

The emergence of open source technology for CDISC conversion

An innovative solution to easily convert clinical data to CDISC SDTM

Introduction

Clinical trials have become increasingly complex and, as a result, costly. Only 333 drugs and biologics have been approved between 2000 and 2010 due to stricter regulatory procedures while spending has increase by 15 in the same period of time.

The need for innovation is critical in the pharmaceutical and biotechnology industry. Life science companies and service providers are looking for innovative solutions to improve study performance and minimize their risks.

Complying to CDISC standards is a way to streamline the clinical trial process. As the standard format recommended by the FDA for clinical trial data submission, using CDISC standards:

- Facilitates the FDA review process
- Improves efficiency for clinical data exchange
- Ultimately reduces costs and speeds up time to market

However, clinical conversion to CDISC SDTM is often done manually, which can quickly become error-prone and time-consuming. This article will demonstrate how open source technologies present an innovative solution to address this, and ultimately help bring medical innovations faster to patients.

What is open source?

Open source is a type of software license.

There are various types of open source licenses, but the common characteristic to all is allowing free distribution of the underlying source code.

Famous open source systems include Linux, Apache, MySQL, and many others.



Definition of Open-Source Software

1. Free redistribution
2. Source code
3. Derived works
4. Integrity of the author's source code
5. No discrimination against persons or groups
6. No discrimination against fields of endeavor
7. Distribution of license
8. License must not be specific to a product
9. License must not restrict other software

10. License must be technology-neutral

Taken from Opensource.org. See <http://opensource.org/docs/definition.php> for an annotated description of the above points.

Open Source in the Clinical Trial Industry

While open source is prevalent in many industries, this technology is still emerging in the field of clinical trials.

Two pioneers in open source technology for clinical trials are Cynthia Brandt and Prakash Nadkarni of the Yale Center for Medical Informatics, with their TrialDB system (<http://ycmi.med.yale.edu/trialdb/>), an open-source Clinical Study Data Management System (CSDMS) for the storage and management of clinical data initiated in the 1990's.

The US National Cancer Institute launched a wide-ranging, open-source friendly initiative named CaBIG (Cancer Biomedical Informatics Grid - <https://cabig.nci.nih.gov>), that aims to develop a collaborative information network to accelerate the detection, diagnosis, treatment, and prevention of cancer.

Open source software is also used for electronic data capture (OpenClinica, ClinCapture), clinical research (LabKey Server), Electronic health or medical record (OpenEMR), analysis (R project), and CDISC conversion (CDISC Express, OpenCDISC).



OpenClinica[®]
Open Source for Clinical Research



Tolven[™]
Healthcare Innovations



OpenCDISC



clinCapture



LabKey Software Foundation
Open Source Software for Scientists



CDISC[®] express



caBIG[™]
cancer Biomedical Informatics Grid[™]

Benefits of open source technologies for clinical trials

The development of open source technology in the clinical arena has been quickly growing. Eric Morrie, Manager for Clinical Programming in one of the worldwide leading medical device companies, shared his extensive experience on open source technologies at a Silicon Valley BioTalks (<http://www.clinovo.com/biotalks/open-source/article>). Eric explained how open source technologies save time, improve re-usability and simplify the customization of systems to a company's needs.

- Provide state-of-the-art, cost-effective solutions

Proprietary systems for clinical data management are often too expensive for individual researchers and smaller companies. As a result, they often use slow, error-prone paper-based methods.

Ale Gicqueau, President and CEO of Clinovo, a CRO based in the Bay Area, explains that with open source technologies, the license fee for proprietary systems is no longer a barrier entry for small and

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Sophie McCallum, Clinovo - 12/10/2011

mid-size companies (<http://www.clinovo.com/biotalks/open-source/article>). Open source clinical data management systems save money by eliminating the reliance of using expensive proprietary systems, while insuring the same levels of quality. It provides a means for smaller companies to access high quality technologies for clinical data management and comply with international regulatory standards.

- Avoids the risks of vendor lock-in

Proprietary systems lock a customer into a vendor's product from which they cannot escape without substantial switching costs. Such dependence includes reliance for maintenance and support, and the necessity to accept version upgrades that the buyer may not need.

