Pinnacle 21 Enterprise Training Exercises

This training also applies to ADaM data – the choice is yours for the type of data you select.

# Exercise 1: Log in to Citrix

## Problem

Log in to Citrix and locate folders and applications required

## Solution

* Log in to Citrix (<https://citrix.lilly.com>) – network or VPN required
* 2 locations are required
  + For SAS activities (and file processing)
    - Open folder AWE 🡪 English then select application AWE 101-300
    - Click OK on the Windows Login screen
    - File Explorer opens at the awe.grp location
    - Navigate to SDDEXT255 / Pinnacle / Training
  + For Pinnacle Enterprise
    - Open folder Z1\_OpenCDISC then select application Z1\_OpenCDISC
    - Click OK on the Windows Login screen

# Exercise 2: Get the data into XPT format

## Problem

Datasets are stored in SAS dataset format – SAS7BDAT – and need to be converted to SAS Transport Files for use in Pinnacle Enterprise.

## Solution

* In File explorer, navigate to \\Mango\awe.grp\SDDEXT255\Pinnacle\Training\Programs
* Right click on create\_xpt.sas file and select Open with SAS 9.2 (The program editor opens in SAS)
* Edit the output path (scroll to the following line and edit it to reflect **your** output folder where it says <name> - Take note of the drive letter mapping):

libname out&iter xport "Z:\SDDEXT255\Pinnacle\Training\Data\Training Trial SDTM xpts 1\&inMember..xpt";

… to…

libname out&iter xport "Z:\SDDEXT255\Pinnacle\Training\**Users\<name>\xpt**\&inMember..xpt";

(Check the following folder to check/find the name of your user folder: "Z:\SDDEXT255\Pinnacle\Training\**Users”**

**If using ADaM data, also update**

libname indata "Z:\SDDEXT255\Pinnacle\Training\Data\Training Trial **SDTM** SASData";

**to**

libname indata "Z:\SDDEXT255\Pinnacle\Training\Data\Training Trial **ADAM** SASData";

\* Note – if the drive letter mapping is another letter, please just use that one instead!

* Click the running man icon to execute the program.
* Check the folder for the existence of XPT files. (\\Mango\awe.grp\SDDEXT255\Pinnacle\Training\Users\***<name>***\xpt)

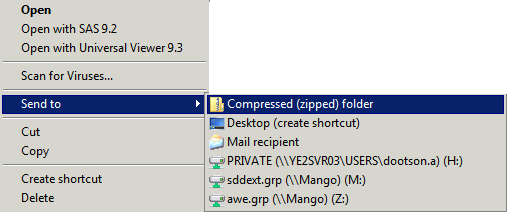
# Exercise 3: Create the Zip file

## Problem

Prepare the zip file for data compliance

## Solution

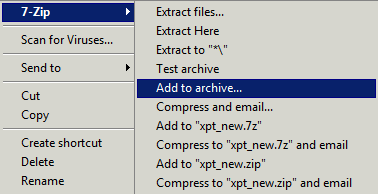
* In the folder of XPT files (\\Mango\awe.grp\SDDEXT255\Pinnacle\Training\Users\<***name>***\xpt)
  + Select all the files (all xpt) and right click 🡪 Send to 🡪 compressed (zipped) folder



* Change the name of the archive to something that you recognize i.e. Training Trial 1.zip
* Select OK
  + The zip file now exists in the same folder

\* Should you find that the compressed file is created automatically and there is not the chance to name the file and do not have to select ok, the file will be auto-named, which can then be renamed

If the option is to use 7-zip (It depends on the AWE server that you connect to automatically) then follow the steps below:



* Select all the files (all xpt) and right click 🡪 select 7-Zip 🡪 Add to archive…
* Change the name of the archive to Training Trial SDTM 1.zip (or Training Trial ADaM 1.zip)
* Change the archive format to zip

# Exercise 4: Logging in to Pinnacle Enterprise

## Problem

Log in correctly to Pinnacle Enterprise

## Solution

* From the homepage in Citrix (<https://lilly.opencdisc.com>) click on Log in with Single Sign on
  + It should log you on without any intervention
* Pinnacle Enterprise appears at the Home Page.

