

SCREEN SHOTS

Start PKView

Go to link [/localhost](http://localhost) using Firefox, Google Chrome, or MS Edge

Project ID	Project Name	Status	Action
DRUG000	New pk analysis	Green	More
DRUG006	DRUG006-more	Green	More
DRUG006	DRUG006	Green	More
DRUG010	LEEP 2016-03-15-085010	Green	More
DRUG026	DRUG026 6-28-2016	Green	More
DRUG031	LEEP 2015-05-24-070919	Green	More
DRUG035C	LEEP 2015-08-25-073447	Green	More
DRUG037	DRUG037-pilot	Green	More
DRUG039	DRUG039-005	Green	More
DRUG039	Drug039-meta analysis	Green	More
DRUG039	DRUG039-pilot	Green	More

Create or Modify a Project

Click “Advance” and select “+New”

The screenshot shows the iPortal interface with the 'PkView' tab selected. The main area displays a list of projects under 'Your projects'. A context menu is open over the first project, 'DRUG000', with options: '+ New', 'Share', and 'Import'. The list includes the following items:

Project ID	Project Name	Actions
DRUG000	New_pk_analysis	[New, Share, Import]
DRUG006	DRUG006-more	[New, Share, Import]
DRUG006	DRUG006	[New, Share, Import]
DRUG010	LEEP_2016-03-15-085010	[New, Share, Import]
DRUG026	DRUG026 6-28-2016	[New, Share, Import]
DRUG031	LEEP_2015-05-24-070919	[New, Share, Import]
DRUG035C	LEEP_2015-08-25-073447	[New, Share, Import]
DRUG037	DRUG037-pilot	[New, Share, Import]
DRUG039	DRUG039-005	[New, Share, Import]
DRUG039	Drug039-meta analysis	[New, Share, Import]
DRUG039	DRUG039-pilot	[New, Share, Import]

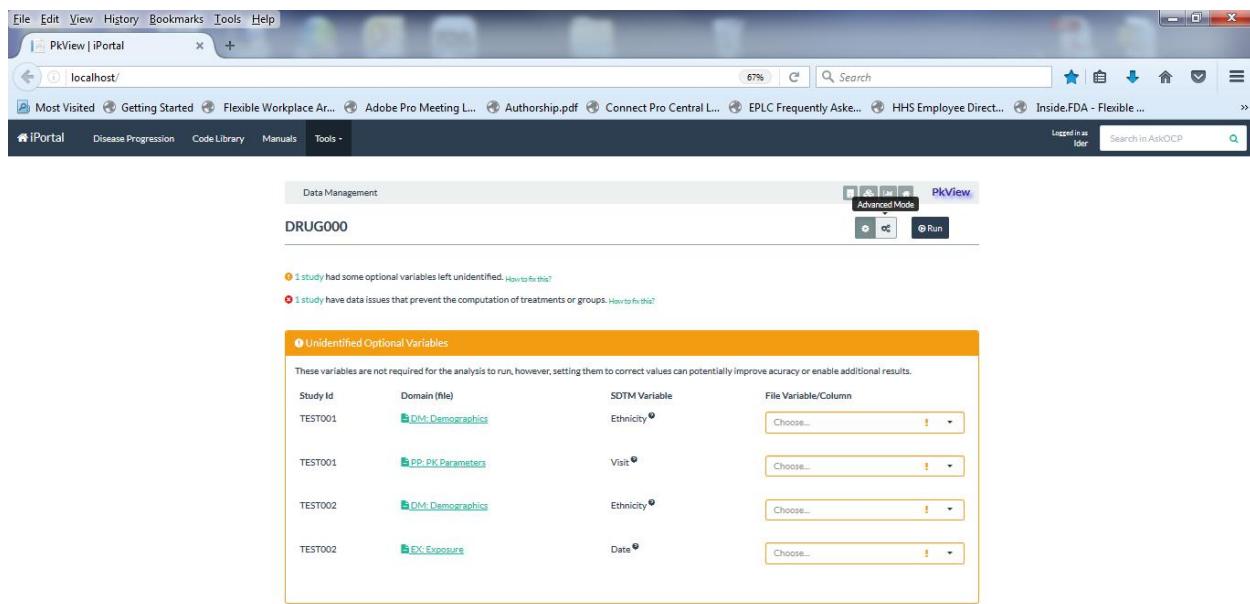
Select 'DRUG000' in the "Submission" box

Give a "Project Name"

Click "Create Project"

The screenshot shows the iPortal interface with the 'PkView' tab selected. A 'New project' dialog box is open in the center. It contains fields for 'Submission' (set to 'DRUG000') and 'Project name' (set to 'New_pk_analysis'). A 'Create project' button is at the bottom right of the dialog. The background shows the 'Your projects' list, which is identical to the one in the first screenshot.

Go to “Advance mode”



The screenshot shows a web browser window titled "PKView | iPortal" with the URL "localhost". The top navigation bar includes "File", "Edit", "View", "History", "Bookmarks", "Tools", and "Help". Below the toolbar, there's a search bar and a menu bar with links like "Most Visited", "Getting Started", "Flexible Workplace Ar...", "Adobe Pro Meeting L...", "Authorship.pdf", "Connect Pro Central L...", "EPLC Frequently Asked Q...", "HHS Employee Direct...", "Inside.FDA - Flexible ...". The main content area is titled "Data Management" and displays a study named "DRUG000". A prominent button labeled "Advanced Mode" is visible. Below the study title, there are two status messages: "1 study had some optional variables left unidentified." and "1 study have data issues that prevent the computation of treatments or groups." A large orange box highlights the "Unidentified Optional Variables" section. This section lists four entries, each with a "Domain (file)" link, an "SDTM Variable", and a "File Variable/Column" dropdown menu. The entries are:

Study Id	Domain (file)	SDTM Variable	File Variable/Column
TEST001	DM-Demographics	Ethnicity <small>?</small>	Choose... <small>!</small>
TEST001	PP-PK Parameters	Visit <small>?</small>	Choose... <small>!</small>
TEST002	DM-Demographics	Ethnicity <small>?</small>	Choose... <small>!</small>
TEST002	EX-Exposure	Date <small>?</small>	Choose... <small>!</small>

Data Management

Make the following mapping for each option:

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PkView | iPortal localhost/ 80% Search

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Logged in as Ider Search in AskOCP

DRUG000 - TEST002

TEST001 2 TEST002 2

General Study Information

Study Design Crossover Reference Trt/Grp FASTED

Determine study design based on DM (not EX) Determine treatments/groups based on EX (not DM)

Use SUPPDIM to help determine treatments/groups Use user reviewed study arms

Additional options

Disable initial PC data cleanup Cumulative in report

Subject C_T Correlation in report Scatter Plot in report

Demographic table in report

DM - Demographics

Subject Id USUBJID - USUBJID Arm ARM - Description of Planned Arm

Age AGE - Age Sex SEX - Sex

Race RACE - Race Country COUNTRY - Country

View Data

File Edit View History Bookmarks Tools Help

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Logged in as Ider Search in AskOCP

DM - Demographics

Subject Id USUBJID - USUBJID Arm ARM - Description of Planned Arm

Age AGE - Age Sex SEX - Sex

Race RACE - Race Country COUNTRY - Country

Ethnicity Choose...

View Data

EX - Exposure

Treatment EXTRT - Name of Actual Treatment Date Choose...

Visit EPOCH - Epoch

View Data

PC - Concentration

Visit VISIT - Visit Name Test PCTESTCD - Pharmacokinetic Test Short

Result PCSTRESN - Numeric Result/Finding in S. Planned Tp. PCTPT - Planned Time Point Name!

View Data

PP - PK Parameters

Visit VISIT - Visit Name Category PPCAT - Parameter Category

Result PPSTRESN - Numeric Result/Finding in S. Test PPTESTCD - Parameter Short Name

View Data

Click "Edit" button for "PP: VISIT".

Check “Use user defined value mappings”, and enter ‘Day 01’ and ‘Day 02’ as shown

Click “Save and close”

Note: For each subject, the following rules must be met.

- The alphabetical order of “PP:VISIT” must correspond to its chronological order.
- The corresponding values in “PP:VISIT” and “PC:VISIT” must be matched on the PK sampling days.
- The chronological order of “PP:VISIT” must match the order of periods in “DM:ARM”. The number of unique values in “PP:VISIT” and “DM:ARM” must be the same.
- VISIT will be sorted as Character. For example: the set (Day 1, Day 2, Day 3, Day 10, Day 11) will be sorted as (Day 1, Day 10, Day 11, Day 2, Day 3). Therefore the correct entries should be (Day 01, Day 02, Day 03, Day 10, Day 11).

File Edit View History Bookmarks Tools Help

PkView | iPortal

localhost/

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Search

Edit PP:VISIT (VISIT)

Use user defined value mappings

Original value	User defined value
TRT PERIOD1-D1	DAY 01
TRT PERIOD2-D1	DAY 02

Recalculate Save and close

Treatment EXTRT - Name of Actual Treatment Choose...

