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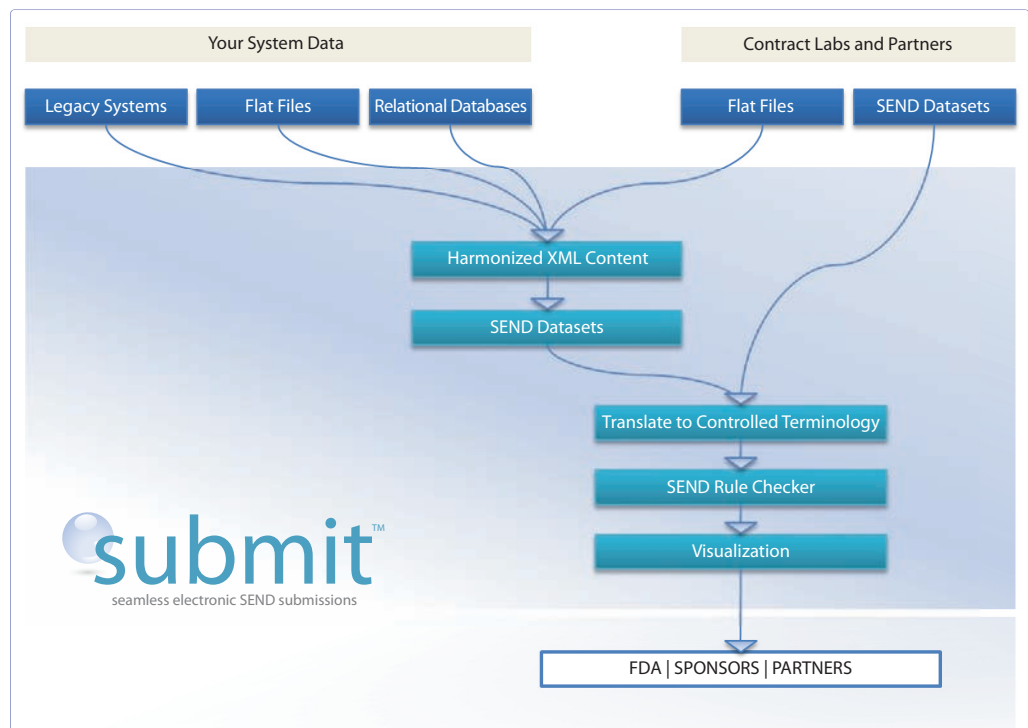
[instem.com](http://instem.com)

Submit™ is a fully integrated nonclinical solution suite developed to support companies using CDISC's Standard for Exchange of Nonclinical Data (SEND).

The submit solution creates and manages SEND study datasets throughout their lifecycle, and allows sponsors, CROs and regulators to share, visualize and analyze study data more efficiently.

### Business Benefits

- Enables efficient electronic exchange between sponsors, CROs & regulators
- Reduces manual processes & errors
- Adapts as your data collection systems evolve
- SEND datasets created in a few simple steps saving significant time
- Technology value beyond regulatory submissions



### Submit Capabilities

- Creates SEND files from data management systems and files
- Manages SEND files received from CROs and partners
- Translates to controlled terminology with no change to data collection
- Checks against SEND guide and 'good data' rules
- Manually adds and edits data with audit trail
- Merges files to create a single comprehensive dataset
- Produces and converts XPT, XML, XLS and XLSX formats
- Conducts efficient SEND dataset review

### Improving Processes

FDA reviewers continue to receive mostly paper or electronic paper (PDF) submissions. Manually entering data for further analysis is time consuming and inefficient, taking time away from the primary mission of reviewing the content of submissions. The SEND format enables more efficient review of nonclinical data, offering improved data quality, accessibility and predictability.

The same benefits can be realized for any organization. Receiving SEND datasets from contract research laboratories and partners throughout the course of a study will allow sponsors to see early indications of drug effect and to assess the conduct of the study, using SEND electronic data in the same way as internal studies. Using data in SEND format, the industry can help improve the safety review process while streamlining the flow of data from collection through submission and facilitate data interchange within their organizations and with external study partners.

