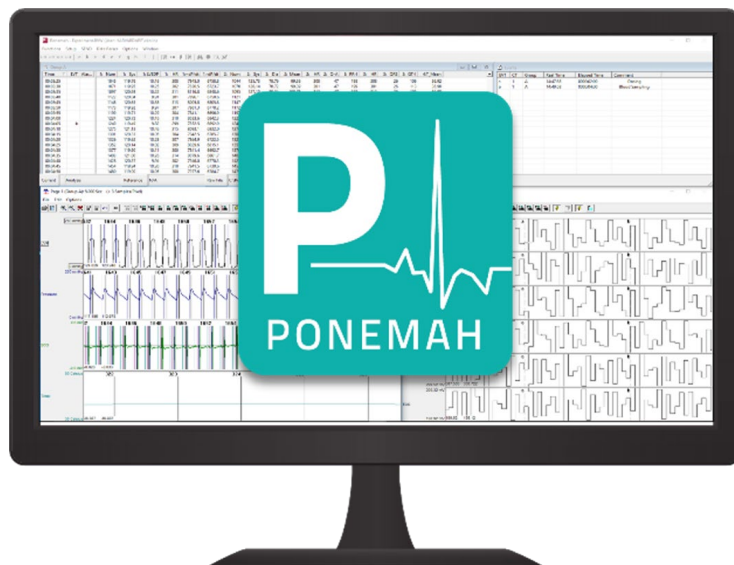




SEND 3.1: Standard for Exchange of Nonclinical Data

USER MANUAL

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Welcome

Congratulations on joining the community of users worldwide who rely on DSI products to perform preclinical physiologic research. Thank you for your interest in DSI products. We are committed to providing you with quality products and services.

The structure of this manual was designed to sequentially guide you through setup of the various SEND components and ultimately generating the standardized output needed for data submission. This manual references functionality that may not be fully detailed here. It may be necessary to reference additional Ponemah manuals for detailed feature information. This information can be found under the Help menu within Ponemah.

WHAT YOU WILL BE LEARNING

1. Determine what functions are needed in order to generate SEND information
2. Understand how to configure SEND specific features
3. Generate SEND output

Background

SEND (Standard for Exchange of Nonclinical Data) is a standardized method to exchange data between organizations and for data submission to the FDA or other regulatory bodies for non-clinical data. Detailed information on formatting, standards, terminology and other information can be found at <https://www.cdisc.org/>.

In order to produce output using the SEND module, users must ensure the following:

- SEND Output or SEND SQL Server Output has been enabled in license file
- Derived Parameters selected
 - Not all derived parameters generated by Ponemah are currently defined by CDISC. Derived parameters will only be present in SEND output if those parameters defined by CDISC have been enabled in the Channel Input Setup menu.
 - See Appendix 1 for a list of currently accepted parameters
 - Data reduction enabled for subjects.
 - The currently defined calculations are Average (Avg), Maximum (Max), and Minimum (Min)
- The Controlled Terminology dialog has the desired mappings configured
 - The Controlled Terminology dialog provides a mapping of the terminology between the Ponemah derived nomenclature and the expected SEND controlled terminology. This dialog can be modified by the user to include additional Ponemah parameters. Additionally, as parameters are updated by CDISC, this dialog can be easily modified to include the new information.

This manual assumes users have read and understand the core components of the Ponemah software application. In some instances, SEND is built upon existing menus or functions in the software. If additional information is needed on functionality outside of the SEND application, please review the manuals located under the Help pull-down menu in the Ponemah application.

SEND Setup from PPP3 Setup

In order to create SEND output, users must have enabled Data Reduction, selected derived parameters in the Channel Input Setup menu that correspond to output designated by CDISC, and performed a Save of the data while in Review (Save Marks Section, Save Derived Data, or Save Run).

SEND output can be generated within or outside of the Study Protocol Option (Study). This section will describe how to set up components that are used both with and without Study. Specific use with Study will be described in a later section.

SEND dialog

SEND can be configured in idle mode and saved as part of the protocol or modified after collection in Review. To modify SEND settings, select P3 Setup from the Setup pull-down menu and click on SEND in the tree-view menu on the left-hand side of the dialog. By default, SEND will be disabled. In order to edit, select “Enable SEND Output”. Once enabled, fields will become editable.

Definitions for the functions displayed in the SEND dialog are listed below.

PPP3 Setup - SEND

— PPP3 Setup — — SEND —

Groups
Channel Input Setup
Template Setup ...
Events
Experimental Protocol Header
Data Reduction Setup
Variability Analysis ...
Graph Setup
Settings
SEND

☒ Enable SEND Output
☒ Enable Excel Output

Study Name: NonToxTest2 ☐ Edit Study Name
Study Day: 1 ☐ Edit Study Day
Workup: ☐ Edit Workup
Laboratory Name:

☐ Append Subject ID to Study Name Subject Separator: _
☐ Update SEND during Acquisition

Consciousness State: CONSCIOUS
Position: UNCONSTRAINED
EG Method: 12 LEAD STANDARD
CV Method: INTRAVASCULAR
RE Method: HEAD OUT PLETHYSMOGRAPH

OK Cancel Apply

Figure 1. – SEND dialog from the PPP3 Setup menu.

1 – Enable SEND Output

Toggles the ability to modify the editable fields displayed in Figure 1 and controls whether or not SEND output is turned on or off.

2 – Enable Excel Output

SEND output can be ported to Microsoft Excel along with the derived, log, and subject information currently created when saving a Marks section, Derived Data, or a Run (within Study). If enabled, a new worksheet for each SEND domain will be created within the Excel workbook that contains SEND information along with the expected Derived, Data Reduction, and Experimental Log information. Refer to section SEND Export To Excel for details on the output generated when enabling this feature.

If this option is not checked, SEND output can be generated by creating a CSV file using SEND Viewer (see SEND Viewer below).

3 – Study Name

Allows the user to create a unique study name for the SEND output. If using the Study Protocol Option, this information will be automatically pulled by the software. However, the option to modify the Study name is possible by checking the box next to the edit field. This may be needed to further define a set of data or update an incorrect Study name that may have been created.

4 – Study Day

The day of collection may be entered here. Note that CDISC does not recognize Day 0. If using the first day of the study collection, a “1” should be entered. If using the Study Protocol Option, this information will be automatically pulled by the software. However, the option to modify the Study Day is possible by checking the box next to the edit field. This may be needed to further define a set of data or update an incorrect Study entry.

5 – Workup

A Workup can be manually defined, or If using the Study option, this information can be automatically pulled by the software. If pulled from Study, users can modify the workup name used in Study by checking the box next to the edit field.

7 – Laboratory Name

Allows a unique identifier to be manually entered which will populate the EGNAM variable in the SEND output for the EG Domain

8 – Append Study ID to Subject Name

Will append the Subject ID to the Study Name in the SEND output. By default, the separator is “_” but can be changed. This modifies USUBJID in the SEND output for the domain.

9 – Update SEND during acquisition

Generation of SEND data will typically be generated during Review after post processing the data. However, there may be instances where post analysis of the data is not needed such as in short duration Tox applications. Enabling this checkbox will allow data generated during acquisition to be used by SEND.

10 – Consciousness State

Pull-down field allows selection of CDISC controlled terminology that represents the state of the animal, such as conscious or unconscious. These definitions are managed in the Controlled Terminology dialog.

11 – Position

Presents a pull-down menu allowing the selection of CDISC controlled terminology that represents the subjects position from unconstrained to various restrained states. These definitions are managed in the Controlled Terminology dialog.

12 – EG Method

Allows the selection of the CDISC controlled terminology that represents the ECG lead presentation used for collection. These definitions are managed in the Controlled Terminology dialog.

13 – CV Method

Allows the selection of CDISC controlled terminology for definition of pressure measurements. These definitions are managed in the Controlled Terminology dialog.

14 – RE Method

Permits selection of CDISC controlled terminology such as Head Out Plethysmograph, Whole Body Plethysmograph, or Invasive to describe the respiratory system being used. These definitions are managed in the Controlled Terminology dialog.

Subject Setup

The Subject Setup dialog allows the user to control the Subject name and dose which is associated with a given Subject. To edit the Study Subject Name or Study Dose, click in the edit field under the appropriate column. If the boxes are checked at the top of the window the fields will not be editable, as explained in the next section.

Subject Setup

Search subject here...

Subject Details

☒ Use Study Subjects/Sex ☒ Use Study Doses

Study Subject Name: Subject500

Enabled: ☒

Study Dose: veh

Cage:

Sex: ☒ Male ☐ Female ☐ N/A

Species: Dog

Camera: <none>

Analysis	Label	Units	Precision	Trigger	Enabled
Demo1.500					
BP	Pressure	mmHg	0000.	☒	☒
ECG	LEAD II	mV	0000.	☐	☒
APR - 2802					
BARO	Ambient	mmHg	00.00	☐	☒

Apply to Similar Subjects

OK Cancel

Figure 2. –Subject Setup dialog from the PPP3 Setup menu.

Providing a unique name in the Subject Setup dialog will propagate the subject information to SEND.

Two check boxes are available at the top of the Subject Setup dialog, Use Study Subjects and Use Study Doses. These two features are related to data generated using the Study Protocol Option. If enabled, Subject, Sex and Dose information entered in Study will be automatically pulled into the Subject Setup. When these features are enabled, manually editing Study Subject Name and Study Dose will not be permitted. However, it may be necessary to update or correct information that was entered incorrectly into the Study Protocol Option. If needed, uncheck these boxes and enter the appropriate information manually. When these boxes are unchecked, the column headers revert to the default values of Name and Dose. If not using the Study Protocol Option, these features do not need to be enabled.

1 – Use Study Subjects

Subject information defined within the Study Protocol Option can be automatically pulled into SEND output by selecting this checkbox

2 – Use Study Doses

Dose information entered within the Study Protocol Option will be pulled into SEND by selecting this checkbox

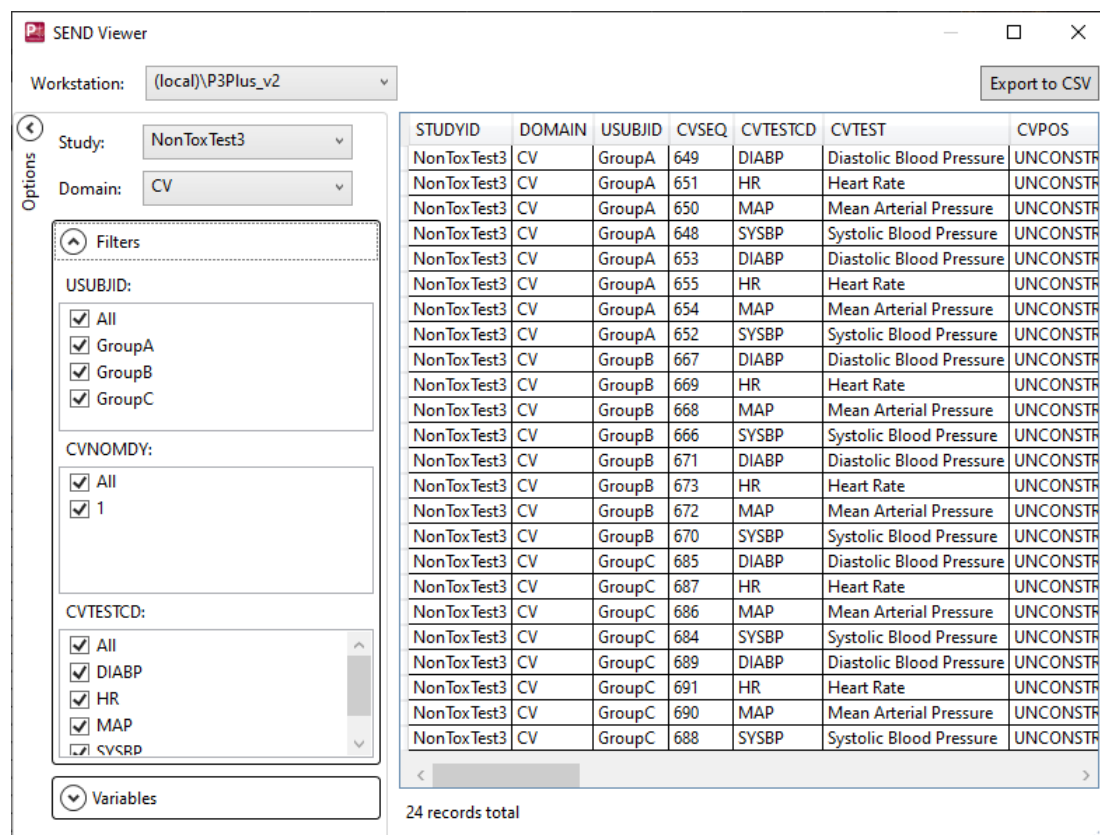


Figure 3. – Example SEND Viewer dialog showing Group information pulled into SEND (USUBJID).

Data Reduction

Data Reduction must be enabled for all desired Subjects to generate SEND output. Only parameters defined by CDISC will be available in the SEND output.

With SEND enabled, users can no longer create user specified labels as that will be handled automatically to conform to SEND requirements. When SEND has been enabled, Data Reduction will display “SEND compatibility enabled” at the top of the dialog to notify users that they will be complying with SEND requirements and some functions will not be able to be modified.

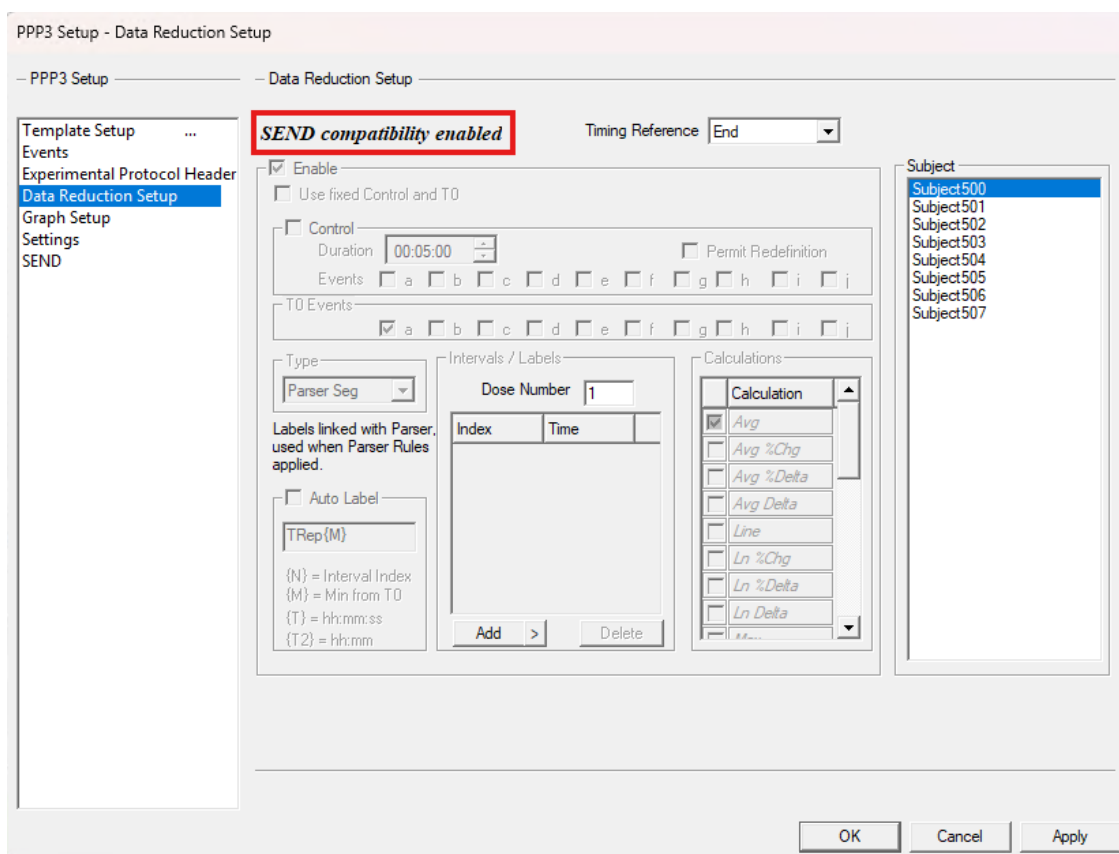


Figure 4. – Data Reduction dialog showing SEND enabled.

Several features have been added to the Data Reduction dialog to provide details on the data generated for SEND output.

1 – Timing Reference

The Timing Reference selection determines the point on each data reduction interval that will be used to report timing information for the interval (Figure 5). This is used to define Data Reduction labels along with TPT and ELTM.