Visit EPOCH - Epoch

PC - Concentration

Visit VISIT - Visit Name Test PCTESTCD - Pharmacokinetic Test Short

Result PCSTRESN - Numeric Result/Finding in S. Planned Tp. PCTPT - Planned Time Point Name

PP - PK Parameters

Visit VISIT - Visit Name Category PPCAT - Parameter Category

Result PPSTRESN - Numeric Result/Finding in S. Test PPTESTCD - Parameter Short Name

Click “Edit” button for “PC: VISIT”.

Check “Use user defined value mappings”, and enter values as shown

Click “Save and close”

Note: For each subject, the following rules must be met.

- The alphabetical order of “PC:VISIT” must correspond to its chronological order.

- The corresponding values in “PP:VISIT” and “PC:VISIT” must be matched on the PK sampling days. “PC:VISIT” may have more visits than “PP:VISIT”, for example: visits during screening, washout, follow-up.

Edit PC:VISIT (VISIT)

Original value	User defined value
TRT PERIOD1-D1	DAY 01
TRT PERIOD1-D2	DAY 01
TRT PERIOD1-D3	DAY 01
TRT PERIOD2-D1	DAY 02
TRT PERIOD2-D2	DAY 02
TRT PERIOD2-D3	DAY 02

PP - PK Parameters

Visit	VISIT - Visit Name
Category	PPCAT - Parameter Category
Result	PPSTRESN - Numeric Result/Finding in S.

Test

Test	PPTESTCD - Parameter Short Name
------	---------------------------------

Change PC: “Planned Tp” to ‘PCTPT’

The screenshot shows the PKView iPortal software interface. At the top, there's a navigation bar with links like 'File', 'Edit', 'View', 'History', 'Bookmarks', 'Tools', and 'Help'. Below the navigation bar, the title 'PKView | iPortal' is displayed. The main area contains several data entry forms:

- Demographics**: Fields include Subject Id (USUBJID - USUBJID), Age (AGE - Age), Race (RACE - Race), Ethnicity (Choose...), Arm (ARM - Description of Planned Arm), Sex (SEX - Sex), and Country (COUNTRY - Country).
- EX - Exposure**: Fields include Treatment (EXTRT - Name of Actual Treatment) and Visit (EPOCH - Epoch). A 'Date' field is also present.
- PC - Concentration**: Fields include Visit (VISIT - Visit Name) and Result (PCSTRESN - Numeric Result/Finding in S.). A dropdown menu for 'Test' is open, showing options like PCTESTCD - Pharmacokinetic Test Short, PCTEST - Pharmacokinetic Test Name, and PCTPT - Planned Time Point Name.
- PP - PK Parameters**: Fields include Visit (VISIT - Visit Name) and Result (PPSTRESN - Numeric Result/Finding in S.). A dropdown menu for 'Test' is open, showing options like PCTESTCD - Pharmacokinetic Test Short Name, PCTPT - Planned Time Point Name, PCTPTNUM - Planned Time Point Number, and PCTPTREF - Time Point Reference.

Click the “EDIT” button on the right of “Planned tp”, and verify the time points format.

Note:

- PKView has built in function to stripped the characters from the “Planned tp” values. Currently, it can recognize
 - H, Hr, hour, min, minute, etc
 - Pre-dose, post-dose, after, before, etc ...
- If there are unusual time point formats, the user can map it to the typical format

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Edit PC:PCTPTNUM (PCTPT)

Use user defined value mappings

Original value	User defined value
PRE-DOSE	PRE-DOSE
1H AFTER DOSING	1H AFTER DOSING
2H AFTER DOSING	2H AFTER DOSING
0-3 H	0-3 H
3H AFTER DOSING	3H AFTER DOSING
4H AFTER DOSING	4H AFTER DOSING
6H AFTER DOSING	6H AFTER DOSING
9H AFTER DOSING	9H AFTER DOSING
12H AFTER DOSING	12H AFTER DOSING
15MIN AFTER DOSING	15MIN AFTER DOSING

Recalculate Save and close

Click “Use user reviewed study arms”

File Edit View History Bookmarks Tools Help

PkView | iPortal localhost/ 90% Search

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iPortal Disease Progression Code Library Manuals Tools

Data Management DRUG000 - TEST002

TEST001 2 TEST002 2

Run

General Study Information

Study Design Crossover Reference Trt/Grp FASTED

Determine study design based on DM (not EX) Determine treatments/groups based on EX (not DM)
 Review the study arms
 Use user reviewed study arms

Additional options

Disable initial PC data cleanup Cumulative in report
 Subject C_T Correlation in report Scatter Plot in report
 Demographic table in report

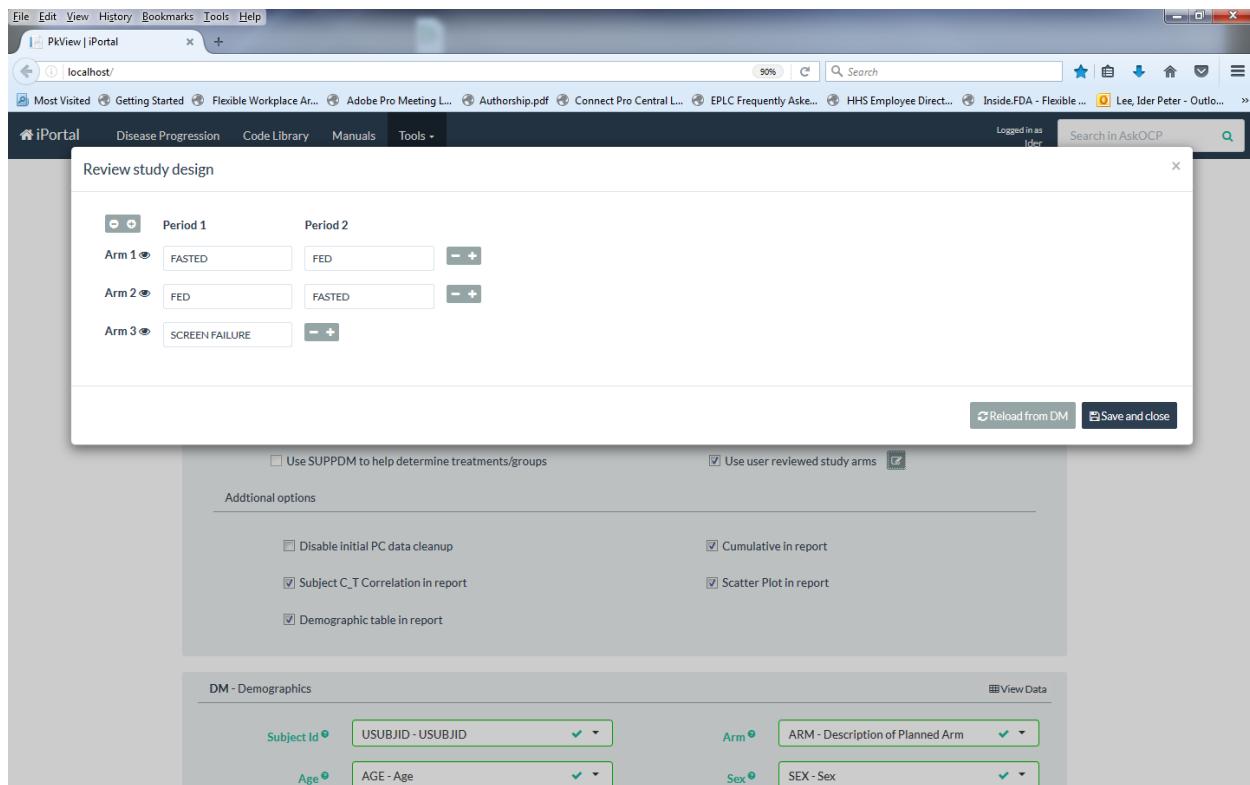
DM - Demographics View Data

Subject Id	USUBJID - USUBJID	Arm	ARM - Description of Planned Arm
Age	AGE - Age	Sex	SEX - Sex

Enter “Period 1” and “Period 2” for the 3 “Arms”, and “Save”

Note: For each subject

- The chronological order of “PP:VISIT” must match the order of periods in “DM:ARM”.
The number of unique values in “PP:VISIT” and “DM:ARM” must be the same.
- The alphabetical order of “Period” in each “ARM” must correspond to its chronological order
- “Period” is sorted as character.



Select ‘Crossover’ for “Study design”

Note:

- If there are multiple cohorts in a single study, all cohorts must have the same design (crossover or sequential)

The screenshot shows the PKview iPortal software interface. At the top, the menu bar includes File, Edit, View, History, Bookmarks, Tools, and Help. The toolbar has icons for Home, Print, Copy, Paste, and others. The main navigation bar includes iPortal, Disease Progression, Code Library, Manuals, Tools, and Data Management. A search bar at the top right says "Search in AskOCP". The current page is titled "DRUG000 - TEST002".

General Study Information

Study Design: Crossover (selected from dropdown) | Reference Trt/Grp: FASTED

Determine study design based on EX (not DM)
 Use user reviewed study arms

Additional options:

Disable initial PC data cleanup
 Cumulative in report
 Subject C_T Correlation in report
 Scatter Plot in report
 Demographic table in report

DM - Demographics

View Data

Subject Id	USUBJID - USUBJID	Arm	ARM - Description of Planned Arm
Age	AGE - Age	Sex	SEX - Sex

The “Reference Trt/Grp” will be calculated

The screenshot shows the PKview iPortal software interface. At the top, the menu bar includes File, Edit, View, History, Bookmarks, Tools, and Help. The toolbar has icons for Home, Print, Copy, Paste, and others. The main navigation bar features iPortal, Disease Progression, Code Library, Manuals, Tools, and Data Management. A search bar at the top right says "Search in AskOCP". The current page is titled "DRUG000 - TEST002". Below the title, there are tabs for "TEST001" and "TEST002".

