically** (see [Figure 19](#)).

**Figure 19: Remote Desktop Connection—Experience Tab Defaults**



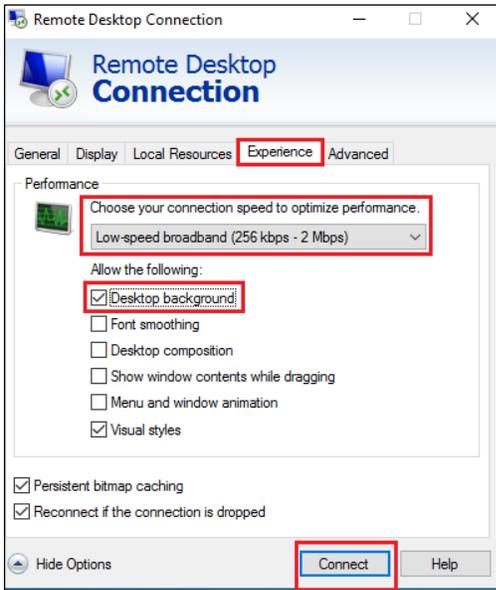
If your connection is slow, the RDC connection may not refresh the desktop background, and you will instead have a black background (see [Figure 20](#)).

**Figure 20: Desktop Background When Not Refreshed**



To try to rectify and get the blue background, navigate to the **Experience** tab and, from the drop-down menu, select **Low-speed broadband (256 kbps – 2 Mbps)**. You will then have six checkboxes to check/uncheck. Check the **Desktop background** checkbox, and then click **Connect** (see [Figure 21](#)).

**Figure 21: Remote Desktop Connection—Experience Tab Selections**



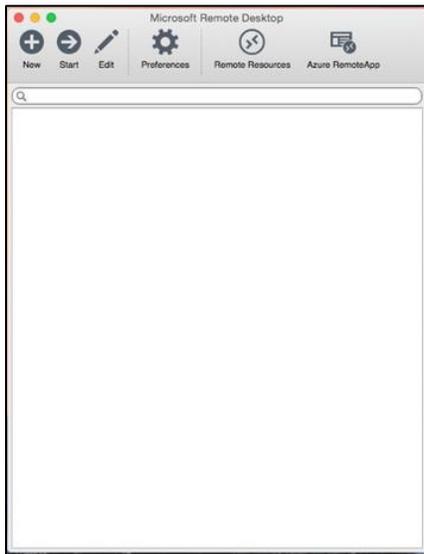
**PLEASE NOTE:** If the background image is different than what is presented in the screenshots (usually the background possibly stays as the black color no matter the speed chosen in the RDC Experience tab), this is due to a known Microsoft issue that has no resolution at this time.

### 3.1.2 Mac Users

When you get to the terminal server, you should now see the blue background. Keep in mind that this is a cosmetic item, and in no way does it interfere or prevent the user from using all SAS Clinical Trial Data Transparency terminal server environment functionality.

1. Open the application by clicking through the grey **Launchpad** icon and clicking on the **Remote Desktop** app icon: 

The application should open with a window like the one shown in [Figure 22](#).

