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	Statistical Programming sFTP Structure and Data Processing	
Company Confidential	Document No.: VV-QDOC-14393 Version: 1.0, Effective Date: 21 Dec 2020	

1. PURPOSE

This document describes the process of receiving, sending and organizing of data by Statistical Programming team utilizing the secure File Transfer Protocol (sFTP), and provides the necessary organizational folder structure within for Statistical Programming's sFTP folder.

2. SCOPE

This Work Instruction (WI) applies to all BeiGene staff, Functional Service Providers (FSP), and Contract Research Organizations (CROs) that gain access to BeiGene Statistical Programming sFTP folder. The data definition and data processing steps defined in this document are applicable to all ongoing studies while the standard folder structure will only be applicable to studies starting after the document's effective date.

3. ABBREVIATIONS AND DEFINITIONS

3.1   **ADaM** - Analysis Dataset Model

3.2   **AWS:** Amazon Web Services Workspace – A secured virtual environment/directory in which Statistical and Clinical programs are developed and maintained.

3.3   **Blinding:** A procedure in which one or more parties to the trial are kept unaware of treatment assignment.

3.4   **Blinded Data:** The data where the treatment assignment for the patients are either scrambled or hidden from one or more parties involved with the trial.

3.5   **Case Report Form (CRF)**: A printed, optical, or electronic document designed to record all the protocol required information to be reported to the sponsor on each trial subject.

3.6   **Case Report Form Database (CRF Database):** A relational database software application, often an Electronic Data Capture System (EDC), in which clinical trial CRF data is entered and maintained by the site.

3.7   **EDC:** Electronic Data Capture – A validated software application for the collection and management of Case Report Form (CRF) data.

3.8   **External Electronic Data:** All subject non-CRF data received and maintained outside of the CRF Database such as, but not limited to, central lab and pharmacokinetics data.

3.9   **IRT:** Interactive Response Technology – A web-based computerized system used to manage randomization, subject visits, drug dispensation to subjects, and drug inventory/supply.

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3.10 **MoveIT:** A vendor product used by BeiGene to provide sFTP services.

3.11 **Masked Data:** The data in which the treatment effect data of the patients is either scrambled or hidden from one or more parties involved with the trial.

3.12 **SDTM** – Study Data Tabulation Model

3.13 **sFTP:** Secure File Transfer Protocol: A secure version of File Transfer Protocol (FTP), which facilitates data transfer over a Secure Shell (SSH) data stream.

3.14 **Unblinded Data:** The data where the treatment assignment for the patients is readily available for the individuals involved with the trial.

3.15 **Unmasked Data:** The data in which the treatment effect data of the patients is readily available for individuals involved with the trial.

4. RESPONSIBILITIES

4.1 IT Support Representative:

   4.1.1 Creates an account in the sFTP system for any individuals requiring access to sFTP.

   4.1.2 Receives requests from completion of Statistical Programming sFTP Access Management form in JIRA and within 2 business days of request receipt:

   4.1.2.1 Confirms proper approvals have been received on the form

   4.1.2.2 Creates or deletes folders in the sFTP system as requested

   4.1.2.3 Grants, modifies, or revokes access to individuals as requested

4.2 Statistical Programming Product Program Lead:

   4.2.1 Within 2 business days of request receipt, reviews and approves/rejects any requests received via Statistical Programming sFTP Access Management form in JIRA for a study folder creation and/or granting access for an individual to a study folder in sFTP.

   4.2.2 Checks with the Study Programmer for any request outside the Statistical Programming team, to ensure the validity of the request.

4.3 Statistical Study Programmer:

   4.3.1 Identifies the need for using sFTP to exchange data with vendor/collaborators and confirms with vendor/collaborators for any request already requested.

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4.3.2   Requests the folder structure creation for a study and any of its sub-folders.

4.3.3   Identifies and completes the Statistical Programming sFTP Access Management form in JIRA for adding, updating, and removing users to any folders in sFTP.

4.3.4   Communicates the folder link and access status to the vendor/collaborator.

4.3.5   Setup automated scripts or transfer the data received in sFTP manually to AWS if automated scripts cannot be used.

4.3.6   Requests for folder deletion after the completion of the study.

4.4   Vendor/collaborator:

4.4.1   Provides the credentials of individuals to the Study Programmer who will be responsible in posting or retrieving the data from the sFTP folder.