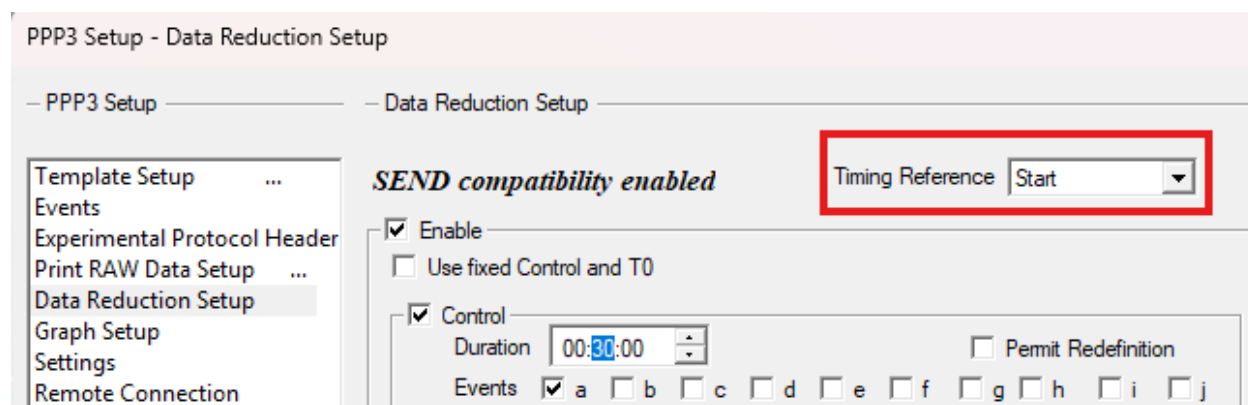


Figure 5. – Data Reduction showing Timing Reference selection.

Three selections are available which include Start, Middle, and End. The selection chosen will update the Data Reduction label to display the time information at the start of the logging interval, the middle of the interval, or the end of the interval as shown in Figures 6 and 7.

Figure 6 shows labels starting at 0s and incrementing by 10 minutes (10m, 20m, 30m) as dictated by the “Duration of Interval” chosen by the user.

Ponemah - SampleECGData.RVW (User: mjb) - [Data Reduction: a]

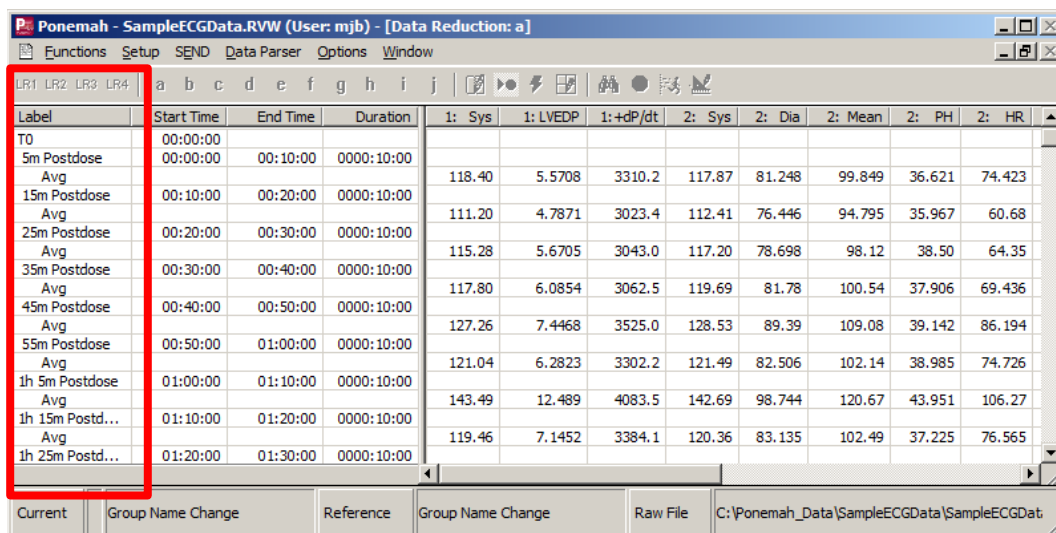
Functions Setup SEND Data Parser Options Window

Label	Start Time	End Time	Duration	1: Sys	1: LVEDP	1: +dP/dt	2: Sys	2: Dia	2: Mean	2: PH	2: HR
T0	00:00:00										
0s Postdose	00:00:00	00:10:00	0000:10:00	118.40	5.5708	3310.2	117.87	81.248	99.849	36.621	74.423
Avg				111.20	4.7871	3023.4	112.41	76.446	94.795	35.967	60.68
10m Postdose	00:10:00	00:20:00	0000:10:00	115.28	5.6705	3043.0	117.20	78.698	98.12	38.50	64.35
Avg				117.80	6.0854	3062.5	119.69	81.78	100.54	37.906	69.436
20m Postdose	00:20:00	00:30:00	0000:10:00	127.26	7.4468	3525.0	128.53	89.39	109.08	39.142	86.194
Avg				121.04	6.2823	3302.2	121.49	82.506	102.14	38.985	74.726
30m Postdose	00:30:00	00:40:00	0000:10:00	143.49	12.489	4083.5	142.69	98.744	120.67	43.951	106.27
Avg				119.46	7.1452	3384.1	120.36	83.135	102.49	37.225	76.565
40m Postdose	00:40:00	00:50:00	0000:10:00								
Avg											
50m Postdose	00:50:00	01:00:00	0000:10:00								
Avg											
1h Postdose	01:00:00	01:10:00	0000:10:00								
Avg											
1h 10m Postd...	01:10:00	01:20:00	0000:10:00								
Avg											
1h 20m Postd...	01:20:00	01:30:00	0000:10:00								

Current: Group Name Change Reference Group Name Change Raw File C:\Ponemah_Data\SampleECGData\SampleECGData

Figure 6. – Data Reduction label showing “Start” selected for the Timing Reference.

Figure 7 shows the same Start Time, End Time, Duration and averages for the data, but the label has been modified to display the “Middle” selection. Since the duration of the averaging interval is 10 minutes, selecting Middle will update the label information to specify the middle of that logging interval. Figure 7 shows those updated labels starting at 5m and incrementing every 10 minutes (5m, 15m, 25m, etc.).



Label	Start Time	End Time	Duration	1: Sys	1: LVEDP	1: +dP/dt	2: Sys	2: Dia	2: Mean	2: PH	2: HR
T0	00:00:00	00:10:00	0000:10:00								
5m Postdose Avg	00:00:00	00:10:00	0000:10:00	118.40	5.5708	3310.2	117.87	81.248	99.849	36.621	74.423
15m Postdose Avg	00:10:00	00:20:00	0000:10:00	111.20	4.7871	3023.4	112.41	76.446	94.795	35.967	60.68
25m Postdose Avg	00:20:00	00:30:00	0000:10:00	115.28	5.6705	3043.0	117.20	78.698	98.12	38.50	64.35
35m Postdose Avg	00:30:00	00:40:00	0000:10:00	117.80	6.0854	3062.5	119.69	81.78	100.54	37.906	69.436
45m Postdose Avg	00:40:00	00:50:00	0000:10:00	127.26	7.4468	3525.0	128.53	89.39	109.08	39.142	86.194
55m Postdose Avg	00:50:00	01:00:00	0000:10:00	121.04	6.2823	3302.2	121.49	82.506	102.14	38.985	74.726
1h 5m Postdose Avg	01:00:00	01:10:00	0000:10:00	143.49	12.489	4083.5	142.69	98.744	120.67	43.951	106.27
1h 15m Postd... Avg	01:10:00	01:20:00	0000:10:00	119.46	7.1452	3384.1	120.36	83.135	102.49	37.225	76.565
1h 25m Postd...	01:20:00	01:30:00	0000:10:00								

Figure 7. – Data Reduction label showing “Middle” selected for the Timing Reference.

2 – Dose Number

Dose Number is manually edited and refers to the dose that will be referenced in the SEND output. The dose number listed here will be placed in the SEND output under TPT. By default, **the value is “1” but can be modified to represent the desired dose if multiple dosing** events occur in a single day. If SEND is not enabled in the SEND dialog, this field will not be editable.

PPP3 Setup - Data Reduction Setup

PPP3 Setup — Data Reduction Setup

Template Setup ...
Events
Experimental Protocol Header
Data Reduction Setup
Graph Setup
Settings
SEND

SEND compatibility enabled Timing Reference End

☒ Enable
☐ Use fixed Control and T0

☐ Control Duration: 00:05:00 ☐ Permit Redefinition

Events ☐ a ☐ b ☐ c ☐ d ☐ e ☐ f ☐ g ☐ h ☐ i ☐ j

T0 Events ☒ a ☐ b ☐ c ☐ d ☐ e ☐ f ☐ g ☐ h ☐ i ☐ j

Type: Parser Seg

Labels linked with Parser, used when Parser Rules applied.

☐ Auto Label TRep(M)

(N) = Interval Index
(M) = Min from T0
(T) = hh:mm:ss
(T2) = hh:mm

Index	Time
Dose Number	1

Add > Delete

Calculations

Calculation
☒ Avg
☐ Avg %Chg
☐ Avg %Delta
☐ Avg Delta
☐ Line
☐ Ln %Chg
☐ Ln %Delta
☐ Ln Delta

Subject

- Subject500
- Subject501
- Subject502
- Subject503
- Subject504
- Subject505
- Subject506
- Subject507

OK Cancel Apply

Figure 8. – Data Reduction dialog showing Dose Number edit field.

3 – Use Fixed Control and T0

The Use Fixed Control and T0 function allows the designation of the start of the Data Reduction without the use of an event. Entering in date and time into the T0 Time edit fields will trigger the start of Data Reduction. When using Time as the Data Reduction “Type”, all labels will be controlled by Ponemah for SEND compliance.

A time of 11:00AM was entered into the T0 Time field. In the list view dialog, the “0s Postdose” label is entered and controlled by Ponemah and the first logged line of data is at 11:00AM. All subsequent intervals are based on the Duration of Interval configured.

Ponemah - NonToxTest3_WorkingRvw_TROY-20941.RVW (User: HARVARDAPP\TVelie, Role: SuperAdmin)

Functions Setup SEND Data Parser Options Window

LR1 LR2 LR3 LR4 | a b c d e f g h i j | [Icons]

Data Reduction: a

Label	Start Time	End Time	Duration	1: Num	1: Sys	1: Dia	1: Mean	1: HR	1: Ci
T0	-0000:04:38 11:00:00 03/31/2022								
4m 38s Po...	0000:00:00 11:04:38 03/31/2022	0000:00:02 11:04:40 03/31/2022	0000:00:02						
Avg				x	x	x	x	x	
4m 40s Po...	0000:00:02 11:04:40 03/31/2022	0000:00:07 11:04:45 03/31/2022	0000:00:05						
Avg				2.00	4.5712	-4.572	-0.00	30.00	
4m 45s Po...	0000:00:07 11:04:45 03/31/2022	0000:00:12 11:04:50 03/31/2022	0000:00:05						
Avg				4.00	4.5712	-4.572	-0.00	30.00	
4m 50s Po...	0000:00:12 11:04:50 03/31/2022	0000:00:17 11:04:55 03/31/2022	0000:00:05						
Avg				7.00	4.5712	-4.572	-0.00	30.00	
4m 55s Po...	0000:00:17 11:04:55 03/31/2022	0000:00:22 11:05:00 03/31/2022	0000:00:05						
Avg				9.00	4.5712	-4.572	-0.00	30.00	
5m Postd...	0000:00:22 11:05:00 03/31/2022	0000:00:27 11:05:05 03/31/2022	0000:00:05						
Avg				12.00	4.5712	-4.572	-0.00	30.00	
5m 5s Pos...	0000:00:27 11:05:05 03/31/2022	0000:00:32 11:05:10 03/31/2022	0000:00:05						
Avg				14.00	4.5712	-4.572	-0.00	30.00	
5m 10s Po...	0000:00:32 11:05:10 03/31/2022	0000:00:37 11:05:15 03/31/2022	0000:00:05						
Avg				17.00	4.5712	-4.572	-0.00	30.00	
5m 15s Po...	0000:00:37 11:05:15 03/31/2022	0000:00:42 11:05:20 03/31/2022	0000:00:05						
Avg				19.00	4.5712	-4.572	-0.00	30.00	
5m 20s Po...	0000:00:42 11:05:20 03/31/2022	0000:00:47 11:05:25 03/31/2022	0000:00:05						
Avg				22.00	4.5712	-4.572	-0.00	30.00	

Current: Run4 Reference: N/A Server(http://localhost:23332/): Connected

Figure 9. – Data Reduction with Use fixed Control and T0 enabled.

Parser Segments can also be configured and used for Data Reduction. When using Parser Segments, the ability to add user defined labels is permitted. Figure 10 shows the Add button expanded under the Intervals/Labels field. All labels manually entered here will be fixed in the Data Reduction list view and any additional reduction line labels will be handled by Ponemah.

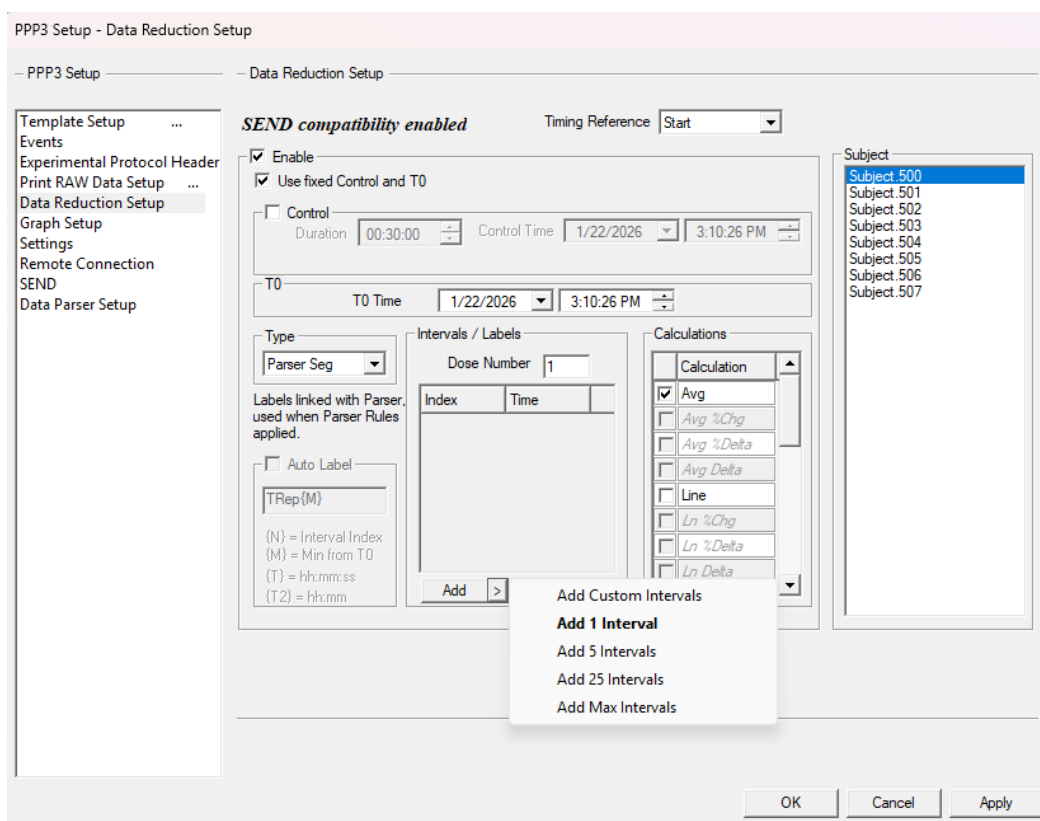


Figure 10. – Use of Parser Segments with Fixed Control enabled.

If Use fixed Control and T0 has been enabled, any parser segment prior to your T0 Time will be listed as a “Predose” time point. If Control has been enabled, the parser segment prior to your T0 Time will be used as your control value. If parser segments exist before the Control segment, they will be labeled as Predose.

Ponemah - NonToxTest3_WorkingRvw_TROY-20941.RVW (User: HARVARDAPP\TVelie, Role: SuperAdmin)

Functions Setup SEND Data Parser Options Window

LR1 LR2 LR3 LR4 | a b c d e f g h i j | [Icons]

Data Reduction: a

Label	Start Time	End Time	Duration	1: Num	1: Sys	1: Dia	1: Mean	1: HR
17s Predose Avg	0000:00:04 11:04:42 03/31/2022	0000:00:11 11:04:49 03/31/2022	0000:00:07	4.00	4.5712	-4.572	-0.00	30.00
T0	0000:00:22 11:05:00 03/31/2022							
5s Postdose Avg	0000:00:43 11:05:21 03/31/2022	0000:00:49 11:05:27 03/31/2022	0000:00:05	23.00	4.5712	-4.572	-0.00	30.00
10s Postdose Avg	0000:01:02 11:05:40 03/31/2022	0000:01:11 11:05:49 03/31/2022	0000:00:09	34.00	4.5712	-4.572	-0.00	30.00

Current: Run4 Reference: N/A Server(http://localhost:23332/): Connected

Figure 11. – Parser Segments prior to T0 Time shown as Predose, Control not enabled.

