clinovo
Clinical Data Solutions

Open Source Technologies for Clinical Trials

Innovative Solutions to Overcome Current Challenging Climate

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.

This article will demonstrate how open source technology presents an innovative solution to this challenging environment, and ultimately helps 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.

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Sophie McCallum, Clinovo - 11/10/2011

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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).

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 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."

A rising trend: Open source for electronic data capture

EDC systems are often prohibitively expensive, ranging in the hundreds of thousands of dollars. As a result, open source technology has been particularly well-received in the field of electronic data capture. Open source EDC platforms deliver the same benefits as proprietary EDC systems but without the license fee.

One of the most famous and number one open source system for clinical trials is OpenClinica, with a community of over 12,000 developers.

The one I am most familiar with is an open source EDC system developed by Clinovo : ClinCapture. It is a validated and enhanced version of the #1 open source EDC platform, fully customizable to any clinical study. Learn more

This open source EDC system has been successfully implemented by major pharmaceutical, medical device and biotech companies. Victor Chen, Director of Clinical Affairs at Intuitive Surgical, explains that he decided to use this technology due to the low price and the flexibility that suits adaptive clinical trials. However, he emphasizes on the importance of rigorously assessing any open source system vs. proprietary systems and evaluating the cost for validation. Read case study

The emergence of open source based tools for CDISC

CDISC SDTM data is the standard format recommended by the FDA for clinical trial data submission. The mission of CDISC is to develop and support global, platform-independent data standards to improve medical research.

Converting clinical data to the widely recognized CDISC SDTM standard is often done manually, which can quickly become tedious, error-prone, and time-consuming.

Clinovo developed an open-source system to help with this conversion to CDISC SDTM: CDISC Express. CDISC Express is a powerful open source SAS®-based system that automatically converts clinical data into CDISC SDTM using an Excel framework.

The CDISC Express framework is highly extensible. The system significantly speeds-up CDISC SDTM conversion, and has been successfully implemented for major biotechnology and pharmaceutical companies. Download for free

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. Open source technologies are an innovative way to lower the cost of clinical trials and minimize risk, while ensuring the same level of quality as proprietary systems.

Ultimately, open source technologies increase the scope and variety of clinical trials, by enabling smaller institutions to pursue their clinical research that would otherwise be out-of-reach and beyond financial capacity. “We believe that an open-source approach has the best chance of ensuring that all kind of groups can be involved with the development of systems that have bearing on global public health”, explains Greg W. Fegan and Trudie A. Lang in their featured article *Could an Open-Source Clinical Trial Data Management System Be What We Have All Been Looking For?*

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Download

- CDISC Express: www.clinovo.com/cdisc
- ClinCapture brochure: http://www.clinovo.com/resources/brochures/clincapture
- Clinovo case studies on open source systems: 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.

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