4.4.2   Posts or retrieves the data from the sFTP folder.

5.   INSTRUCTION

5.1   Background

For a clinical trial, there are various sources of data (e.g.; data entered in CRF Database, lab data, IRT data, etc.). The method in which the data will be acquired by BeiGene is dictated by the type of data and its source, which can vary from one clinical study to another.

The infrastructure used by BeiGene to exchange external electronic data with its vendor/collaborator is through secure File Transfer Protocol (sFTP) service platform. sFTP is used to securely transfer data between the organizations and follows a structured process described in this document. Any data which is exchanged through sFTP will be required to be moved to a permanent location as sFTP is only a temporary data exchange platform and not a storage location to store the data permanently. BeiGene uses MoveIT as its service provider for sFTP system and 'MoveIT' is often used synonymously to sFTP within the organization.

5.2   Type of Data Stored in Statistical Programming's Analysis sFTP Folder:

5.2.1   Any analysis data related to a clinical or nonclinical study which needs to be exchanged with any external vendor/collaborator. This includes all incoming or outgoing study data for analysis, such as SDTM, ADaM, Results data to DMC, data to publication vendor, etc.

5.2.2   *Analysis* folder should be strictly used to exchange data where Statistical

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Programming team is responsible for either acquiring, sending, and reviewing of the data.

5.2.3　For data where there are no actions required from the Statistical Programming team or the Statistical Programming team will not be using the data received from the vendor/collaborator, this data should not be exchanged through the *Analysis* folder in sFTP. Such data needs to be exchanged with the vendor/collaborator using a folder outside of *Analysis* sFTP folder. The team responsible for using such data will need to establish a data exchange folder with the vendor/collaborators in sFTP outside of *Analysis* sFTP folder.

Example: Contracting documents created for Clinical Operations, etc.

5.3　Standard Folder Structure of *Analysis* sFTP Folder:

5.3.1　The *Analysis* folder will follow a standard structure for all products and studies where an sFTP folder is required for an electronic file exchange. This standard and consistent folder structure will streamline the process of using sFTP and aid in effectively manage restrictions to folders.

5.3.2　The root *Analysis* folder will consist of subfolders based on each product.

5.3.3　Every product subfolder under the *Analysis* folder will be further broken down into three levels:

　　5.3.3.1　Blinded Data – Used for exchanging blinded/masked data on product level.

　　5.3.3.2　Unblinded Data – Used for exchanging unblinded/unmasked data on product level.

　　5.3.3.3　Studies – Used for exchanging study level information.

5.3.4　Studies folder is further divided into two levels:

　　5.3.4.1　Blinded Data – Used for exchanging blinded/masked data on study level.

　　5.3.4.2　Unblinded Data – Used for exchanging unblinded/unmasked data on study level.

5.3.5　All files related to a study will be stored either under the blinded data or under the unblinded data folder by creating the subfolder underneath them. The subfolder being created should be named with the vendor/collaborator name with whom the files will be exchanged.
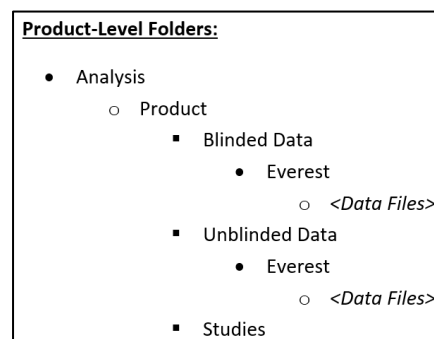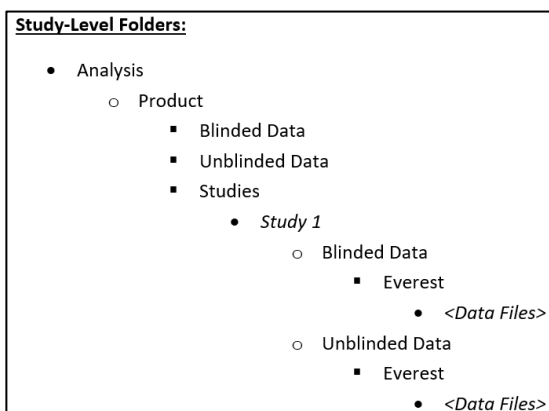
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5.3.6   If files are exchanged over a period with the same vendor/collaborator, the same subfolder needs to be reused.