Using Study Protocol Option and SEND

The following outlines the differences in SEND options when using the Study Protocol Option. Refer to previous sections outlining the setup required for the SEND, Groups and Data Reduction dialogs to ensure requirements for generating SEND output have been configured.

SEND Configuration When Using Study

If using the Study Protocol Option, the study configuration has been previously configured and saved as part of the Study prior to any collections. This includes Data Reduction, Subject IDs and other information. When using the Study Protocol Option, information can be automatically pulled into the SEND dialog and other menus. However, it may be necessary to modify information prior to generating SEND output to correct entry errors or further define a set of SEND generated data.

Functions specific to the Study Protocol Option in the SEND dialog include the ability to automatically load the Study Name, Study Day, and Workup. For the Study information to be displayed in the SEND dialog, you must have accessed a Review file within the Run Study dialog. With the Review file open, navigating to the SEND dialog will display the information for the Study that is currently accessed. Additionally, a Review file created within Study can be opened outside of Study with access to this information.

When the checkboxes have been disabled as in Figure 12, the information created using the Study option will be pulled into the SEND dialog. However, no modification of these fields will be allowed.

Figure 12. – Study Name, Study Day, and Workup pulled from the Study Protocol Option.

To modify Study information, place a check in the Edit Study Name, Edit Study Day, or Edit Workup checkbox. If the check marks beside these options are enabled as shown in Figure 13, these fields may be manually modified from their original values from when the Study was created.

Figure 13. – Edit Study Name, Edit Study Day, and Edit Workup allows Study information to be edited.

As with the SEND dialog, the Subject Setup dialog will also automatically fill Study Subject Name and Study Dose information. Deselecting Use Study Subjects and Use Study Doses will allow modification of the Study Protocol Option generated information.

The information populated here is based on the information contained in the Review file opened when in the Run Study dialog or outside of Study. For example, Study Dose information will update appropriately if running a Latin Square design based on the information contained in the Review file that was opened.

Subject Setup

Subject Details

☒ Use Study Subjects/Sex
 ☒ Use Study Doses

▼ Subject.500 (Subject500)

Pressure

LEAD II

Ambient

▼ Subject.501 (Subject501)

Pressure

LEAD II

Ambient

▼ Subject.502 (Subject502)

Pressure

LEAD II

Ambient

▼ Subject.503 (Subject503)

Pressure

LEAD II

Ambient

▶ Subject.504 (Subject504)

▶ Subject.505 (Subject505)

▶ Subject.506 (Subject506)

▶ Subject.507 (Subject507)

Study Subject Name

Enabled ☒

Study Dose

Cage

Sex ☒ Male ☐ Female ☐ N/A

Species

Camera

	Analysis		Label	Units	Precision	Trigger	Enabled
(Removed)							
	BP		Pressure	mmHg	0000.	☒	☒
	ECG		LEAD II	mV	0000.	☐	☒
APR - 2802							
	BARO		Ambient	mmHg	00.00	☐	☒

Figure 14. – Subject Setup dialog with subject and dose information pulled from Study.

SEND Manager

SEND Manager is available from the SEND pull-down menu in Ponemah while in idle mode and allows you to access collections that have been previously saved. If in Review, SEND Manager will not be available (selection will be grayed out).

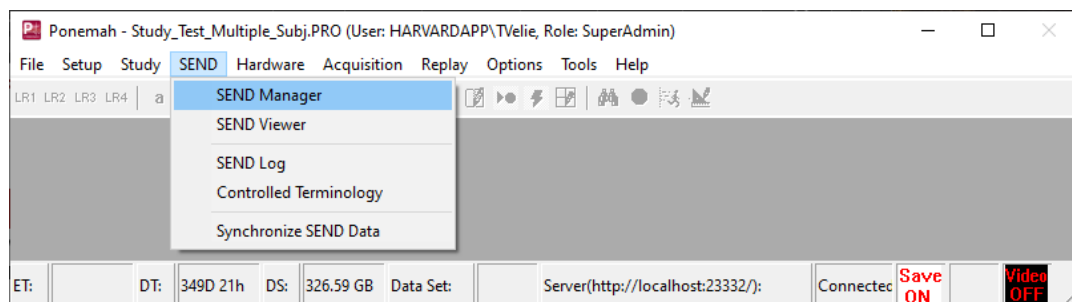


Figure 15. – SEND Manager access point from the SEND pull-down menu.

In addition to listing the collections available with SEND information, SEND Manager has backup and restore capabilities as described below. Each time a unique SEND study name is created, and data is saved, that study name will be listed in the dialog below.

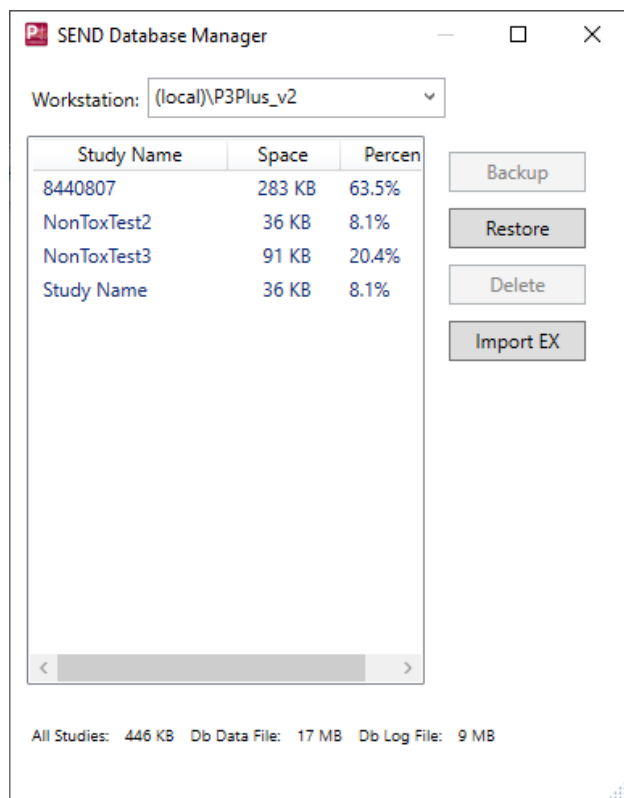


Figure 16. – SEND Manager dialog.

1 – Workstation

Lists the local Ponemah SQL Instance, P3Plus_v2, by default. If networked, users can select the P3Plus_v2 Instances on other networked workstations or can choose the Ponemah Server that all stations are connected to.

2 – Study Name and Space

Lists all available study names with previously saved SEND information and the amount of disk space that each study occupies.

3 – Backup

Allows the studies to be backed up and moved to other workstations or for archival purposes. The backup dialog is shown below. Use the typical Windows navigation to browse to the desired folder location and specify a file name for the backup file. The file type will automatically default to “.sendbkup”.

NOTE: If migrating the SEND database from the version found in 5.32 to 5.40, you may first want to backup all SEND databases. See Upgrade 5.32 Data below.

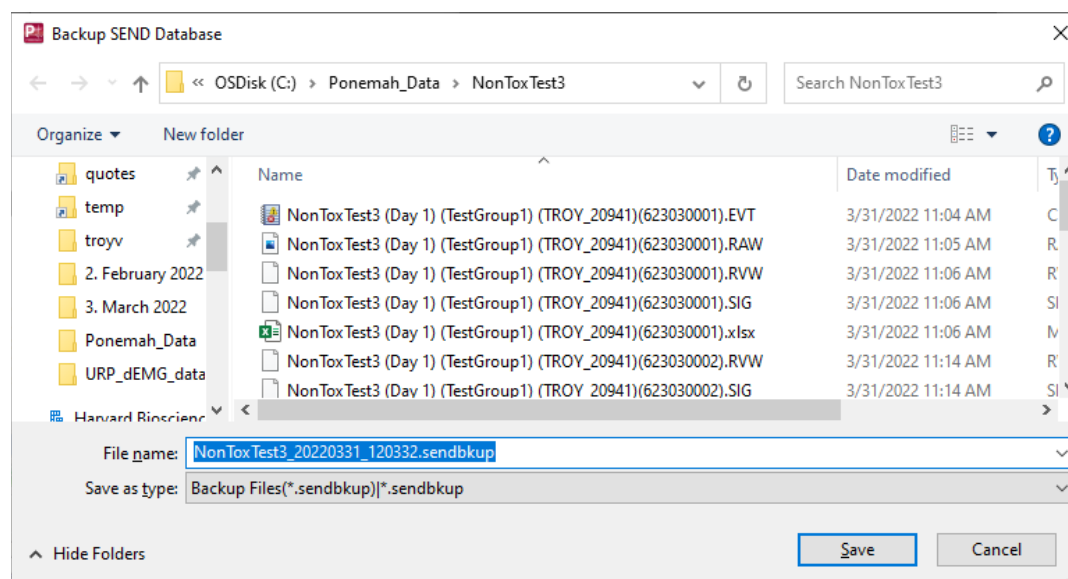


Figure 17. – Example SEND backup file being saved.

4 – Restore

Allows studies to be restored from other workstations or reopened from an archival location. This feature functions similar to that described under Backup shown above.

5 – Delete

The Delete function will remove the Study from the list in the SEND Manager dialog and will also remove any SEND associated data (SEND database) with the study from the SQL database. Size information (All Studies, Db Data File, and Db Log File) is provided at the bottom of the window. This change will be reflected under All Studies as the data size will decrease. Even though the SEND data was deleted, the space allocated for that data will remain and may appear as if the size of the database has not changed for the Db Data and Log Files. When new SEND data is generated, that space will be utilized by the new data.

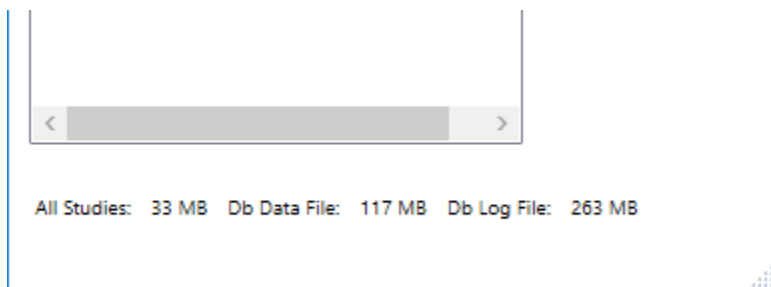


Figure 18. – SEND Manager Data size information.

6 – Import EX

The ability to import information is possible by creating a CSV file and using the Import EX function in SEND Database Manager. The required columns for successful import are STUDYID, USUBJID, EXSTDTC, EXSTDY, and optionally EXENDTC may be provided. Exposure domain information is not available in Ponemah, although some Variables require exposure data. Exposure data can be brought into Ponemah by importing an EX domain that has been exported from a LIMS system or other repository.

The following variables will report NULL unless an Exposure domain containing actual dose times is imported (DY, ENDY, RFTDTC). The EX domain can be imported at any point prior to exporting the CSV.

SEND Viewer and Output

The following sections detail the output options available for SEND generated data and the tools which can be used to view and modify the output.

SEND Export To Excel

To generate SEND data to Excel, the Enable Excel Output function must be selected in the SEND setup tab of the P3 Setup menu. Excel output is available for both license file options, SEND Output and SEND SQL Server Output. Additionally, users must have enabled Data Reduction and selected derived parameters in the Channel Input Setup menu that correspond to output designated by CDISC (refer to SEND Setup from PPP3 Setup section for configuration information).

SEND output will be generated and included in the Microsoft Excel workbook created upon Saving a Marks Section (Run) or Derived Data within a Review session along with other Ponemah data related worksheets. Note that not all Ponemah derived parameters are defined by CDISC. Only those CDISC defined variables will be present in the output generated.

	C	D	E	F	G	H	I	J	K	L	M	
1	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVSTAT	CVRE
2	CV	Group A	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	118.40	'mmHg'	118.40	118.40	'mmHg'	NULL	NULL
3	CV	Group A	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.5708	'mmHg'	5.5708	5.5708	'mmHg'	NULL	NULL
4	CV	Group A	HR	Heart Rate	UNCONSTRAINED	74.319	'bpm'	74.319	74.319	'bpm'	NULL	NULL
5	CV	Group A	DPDTAVG	dP/dt Average	UNCONSTRAINED	3310.2	'mmHg/s'	3310.2	3310.2	'mmHg/s'	NULL	NULL
6	CV	Group A	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.87	'mmHg'	117.87	117.87	'mmHg'	NULL	NULL
7	CV	Group A	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	81.248	'mmHg'	81.248	81.248	'mmHg'	NULL	NULL
8	CV	Group A	MAP	Mean Arterial Pressure	UNCONSTRAINED	99.849	'mmHg'	99.849	99.849	'mmHg'	NULL	NULL
9	CV	Group A	PULSEPR	Pulse Pressure	UNCONSTRAINED	36.621	'mmHg'	36.621	36.621	'mmHg'	NULL	NULL
10	CV	Group A	ACTIVITY	Activity	UNCONSTRAINED	0.0164	"	0.0164	0.0164	"	NULL	NULL
11	CV	Group A	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	111.20	'mmHg'	111.20	111.20	'mmHg'	NULL	NULL
12	CV	Group A	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	4.7871	'mmHg'	4.7871	4.7871	'mmHg'	NULL	NULL
13	CV	Group A	HR	Heart Rate	UNCONSTRAINED	60.679	'bpm'	60.679	60.679	'bpm'	NULL	NULL
14	CV	Group A	DPDTAVG	dP/dt Average	UNCONSTRAINED	3023.4	'mmHg/s'	3023.4	3023.4	'mmHg/s'	NULL	NULL
15	CV	Group A	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	112.41	'mmHg'	112.41	112.41	'mmHg'	NULL	NULL
16	CV	Group A	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	76.446	'mmHg'	76.446	76.446	'mmHg'	NULL	NULL
17	CV	Group A	MAP	Mean Arterial Pressure	UNCONSTRAINED	94.795	'mmHg'	94.795	94.795	'mmHg'	NULL	NULL
18	CV	Group A	PULSEPR	Pulse Pressure	UNCONSTRAINED	35.967	'mmHg'	35.967	35.967	'mmHg'	NULL	NULL
19	CV	Group A	ACTIVITY	Activity	UNCONSTRAINED	NULL	NULL	NULL	NULL	NULL	'NOT DONE'	'INCC'
20	CV	Group A	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	115.28	'mmHg'	115.28	115.28	'mmHg'	NULL	NULL
21	CV	Group A	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.6705	'mmHg'	5.6705	5.6705	'mmHg'	NULL	NULL
22	CV	Group A	HR	Heart Rate	UNCONSTRAINED	64.359	'bpm'	64.359	64.359	'bpm'	NULL	NULL
23	CV	Group A	DPDTAVG	dP/dt Average	UNCONSTRAINED	3043.0	'mmHg/s'	3043.0	3043.0	'mmHg/s'	NULL	NULL
24	CV	Group A	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.20	'mmHg'	117.20	117.20	'mmHg'	NULL	NULL
25	CV	Group A	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	78.698	'mmHg'	78.698	78.698	'mmHg'	NULL	NULL
26	CV	Group A	MAP	Mean Arterial Pressure	UNCONSTRAINED	98.12	'mmHg'	98.12	98.12	'mmHg'	NULL	NULL
27	CV	Group A	PULSEPR	Pulse Pressure	UNCONSTRAINED	38.50	'mmHg'	38.50	38.50	'mmHg'	NULL	NULL

Figure 20. – Example output when enabling Excel in the SEND dialog.

If the collection contains data from more than one Domain, multiple worksheets will be created within the Excel workbook. Since the study shown in Figure 20 incorporated both CV and EG domain data, two worksheets are created in the Excel workbook with the appropriate information for each Domain.

SEND Viewer

Selecting SEND Viewer from the SEND pulldown menu will display the following dialogs. In order to view SEND information, users must have enabled Data Reduction and selected derived parameters in the Channel Input Setup menu that correspond to output designated by CDISC (refer to SEND Setup from PPP3 Setup section for configuration information).

SEND Viewer allows selection and filtering of the study data and information for export to a CSV formatted file to be imported into other systems. Figure 21 shows the SEND Viewer dialog populated with data from the CV Domain and the associated CDISC controlled terminology displayed in the column headers. Scroll bars on the bottom and right side of the dialog allow the user to scroll and view the entire contents of the window.

The Workstation pulldown menu lists the local Ponemah SQL instance, P3Plus_v2, by default along with any designated Output Server that has been configured. If networked, users can select P3Plus_v2 Instances on other networked workstations or servers. This allows access to the local Ponemah SEND database as well as other Ponemah SEND databases on workstations that are accessible on the network. Selecting a workstation will display any previously collected information (studies) that is available for export. The pull-down menu will be populated with workstation information if studies have been created using the Study Protocol Option. All workstations that were configured for a given study will be loaded and available via the pull-down menu. The list of workstations available may change based on the study that is selected in the Manage Studies dialog.