# Exercise 5: Run Data Validation

## Problem

Run data validation on our data

## Solution

* On the home page you will see studies you have access to (Training\_<yourname>)
  + There will be one entry for each data package (i.e. one for SDTM and one for ADaM)
* From the home page, click Validate Study that appears in the row for the study with the relevant data package
* Click Select File on the Validate Data screen
* Navigate to \\Mango\awe.grp \SDDEXT255\Pinnacle\Training\Users\<name>\xpt
* Select the zip file, Training Trial SDTM (or ADaM) 1.zip and click Open
* Click Validate
  + The Aspera client will launch, click Allow, and you can see the data loading (Make sure you are in Citrix)
  + Close the Aspera popup window after the Aspera data loading is marked “Done”
  + The Validation Log screen appears
  + Click Refresh and wait until your study appears as Complete (the status may initially read “Pending” or “InProgress”)

# Exercise 6: Manage Issues

## Problem

Check and manage issues for the study

## Solution

* From the Validation Log screen click View Reports for the study
* Review the Data Fitness Scorecard
* Review Datasets and Issues
* Export the Validation Report and Save-as to your User folder
* Review the Validation Report
* Action Multiple issues
  + Select the first two AE (or ADAE if using ADaM data) issues (click the check boxes on the left side) and click Actions 🡪 Comment
  + Add your comment to the issues
  + Click Comment
  + Review changes to Issue tab
* Assign issues
  + Select multiple issues
  + Click Actions 🡪 Assign
  + Choose your user name
  + Click Assign
  + Review what happens
* Close issues
  + Select multiple issues
  + Click Actions 🡪 Change Status 🡪 Closed then click Change Status
  + Review the outcome

# Exercise 7: Validate Updated Datasets

## Problem

Data has been reviewed and updated and now needs to be run through the data validation process again

## Solution

* From the home page, click Validate Study that appears in the row for the study with the relevant data package
* Click Select File on the Validate Data screen
* Navigate to \\Mango\awe.grp\SDDEXT255\Pinnacle\Training\Users\<name>
* Select the zip file, Training Trial SDTM (or ADaM ) 2.zip and click Open
* Click Validate
  + The Aspera client will launch and you can see the data loading
  + The Validation Log screen appears
* Click Refresh and wait until your study appears as Complete

# Exercise 8: Compare Current to Prior Data

## Problem

Data has been reviewed and updated and re-run and now needs to be compared

## Solution

* From the Validation Log screen click View Reports
* Click the “History” tab on the dashboard screen
* Scroll down the page, select the top 2 dates - i.e. the latest 2 validation runs (these are selected by default) then click Compare
* A new Comparison tab opens and you can review the New, Updated, Resolved issues
* Click back to the issues tab to continue managing issues

# Exercise 9: Create a Study

## Problem

Once the System Manager has created the project and assigned the Project Manager, the Project Manager creates a study

## Solution

* On the home page you will see studies you have access to
* On the left, click on Configure, then click on Studies
* That will bring up a page showing studies you already have access to
* Click on the ‘+ New Study’ button in green at the top of the page
  + Name is a required field– this is the name of your study
  + Below Name, there is a Project drop-down box.  Only Projects that you have access to will be shown as options
  + Description, Protocol Name, Phase, Indication, Vendors, Users, and Groups are optional fields
  + Any people you want to have access to the study need to be added to Users.  When you click in Users, a drop down box will pull up all people with accounts
* Click Save
  + After clicking ‘Save’; ‘Add Data Package’ and ‘Create another Study’ will appear as options next to the ‘Save’ button

# Exercise 10: Create a Data Package

## Problem

The study is created but it is not possible to validate everything at once (I.e. SDTM, ADaM, Blinded etc), so create a Data Package

## Solution

* Click on Configure, then Studies
* Click on the name of a Study
* To add a data package, hit ‘Data Packages’ at the top of the page
* Click ‘+ Add Data Package’ green button at the top of the page
  + Pick a name for your Data Package like SDTM 3.1.3, ADaM 1.0, Blinded, Unblinded
  + Study is a drop down with all the studies you have access to
  + Standard is a drop down box.  Choose the appropriate standard.  That will automatically populate Dictionaries section
  + If you want other people to have access to your data package, you will need to add them under Users
* Click Save