



## WORK INSTRUCTION

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## SAS and AWS User Training

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## 1. PURPOSE

This work instruction describes the process of requesting access and setup of AWS and SAS system. It also describes additional information on the methods for the execution of SAS programs and AWS general structure and environment setup.

## 2. SCOPE


This work instruction applies to all SAS users performing activities on the AWS SAS Server.

## 3. ABBREVIATIONS AND DEFINITIONS

- 3.1 **AWS:** Amazon Web Services Workspace. A secured virtual environment/directory in which Statistical and Clinical programs are developed and maintained.
- 3.2 **JIRA:** Web-based system to manage system access requests and technical issues.
- 3.3 **SAS Computing Environment:** SAS server installed on AWS where SAS, SAS EG are installed.
- 3.4 **SAS EG:** SAS Enterprise Guide.
- 3.5 **GSDS:** Global Statistics and Data Science
- 3.6 **GTS:** Global Technology Solutions (normally known as IT)
- 3.7 **FSP:** Functional Service Provider

## 4. RESPONSIBILITIES

- 4.1 **Statistical Programming Product Lead (SPPL)** is responsible for approving product/study/analysis level AWS directory permission changes prior to implementation, maintaining the records of verification process and managing the overall project or clinical study.
- 4.2 **SAS Users** are responsible for completing the required training and following the practices outlined in this Work Instruction.
- 4.3 **SAS System Administrators (GTS)** are responsible for providing technical support and user access management and ensures SAS training completion in LMS, prior to granting permission to the SAS environment.

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## 5. INSTRUCTION

### 5.1 Getting Access to SAS (SAS EG, SAS Batch)

5.1.1 Users must complete this training and submit a training completion certificate to [AskIT@beigene.com](mailto:AskIT@beigene.com). If this WI is not already assigned to you, please follow the steps below to ensure training is assigned.

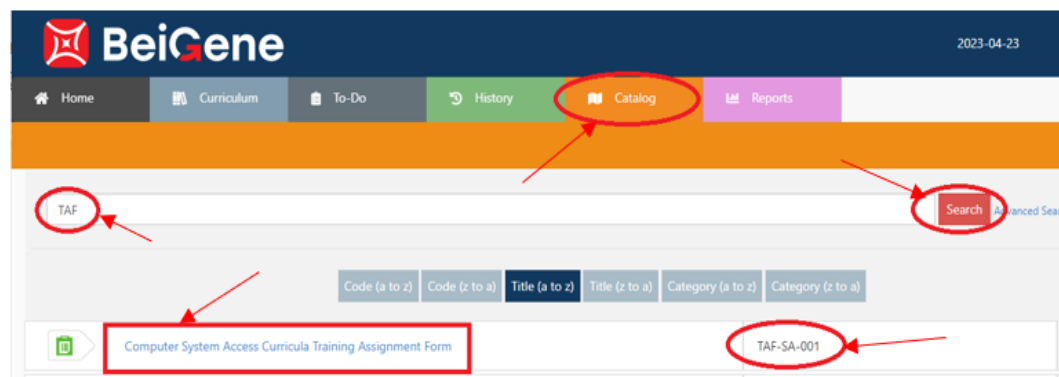
5.1.1.1 To have SAS training item assigned to user To Do tab, complete a TAF-SA-001, an electronic Training Access Form. Training items will be automatically assigned to the To Do Tab in the LMS once the TAF-SA-001 is completed. Follow the instructions below to have required training assigned.

5.1.1.2 Go to Enterprise LMS from [MyApps](#).

5.1.1.3 Select GXP from the LMS home page.



5.1.1.4 From the GXP **Catalog** search for the Training Assignment Form using the acronym **TAF** and select the correct TAF.

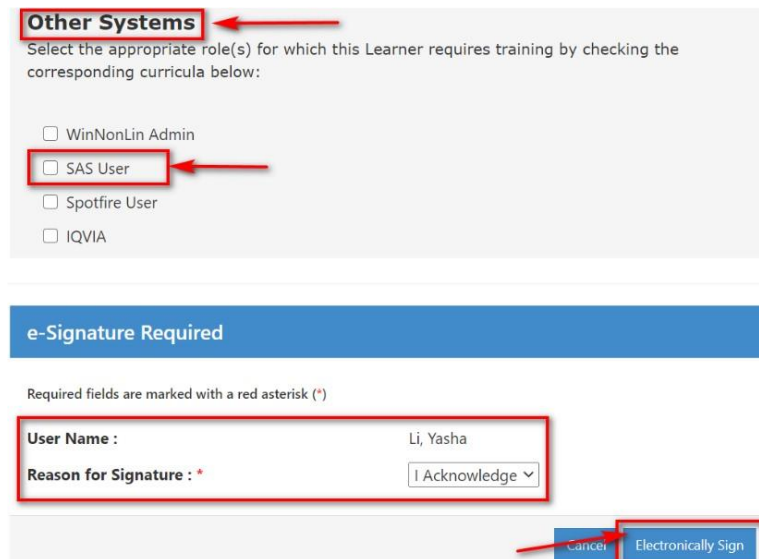


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- 5.1.1.5 **Launch** the Training Assignment Form (TAF) and select the appropriate SAS Role. After the SAS role is selected, Electronically Sign the form to have training items automatically assigned to user To Do tab in the LMS.



