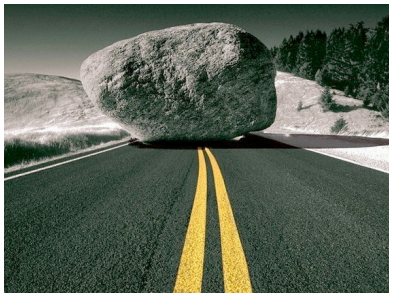
Overcoming EDC Obstacles via Open Source

A white paper illustrating how OpenClinica's open source approach enhances the productivity and success of clinical studies.

OpenClinica
Open Source for Clinical Research

Removing Obstacles

We all know clinical research is complicated, and it's not just the science. Phase III therapeutic trials at NCI cooperative groups require on average 769 steps, 36 approvals, and a median of approximately 2.5 years from formal concept review to study opening.[1] Furthermore, trials requiring a development time of over a year are significantly less likely to achieve enrollment goals than those which start within 12 months of concept formulation.[2]



All too often, a contributing factor to the delay in getting to first patient in (FPI) is the selection, validation, training, and implementation of electronic software systems for the study.

The scientific, regulatory, contractual, and patient safety obstacles to start a clinical study are difficult enough—technology should not be part of that list. OpenClinica, the open source[3] clinical trials software, was born out of frustration with existing proprietary electronic data capture (EDC) systems that are inflexible, expensive, and impose obstacles to fast, efficient study start-up. First released in 2005, OpenClinica has today become the world's fastest growing clinical trials software, in part because it helps eliminate these obstacles.

Obstacle: Evaluating EDC Software

Obstacles to the productive use of clinical trial software begin with the evaluation process. Most EDC providers offer only one option for evaluating their technology: contact the company and let it start its sales machine. The website typically offers little more than 1-2 page product marketing collateral and maybe (if you're lucky) a couple of screenshots.

The open source model behind OpenClinica changes this equation. OpenClinica believes users deserve greater transparency and fewer barriers when it comes to inspecting the technology. In short, a software product should be good enough to be put in the hands of users so it can be thoroughly evaluated and "sell" itself.

Therefore, the fully functional OpenClinica Community Edition EDC software is free to download, evaluate, and even use in production, independently, with no license fees.

The OpenClinica website also provides a pre-configured live demo instance of the software and tutorial videos to make it even easier to understand what OpenClinica is all about.

This level of transparency shows both the good with the bad. While perhaps counterintuitive, we believe this has some important benefits. First, you know what you're getting. No software is perfect for every circumstance. Knowing more about what you're adopting before you commit increases the likelihood of a successful implementation and happy users.

Second, this transparency produces higher quality software. Allowing people to fully inspect the technology and put it through whatever tests they choose, provides invaluable feedback which fuels improvements to the software.

Obstacle: Effective Study Start-up

Since we have removed much of the fear, uncertainty, and doubt from the evaluation process, users can proceed with greater confidence and better position their implementation for success. The next (and probably biggest) obstacle to successful EDC is ensuring your ability to quickly deploy your clinical studies regardless of study size, scope, language, budget, and other factors. Success at this stage requires four key elements:

1. *Rapid deployment of the technology*
2. *Use of proven methods for ensuring regulatory compliance*
3. *Knowledge transfer from experts*
4. *Software that is intuitive and easy to use*

Rather than trying to justify exhorbitant license fees and a steep learning curve, OpenClinica offers a technology platform that is downloadable for free, fully usable out of the box, and that allows for easy modification and redistribution.

1 Dilts DM, Cheng SK, Crites JS, Sandler AB, Doroshow JH, Phase III clinical trial development: a process of chutes and ladders. Clin Cancer Res. 2010 Nov 15;16(22):5381-9. Epub 2010 Nov 9.

