**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 (SEND IG v3.0) is now available at** [http://www.cdisc.org/send](http://www.cdisc.org/send)

- This IG will evolve, to accommodate additions for reproductive toxicology, safety pharmacology, and veterinary studies.
- SEND and STDM terminology that will be used by SEND v3.0 is available at [http://evs.nci.nih.gov/ftp1/CDISC/SEND](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.

**Current Developments:**
- SEND terminology codelists are maintained by the 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.

**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 will assist 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’. ‘Buffers’ 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.
- INHAND GESC will map the current published terminology to the SEND codelist, i.e. map the INHAND terminology to the appropriate ‘buckets’ for SEND.
- Publication as an article or supplement determined on a case-by-case basis. New terminology would then be mapped to SEND controlled terminology codelists.

**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):**

**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.
- Act as a ‘scientific advisory board’ to the SEND CT committee (or other group) charged with maintaining and updating the SEND terminology.