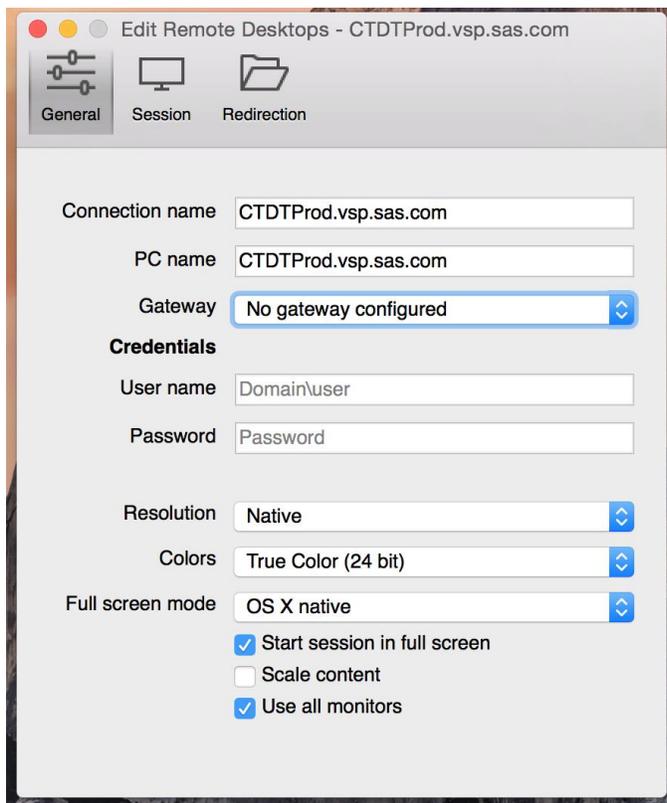
**Figure 22: Application Window**

2. Click **New** in the top left of the Microsoft Remote Desktop screen. You will be prompted to fill in a few fields ([Figure 23](#)).

**Figure 23: Edit Remote Desktop Window**

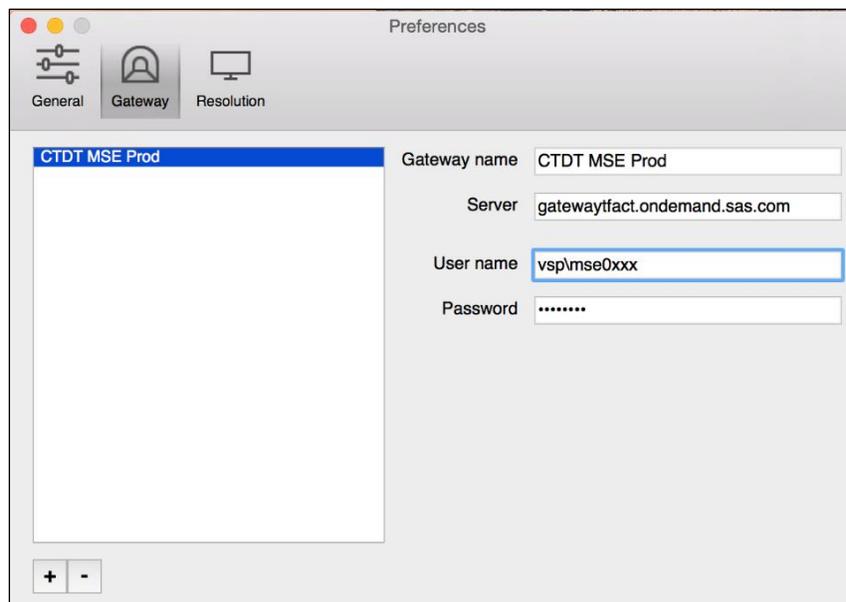
3. You will need to input the connection name and PC name. Both of these should be named "CTDTProd.vsp.sas.com" (see [Figure 24](#)).

Figure 24: Remote Desktop Edits



- Next, you will need to add the gateway. Click the drop-down menu, and select **Add**, which will display the preferences window (see [Figure 25](#)). The gateway name should be "CTDT MSE Prod." The server will be "gatewayfact.ondemand.sas.com." The username will be your VSP account that you set up earlier (i.e., "vsp\mse0xxx"). Finally, input your password, and exit this window.