2 Cheng SK, Dietrich MS, Dilts DM. A Sense of Urgency: Evaluating the Link between Clinical Trial Development Time and the Accrual Performance of Cancer Therapy Evaluation Program (NCI-CTEP) Sponsored Studies, Clin Cancer Res November 15, 2010 16:5557-5563; Published Online First November 14, 2010; doi:10.1158/1078-0432.CCR-10-0133

3 What is open source? Fundamentally, open source is a type of software license that by definition allows people to freely review, modify, and distribute an application's underlying source code. There are many different "flavors" of open source licenses. OpenClinica uses the LGPL (Lesser General Public License) which is one of the most widely used open source licenses. For more information on why OpenClinica is open source, see https://openclinica.com/open-source-clinical-trial-software.

The more than 17,000 member community, open mailing lists for community based support, free online electronic case report form (CRF) library, and robust online documentation are invaluable resources for many people getting started with OpenClinica-powered studies.

In addition to these readily available resources, formal training is regularly delivered in-person at locations worldwide and via the Web. With the open technology and comprehensive training, what is typically known as "tech transfer"—an often long and arduous process—is accomplished in often just a few days with OpenClinica.

OpenClinica puts in the user's hands a full set of tools to quickly and inexpensively get studies up and running on a robust web based, multi-site, multi-lingual platform. For trials that require a guaranteed level of support, improved performance, assistance with regulatory compliance, and turn-key hosting, the OpenClinica Enterprise Edition offers a complete package backed by commercial-grade service level agreements (SLAs), at a cost typically well below comparable alternatives.

Scaling and Evolving

Most research teams operate more than a single study. Each study invariably has unique characteristics, and the needs of most teams needs constantly evolve. Open source licensing provides guaranteed freedom from becoming locked-in to a rigid operational model controlled by a single vendor. By increasing flexibility and choice, OpenClinica adopters ensure their ability to always make the right decision for a given study and its circumstances.

The freedom and control benefits of open source are widely recognized. Even very large organizations, like the United States federal government, recognize the advantages of open source software over proprietary software. Casey Coleman, CIO of the US Federal Government's General Services Administration, cites some key reasons why they deploy open source software:

> *By using open source, the agency won't be locked in to using a proprietary software program, at least for the duration of the contract. Not having sunk costs in a commercial software program also means the agency can move to a new program more quickly should its needs change. The general openness also means the agency could become a collaborator in the further development of the software itself. You get much more transparency and interoperability, and that reduces your risk.*[4]

It can be particularly difficult for organizations operating smaller, shorter studies to achieve positive return-on-investment with proprietary EDC systems. While it is generally agreed upon that EDC technology reduces the per patient data entry and query resolution efforts, these per-patient savings often do not offset the high up front cost and overhead of traditional, proprietary EDC systems. The high fixed costs are an obstacle to justify use of proprietary EDC, and instead these trials are stuck using slow, error-prone paper-based methods and processes.

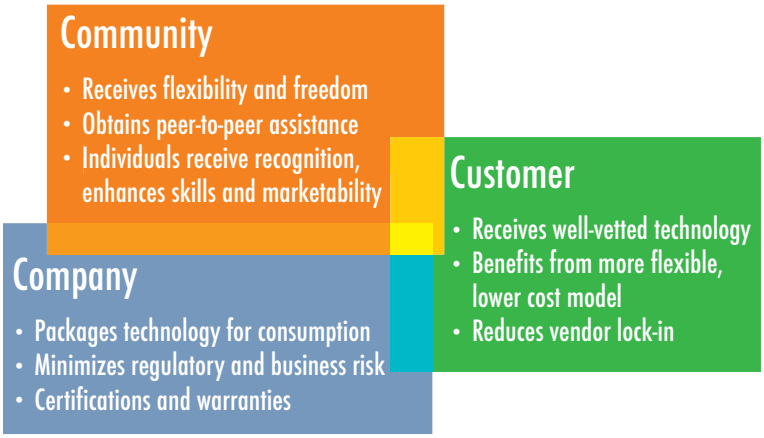
The highly flexible, low-cost OpenClinica architecture allows research groups to efficiently run multiple trials on a single instance of the software. CRFs, user accounts, and other study objects can be easily provisioned across studies, making it possible to scale multi-study operations on a single instance of OpenClinica.

