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.

Data Sciences International

119 14TH STREET NW SUITE 100 ST. PAUL, MN 55112 USA

(651)481-7400 • 1(800)262-9687

www.datasci.com

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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.
 - o See Appendix 1 for a list of currently accepted parameters
- Data reduction enabled for subjects
 - 0
 - The currently defined calculations are Average (Avg), Maximum (Max), and Minimum (Min)
- SEND.XML file is created and listed in the Ponemah directory or the location where the Ponemah software has been installed (automatically created with software installation)
 - The SEND.XML file provides a mapping of the terminology between the Ponemah derived nomenclature and the expected SEND controlled terminology. This file can be modified by the user to include additional Ponemah parameters. Additionally, as parameters are updated by CDISC, this file 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.

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

PPP3 Setup - SEND		
- PPP3 Setup	SEND	
Channel Input Setup Template Setup Groups Events Experimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEIND	 Enable SEND Output Enable Excel Output Study Name Study Day Workup Output Server Laboratory Name Append Subject ID 	Istudy Name I Edit Study Name Edit Study Day Edit Study Day Edit Workup Test connection
	Update SEND data	abase during Acquisition
	Consciousness State	
	Position	UNCONSTRAINED
	EG Method	12 LEAD STANDARD
	CV Method	INTRAVASCULAR
	RE Method	HEAD OUT PLETHYSMOGRAPH
,		OK Cancel Apply

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

1 – Enable SEND Output

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

2 – Enable Excel Output

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

If this option is not checked, SEND output can be generated by creating a CSV file using SEND Viewer (see SEND Viewer below) only with the SEND SQL Output Server option enabled in the license file. The SEND Output option only allows output to Excel.

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 by the SEND.XML file.

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 by the SEND.XML file.

12 – EG Method

Allows the selection of the CDISC controlled terminology that represents the ECG lead presentation used for collection. These definitions are managed by the SEND.XML file.

13 – CV Method

Allows the selection of CDISC controlled terminology for definition of pressure measurements. These definitions are managed by the SEND.XML file.

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 by the SEND.XML file.

See Technical Support for details, if modification to the SEND.XML file is needed.

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.

hannel Input Setup emplate Setup roups		Use Study	Subjects 🔽	Jse Study Doses		
Events Experimental Protocol Header	Group	Study Subject Name	Trigger	Camera	Species	Study Dose
ata Reduction Setup	Group A	1	1 - (LVP1)		Dog	Omg/kg
raph Setup	Group B	2	5 - (LVP2)		Dog	30mg/kg
ettings	Group C				Dog	
IND	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				Dog	

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

SEND Vi	ewer						<u>_0 ×</u>
Workstatio	n: (local) \P3Plus						Export to CSV
<		STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST
Study:	CV Test3	CV Test3	CV	ID 123	641559	LVSYSBP	Left Ventricular Systolic Pressure
in the second se		CV Test3	CV	ID 123	641560	LVEDP	Left Ventricular End Diastolic Pressure
Domair	CV 🔽	CV Test3	CV	ID 123	641561	DPDTAVG	dP/dt Average
		CV Test3	CV	ID 123	641562	SYSBP	Systolic Blood Pressure
~ F	ilters	CV Test3	CV	ID 123	641563	DIABP	Diastolic Blood Pressure
		CV Test3	CV	ID 123	641564	MAP	Mean Arterial Pressure
	rishles	CV Test3	CV	ID 123	641565	PULSEPR	Pulse Pressure
- V	anabies	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 I
		CV Test3	CV	ID 123	641575	HR	Heart Rate I
		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 I
		CV Test3	CV	ID 123	641584	HR	Heart Rate I
		CV Test3	CV	ID 123	641585	ACTIVITY	Activity I
		CV Test3	CV	ID 123	641586	LVSYSBP	Left Ventricular Systolic Pressure
		CV Test3	lev	ID 123	641587		I eft Ventricular End Diastolic Pressure
		5220 record	s total				//

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.

PPP3 Setup - Data Reduction	Setup		
PPP3 Setup - Data Reduction - PPP3 Setup Channel Input Setup Template Setup Groups Events Digital Display Setup Alarm Setup Experimental Protocol Header Print RAW Data Setup Data Reduction Setup Graph Setup Binary Data Convert Settings Remote Connection SEND Data Parser Setup	Setup Data Reduction A- Group A B- Group B C- Group C D- Group D E- Group C F- Group F G- Group G H- Group H I- Group I J- Group L K- Group L M- Group M N- Group N O- Group Q - Group Q - -	Setup SEND compatibility enabled SEND compatibility enabled SEND compatibility enabled Use fixed Control and T0 Control Dyration Control Dyration Control Dyration Duration of Interval Intervals Controlled Setup Interval Interval	Iming Reference Stat Iming Reference Permit Redefinition Iming Reference Iming Reference
			OK Cancel Apply

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	Jiming Reference	Start 💌
Groups	A- Group A	Enable		
Events Dioital Dionlay 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	Duration 00:05:00	Г	Permit Redefinition
Data Reduction Setup	E- GIOUD E	Events 🖓 a 🗂 b Г с Г	d Te Ff Fg	Th Fi Fi

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.