Selecting the Options in the upper left-hand side of the dialog will expand and display filters that allow you to select the desired information for export. This includes the study, subjects, days and CDISC defined parameters.

SEND Viewer

Workstation: (local)\P3Plus_v2

Export to CSV

Options

STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	CVSTRESC	CVSTRESU
8440807	CV	8440807-P0001	277	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	73.982	mmHg	73.982	73.982
8440807	CV	8440807-P0001	280	HR	Heart Rate	UNCONSTRAINED	205.48	beats/min	205.48	205.48
8440807	CV	8440807-P0001	278	MAP	Mean Arterial Pressure	UNCONSTRAINED	95.967	mmHg	95.967	95.967
8440807	CV	8440807-P0001	279	PULSEPR	Pulse Pressure	UNCONSTRAINED	44.819	mmHg	44.819	44.819
8440807	CV	8440807-P0001	276	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	118.8	mmHg	118.8	118.8
8440807	CV	8440807-P0001	282	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	75.895	mmHg	75.895	75.895
8440807	CV	8440807-P0001	285	HR	Heart Rate	UNCONSTRAINED	197.8	beats/min	197.8	197.8
8440807	CV	8440807-P0001	283	MAP	Mean Arterial Pressure	UNCONSTRAINED	97.37	mmHg	97.37	97.37
8440807	CV	8440807-P0001	284	PULSEPR	Pulse Pressure	UNCONSTRAINED	45.67	mmHg	45.67	45.67
8440807	CV	8440807-P0001	281	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	121.57	mmHg	121.57	121.57
8440807	CV	8440807-P0001	287	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	77.106	mmHg	77.106	77.106
8440807	CV	8440807-P0001	290	HR	Heart Rate	UNCONSTRAINED	197.37	beats/min	197.37	197.37
8440807	CV	8440807-P0001	288	MAP	Mean Arterial Pressure	UNCONSTRAINED	100.28	mmHg	100.28	100.28
8440807	CV	8440807-P0001	289	PULSEPR	Pulse Pressure	UNCONSTRAINED	46.365	mmHg	46.365	46.365
8440807	CV	8440807-P0001	286	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	123.47	mmHg	123.47	123.47
8440807	CV	8440807-P0001	292	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	75.356	mmHg	75.356	75.356
8440807	CV	8440807-P0001	295	HR	Heart Rate	UNCONSTRAINED	142.63	beats/min	142.63	142.63
8440807	CV	8440807-P0001	293	MAP	Mean Arterial Pressure	UNCONSTRAINED	99.811	mmHg	99.811	99.811
8440807	CV	8440807-P0001	294	PULSEPR	Pulse Pressure	UNCONSTRAINED	47.627	mmHg	47.627	47.627
8440807	CV	8440807-P0001	291	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	122.98	mmHg	122.98	122.98
8440807	CV	8440807-P0001	297	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	77.74	mmHg	77.74	77.74
8440807	CV	8440807-P0001	300	HR	Heart Rate	UNCONSTRAINED	144.58	beats/min	144.58	144.58
8440807	CV	8440807-P0001	298	MAP	Mean Arterial Pressure	UNCONSTRAINED	101.44	mmHg	101.44	101.44
8440807	CV	8440807-P0001	299	PULSEPR	Pulse Pressure	UNCONSTRAINED	47.591	mmHg	47.591	47.591
8440807	CV	8440807-P0001	296	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	125.33	mmHg	125.33	125.33
8440807	CV	8440807-P0001	302	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	78.093	mmHg	78.093	78.093
8440807	CV	8440807-P0001	305	HR	Heart Rate	UNCONSTRAINED	143.88	beats/min	143.88	143.88
8440807	CV	8440807-P0001	303	MAP	Mean Arterial Pressure	UNCONSTRAINED	101.37	mmHg	101.37	101.37
8440807	CV	8440807-P0001	304	PULSEPR	Pulse Pressure	UNCONSTRAINED	46.324	mmHg	46.324	46.324

120 records total

Figure 21. – SEND Viewer dialog.

Figure 22 shows the Options pin expanded. Four filters are available to tailor the SEND output to CSV format.

1 – Study

Lists previously collected studies that are present on the workstation selected. Selecting a study will load any SEND related information. Figure 22 shows CVTest1 selected and its associated data displayed.

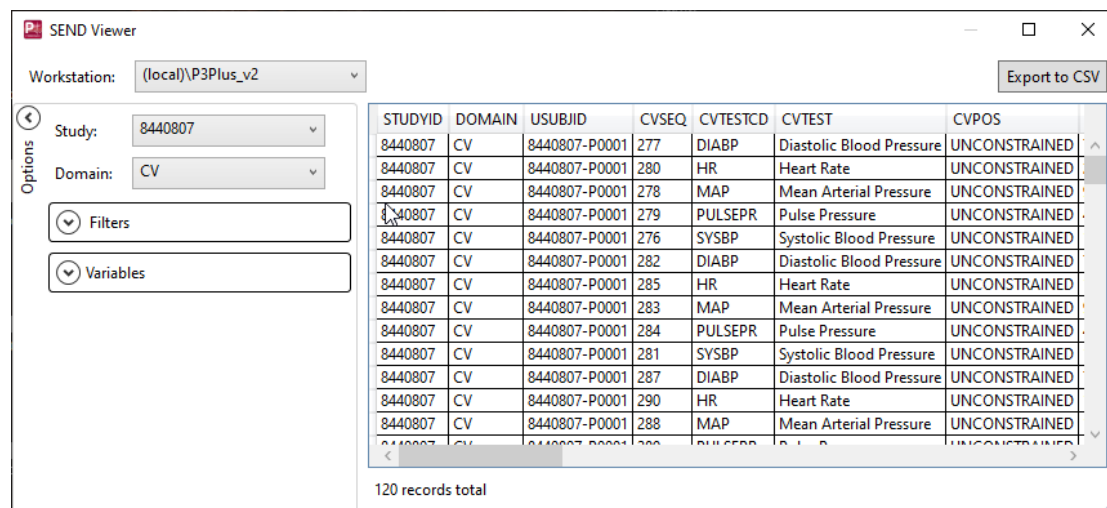


Figure 22. – SEND Viewer dialog.

2 – Domain

After the Study has been chosen, the correct SEND Domain must be selected. If an incorrect Domain is selected, the appropriate data will not populate in the window.

3 – Filters

Expanding the Filters option allows the user to define what information will be displayed and available for output to CSV. This includes USUBJID, EGNOMDY, and EGTESTCD for the given Domain.

The “All” checkbox allows the user to toggle all variables on or off. Additionally, each variable may be selected or deselected individually to create the desired output.

It is important to note that not all Ponemah generated parameters are required by CDISC (TESTCD). Only parameters defined by CDISC will be displayed.

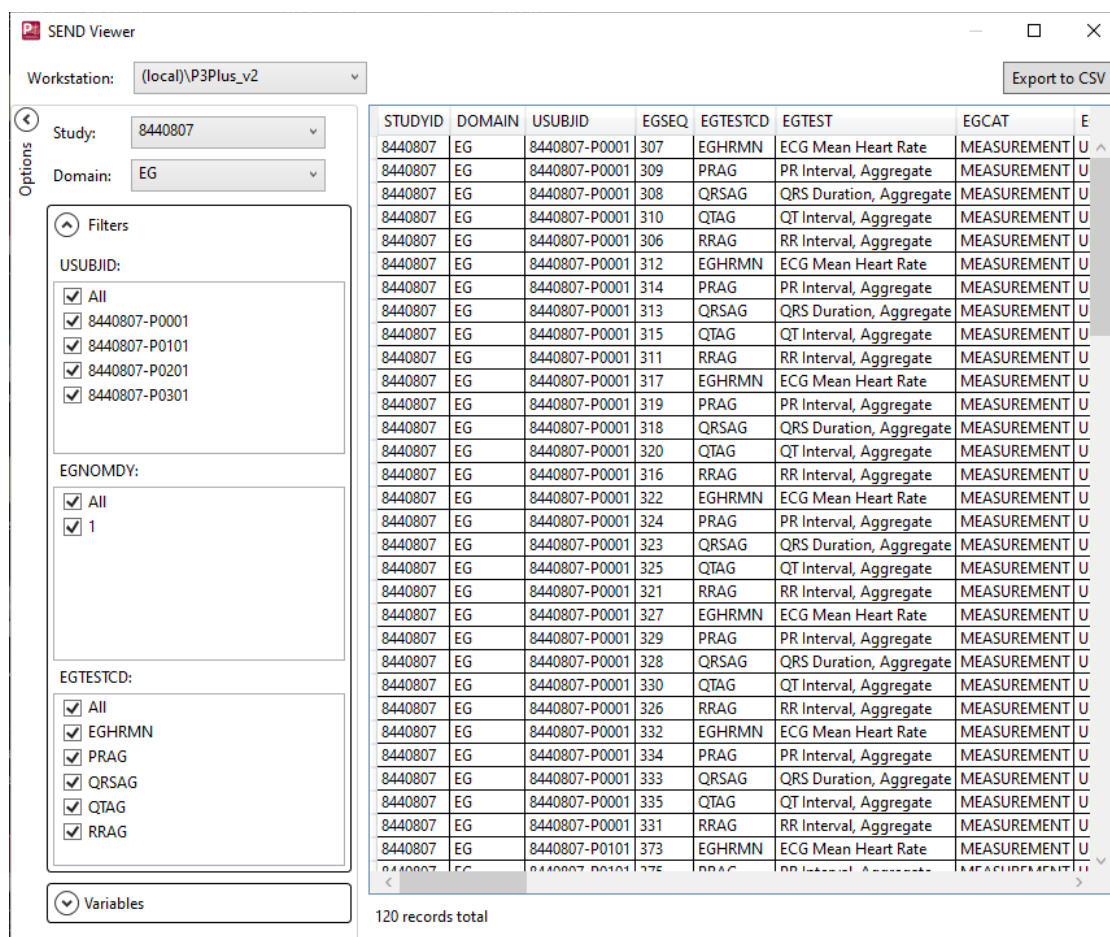


Figure 23. – SEND Viewer dialog displaying available filters.

4 – Variables

The Variables option controls which CDISC defined variables will be displayed and outputted to the CSV formatted file. Toggling specific variables will enable or disable the variables in the viewer and the associated CSV file when generated. This may be used to remove variables that are not populated with information.

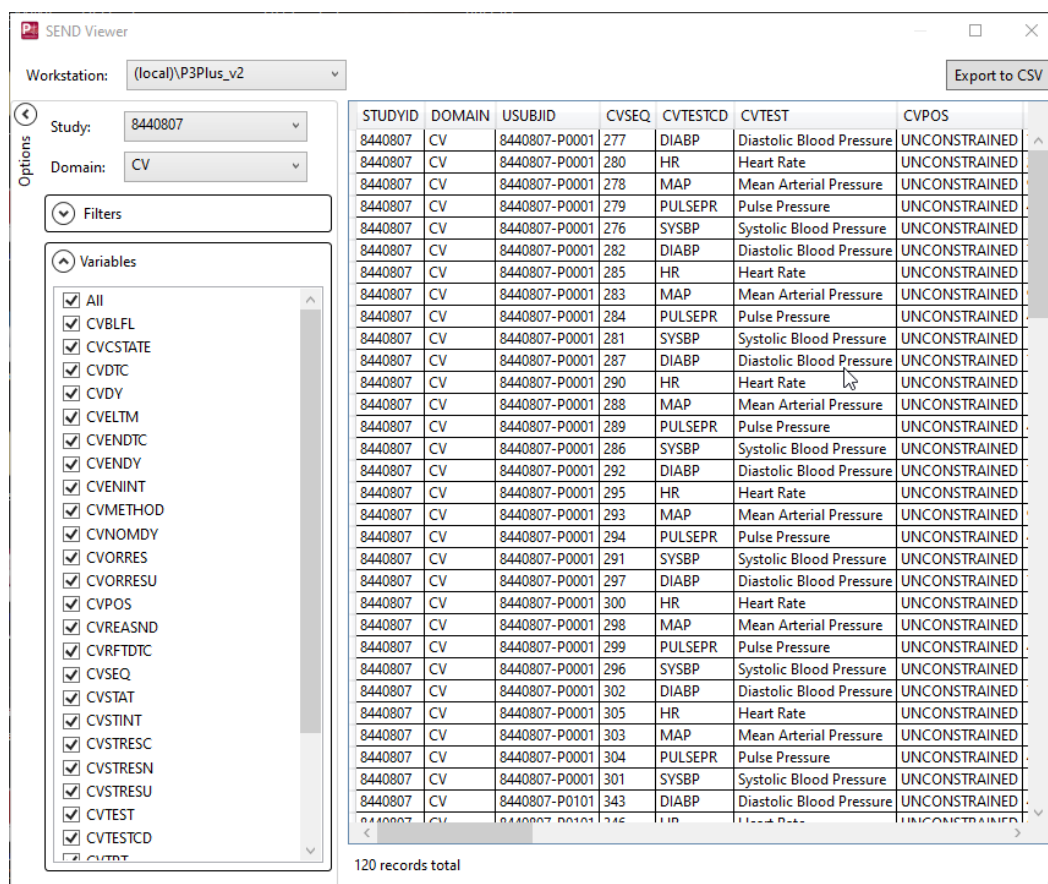


Figure 24. – SEND Viewer dialog with Variables option expanded.

In the example study above (CVTest3 from Figure 24), EG Domain data was collected along with CV Domain data. In order to get the EG Domain variables, simply select the EG Domain as shown in Figure 25 and update the remaining Options to provide the desired output.

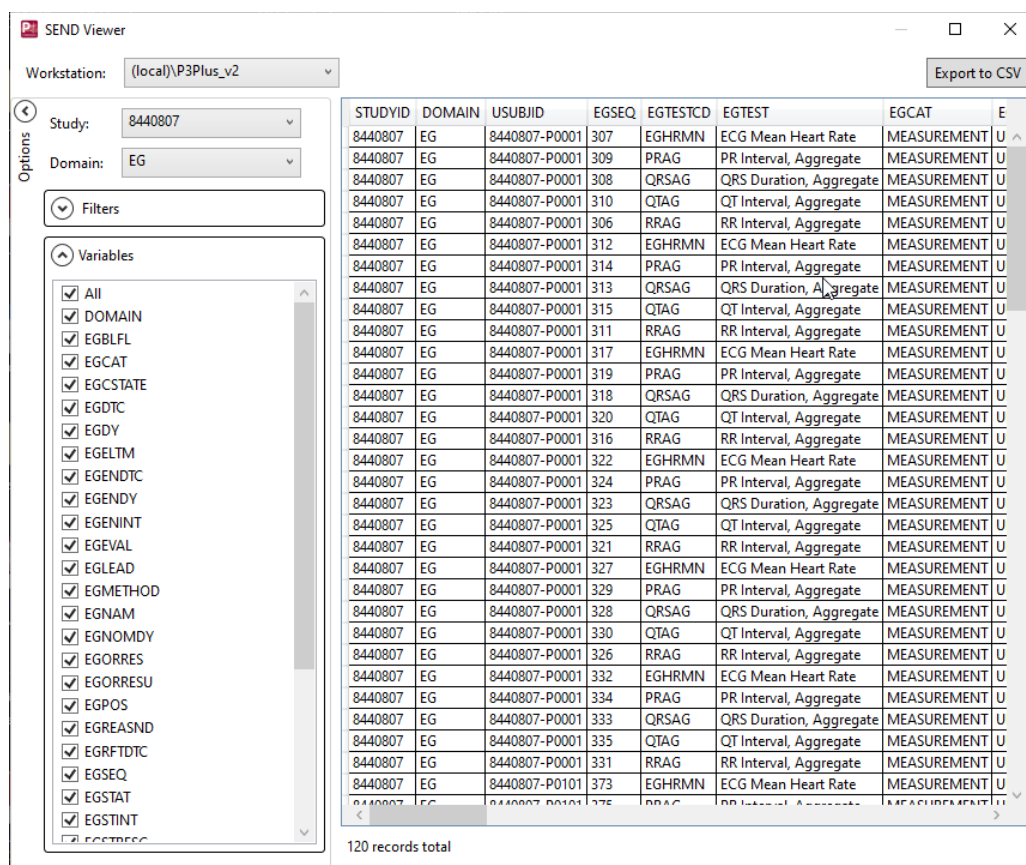


Figure 25. – SEND Viewer dialog with Variables option expanded and EG Domain selected.

Send Export to CSV

Once the appropriate filters and variables have been defined as outlined in the SEND Viewer section, the data is ready to export to a CSV formatted file. This is accomplished by selecting the Export to CSV button in the top, right-hand portion of the dialog.

NOTE: It is important to note that this functionality is only available if the SEND SQL Server Option has been enabled in the license file. If only SEND Output is enabled, these features will not be available.