**Other Systems**

Select the appropriate role(s) for which this Learner requires training by checking the corresponding curricula below:

☐ WinNonLin Admin

☐ **SAS User**

☐ Spotfire User

☐ IQVIA

---

**e-Signature Required**

Required fields are marked with a red asterisk (\*)

User Name : Li, Yasha

Reason for Signature : \* I Acknowledge ▾

Cancel Electronically Sign

- 5.1.2 For FSP, contact line manager to work with Quality Training to get training assigned in LMS.
- 5.1.3 Once assigned training is complete, please save a copy of the certificate of completion.
- 5.1.4 Request access to SAS by emailing [AskIT@beigene.com](mailto:AskIT@beigene.com) and attach the certificate of completion.
- 5.1.5 After training has been verified, SAS System Administrator will create the AWS Workspace for the user, add the user to **SAS-USERFILES-P** group and send a welcome email with log in instructions within 24-48 hours. Refer to Appendix 1 for onboarding workflow for SAS collectively.

## 5.2 Getting into AWS Workspace

To access SAS, the SAS User needs to first log into the AWS Workspace per below AWS Workspace onboarding instructions.

- 5.2.1 Install the AWS Workspace Client from the windows Company Portal or email GTS support team [AskIT@beigene.com](mailto:AskIT@beigene.com) to help install the AWS Workspace Windows client.

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5.2.2 Once installed, launch the application, and register the BeiGene AWS Workspace code the first time: The code will be provided by GTS through AWS onboarding letter.

5.2.3 At the log in prompt: enter username (first.lastname without the @beigene.com). Password will be the same as Office365 password.

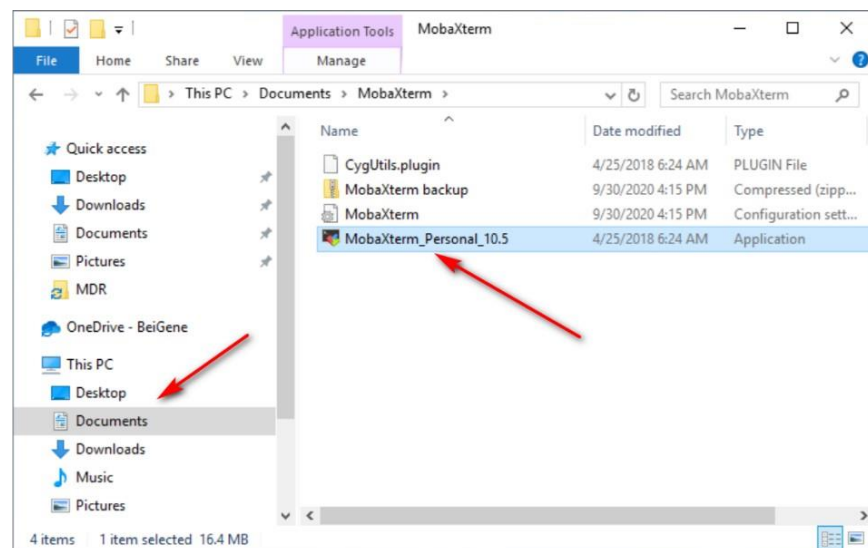
### 5.3 Set Up SAS Environment

SAS can be accessed via batch mode using command line SSH using MobaXterm or using Enterprise Guide (EG). User needs to set up the SAS environment the first time they log in to SAS system through AWS Workspace following the instructions below to create a /home directory.

#### 5.3.1 Create homedrive using MobaXterm

5.3.1.1 Find MobaXterm in the: MyDocuments\MobaXterm folder.

5.3.1.2 Click on File Explorer>My Documents>MobaXterm folder. A shortcut can be dragged to the desktop for future convenience.



5.3.1.3 Once MobaXterm is running, create an SSH Session using below connection settings:

5.3.1.3.1 Fill Remote host: sas94p (for AWS US) or cnax-sas-p-1 (for AWS China).

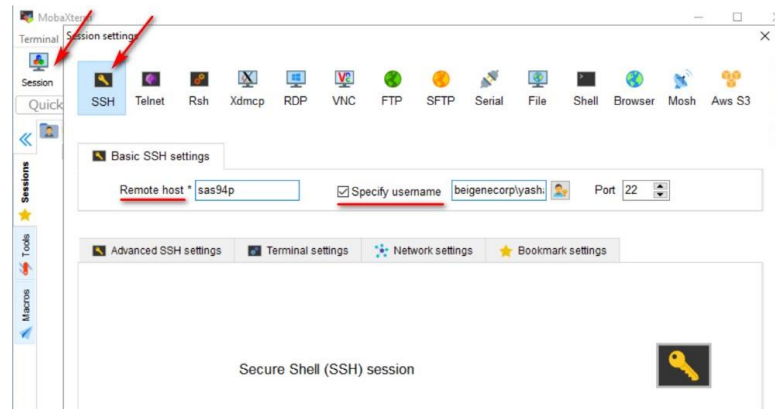
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5.3.1.3.2 Fill Specify username: beigenecorp\first.lastname

5.3.1.3.3 Enter user password when prompted for password in the SSH session.



5.3.1.4 Close MobaXterm and continue to next step when seeing a successful "Creating home directory for username" message and a command prompt.