Figure 25: Gateway Settings



5. Make sure to enter your username and password for your credentials (see [Figure 26](#)).

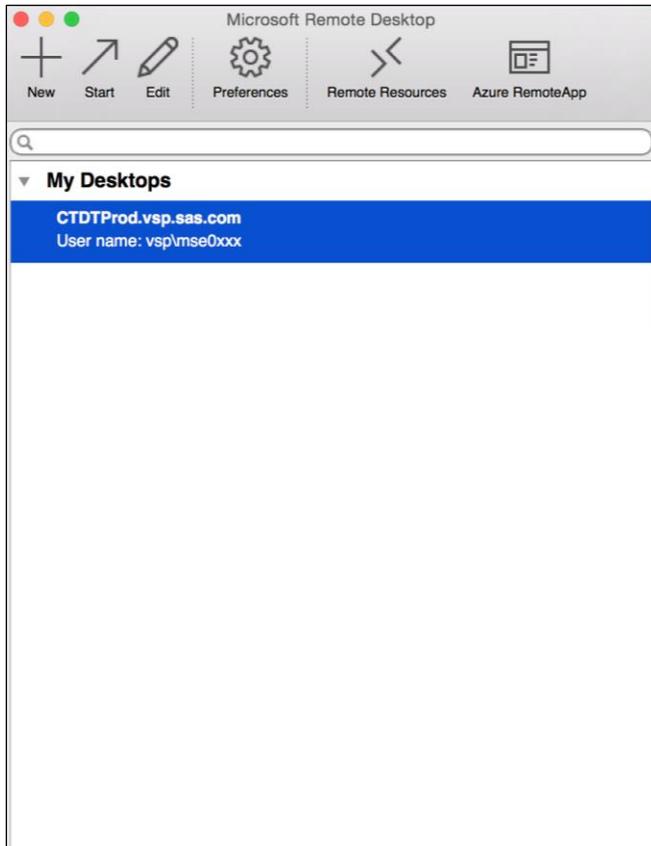
**Figure 26: Credentials**

The screenshot shows the 'Edit Remote Desktops' window for 'CTDTProd.vsp.sas.com'. The 'General' tab is active. The fields are as follows:

- Connection name: CTDTProd.vsp.sas.com
- PC name: CTDTProd.vsp.sas.com
- Gateway: CTDT MSE Prod
- Credentials**
  - User name: vsp\mse0xxx
  - Password: [Redacted]
- Resolution: Native
- Colors: True Color (24 bit)
- Full screen mode: OS X native
- Start session in full screen
- Scale content
- Use all monitors

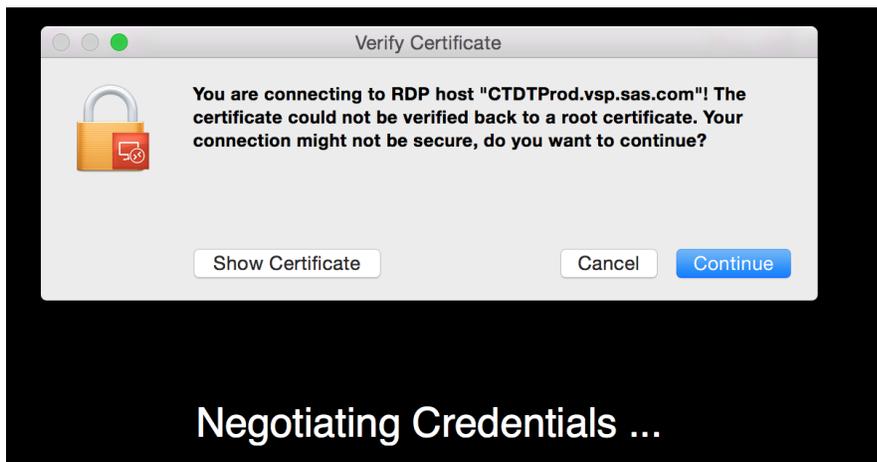
- Exit the Edit Remote Desktop window. Click on the new connection to connect to the MSE environment (see [Figure 27](#)).

**Figure 27: New Connection**



- A popup window will display to ask you if you want to continue to log on. Click **Continue** (see [Figure 28](#)).

**Figure 28: Certificate Verification**



8. At this point, you should be at the main terminal server screen ([Figure 29](#)).

**Figure 29: Main Terminal Server Screen**

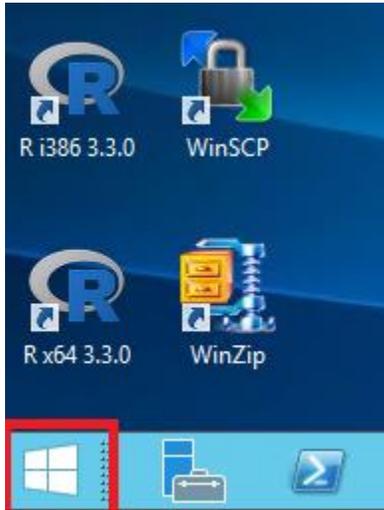


### 3.1.3 Logging Off (Sign Out)

To log off the research environment, navigate to **Start Menu > Sign out** ([Figure 30](#)).

