SEND 3.1: Standard for Exchange of Nonclinical Data



OVERVIEW

This manual highlights how DSI's SEND 3.1 can be used to produce output needed for data submission to the FDA. This document will provide an overview of the system components and basic operation.

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WELCOME

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 pulldown 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 our 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.

PPP3 Setup - SEND			
- PPP3 Setup	- SEND		
Channel Input Setup Template Setup Groups Events Experimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEND	 Enable SEND Output Enable Excel Output Study Name Study Day Workup Output Server Laboratory Name Append Subject ID Update SEND data Consciousness State Position EG Method CV Method RE Method 	Study Name	Edit Study Name Edit Study Day Edit Workup Test connection arator APH
1			OK Cancel <u>Apply</u>
			OK Cancel <u>A</u> pply

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



4 | Page

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 – Workups

Workups 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.

6 – Output Server

Permits defining a dedicated server or workstation as the primary repository for SEND data. Additionally, the SEND instance name, as it is installed with the application, must be appended to the server/workstation name. Example naming convention would be "server name\P3Plus_V2". P3Plus_V2 is the SQL Instance used by Ponemah for SEND related data.

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, this feature will not be available.

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 database 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.

GROUPS

The Groups dialog allows the user to control the Group name and dose which is associated with a given Subject. In order to edit the Study Subject Name or Study Dose, click in the edit field under the appropriate column. Figure 2 shows subjects one and two (Group A and Group B) with the names and doses modified.

nannel Input Setup emplate Setup roups	-Group Informa	Use Study	Subjects 🔽	Use Study Doses		
xperimental Protocol Header	Group	Study Subject Name	Trigger	Camera	Species	Study Dose
ata Reduction Setup	Group A	1	1 - (LVP1)		Dog	Omg/kg
anability Analysis aph Setup	Group B	2	5 - (LVP2)		Dog	30mg/kg
ettings	Group C				Dog	
END	Group D				Dog	
	Group E				Dog	
	Group F				Dog	
	Group G				Dog	
	Group H				Dog	
	Group I				Dog	
	Group J				Dog	
	Group K				Dog	
	Group L				Dog	
	Group M				Dog	
	Group N				Dog	
	Group O				Dog	
	Group P			I	Dec	

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

Providing a unique name in the Groups dialog will propagate the subject information to SEND. Below shows example SEND output where Group A Study Subject Name was changed in the Groups tab (Figure 2). This identifier, ID 123, is shown under USUBJID in Figure 3.

Two check boxes are available at the top of the Groups dialog, Use Study Subjects and Use Study Doses. These two features are related to data generated using the Study Protocol Option. If enabled, Subject and Dose information entered in Study will be automatically pulled into the Groups tab. 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 back 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

	•						Export to CS
		STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST
Study: CV Test3	_ [0	CV Test3	CV	ID 123	641559	LVSYSBP	Left Ventricular Systolic Pressure
		CV Test3	CV	ID 123	641560	LVEDP	Left Ventricular End Diastolic Pressure
Domain: CV	-	CV Test3	CV	ID 123	641561	DPDTAVG	dP/dt Average
		CV Test3	CV	ID 123	641562	SYSBP	Systolic Blood Pressure
✓ Filters		CV Test3	CV	ID 123	641563	DIABP	Diastolic Blood Pressure
	[CV Test3	CV	ID 123	641564	MAP	Mean Arterial Pressure
Variables		CV Test3	CV	ID 123	641565	PULSEPR	Pulse Pressure
▼ Variables		CV Test3	CV	ID 123	641566	HR	Heart Rate
		CV Test3	CV	ID 123	641567	ACTIVITY	Activity
		CV Test3	CV	ID 123	641568	LVSYSBP	Left Ventricular Systolic Pressure
		CV Test3	CV	ID 123	641569	LVEDP	Left Ventricular End Diastolic Pressure
		CV Test3	CV	ID 123	641570	DPDTAVG	dP/dt Average
		CV Test3	CV	ID 123	641571	SYSBP	Systolic Blood Pressure
		CV Test3	CV	ID 123	641572	DIABP	Diastolic Blood Pressure
		CV Test3	CV	ID 123	641573	MAP	Mean Arterial Pressure
		CV Test3	CV	ID 123	641574	PULSEPR	Pulse Pressure
		CV Test3	CV	ID 123	641575	HR	Heart Rate
		CV Test3	CV	ID 123	641576	ACTIVITY	Activity
		CV Test3	CV	ID 123	641577	LVSYSBP	Left Ventricular Systolic Pressure
		CV Test3	CV	ID 123	641578	LVEDP	Left Ventricular End Diastolic Pressure
		CV Test3	CV	ID 123	641579	DPDTAVG	dP/dt Average
		CV Test3	CV	ID 123	641580	SYSBP	Systolic Blood Pressure
		CV Test3	CV	ID 123	641581	DIABP	Diastolic Blood Pressure
		CV Test3	CV	ID 123	641582	MAP	Mean Arterial Pressure
		CV Test3	CV	ID 123	641583	PULSEPR	Pulse Pressure
		CV Test3	CV	ID 123	641584	HR	Heart Rate
		CV Test3	CV	ID 123	641585	ACTIVITY	Activity
		CV Test3	CV	ID 123	641586	LVSYSBP	Left Ventricular Systolic Pressure
	la la	CV Test3	CV	ID 123	641587		l eft Ventricular End Diastolic Pressure

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

DATA REDUCTION

Data Reduction must be enabled for all desired subjects in order 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.

PPP3 Setup	- Data Reduction	Setup		
Channel Input Setup		SEND compatibility enabled	Timing Reference	Start 💌
Groups	A- Group A	F Enable		
Events Digital Display Setup	B- Group B	Lise fixed Control and T0		
Alarm Setup	C- Group C	Control		
Experimental Protocol Header Print RAW Data Setup	D- Group D	Dyration 00:05:00	Г	Permit Redefinition
Data Reduction Setup	E- Group E	Events 🖓 a 🗂 b 🗂 c 🗂	d Te Ff Fg	;

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 - Sa	mpleECGDat	ta.RVW (Use	r: mjb) - [Dat	a Reduction	:a]							\times
Eunctions Set	up S <u>E</u> ND [<u>)</u> ata Parser	<u>O</u> ptions <u>W</u> ind	ow							_ 8	\times
LR1 LR2 LR3 LR4	a b c	d e f	g h i	j 🕅 🕨	• 🗲 🛃	M • •	3. <u>M</u>					
Label	Start Time	End Time	Duration	1: Sys	1: LVEDP	1:+dP/dt	2: Sys	2: Dia	2: Mean	2: PH	2: HR	
TO	00:00:00											
Os Postdose	00:00:00	00:10:00	0000:10:00									
Avg				118.40	5.5708	3310.2	117.87	81.248	99.849	36.621	74.423	
10m Postdose	00:10:00	00:20:00	0000:10:00									_
Avg				111.20	4.7871	3023.4	112.41	76.446	94.795	35.967	60.68	_
20m Postdose	00:20:00	00:30:00	0000:10:00									-
Avg				115.28	5.6705	3043.0	117.20	78.698	98.12	38.50	64.35	
30m Postdose	00:30:00	00:40:00	0000:10:00									
Avg				117.80	6.0854	3062.5	119.69	81.78	100.54	37.906	69.436	-
40m Postdose	00:40:00	00:50:00	0000:10:00	407.00	7.4450	0505.0	400.50	00.00	100.00	00.440	05.404	-
AVg	00.50.00	01.00.00	0000.10.00	127.26	7.4468	3525.0	128.53	89.39	109.08	39,142	86,194	-
50m Postdose	00:50:00	01:00:00	0000:10:00	121.04	6 2022	2202.2	101.40	00.505	102.14	20.005	74 700	-
Avg 1b Destdess	01:00:00	01.10.00	0000+10-00	121.04	0.2023	3302.2	121,49	02,300	102.14	20,902	/4./20	-
Ave	01:00:00	01:10:00	0000:10:00	142.40	12 490	4092 E	142.60	09 744	120.67	42.051	106.27	-
1h 10m Postd	01:10:00	01.20.00	0000+10+00	143.49	12,709	4003.5	142.05	50.744	120.07	43,931	100.27	-
Ava	01.10.00	01.20.00	0000.10.00	110.46	7 1452	3394-1	120.36	83 135	102.40	37 225	76 565	-
1h 20m Postd	01.20.00	01-30-00	0000-10-00	115.10	7.1152	550 1.1	120.00	00.100	102.15	571225	70.000	-
211 2011 1 0300111	01.20.00	01.00.00	0000.10.00	•							•	
												<u>_</u>
Current Group	Name Chang	e	Reference	Group Name (Change	Raw	File C:\F	onemah_D	ata\SampleE	CGData\Sa	mpleECGDa	ti //.

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.).