## 5.3.2 Using SAS Enterprise Guide (EG)

5.3.2.1 Click START scroll down and click on the SAS Enterprise Guide Icon.

5.3.2.2 User will be prompted to create a new EG profile. Choose yes Creating the EG profile.

5.3.2.3 Click Profile on the upper left (if not prompted to create a new profile) and click "Add..." profile to enter the following settings:

5.3.2.3.1 Fill Name: sas94p (for AWS US) or AWS China SAS (for AWS China).

5.3.2.3.2 Fill Remote Server Machine: sas94p (for AWS US) or cnax-sas-p-1 (for AWS China).

5.3.2.3.3 Fill User: beigenecorp\first.lastname

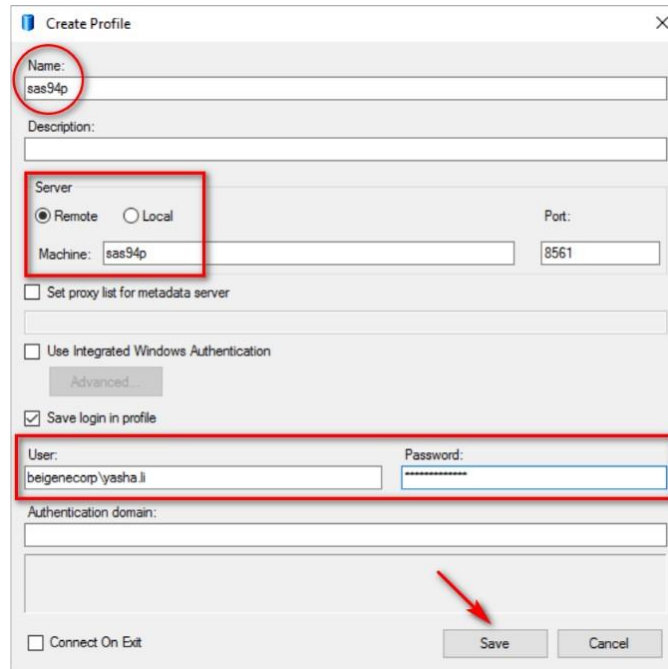
5.3.2.3.4 Fill Password: your Amazon workspace password

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5.3.2.3.5 Click “Save” and click “Set Active” to active the created profile.



**Note:** Above screenshot depicts only AWS US settings. For AWS China follow setting mentioned in the above bullets.

## 5.4 Access and Execute SAS Programs

5.4.1 SAS user can access, create, and execute programs in Interactive mode and Batch mode.

5.4.1.1 For Interactive Mode, use Enterprise Guide (EG). Open and Save programs on one of the two Metadata Servers:

**SASApp\_en** - allow to work with data with LATIN encoding (e.g. English)

**SASApp\_u8** - allow to work with data with UTF-8 encoding (e.g. Chinese)

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5.4.1.2 For Batch Mode, use MobaExterm:

**sasen <program name>.sas** – command line to execute program reading data with LATIN encoding

**sasu8 <program name>.sas** – command line to execute program reading data with UTF-8 encoding

5.4.1.3 Linux is case sensitive. Follow the best practices outlined in [WI \(VV-QDOC-00169 Statistical Programming\)](#) for file and folder names. Use lower case, and only use alphanumeric characters and underscores instead of space when working with command lines.

5.4.2 Please refer to the [Stat-Programming Training SharePoint site](#) for additional training materials or contact your line manager for further guidance.

## 5.5 Getting Access to GSDS AWS File Share

5.5.1 Access to clinical data in GSDS AWS file share is provided on a study-by-study level using the Global Statistics and Data Sciences (GSDS) Access Management Forms in JIRA. SAS Users will need to request read-only or read-write access to the study or product-level folders related to the studies/products they will be working on prior to executing any programs accessing the clinical data. A workflow will be generated for access request approval based on the request type. Refer to [WI \(VV-QDOC-14391 GSDS Data Access Request and Access Management\)](#), and [SOP \(VV-QDOC-12052 GSDS Data Access and Control\)](#) for steps to apply for AWS file share access through JIRA form.

5.5.1.1 Log onto <https://myapps.microsoft.com>.

5.5.1.2 Click “GSDS Access Request Form” icon.



GSDS Access Req...

5.5.1.3 Select “Clinical AWS US Access Management Form” for AWS US folder access request OR select “Clinical AWS China Access Management Form” for AWS China folder access request.

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5.5.1.4 Enter required information related to the study/folder the user needs access for, complete the form and submit.

5.5.2 Approval must be consistent with instructions in the [WI \(VV-QDOC-01327 Data Integrity Protection in Clinical Trials\)](#) , and [WI \(VV-QDOC-00248 Unblinding of Individual and Group Treatment Assignments in Clinical Trials\)](#) . Refer to [WI \(VV-QDOC-14391 GSDS Data Access Request and Access Management\)](#) and [SOP \(VV-QDOC-12052 GSDS Data Access and Control\)](#) for instructions on approving these study-specific access requests.

## 5.6 Set Up AWS Environment

5.6.1 Watch [video m1\\_setup\\_aws\\_desktop.mp4](#) (in Stat-Programming Training Beep site /GSPR/Trainings/Presentations/m1\_setup\_aws\_desktop.mp4) to setup the AWS workspace desktop, start menu and task bar.