**Note:** If you close the session window without logging off, this can result in a hung session. You may not be able to get back into the system unless you first contact the SAS Multi-Sponsor Environment administrator so they can free up the session cleanly, and then you log back on.

Figure 30: Logging Off the Research Environment



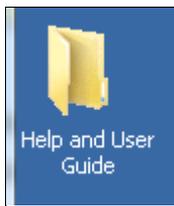
## 4 Online Help

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

**Note:** The folder will be available on the environment, but the videos and user guide may not be in it yet as of when the researchers are doing user acceptance testing in the system.

1. A user guide and other help are available at [https://mseportal.ondemand.sas.com/ctdt/help\\_nosess.jsp](https://mseportal.ondemand.sas.com/ctdt/help_nosess.jsp).
2. From the research environment desktop, open the **Help and User Guide** folder ([Figure 31](#)).

**Figure 31: Help and User Guide Desktop Icon**



-OR-

From the SAS Clinical Trial Data Transparency portal, click **Help** at the top of the screen ([Figure 32](#)).

**Figure 32: Help Link**



3. The SAS Clinical Trial Data Transparency portal Help screen displays guides and how-to videos ([Figure 33](#)). To access them, click **View**.

**Figure 33: Help Screen**

Help:			
Role: Lead Researcher			
Type	Name	Description / Notes	
Document / User Guide	Getting Started Guide	<ul style="list-style-type: none"> <li>Updated December 22nd, 2014</li> <li>Use this guide to help with setting up your account, during the welcome email process. The main user guide also includes these chapters.</li> </ul>	<a href="#">View</a>
Document / User Guide	User Guide - Main	<ul style="list-style-type: none"> <li>Updated December 22nd, 2014</li> <li>Main user guide for all users.</li> </ul>	<a href="#">View</a>
Document / User Guide	User Guide - CTD Repository	Full user guide on the CTD Repository system. Some sections of this are detailed in the main CTD User Guide	<a href="#">View</a>
Video	Introduction to the Research Environment	<ul style="list-style-type: none"> <li>Updated June 11th, 2014</li> <li>2:19 (minutes) Duration</li> <li>Overview of the research environment and applications</li> </ul>	<a href="#">View</a>
Video	Clinical Trial Data Transparency Repository Overview	<ul style="list-style-type: none"> <li>Updated June 10th, 2014</li> <li>3:28 (minutes) Duration</li> <li>Overview of the Clinical Trial Data Transparency Repository</li> <li>Accessing projects and files</li> <li>Download files to research server for R use</li> </ul>	<a href="#">View</a>
Video	Clinical Trial Data Transparency Repository Login/Overview	<ul style="list-style-type: none"> <li>Updated June 11th, 2014</li> <li>2:56 (minutes) Duration</li> <li>Logging into the Clinical Trials Data Transparency Repository</li> <li>Overview of interface</li> </ul>	<a href="#">View</a>
Video	Account Setup (All Users)	<ul style="list-style-type: none"> <li>Updated August, 2013</li> <li>5:40 (minutes) Duration</li> <li>Overview of research environment account setup</li> <li>Setup of VIP access application for secondary token used at login</li> <li>All users (Windows or Mac) should view this video</li> </ul>	<a href="#">View</a>
Video	Login (Windows Users)	<ul style="list-style-type: none"> <li>Updated August, 2013</li> <li>1:53 (minutes) Duration</li> <li>Overview of logging into the research environment for Windows Users</li> </ul>	<a href="#">View</a>
Video	Logon (Mac Users)	<ul style="list-style-type: none"> <li>Updated July, 2013</li> <li>1:40 (minutes) Duration</li> <li>Overview of logging into the research environment for Mac Users</li> </ul>	<a href="#">View</a>
Video	Browsing Data in the Clinical Data	<ul style="list-style-type: none"> <li>Updated June 10th, 2014</li> <li>6:26 (minutes) Duration</li> </ul>	<a href="#">View</a>

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

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

## 5 Troubleshooting

[Table 1](#) provides a quick reference for troubleshooting the most common issues.