Ponemah - Sa	Ponemah - SampleECGData.RVW (User: mjb) - [Data Reduction: a]										X	
LNT LNZ LNO LN4	a u c											
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									-
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 Destdese	01:00:00	01-10-00	0000+10-00	121.04	0.2823	3302.2	121.49	82.506	102,14	38.985	/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	-
1b 10m Postd	01-10-00	01:20:00	0000+10+00	143.45	12,709	4003.5	142.05	50.744	120.07	-3.931	100.27	-
Ava	01.10.00	01.20.00	0000.10.00	110.46	7 1452	3384.1	120.36	83 135	102.40	37 225	76 565	-
1h 20m Postd	01.20.00	01-30-00	0000-10-00	115.40	7.1452	5504.1	120.30	03,133	102.19	57.225	70.303	-
211 20111 0300111	01.20.00	01.00.00	0000.10.00	•								
Current Group	Name Chang	je	Reference	Group Name O	Change	Raw	File C:\F	onemah_D	ata\SampleE	CGData\Sa	mpleECGDa	iti

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.

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	😫 Ponemah - SampleECGData.RVW (User: mjb) - [Data Reduction: a]											
Eunctions Set	tup S <u>E</u> ND <u>D</u>	ata Parser 🧕	Options <u>W</u> indo	w							_ 8	\times
un u												
Label	Start Time	End Time	Duration	1: Sys	1: LVEDP	1:+dP/dt	2: Sys	2: Dia	2: Mean	2: PH	2: HR	
то	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
				•							<u> </u>	
current Group	Name Chang	e	Reference	Group Name (Change	Raw	File C:\F	onemah_D	ata\SampleE	CGData\Sa	mpleECGDa	,ti
Group	p Name Chang	e	Reference	Group Name (unange	Raw	File C: W	-oneman_D	ata pampiec	cobata (sa	прессора	u

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 Reference	e Start 💌
Groups	A- Group A	Enable		
Events Dioital Dioplay Satura	B- Group B	Les 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 Г b Г c Г	d 🗆 e Гf Г	g 🗆 h 🗖 i 🗂 j
Variability Analysis Graph Setup	F- Group F	T0 Events		
Binary Data Convert	G- Group G	Malbici	dieiti	glhlilj
Settings Remote Connection	H- Group H	Type Rervos / La		Calculations
SEND	I- Group I	Time Dose Nu	mber 1	Ciculation
Jata Parser Setup	J- Group J	Duration of Interval Index	Laber	
	K- Group K	01:00:00 ÷ Controlled	SEND	T Avg %Chg