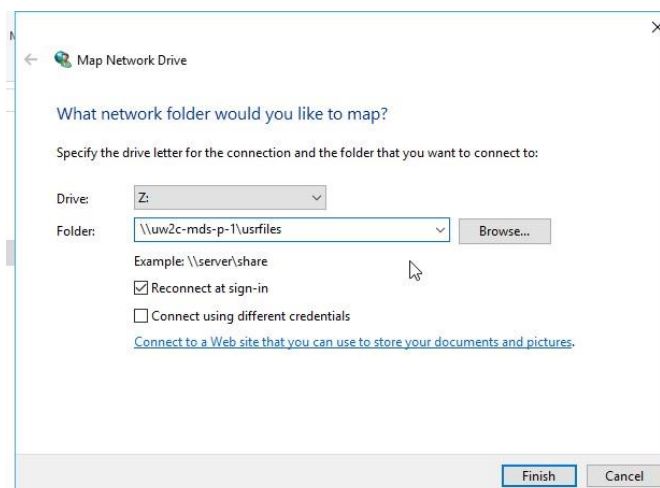
5.6.2 Map the USRFILES paths. Connect to Z: drive when got access to AWS file share following below steps.

5.6.2.1 Open File Explorer.

5.6.2.2 Click “This PC”.

5.6.2.3 At the top, select the “Computer” tab then select Map network drive.

5.6.2.4 Use address specified in AWS welcome letter send by GTS to map to Z: drive (that is \\uw2c-mds-p-1\usrfiles for AWS US or \\cnax-sas-p-1\usrfiles for AWS China).





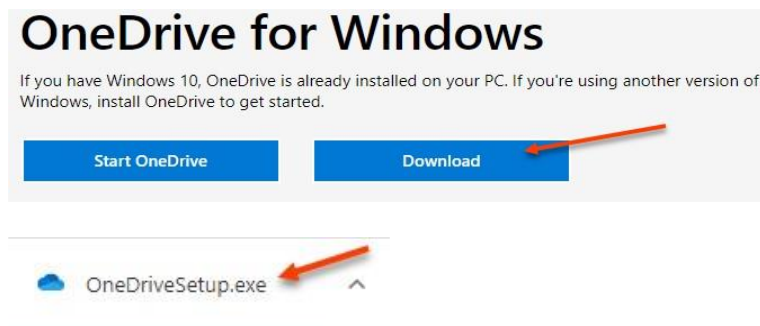
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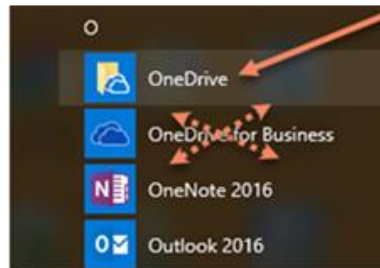
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5.6.3 Using Microsoft OneDrive on AWS Workspace. Only files stored on the BeiGene OneDrive account will be permanently stored. Saving files on OneDrive is also a good way to sync files between user AWS workspace and BeiGene laptop.

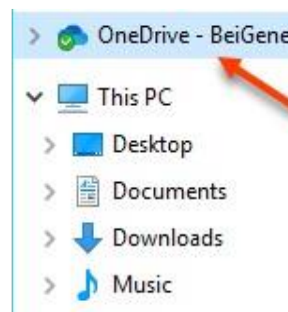
- 5.6.3.1 Download OneDrive from Microsoft website  
<https://www.microsoft.com/en-us/microsoft-365/onedrive/download>.  
Double click on the OneDriveSetup.exe icon and allow the install to finish.



- 5.6.3.2 Wait about 3 minutes. Click on Start menu on the AWS workspace and click on the folder icon called "OneDrive". DO NOT CLICK ON "OneDrive For Business".



- 5.6.3.3 From the Office365 Sign on Page, enter Office365 username and password to complete user OneDrive set up.