General Study Information

Study Design: Crossover

Reference Trt/Grp: FASTED

Options:

- Determine study design based on DM (not EX)
- Use SUPPDM to help determine treatments/groups
- Use user reviewed study arms

Additional options:

- Disable initial PC data cleanup
- Cumulative in report
- Subject C_T Correlation in report
- Scatter Plot in report
- Demographic table in report

DM - Demographics

View Data

Subject Id	USUBJID - USUBJID	Arm	ARM - Description of Planned Arm
Age	AGE - Age	Sex	SEX - Sex

Clicking “View Data” on the right of “DM-Demographics”, will display the data contents

File Edit View History Bookmarks Tools Help

iPortal Disease Progression Code Library Manuals Tools -

Logged in as Ider Search in AskOCP

Demographics File Data

10 records per page Search

USUBJID	STUDYID	DOMAIN	SUBJID	SITEID	AGE	AGEU	SEX	RACE	ARMCD	ARM	COUNTRY
DRUG121861120001	DRUG X	DM	001-0001	001	100	YEARS	M	WHITE	AB	FASTED\FED	USA
DRUG121861120002	DRUG X	DM	001-0002	001	90	YEARS	M	BLACK OR AFRICAN AMERICAN	BA	FED\FASTED	USA
DRUG121861120003	DRUG X	DM	001-0003	001	80	YEARS	M	WHITE	BA	FED\FASTED	USA
DRUG121861120004	DRUG X	DM	001-0004	001	70	YEARS	M	WHITE	AB	FASTED\FED	USA
DRUG121861120005	DRUG X	DM	001-0005	001	60	YEARS	M	WHITE	AB	FASTED\FED	USA
DRUG121861120006	DRUG X	DM	001-0006	001	50	YEARS	M	OTHER	BA	FED\FASTED	USA
DRUG121861120007	DRUG X	DM	001-0007	001	40	YEARS	M	WHITE	BA	FED\FASTED	USA
DRUG121861120008	DRUG X	DM	001-0008	001	30	YEARS	M	WHITE	AB	FASTED\FED	USA
DRUG121861129001	DRUG X	DM	001-9001	001	20	YEARS	M	WHITE	SCRNFAIL	SCREEN FAILURE	USA
DRUG121861129002	DRUG X	DM	001-9002	001	10	YEARS	M	WHITE	SCRNFAIL	SCREEN FAILURE	USA

Showing 1 to 10 of 10 entries -- Previous 1 Next --

DM - Demographics View Data

Subject Id: USUBJID - USUBJID Arm: ARM - Description of Planned Arm

Age: AGE - Age Sex: SEX - Sex

Select “Additional options”

Note:

- The additional options might prolong the run time, particularly “Subject C_T Correlation in report”
- Some options might not work for certain types of studies, and cause SAS errors. If errors are encountered during the analysis, de-select the additional options.

The screenshot shows the PKView software interface. At the top, there's a browser-like header with tabs for 'PkView | iPortal' and 'localhost/'. Below the header, a navigation bar has links for 'iPortal', 'Disease Progression', 'Code Library', 'Manuals', and 'Tools'. A search bar says 'Search in AskOCP'. On the right, it says 'Logged in as [username]'. The main content area is titled 'Data Management' and shows 'DRUG000 - TEST002'. There are two tabs: 'TEST001' (with 2 notifications) and 'TEST002' (with 2 notifications). Under 'General Study Information', there are dropdowns for 'Study Design' (set to 'Crossover') and 'Reference Trt/Grp' (set to 'FASTED'). Several checkboxes are present: 'Determine study design based on DM (not EX)', 'Determine treatments/groups based on EX (not DM)', 'Use SUPPDM to help determine treatments/groups', 'Use user reviewed study arms' (checked), 'Disable initial PC data cleanup', 'Cumulative in report' (checked), 'Subject C_T Correlation in report' (checked), 'Scatter Plot in report' (checked), and 'Demographic table in report'. At the bottom, there are tabs for 'DM - Demographics' (selected), 'View Data', 'Subject Id' (set to 'USUBJID - USUBJID'), 'Arm' (set to 'ARM - Description of Planned Arm'), and another 'View Data' tab.

Run Analysis

Click the “run analysis only for this study” button (the triangle sign next to “Run”) to execute the analysis. The analysis will take minutes.

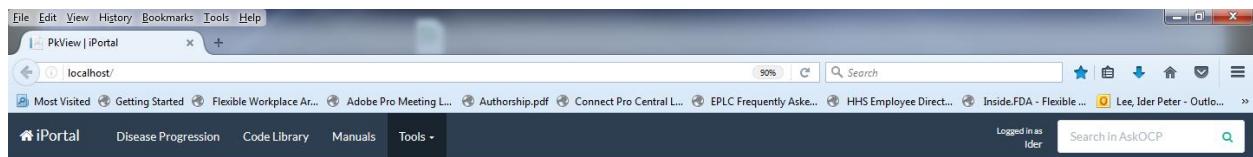
Note: Based on the prior experiences with > 200 NDA's and BLA's

- Some studies will require data cleaning to be correctly loaded into and analyzed by PKView. The recognition of the need for data cleaning will greatly depend on the user's experience with SDTM data and PKView.
- In general, studies with the following natures are more problematic
 - Protocol deviations, such as extra PK visits
 - Subjects with missing records of visits, sampling time points, PK parameters (SDTM requires blank records for missing observations)
 - Unmatched number of visits between ARM:Period, PC:VISIT, and PP:VISIT
 - Large number of washout concentrations with sparse sampling time, other than “pre-dose”

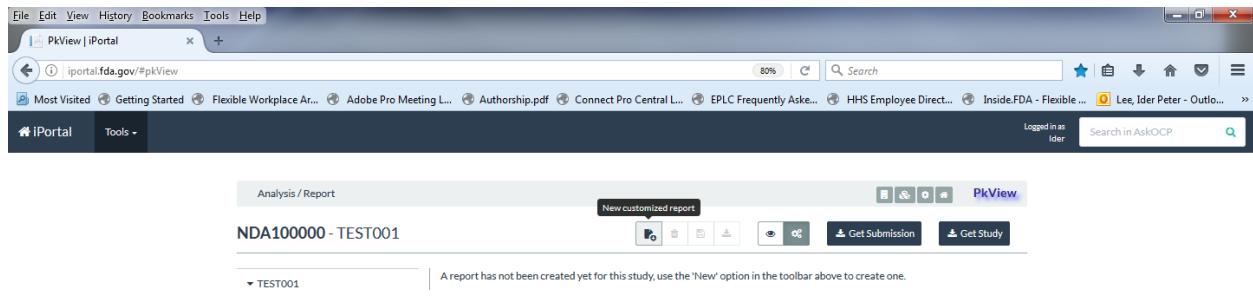
The screenshot shows a web browser window for 'PkView | iPortal' on 'localhost'. The main title bar says 'DRUG000 - TEST002'. Below it, two tabs are open: 'TEST001' and 'TEST002'. The 'TEST002' tab is active. The page displays 'General Study Information' with dropdown menus for 'Study Design' (set to 'Crossover') and 'Reference Trt/Grp' (set to 'FASTED'). There are several checkboxes for study design options, with 'Use user reviewed study arms' checked. Under 'Additional options', checkboxes for 'Disable initial PC data cleanup', 'Subject C_T Correlation in report' (checked), 'Demographic table in report' (checked), 'Cumulative in report' (checked), and 'Scatter Plot in report' (checked) are present. At the bottom, a section titled 'DM - Demographics' shows dropdown menus for 'Subject Id' (set to 'USUBJID - USUBJID'), 'Arm' (set to 'ARM - Description of Planned Arm'), and a 'View Data' button.

