

UPDATE



INHAND: International Harmonization of Nomenclature and Diagnostic Criteria Collaboration with the FDA on SEND – Standard for the Exchange of Nonclinical Data

Background:

In 2012, members of the **INHAND Global Editorial Steering Committee (GESC)** attended regular meetings to assist in adapting INHAND terminology for standardized nonclinical data submission to the FDA. The Standard for Exchange of Non-Clinical Data (SEND) is an implementation of the CDISC (Clinical Data Interchange Standards Consortium) Study Data Tabulation Model (SDTM) for non-clinical studies. This standard was developed by the CDISC SEND Team for non-clinical data from animal toxicology studies.

- SEND Implementation Guide production version 3.0 (SENDIG 3.0) is now available at <http://www.cdisc.org/send>
- This IG will evolve, to accommodate additions for reproductive toxicology, safety pharmacology, and veterinary studies.

- SEND and SDTM terminology that will be used by SEND v3.0 is available at <http://evs.nci.nih.gov/ftp1/CDISC/SEND>

- **FDA has indicated a preference to utilize microscopic pathology terminology developed by INHAND as this will be published in a peer-reviewed journal.**

- SEND terminology codelists are maintained by National Cancer Institute Enterprise Vocabulary Service (NCI-EVS)
- FDA Center for Drug Evaluation and Research (CDER) currently supports SEND IG v3.0 for regulatory submissions of tabulated toxicology data in electronic format provided that a complete study report is also submitted. Sponsors can consult the Study Data Standards for Submission to CDER website for additional information.

Current Developments:

- FDA released 3 draft guidances covering Regulatory Submissions in Electronic Format for comment Feb 6, 2014.

<http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

- The guidance provides a timeline for the requirement to provide regulatory submissions and data in electronic format. An example is shown below.

Example timeline
for implementation of electronic
submissions and data



INHAND Collaboration (2013 – 2014)

- INHAND and GESC will continue current Organ Working Groups until publication of all systems is complete.
- INHAND GESC assists the SEND Controlled Terminology (CT) Committee in setting up categories to segment (bucket) microscopic terminology and help to provide appropriate definitions for each category or 'bucket'. 'Buckets' include the diagnosis or "basic process" (e.g. necrosis) and various types of modifiers such as severity or distribution. Two members of the GESC sit as ad hoc members of the SEND CT.
- INHAND GESC will map the current published terminology to the SEND codelist, i.e. map the INHAND terminology to the appropriate 'buckets' for SEND.
- INHAND will assist the SEND CT committee in providing definitions for base processes and modifiers associated with the INHAND published terminology. INHAND ad hoc members of the SEND CT committee participate in this endeavor and take issues to the full GESC and/or appropriate OWG for resolution.
- Pathology findings syntax - Basic Process and Modifier codelists – maintained by NCI-EVS
- Diagnosis details and images – maintained by goRENI

NEW function for the GESC -

GESC will be a permanent standing committee of the various STP's with a defined appointment and term of members and several roles:

- Act as a clearing house for comments, requests for updates, etc. to the INHAND terminology from the STP memberships. **A formal change control process was implemented in 2013.**
- Manuscript updates/creation and coordinating the manuscript updates with help of experts from the profession based on received comments/requests. Manuscripts could be added to goRENI and/or published on a case-by-case basis.
- Continue to liaise with goRENI and contacts at various journals so basic structure for future endeavors is maintained and
- Act as a 'scientific advisory board' to the SEND CT committee (or other group) charged with maintaining and updating the SEND terminology.

INHAND Collaboration (2013 -2015)

NEW objective for INHAND:

- **Species-specific committees have been established under GESC – dog, monkey, rabbit and minipig.**
- Committees are reviewing the rodent nomenclature as the starting point and then providing a manuscript on terminology that would be unique for each species as well as rodent terminology not appropriate for use in non-rodents. This information would be posted on goRENI. Publication as an article or supplement determined on a case-by-case basis. New terminology would then be mapped to SEND controlled terminology codelists.

- CONTACT GESC members if you are interested in joining a working group.

INHAND Collaboration (ongoing)

Role as 'Scientific Advisory Board' to SEND CT committee would involve reviewing requests for additional terminology to be added to the SEND lists.

- These requests would be sent to the INHAND GESC by a CDISC/NCI group currently responsible handling such requests for other areas.
- INHAND GESC would be responsible for reviewing the requests, determining whether an appropriate synonym already exists or the term requested is a new term, advise on appropriateness of the definition provided by the requestor and assist in mapping the term, if necessary. INHAND GESC would also decide whether this is a term that is appropriate to add to the INHAND GESC nomenclature, either now or in the future. If necessary, the GESC would arrange to have the term added to goRENI.
- GESC could call on experts in the field to assist in any aspect of their role as a 'Scientific Advisory Board'.