📴 Ponemah - Sa	mpleECGDat	a.RVW (Use	r: mjb) - [Dat	a Reductior	1: a]						_ 0	\times
Eunctions Set	tup S <u>E</u> ND <u>D</u>	ata Parser 🤅	Options <u>W</u> indo	w							_ 8	\times
LNT LNZ LNG LNG	a b c	d e f	g h i	j 🕅 🕨	• 🗲 🛃	M • •	3 📐					
Label	Start Time	End Time	Duration	1: Sys	1: LVEDP	1:+dP/dt	2: Sys	2: Dia	2: Mean	2: PH	2: HR	
TO	00:00:00											
5m Postdose	00:00:00	00:10:00	0000:10:00									
Avg				118.40	5.5708	3310.2	117.87	81.248	99.849	36.621	74.423	
15m Postdose	00:10:00	00:20:00	0000:10:00									
Avg				111.20	4.7871	3023.4	112.41	76.446	94.795	35.967	60.68	
25m Postdose	00:20:00	00:30:00	0000:10:00									
Avg				115.28	5.6705	3043.0	117.20	78.698	98.12	38.50	64.35	_
35m Postdose	00:30:00	00:40:00	0000:10:00									
Avg				117.80	6.0854	3062.5	119.69	81.78	100.54	37.906	69.436	
45m Postdose	00:40:00	00:50:00	0000:10:00									
Avg				127.26	7.4468	3525.0	128.53	89.39	109.08	39.142	86.194	
55m Postdose	00:50:00	01:00:00	0000:10:00									
Avg				121.04	6.2823	3302.2	121.49	82.506	102.14	38.985	74.726	_
1h 5m Postdose	01:00:00	01:10:00	0000:10:00									_
Avg				143.49	12.489	4083.5	142.69	98.744	120.67	43.951	106.27	_
1h 15m Postd	01:10:00	01:20:00	0000:10:00									_
Avg				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	L,								ᆀ
				•							•	
Current Group	Name Change	2	Reference	Group Name (Change	Raw	File C:\F	onemah_D	ata\SampleE	CGData\Sa	mpleECGDa	ti //

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 S	Setup		
Channel Input Setup		SEND compatibility enabled	Timing Referen	ice Start 💌
Groups	A- Group A	- 🔽 Enable		
Events	B- Group B	Les fixed Control and T0		
Alarm Setup	C- Group C	- Z Control		
Experimental Protocol Header	D. George D	Duration 00:05:00		Permit Redefinition
Print RAW Data Setup Data Reduction Setup	E. Comp.E.	Events Fa Tb Tc T	d E e E f F	
Variability Analysis	E- Gloop E	T0 Events	antin des finnende. De	
Graph Setup Binary Data Convert	F GIOOP F	Pa Tb Tc T	d 🗆 e 🗆 f 🛛	G Ch Ci Ci
Settings	G+ Group G	Type In Type	765	Calcus ions
Remote Connection	H- Group H	Time Dose Nu	mber 1	Condition -
Data Parser Setup	I- Group I			
	J- Group J	Duration of Interval Index	Label	E Ave 10he
	K- Group K	01:00:00 🚖 Controlled	SEND	C Ave VDeta

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

3 – Use Fixed Control and TO

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 9:00AM 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 9:00AM. All subsequent intervals are based on the Duration of Interval configured.

PPP3 Setup		– Data Reduc	tion Setup									
												_
Channel Input Setu Template Setup	р		SEND o	compatibi	lity enab	led	<u>T</u> ìr	ning Ref	erence	Start		<u> </u>
Groups		A- Group A	Enab	le								
Events Experimental Protoc	ol Header	B- Group B	<mark>⊡ U</mark> se	fixed Contro	l and TO							
Data Reduction Set	up	C+ Group C	Co 🗌 🗌	ontrol		_						
Variability Analysis Graph Setup		D- Group D		Duration 0	0:05:00	÷ Con	trol Time	5/17/	/2007	▼ 9:0	0:00 AM	-
Settings		E- Group E										
SEND		F- Group F	ТО	TO	Time	5/17/20	07 🔻	9.00.0	0 AM -	3		
		G- Group G	i				•/•]	0.00.0		-		
		H- Group H	l lype -			rvais / Lac	is			alculation	15	
		I- Group I	lime		의 _	Dose Nu	mber 1		╴║╟╴	Calcu	lation	
		J- Group J	Durati	on of Interva	I Inc	lex	Label			Avg		
		K- Group K	00:1	0:00		ontrolled	SEND			Avg :	Chg	-
		L- Group L		rto Label —						Avg 2	oDelta	╡┛║┃
		M- Group N	4	(51)	-				Ľ		Jeild	-
		N- Group N	ТКер	{N}							Tha	- 11
		0- Group C	{N} =	Interval Inde	×				l l í	Ln %	Delta	-
		P- Group E	$\{M\} = \{T\} $	Min from TU bloomiee						Ln De	elta	╡
		Q- Group ({T2} =	= hh:mm		Add >		<u>D</u> elete				
								ОК		Cancel	1	Apply
								ОК		Cancel		Apply
Ponemah - CV Pro.RVV	W (User: mjb)							ок		Cancel		
Ponemah - CV Pro.RVV nctions Setup SEND	W (User: mjb) Data Parser <u>C</u> c d e	2 20tions <u>Wi</u> ndow						ОК		Cancel		Apply
Ponemah - CV Pro.RVN nctions Setup SEND I LR2 LR3 LR4 a b Data Reduction: a	W (User:mjb) Data Parser <u>C</u> c d e) Dotions <u>Wi</u> ndow f g h i j		. • 1% 2				OK		Cancel		
Ponemah - CV Pro.RVN nctions Setup SBND I LR2 LR3 LR4 a b Data Reduction: a bel	W (User: mjb) Data Parser C c d e	2ptions <u>Window</u> f g h i j Start Time		🕯 💿 🖂 🕍 End Time	Duration	1: Sys	1: LVEDP	OK 1: HR	1:+dP/dt	Cancel 2: Sys	2: Dia	Apply
Ponemah - CV Pro.RVI nctions Setup SEND I I LR2 LR3 LR4 a b Data Reduction: a bel > Postdose	W (User: mjb) Data Parser C c d e 0001:01:12 (0001:01:12 (2ptions <u>Window</u> f g h i j Start Time 99:00:00 05/17/2007	12 ▶ ● 7 日 4 0001:11:12 09:10:00	End Time	Duration_ 0000:10:00	1: Sys	1: LVEDP	OK 1: HR	1:+dP/dt	Cancel	2: Dia	Apply
Ponemah - CV Pro.RVI nctions Setup SEND LR2 LR3 LR4 a b Data Reduction: a abel) s Postdose Avg m Post	W (User: mjb) Data Parser <u>C</u> c d e 0001:01:12 (0001:01:12 (0001:11:12 (2ptions Window f g h i j 29tions0 05/17/2007 295/00:00 05/17/2007 295:10:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00	End Time 05/17/2007	Duration 0000:10:00	1: Sys 143.64	1: LVEDP 12.826	OK 1: HR 106.97	1:+dP/dt 4080.8 2425 4	Cancel 2: Sys 142.74	2: Dia 99.035 82.222	Apply
Ponemah - CV Pro.RVI nctions Setup SEND LR2 LR3 LR4 a b Data Reduction: a abel) s Posthose Avg m Post	W (User: mjb) Data Parser <u>C</u> c d e 0001:01:12 (0001:01:12 (0001:11:12 (0001:21:12 (2ptions Window f g h i j 2ptions 0 05/17/2007 2pti00:00 05/17/2007 2pti00:00 05/17/2007 2pti00:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:31:12 09:30:00	End Time 05/17/2007 05/17/2007 05/17/2007	Duration) 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18	1: LVEDP 12.826 6.5803 2.406 1	OK 1: HR 106.97 77.269	1:+dP/dt 4080.8 3435.4 2673.5	Cancel 2: Sys 142.74 119.90	2: Dia 99.035 82.338 75.577	Apply
Ponemah - CV Pro.RVI nctions Setup SEND I LR2 LR3 LR4 a b Data Reduction: a abel s Postdose Avg On Post Avg Om Post	W (User: mjb) Data Parser (User: mjb) C d c 0001:01:12 (C 0001:01:12 (C 0001:11:12 (C 0001:21:12 (C) 0001:21:12 (C) 0001:21:12 (C)	2ptions Window f g h i j 2ptions 05/17/2007 99:00:00 05/17/2007 99:10:00 05/17/2007 99:10:00 05/17/2007 99:20:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:31:12 09:30:00 0001:41:12 09:40:00	End Time 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007	Duration 0000:10:00 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18 116.34	1: LVEDP 12.826 6.5803 3.4061 3.164	OK 1: HR 106.97 77.269 74.239 79.70	1:+dP/dt 4080.8 3435.4 3672.5 3804.6	Cancel 2: Sys 142.74 119.90 115.41	2: Dia 99.035 82.338 75.577 75.991	Apply = 0, 2: Mean = 120.88 101.84 95.801 95.801 95.801
Ponemah - CV Pro.RVI nctions Setup SEND 1 LR2 LR3 LR4 a b Data Reduction: a abel b) on Post Avg On Post Avg On Post Avg On Post Avg On Post	W (User: mjb) @ata Parser (User: mjb) @ ta Parser (User: mjb) @ ta Parser (User: mjb) @ 0001:01:12 (User: mjb) @ 0001	2ptons Window f g h i j 2ptons 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:30:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:31:12 09:30:00 0001:41:12 09:40:00 0001:51:12 09:50:00	End Time 05/17/2007 05/17/2007 05/17/2007 05/17/2007 05/17/2007	Duration 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18 116.34 119.50 118.43	1: LVEDP 12.826 6.5803 3.4061 3.1541 6.4415	OK 1: HR 106.97 77.269 74.239 79.70 66 17	1:+dP/dt 4080.8 3435.4 3672.5 3804.6 3441.6	2: Sys 142.74 119.90 115.41 117.94	2: Dia 99.035 82.338 75.577 75.991 29.705	Apply
Ponemah - CV Pro.RVI nctions Setup SEND 1 LR2 LR3 LR4 a b Data Reduction: a abel b) on Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post	W (User: mjb) @ata Parser (User: mjb) @ c d c 0001:01:12 (0001:01:12 (0001:01:12 (0001:21:12 (0001:31:12 (0001:31:1	2ptions Window f g h i j 2ptions 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:00:00 05/17/2007 99:40:00 05/17/2007 99:50:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:31:12 09:30:00 0001:41:12 09:40:00 0001:51:12 09:50:00 0001:51:12 09:50:00	End Time 05/17/2007 05/17/2007 05/17/2007 05/17/2007 05/17/2007 05/17/2007	Duration 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18 116.34 119.50 118.41 121.06	1: LVEDP 12.826 6.5803 3.4061 3.1541 6.4415 5.88415	OK 1: HR 106.97 77.269 74.239 79.70 66.17 73.593	1:+dP/dt 4080.8 3435.4 3672.5 3804.6 3441.6 3441.6	2: Sys 142.74 119.90 115.41 117.94 118.18	2: Dia 99.035 82.338 75.577 75.991 79.706 79.766	Apply
Ponemah - CV Pro.RVI nctions Setup SEND 1 LR2 LR3 LR4 a b Data Reduction: a abel 5 bottose Avg 0n Post Avg 0n Post Avg 0n Post Avg 0n Post Avg 0 Post Avg 0 Post Avg 0 D	W (User: mjb) Qata Parser (c d c 0001:01:12 (0001:01:12 (0001:01:12 (0001:11:12 (0001:21:12 (0001:31:12 (0001:31	2010005 Window f g h i j 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:21:12 09:20:00 0001:31:12 09:30:00 0001:41:12 09:40:00 0001:51:12 09:50:00 0002:01:12 10:00:00 0002:11:12 10:10:00	End Time 0 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007 0 05/17/2007	Duration 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18 116.34 119.50 118.41 121.06	1: LVEDP 12.826 6.5803 3.4061 3.1541 6.4415 5.8841 5.8841 5.8841	OK 1: HR 106.97 77.269 79.70 66.17 73.593	1:+dP/dt 4080.8 3435.4 3672.5 3804.6 3441.6 3605.2 4829.7	Cancel 2: Sys 142.74 119.90 115.41 117.94 118.18 119.84 119.84	2: Dia 99.035 82.338 75.577 75.991 79.706 99.764	Apply
Ponemah - CV Pro.RVI nctions Setup SEND 1 LR2 LR3 LR4 a b Data Reduction: a abel b) s Positions Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg On Post Avg Vag On Post Avg Data Reduction: a abel b) s Positions Avg On Post Avg Data Reduction: a abel b) s Positions Avg On Post Avg Data Reduction: a abel b) s Positions Avg Data Reduction: a Avg Data Reduction: a Avg Davg Data Reduction: a Avg Data Reduction: a Avg Data Reducti	W (User: mjb) Qata Parser Q c d c 0001:01:12 (0001:01:12 (0001:01:12 (0001:11:12 (0001:21:12 (0001:31:12 (0001:31:12 (0001:31:12 (0001:51:12 (0002:01:12 1)	2010005 Window f g h i j 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 09:00:00 05/17/2007 10:00:00 05/17/2007 10:10:00 05/17/2007	0001:11:12 09:10:00 0001:21:12 09:20:00 0001:21:12 09:20:00 0001:31:12 09:30:00 0001:51:12 09:50:00 0001:51:12 09:50:00 0002:01:12 10:00:00 0002:21:12 10:20:00	 Image: Constraint of the second second	Duration 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00 0000:10:00	1: Sys 143.64 119.18 116.34 119.50 118.41 121.06 137.34 125.10	1: LVEDP 12.826 6.5803 3.4061 3.1541 6.4415 5.8841 5.8841 5.8841	OK 1: HR 106.97 77.269 79.70 66.17 73.593 96.607 01.992	1:+dP/dt 4080.8 3435.4 3672.5 3804.6 3441.6 3605.2 4829.7 460.6	2: Sys 142.74 119.90 115.41 117.94 118.18 119.84 119.84	2: Dia 99.035 82.338 75.577 75.991 79.766 89.754	Apply