Forest Plot

Click “Report setting “ button

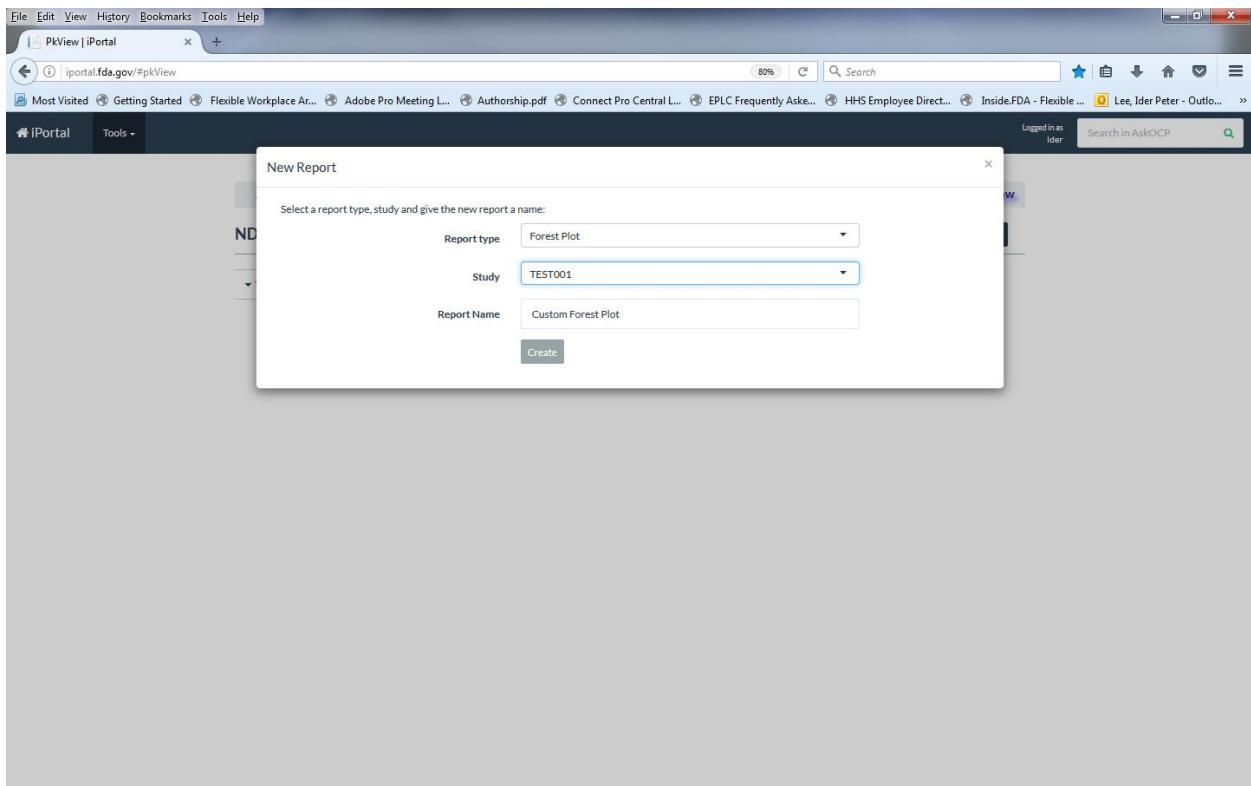


Click “new customized report” button



Select ‘Forest plot’ for report type, and give a “Report name”.

Click “Create”



Select options as shown below.

Note the order of “Category Nesting” can be changed by dragging each level around.

Click “Create”

Analysis / Report

DRUG000 - TEST002

Reference Trt/Grp: FASTED

Analytes: DRUGX

Parameters: AUC AUCO_T CMAX

Statistical Method: Paired

Category Nesting: Analyte Treatment Comparison

Generate

Click the “Down current report” button.

Analysis / Report

DRUG000 - TEST002

Download current report

Reference Trt/Grp: FASTED

Analytes: DRUGX

Parameters: AUC AUCO_T CMAX

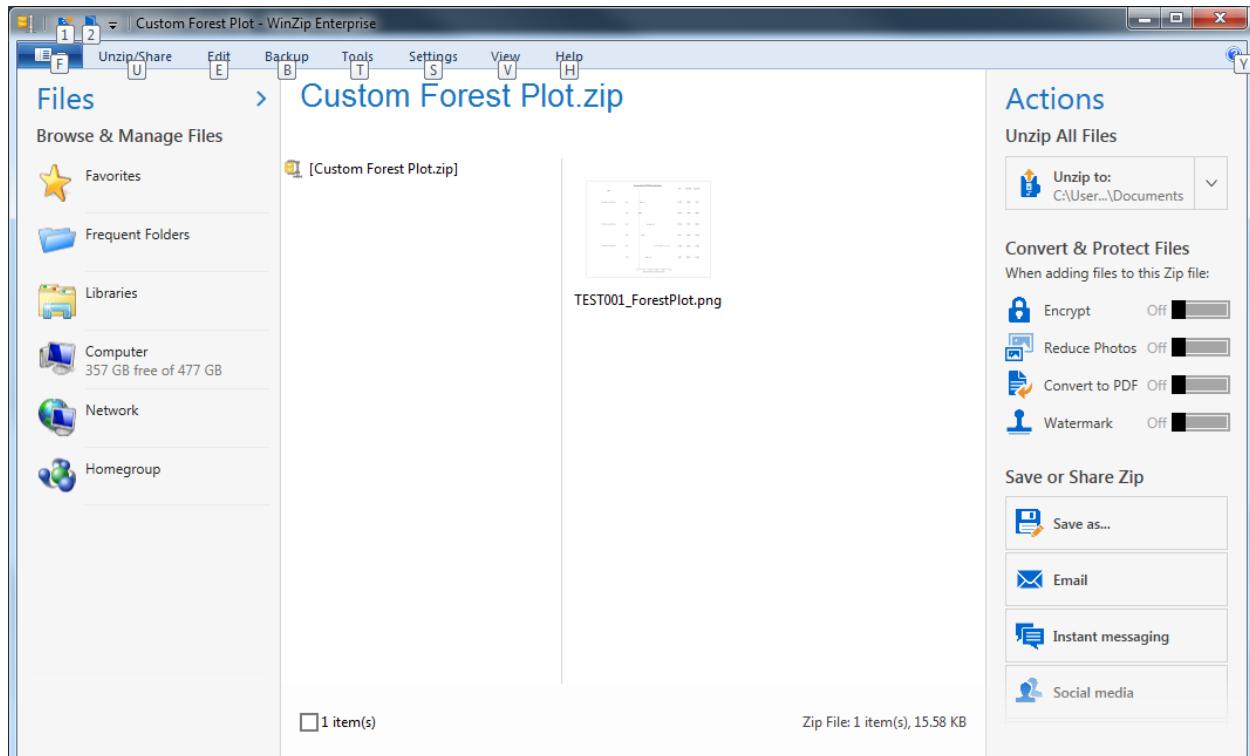
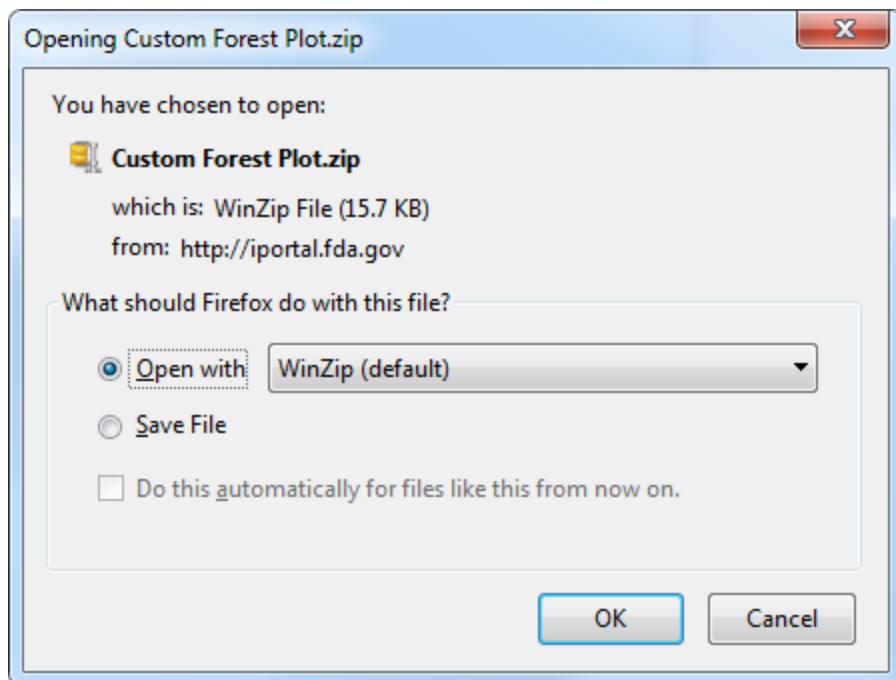
Statistical Method: Paired

Category Nesting: Analyte Treatment Comparison Parameter

Generate

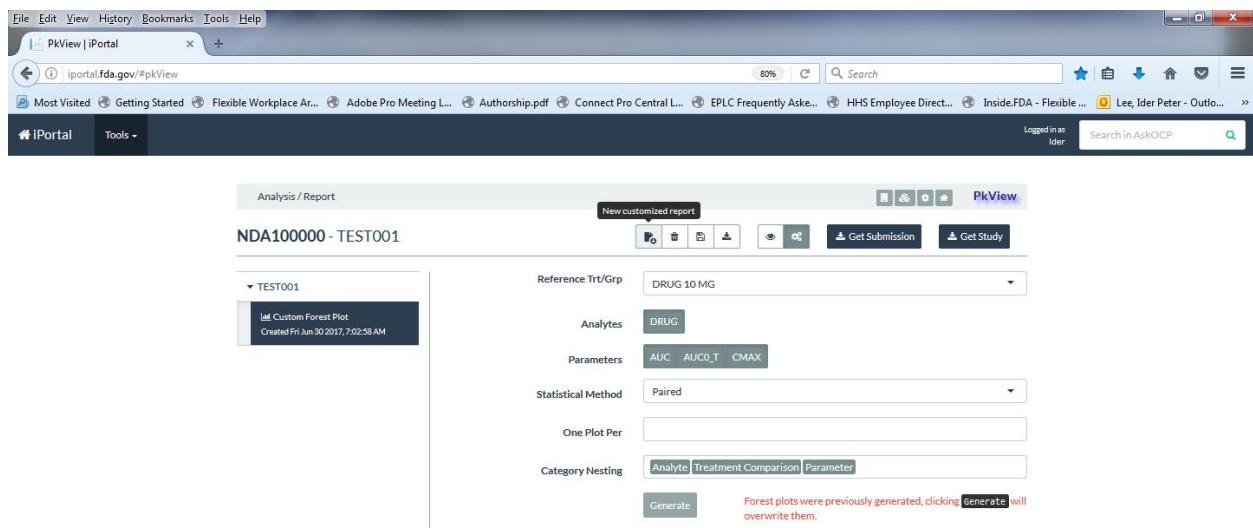
Forest plots were previously generated, clicking Generate will overwrite them.