*Proven.  
Simple.  
Complete.*

*SEND defines how to format nonclinical data once it's captured and provides a standardized, electronic presentation of toxicology study data tabulations*

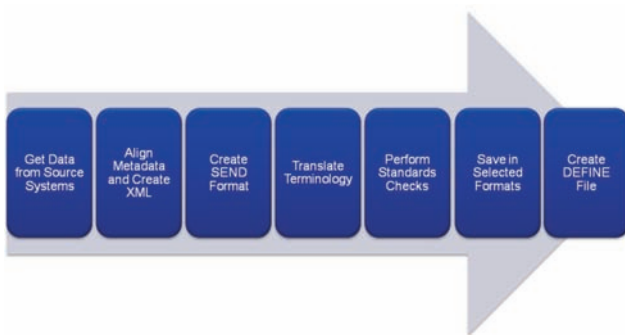
## SEND Legislative Update

The FDA is accepting electronic data in SEND format now and strongly encourages its use for submissions.



### 2012 and beyond

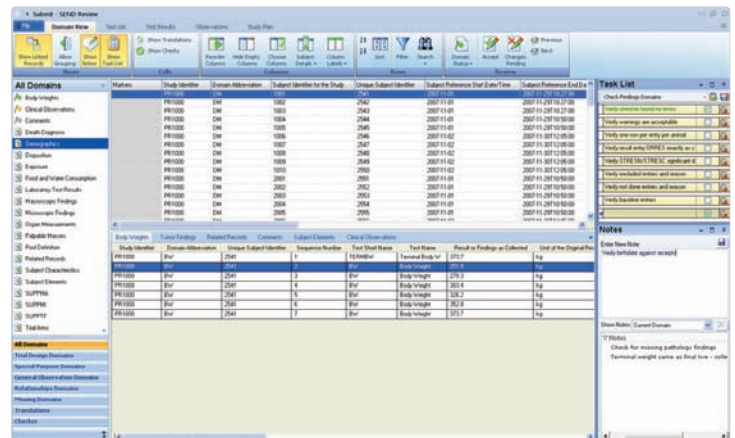
- PDUFA V agreement letter to become US law
- Prescription Drug User Fee Act establishes schedule for mandatory electronic submissions
- FDA to issue draft guidance and standard for public comment
- Final FDA guidance issued following public comment period
- The electronic submission rule to be phased in covering all INDs, NDA and BLA submissions



## Solution Options

Instem's submit solution suite can be deployed as a traditional on-site system or accessed over the Web using our SaaS model, where your dedicated solution will be located in our professionally managed US-based data center.

Instem additionally offers a submit service, where clients simply upload their data and we return it to them in SEND format.



## Submit Requestor

The Requestor module allows a user to schedule the creation of a SEND dataset for a study, and utilizes templates to define a standard list of domains including the data source and translation to use for each domain. Users then simply select the output location and type (XML, XPT, XLS).

## SEND Term Translations

Organizations can leverage SEND Controlled Terminology without a change to data collection systems by using Instem's submit Translator.

They can now translate files received from CROs, created from electronic data collection systems, or can be created manually in one simple step.

## Submit SEND Repository

Organizations can store and manage all SEND files with confidence over an entire drug development program. Using the submit SEND Repository, clients can retain all files received from all contributors to a study, verify format and content, translate to controlled terminology and merge into a consolidated study dataset.

## Submit Viewer

Users can simplify the review and modification of SEND datasets through the submit SEND Viewer. See complex data relationships and term translations, address standards errors, and track review status on easy-to-use screens.

## The Instem Advantage

As the leading provider of integrated toxicology solutions for over 30 years, we have been supporting the SEND standard in very tangible ways. We launched our submit solution in 2005, have worked closely with SEND pilot organizations and the FDA, and are part of the CDISC SEND team in helping to promote the standard.

In addition to our software solutions, when you become an Instem client you benefit from our experience and join a global community of users that receive real value from their technology investments. No other vendor has the experience, in-production solutions and global support that Instem offers to ensure your SEND-readiness.

**Talk to an Instem team member today and find out why we are the global leader in all measures within the nonclinical IT market.**

## SEND Rule Checker

Included in our submit solution is powerful technology to automatically check that the datasets created conform to the rules of the current SEND Implementation Guide, describing error and warning conditions in your dataset, on-screen summaries and an XML detail file. The SEND Rule Checker can additionally be used with datasets created outside of submit.