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

3 – Used 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 Reduction	Setup										
- PPP3 Setup	– Data Redu	ction Setup									
Channel Input Setup		SEND c	ompatib	ility enab	led	D	ming Ref	ference	Start		•
Groups	A- Group /	A 🔽 🔽 Enabl	e								
Events Experimental Protocol Header	B- Group	B 🗹 Use f	fixed Contro	ol and TO							
Data Reduction Setup	C- Group	C Cor	ntrol		_						
Variability Analysis Graph Setup	D- Group	D D,	uration (0:05:00	E Cor	ntrol Time	5/17	/2007	▼ 9:0	0:00 AM	-
Settings	E- Group	E- Group E									
SEND	F- Group	F T0	то	Time	5/17/20	07 -	9.00.0	0 AM 🖃	3		
	G- Group	G		lata			,		-		
	H- Group	H Type -			Deve N	bels			alculation	15	
	I- Group I			<u> </u>	Dose Nu	imper 1		_ -	Calcu	lation	
	J- Group	J Duratio	n of Interva	al Inc	lex	Label		_	Avg	~~~	-
	K- Group	K 00:10	:00	: 🗋	ontrolled	. SEND		H	Avg	%Cng %Do#a	
	L- Group		o Label —						Aval	Delta	
	M- Group	M TBen/	N}	-				i i i	Line		-
	N- Group	N							Ln %	Chg	
	0- Group	O $\{N\} = $ $\{M\} = h$	nterval Inde dia from TO	ex				ſ	Ln %	Delta	
	P- Group	P {T} = h	h:mm:ss			1			Ln De	elta	
	Q- Group	Q {T2} =	hh:mm		Add >		<u>D</u> elete		- I.M		
	-										
							ОК		Cancel		Apply
Eunctions Setup SEND Data Parser O	otions <u>W</u> indow										
LR1 LR2 LR3 LR4 a b c d e	fgh i	j 🗊 🍉 🗲 📴 🏘	• 🛪 🖬								
Data Reduction: a								1			
T0 0001:01:12 0	Start Tim 9:00:00 05/17/200	e7	End Time	Duration	1: Sys	1: LVEDP	1: HR	1: +dP/dt	2: Sys	2: Dia	2: Mean • /
Os Postdose 0001:01:12 0 Avg	9:00:00 05/17/200	7 0001:11:12 09:10:00	05/17/2007	0000:10:00	143.64	12.826	106.97	4080.8	142.74	99.035	120.88
10m Post 0001:11:12 0 Avg	9:10:00 05/17/200	7 0001:21:12 09:20:00	05/17/2007	0000:10:00	119.18	6.5803	77.269	3435.4	119.90	82.338	101.84
20m Post 0001:21:12 0 Avg	9:20:00 05/17/200	7 0001:31:12 09:30:00	05/17/2007	0000:10:00	116.34	3.4061	74.239	3672.5	115.41	75.577	95.801
30m Post 0001:31:12 0 Avg	9:30:00 05/17/200	/ 0001:41:12 09:40:00	05/17/2007	0000:10:00	119.50	3.1541	79.70	3804.6	117.94	75.991	96.84
40m Post 0001:41:12 0 Avg	9:40:00 05/17/200	/ 0001:51:12 09:50:00	05/17/2007	0000:10:00	118.41	6.4415	66.17	3441.6	118.18	79.706	98.018
SUM POST 0001:51:12 0 Avg	9:50:00 05/17/200	7 0002:01:12 10:00:00	05/17/2007	0000:10:00	121.06	5.8841	73.593	3605.2	119.84	79.766	99.597
In Postaose 0002:01:12 10 Avg	05/17/200	7 0002:11:12 10:10:00	05/17/2007	0000:10:00	137.34	5.8307	96.607	4829.7	136.31	89.754	112.78
0002:11:12 1	5:10:00 05/17/200	0002:21:12 10:20:00	05/1//2007	0000:10:00	125 10	E 2027	01.097	4460 E	176 10	01 525	112 74
Current ik	Reference N	/A	Raw File	C:\Ponemah_[Data \SampleE	ECGData\Sam	pleECGDat	a.RAW			

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
- PPP3 Setup Channel Input Setup Template Setup Groups Evperimental Protocol Header Data Reduction Setup Variability Analysis Graph Setup Settings SEND	- Data Reduction Setup SEND compatibility enabled Iming Reference A - Group A Iming Reference A - Group A Iming Reference Iming Reference A - Group A Iming Reference Iming Re
	OK Cancel Apply

Figure 10. – I know I will add something here.

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 11, the information created using the Study option will be pulled into the SEND dialog. However, no modification of these fields will be allowed. Figure 11 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: Send Output Image: Send Output Image: Send Output Study Name Study Day Workup Output Server Laboratory Name Image: Append Subject ID Image: Update SEND data Consciousness State Position EG Method CV Method RE Method	ut CVStudy 1 1 0 to Study Name Subject Sep abase during Acquisition CONSCIOUS UNCONSTRAINED 12 LEAD STANDARD INTRAVASCULAR HEAD OUT PLETHYSMOGRA	Edit Study Name Edit Study Day Edit Workup Test connection
			OK Cancel <u>A</u> pply

Figure 11. – 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 12, 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 SEIND	Enable SEND Output Study Name Study Name Study Day Image: Image: Study Day Image: Im
	OK Cancel <u>Apply</u>

Figure 12. – 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.

PPP3 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
Variability Analysis	Group A	1	1 - (LVP1)		Dog	Omg/kg
Graph Setup	Group B	2	5 - (LVP2)		Dog	30mg/kg
SEND	Group C				Dog	
	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		l	I	Dog	
					0K	Cancel <u>A</u> pply

Figure 13. – 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).

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.

🔛 Ponemah - defa	ault.pro (User: mjb)	
File Setup Study	SEND Hardware Acquisition Replay Options Tools Help	
LR1 LR2 LR3 LR4	SEND Manager j 📝 🕨 🦻 🔀 🏘 🖝 👯 🔛	
	Synchronize SEND Data Synchronize SEND Study Data	

Figure 14. – 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.

ł	SEND Database Man	ager		
	Workstation: (local)\P3	Plus_v2	•	
	Study Name	Space(KB)		
	CVStudy CVStudyMod SvncStudy	263 527 15413		Backup
	-,,			Restore
				Delete
				Import EX
				1.

Figure 15. – 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".

Backup SEND Database					x
🕞 🖓 🗸 - Computer	▼ OS (C:) ▼ Ponemah_Data ▼ SampleECGData ▼	•	Search SampleECC	GData	2
Organize 🔻 New folder				•	0
-	Name *	Date modified	Туре	Size	
Documents	길 Archives	8/10/2018 11:32 AM	File folder		
J Music					
Pictures					
Hamagaun					
Nonegroup					
Computer					
🏭 OS (C:)					
👝 Removable Disk (E:					
File name:					<u> </u>
Save as type: Backup) Files(*.sendbkup)				_
Hide Folders			Save	Cancel	

Figure 16. – 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 associated data with the study from the SQL database.