Click “OK” to get the download files.

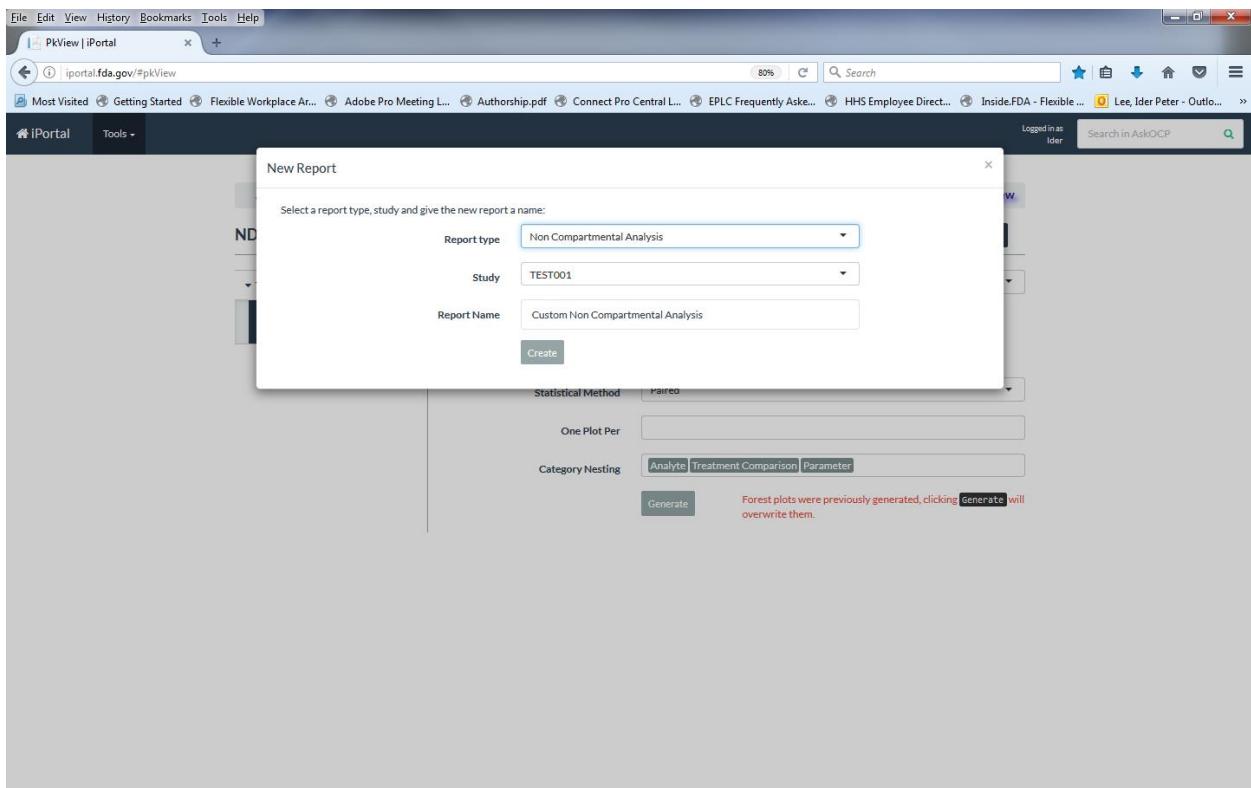


NCA Analysis

Click “New Customized Report”

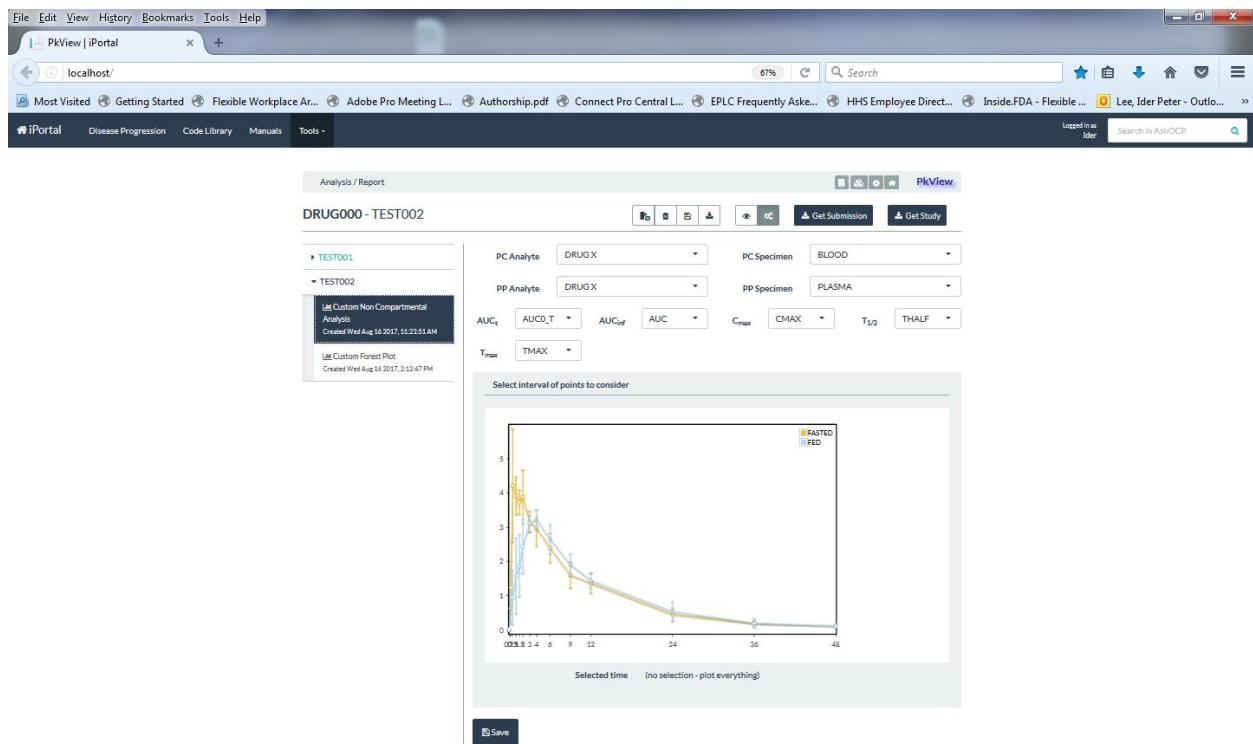


Select ‘Non Compartmental Analysis’ as the “Report Type”

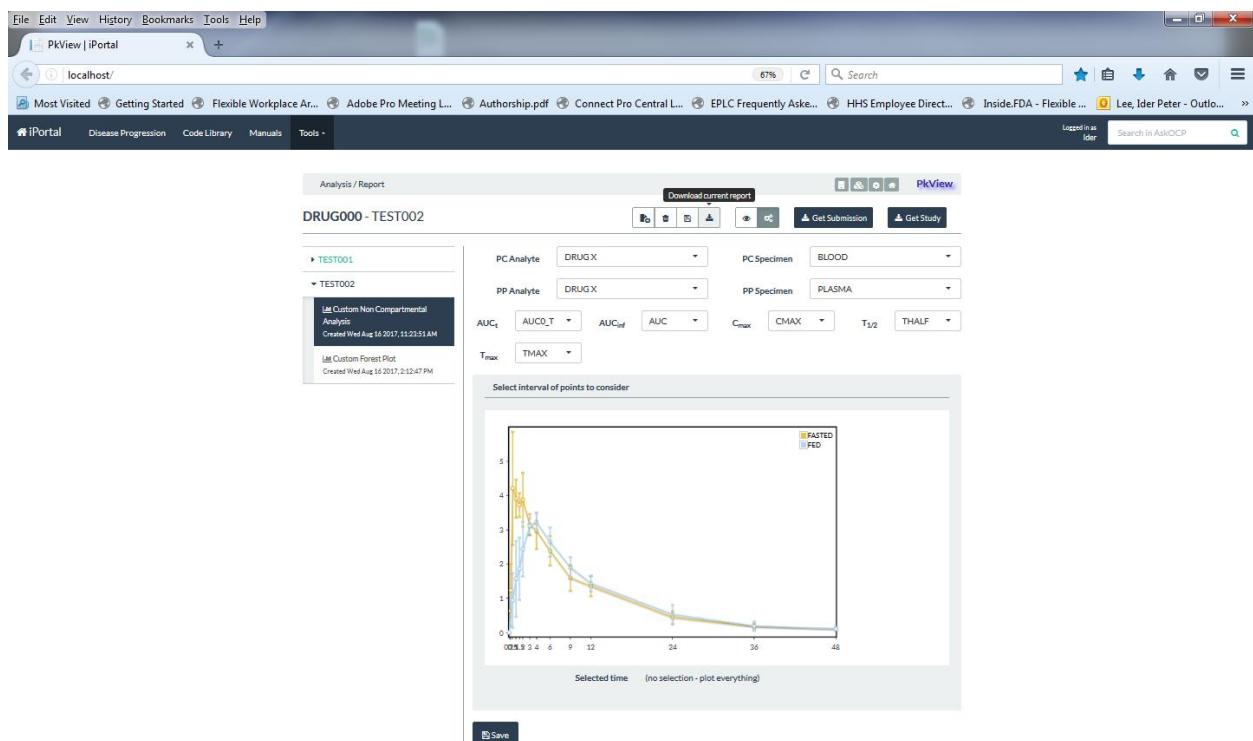


Make selections as shown.