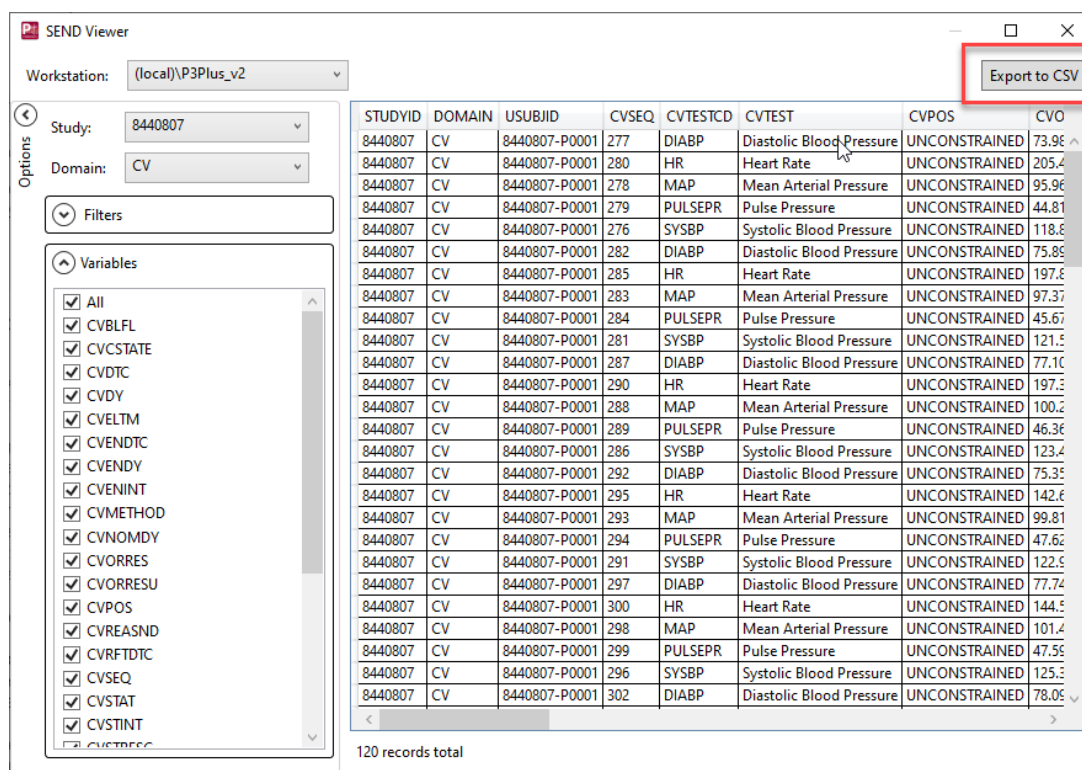


Figure 26. – SEND Viewer dialog with Export to CSV button highlighted.

A Windows dialog will be displayed with the default location set to the study folder within the Ponemah_Data directory. The file name will include the study name and date and will be configured to save in the CSV format. The name and location for saving the file may be changed by modifying the “File name” edit field and using the browse feature to specify a different location.

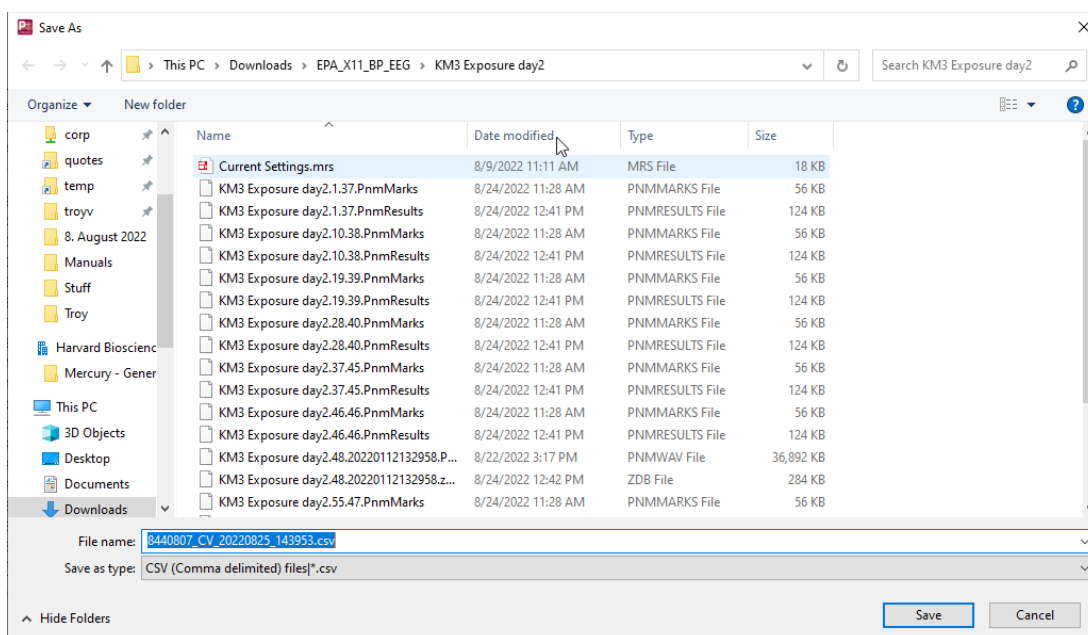


Figure 27. – Default location and file type for saving SEND output via SEND Viewer.

Once the file has been saved, browsing to the location and opening the file will display the data as configured in SEND Viewer. Figure 28 shows the CSV output opened using Microsoft Excel.

	A	B	C	D	E	F	G	H	I	J
	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESI	CVSTRESC
1	CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	118.37	mmHg	118.37
2	CV Test1	CV	Group A	2322	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.5588	mmHg	5.5588
3	CV Test1	CV	Group A	2323	HR	Heart Rate	UNCONSTRAINED	74.33	bpm	74.33
4	CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average	UNCONSTRAINED	3310.4	mmHg/s	3310.4
5	CV Test1	CV	Group A	2325	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.83	mmHg	117.83
6	CV Test1	CV	Group A	2326	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	81.212	mmHg	81.212
7	CV Test1	CV	Group A	2327	MAP	Mean Arterial Pressure	UNCONSTRAINED	99.818	mmHg	99.818
8	CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	UNCONSTRAINED	36.623	mmHg	36.623
9	CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricular Maximum Positive dP/dt	UNCONSTRAINED	10566	mmHg/s	10566
10	CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricular Minimum Positive dP/dt	UNCONSTRAINED	2565.3	mmHg/s	2565.3
11	CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	111.21	mmHg	111.21
12	CV Test1	CV	Group A	2332	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	4.7925	mmHg	4.7925
13	CV Test1	CV	Group A	2333	HR	Heart Rate	UNCONSTRAINED	60.651	bpm	60.651
14	CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average	UNCONSTRAINED	3023.2	mmHg/s	3023.2
15	CV Test1	CV	Group A	2335	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	112.43	mmHg	112.43

Figure 28. – Example of CSV output.

SEND Log

The SEND Log provides information regarding changes to the data stored in the SEND database on the local system or the server.

NOTE:

Only log information pertaining to the most recently saved data for a given collection is preserved in the SEND Log. This is due to the fact that the SEND database only contains the most recently saved information for a given subject or collection of subjects from a collection. Data is not appended in the SEND database. Only data that matches the Study and subject for the associated acquisition (day and time) is replaced. For example, if Day 7 data is analyzed and SEND data is generated, only Day 7 data would be affected, not previously saved SEND data for prior collection days.

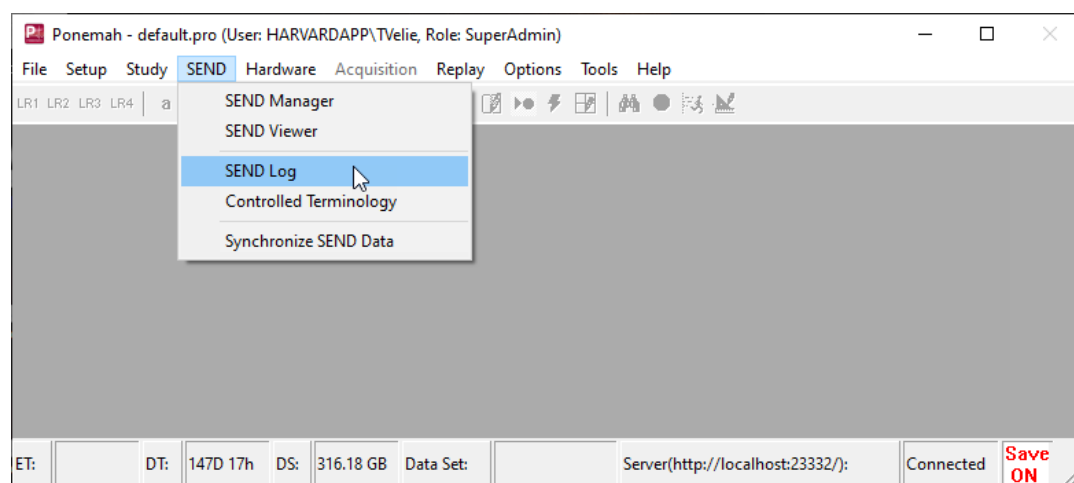


Figure 29. – SEND Log access point from the SEND pull-down menu.

The SEND Log displayed below will provide information about changes to the SEND database. Additional details may be found in the Application Log depending on the function performed.

SEND Log

Workstation: (local)\P3Plus_v2

Export to CSV

Domain	NOMDY	USUBJID	Review File Name	RAW File Start	RAW File End	User	Workstation Name	Action Date	Action
CV	1	8440807-P0001	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:02	Save - Review
EG	1	8440807-P0001	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:02	Save - Review
VS	1	8440807-P0001	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:02	Save - Review
CV	1	8440807-P0101	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
EG	1	8440807-P0101	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
VS	1	8440807-P0101	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
CV	1	8440807-P0201	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
EG	1	8440807-P0201	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
VS	1	8440807-P0201	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
CV	1	8440807-P0301	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
EG	1	8440807-P0301	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review
VS	1	8440807-P0301	8440807_Dose_update (Day 15) (Group 1) (25940002).RVW	2020-09-02T06:48:12	2020-09-03T09:20:02	ADMIN	TROY-20941	2021-04-15T16:30:03	Save - Review

12 records total

Figure 30. – SEND Log.

1 – Workstation

Defaults to the local instance. However, if workstations are networked, users can access the SEND Log on other workstations.

2 – Options

The Options flyout is available in the left hand edge of the menu. Users can filter on Domain, Subjects, Review File Name, and all available columns in the log itself as shown below.

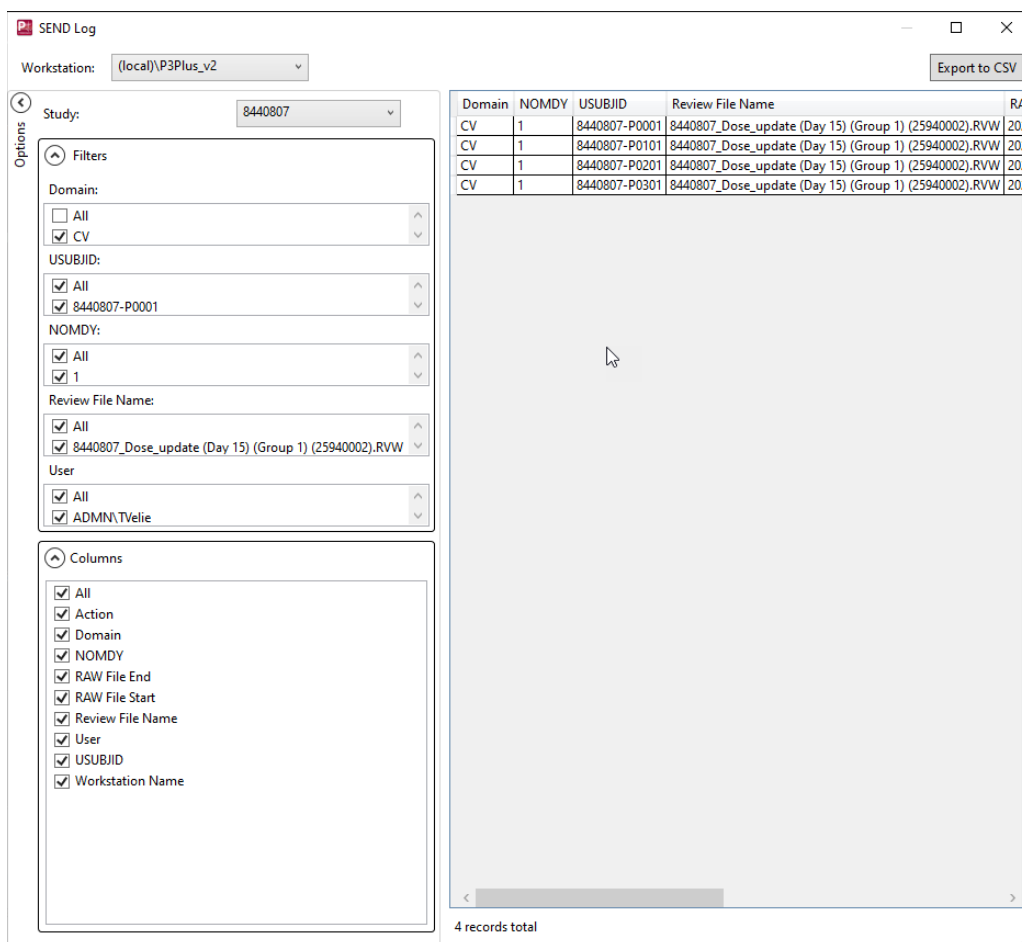


Figure 31. – SEND Log showing available Options for filtering information presented in the Log.

3 – Export To CSV

Allows the log information to be exported to a .CSV file. The default location is Ponemah_Data but the file can be saved to any location using Windows browse function.

4 – Log Information

Displays information on the Domain, Day of collection, file information, User and the Action initiated which resulted in the log being created.

Controlled Terminology

The Controlled Terminology menu allows the user to view or modify the terminology used for SEND submission. Select Controlled Terminology from the SEND pull-down menu.

NOTE: If installing Ponemah version 5.40 over an existing 5.32 installation, Ponemah will automatically pull in the existing information contained in the SEND.xml file from version 5.32. Therefore, any modifications to the Controlled terminology, EG Methods, etc. from 5.32 will be preserved and loaded into 5.40. If 5.32 has been uninstalled, the SEND.xml simply needs to be present in the directory that 5.40 will be installed.

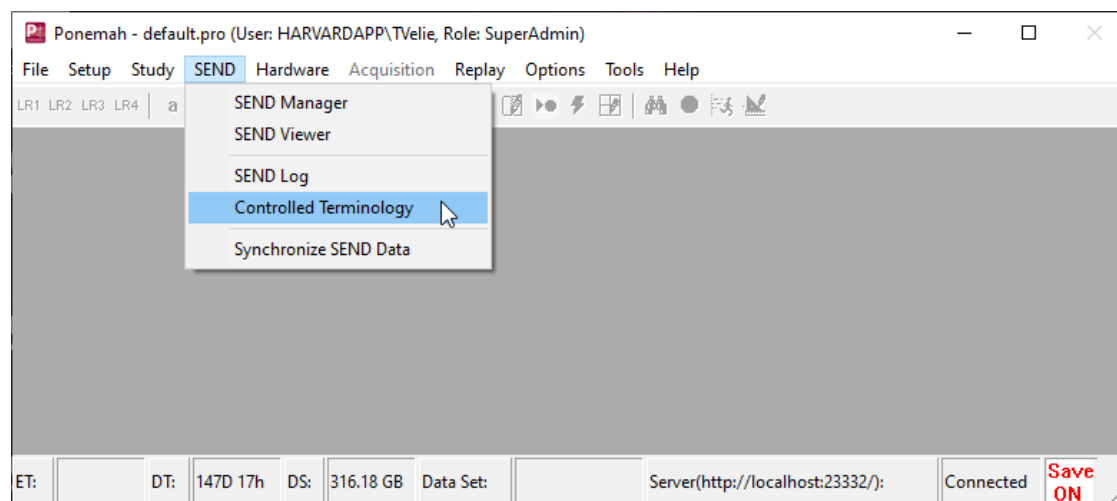


Figure 32. – Access point for Controlled Terminology.

The currently approved CDISC terminology has been prepopulated in the Test Codes menu shown below. Please note that this menu does not determine SEND output when data is saved. This is a table of the parameters and terminology that will be available in the SEND Viewer menu.