Widely adopted open source systems on the other hand have multiple vendors supporting it. Surveys demonstrate that early adopters of open source technologies are driven by the "reduced dependence on software vendors", often seen as one of the most important advantages of open source technology.

- Enables a larger community to maintain and enhance the source code

The open source model enables quick improvements by giving access to the underlying source code to a large community of talented developers. In the open source community, developers are encouraged to produce derived works to enhance the existing source code.

"The Open Source community attracts very bright, very motivated developers", explains the UK software consultancy company GB Direct (<http://open-source.gbdirect.co.uk/migration/benefit.html>). "Highly prized factors are clean design, reliability and maintainability, with adherence to standards and shared community values preeminent."

Case Study: CDISC Express

CDISC Express is an open-source SAS®-based system to help that automatically converts clinical data to CDISC SDTM. "CDISC Express is the only CDISC SDTM conversion tool to map all your clinical data in just one click. It keeps the trivial work away from programmers' daily life and allows us to be more efficient and creative in our work", explains Jiangtang Hu , SAS Programmer at Sanofi-Aventis.

Clinovo released CDISC® Express in April 2011. CDISC® Express is the first open source software available for clinical data conversion to CDISC SDTM format. Mapping definitions to convert clinical data into the SDTM domains are done through an Excel spreadsheet which is created by the programmer.





As an open source software, CDISC Express is easy to adopt without significant costs. In order to promote global standards, CDISC Express is open to the community and evolves with the users' feedback.

Users can define macros according to their clinical study requirements and these can be added to the pool of existing macros for further use with similar studies. The code for data conversion can indeed be reused and adapted for multiple clinical studies, thus saving both time and cost. Chunmao Wang, statistical programmer at National Institutes of Health, explains how she used CDISC Express to map eCRF to SDTM. "At first I tried to map one domain manually. But soon I realized that I would be doomed if I did that manually. So I downloaded CDISC Express, and I saw that the software and the codes would save my life! This tool is amazing!"

Conclusion

Today, it takes on average 10 to 15 years to develop a drug and costs near \$1.2 billion. With only 2 of 10 marketed drugs returning revenues that match or exceed R&D costs, developing medical innovations has become more and more risky.

The convergence of open innovations such as the CDISC SDTM standard and the free SAS-based CDISC Express has brought an innovative solution to address those challenges, by providing an easy way for sponsor companies and CROs to streamline the clinical trial process.

References

- <http://www.cdisc.org/>
- Silicon Valley BioTalks, June 2011 : <http://www.clinovo.com/node/129>
- "Could an Open-Source Clinical Trial Data Management System Be What We Have All Been Looking For?", By Greg W. Fegan and Trudie A. Lang, March 4, 2008
- "Overcoming Obstacles To Successful Clinical Trials through Open Source", by Benjamin Baumann, Nov 10, 2011
- 2011 profile, *PhRMA Pharmaceutical Industry*
- Opensource.org
- <https://cabig.nci.nih.gov>
- <http://ycmi.med.yale.edu/trialdb/>
- <http://open-source.gbdirect.co.uk/migration/benefit.html>
- Health Decision Webinar "Top 10 Benefits of Adaptive Design", Jan 25, 2011

Download

- CDISC Express: www.clinovo.com/cdisc
- CDISC Express brochure:
http://www.clinovo.com/userfiles/CDISC_Express_Free_SDTM_Mapping_Tool.pdf
- Clinovo case study on CDISC Express: http://www.clinovo.com/case_studies



About Clinovo

Clinovo is a leading Clinical Data Solutions Provider. Its provides full-service biometrics to medical device, biotechnology and pharma companies. The company leverages cutting-edge technology to develop turn-key solutions that accelerate clinical trials.

Founded in 2003, Clinovo is located in Sunnyvale and San Diego, CA.

Contact information

Sophie McCallum

Marketing Manager at Clinovo

408-773-6258

sophie.mccallum@clinovo.com

www.clinovo.com

1208 E. Arques avenue, #114

Sunnyvale CA 94085