Figure 9. – Data Reduction with Use fixed Control and TO 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.

PPP3 Setup - Data Reduction	Setup
- PPP3 Setup	Data Reduction Setup
Channel Input Setup Template Setup Groups Events Experimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEND	SEXD compatibility enable Iming Reference Sat A. Group A B. Group B C. Group D D. Group D B. Group B C. Group D B. Group B B. Group B G. Group D B. Group B B. Min from TO B. Min from TO B. Min
	OK Cancel Anniv

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.

🖄 Data Reduction: a							, •	23
Label	Start Time	End Time	Duration	1: Sys	1: Dia	1: Mean	1: PH	
2h 38m 14s Predose	0000:00:0	0000:01:0	0000:01:00					
Avg				126.23	73.776	93.613	52.458	
1h 38m 14s Predose	0001:00:0	0001:01:0	0000:01:00					
Avg				149.14	95.849	116.43	53.288	
38m 14s Predose	0002:00:0	0002:01:0	0000:01:00					
Avg				163.28	104.51	126.84	58.773	
то	0002:39:1							
21m 46s Postdose	0003:00:0	0003:01:0	0000:01:00					
Avg				134.39	81.159	101.41	53.232	
1h 21m 46s Postdose	0004:00:0	0004:01:0	0000:01:00					
Avg				136.86	84.099	103.77	52.76	
2h 21m 46s Postdose	0005:00:0	0005:01:0	0000:01:00					
Avg				138.31	81.749	102.57	56.566	
3h 21m 46s Postdose	0006:00:0	0006:01:0	0000:01:00					-
				•				• 🗌

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. In order 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 shows CVStudy and Study Day 1 pulled from the Study configuration. Workup has no information since Workups were not configured as part of this Study.

PPP3 Setup - SEND	
- PPP3 Setup	- SEND
Channel Input Setup Template Setup Groups Events Experimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEND	Image: Sende Sende Output Study Name Study Day Study Day Image: Study Day
	OK Cancel Apply

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.

PPP3 Setup - SEND	
- PPP3 Setup	- SEND
Channel Input Setup Template Setup Groups Events Experimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEND	Enable SEND Output Study Name Study Name Study Day Image: Study Day
	OK Cancel Apply

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

As with the SEND dialog, the Groups 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. To modify, simply type in the desired information for each Subject (Group).

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.

PP3 Setup - Groups						
- PPP3 Setup	- Groups					
Channel Input Setup Template Setup Groups Events	Group Informa	tion	Subjects 🔽	Use Study Doses		
Experimental Protocol Header	Group	Study Subject Name	Trigger	Camera	Species	Study Dose 🔺
Data Reduction Setup Variability Analysis	Group A	1	1 - (LVP1)		Dog	Omg/kg
Graph Setup	Group B	2	5 - (LVP2)		Dog	30mg/kg
Settings	Group C				Dog	
SEND	Group D				Dog	
	Group E				Dog	
	Group F				Dog	
	Group G				Dog	
	Group H				Dog	
	Group I				Dog	
	Group J				Dog	
	Group K				Dog	
	Group L				Dog	
	Group M				Dog	
	Group N				Dog	
	Group O				Dog	
	Gmun P		l		Dea	
					ОК	Cancel <u>A</u> pply

Figure 14. – Groups 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).

🞴 Ponemah - defau	ult.pro	(User: mjb)	– – ×
File Setup Study	SEN	D Hardware Acquisition Replay	Options Tools Help
LR1 LR2 LR3 LR4 a		SEND Manager	● チ 団 ぬ ● 陽 🕍
	i	SEND Viewer	
		SEND Log	
		Controlled Terminology	
		Synchronize SEND Data	
ET: DT:	420	Synchronize SEND Study Data	Save Video ON OFF

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.

SEND Database Man	ager	_		×
Workstation: (local)\P	3Plus_v2	~		
Study Name	Space	Percen	Backup Restore Delete Import EX Upgrade 5.32 Data	
All Studies: Db Data File	: Db Log File	:		

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.

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.

Backup SEND Database					x
🕞 🖓 🗸 - Computer	▼ OS (C:) ▼ Ponemah_Data ▼ SampleECGData ▼	•	Search SampleECC	Data	2
Organize 🔻 New folder				•	?
▲	Name ^	Date modified	Туре	Size	
Libraries	Archives	8/10/2018 11:32 AM	File folder		
J Music					
Pictures					
Videos					
輚 Homegroup					
🖳 Computer					
🏭 OS (C:)					
🚗 Removable Disk (E:					
File <u>n</u> ame:					
Save as type: Backup	Files(*.sendbkup)				_
Hide Folders			Save	Cancel	

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.