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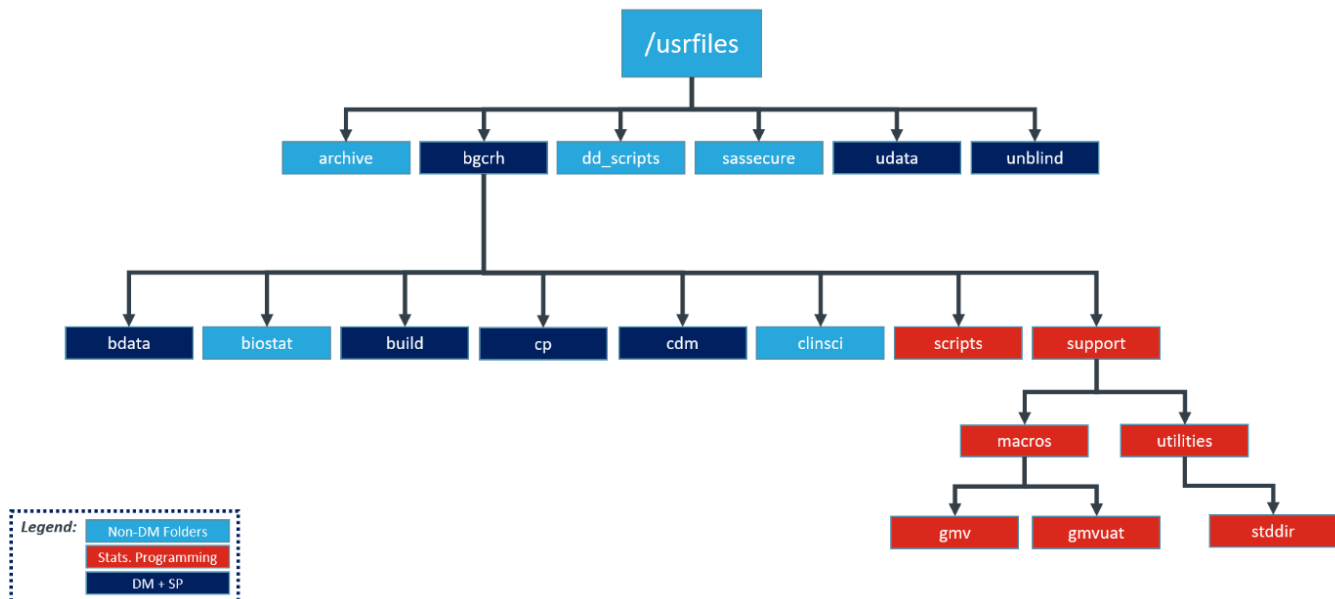
- 5.6.3.4 User can also access OneDrive online from <https://myapps.microsoft.com>.
- 5.6.4 For convenience of working within the workspace, the following applications will be accessible:
  - 5.6.4.1 **Microsoft Office** Package, including Outlook
  - 5.6.4.2 **Microsoft Teams** for instant message communication
  - 5.6.4.3 **Notepad++** - to view text files
  - 5.6.4.4 **Adobe Acrobat** - view PDF files
  - 5.6.4.5 **ExamDiff** - compare text files
  - 5.6.4.6 **FileZilla** - access to sFTP for secure file transfers
  - 5.6.4.7 **R**
  - 5.6.4.8 **Enterprise Guide (EG)** - to develop and execute programs
  - 5.6.4.9 **MobaExterm** - to use Linux commands
  - 5.6.4.10 **SAS Universal Viewer** - to view data
  - 5.6.4.11 **7-Zip** - to compress and un-compress ZIP files
- 5.6.5 Changing Passwords
  - 5.6.5.1 Passwords for AWS and Office365 are synced. The change to AWS password will update Office365 password automatically. AWS password expires every 90 days. Ensure to change the password when an email reminder is received.
  - 5.6.5.2 Once AWS password is changed, wait for approximately 15 minutes for it to sync with Office 365 password.
  - 5.6.5.3 When AWS password is changed, ensure to update the password in MobaXterm and SAS EG connection.

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### 5.7 AWS US General Directory Structure



5.7.1 AWS root file share is /usrfiles. It is the primary root folder for data storage and programming file shares.

5.7.2 Under usrfiles folder is archive, bgcrh, dd\_scripts, sassecure, udata and unblind.

5.7.2.1 **archive** folder is used to archive analyses programs and outputs for clinical study deliverables that have been completed and closed.


5.7.2.2 **bgcrh** stands for BeiGene Clinical Reporting Hub and contains sub-directory file shares for data storage and programming for blinded/masked data.

5.7.2.3 **dd\_scripts** is storage area for automation Data Analytics Engineering (DAE) tasks.

5.7.2.4 **sassecure** is storage area for SAS infrastructure files.

5.7.2.5 **udata** folder contains Unblinded / Unmasked EDC and other clinical source raw data used by unblinded personnel.

5.7.2.6 **unblind** folder contains all Unblinded / Unmasked data related program and outputs used by unblinded personnel.

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### 5.7.3 Below folders are sub-folders to: /usrfiles/bgcrh

Folder	Description / Purpose
bdata	Used for storing blinded/masked data from EDC and other vendors captured as part of the clinical study.
biostat	This folder is not used in the current state and is an artifact of old AWS architecture.
build	Sub-directory folder used for storing all the programming files. Raw data will not be stored in this folder.
cp	<ul style="list-style-type: none"> <li>- AWS working folder for Data Analytics Engineering (DAE) team.</li> <li>- Under CP folder there are 3 sub-folders: blinded, global, and unblinded.</li> <li>- The CP folder and its 3 sub-folders are created during the setup of AWS and no special actions are needed from the Data Analytics Engineering (DAE) team.</li> <li>- The Data Analytics Engineering (DAE) team will be responsible to create sub folders under these folders for their daily processes.</li> </ul>
cdm	This folder is not used in the current state and is an artifact of old AWS architecture.
clinsci	Used for sharing the reports between Clinical Science and Statistical Programming teams.
scripts	Area for global scripts spanning across all Beigene. Artifact of old AWS architecture.
support	Global programs which can be used for any product/study such as global macros are stored in this folder.