6 – Import EX

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

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

SEND VIEWER AND OUTPUT

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

SEND EXPORT TO EXCEL

To generate SEND data to Excel, the Enable Excel Output function must be selected in the SEND setup 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.

X		5• @•	Ŧ				San	npleECGData_	1.xlsx - E	xcel					? 📧 –	□ ×
F	ILE	HOME IN	ISERT PA	GE LAYOUT	FORMULA	S DATA	R	EVIEW VI	EW							Sign ir
Pa	iste	Calibri B I U	- 11 - ↓ □□ - ↓	 ▲ ▲ ▲ ▲ ▲ ▲ 		≫ - 🕞 € 🖅 🗒 ment) - 5	General \$ - % * Number	€.0 .0 € 00.	Condition Formatti	onal Format ing Table	as Cell Styles •	Tinsert • Delete • Format • Cells	∑ - A ↓ Z So e Fit	rt & Find & ter * Select *	~
			~ 4	£											-	
0	4	· · ·	$\wedge \vee$	Jx = CV												~
	С	D	E		F			G		н	1	J	К	L	М	A
1	USUBJI	D CVSEQ	CVTESTCD	CVTEST				CVPOS		CVORRES	CVORRESU	CVSTRESC	CVSTRESN	CVSTRESU	CVSTAT	CVRE
2	CV	Group A	LVSYSBP	Left Ventri	icular Systolic	Pressure		UNCONSTR	AINED	118.40	'mmHg'	118.40	118.40	'mmHg'	NULL	NULL
3	CV	Group A	LVEDP	Left Ventri	icular End Dia	stolic Press	sure	UNCONSTR	AINED	5.5708	'mmHg'	5.5708	5.5708	'mmHg'	NULL	NULL
4	CV	Group A	HR	Heart Rate				UNCONSTR	AINED	74.319	'bpm'	74.319	74.319	'bpm'	NULL	NULL
5	CV	Group A	DPDTAVG	dP/dt Ave	rage			UNCONSTR	AINED	3310.2	'mmHg/s'	3310.2	3310.2	'mmHg/s'	NULL	NULL
6	CV	Group A	SYSBP	Systolic Bl	ood Pressure			UNCONSTR	AINED	117.87	'mmHg'	117.87	117.87	'mmHg'	NULL	NULL
7	CV	Group A	DIABP	Diastolic B	lood Pressure	2		UNCONSTR	AINED	81.248	'mmHg'	81.248	81.248	'mmHg'	NULL	NULL
8	CV	Group A	MAP	Mean Arte	rial Pressure			UNCONSTR	AINED	99.849	'mmHg'	99.849	99.849	'mmHg'	NULL	NULL
9	CV	Group A	PULSEPR	Pulse Pres	sure			UNCONSTR	AINED	36.621	'mmHg'	36.621	36.621	'mmHg'	NULL	NULL
10	CV	Group A	ACTIVITY	Activity				UNCONSTR	AINED	0.0164		0.0164	0.0164		NULL	NULL
11	CV	Group A	LVSYSBP	Left Ventri	icular Systolic	Pressure		UNCONSTR	AINED	111.20	'mmHg'	111.20	111.20	'mmHg'	NULL	NULL
12	CV	Group A	LVEDP	Left Ventri	icular End Dia	stolic Press	sure	UNCONSTR	AINED	4.7871	'mmHg'	4.7871	4.7871	'mmHg'	NULL	NULL
13	CV	Group A	HR	Heart Rate				UNCONSTR	AINED	60.679	'bpm'	60.679	60.679	'bpm'	NULL	NULL
14	cv	Group A	DPDTAVG	dP/dt Ave	rage			UNCONSTR	AINED	3023.4	'mmHg/s'	3023.4	3023.4	'mmHg/s'	NULL	NULL
15	CV	Group A	SYSBP	Systolic Bl	ood Pressure			UNCONSTR	AINED	112.41	'mmHg'	112.41	112.41	'mmHg'	NULL	NULL
16	cv	Group A	DIABP	Diastolic B	lood Pressure	2		UNCONSTR	AINED	76.446	'mmHg'	76.446	76.446	'mmHg'	NULL	NULL
17	cv	Group A	MAP	Mean Arte	rial Pressure			UNCONSTR	AINED	94.795	'mmHg'	94.795	94.795	'mmHg'	NULL	NULL
18	cv	Group A	PULSEPR	Pulse Pres	sure			UNCONSTR	AINED	35.967	'mmHg'	35.967	35.967	'mmHg'	NULL	NULL
19	cv	Group A	ACTIVITY	Activity				UNCONSTR	AINED	NULL	NULL	NULL	NULL	NULL	'NOT DONE'	'INCC
20	CV	Group A	LVSYSBP	Left Ventri	icular Systolic	Pressure		UNCONSTR	AINED	115.28	'mmHg'	115.28	115.28	'mmHg'	NULL	NULL
21	CV	Group A	LVEDP	Left Ventri	icular End Dia	stolic Press	sure	UNCONSTR	AINED	5.6705	'mmHg'	5.6705	5.6705	'mmHg'	NULL	NULL
22	CV	Group A	HR	Heart Rate				UNCONSTR	AINED	64.359	'bpm'	64.359	64.359	'bpm'	NULL	NULL
23	cv	Group A	DPDTAVG	dP/dt Ave	rage			UNCONSTR	AINED	3043.0	'mmHg/s'	3043.0	3043.0	'mmHg/s'	NULL	NULL
24	cv	Group A	SYSBP	Systolic Bl	ood Pressure			UNCONSTR	AINED	117.20	'mmHg'	117.20	117.20	'mmHg'	NULL	NULL
25	CV	Group A	DIABP	Diastolic B	lood Pressure	2		UNCONSTR	AINED	78.698	'mmHg'	78.698	78.698	'mmHg'	NULL	NULL
26	cv	Group A	MAP	Mean Arte	rial Pressure			UNCONSTR	AINED	98.12	'mmHg'	98.12	98.12	'mmHg'	NULL	NULL
27	CV	Group A	PULSEPR	Pulse Pres	sure			UNCONSTR	AINED	38.50	'mmHg'	38.50	38.50	'mmHg'	NULL	NULL
	4 →	DataR	eductionB	GroupB	Message	CVdomai	in	EGdomain	(+) :	4					
RE					-					-		=	a II	-	++	100%