7 – Upgrade 5.32 Data

If a 5.32 SEND database exists, the user will be prompted to upgrade the SEND database in order to be compatible with Ponemah version 5.40. This is also true if attempting to access a remote database. Launching Ponemah 5.40 with a previous version of the SEND database being utilized will display the following message and allow the conversion of the 5.32 SEND database to be completed. Selecting Cancel will not allow the upgrade and automatically close Ponemah. The Upgrade 5.32 Data button, in SEND Manager, should be used to update the SEND database.

NOTE: It is highly recommended to back up the SEND database prior to upgrading to version 5.40



Figure 19. – Message confirming that the SEND database will be upgraded for version 5.40.

A dialog will post listing the data being converted along with a progress dialog.

Once the SEND database has been converted, the Upgrade 5.32 Data button will no longer be displayed in the SEND Manager dialog.

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 dialog. 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.

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Paste	Calibri B I <u>U</u>	• 11 • • • Font	A^ A ≡ ≡ ♥ P B C A A F E E E E C Alignment G	General \$ - % .*	Conditi Formatt	onal Format a ing • Table • Styles	as Cell Styles ≠	Ensert • Delete • Format • Cells	∑ - A Z Z So Filt Ec	rt & Find & ter * Select * liting	~
C4	-	× ✓	fr cv								~
											· ·
<u> </u>	D	E	F	G	H	1	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'	'INCO
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 _
	. DataR	eductionB	GroupB Message CVdomain	EGdomain (- (I	4					
DEADY	1										4000/

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.

S EI	ND Viewer									
Work	station:	(local) \P3Plu	s	•]				Export to C	SV
>	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	$(\mathbf{r}_{i})^{(1)}$
s	CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	118.37	mmHg	T 🔺
<u>i</u>	CV Test1	CV	Group A	2322	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.5588	mmHg	
8	CV Test1	CV	Group A	2323	HR	Heart Rate	UNCONSTRAINED	74.33	bpm	Ť
	CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average	UNCONSTRAINED	3310.4	mmHg/s	Ť
	CV Test1	CV	Group A	2325	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.83	mmHg	Ť
	CV Test1	CV	Group A	2326	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	81.212	mmHg	T I
	CV Test1	CV	Group A	2327	MAP	Mean Arterial Pressure	UNCONSTRAINED	99.818	mmHg	T
	CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	UNCONSTRAINED	36.623	mmHg	T
	CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricular Maximum Positive dP/dt	UNCONSTRAINED	10566	mmHg/s	T
	CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricular Minimum Positive dP/dt	UNCONSTRAINED	2565.3	mmHg/s	ΤI
	CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	111.21	mmHg	ΤI
	CV Test1	CV	Group A	2332	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	4.7925	mmHg	T
	CV Test1	CV	Group A	2333	HR	Heart Rate	UNCONSTRAINED	60.651	bpm	T
	CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average	UNCONSTRAINED	3023.2	mmHg/s	Τ
	CV Test1	CV	Group A	2335	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	112.43	mmHg	ΤI
	CV Test1	CV	Group A	2336	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	76.463	mmHg	Ι
	CV Test1	CV	Group A	2337	MAP	Mean Arterial Pressure	UNCONSTRAINED	94.816	mmHg	Τ
	CV Test1	CV	Group A	2338	PULSEPR	Pulse Pressure	UNCONSTRAINED	35.969	mmHg	Ι
	CV Test1	CV	Group A	2339	DPDTMAX	Left Ventricular Maximum Positive dP/dt	UNCONSTRAINED	3589.6	mmHg/s	Τ
	CV Test1	CV	Group A	2340	DPDTMIN	Left Ventricular Minimum Positive dP/dt	UNCONSTRAINED	2594.9	mmHg/s	ΤI
	CV Test1	CV	Group A	2341	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	115.27	mmHg	Т
	CV Test1	CV	Group A	2342	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.6718	mmHg	Ι
	CV Test1	CV	Group A	2343	HR	Heart Rate	UNCONSTRAINED	64.312	bpm	Ī
	CV Test1	CV	Group A	2344	DPDTAVG	dP/dt Average	UNCONSTRAINED	3042.7	mmHg/s	Τ
	CV Test1	CV	Group A	2345	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.19	mmHg	ΤI
	CV Test1	CV	Group A	2346	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	78.691	mmHg	ΤI
	CV Test1	CV	Group A	2347	MAP	Mean Arterial Pressure	UNCONSTRAINED	98.115	mmHg	T
	CV Test1	CV	Group A	2348	PULSEPR	Pulse Pressure	UNCONSTRAINED	38.502	mmHg	Ι_
	CV Test1	lcv	Group A	2349		l eft Ventricular Maximum Positive dP/dt		4766 2	mmHa/s	J
	6235 record	ls total								1

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.

Workstation:	(local) \P3Plus	•						Export to CSV
<			STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST
2 Study:	CV Test1		CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricular Systolic Pressure
	CV Test1		CV Test1	CV	Group A	2322	LVEDP	Left Ventricular End Diastolic Pressure
Domain:	CV Test3		CV Test1	CV	Group A	2323	HR	Heart Rate
	Cviest2		CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average
✓ Filte	rs		CV Test1	CV	Group A	2325	SYSBP	Systolic Blood Pressure
			CV Test1	CV	Group A	2326	DIABP	Diastolic Blood Pressure
Varia	bl		CV Test1	CV	Group A	2327	MAP	Mean Arterial Pressure
Varia	bies		CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure
			CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricular Maximum Positive dP/dt
			CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricular Minimum Positive dP/dt
			CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricular Systolic Pressure
			CV Test1	CV	Group A	2332	LVEDP	Left Ventricular End Diastolic Pressure
			CV Test1	CV	Group A	2333	HR	Heart Rate
			CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average
			CV Test1	CV	Group A	2335	SYSBP	Systolic Blood Pressure
			CV Test1	CV	Group A	2336	DIABP	Diastolic Blood Pressure
			<u>ا</u>	•				Ì

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, NOMDAY, and TESTCD 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.

/orkstation: (local)\P3Plus	•					Export to	CSV
	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	С
Study: CV Test3	CV Test3	CV	Group A	638949	LVSYSBP	Left Ventricular Systolic Pressure	U 🔺
	CV Test3	CV	Group A	638950	LVEDP	Left Ventricular End Diastolic Pressure	U-
Domain: CV	CV Test3	CV	Group A	638951	DPDTAVG	dP/dt Average	U
	CV Test3	CV	Group A	638952	SYSBP	Systolic Blood Pressure	U
▲ Filters	CV Test3	CV	Group A	638953	DIABP	Diastolic Blood Pressure	U
	CV Test3	CV	Group A	638954	MAP	Mean Arterial Pressure	U
USUBJID:	CV Test3	CV	Group A	638955	PULSEPR	Pulse Pressure	U
	CV Test3	CV	Group A	638956	HR	Heart Rate	U
Group B	CV Test3	CV	Group A	638957	ACTIVITY	Activity	U
Group A	CV Test3	CV	Group A	638958	LVSYSBP	Left Ventricular Systolic Pressure	U
	CV Test3	CV	Group A	638959	LVEDP	Left Ventricular End Diastolic Pressure	U
	CV Test3	CV	Group A	638960	DPDTAVG	dP/dt Average	U
CVNOMDY:	CV Test3	CV	Group A	638961	SYSBP	Systolic Blood Pressure	U
	CV Test3	CV	Group A	638962	DIABP	Diastolic Blood Pressure	U
	CV Test3	CV	Group A	638963	MAP	Mean Arterial Pressure	U
	CV Test3	CV	Group A	638964	PULSEPR	Pulse Pressure	U
	CV Test3	CV	Group A	638965	HR	Heart Rate	U
	CV Test3	CV	Group A	638966	ACTIVITY	Activity	U
	CV Test3	CV	Group A	638967	LVSYSBP	Left Ventricular Systolic Pressure	U
CVIESTCD:	CV Test3	CV	Group A	638968	LVEDP	Left Ventricular End Diastolic Pressure	U
	CV Test3	CV	Group A	638969	DPDTAVG	dP/dt Average	U
	CV Test3	CV	Group A	638970	SYSBP	Systolic Blood Pressure	U
	CV Test3	CV	Group A	638971	DIABP	Diastolic Blood Pressure	U
ACTIVITY	CV Test3	CV	Group A	638972	MAP	Mean Arterial Pressure	U
	CV Test3	CV	Group A	638973	PULSEPR	Pulse Pressure	U
	•						•
Variables	2610 record	ls total					

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.