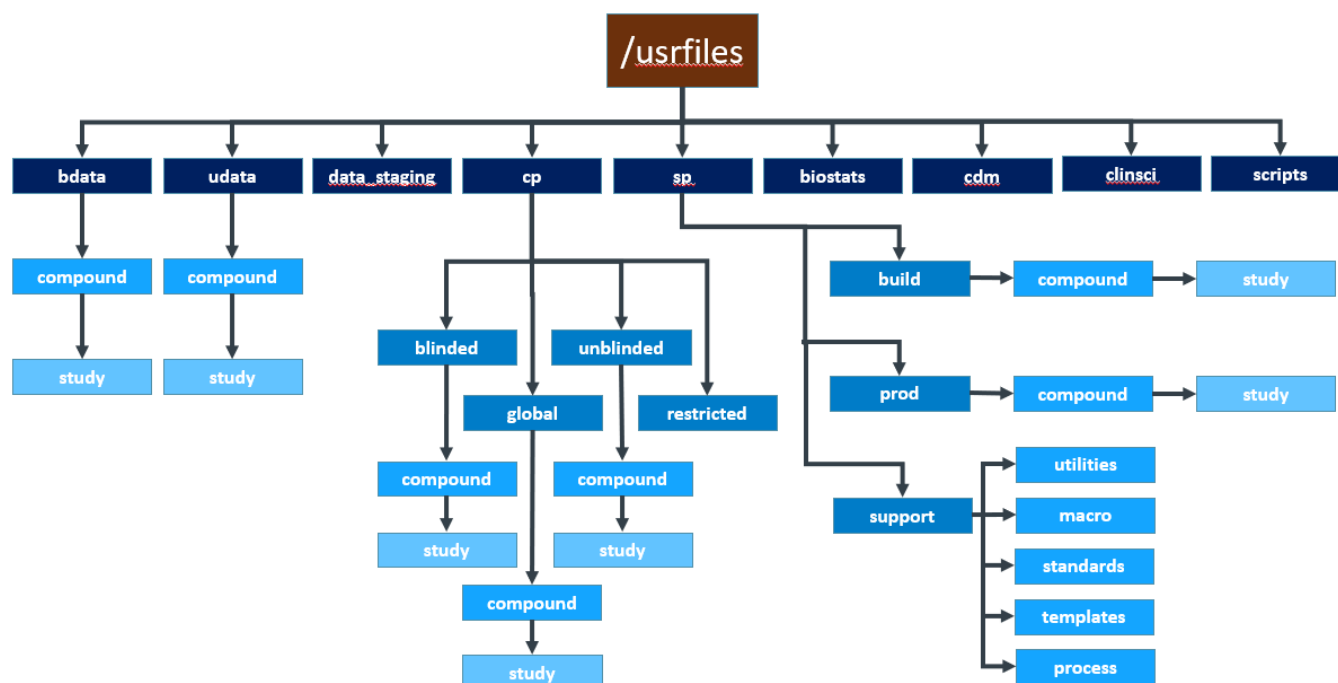
### 5.7.4 Refer to [WI \(VV-QDOC-00169 Statistical Programming\)](#) for more information of AWS directory structure.

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## 5.8 AWS China General Directory Structure



5.8.1 AWS root file share is /usrfiles. It is the primary root folder for data storage and programming file shares.

5.8.2 Under usrfiles folder is bdata, udata, data\_staging, cp, sp, biostats, cdm, clinsci and scripts. Unlike AWS US, the folders are separated by function in AWS China.

Folder	Description / Purpose
bdata	Used for storing blinded/masked data from EDC and other vendors captured as part of the clinical study.
udata	The same level with bdata. Used for storing unblinded/unmasked EDC and other clinical source raw data used by unblinded personnel.
cp	<ul style="list-style-type: none"> <li>- AWS working folder for Data Analytics Engineering (DAE) team.</li> <li>- Under cp folder there are 4 sub-folders: blind, global, restricted and unblinded.</li> <li>- These 4 folders will be created during the setup of AWS and no special actions are needed from the Data Analytics Engineering (DAE) team.</li> <li>- The Data Analytics Engineering (DAE) team will be responsible to create sub folders under these folders for their daily processes.</li> </ul>



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Folder	Description / Purpose
sp	<ul style="list-style-type: none"> <li>- All Statistical Programming activities will be done in this area.</li> <li>- Under sp folder is build, prod and support.</li> <li>- /build folder is for development, /prod folder is for production, macros and other utilities are in /support.</li> <li>- Under build, the folder structure is compound/ study/ analysis.</li> <li>- Folder for compound and study will be created by GTS.</li> <li>- Study lead programmer can create analysis folder.</li> <li>- Analysis folder can be restricted (limit only a few users to access) to handle the unblind information.</li> </ul>
biostats	AWS working folder for Statistics.
cdm	This folder is not used in the current state and is an artifact of old AWS architecture.
clinsci	AWS working folder for Clinical Science.
scripts	Area for global scripts spanning across all Beigene. Artifact of old AWS architecture.

5.8.3 Refer to [WI \(VV-QDOC-00169 Statistical Programming\)](#) for more information of Statistical Programming AWS directory structure. Refer to [WI \(VV-QDOC-16907 Data Management Guide to AWS US Fileshare\)](#) for more information of Data Management and Data Analytics Engineering (DAE) AWS directory structure.


## 5.9 Issue Reporting

5.9.1 AWS Workspace will go into suspend mode after 1 hour of inactivity. It may take up to 3-5 minutes for AWS Workspace to launch. AWS needs to start up after suspend mode. Be patient during the spinning wheel loading screen.

5.9.2 Report issues to [AskIT@beigene.com](mailto:AskIT@beigene.com). For Urgent issues related to macros, utilities or SAS programs, email to [AskIT@beigene.com](mailto:AskIT@beigene.com) and CC [yan.qiao@beigene.com](mailto:yan.qiao@beigene.com).

## 5.10 Data Archival and Retrieval

Refer to Appendix 2 - Data Archival and Retrieval for details.

