Clinical Data Acquisition Standards Harmonization (CDASH) version 1.0

Setting the Global Standard for Clinical Data

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

French CDISC User Group

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CDASH version 1.0

- Version pour application disponible depuis le 03 octobre 2008 (CDASH_STD-1_0_2008-10-01.pdf)
- Publication des commentaires des 3 zones ICH (Public_Comment_Spreadsheet_093008.pdf)
- Document de 137 pages

CDASH version 1.0

- L'initiative CDASH prend en charge la recherche clinique en rationalisant la collecte des données afin de favoriser l'interopérabilité entre la recherche biomédicale et le développement de nouveaux produits, et en améliorant l'interfaçage avec les systèmes hospitaliers et le DMP.
- CDASH se concentre autour du développement de “content standards” -- notamment par rapport: au nom de l'élément, à sa définition, et aux méta données – pour un ensemble de variables globales (en partant du modèle CDISC SDTM).

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Conclusion

- One key goal of this initiative is to facilitate the participation of investigators and investigative site personnel in clinical trials by allowing them to enter data in a common format across trials.
  => A suivre...
- This harmonization will ensure that there is an integrated flow of data from site through submission and warehousing/archive
  => Illustration of CDASH standardization into ODM (pour la prochaine session)
- Besoin d'un CDASH French?