Click "Save"



Click "Download current report button" to get the analysis results.



Copy the contents of the zip folder to a local folder in C: drive. Open the excel file "TEST002NCAInput.xls".

View the "Conc" sheet. Revise the terminal phase time points in the "Ke_First" and "KeLast" column. Revise missing concentration points if needed.

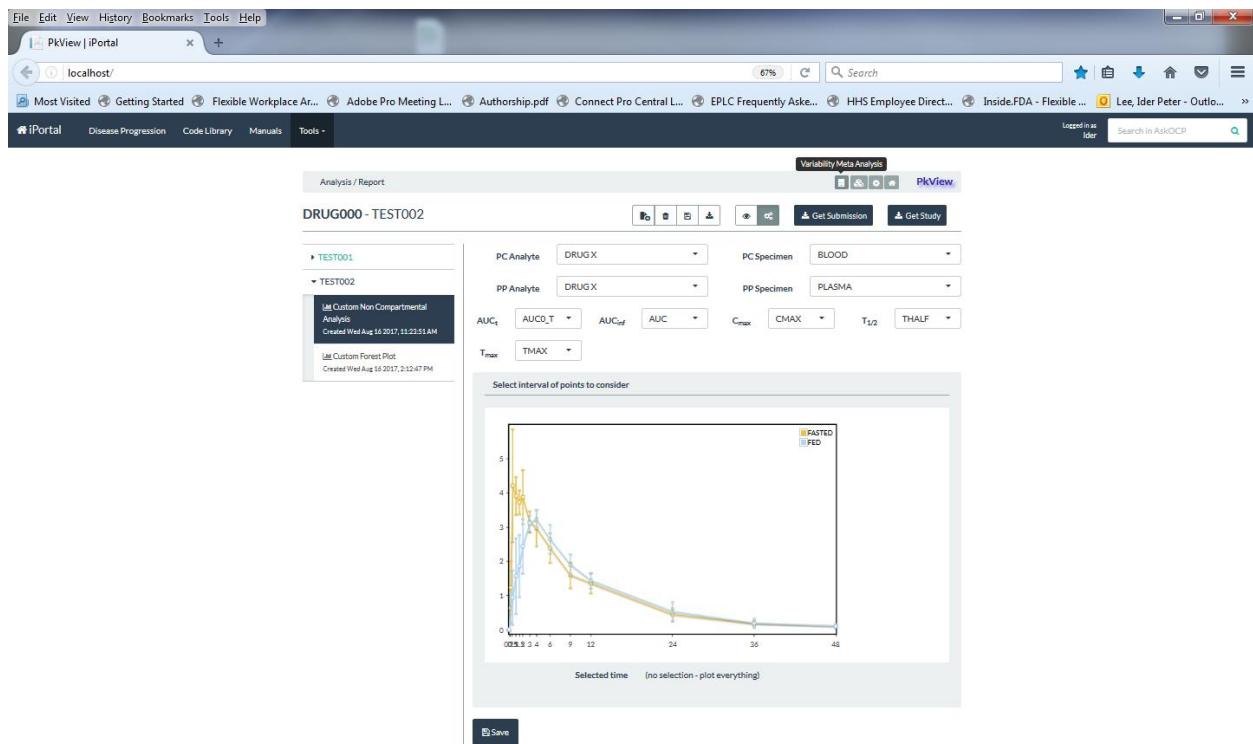
Save the revised Excel files and keep it open while running the SAS code "ncaRun_BLOOD_DRUG X.SAS"

The outputs compare the NCA analysis results between FIRM and FDA calculations.

	H	C4	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	T
1		C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	Ke_First	Ke_Last	T1	T2	T3		
2	4.164544	4.629434	3.560104	3.422852	2.96647	1.954918	1.772741	0.695538	0.327573	0.186518	.	11	13	0.25	0.5			
3	2.136439	2.381551	2.967356	3.243412	3.409012	2.475184	1.739887	1.111453	0.493914	0.213806	.	11	13	0.25	0.5			
4	1.290467	2.140192	2.960117	3.2921	2.505133	1.561837	1.09673	0.251445	0.068699	.	10	12	0	0.5				
5	4.019382	3.306323	3.030562	3.215405	2.438351	1.45864	0.937982	0.265998	.	.	9	11	0.25	0.5				
6	1.489767	2.382806	3.12009	3.326555	2.578764	2.095397	1.487071	0.586606	0.207197	0.09804	.	11	13	0.25	0.5			
7	3.203652	4.419835	3.425474	3.20418	2.508958	1.181497	1.423511	0.627485	0.240853	0.099876	.	11	13	0	0.5			
8	4.081705	3.949581	2.867986	2.899489	2.436819	1.963326	1.95784	1.388154	0.494001	0.190004	0.094273	12	14	0	0.25	0		
9	3.156919	3.110592	2.833854	3.099142	2.505157	1.905122	1.54604	0.592689	0.224389	0.098151	.	11	13	0.25	0.5			
10	3.589744	4.145632	3.249172	2.856728	2.566956	1.943768	1.445294	0.496595	0.193904	0.091369	.	11	13	0.25	0.5			
11	2.008777	2.454246	2.895819	3.476235	2.710582	2.135161	1.666401	1.72144	0.666181	0.210283	0.097448	12	14	0	0.25	0		
12	1.209173	3.414432	3.216804	2.324922	1.599217	1.223003	0.207206	0.108292	.	.	.	9	11	0.5	1	1		
13	3.550069	3.563207	3.225761	2.6005	2.309841	1.686457	1.075259	1.076455	0.180292	0.073608	.	11	13	0	0.25	0		
14	1.347908	1.719623	2.930201	3.716089	3.138935	1.992475	1.341357	0.434874	0.115094	.	10	12	0.25	0.5				
15	4.0502	3.653642	3.394073	3.132938	2.545949	2.180329	1.462971	1.136574	0.278455	0.0737	.	11	13	0	0.25	0		
16	4.158039	5.077114	3.354673	3.845444	2.839271	2.12234	1.688599	0.546241	0.162902	.	10	12	0.25	0.5				
17	2.164623	2.715341	3.721708	3.21221	3.249326	2.636729	1.966922	1.399552	0.434347	0.161799	0.061661	12	14	0	0.25	0		
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Meta Analysis - Variability

Click "Variability Meta Analysis" button



Enter values as shown. Make sure to select all “Trt/Grp” by clicking each of them.