In addition, having the ability to match the appropriate method of deployment and level of support with each study provides advantages for scaling. For example, a single instance of OpenClinica could run all studies, or separate instances could be easily set-up for individual studies. A hosted version of OpenClinica Enterprise Edition could be used in a mission critical setting for guaranteed support, no server maintenance worries, and assured regulatory compliance.

At the very same time, one or more instances of OpenClinica Community Edition may be run for smaller, lower-budget studies supported internally, with informal community assistance. The ability to optimize the software and support solution with each study's needs enables organizations to reap significant efficiencies from standardizing on the same fundamental platform.

This flexibility is possible because of the symbiotic relationship that exists in a professional open source model between the community, company, and the customer.

The symbiotic relationship between OpenClinica community members, customers and OpenClinica, LLC



4 "Open source 'reduces risk,' federal agency's CIO says" (http://news.cnet.com/8301-13505_3-9921115-16.html)

The open source community of users and developers acts as a forge for continually refining and improving the platform. Commercial support makes the open source platform more easily consumable and appropriate for mission-critical operations by delivering packaged deployments, enabling regulatory compliance, increasing delivery capacity, and guaranteeing high service levels. Customers benefit by obtaining a well vetted technology and more flexible infrastructure while maintaining greater control over their destiny.

The Coming Integration Revolution

Clinical trials are conducted within a complex, heterogeneous universe of healthcare and research data and systems. The Electronic Case Report Forms (eCRFs) housed and managed by an EDC system is at the hub of this universe. The FDA in its recent draft guidance, "Electronic Source Documentation in Clinical Investigation", has defined the eCRF as the central system for integrating multiple feeds of data.[5]

This FDA guidance, combined with increasing adoption of electronic health records (EHRs) and increasing demands on businesses to be more automated, accurate, and efficient, are driving the evolution in how we integrate data. The days of merging disparate datasets using SAS at the end of the study are slowly coming to an end, as are the days of days of point-to-point, proprietary interfaces for integrating applications. These approaches are brittle, costly, and do not scale well as third- or fourth-party systems need to be added to the transaction. Secretive interfaces and file formats are quite valuable to proprietary vendors who require their consulting services be used every time a connection needs to be made, but impose a huge obstacle for users and introduce unnecessary business risk.

Even if these interfaces are included as part of the basic product, they still are not accessible to third-party developers, and so it is impossible for a rich ecosystem of proven integrations to emerge.

OpenClinica provides a fresh and useful alternative with interfaces that are based on open standards and are published freely and openly. Any developer can use these specifications to perform integration, and often these integrations are shared freely with the rest of the community. For instance, OpenClinica supports SOAP and REST web services[6] and CDISC ODM. The open source development and licensing model encourages experimentation, reduces "reinvention of the wheel," and allows otherwise unaffiliated parties to build on the work of others. Many members of the OpenClinica community have published and documented their integration interfaces for others to learn from and reuse.[7] In this way, a community-driven open source offering that harnesses open standards produces a more robust, innovative technology solution. The result is that open source is a key driver of increased IT efficiency. It creates reusable processes and wrings out unnecessary costs. In many cases, users can have the best of all worlds: the flexibility to develop and extend their systems as they choose, the knowledge they are part of a open source community ushering clinical trial technologies into a new highly integrated future, and the ability to reduce risk by obtaining proactive, commercial support.

For more information, visit us at @ https://www.openclinica.com/contact

[5] See "FDA Pushes for E-source" (http://www.clinpage.com/article/fda_pushes_for_esource/C9. The official guidance is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf

[6] See https://docs.openclinica.com/3.1/openclinica-web-service-guide

[7] See, for example, "Pipes, Hats ... and OpenClinica: Digesting HL7 in OpenClinica" (http://clinical research.wordpress.com/2010/03/05/pipes-hats-and-openclinica-digesting-h17-in-openclinica/) and "Using OpenClinica for ICF-based Data Acquisition" (http://clinicalresearch.wordpress.com/2008/12/03/using-openclinica-for-icf-based-data-acquisition/)

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