DOMAIN CV CV	USUBJID Group A Group A	CVSEQ 638949 638950 638951 638952 638953 638955 638955 638956 638957 638958 638959 638959	CVTESTCD LVSYSBP LVEDP DPDTAVG SYSBP DIABP MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	CVTEST Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average Systolic Blood Pressure Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular Systolic Pressure dP/dt Average	
CV	Group A Group A	638949 638950 638951 638952 638953 638954 638955 638955 638957 638958 638959 638959 638960	LVSYSBP LVEDP DPDTAVG SYSBP DIABP MAP PULSEPR HR ACTIVITY LVSSBP LVEDP DPDTAVG	Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average Systolic Blood Pressure Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular Systolic Pressure dP/dt Average	cicicicicicicicicicie
CV CV CV CV CV CV CV CV CV CV CV CV CV C	Group A Group A Group A Group A Group A Group A Group A Group A Group A Group A	638950 638951 638952 638953 638954 638955 638955 638957 638958 638959 638959 638960	LVEDP DPDTAVG SYSBP DIABP MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Left Ventricular End Diastolic Pressure dP/dt Average Systolic Blood Pressure Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular Systolic Pressure dP/dt Average	cicicicicicicicici
CV CV CV CV CV CV CV CV CV CV CV CV CV C	Group A Group A Group A Group A Group A Group A Group A Group A Group A Group A	638951 638952 638953 638954 638955 638956 638957 638958 638959 638959 638959	DPDTAVG SYSBP DIABP MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	dP/dt Average Systolic Blood Pressure Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	cicicicicicicici
CV CV CV CV CV CV CV CV CV CV CV CV	Group A Group A Group A Group A Group A Group A Group A Group A Group A	638952 638953 638954 638955 638956 638957 638958 638959 638959 638959	SYSBP DIABP MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Systolic Blood Pressure Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	cicicicicicici
CV CV CV CV CV CV CV CV CV CV CV	Group A Group A Group A Group A Group A Group A Group A Group A	638953 638954 638955 638956 638957 638958 638959 638959 638960	DIABP MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Diastolic Blood Pressure Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	cicicicicici
CV CV CV CV CV CV CV CV CV CV	Group A Group A Group A Group A Group A Group A	638954 638955 638956 638957 638958 638959 638959 638960	MAP PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Mean Arterial Pressure Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	cicicicicic
CV CV CV CV CV CV CV CV	Group A Group A Group A Group A Group A Group A	638955 638956 638957 638958 638959 638959 638960	PULSEPR HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Pulse Pressure Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure <i>dP (rt Averane</i>	: c c c c c
CV CV CV CV CV CV CV	Group A Group A Group A Group A Group A	638956 638957 638958 638959 638960	HR ACTIVITY LVSYSBP LVEDP DPDTAVG	Heart Rate Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure d//dt Averane	cccc
CV CV CV CV CV	Group A Group A Group A Group A	638957 638958 638959 638960	ACTIVITY LVSYSBP LVEDP DPDTAVG	Activity Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	: c c c
CV CV CV CV	Group A Group A Group A	638958 638959 638960	LVSYSBP LVEDP DPDTAVG	Left Ventricular Systolic Pressure Left Ventricular End Diastolic Pressure dP/dt Average	UU
CV CV CV	Group A Group A	638959 638960	LVEDP DPDTAVG	Left Ventricular End Diastolic Pressure	U.
CV CV	Group A	638960	DPDTAVG	dP/dt Average	
CV				a facture age	0
	Group A	638961	SYSBP	Systolic Blood Pressure	U
CV	Group A	638962	DIABP	Diastolic Blood Pressure	U
CV	Group A	638963	MAP	Mean Arterial Pressure	U
CV	Group A	638964	PULSEPR	Pulse Pressure	U
CV	Group A	638965	HR	Heart Rate	U
CV	Group A	638966	ACTIVITY	Activity	U
CV	Group A	638967	LVSYSBP	Left Ventricular Systolic Pressure	U
CV	Group A	638968	LVEDP	Left Ventricular End Diastolic Pressure	U
CV	Group A	638969	DPDTAVG	dP/dt Average	U
CV	Group A	638970	SYSBP	Systolic Blood Pressure	U
CV	Group A	638971	DIABP	Diastolic Blood Pressure	U
CV	Group A	638972	MAP	Mean Arterial Pressure	U
CV	Group A	638973	PULSEPR	Pulse Pressure	U -
					•
	CV cv	CV Group A CV Group A	CV Group A 638964 CV Group A 638965 CV Group A 638966 CV Group A 638967 CV Group A 638967 CV Group A 638967 CV Group A 638968 CV Group A 638969 CV Group A 638970 CV Group A 638971 CV Group A 638973 CV Group A 638973	CV Group A 638965 IMAF CV Group A 638965 HR CV Group A 638965 HR CV Group A 638965 LVSYSBP CV Group A 638966 ACTIVITY CV Group A 638967 LVSYSBP CV Group A 638967 DPDTAVG CV Group A 638967 DPDTAVG CV Group A 638970 SYSBP CV Group A 638971 DIABP CV Group A 638973 PULSEPR	CV Group A 638963 IPIAP IPIAent Automin Pressure CV Group A 638965 HR Heart Rate CV Group A 638966 ACTIVITY Activity CV Group A 638966 ACTIVITY Activity CV Group A 638966 ACTIVITY Activity CV Group A 638966 DPDTAVG dP/dt Average CV Group A 638969 DPDTAVG dP/dt Average CV Group A 638970 SYSBP Systolic Blood Pressure CV Group A 638971 DIABP Diastolic Blood Pressure CV Group A 638972 MAP Mean Arterial Pressure CV Group A 638972 PLSEP Pulse Pressure

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.

SEND Viewer							
Workstation: (local)\P3Plus	·						Export to CSV
<	STUDYID	DOMAIN	USUBJID	EGSEQ	EGTESTCD	EGTEST	EGCAT
Study: CV Test3	CV Test3	EG	Group A	362206	RRAG	RR Interval, Aggregate	MEASUREMEN -
	CV Test3	EG	Group A	362207	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
EG	CV Test3	EG	Group A	362208	QRSAG	QRS Duration, Aggregate	MEASUREMEN
	CV Test3	EG	Group A	362209	PRAG	PR Interval, Aggregate	MEASUREMEN
✓ Filters	CV Test3	EG	Group A	362210	QTAG	QT Interval, Aggregate	MEASUREMEN
	CV Test3	EG	Group A	362211	RRAG	RR Interval, Aggregate	MEASUREMEN
	CV Test3	EG	Group A	362212	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
▲ variables	CV Test3	EG	Group A	362213	QRSAG	QRS Duration, Aggregate	MEASUREMEN
	CV Test3	EG	Group A	362214	PRAG	PR Interval, Aggregate	MEASUREMEN
	CV Test3	EG	Group A	362215	QTAG	QT Interval, Aggregate	MEASUREMEN
DOMAIN	CV Test3	EG	Group A	362216	RRAG	RR Interval, Aggregate	MEASUREMEN
USUBJID	CV Test3	EG	Group A	362217	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
I EGSEQ I EGTESTOD	CV Test3	EG	Group A	362218	QRSAG	QRS Duration, Aggregate	MEASUREMEN
EGTEST	CV Test3	EG	Group A	362219	PRAG	PR Interval, Aggregate	MEASUREMEN
EGCAT EGCAT	CV Test3	EG	Group A	362220	QTAG	QT Interval, Aggregate	MEASUREMEN
EGPOS	CV Test3	EG	Group A	362221	RRAG	RR Interval, Aggregate	MEASUREMEN
EGORRES	CV Test3	EG	Group A	362222	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
I EGORRESO I EGSTRESC	CV Test3	EG	Group A	362223	QRSAG	QRS Duration, Aggregate	MEASUREMEN
✓ EGSTRESN	CV Test3	EG	Group A	362224	PRAG	PR Interval, Aggregate	MEASUREMEN
✓ EGSTRESU	CV Test3	EG	Group A	362225	QTAG	QT Interval, Aggregate	MEASUREMEN
EGSTAT	CV Test3	EG	Group A	362226	RRAG	RR Interval, Aggregate	MEASUREMEN
EGREASND	CV Test3	EG	Group A	362227	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
I ■ EGMETHOD	CV Test3	EG	Group A	362228	QRSAG	QRS Duration, Aggregate	MEASUREMEN
EGLEAD	CV Test3	EG	Group A	362229	PRAG	PR Interval, Aggregate	MEASUREMEN
EGCSTATE	CV Test3	EG	Group A	362230	QTAG	QT Interval, Aggregate	MEASUREMEN
EGBLFL ECEVAL	4				+-		Þ
	1450 record	s total					

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



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.

SEND Viewer								IN	
Workstation: (local)\P3Plus							Export to C	sv	
< a	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST			
Study: CV Test1	CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricula	ar Systolic Pressure		
	CV Test1	CV	Group A	2322	LVEDP	Left Ventricula	ar End Diastolic Pressure		
B Domain: CV	CV Test1	CV	Group A	2323	HR	Heart Rate			
	CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average	2		
✓ Filters	CV Test1	CV	Group A	2325	SYSBP	Systolic Blood	Pressure		
	CV Test1	CV	Group A	2326	DIABP	Diastolic Blood	Pressure		
Variables	CV Test1	CV	Group A	2327	MAP	Mean Arterial	Pressure		
variables	CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	2		
	CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricula	ar Maximum Positive dP/dt		
STUDYID	CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricula	ar Minimum Positive dP/dt		
DOMAIN	CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricula	ar Systolic Pressure		
USUBJID	CV Test1	CV	Group A	2332	LVEDP	Left Ventricula	ar End Diastolic Pressure		
	CV Test1	CV	Group A	2333	HR	Heart Rate			
CVTEST	CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average	2		
CVPOS	CV Test1	CV	Group A	2335	SYSBP	Systolic Blood	Pressure		
CVORRES	CV Test1	CV	Group A	2336	DIABP	Diastolic Blood	Pressure		
	CV Test1	CV	Group A	2337	MAP	Mean Arterial	Pressure		
CVSTRESN	CV Test1	CV	Group A	2338	PULSEPR	Pulse Pressure	2		
CVSTRESU	CV Test1	CV	Group A	2339	DPDTMAX	Left Ventricula	ar Maximum Positive dP/dt		
CVSTAT	CV Test1	CV	Group A	2340	DPDTMIN	Left Ventricula	ar Minimum Positive dP/dt		
	CV Test1	CV	Group A	2341	LVSYSBP	Left Ventricula	ar Systolic Pressure		
CVCSTATE	CV Test1	CV	Group A	2342	LVEDP	Left Ventricula	ar End Diastolic Pressure		
CVBLFL	CV Test1	CV	Group A	2343	HR	Heart Rate			
CVDTC	CV Test1	CV	Group A	2344	DPDTAVG	dP/dt Average	2		
	CV Test1	CV	Group A	2345	SYSBP	Systolic Blood	Pressure	<u> </u>	
							•		
	6235 record	s total						1.	