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## 6. REFERENCES

### 6.1 Controlled Documents

6.1.1 SOP (VV-QDOC-12052 GSDS Data Access and Control)

6.1.2 WI (VV-QDOC-00169 Statistical Programming)

6.1.3 WI (VV-QDOC-00248 Unblinding of Individual and Group Treatment Assignments in Clinical Trials)

6.1.4 WI (VV-QDOC-01327 Data Integrity Protection in Clinical Trials)

6.1.5 WI (VV-QDOC-14391 GSDS Data Access Request and Access Management)

6.1.6 WI (VV-QDOC-16907 Data Management Guide to AWS US Fileshare)

### 6.2 Regulatory References

6.2.1 N/A


### 6.3 Other References

6.3.1 N/A

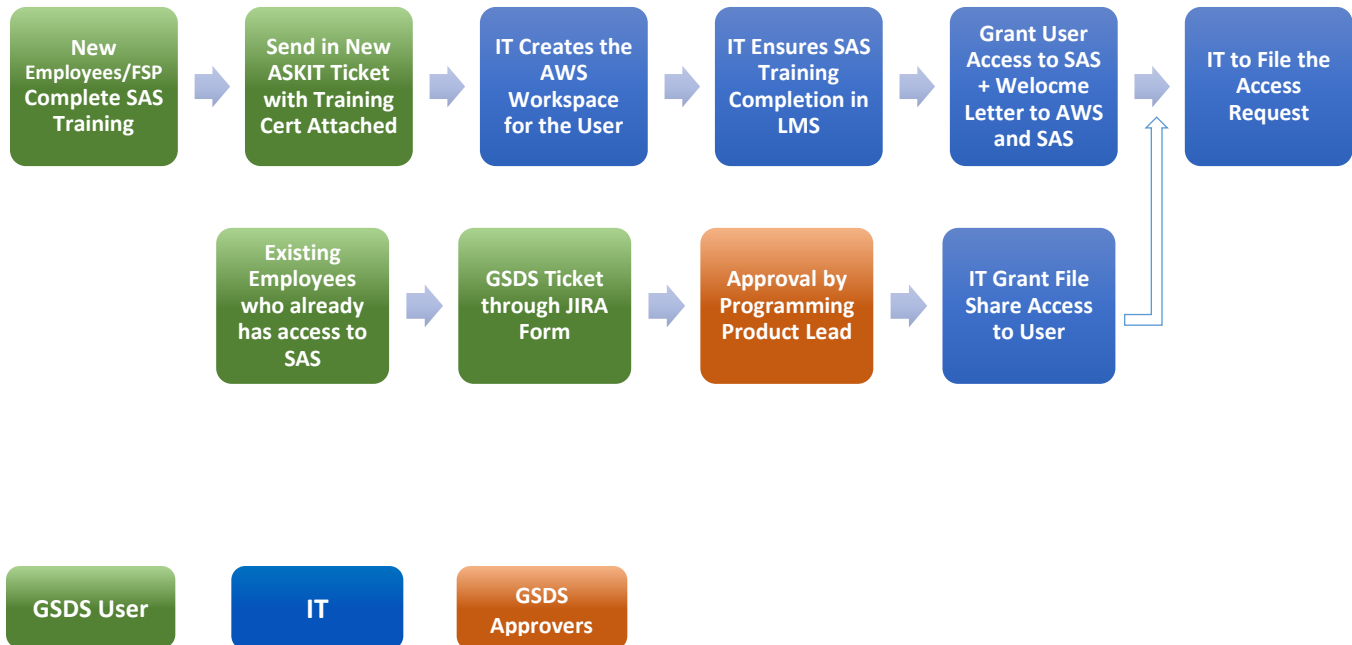
## 7. APPENDICES

7.1 Appendix 1 - Onboarding Workflow for SAS collectively

7.2 Appendix 2 - Data Archival and Retrieval

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## Appendix 1: Onboarding Workflow for SAS collectively







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**Appendix 2: Data Archival and Retrieval****A1 PURPOSE**

The purpose is to archive data/file in a cost-effective way and save space for AWS storage.

**A2 SCOPE**

The folders meet the criteria below and confirmed by functional SME would follow this process:

**A. Archive folders of bdata/udata:**

/usrfiles/udata/<Compound>/<Study>/current/sftp/\*/archive

/usrfiles/bgcrh/bdata/<Compound>/<Study>/current/sftp/\*/archive

**B. Analysis folder under build/unblind which are inactive in the last 18months (no changes):**

/usrfiles/bgcrh/build/<Compound>/<Study>/<Analysis>

/usrfiles/unblind/<Compound>/<Study>/<Analysis>

**C. Study CP folders with inactive data in the last 18 months (no change):**

/usrfiles/bgcrh/cp/blinded/<Compound>/<Study>/

/usrfiles/bgcrh/cp/unblinded/<Compound>/<Study>/

**Note:** further selection criteria of data archive could be defined by GTS and functional lead as needed.

**A3 INSTRUCTION****A3.1 Move Inactive Data to Cool Tier**

A3.1.1 GTS Identify the folders to be moved on a regular base.

A3.1.2 GSDS SME reviews and confirms the folders to be moved.

A3.1.3 GTS assess the validation effort and timeline with support from GSDS.

A3.1.4 GTS moves the target data/folders from hot tier to cool tier and informs GSDS user the completion of data movement.

A3.1.5 SAS User evaluates the performance and readability of data move to cool tier.