Figure 17. – 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 17 incorporated both CV and EG domain data, two worksheets are created in the Excel workbook with the appropriate information for each Domain.

SEND VIEWER

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.

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 18 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.

station:	(local)\P3Plu	S	•	·				Export to
STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU
CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	118.37	mmHg
CV Test1	CV	Group A	2322	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.5588	mmHg
CV Test1	CV	Group A	2323	HR	Heart Rate	UNCONSTRAINED	74.33	bpm
CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average	UNCONSTRAINED	3310.4	mmHg/s
CV Test1	CV	Group A	2325	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.83	mmHg
CV Test1	CV	Group A	2326	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	81.212	mmHg
CV Test1	CV	Group A	2327	MAP	Mean Arterial Pressure	UNCONSTRAINED	99.818	mmHg
CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	UNCONSTRAINED	36.623	mmHg
CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricular Maximum Positive dP/dt	UNCONSTRAINED	10566	mmHg/s
CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricular Minimum Positive dP/dt	UNCONSTRAINED	2565.3	mmHg/s
CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	111.21	mmHg
CV Test1	CV	Group A	2332	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	4.7925	mmHg
CV Test1	CV	Group A	2333	HR	Heart Rate	UNCONSTRAINED	60.651	bpm
CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average	UNCONSTRAINED	3023.2	mmHg/s
CV Test1	CV	Group A	2335	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	112.43	mmHg
CV Test1	CV	Group A	2336	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	76.463	mmHg
CV Test1	CV	Group A	2337	MAP	Mean Arterial Pressure	UNCONSTRAINED	94.816	mmHg
CV Test1	CV	Group A	2338	PULSEPR	Pulse Pressure	UNCONSTRAINED	35.969	mmHg
CV Test1	CV	Group A	2339	DPDTMAX	Left Ventricular Maximum Positive dP/dt	UNCONSTRAINED	3589.6	mmHg/s
CV Test1	CV	Group A	2340	DPDTMIN	Left Ventricular Minimum Positive dP/dt	UNCONSTRAINED	2594.9	mmHg/s
CV Test1	CV	Group A	2341	LVSYSBP	Left Ventricular Systolic Pressure	UNCONSTRAINED	115.27	mmHg
CV Test1	CV	Group A	2342	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	5.6718	mmHg
CV Test1	CV	Group A	2343	HR	Heart Rate	UNCONSTRAINED	64.312	bpm
CV Test1	CV	Group A	2344	DPDTAVG	dP/dt Average	UNCONSTRAINED	3042.7	mmHg/s
CV Test1	CV	Group A	2345	SYSBP	Systolic Blood Pressure	UNCONSTRAINED	117.19	mmHg
CV Test1	CV	Group A	2346	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	78.691	mmHg
CV Test1	CV	Group A	2347	MAP	Mean Arterial Pressure	UNCONSTRAINED	98.115	mmHg
CV Test1	CV	Group A	2348	PULSEPR	Pulse Pressure	UNCONSTRAINED	38.502	mmHg
CV Test1	CV	Group A	2349		I eft Ventricular Maximum Positive dP/dt	UNCONSTRATINED	4266.2	mmHa/s

Figure 18. – SEND Viewer dialog.