**Table 1: Common Issues**

Issue	Steps to Remedy
<b>Trouble connecting to the research environment (terminal server session)</b>	<ul style="list-style-type: none"> <li>• Verify that you have performed all steps of the one-time setup of your Secure Access Management access credential ID.</li> <li>• Verify that your account is not locked out, by clicking <b>My account is locked</b> in the problem menu under the Account Help tab at <a href="https://www.ondemand.sas.com/sam">https://www.ondemand.sas.com/sam</a>.</li> </ul>
<b>Lost password or account information</b>	<ul style="list-style-type: none"> <li>• Visit <a href="https://www.ondemand.sas.com/sam">https://www.ondemand.sas.com/sam</a>.</li> <li>• Click <b>Account Help</b>.</li> <li>• Select an appropriate problem in the menu under the Account Help tab.</li> </ul>
<b>Account is locked</b>	Contact SAS Technical Support as follows: <ul style="list-style-type: none"> <li>• Email: <a href="mailto:CTDTsupport@sas.com">CTDTsupport@sas.com</a></li> <li>• URL: <a href="http://support.sas.com/ctx/supportform/index.jsp">http://support.sas.com/ctx/supportform/index.jsp</a></li> <li>• North America: Call 919-677-8008</li> </ul>
<b>Trouble viewing how-to videos in the Windows Media Player</b>	<p>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 SAS 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.</p> <p>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.</p> <p>To download the how-to video to their local computer, the user should right click <b>View</b>, then click <b>Save target as...</b> 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 <a href="https://www.apple.com/quicktime/download/">https://www.apple.com/quicktime/download/</a>.</p>

## Appendix A: Terms of Use

The Usage Rules detailed below apply to any Researcher who is given access to sponsor data via this Clinical Trial Data Transparency Portal (“access system”). Use of sponsor data within this system must adhere to these usage rules and must also be in adherence with the signed Data Sharing Agreement (DSA) or Data Use Agreement (DUA) (hereinafter referred to as DSA) between the Sponsor(s) who provided access to the data and the lead Researcher and/or their research institution.

The secure data access system is a hosted environment managed by the Access System Manager (SAS Institute Inc., located at SAS Campus Drive, Cary, North Carolina 27513). These Usage Rules are being provided to you by the Sponsor(s) who have granted access to their study data. Researcher may not assign its rights or obligations as set forth in these Usage Rules. Sponsor or Access System Manager may limit or terminate a Researcher’s access to the Access System and/or pursue other legal action available to either of them in the event of Researcher’s noncompliance with these Usage Rules. As needed, these Usage Rules shall be interpreted and governed exclusively by the laws and the jurisdiction of the competent courts of the country/government agreed to in the DSA for a given project.

By clicking the “**Accept**” button, you confirm that you have reviewed and understand these Usage Rules and the approved DSA(s) for your project(s), and agree to comply with them.

### Access System and Software Terms of Use

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## Document Information

### Document Control

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### Revision History

JIRA Ticket	Date	Version	Name	Description
<a href="#">MSE-612</a>	06-JUN-2017	0.1	Robin MacBain	Set up version for edits.
<a href="#">MSE-612</a>	24-JUL-2017	0.2	Laura James	Edited draft version 0.2.
<a href="#">MSE-612</a>	28-AUG-2017	0.3	Laura James	Edited draft version 0.3.
<a href="#">MSE-612</a>	12-SEPT-2017	0.4	Laura James	Edited draft version 0.4.
<a href="#">MSE-612</a>	26-OCT-2017	0.5	Laura James	Finalized draft version 0.5.
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<a href="#">MSE-612</a>	30-OCT-2017	0.7	Laura James	Finalized draft version 0.7.
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<a href="#">MSE-612</a>	14-DEC-2017	0.8	Laura James	Finalized draft version 0.8.
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<a href="#">MSE-612</a>	19-JAN-2018	1.0	Laura James	Finalized version 1.0.