SEND Controlled Terminology Manager

Workstation: (local)\P3Plus_v2

Display: TestCodes

Export Import

☐ Replace on Import

Enabled	Domain	Analysis	Derived Parameter	DR Calc	TESTCD	TEST	Units
☒	CV	ACT	A_TA	Avg	ACTIVITY	Activity	
☒	CV	BP	Dia	Avg	DIABP	Diastolic Blood Pressure	mmHg
☒	CV	BP	HR	Avg	HR	Heart Rate	beats/min
☒	CV	BP	Mean	Avg	MAP	Mean Arterial Pressure	mmHg
☒	CV	BP	PH	Avg	PULSEPR	Pulse Pressure	mmHg
☒	CV	BP	Q-A	Avg	QAMEAN	Summary (Mean) QA Interval	msec
☒	CV	BP	Q-A	Max	QAMAX	Summary (Max) QA Interval	msec
☒	CV	BP	Q-A	Min	QAMIN	Summary (Min) QA Interval	msec
☒	CV	BP	Sys	Avg	SYSBP	Systolic Blood Pressure	mmHg
☒	CV	LVP	+dP/dt	Avg	DPDTAVG	dP/dt Average	mmHg/s
☒	CV	LVP	+dP/dt	Max	DPDTMAX	Left Ventricular Maximum Positive dP/dt	mmHg/s
☒	CV	LVP	+dP/dt	Min	DPDTMIN	Left Ventricular Minimum Positive dP/dt	mmHg/s
☒	CV	LVP	-dP/dt	Max	DPDTNEG	Left Ventricular Maximum Negative dP/dt	mmHg/s
☒	CV	LVP	HR	Avg	HR	Heart Rate	beats/min
☒	CV	LVP	LVEDP	Avg	LVEDP	Left Ventricular End Diastolic Pressure	mmHg
☒	CV	LVP	Sys	Avg	LVSYSBP	Left Ventricular Systolic Pressure	mmHg
☒	CV	SBF	TPR	Avg	TPR	Total Peripheral Resistance	mmHg/mL/min

OK Cancel

Figure 33. – Test Codes listing within Controlled Terminology.

1 – Workstation

Defaults to the local instance. However, if workstations are networked, users can access Controlled Terminology menus on other workstations.

2 – Display

Allows the selection of the following menus which can be modified by the user. The information entered here will be the available options displayed in SEND Viewer for generating SEND output.

- TestCodes
- EG Methods
- EG Leads
- CV Methods
- RE Methods
- CStates
- Position
- ECG Results

3 – Export

Allows the currently saved settings to be exported to a .xml file for importing into other workstations.

4 – Import

Allows previously exported .xml files to be imported. This will automatically update the current settings to minimize manual changes on each workstation. If information differs between the .xml file currently stored and the file being imported, the differences will be appended. Information is not overwritten using this function.

Each of the options available under the Display pull-down menu can be modified as mentioned. Figure 34 shows the addition of the TTI derived parameter. To add a parameter that is available in the Ponemah derived parameter list (but not defined by CDISC), scroll to the bottom of the list and click in the available cells under the various column headers. A drop down list will be displayed to provide available selections. In this example, CV was selected for the Domain, LVP was selected for the analysis module, and TTI was the derived parameter of interest. The DR Calc column shows the cell being modified and the three available options.

When adding parameters not defined by default, TESTCD, TEST, and Units will be manually entered.

The option to disable and delete entries is also available. In the case of the TestCode menu, deselecting the check mark under the Enable column for a Test Code will preserve the entry but will remove it from the SEND Viewer menu and not allow reporting of that parameter through SEND. When a TestCode has been disabled, it will drop down to the bottom of the list for that Domain (list is sorted by Domain).

To delete an entry, right click on the desired item and the option to delete will be available. Multiple entries can be selected and deleted at once using the shift key. Note that entries will be removed from the list and will need to be manually entered if needed in the future.

It is recommended to Export the list prior to making any changes and save the .xml file for future use. When importing a file, the Controlled Terminology dialog must be closed and reopened to view changes. Any new entries will be displayed in the list but will be disabled by default.

The Replace on Import checkbox provides a method to remove all information currently available in the Controlled Terminology dialog. Check this box prior to importing an xml file. Next, use the Import button to browse to and load the desired SEND xml file. Only the contents of the xml file being loaded will be available within the Controlled Terminology dialog as the previous information will be deleted. This is useful when updating multiple workstations to ensure the all workstations have the same information.

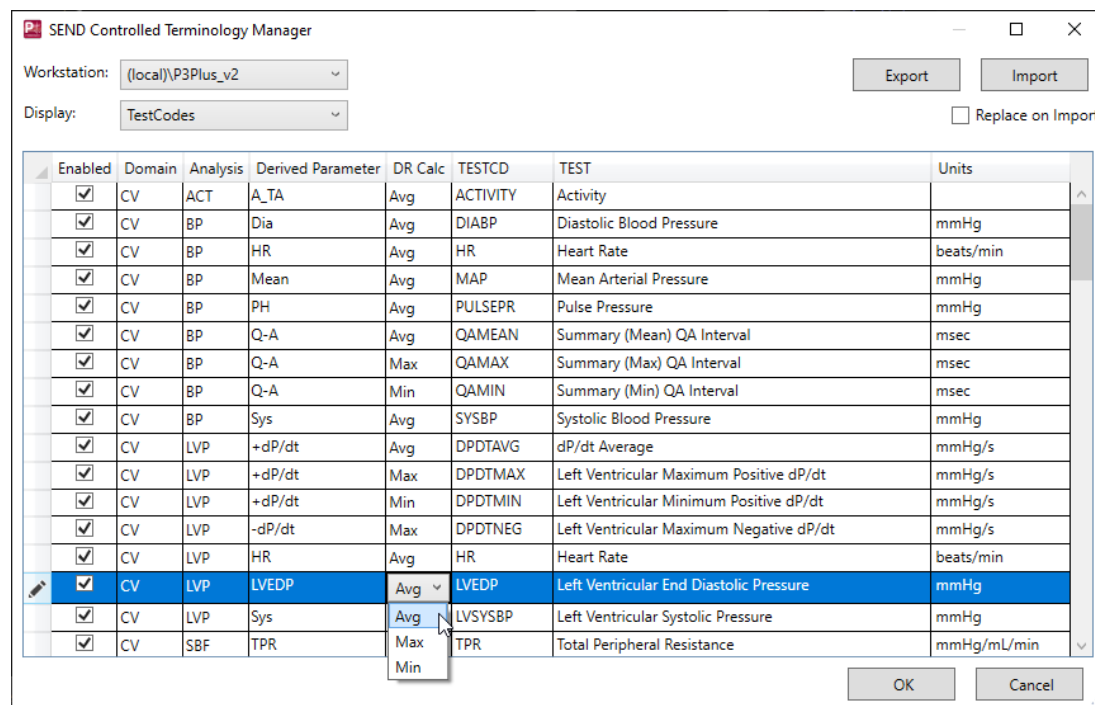


Figure 34. – Modification of Test Code calculation.

Figure 35 shows the EG Leads currently configured. All available options under the Display pull-down menu allow modification as described above.

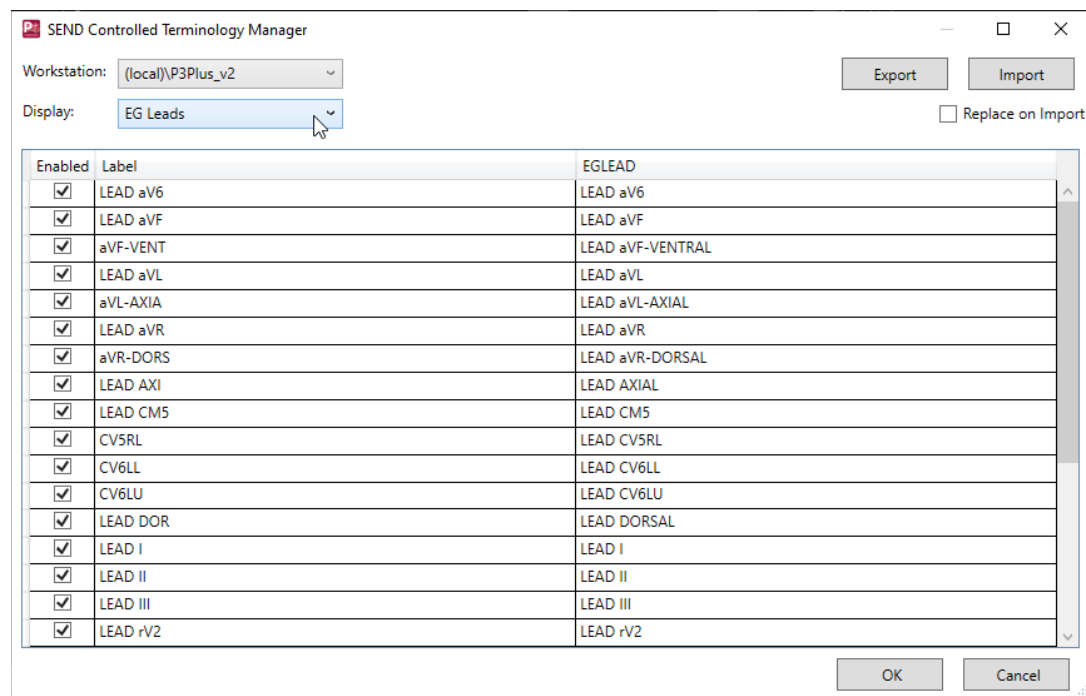


Figure 35. – EG Leads list shown.

Synchronize SEND Data

Send information can be synchronized to a dedicated server or workstation.

NOTE: It is important to note that this functionality is only available if the SEND SQL Server Option has been enabled in the license file. If only SEND Output is enabled, these features will not be available.

Send Remote Server Synchronization Setup

The following instructions require the Ponemah SEND v3.1 module and apply to Ponemah v5.31 and greater.

1 – Create a SQL Server Instance

Consult your local IT group for assistance configuring the instance required for use with SEND. On the server, configure an instance name P3Plus_v2. Add a temporary SQL user with the following rights. Do not use P3StudyUsers as the name of the temporary SQL user.

- dbcreator
- securityadmin
- Set password to never expire

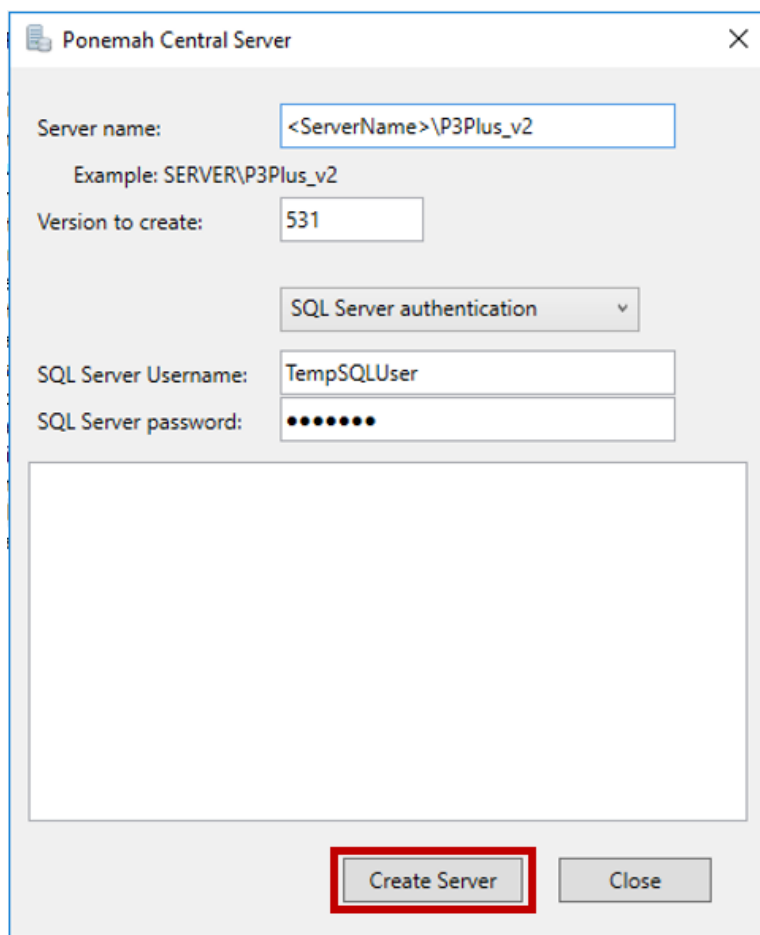
Do not require a password change on the first logon

Two firewall ports need to be opened for Ponemah workstations to locate and use the remote SEND SQL database. Open the following ports:

- Inbound port TCP 1433
- Inbound port UDP 1434

2 – Central Server Utility

Please note that the example below uses Ponemah v5.31 but this utility can be used with Ponemah versions 5.31 and greater. Substitute v531 with the Ponemah version being used, example 532, 540, etc.



The screenshot shows the 'Ponemah Central Server' utility window. It contains the following fields and controls:

- Server name:** A text box containing '<ServerName>\P3Plus_v2'. Below it, an example is shown: 'Example: SERVER\P3Plus_v2'.
- Version to create:** A text box containing '531'.
- SQL Server authentication:** A dropdown menu currently set to 'SQL Server authentication'.
- SQL Server Username:** A text box containing 'TempSQLUser'.
- SQL Server password:** A text box filled with dots.
- Buttons:** At the bottom, there are two buttons: 'Create Server' (which is highlighted with a red rectangle) and 'Close'.

Figure 36. – Output Server configuration using the Central Server Utility.

3– Run Ponemah.CentralServer.exe

The Ponemah Central Server utility can be found at C:\Ponemah\Utilities\Ponemah.CentralServer\. Enter the following information:

- Server name:
 - <ServerName>\P3Plus_v2
 - <ServerName>\P3Plus_v2<port> (if a specific port is being used)
- Version to create:
 - Use the version of the Ponemah software installed, example, 540, 550, etc.
 - Select SQL Server authentication

- SQL Server Username: Name of the temporary SQL account
- SQL Server password: Password of the temporary SQL account
- Select Create Server
- Note any messages/errors that are listed in the application
- The following actions will be taken
 - A P3StudyUsers account will be setup by the application with dbcreator rights
 - P3Plus_531 database (or appropriate version) will be created.
 - P3Studies database and tables will be created

4 – Create SEND_31 Database

Launch Ponemah and select Help and then View License. Under the Loda New License, Ponemah must be connected to the Central Server where the SEND database will be located. Verify the Central Server Url is registered as displayed below.

SEND uses the same database connection as does the reset of Ponemah.

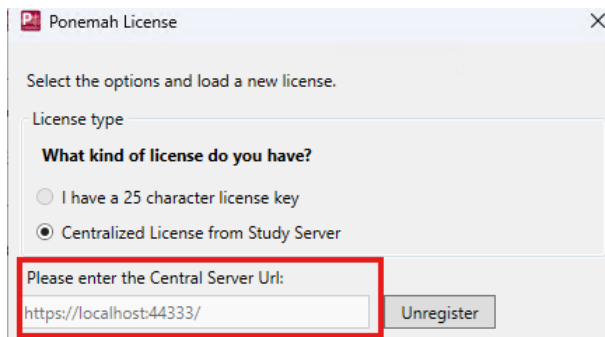


Figure 37. – Central Server configuration in License dialog.

If no Output Server has been configured, attempting to synchronize study data will post a message requesting that the server be configured in P3 Setup.

Synchronize SEND Data

The Synchronize SEND Data feature allows SEND data contained within SQL on a workstation to be synchronized with another workstation, or server, to create a single repository for SEND data. This requires configuration of the Output Server in the SEND setup dialog.

NOTE: It is important to note that when performing a sync within Review with a subset of subjects loaded, all subjects associated with the Review file will be synced. In addition, if only a single channel from a subject is loaded in review, saved, and a sync performed, all existing SEND data will be replaced for that subject in the current review file.

After verifying the Central Server Url, navigate to the Synchronize SEND Data as shown in Figure 39. The SEND data for the currently loaded Review file will be automatically synchronized to the SEND database on the Output Server (Synchronize SEND Study Data is not available within a Review session). Only data from the current Review session will be synchronized to the Output Server when in Review.

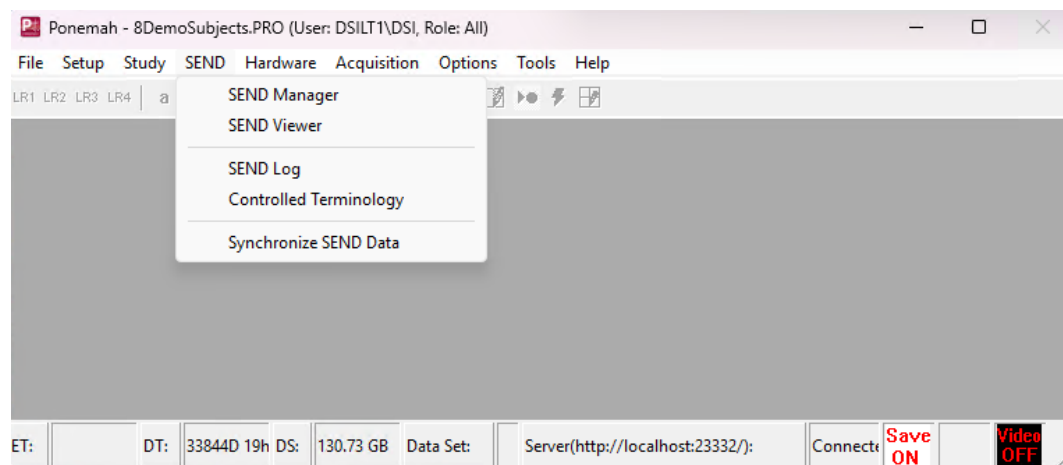


Figure 38. – Synchronize SEND Data dialog selection from SEND pull-down menu.