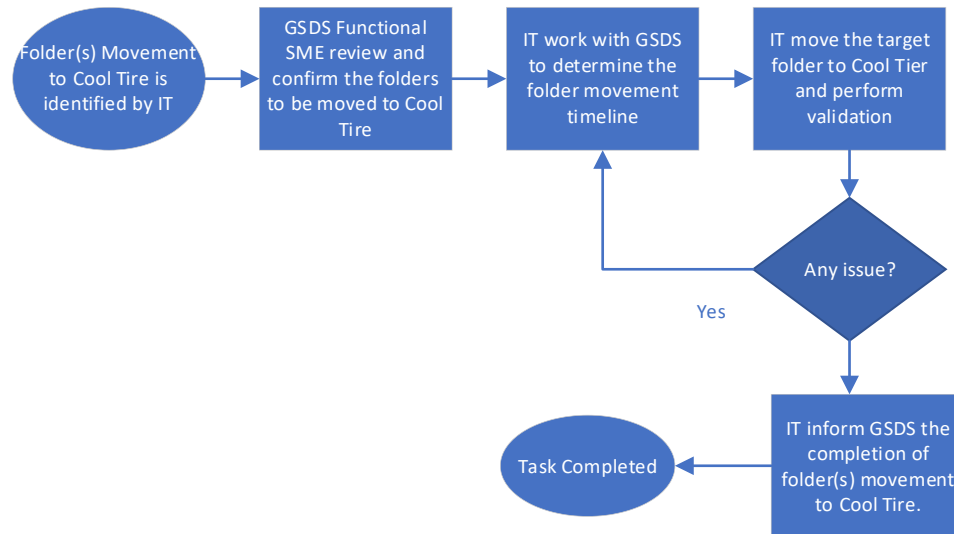
A3.1.6 GTS monitor the performance of cool tier to support daily access.

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### A3.1.7 Workflow Diagram



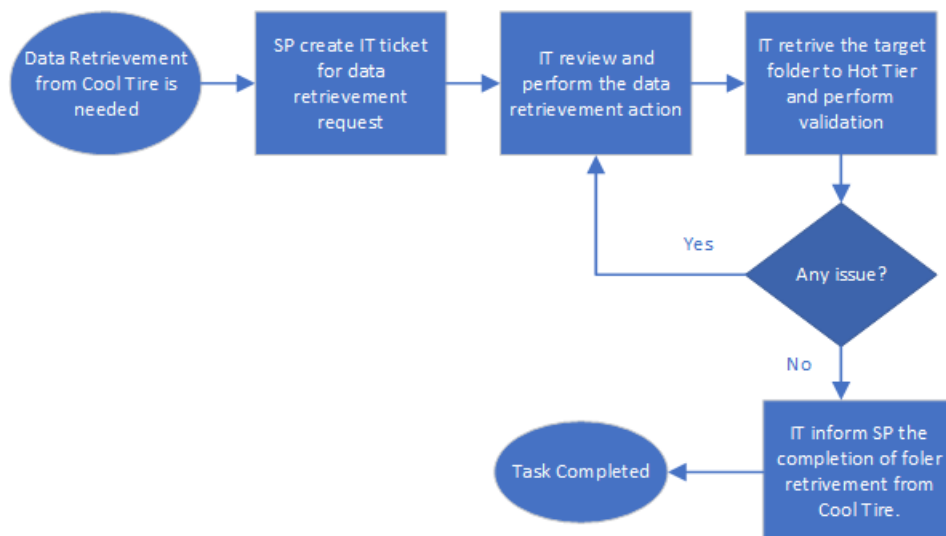
### A3.2 Retrieve Data from Cool Tier


A3.2.1 Upon necessary, SAS User identify the data/folder to be retrieved from cool tier.

A3.2.2 SAS User submits data/folder movement request via GTS ticket, eg. ASKIT ticket, with SPPL approval.

A3.2.3 GTS performs the data/folder movement task and informs SAS User the completion of data movement.

#### A3.2.4 Workflow Diagram



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## 8. DOCUMENT HISTORY PAGE

Version	Effective Date	Brief Description of Change
1.0	10 Aug 2018	Original Work Instruction.
2.0	23 Feb 2021	<ul style="list-style-type: none"> <li>○ Update the Work Instruction with the new template. Original WI is in PowerPoint format.</li> <li>○ Rename the Work Instruction from “SAS User Training” to “SAS and AWS User Training”.</li> <li>○ Split SAS and AWS Fileshare as two separate “Systems”. Add instructions for applying for access of SAS and AWS respectively.</li> <li>○ Remove the approval step of Head of Statistical Programming when user apply for SAS access.</li> </ul>
3.0	15 Oct 2021	<ul style="list-style-type: none"> <li>○ Update connection settings for Lustre Migration and AWS China Migration in section 5.3.1.3.1, 5.3.2.3.1, 5.3.2.3.2, 5.6.2 and 5.6.2.4.</li> <li>○ Update access request form name in section 5.5.1.3.</li> <li>○ Added section 5.8 to include general directory structure for AWS China.</li> <li>○ Update section 5.5.2, 6.1.2 and 5.7.2.3 for administrative change.</li> <li>○ Updated Data Processing team name to Clinical Data Engineering.</li> </ul>
4.0	24 Jul 2023	<ul style="list-style-type: none"> <li>○ Updates: <ul style="list-style-type: none"> <li>• Updated AWS US folder hierarchy map.</li> <li>• Changed Clinical Data Engineering to Data Analytics Engineering (DAE).</li> <li>• Changed IT to GTS.</li> <li>• Updated the screenshot in section 5.1.1.3 and 5.1.1.4 to consistent with current system version.</li> </ul> </li> <li>○ Added GSDS, GTS and FSP in section 3.</li> <li>○ Added new section 5.10 Data Archival and Retrieval</li> <li>○ Added Appendix 2 - Data Archival and Retrieval</li> </ul>

## Document Approvals

Approved Date: 21 Jun 2023

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