

SEND Implementation Resources

Table of Contents

<i>Common Resources in the SEND World</i>	2
CDISC/SEND Links	2
FDA Links.....	2
FDA Draft Guidances and Federal Registry Notices for Electronic Submissions	2

Common Resources in the SEND World

CDISC/SEND Links

- [CDISC SEND](#) - This page has links to the SEND Implementation Guide and Controlled Terminology
- [SEND Implementation News](#) - For updates in the SEND world
- [SEND Implementation Forum](#) - For asking questions about SEND Implementation

FDA Links

- [FDA Study Data Standards Resources](#) - with various resource links
- [Study Data Standards for Submission to CDER](#) - with some additional information related to submissions to CDER

FDA Draft Guidance's and Federal Registry Notices for Electronic Submissions

- [FDA Newly Added Guidance Documents](#)
- FDA Study Data Technical Conformance Guide - see [FDA Study Data Standards Resources](#) for the most up-to-date link
- FDA Data Standards Catalogue - see [FDA Study Data Standards Resources](#) for the most up-to-date link
- [Providing Regulatory Submissions in Electronic Format - Standardised Study Data](#) (Most recent Guidance and Register Notice linked from here) - aka Docket FDA-2012-D-0097
- [Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A\(a\) of the Federal Food, Drug, and Cosmetic Act](#) (Most recent Guidance and Register Notice linked from here) - aka FDA-2014-D-0085