Figure 39 shows the pop-up dialog that allows selection of the Study. Clicking the OK button will synchronize the selected study. This will include all SEND data associated with that study, whereas when in a Review session, only the data for the currently loaded Review file will be synchronized.

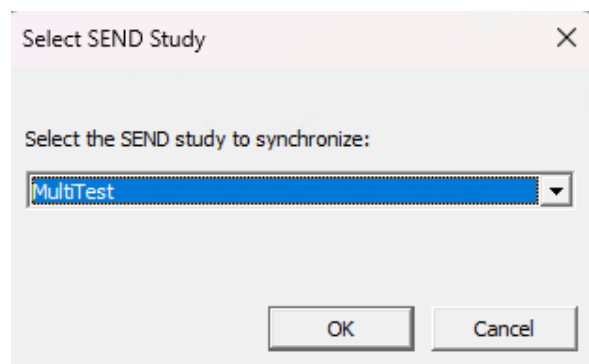


Figure 39. – Synchronize SEND Data dialog outside of Review session.

Below, figure 40, is an example of the conflict resolution dialog. The Options fly out menu in the upper left hand portion of the dialog will allow you to expand or reduce the information shown. The dialog provides two columns, one column showing data from the workstation performing the sync and a second column showing a server (or second workstation) where data is being synced. In the example, both the workstation and server contain SEND data for these two subjects.

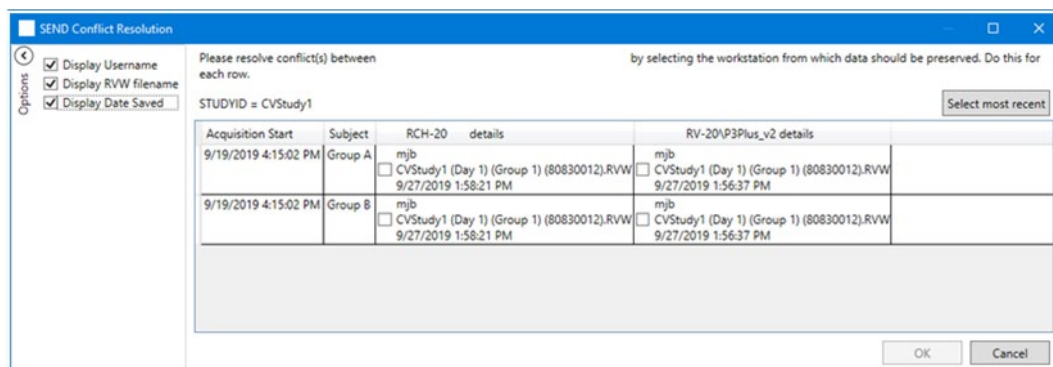


Figure 40 . – Conflict Resolution dialog.

Since the information that exists in both SEND databases does not match, the Conflict Resolution dialog is posted allowing the user to select the most appropriate data for each animal. In this example, data was reanalyzed and new values for the derived data were created. Figure 41 shows the Run information along with the time that data was saved. Time 1:58:21pm is the newly analyzed data. The option to select the most recent data, or previous data, is available per subject. Once selected, the cell is highlighted in green to easily see which runs will be synchronized to the SEND databases of each.

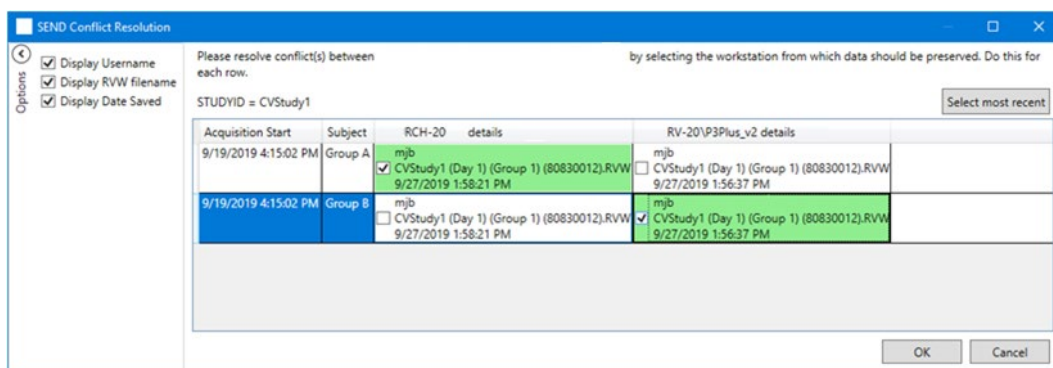


Figure 41 . – Conflict Resolution dialog.

The Select most recent button (Figure 42) instructs the software to select the most recent information for each subject. Again, all highlighted subjects will be show in green.

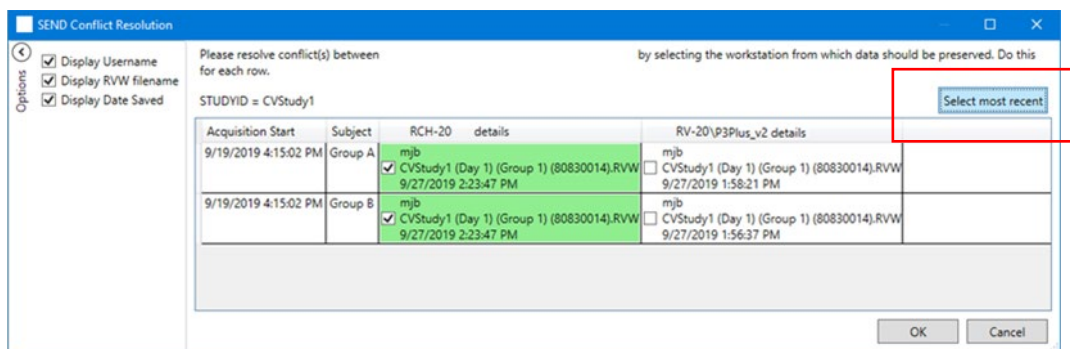


Figure 42 . – Conflict Resolution dialog, most recent information highlighted.

High Level Process Flow for Generating SEND Output

The previous sections have described how to configure and generate SEND output. This section will provide two scenarios and the high-level process flow needed to generate SEND output. No detailed configuration information is provided below, refer to previous sections for additional information.

While the following two examples provides guidance on creating SEND output, which includes configuration information, once a SEND configuration has been completed and saved in the protocol, only saving of the derived data is necessary to generate SEND output.

Generating SEND Output to Excel (outside of the Study Protocol Option)

- Ensure SEND Output or SEND SQL Server Output option is enabled in the license file
- Open a Review file (.RVW)
- Configure Data Reduction, if not previously configured, with CDISC defined variables
 - Ensure the event to trigger Data Reduction has been initiated
- Update Subject Setup tab with appropriate Name and Dose information for each subject
- Enable the SEND dialog under P3 Setup and update the appropriate fields
 - Select the checkbox for Enable Excel Output
- Perform a Save Marks Section or Saved Derived Data to generate the Data Reduction output to SEND
- Navigate to the Ponemah_Data directory or the location where the Excel file was saved
 - Open Excel workbook and verify that the appropriate worksheets exist for the Domains used

Generating SEND Output to CSV using the Study Protocol Option

- Ensure SEND SQL Server Output option is enabled in the license file in order to generate CSV files
- Select the desired Study from the Manage Studies dialog
- Enter the Run Study dialog and select the desired Run from the Previous Runs list
- Data Reduction should have been previously configured and saved as part of the Study configuration (protocol file) with CDISC defined variables. Modification of Data Reduction is not permitted after data collection within the Study Protocol Option
 - Ensure the event to trigger Data Reduction has been initiated
- Subjects should have been configured with the appropriate Name and Dose information for each subject as part of the Study configuration.
 - Select Use Study Subjects and Use Study Doses to automatically pull information from the Study configuration.
 - Uncheck Use Study Subjects and Use Study Doses if edits are necessary to correct entry errors from Study configuration
- Enable the SEND dialog under P3 setup and updated the appropriate fields if not previously saved in the protocol
 - Uncheck the following to allow previously defined Study information to be pulled into SEND automatically
 - Edit Study Name
 - Edit Study Day
 - Edit Study Workup

- If desired, uncheck these edit boxes to allow for manual edits to better define the output being generated or correct for entry errors when creating the Study
- Perform a Save Run (Marks Section) to generate the Data Reduction Output to SEND
- Navigate to the Send Viewer and select the desired Study to generate a CSV file output
 - Select the appropriate Domain, Filters, and Variables
 - Use the Export to CSV button to generate the SEND output file
- Optionally, use the Synchronize SEND Data and Synchronize SEND Study Data to synchronize data across workstations or servers

Troubleshooting

This section outlines common messages encountered with incorrect settings when SEND is enabled. Each item will list the issue or message that may be posted along with a resolution.

Messages Posted Due to Incorrect SEND Configuration

Incorrect ECG labels

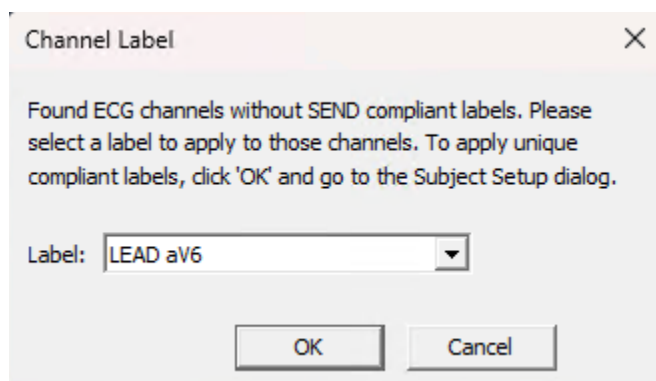


Figure 45. – Incorrect ECG labels in Channel Input Setup.

Issue: CDISC dictates specific labeling terminology for ECG lead presentations. If the label entered in the Subject Setup menu does not match that used by CDISC, the above message will be posted.

Resolution: Enter the correct label in the dialog to update the labeling for the ECG channels identified in the message posted. When you select the Label column, you will have a drop-down list that allows you to select the correct lead presentation.

Duplicate TESTCDs

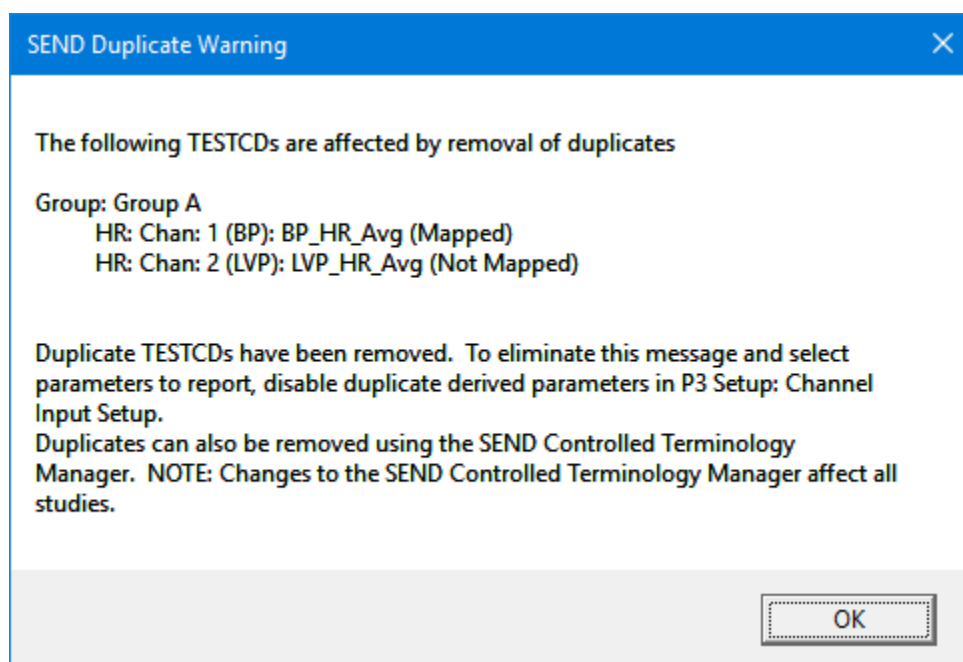


Figure 46 . – Duplicate TESTCDs message.

Issue: A CDISC TESTCD can only be reported once for a subject in a given interval in a single domain. The above error will be displayed if duplicate derived parameters exist across multiple analysis algorithms. In the example above, the HR (Heart Rate) parameter is enabled in both the Blood Pressure and Left Ventricular Pressure analysis algorithms.

Resolution: Enter the Channel Input Setup menu and update the derived parameters list for the Subject(s) listed in the warning message. Resave the file to generate the desired output. If you say OK to the message, the software automatically uses the TESTCD (in this case HR) from the first channel where the conflict was identified. In this case, the hardware configuration had BP pressure as channel 1 and LV defined as channel 2. The HR parameter was reported for the BP channel and removed from the LV channel.

NO SEND data in Excel or SEND Viewer

Issue: Data not present in the Excel file or in SEND Viewer after performing a save of the Marks Section/Run or Derived Data.

Resolution: Several reasons may exist which will result in no data available in the output file.

- SEND has not been enabled in P3 Setup
 - If using SEND to Excel, ensure checkbox in SEND dialog has been enabled
- Data Reduction has not been configured
- CDISC TESTCDs are not enabled in Data Reduction. Not all derived parameters (Data Reduction) are currently defined by CDISC
- Ensure the Event to trigger Data Reduction has been placed
- If SEND does not appear in your P3 Setup menu, the current Ponemah license file likely does not have the SEND option enabled. This information can be found under the View License File dialog from the Help

pull-down menu. These features will be listed under the Options box. The SEND pull-down menu while in idle mode is only available (accessible) if the SEND option is enabled. Contact Technical Support for assistance.

No subject ID for USUBJID TESTCD

Issue: No user defined subject ID present in the SEND output for USUBJID.

Resolution: When not using the Study Protocol Option and pulling in Subject information automatically, the default label (Group A, Group B, etc.) will be placed in the SEND output. From P3 Setup, enter the Groups dialog and modify the Name column. Perform a Save Derived Data or Save Marks Section to update.

No Data in SEND Viewer

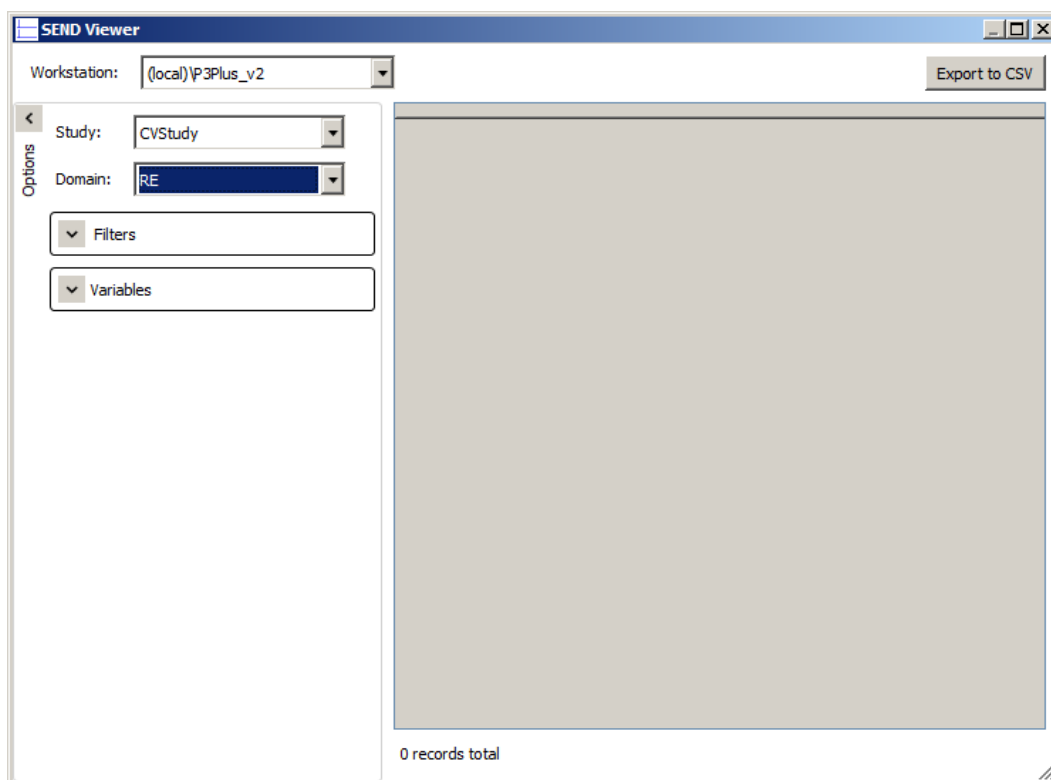


Figure 48 . – No SEND data currently visible in SEND Viewer.

