SEND UPDATE

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Background

- Standard for the Exchange of Nonclinical Data
- A Clinical Data Interchange Standards Consortium (CDISC) standard representation of datasets and terminologies to simplify data sharing and enable tools for analytics, search and visualization.

Background

- Prescription Drug User Fee Act (PDUFA)
  - Provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products.
  - As part of PDUFA V, the FDA will require nonclinical study data to be submitted in the SEND format.

Background

- Provides a standardized presentation of toxicology study data in a electronic format.
- Enables the development and use of visualization and analytical tools for these types of data
- Enables more effective and efficient review of nonclinical tox data.

Timeline

- Twenty-four (24) months after publication of the final guidance: All new original NDA and BLA submissions, all new NDA and BLA efficacy supplements and amendments, all new NDA and BLA labeling supplements and amendments, all new manufacturing supplements and amendments, and all other new NDA submissions.
- •Thirty-six (36) months after publication of the final guidance: All original commercial INDs and amendments, except for submissions described in section 561 of the Federal Food, Drug, and Cosmetic Act.

Timeline

- As of this month, all pharm/tox reviewers have been trained.
- Have already been getting SEND submissions
- It makes FDA reviewers happy!

Timeline

- General tox and carcinogenicity studies are the main focus.
- Safety pharmacology and reprotox are going through informal testing.
- Final Guidance? Maybe this year??

Timeline

- Study Data Specifications are already on the FDA website.
- CDER published validation rules for SEND Format studies,
  - Includes a link to how the FDA validates the data (not a full set of conformance rules)
  - Includes business rules (how well the data may support meaningful analyses)
- Changes will be published in the Federal Register.
- Common errors will be published.

Seamless data entry

- Validated
- QA audit

Data Entered by Lab

- Study name, title, number, design, dates
- Test system species, strain, age, gender
- Test article, vehicle
- Interim, final, recovery sacrifice
- Facility details
- Housing details
- Etc.

Concerns with SEND

- Several vendors commercializing software packages which may lead to discrepancies in data and/or interpretation between agencies or institutions.
- Who will sign off on data and when?
- Additional, duplicate QA reviews

What will happen

- Sponsor submits to the FDA
  - Data may be from multiple labs
- FDA runs dataset through a SEND validator
- Are data sets acceptable? If yes: nonclinical study data repository – reviewer analytics…

Businesses ready?

- Now that the FDA published the validation rules, no reason to not be ready
- Get involved in testing and groups.
- Data specification rules: Get involved in the conversations
- Prepare your e-data standardization now!
- Steep learning curve… It is important to learn how to use this now!