Click “Generate Meta analysis” Button

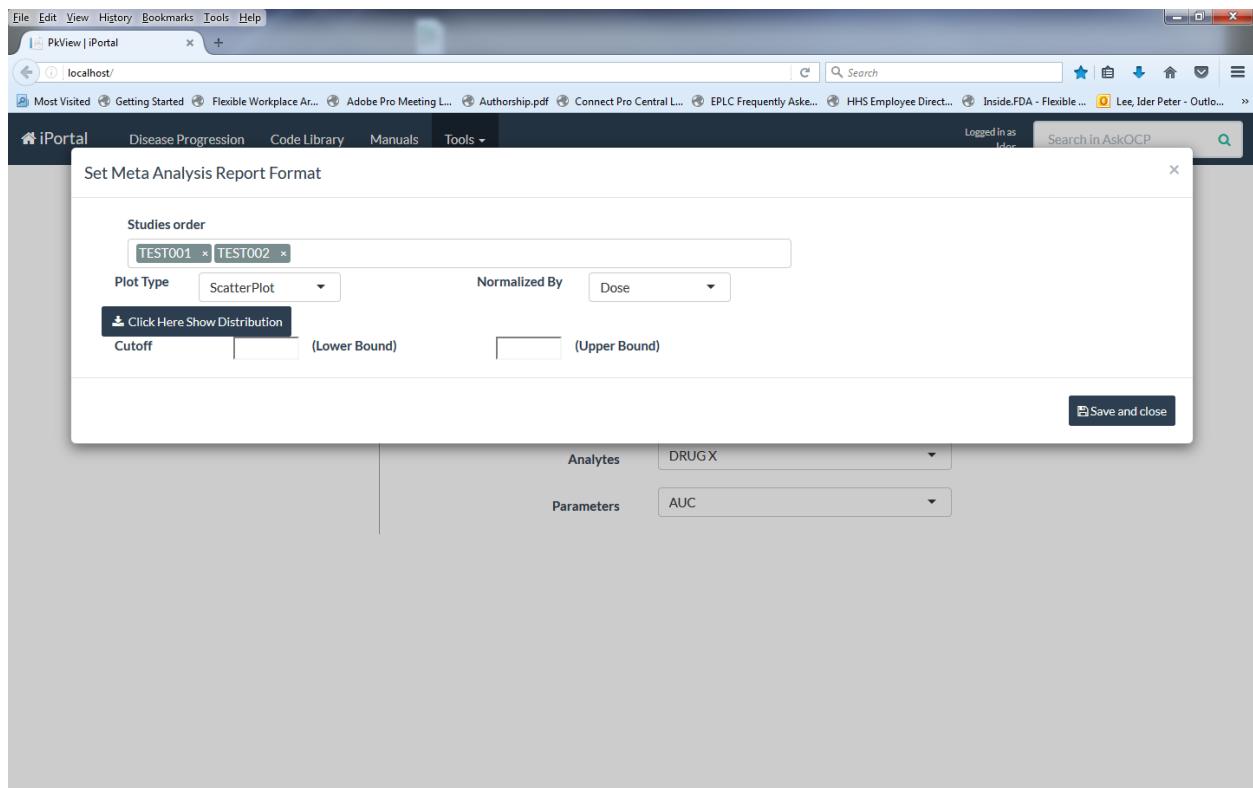
The screenshot shows a web browser window titled "PkView | iPortal" with the URL "localhost/". The browser's address bar also displays "PkView | iPortal". The page content is titled "Variability Meta Analysis" and shows a form for "DRUG000 - TEST002". On the left, there is a sidebar with two items: "TEST001" (selected) and "TEST002". On the right, there are several input fields: "Cohort: FASTED-FED", "Trt/Grp: FASTED FED" (with "FASTED" selected), "Dose: 99", "Analytes: DRUG X", and "Parameters: AUC". There are also buttons for "Generate Meta Analysis" and "Download Package".

Select “Study order” as shown.

Click “Show Distribution” to download the distribution plot.

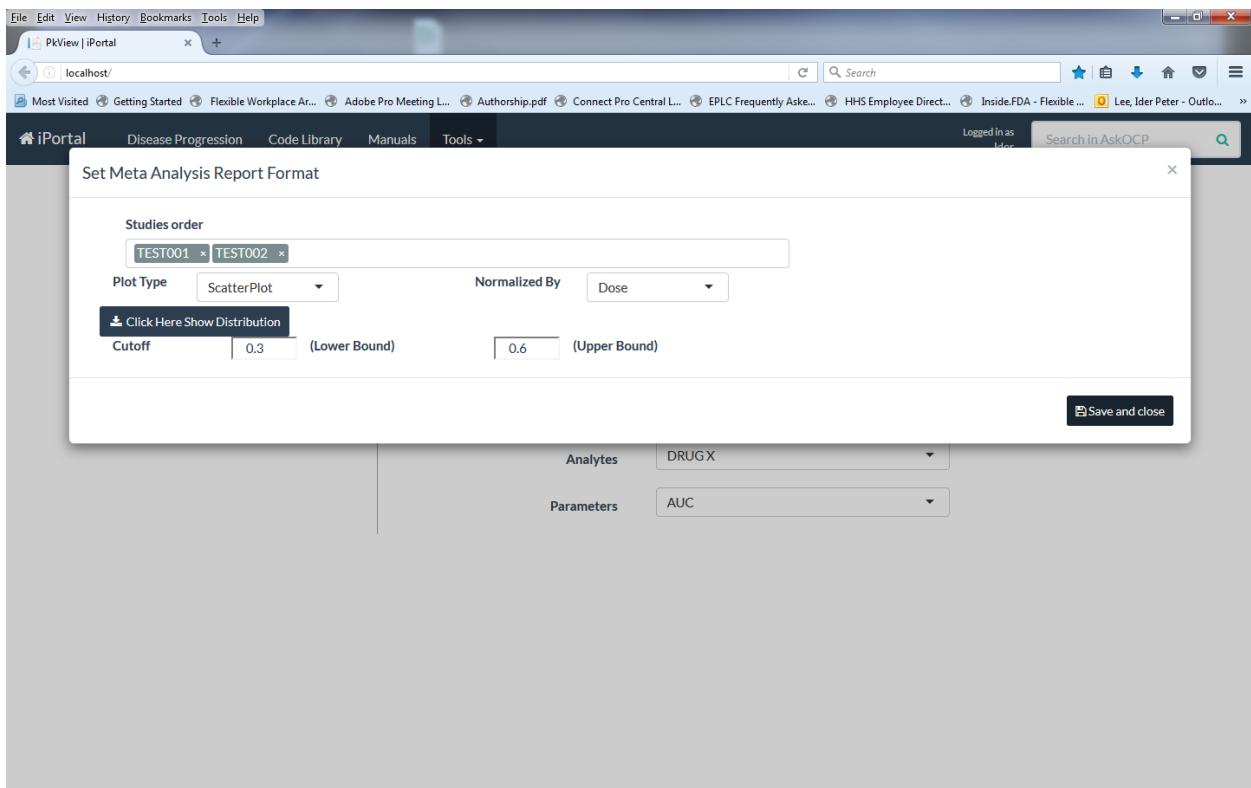
Note:

- Meta-analyses can be performed on multiple studies



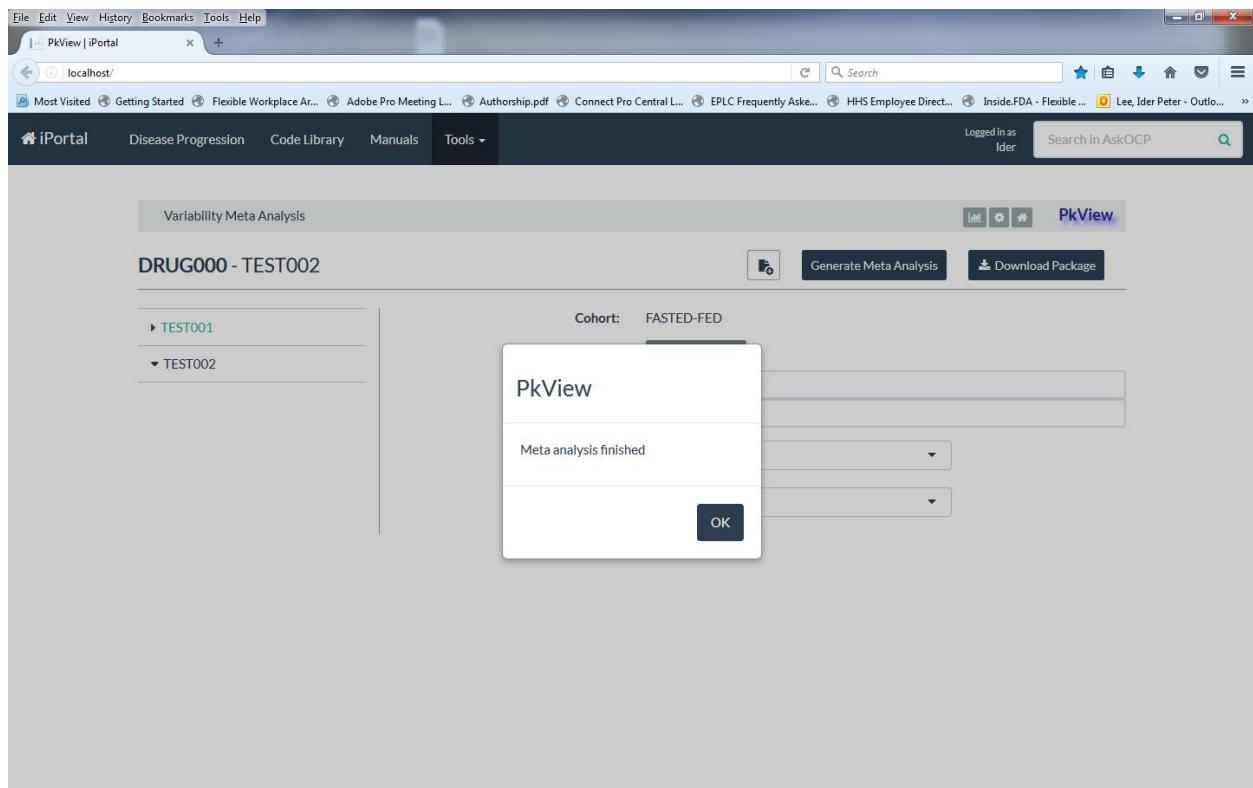
Enter the “Cut off value”

Click “Save and close”



Click “OK”

Click “Download Package” to get the analysis results.



Meta Analysis – Forest Plot

Click “Analysis/ Report” Button to switch to the Report page.

The screenshot shows the PkView | iPortal software interface. The main window title is "Variability Meta Analysis" for "DRUG000 - TEST002". On the left, there is a sidebar with two entries: "TEST001" and "TEST002". The main panel contains several input fields and dropdown menus:

- Cohort: FASTED-FED
- Trt/Grp: FASTED FED
- Dose: 99
- Analytes: DRUG X
- Parameters: AUC

At the top right, there are buttons for "Generate Meta Analysis" and "Download Package". The top navigation bar includes links for "File", "Edit", "View", "History", "Bookmarks", "Tools", and "Help". The address bar shows "localhost/".

