



# 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

STUDID	DOMAIN	USUBID	CYSD	CYSYCD	CYSCT	CUSP	CYBRES	CYBRSU	CYSYSC	CYSYSD
P0001	EG	EG001	EG001	EG001	EG001	EG001	EG001	EG001	EG001	EG001
P0001	CV	CV001	CV001	CV001	CV001	CV001	CV001	CV001	CV001	CV001
P0001	RE	RE001	RE001	RE001	RE001	RE001	RE001	RE001	RE001	RE001
P0001	VS	VS001	VS001	VS001	VS001	VS001	VS001	VS001	VS001	VS001

Ponemah SEND Viewer

### 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

### 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.