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.

Save As					X
🕞 🕞 🗸 🕹 🗸 Computer	▼ OS (C:) ▼ Ponemah_Data ▼ SampleECGData	•	Search SampleEC	GData	2
Organize 🔻 New folder				-	0
🍌 Ponemah_Data 🔺	Name *	Date modified	Туре	Size	
Ponemah530 Program Files	CV Test1_CV_20180629_132052.csv	6/29/2018 1:21 PM	Microsoft Excel Com	1,440 KB	
Program Files (x8					
🍌 ProgramData					
J Temp					
Users					
WINDOWS					
Removable Disk (E:					
🗣 Network 🗾					
File name: CV Tes	st3_CV_20180808_091432.csv				-
Save as type: CSV (C	omma delimited) files (*.csv)				-
Hide Folders			Save	Cancel	

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.

🚺 🔒 🍤 · 🔿 · 🗧	CV Test3_CV_20180808_091432.csv - Excel		? 📧 – 🗆 🗙
FILE HOME INSERT PAGE LAYOUT	FORMULAS DATA REVIEW VIEW		Sign ir
$\begin{array}{c c} & & \\ & & \\ \hline \\ Paste \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ $	Image: second secon	nal Formatting * 🔛 Insert * s Table * 🛣 Delete * s * 🔛 Format *	
	Alignment is Number is 3	Cells	
A1 $\overline{}$: $X \sqrt{f_x}$ stu	IDYID		~
A B C D	E F	G H	I J 🔺
1 STUDYID DOMAIN USUBJID CVSEQ	CVTESTCD CVTEST C	CVPOS CVORRES	CVORRESI CVSTRESC
2 CV Test1 CV Group A 2321	LVSYSBP Left Ventricular Systolic Pressure	JNCONSTRAINED 118.37	mmHg 118.37
3 CV Test1 CV Group A 2322	LVEDP Left Ventricular End Diastolic Pressure U	JNCONSTRAINED 5.5588	mmHg 5.5588
4 CV Test1 CV Group A 2323	HR Heart Rate L	JNCONSTRAINED 74.33	bpm 74.33
5 CV Test1 CV Group A 2324	DPDTAVG dP/dt Average	JNCONSTRAINED 3310.4	mmHg/s 3310.4
6 CV Test1 CV Group A 2325	SYSBP Systolic Blood Pressure L	JNCONSTRAINED 117.83	mmHg 117.83
7 CV Test1 CV Group A 2326	DIABP Diastolic Blood Pressure L	JNCONSTRAINED 81.212	mmHg 81.212
8 CV Test1 CV Group A 2327	MAP Mean Arterial Pressure L	JNCONSTRAINED 99.818	mmHg 99.818
9 CV Test1 CV Group A 2328	PULSEPR Pulse Pressure L	JNCONSTRAINED 36.623	mmHg 36.623
10 CV Test1 CV Group A 2329	DPDTMAX Left Ventricular Maximum Positive dP/dt	JNCONSTRAINED 10566	mmHg/s 10566
11 CV Test1 CV Group A 2330	DPDTMIN Left Ventricular Minimum Positive dP/dt U	JNCONSTRAINED 2565.3	mmHg/s 2565.3
12 CV Test1 CV Group A 2331	LVSYSBP Left Ventricular Systolic Pressure	JNCONSTRAINED 111.21	mmHg 111.21
13 CV Test1 CV Group A 2332	LVEDP Left Ventricular End Diastolic Pressure	JNCONSTRAINED 4.7925	mmHg 4.7925
14 CV Test1 CV Group A 2333	HR Heart Rate U	JNCONSTRAINED 60.651	bpm 60.651
15 CV Test1 CV Group A 2334	DPDTAVG dP/dt Average U	JNCONSTRAINED 3023.2	mmHg/s 3023.2
16 CV Test1 CV Group A 2335	SYSRP Systolic Blood Pressure	INCONSTRAINED 112.43	mmHø 112.43 🔻
CV Test3_CV_20180808_09143	32 (+)		Þ
READY		III	+ 100%

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: Migrating from version 5.32 to 5.40 will result in the SEND database from version 5.32 being converted to conform to the current schema used in Ponemah version 5.40. After conversion, the database will no longer be functional for version 5.32. Therefore, consideration must be taken to determine if separate storage (servers or workstations) and Ponemah 5.32 acquisition and Post systems should be maintained separately from 5.4 workstations and servers. Or, if updating the 5.32 SEND database is applicable to your given situation. Ponemah versions 5.32 and 5.4 cannot be used simultaneously for generating SEND output. If a migration has been performed, this will be listed in the SEND log as "Upgrade" under the Action column. See also Upgrade 5.32 Data. 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.

🞴 Ponemah - defau	lt.pro (User: mjb)		\times
File Setup Study	SEND Hardware Acquisition Replay Options Tools Help		
LR1 LR2 LR3 LR4 a	SEND Manager 🔸 🦻 📝 🎼 🆓 🔍		
	SEND Log		
	Controlled Terminology		
	Synchronize SEND Data Synchronize SEND Study Data		
ET: DT:	42D 12h DS: 90.99 GB Data Set: default ON OFF		

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.

S	END Log								— D X
Wor	kstation:	(local)\P	3Plus_v2	v					Export to CSV
\odot	Domain	NOMDY	USUBJID	Review File Name	RAW File Start	RAW File End	User	We Action Date	Action
2	CV	1	Group A	CVStudy1 (Day 1) (Group 1) (80830009).RVW	2019-09-19T16:15:02	2019-09-19T16:18:24	mjb	MB 2019-09-23T09:26:05.570	Save - Review
ptio	CV	1	Group B	CVStudy1 (Day 1) (Group 1) (80830009).RVW	2019-09-19T16:15:02	2019-09-19T16:18:24	mjb	MB 2019-09-23T09:26:05.840	Save - Review
ō	CV	1	Group A	CVStudy1 (Day 1) (Group 1) (80830009).RVW	2019-09-19T16:15:02	2019-09-19T16:18:24	mjb	MB 2019-09-23T10:32:00.863	Delete
	CV	1	Group A	CVStudy1 (Day 1) (Group 1) (80830009).RVW	2019-09-19T16:15:02	2019-09-19T16:18:24	mjb	MB 2019-09-23T11:33:17.213	Delete
	4 records t	otal							

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.

SEND Log										—	0 :	×
Workstation: (local)\P3Plus_v2	*									Б	port to C	SV
SEND Log Workstation: (Iocal)(P3Plus_v2 Study: CVStudy1 geg (Iocal)(P3Plus_v2 (Iocal)(P3Plus_v2 (Iocal)(P3Plus_v2	× × × × × × × × × × × × × ×	Domain NOM CV 1 CV 1 CV 1	DV USUBJID Group A Group B	Review File Name CVStudy1 (Day 1) (Grou CVStudy1 (Day 1) (Grou	p 1) (80830015).RVW p 1) (80830015).RVW	RAW File Start 2019-09-19T16-15:02 2019-09-19T16-15:02	RAW File End 2019-09-19T16:18:24 2019-09-19T16:18:24	User Wo	Action Date 2019-09-30115:03: 2019-09-30115:03:	E Action 13.790 Save - R 14.800 Save - R	c : : eview eview eview	× SV
Domain Onder ARW File Start RAW File Start RAW File Start Rever File Name User User User User Workstation Name												
		2 records total										4

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 C	Controlled	Terminol	ogy Manager			-		×
,	Norkstatio	n: (loca	I)\P3Plus_v	v2 ~			Export	Import	
1	Display:	Test	odes	~] Replace on Im	port
	Enabled	Domain	Analysis	Derived Parameter	DR Calc	TESTCD	TEST	Units	
	~	cv	ACT	A_TA	Avg	ACTIVITY	Activity		\sim
	~	CV	BP	Dia	Avg	DIABP	Diastolic Blood Pressure	mmHg	1
	~	CV	BP	HR	Avg	HR	Heart Rate	beats/min	1
	~	cv	BP	Mean	Avg	MAP	Mean Arterial Pressure	mmHg	1
	~	CV	BP	РН	Avg	PULSEPR	Pulse Pressure	mmHg	1
	~	CV	BP	Q-A	Avg	QAMEAN	Summary (Mean) QA Interval	msec	1
	~	CV	BP	Q-A	Max	QAMAX	Summary (Max) QA Interval	msec	1
	~	CV	BP	Q-A	Min	QAMIN	Summary (Min) QA Interval	msec	1
	~	CV	BP	Sys	Avg	SYSBP	Systolic Blood Pressure	mmHg	1
	~	CV	LVP	+dP/dt	Avg	DPDTAVG	dP/dt Average	mmHg/s	1
	~	CV	LVP	+dP/dt	Max	DPDTMAX	Left Ventricular Maximum Positive dP/dt	mmHg/s	1
	✓	CV	LVP	+dP/dt	Min	DPDTMIN	Left Ventricular Minimum Positive dP/dt	mmHg/s	\sim
						5	ОК	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.