Figure 19 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 19 shows CVTest1 selected and its associated data displayed.

Workstation:	(local)\P3Plus	•						Export to C	sv
<			STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	
Study:	CV Test1		CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricular Systolic Pressure	
Log	CV Test1	i II	CV Test1	CV	Group A	2322	LVEDP	Left Ventricular End Diastolic Pressure	
Domain:	CV Test3	l Ií	CV Test1	CV	Group A	2323	HR	Heart Rate	Ī
	CvTest2	51	CV Test1	CV	Group A	2324	DPDTAVG	dP/dt Average	Ī
✓ Filter	s		CV Test1	CV	Group A	2325	SYSBP	Systolic Blood Pressure	Ī
			CV Test1	CV	Group A	2326	DIABP	Diastolic Blood Pressure	Ī
Marriel			CV Test1	CV	Group A	2327	MAP	Mean Arterial Pressure	Ī
Varia	DIES		CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	Ī
			CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricular Maximum Positive dP/dt	Ī
			CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricular Minimum Positive dP/dt	Ī
			CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricular Systolic Pressure	Ī
			CV Test1	CV	Group A	2332	LVEDP	Left Ventricular End Diastolic Pressure	t
			CV Test1	CV	Group A	2333	HR	Heart Rate	t
			CV Test1	CV	Group A	2334	DPDTAVG	dP/dt Average	t
			CV Test1	CV	Group A	2335	SYSBP	Systolic Blood Pressure	T
			CV Test1	CV	Group A	2336	DIABP	Diastolic Blood Pressure	-
			4	i		1	•	•	
		6	5235 record	s total					

Figure 19. – 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
All	CV Test3	CV	Group A	638956	HR	Heart Rate	U
Group B	CV Test3	CV	Group A	638957	ACTIVITY	Activity	U
I⊈ 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
CUTTOTOD:	CV Test3	CV	Group A	638967	LVSYSBP	Left Ventricular Systolic Pressure	U
CVIESTOD:	CV Test3	CV	Group A	638968	LVEDP	Left Ventricular End Diastolic Pressure	U
All	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
	4						•

Figure 20. – 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.

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
A Veriebles	CV Test3	CV	Group A	638955	PULSEPR	Pulse Pressure	U
	CV Test3	CV	Group A	638956	HR	Heart Rate	U
	CV Test3	CV	Group A	638957	ACTIVITY	Activity	U
	CV Test3	CV	Group A	638958	LVSYSBP	Left Ventricular Systolic Pressure	U
DOMAIN	CV Test3	CV	Group A	638959	LVEDP	Left Ventricular End Diastolic Pressure	U
USUBJID	CV Test3	CV	Group A	638960	DPDTAVG	dP/dt Average	U
CVIESTOD	CV Test3	CV	Group A	638961	SYSBP	Systolic Blood Pressure	U
CVTEST	CV Test3	CV	Group A	638962	DIABP	Diastolic Blood Pressure	U
CVPOS	CV Test3	CV	Group A	638963	MAP	Mean Arterial Pressure	U
CVORRES .	CV Test3	CV	Group A	638964	PULSEPR	Pulse Pressure	U
IM CVORRESU	CV Test3	CV	Group A	638965	HR	Heart Rate	U
CVSTRESC CVSTRESN	CV Test3	CV	Group A	638966	ACTIVITY	Activity	U
CVSTRESU	CV Test3	CV	Group A	638967	LVSYSBP	Left Ventricular Systolic Pressure	U
CVSTAT	CV Test3	CV	Group A	638968	LVEDP	Left Ventricular End Diastolic Pressure	U
CVREASND	CV Test3	CV	Group A	638969	DPDTAVG	dP/dt Average	U
	CV Test3	CV	Group A	638970	SYSBP	Systolic Blood Pressure	U
CVBLFL	CV Test3	CV	Group A	638971	DIABP	Diastolic Blood Pressure	U
CVDTC	CV Test3	CV	Group A	638972	MAP	Mean Arterial Pressure	U
CVENDTC	CV Test3	CV	Group A	638973	PULSEPR	Pulse Pressure	۰U
	•		1				•

Figure 21. – SEND Viewer dialog with Variables option expanded.

In the example study above (CVTest3 from Figure 21), 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 22 and update the remaining Options to provide the desired output.