5.3.7   No subfolders within the vendor/collaborator should be created. The file naming convention should help indicate the necessary information for the file. Information such as date of receipt, type of data included, etc.

Below is the structure of the Study-Level and Product-Level folder structure within the *Analysis* folder:

Study-Level Folders:

- Analysis
  - Product
    - Blinded Data
    - Unblinded Data
    - Studies
      - *Study 1*
        - Blinded Data
          - Everest
            - *<Data Files>*
        - Unblinded Data
          - Everest
            - *<Data Files>*

Product-Level Folders:

- Analysis
  - Product
    - Blinded Data
      - Everest
        - *<Data Files>*
    - Unblinded Data
      - Everest
        - *<Data Files>*
    - Studies

Note: For any outsourced trial, the folder structure should be consistent with any in-house trials.

5.4   sFTP Structural Details

5.4.1   sFTP can be accessed through the BeiGene myapplications.microsoft.com page and by clicking on the MoveIT Transfer tile. To get the tile on the myapplications page, request access to MoveIT by sending an email to AskIT@beigene.com.

5.4.2   IT Support Representative will be creating all the folders in sFTP and will help grant access to appropriate users mentioned in the access request. Request should be made to IT Support Representative via the Statistical Programming sFTP Access Management form in JIRA. Refer to WI *GSDS Data Access Request and Access Management* (VV-QDOC-14391) for more information on the process of requesting access to sFTP via forms in JIRA.

5.4.3   All sub-folders created within any folder will inherit access permissions from its parent study/product folder and caution needs to be taken when creating folders to be shared with vendor/collaborators. Example: If User A has access to a study BGB-1234-123, then that User A will automatically get access to all sub-folders created under that study.

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5.4.4 If any folder/sub-folder needs restricted access, the request needs to be made to IT Support Representative via the Statistical Programming sFTP Access Management form in JIRA.

5.4.5 Approvals from the Statistical Programming Product Lead will be required prior to the creation of and gaining access to any study's folders.

5.4.6 For access to all product and all studies, the functional head's approval will be required prior to requesting access to all study folders. Refer to the SOP *GSDS Data Access and Control* (VV-QDOC-12052) and WI *GSDS Data Access Request and Access Management* (VV-QDOC-14391) for more details on sFTP access management.

5.5 Data Processing

5.5.1 sFTP is a temporary data exchange platform and not a permanent location to store any study related data. All data received in the *Analysis* sFTP folder will need to be moved to a permanent storage area for further usage. AWS is used as the permanent location; the data will need to be moved to the appropriate folder in AWS. Refer to the WI *Statistical Programming* (VV-QDOC-00169) for further information on storing data in AWS, dependent on the type of data.

5.5.2 Statistical Programming Product Lead or Study Programmer will be responsible for any data received in the *Analysis* folder and its move to the permanent location in AWS.

5.5.2.1 Data received in sFTP can either be moved using automated scripts, manually, or by using applications such as FileZilla, etc.

5.6 Data Purging Rule

5.6.1 Data in the sFTP *Analysis* folder will be deleted after 15 calendar days of the receipt of the data.

5.6.2 Data that requires manual move to its permanent location will need to be moved prior to the 15th day from the receipt of the data.

5.7 Folder Deletion

5.7.1 Study Programmer is responsible to request deletion of folder(s) for a study after the study is completed. Use the Statistical Programming sFTP Access Management form in JIRA to initiate this request to IT Support Representative.

5.7.2 IT Support Representative will delete the folder as requested through the completion

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of Statistical Programming sFTP Access Management form in JIRA.

6. REFERENCES

6.1 Controlled Documents

6.1.1 VV-QDOC-00169 - WI - *Statistical Programming*

6.1.2 VV-QDOC-12052 - SOP - *GSDS Data Access and Control*

6.1.3 VV-QDOC-14391 - WI - *GSDS Data Access Request and Access Management*

6.2 Regulatory References

6.2.1 N/A

6.3 Other References

6.3.1 N/A

7. APPENDICES

7.1 N/A

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8.   DOCUMENT HISTORY PAGE

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1.0	21 Dec 2020	Original Work Instruction.

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