33 | Page

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 with 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.

		SEND Con	trolled Te	rminology	/ Manager			-	- 🗆	×
,	Wor	kstation:	(local)\P	3Plus_v2	2			Export	Import	
1	Disp	lay:	TestCod	es	~			Ξ	Replace on Im	nport
		Enabled	Domain	Analysis	Derived Parameter	DR Calc	TESTCD	TEST	Units	
		\checkmark	RE	PVO	TV	Avg	TIDALVOL	Tidal Volume	mL	\sim
		~	RE	URP	BPM	Avg	RESPRATE	Respiratory Rate	breaths/min	1
		\checkmark	RE	URP	ET	Avg	EXPTIME	Expiration Time	msec	1
		\checkmark	RE	URP	п	Avg	INSTIME	Inspiration Time	msec	1
		~	RE	URP	MV	Avg	MV	Minute Volume	mL/min	1
		\checkmark	RE	URP	PEF	Avg	PEF	Peak Expiratory Flow	L/min	1
		~	RE	URP	PIF	Avg	PKINSFL	Peak Inspiratory Flow	L/min	1
		\checkmark	RE	URP	TV	Avg	TIDALVOL	Tidal Volume	mL	1
		\checkmark	VS	TEMP	T_Mean	Avg	TEMP	Temperature	С	1
		✓	CV	LVP	ττι	~				
	*					Avg				
					•	Max			1	~
						Min		ОК	Cancel	

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.

SEND O	Controlled Terminology Manager	- 0	×
Workstatic	n: (local)\P3Plus_v2 ~	Export Impo	rt
Display:	EG Leads ~	Replace on	Import
	TestCodes		
Enabled	La EG Methods	EGLEAD	
~	LE/ EG Leads	LEAD aV6	\sim
✓	LE/ CV Methods	LEAD aVF	
~	aV RE Methods	LEAD aVF-VENTRAL	
~	LE, CStates	LEAD aVL	-
~	aV Position	LEAD aVL-AXIAL	-
~	LEA BEST	LEAD aVR	
~	aVR-DORS	LEAD aVR-DORSAL	\neg
~	LEAD AXI	LEAD AXIAL	-
~	LEAD CM5	LEAD CM5	
✓	CV5RL	LEAD CV5RL	
~	CV6LL	LEAD CV6LL	
✓	CV6LU	LEAD CV6LU	~
		OK Cance	

Figure 35. – EG Leads list shown.

SYNCHRONIZE SEND DATA

Send information can be synchronized to a dedicated server or workstation. There are two types of synchronization, Synchronize SEND Data and Synchronize SEND Study Data.

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

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.

erver name:	<servername>\P3Plus_v2</servername>	
Example: SERVER\P3	3Plus_v2	
/ersion to create:	531	
	SQL Server authentication v	
QL Server Username:	TempSQLUser	
QL Server password:	•••••	

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:

- Sever name:
 - o <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, 531, 532, 540, etc.
 - Select SQL Server authentication
 - \circ ~ 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
 - o A P3StudyUssers 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 P3 Setup from the Setup pull-down menu. In the tree view on the left hand side, select SEND and enter the server name in the Output Server edit field and select Test Connection

END Enable SEND Output Enable Excel Output Study Name Study Day Workup Output Server Laboratory Name	ut 	Edit Study N	lame)ay	
 Enable SEND Output Enable Excel Output Study Name Study Day Workup Output Server Laboratory Name 	ut 	Edit Study N	lame)ay)	
Append Subject ID) to Study Name Subje	ct Separator		
Update SEND data	abase during Acquisition		-	
Position				
EG Method	12 LEAD STANDARD			
CV Method	INTRAVASCULAR		•	
RE Method	HEAD OUT PLETHYSN	MOGRAPH	-	
	Append Subject ID Update SEND data Consciousness State Position EG Method CV Method RE Method	Append Subject ID to Study Name Subject Update SEND database during Acquisition Consciousness State CONSCIOUS Position UNCONSTRAINED EG Method 12 LEAD STANDARD CV Method INTRAVASCULAR RE Method HEAD OUT PLETHYSM	Append Subject ID to Study Name Subject Separator	Append Subject ID to Study Name Subject Separator Update SEND database during Acquisition Consciousness State CONSCIOUS Position UNCONSTRAINED EG Method 12 LEAD STANDARD CV Method INTRAVASCULAR RE Method HEAD OUT PLETHYSMOGRAPH

Figure 37. – SEND configuration tab.

Enter the Server name or dedicated workstation name and use the Test Connection button to verify that the connection is valid. Along with the server name, the SQL Instance (P3Plus_v2) must also be defined, example "server name\P3Plus_V2". If successful, a message will post stating that the connection to the SEND database was successful.

PPP3 Setup	- SEND			
Channel Input Setup	Enable SEND Output			
emplate Setup Groups	Enable Excel Outp	ut		
Events Dicital Dicelau Sotup				
larm Setup	Study Name	Study Name	Edit Study Name	
experimental Protocol Header	Study Day	1	🔽 Edit Study Day	
Data Reduction Setup	Workup			
ariability Analysis	Output Server	MBSW\P3Plus v2	▼ Test connection	
linary Data Convert	Laboratory Name	-		
Settings				
END	Append Subject I	to Study Name Subject	Separator	
ata Parser Setup	Lindate SEND dat	abase during Acquisition		
	Consciousness State		*	
	CONSCIOUSI ICSS SLOLE	Jeonocious		
	Position	UNCONSTRAINED	<u> </u>	
	Position EG Method	UNCONSTRAINED 12 LEAD STANDARD	<u> </u>	
	Position EG Method CV Method	UNCONSTRAINED 12 LEAD STANDARD INTRAVASCULAR	<u> </u>	
	Position EG Method CV Method RE Method	UNCONSTRAINED 12 LEAD STANDARD INTRAVASCULAR HEAD OUT PLETHYSMO	SGRAPH	

Figure 38. – Output Server configuration in SEND 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 configuring the Output Server, 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.

🞴 Ponemah - defau	lt.pro (User: mjb)	—	\times
File Setup Study	SEND Hardware Acquisition Replay Options Tools Help		
LR1 LR2 LR3 LR4 a	SEND Manager 🔸 🦸 🔢 🛤 电 🖂 🕍		
	SEND Log Controlled Terminology		
	Synchronize SEND Data		
	Synchronize SEND Study Data		
ET: DT:	42D 12h DS: 90.99 GB Data Set: default Save OFF		

Figure 39. – Synchronize SEND Data dialog selection from SEND pull-down menu.

The Synchronize Study Data function can also be used when outside of a Review session. Figure 40 shows the popup dialog that allows selection of the Study and Output Server. Clicking the OK button will synchronize the selected study to the designated Output Server defined. 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.

Select SEND Study	×
Select the SEND study to synchronize:	[
MBWST-20740123\P3Plus_v2	
Test Connection	
	·
OK Cano	el

Figure 40. – Synchronize SEND Data dialog outside of Review session.

SYNCHRONIZE SEND STUDY DATA

The Synchronize SEND Study Data will synchronize from all workstations connected and visible on the network to the workstation performing the sync and to the Output Server. Both the workstation performing the sync and the Output server will then contain the same SEND information.

The Output Server defined in the SEND dialog must be part of the Study configuration, otherwise a message will post stating that they sync cannot be performed to the Output Server.

StudyMa	nager	×
<u>^</u>	This will Sync SEND_31 data with all Study Workstations. Ensure that all Study Workstations are connected to the network. Ensure that Ponemah is not running on any network workstation.	
	OK Cancel	

Figure 41. – Synchronize SEND Study Data notification.

The Synchronize SEND Study Data function is only available in idle mode and will not be available while in a Review session.

When performing a sync, the Output Server will be locked out from other workstations until the current sync has been completed. If an attempt to synchronize to the Output Sever is initiated by a second workstation, a message will be posted that the server (workstation) is in use and attempts to synchronize the data should be retried at a later time. In addition, error checking is performed during the synchronization. If conflicts between the data on the Output Server and the workstation performing the synch, Conflict Resolution dialog will be presented to allow the appropriate information to be updated.

Below, figure 42, 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 synched. In the example, both the workstation and server contain SEND data for these two subjects.

Display Username	each row.) betweer		by selecting the workstation from which data should b	e preserved.	Do this	for
Display Date Saved	STUDYID = CVStudy1				Select	most re	ecer
	Acquisition Start	Subject	RCH-20 details	RV-20\P3Plus_v2 details			
	9/19/2019 4:15:02 PM	Group A	mjb CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:58:21 PM	mjb V CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM			
	9/19/2019 4:15:02 PM	Group B	mjb CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:58:21 PM	mjb V CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM			

Figure 42. – 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 43 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.