SEND Viewer							<u>_ 0 ×</u>
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
B Domain:	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
STUDYID	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
EGSEQ	CV Test3	EG	Group A	362218	QRSAG	QRS Duration, Aggregate	MEASUREMEN
I 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
IV EGORRESO IV 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
	CV Test3	EG	Group A	362227	EGHRMN	ECG Mean Heart Rate	MEASUREMEN
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	<u>ं</u> ।						
	1450 record	s total					

Figure 22. – 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									
Workstation: (local)\P3Plus							Export to C	sv	
<pre></pre>	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST			
Study: CV Test1	CV Test1	CV	Group A	2321	LVSYSBP	Left Ventricula	r Systolic Pressure		
	CV Test1	CV	Group A	2322	LVEDP	Left Ventricula	r 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		
A Variables	CV Test1	CV	Group A	2327	MAP	Mean Arterial	Pressure		
vanabies	CV Test1	CV	Group A	2328	PULSEPR	Pulse Pressure	2		
	CV Test1	CV	Group A	2329	DPDTMAX	Left Ventricula	r Maximum Positive dP/dt		
STUDYID	CV Test1	CV	Group A	2330	DPDTMIN	Left Ventricula	r Minimum Positive dP/dt		
DOMAIN	CV Test1	CV	Group A	2331	LVSYSBP	Left Ventricula	r Systolic Pressure		
	CV Test1	CV	Group A	2332	LVEDP	Left Ventricula	r 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		
VORRESU	CV Test1	CV	Group A	2337	MAP	Mean Arterial	Pressure		
VSTRESN	CV Test1	CV	Group A	2338	PULSEPR	Pulse Pressure	2		
CVSTRESU	CV Test1	CV	Group A	2339	DPDTMAX	Left Ventricula	r Maximum Positive dP/dt		
CVSTAT	CV Test1	CV	Group A	2340	DPDTMIN	Left Ventricula	r Minimum Positive dP/dt		
I CVREASND	CV Test1	CV	Group A	2341	LVSYSBP	Left Ventricula	r Systolic Pressure		
CVCSTATE	CV Test1	CV	Group A	2342	LVEDP	Left Ventricula	r 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 23. – 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					×
🕞 🖓 🗸 🕹 🗸	▼ OS (C:) ▼ Ponemah_Data ▼ SampleECGData	•	Search SampleEC	GData	2
Organize 🔻 New folder				-	?
🍌 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					
Jemp					
Users					
WINDOWS					
👝 Removable Disk (E:					
C RECOVERY (Y:)					
🗣 Network 📃					
File name: CV Tes	st3_CV_20180808_091432.csv				-
Save as type: CSV (C	omma delimited) files (* csv)				Ţ
bare as gyper fear (co					
Hide Folders			Save	Cancel	

Figure 24. – 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 25 shows the CSV output opened using Microsoft Excel.

🕅 🔒 🐬 r 🗟 r 📼	CV Test3_CV_20180808_091432.csv - Excel		? 📧 – 🗆 🗙
FILE HOME INSERT PAGE LAYOUT	FORMULAS DATA REVIEW VIEW		Sign ir
$\begin{array}{c c} & & \\ & & \\ \hline \\ Paste \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ & \\ $	$ \begin{array}{c} \blacksquare \blacksquare \blacksquare \textcircled{\begin{tabular}{c} \bullet \bullet \bullet \bullet \\ \blacksquare \blacksquare$	nal Formatting • 🔛 Insert • s Table • 🛣 Delete • s • 📰 Format •	$\sum_{\mathbf{v}} \cdot \frac{\mathbf{A}}{2} \mathbf{v} \cdot$ $\bigcup_{\mathbf{v}} \cdot \mathbf{A} \cdot$ Editing
A1 \checkmark : $\times \checkmark f_x$ STUE	DYID	cens	v
A B C D	E F	G H	IJA
1 STUDYID DOMAIN USUBJID CVSEQ	CVTESTCD CVTEST C	CVPOS CVORRES	CVORRESI CVSTRESC
2 CV Test1 CV Group A 2321 L	LVSYSBP Left Ventricular Systolic Pressure	INCONSTRAINED 118.37	mmHg 118.37
3 CV Test1 CV Group A 2322 L	LVEDP Left Ventricular End Diastolic Pressure L	JNCONSTRAINED 5.5588	mmHg 5.5588
4 CV Test1 CV Group A 2323 H	HR Heart Rate U	JNCONSTRAINED 74.33	bpm 74.33
5 CV Test1 CV Group A 2324 E	DPDTAVG dP/dt Average	JNCONSTRAINED 3310.4	mmHg/s 3310.4
6 CV Test1 CV Group A 2325 S	SYSBP Systolic Blood Pressure L	JNCONSTRAINED 117.83	mmHg 117.83
7 CV Test1 CV Group A 2326 D	DIABP Diastolic Blood Pressure U	JNCONSTRAINED 81.212	mmHg 81.212
8 CV Test1 CV Group A 2327 M	MAP Mean Arterial Pressure L	JNCONSTRAINED 99.818	mmHg 99.818
9 CV Test1 CV Group A 2328 F	PULSEPR Pulse Pressure L	JNCONSTRAINED 36.623	mmHg 36.623
10 CV Test1 CV Group A 2329 D	DPDTMAX Left Ventricular Maximum Positive dP/dt	JNCONSTRAINED 10566	mmHg/s 10566
11 CV Test1 CV Group A 2330 E	DPDTMIN Left Ventricular Minimum Positive dP/dt U	JNCONSTRAINED 2565.3	mmHg/s 2565.3
12 CV Test1 CV Group A 2331 L	LVSYSBP Left Ventricular Systolic Pressure L	JNCONSTRAINED 111.21	mmHg 111.21
13 CV Test1 CV Group A 2332 L	LVEDP Left Ventricular End Diastolic Pressure L	JNCONSTRAINED 4.7925	mmHg 4.7925
14 CV Test1 CV Group A 2333 H	HR Heart Rate L	JNCONSTRAINED 60.651	bpm 60.651
15 CV Test1 CV Group A 2334 C	DPDTAVG dP/dt Average	JNCONSTRAINED 3023.2	mmHg/s 3023.2
16 CV Test1 CV Group Δ 2335 S	SYSRP Systolic Blood Pressure	INCONSTRAINED 112.43	mmHg 112 43
CV Test3_CV_20180808_09143	52 (+) : I		Þ
READY		─────────	+ 100%

