CDISC/University of Rochester Pain/Analgesic Standards

CDISC initiated the Pain/Analgesics Standards project with the University of Rochester Scholl of Medicine and Dentistry, NY, in December 2010. The University of Rochester received a contract from FDA to launch the Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership. ACTTION is currently sponsoring the development of “STandardized ANalgesic DAtabase for Research, Discovery, and Submissions” (STANDARDS) that involves the preparation of a comprehensive CDISC-compliant clinical trial database structure for analgesic clinical trials. Please visit the newly revised and updated ACTTION website www.acttion.org for more information about ACTTION and all of its activities. The major objectives of STANDARDS include facilitating transformation and pooled analyses of data from analgesic trials that have already been submitted to FDA, and also providing a recommended database format for the preparation and submission of future analgesic trials.

In order to accomplish this objective, the University of Rochester has subcontracted with CDISC, which is spearheading the project. The STANDARDS Working Group was established in February, consisting of 17 members representing 11 organizations in the Pharmaceutical Industry, Academia and FDA. Robert H. Dworkin, PhD, Professor of Anesthesiology, Neurology, Oncology, and Psychiatry Professor, Center for Human Experimental Therapeutics; Director, ACTTION and Rob Allen, MD, a neurologist at Pfizer who has extensive experience in industry and Steve Kopko, CDISC, agreed to Co-Chair this Working Group, which is not only working with CDISC but also with other ACTTION committees, industry, and interested clinical trial experts to ensure that STANDARDS is as comprehensive as possible.

The STANDARDS co-chairs presented an overview of the Pain/Analgesics standards development process at the inaugural Scientific Workshop – ACTTION and FDA Public-Private Partnership on June 15 at the FDA office.
Therapy Areas of Focus

- **Chronic pain conditions:**
  1. Osteoarthritis (OA)
  2. Low back pain (LBP)
  3. Fibromyalgia (FM)
  4. Painful diabetic peripheral neuropathy (DPN)
  5. Postherpetic neuralgia (PHN)
  6. HIV neuropathy (HIV)
  7. Post-traumatic neuralgia and mixed neuropathic pain conditions
  8. Cancer pain
  9. Central neuropathic pain

- **Acute pain conditions:**
  1. Third molar extraction
  2. Bunionectomy or other orthopedic surgery (e.g., arthroplasty)
  3. Abdominal surgery (e.g., hysterectomy, hernia repair)
  4. Dysmenorrhea
  5. Acute pain treatment in chronic pain patients

Accomplishments to Date

- **Established a STANDARDS Working Group** of ACTION committee, industry, and interested clinical trial experts to ensure that STANDARDS is as comprehensive as possible. (November /2010)
- **Engaged CDISC Support Early** in this process to lead the preparation of a comprehensive CDISC-compliant, analgesic clinical trial database structure for analgesic clinical trials
- **Enlisted Members** from Academia, Clinicians & representatives from professional societies, CDISC, Industry and FDA (January / 2011)
- **Defined Pain/Analgesic primary and secondary efficacy endpoints** that could be used as a framework to design clinical trials
- **Agreed on specific Pain conditions areas of interest** within Acute and Chronic Pain
- **Defined criteria for inclusion of a specific Pain conditions in CDISC process:** i.e. minimum of two different companies providing standard docs for given area.
- **Ensured the Confidentiality of Documents** shared by pharmaceutical companies
- **Pain Measurement Copy write Issues** being addressed through CDISC
- **Coordinated Submission of Docs to CDISC:** i.e. **Study Synopsis and CRF’s** from specified group of clinical studies in Pain (March/ 2011 to Present)
  - 167 protocols supplied for review / 92 aligned to Pain Conditions
STANDARDS Working Group Limitations / Need for Improvement

- **Pain/Analgesic Standards need to be Global:**
  - Initial membership is US centric, but Non-US input would be appreciated to cover global needs
  - Address Cultural Differences

- **Future needs for consideration:**
  - Pediatric Trials / No CRF’s collected
  - Prevention Trials

- **Other Gaps TBD**

**TIMELINE 2011-2012**

- July-Sept   WG Parse out unnecessary data elements and develop/finalize draft set of data elements, clinical definitions and controlled terminology
- Oct-Nov   Align with CDISC standards and develop CDISC products
- Dec   Public Review of draft Analgesics CDISC SDTM data standards
- Jan   CDISC addresses public comments and updates all documentation
- Feb   Release v1.0 of STANDARDS WG Analgesic CDISC SDTM Data Standard
- 2Q12   STANDARDS Manuscript on the Analgesics Standardization Process