Issue: No data is present when opening the SEND Viewer dialog for a given study when all information has been configured properly (SEND, Data Reduction, etc.) and a save of the data has been performed.

Resolution: Ensure that the correct Domain is listed for the study that has been selected. Data currently exists for the CVStudy example shown above. However, no data in the RE Domain exists. Therefore, no data will populate the window. Select the correct Domain, EG and CV in this example, and the SEND information will be displayed.

Appendix 1

Not all derived parameters calculated by Ponemah are currently defined by CDISC. Below lists the currently accepted parameters by general signal type. Please note that derived parameters may exist in multiple Analysis algorithms. For example, the derived parameter “Sys” is reported by both the Blood Pressure (BP) and Left Ventricular Pressure (LVP) analysis algorithms.

In addition to enabling only the CDISC defined parameters, Data Reduction calculations selected must also be defined by CDISC or no SEND output will be generated. The accepted Data Reductions calculations are Average (AVG), Maximum (Max), and Minimum (Min).

ECG

- Heart Rate
- P-H
- PWdth
- PP-I
- PR-I
- QRS
- QT-I
- QTcb
- QTcf
- QTcv
- QTca
- QTcl
- QTcu
- R-H
- RR-I
- ST-I
- ST-E
- T-H
- T-A
- Tpe-I

Activity

- A_TA

Pressure (includes analysis modules BP and LVP)

- Dia
- +dP/dt
- -dP/dt
- HR
- LVEDP
- Sys
- Mean
- PH

- Q-A
- TPR

Respiratory (includes analysis modules dEMG, PAF, BPR, PAP, PCR/PCRP, PVO and URP)

- TV
- Res
- RT
- ET
- IT
- MV
- Penh
- Max (PCRP analysis module)
- Min (PCRP analysis module)
- PIF
-
- Cdyn
- PEF
- BPM
- RBpm
- DIA (PAP analysis module)
- Mean (PAP analysis module)
- SYS (PAP analysis module)

Temperature

- Mean

Appendix 2

The following is an example of a Multi-lead ECG configuration created using Study with Data Reduction output defined by Parser Segments. The protocol, subjects, and doses have all been created. In this example, Workups will be defined for both pre-dose and post-dose collection times.

When Workups are configured in the appropriate format, the workup label will replace the Data Reduction label and be included in the SEND output. Also, the assumption when configuring a Tox Study design is that there will be only one interval reported for an acquisition, unlike a telemetry collection where multiple Data Reduction intervals will be reported over an extended collection period.

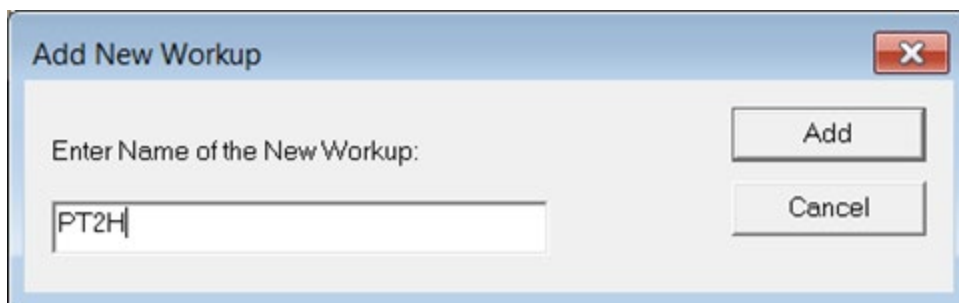
The screenshot displays the 'Study Setup' dialog box, which is organized into several sections:

- Study Information:** Includes fields for 'Study Name' (test), 'Study Type' (Multiple Subject Per Acquisition Study), and 'Start' (Monday, June 15, 2026).
- Setup Components:** A list on the left shows 'Protocols', 'Workups', 'Subjects', and 'Doses'. The 'Doses' list on the right contains '0 mg/kg', '10 mg/kg', '30 mg/kg', and '50 mg/kg'. Below this are 'Add Dose' and 'Delete Dose' buttons, along with an 'Alphabetical Sort' checkbox and 'Up'/'Dn' buttons.
- Day 1 Configuration:** Shows a 'Date' of 6/15/2026. A tree view under 'Group 1' shows 'PRO: FULLDEMO.PRO', 'Workups:', and 'Subjects (Doses):' with a sub-entry '1001 (0 mg/kg)'. To the right are buttons for 'New Day', 'Delete Day', and 'Rename Day'.
- Options:** Includes checkboxes for 'Allow Workups' (checked), 'Consistent Doses' (checked), 'Enable Day 0' (unchecked), 'Enable Stagger Days' (unchecked), and 'Mixed Study Groups' (unchecked).
- Buttons:** 'Verify Study', 'Automation', 'OK', and 'Cancel' are located at the bottom right.
- Message:** A status bar at the bottom states: 'At least one group has subjects without workups. Please assign workups to all groups.'

Study allows any text to be entered and used within this study context. However, only SEND compliant terminology (ISO 8601 interval format) will be able to be pulled into the SEND output. If the workups defined here do not meet the accepted format, acquisition and review sessions will still function as expected, however, the workup label entered above will not appear in the SEND tables as entered.

To define a Workup, click on the Add Workup button. The following dialog will be displayed. To define a two hour post-dose time, enter the time in hh:mm:ss format. Note that zeros used for padding can be dropped as they are not needed, example 04H would simply be 4H.

To remain compliant, a two-hour post-dose collection would include "PT" in the string. P represents the start of the duration and T represents time. The designators must precede the actual time. Therefore, the SEND compliant time point would be entered as "PT2H".



Add New Workup

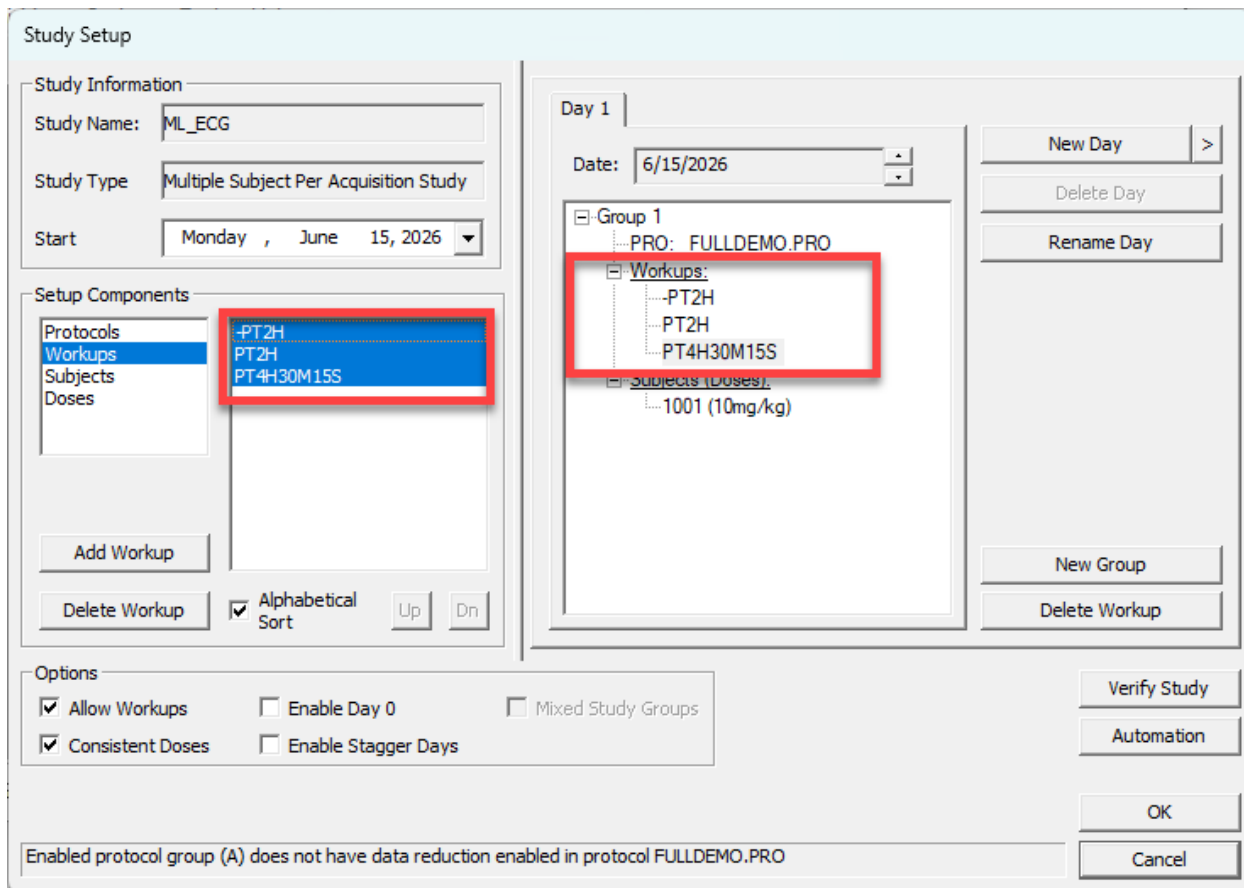
Enter Name of the New Workup:

PT2H

Add

Cancel

Additional timepoints have been entered to represent a two-hour pre-dose timepoint and a post-dose timepoint of 4:30:15 seconds.



Study Setup

Study Information

Study Name: ML_ECG

Study Type: Multiple Subject Per Acquisition Study

Start: Monday, June 15, 2026

Setup Components

Protocols

Workups

Subjects

Doses

-PT2H

PT2H

PT4H30M15S

Add Workup

Delete Workup

☒ Alphabetical Sort

Up

Dn

Day 1

Date: 6/15/2026

New Day

Delete Day

Rename Day

Group 1

PRO: FULLDEMO.PRO

Workups:

-PT2H

PT2H

PT4H30M15S

Subjects (Doses):

1001 (10mg/kg)

New Group

Delete Workup

Options

☒ Allow Workups

☐ Enable Day 0

☐ Mixed Study Groups

☒ Consistent Doses

☐ Enable Stagger Days

Verify Study

Automation

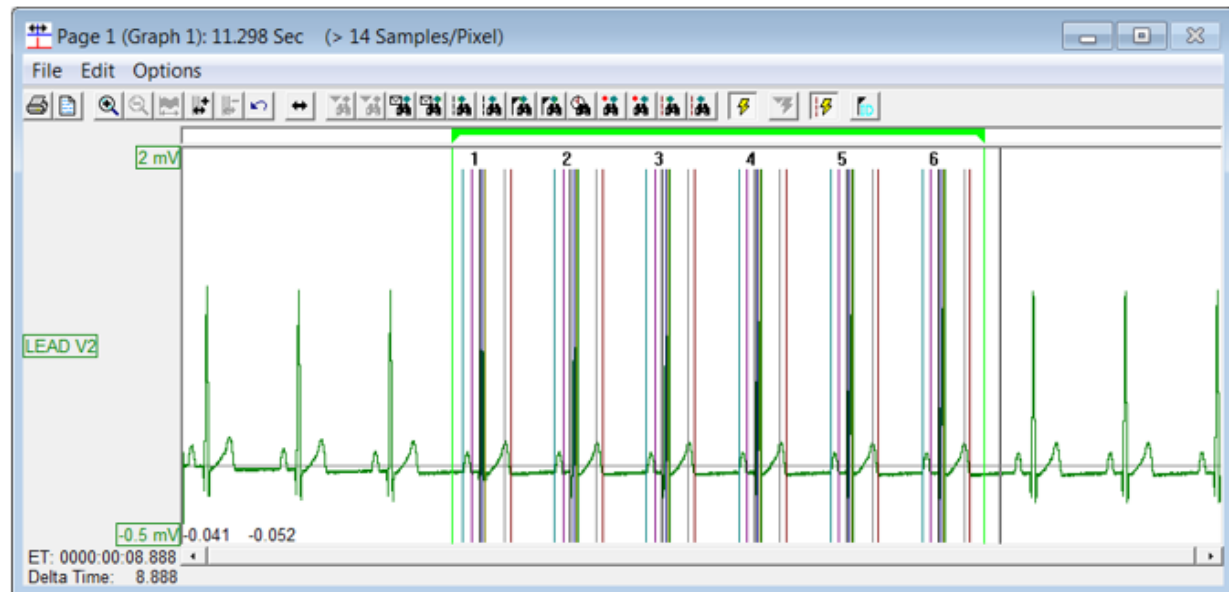
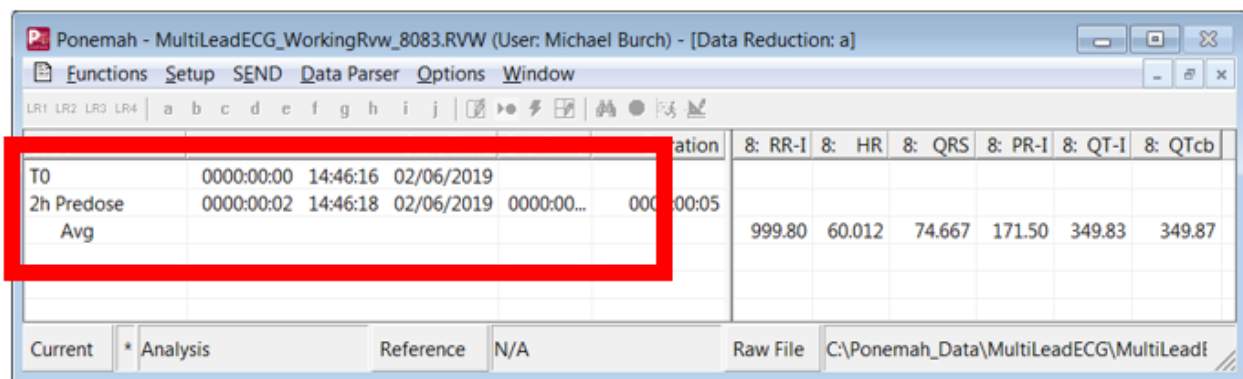
OK

Cancel

Enabled protocol group (A) does not have data reduction enabled in protocol FULLDEMO.PRO

Data Review and SEND Configuration

Below shows the two-hour pre-dose Review session with a single parser segment and the AVG (average) calculated for the enabled derived parameters. It is also worth noting that derived parameters will only be present in SEND output if those parameters have been mapped to a TESTCD in the Controlled Terminology menu and enabled in the Channel Input Setup menu. By default the Controlled Terminology menu only contains mappings for results that are defined by CDISC. Ponemah provides a number of calculations that are not currently defined by CDISC.



SEND information can be configured in idle mode along with other study and setup information. Below is an example of the SEND dialog after configuration. To utilize the automated features with Study, uncheck Edit Study Name, Edit Study Day, and Edit Workup. This will pull in the Study information based on the file that is currently loaded. In this example, it is the 4:30:15 timepoint.

PPP3 Setup - SEND

Channel Input Setup
Template Setup
Groups
Events
Experimental Protocol
Data Reduction Setup
Variability Analysis
Graph Setup
Settings
SEND

☒ Enable SEND Output
☒ Enable Excel Output

Study Name: MultiLeadECG ☐ Edit Study Name
Study Day: 1 ☐ Edit Study Day
Workup: PT4H30M15S ☐ Edit Workup
Output Server: ServerP3PLUS_v2

Laboratory Name: DSI

☒ Append Subject ID to Study Name Subject Separator: -
☐ Update SEND database during Acquisition

Consciousness State: CONSCIOUS
Position: SUPINE
EG Method: 8 LEAD STANDARD
CV Method: INTRAVASCULAR
RE Method: HEAD OUT PLETHYSMOGRAPH

OK Cancel Apply

SEND Output

From the SEND pull-down menu on the main Ponemah window, select SEND Viewer. On the left side of the dialog, select the filters specific to the study and data of interest.

Workup information entered into Study is included in the SEND output under EGTPPT and EGELTM.

SEND Viewer

Workstation: (local)\P3Plus_v2

Study: MultiLeadECG
Domain: EG

Filters
Variables

iENDTC	EGDY	EGE	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EG
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:24			1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:46:56			1	2h Postdose	2	PT2H	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	
19-02-06T14:47:11			1	4h 30m 15s Postdose	3	PT4H30M15S	Day 1 Dose 1:0mk/kg	

18 records total

Contact Information

We are available to help you with your questions and concerns. Should you hit a roadblock or need some additional training, please feel free to visit the DSI Support Center at <https://support.datasci.com> to find articles and helpful information in our knowledge base, chat with an agent, or setup time to receive one-on-one consultation. We are happy to help!

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