



Ponemah SEND Module

Automatically convert your data to a SEND domain format

The Standard for Exchange of Non-clinical Data (SEND) is a data formatting standard required for certain Safety Pharmacology, General Toxicology and Reproductive Toxicology studies for submission to the FDA. The Ponemah SEND Module provides a simple method for converting your Ponemah data to a SEND 3.1-compliant format. The Ponemah SEND Module, compliant to SEND 3.1, is compatible with Ponemah v5.30 and later.

Spend Less Time on Formatting and More Time on the Science

- Easily convert your Data Reduction time points to a SEND-compliant output with a few mouse clicks
- Supports the following SEND domains:
 - ECG Test Results – EG
 - Cardiovascular Test Results – CV
 - Respiratory Test Results – RE
 - Vital Signs - VS
- Integrates with Study Protocol Option to reduce manual data entry

STUDYID	DOMAIN	USUBID	CVSEQ	CVTESTCD	CVTEST	CVPOS	CVORRES	CVORRESU	CVTRESHC	CVTRESH
Pmo_1mm	CV	Pmo_1mm_CC0C21	1	LVSYSP	Left Ventricular Systolic Pressure	UNCONSTRAINED	138.80	mmHg	138.80	138.8
Pmo_1mm	CV	Pmo_1mm_CC0C22	2	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	0.887	mmHg	0.887	0.887
Pmo_1mm	CV	Pmo_1mm_CC0C23	3	HR	Heart Rate	UNCONSTRAINED	107.52	beats/min	107.52	107.52
Pmo_1mm	CV	Pmo_1mm_CC0C24	4	DPDTAVG	dp/dt Average	UNCONSTRAINED	5613.2	mmHg/s	5613.2	5613.2
Pmo_1mm	CV	Pmo_1mm_CC0C25	5	SVSP	Systolic Blood Pressure	UNCONSTRAINED	149.07	mmHg	149.07	149.07
Pmo_1mm	CV	Pmo_1mm_CC0C26	6	HR	Heart Rate	UNCONSTRAINED	95.667	beats/min	95.667	95.667
Pmo_1mm	CV	Pmo_1mm_CC0C27	7	DPDTAVG	dp/dt Average	UNCONSTRAINED	4615.8	mmHg/s	4615.8	4615.8
Pmo_1mm	CV	Pmo_1mm_CC0C28	8	SVSP	Systolic Blood Pressure	UNCONSTRAINED	129.15	mmHg	129.15	129.15
Pmo_1mm	CV	Pmo_1mm_CC0C29	9	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	70.526	mmHg	70.526	70.526
Pmo_1mm	CV	Pmo_1mm_CC0C30	10	MAP	Mean Arterial Pressure	UNCONSTRAINED	93.995	mmHg	93.995	93.995
Pmo_1mm	CV	Pmo_1mm_CC0C31	11	PULSPR	Pulse Pressure	UNCONSTRAINED	58.629	mmHg	58.629	58.629
Pmo_1mm	CV	Pmo_1mm_CC0C32	12	QAMEAN	Summary (Mean) Qa Interval	UNCONSTRAINED	107.19	ms	107.19	107.19
Pmo_1mm	CV	Pmo_1mm_CC0C33	13	DPDTMAX	Left Ventricular Maximum Positive dp/dt	UNCONSTRAINED	5627.7	mmHg/s	5627.7	5627.7
Pmo_1mm	CV	Pmo_1mm_CC0C34	14	DPDTNEG	Left Ventricular Minimum Negative dp/dt	UNCONSTRAINED	4596.7	mmHg/s	4596.7	4596.7
Pmo_1mm	CV	Pmo_1mm_CC0C35	15	QAMAX	Summary (Max) Qa Interval	UNCONSTRAINED	119.00	ms	119.00	119
Pmo_1mm	CV	Pmo_1mm_CC0C36	16	DPDTMIN	Left Ventricular Minimum Positive dp/dt	UNCONSTRAINED	1729.4	mmHg/s	1729.4	1729.4
Pmo_1mm	CV	Pmo_1mm_CC0C37	17	QAMIN	Summary (Min) Qa Interval	UNCONSTRAINED	80.00	ms	80.00	80
Pmo_1mm	CV	Pmo_1mm_CC0C38	18	LVSYSP	Left Ventricular Systolic Pressure	UNCONSTRAINED	139.71	mmHg	139.71	139.71
Pmo_1mm	CV	Pmo_1mm_CC0C39	19	LVEDP	Left Ventricular End Diastolic Pressure	UNCONSTRAINED	8.184	mmHg	8.184	8.184
Pmo_1mm	CV	Pmo_1mm_CC0C40	20	HR	Heart Rate	UNCONSTRAINED	123.56	beats/min	123.56	123.56
Pmo_1mm	CV	Pmo_1mm_CC0C41	21	DPDTAVG	dp/dt Average	UNCONSTRAINED	3524.6	mmHg/s	3524.6	3524.6
Pmo_1mm	CV	Pmo_1mm_CC0C42	22	SVSP	Systolic Blood Pressure	UNCONSTRAINED	135.41	mmHg	135.41	135.41
Pmo_1mm	CV	Pmo_1mm_CC0C43	23	DIABP	Diastolic Blood Pressure	UNCONSTRAINED	77.318	mmHg	77.318	77.318
Pmo_1mm	CV	Pmo_1mm_CC0C44	24	MAP	Mean Arterial Pressure	UNCONSTRAINED	102.25	mmHg	102.25	102.25

Easy Integration with SEND Package Compilation and Submission Solutions

- Compatible with major LIM Systems and SEND submission software, including:
 - Instem Provantis™ and submit™
 - Xybion Pristima™
- Excel output and SQL database support available

Ponemah SEND Viewer

DSI is Here to Help

- To help ensure your success with SEND, DSI has partnered with Instem, the leading global provider of SEND solutions.
 - Instem's SEND experts can help organize, educate and guide you to becoming SEND-Ready and their Safety Pharmacology configuration package in particular can maximize the benefits of SEND while ensuring regulatory compliance.
 - You can begin leveraging Instem's full array of expertise with a SENDReady™ Analysis and/or a practical introduction to SEND through one of their popular training courses.
 - Instem's submit™-for-SEND software suite and their outsourced study services have been adopted at over 85 sites across 15 countries.
 - Through the power of our partnership with Instem, DSI can now meet you at any stage of SEND Readiness to fully support you from system set-up to SEND submission.