Click “Forest plot meta analysis” button.

This screenshot is identical to the one above, showing the PkView | iPortal software interface for "Variability Meta Analysis" of "DRUG000 - TEST002". The sidebar, main panel parameters, and top navigation bar are all the same. The difference is that the "Analysis / Report" button at the top right is highlighted in blue, indicating it has been selected or is active.

Make selections as shown. Make sure to select “TEST”, “Analyte”, “Parameter”, by clicking each available options.

Click “Create meta analysis”

The screenshot shows the PkView software interface. On the left, there's a sidebar titled "Forest Plot Meta Analysis" with a tree view showing "DRUG000 - TEST002" expanded, revealing "TEST001" and "TEST002". On the right, there are several input fields and dropdown menus:

- Reference Trt/Grp:** FASTED (selected)
- Test:** FASTED (selected), FED
- Analytes:** DRUG X
- Parameters:** AUC, AUC0_T, CMAX
- Statistical Method:** Paired
- One Plot Per:** (empty field)
- Category Nesting:** Analyte (selected), Treatment Comparison, Parameter

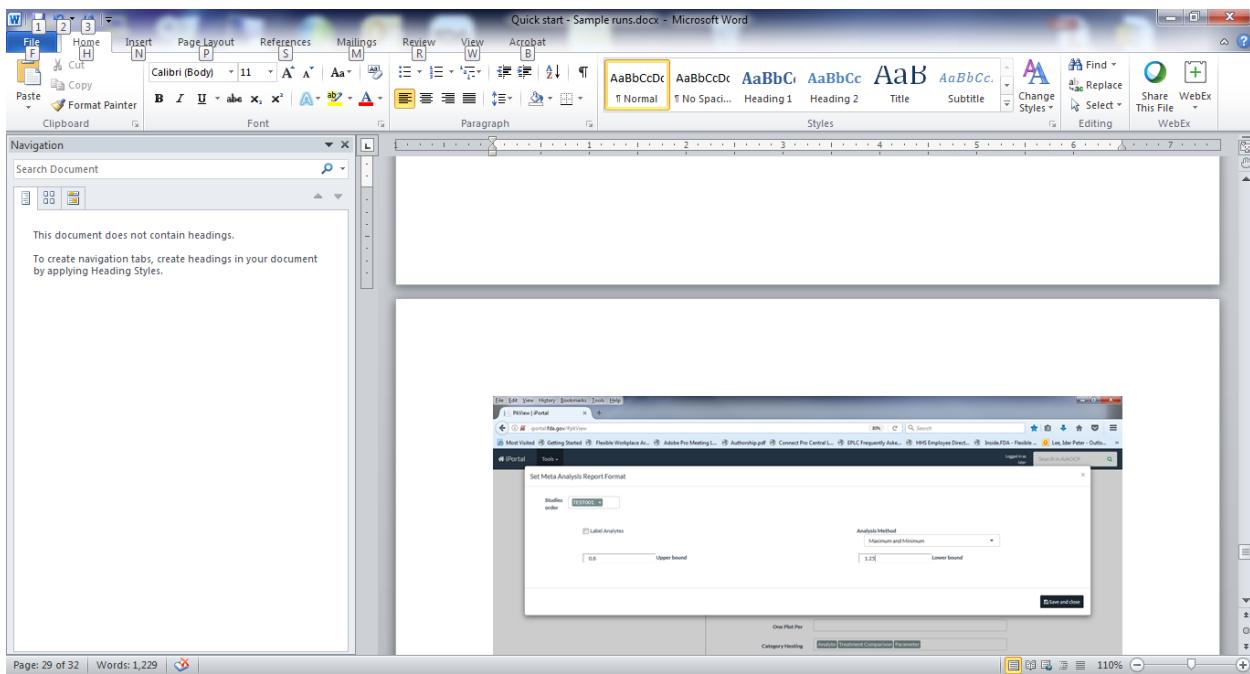
At the top right, there are buttons for "Generate Meta Analysis" and "Download Package". The top navigation bar includes links like "File", "Edit", "View", "History", "Bookmarks", "Tools", "Help", "PkView | iPortal", and a search bar.

Make selects and enter values as shown.

Click “Save and Close”

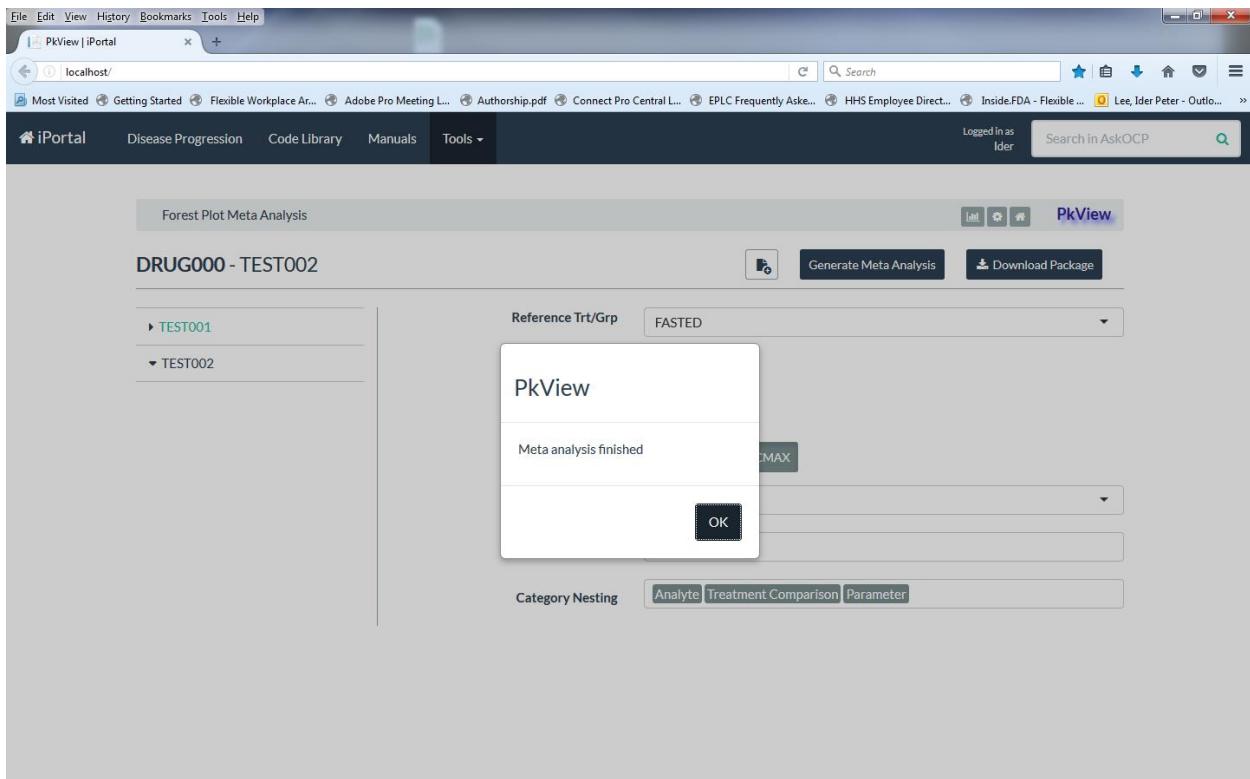
Note:

- Multiple studies can be selected and plotted in 1 graph.



Click "OK"

Click "Download Package" to get analysis results.



Click “Data management” button to switch to the mapping page.

The screenshot shows the PkView software interface. At the top, there's a menu bar with File, Edit, View, History, Bookmarks, Tools, Help, and a tab labeled "PkView | iPortal". Below the menu is a toolbar with icons for back, forward, search, and other functions. The main content area is titled "Forest Plot Meta Analysis" and displays "DRUG000 - TEST002". On the left, there's a sidebar with two entries: "TEST001" and "TEST002". The main panel has several input fields and dropdown menus:

- Reference Trt/Grp: FASTED
- Test: FASTED (selected), FED
- Analytes: DRUG X
- Parameters: AUC, AUC0_T, CMAX
- Statistical Method: Paired
- One Plot Per: (empty field)
- Category Nesting: Analyte, Treatment Comparison, Parameter

A "Data Management" button is located at the top right of the main panel. There are also "Generate Meta Analysis" and "Download Package" buttons.

Click “Advanced mode”

File Edit View History Bookmarks Tools Help

PkView | iPortal localhost/ Search

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iPortal Disease Progression Code Library Manuals Tools Advanced Mode PkView

Logged in as Ider Search in AskOCP

Data Management DRUG000

1 2 studies had some optional variables left unidentified. [How to fix this?](#)

1 Unidentified Optional Variables

These variables are not required for the analysis to run, however, setting them to correct values can potentially improve accuracy or enable additional results.

Study Id	Domain (file)	SDTM Variable	File Variable/Column
TEST001	DM: Demographics	Ethnicity	Choose... !
TEST002	DM: Demographics	Ethnicity	Choose... !
TEST002	EX: Exposure	Date	Choose... !