Groupes des Utilisateurs Francophones de CDISC

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC®

Setting the Global Standard for Medical Research

Réunion du 12 février 2010
Bruxelles

Pierre-Yves Lastic
CDISC E3C Chair-Elect
Senior Director, Data Privacy & Healthcare Interoperability Standards
Sanofi-Aventis R&D

Agenda

- **9h30**: Accueil
- **10h00**: Actualités autour de CDISC, discussion sur le GUF suivi d'un « questions/réponses » par Pierre-Yves Lastic (Sanofi-Aventis)
- **10h45**: CDISC CShare par Isabelle de Zegher (Parexel)
- **11h15**: SDTM 3.1.2 vs SDTM 3.1.1 par Peter Van Reusel (BD Life Sciences)
- **12h15**: Déjeuner
- **13h30**: Expérience SDTM par Yann Kling (Pierre Fabre)
- **14h15**: Retour d'expérience sur l'annotation de CRF au format SDTM par Nathalie Sabin (Clinical Data) et Peter Van Reusel (BD Life Sciences)
- **15h15**: Pause
- **15h45**: "Shortening the CRF Design and Database Set-Up Process with a CDISC ODM Metadata-driven Approach" par Pierre Mayeur (IDDI)
- **16h30**: Fin de la journée

CDISC News

- **BRIDG Release 3.0.1 Now Available**
  - This release of BRIDG is being taken through the ISO Joint Initiative Council (JIC) process which will include HL7 and ISO ballots as well as another CDISC review and comment cycle. This process is being undertaken to advance BRIDG to a global, open, publicly-available standard. The current plan calls for this to effort to complete in mid to late 2010.

- **New PROTOCOL REPRESENTATION MODEL V 1.0 released**
  - The scope of this model includes protocol content including Study Design, Eligibility Criteria, and the requirements from the ClinicalTrials.gov and World Health Organization (WHO) registries. The majority of business requirements were provided by subject matter experts in clinical trial protocols.
  - PRM V1.0 is based on the BRIDG Release 3.0

FDA CDER/CBER – CDISC Executive Committee Meeting (1/3)

- **A CDER/CBER Standards Implementation Plan should be available by end of Feb; they would like to publish all or part of it in the Federal Register**
- They will also be fixing the errors in the PDUFA IT plan. Specifically, it is not correct that in 2013 FDA will only accept HL7 transport, hence this will be removed from the next version of the PDUFA IT plan.
  - **For the foreseeable future CDISC standards (SDTM and ADaM) will be accepted in SASXPT with Define.xml**

FDA CDER/CBER – CDISC Executive Committee Meeting (2/3)

- **CDER and CBER wish to encourage/support the development of 'disease-specific' area standards/efficacy data standards (SDTM/CDASH/Terminology) and the completion of existing projects in this area.**
- **They are creating a more formal process (in conjunction with CDISC), which will include a breadth of stakeholders and increased coordination within FDA.**
  - **The elements should go into SHARE, ensuring that necessary concepts/definitions are included to support multiple uses (e.g. same element for safety and efficacy)**
  - They wish to review the Clinical Genomics work to date
  - Device work was cited as going very well now

FDA CDER/CBER – CDISC Executive Committee Meeting (3/3)

- **CDER and CBER are working on a process to provide feedback to CDISC on observations from reviews of eSubmissions that use CDISC standards (e.g. use of SUPP QUAL).**
  - Interest was expressed in receiving more information about the HITSP EHR-CR IS #158 (Standards recommended: CDA/CCD-RFD-CDASH) as a link from EHRs to clinical research, and the ASTER project.

CDISC European Interchange

26th - 30th April 2010

The Lancaster London Hotel

London, United Kingdom

Registration is open !

Organisation du GUF CDISC

- **Création d'un bureau exécutif**
  - Pierre-Yves Lastic (Sanofi-Aventis)
  - Nicolas de Saint-Jorre (QuanticSoft)
  - Nathalie Sabin (Clinical Data)
  - Xavier Gobert (Business & Decision Life Sciences)
  - Fabien Maugard (APHP)
  - Christel Daniel (APHP / INSERM / ASIP)
  - Michelle Vanderberg (I3)
  - Wafaa Jabert (Pierre Fabre)

Bureau du GUF CDISC

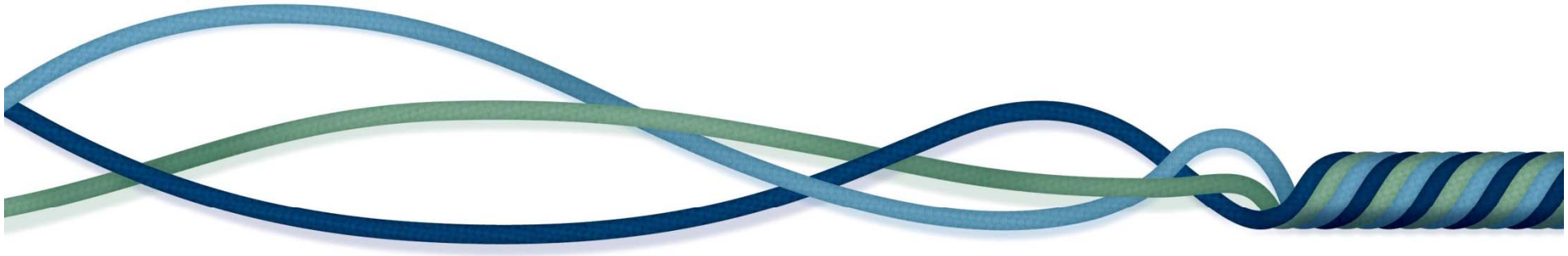
- Il est avant tout responsable de l'organisation de réunions (journées CDISC, ateliers spécifiques) et de téléconférences régulières.
- Il a aussi la responsabilité de la gestion du portail du GUF sur le site CDISC (http://cdiscportal.digitalinfuzion.com/Global%20User%20Networks/Europe/French%20Language/default.aspx), en particulier sa mise en forme, l'administration des utilisateurs et la gestion des documents qui y sont publiés.

Planning des activités 2010

- 3 réunions d'une journée
  - 12 février à Bruxelles chez Business & Decision Life Sciences, organisateur Xavier Gobert
  - 15 juin à l'Hôpital Saint-Louis à Paris, organisateur Fabien Maugard
  - Septembre ou octobre chez Sanofi-Aventis en région parisienne
- Téléconférences mensuelles avec des thèmes à définir
- Reformatage du Portail du groupe pour le rendre plus convivial et plus facile à utiliser (responsables Nicolas de Saint-Jorre et Xavier Gobert)

GUF CDISC

- Questions, suggestions, commentaires….



Strength through collaboration.

As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.

CDISC®