Please resolve conflict(s each row.) between		by selecting the workstation from which data should b	e preserved. Do this for
STUDYID = CVStudy1				Select most recer
Acquisition Start	Subject	RCH-20 details	RV-20\P3Plus_v2 details	
9/19/2019 4:15:02 PM	Group A	mjb CVStudy1 (Day 1) (Group 1) (80830012).RVV 9/27/2019 1:58-21 PM	mjb V CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM	
9/19/2019 4:15:02 PM	Group 8	mjb CVStudy1 (Day 1) (Group 1) (80830012).RVV 9/27/2019 1:58:21 PM	mjb ✓ ✓ CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM	
-		9/27/2019 1:58:21 PM	9/27/2019 1:56:37 PM	
	Please resolve conflict(s each row. STUDID = CVStudy1 Acquisition Start 9/19/2019 4:15:02 PM 9/19/2019 4:15:02 PM	Please resolve conflict(s) between each row. STUDYID = CVStudy1 Acquisition Start Subject 9/19/2019 4:15:02 PM Group A 9/19/2019 4:15:02 PM Group B	Please resolve conflict(s) between each row. STUDYID = CVStudy1 Acquisition Start Subject RCH-20 details 9/19/2019 4:15:02 PM Group A mjb 9/19/2019 4:15:02 PM Group B mjb 0/27/2019 1:58:21 PM 9/19/2019 1:58:21 PM	Please resolve conflict(s) between each row. by selecting the workstation from which data should be seach row. STUDVID = CVStudy1 RV-20\P3Plus_v2 details Acquisition Start Subject RCH-20 9/19/2019 4:15:02 PM Group A mjb VCVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM 9/19/2019 4:15:02 PM Group B mjb VCVStudy1 (Day 1) (Group 1) (80830012).RVW 9/27/2019 1:56:37 PM 9/19/2019 4:15:02 PM Group B CVStudy1 (Day 1) (Group 1) (80830012).RVW 9/19/2019 4:15:02 PM Group B CVStudy1 (Day 1) (Group 1) (80830012).RVW

Figure 43. – Conflict Resolution dialog.

The Select most recent button (Figure 44) instructs the software to select the most recent information for each subject. Again, all highlighted subjects will be show in green.

SEND Conflict Resolution				– 🗆 🗙
C Display Username Display RVW filename C Display Date Saved	Please resolve conflict(s) for each row. STUDYID = CVStudy1	be preserved. Do this Select most recent		
	Acquisition Start	Subject RCH-20 details	RV-20\P3Plus_v2 details	
	9/19/2019 4:15:02 PM	Group A mjb ✓ CVStudy1 (Day 1) (Group 1) (80830014).RVV 9/27/2019 2:23:47 PM	mjb CVStudy1 (Day 1) (Group 1) (80830014).RVW 9/27/2019 1:58:21 PM	
	9/19/2019 4:15:02 PM 0	5roup 8 mjb ✓ CVStudy1 (Day 1) (Group 1) (80830014).RVV 9/27/2019 2:23:47 PM	mjb CVStudy1 (Day 1) (Group 1) (80830014).RVW 9/27/2019 1:56:37 PM	
			C	K Cancel

Figure 44. – 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 Groups 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
- Groups 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
 - \circ ~ 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

1 – Incorrect ECG labels

P3Setup		×
	The following ECG Channel labels are not compatible with SEND: 3 - (A3:) : ECG1 7 - (A7:) : ECG2 Please update the ECG channel labels in the P3 Setup : Channel Input Setup tab	
	ОК	

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 Channel Input Setup menu does not match that used by CDISC, the above message will be posted.

Resolution: Enter the Channel Input Setup menu and 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.

2 – Duplicate TESTCDs

SEND Duplicate Warning	×
The following TESTCDs are affected by removal of duplicates Group: Group A HR: Chan: 1 (BP): BP_HR_Avg (Mapped) HR: Chan: 2 (LVP): LVP_HR_Avg (Not Mapped)	
Duplicate TESTCDs have been removed. To eliminate this message and select parameters to report, disable duplicate derived parameters in P3 Setup: Channel Input Setup. Duplicates can also be removed using the SEND Controlled Terminology Manager. NOTE: Changes to the SEND Controlled Terminology Manager affect all studies.	
ОК	

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.

3- 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
 - o 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.

4 - No Output Sever Defined

StudyMa	nager X
4	Please enter a SEND Output Server in the P3 Settings
	OK

Or

Select SEND Study	×
Select the SEND study to synchronize:	
_	
Output server:	
Test Connection	
OK Cancel	

Figure 47. – Incorrect Output Server configuration.

Issue: No Output Sever has been configured



Resolution: The first message will post when in an active Review session and the second message when in idle mode. Enter the appropriate server/workstation in the SEND dialog under P3 Setup. Ensure that the Ponemah Instance has been included with the server/workstation name.

5 – 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.

\square	SEND Viewe	er	
w	orkstation:	(local)\P3Plus_v2	Export to CSV
< 2	Study:	CVStudy 🗸	
Option	Domain:	RE	
	✓ Filter	s	
	Varial	oles	
			0 records total

6 – 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.

TECHNICAL SUPPORT

DSI[™] is available to help you with your questions and concerns. Should you hit a road block or need some additional training, please feel free to contact us. We are happy to help!

DSI TECHNICAL SUPPORT-NORTH AMERICA

Email: <u>Support@datasci.com</u> Toll-free in U.S. and Canada Phone: 1-800-262-9687 Monday through Friday: 8 AM to 5 PM CST (exceptHolidays)

DSI TECHNICAL SUPPORT-EUROPE

Email: Europe-support@datasci.com Phone: +44 1359 259400 Monday through Friday: 8 AM to 5 PM CET

DSI TECHNICAL SUPPORT-ALL OTHER COUNTRIES

Phone: +1-651-481-7400

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.

Study Informati	on	Devit Devit Devits Devisit		
Study Name:	MultiLeedECG	Day of Day 1 Day 25 Day 30	1	New Day
Study Type	TOX Study	Date: 4/10/2019		Delete Day
Start Date:	Wednesday, February 20, 20 🗸	 <u>Study Group:</u> Group 1 <u>PRO:</u> Multilead ECG.PRO Workups 	î.	
Setup Compor	ents	Subjects (Doses)		
Protocols Workups Subjects Doses Add Worl Delete Wo	wp Nup F Alphabetical Jr Dn	2 (10mg/kg) 3 (30mg/kg) 4 (50mg/kg) 5 (0mk/kg) 6 (10mg/kg) 7 (30mg/kg) 8 (50mg/kg) 9 (0mk/kg) 10 (10mg/kg) 11 (30mg/kg)		New Group Clear Protocol
Options			-1	Verity Study
Allow Work	ups 🦵 Enable Day 0	☐ Network Study		
Consistent	Doses T Enable Stagger Days	Allow Post Workstations		Automation
				OK.
				No. of Concession, Name

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:	Add
PT2H	Cancel
1	

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

Study Information Study Name: MultiLeadECG Study Type TOX Study Start Date: Wednesday, February 20, 20 Setup Components -PT2H Protocols -PT2H
Protocols
Workups Subjects PT2H PT4H30M15S Subjects (Doses); Image: Constraint of the second sec
Add Workup 6 (10mg/kg) New Group Delete Workup Image: Alphabetical Up Dn -7 (30mg/kg) Delete Workup
Options Verify Study
Allow Workups Enable Day 0 Network Study Consistent Doses Enable Stagger Days Allow Post Workstations
OK

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.

	🞴 Ponemah - Mul	a Reductio	on: a]												
	Eunctions Se	tup S <u>E</u> ND	Data Pars	ser Options	Window								- 8 ×		
	LR1 LR2 LR3 LR4 a	b c d e	f g h	i j 🛙	10 9 🕑	M • 1	3.≧								
							ation	8: RR-I	8: HR	8: QRS	8: PR-I	8: QT-I	8: QTcb		
	то	00:00:000	14:46:16	02/06/2019)										
	2h Predose	0000:00:02	14:46:18	02/06/2019	0000:00	000	:00:05								
	Avg							999.80	60.012	74.667	171.50	349.83	349.87		
							_								
							-								
								1							
Current * Analysis				Reference	N/A			Raw File C:\Ponemah_Data\Multil				eadECG\MultiLeadE			



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	
- PPP3 Setup	- SEND
Channel Input Setup Template Setup Groups	Enable SEND Output Enable Excel Output
Experimental Protocol	Study Name MultiLeadECG Edit Study Name
Data Reduction Setup	Study Day
Graph Setup	Workup PT4H30M15S Edit Workup
Settings	Output Sequer Sequer/P3PLUS v2 Test connection
SEIVE	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
1	
	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 EGTPT and EGELTM.

=	END Viewer										- (•	x
w	orkstation:	(local)\P3Plus_v2	Export to CSV										
<	Study:	MultiLeadECG -	;ENDTC	EGDY	EGE	ργ	EGNOMDY	EGTPT	EGTPTNUM	EGELTM	EGTPTREF	EG	т
suc	Study.		19-02-06T14:46:24				1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg		
ptic	Domain:	EG 🗸	19-02-06T14:46:24				1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg		
0			19-02-06T14:46:24				1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg		
	Silter:	5	19-02-06T14:46:24				1	2h Predose	1	-PT2H	Day 1 Dose 1:0mk/kg		
Variables		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										