Figure 25. – Example of CSV output

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.

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.

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		
- PPP3 Setup	SEND	
Channel Input Setup Template Setup Groups Events Digital Display Setup Alarm Setup Experimental Protocol Header Print RAW Data Setup Data Reduction Setup Variability Analysis Graph Setup Binary Data Convert Settings Remote Connection SEIND Data Parser Setup	Enable SEND Output Study Name Study Name Study Name Study Day I Korkop Output Server MBSWT[20740\P3Plus_v2 Test connection Laboratory Name Output Server MBSWT[20740\P3Plus_v2 Test connection Laboratory Name Output Server MBSWT[20740\P3Plus_v2 Test connection Laboratory Name Output Server MDSWT[20740\P3Plus_v2 Test connection Laboratory Name Output Server Output Server <	
	OK Cancel	Apply

Figure 26. – 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.

When performing a synch, the Output Server will be locked out from other workstations until the current synch 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 dialogs will be presented to allow the appropriate information to be updated.

After configuring the Output Server, navigate to the Synchronize SEND Data as shown in Figure 27. 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.

P P	onema	h - CV P	ro.PRO	(User: m	jb)													×
File	Setup	Study	SEND	Hardware	Acquisiti	on Rep	olay Options	Tools	Help									
LR1	LR2 LR3	LR4	SEN	ID Manager ID Viewer			j 02) • <i>4</i>	-	酋		<u>M</u>						
			Syn Syn	chronize SE chronize SE	END Data END Study ()ata												
ET.			150	9D 21b	DS: 811	5 GB D	ata Set:	V Pro	-	-	Save		Video	_	-	_	_	
			. 135	50 2211	00.011.						ON		OFF					11.

Figure 27. – 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 28 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:	
CVStudy	
Output server:	
MBWST-20740\P3Plus_v2	
Test Connection	
OK Cancel	

Figure 28. – Synchronize SEND Data dialog outside of Review session



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.

The Synchronize SEND Study Data will synchronize from all workstations connected and visible on the network to the workstation performing the synch and to the Output Server. Both the workstation performing the synch 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.

StudyMar	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	

Figure 29. – 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.

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
 - 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



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 Chan: 2 (BP 1):HR Group: Group B Chan: 6 (BP2):HR	
Duplicate TESTCDs have been removed. To eliminate this message and select parameters to report, disable duplicate derived parameters in P3 Setup: Channel Input Setup.	
ОК	

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 LV pressure as channel 1 and BP (systemic blood pressure) defined as channel 2 for both Group A and Group B. The HR parameter was reported for the LV channel and removed from the BP 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
 - 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 Output or SEND SQL Server Output 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 SQL Server Output option is enabled. Contact Technical Support for assistance.

4 - No Output Sever Defined



Or

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

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.

SEND Viewer	
Workstation: (local)\P3Plus_v2	Export to CSV
Study: CVStudy	
Domain: RE	
✓ Filters	
Variables	
	0 records total

6 – No Data 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: Support@datasci.com Toll-free in U.S. and Canada Phone: 1-800-262-9687 Monday through Friday: 8 AM to 5 PM CST (except Holidays)

DSI TECHNICAL SUPPORT-EUROPE

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

DSI TECHNICAL SUPPORT—ALL OTHER COUNTRIES

Phone: +1-651-481-7400

APPENDX 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

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

• Tpe-I

Activity

• A_TA

Pressure

- Dia
- +dP/dt
- -dP/dt
- HR
- LVEDP
- Sys
- Mean
- PH
- Q-A
- TPR

Respiratory

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

Temperature

• Mean