The clinical study paradigm hasn't just shifted. It's exploded. Talk about personalized medicine has turned into action. Cutting-edge research now depends on volumes of data unimaginable even five years ago. And with the rise of eSource, paper may soon go the way of the dodo bird.

OpenClinica is embracing the new. From study design to data extract, our CDISC-based cloud platform is built for research teams that need to do the complex quickly. Our solution combines electronic data capture with a collaborative study builder, ePRO/eCOA, randomization, supply management, and intelligent reporting. (So you won't feel like a dodo.)

The result? Better data, faster. Delivered to you on a platform that's as intuitive as it is capable. Talk to us or visit openclinica.com to learn more.

OpenClinica

460 Totten Pond Road #200 | Waltham MA 02451 | +1 617-621-8585

openclinica.com | sales@openclinica.com | @OpenClinica | bit.ly/oclnkdn

OC18

DATA GETS PERSONAL

OpenClinica's 10th Annual User Conference
October 15 and 16 | Cambridge, MA

Le Méridien Boston Cambridge
Hunsaker Ballroom, 3rd Floor
20 Sidney Street
Cambridge, MA 02139

openclinica.com/oc18

OpenClinica

Welcome to Cambridge! Are you ready to get personal? When it comes to your data needs, we are. If you have a logistical question about the conference, please call 617-842-0861 any time to speak with our conference organizer, Bryan.

Program

Monday, October 15

Breakfast, lunch, and all workshops will take place in or adjacent to the Hunsaker Ballroom on the 3rd floor of the hotel.

9am to 10am Breakfast and registration

10am to 11:50am Morning workshops (choose one)

OC4 Architecture and Integration
Krikor Krumlian, Chief Technology Officer, OpenClinica

OC4 is a multi-tenant cloud platform that embraces open source, automates provisioning, and offers validated traceability, massive scalability, and high-grade security. By breaking from the model of a monolithic application and turning to a microservices model built for the cloud, we're able to deploy more user-friendly, productivity-enhancing features quickly and reliably. This nimble model also makes it easy for users and developers to interact with their instances in a programmatic way, from data loading to integrations of applications common to the clinical research environment. Attend this workshop to learn you way around "under the hood."

Graphical Reporting with OC Insight
Renuka Bhatnagar, Product Owner, OpenClinica

Data managers need quantitative (and often visual) snapshots of their study data–snapshots that can be understood at a moment's glance. Historically, through, the burden of creating those snapshots has fallen to the resident Excel expert, who often needs hours and sometimes days to create reports that are almost immediately out of date. OpenClinica developed Insight to replace this "extract-format-repeat" process. Insight taps your study database directly to create up-to-the-hour line graphs, bar charts, scatterplots, pie charts, and more, allowing you to spot trends and share reports at will. In this workshop, you'll learn how Insight works and how to create and share data dashboards.

12pm to 12:50pm Lunch

1pm to 2:50pm Afternoon workshops (choose one)

Validating OpenClina
Laura Keita, Director of Training and Compliance, OpenClinica

Do you know your IQ from your OQ? Wondering if you're living in a traceability matrix? We offer a wealth of resources designed to make it easy for you to achieve, maintain, and demonstrate compliance. But navigating it all can be daunting. Attend this session to make the most of our compliance support.

Voice of the User
Jing Zhang, Senior User Experience Analyst, OpenClinica &
Hoshedar Bamji, UX Design Intern, OpenClinica

OpenClinica users tackle challenging clinical research problems, manage vast amount of data, and make difficult decisions to advance research and improve patient outcomes. A web interface needs to make these tasks easier, not more difficult. Welcome to User Experience, or (UX). UX is not just an industry buzzword at OpenClinica, but a corner-stone of our software development. We sit side-by-side with our users to understand their workflow, conduct in-depth interviews to discover their needs and pain points, and perform testing to gather feedback on designs. In this workshop, we will highlight some of our UX efforts, and invite you to continue to share your insight with us through a series of fun and interactive exercises.

3pm to 4:50pm Demonstrations

Ben Baumann, Chief Operating Officer, OpenClinica
Brittany Stark, Project Manager II, OpenClinica
Renuka Bhatnagar, Product Owner, OpenClinica
Vishal Abrol, CEO, Vigyanix

OpenClinica Core, Modules, and Medical Coding
Get your questions ready as we present interactive demos of each component of our solution: our core data capture and management platform; OpenClinica Randomize OpenClinica Participate (ePRO/eCOA); (randomization and supply management); and OpenClinica Insight (graphical reporting). Then we welcome Vishal Abrol, CEO of Vigyanix, to the stage, for a demo of an add-on application that seamlessly integrates medical coding into your study.

Tuesday, October 16

Breakfast, lunch, and all sessions will take place in or adjacent to the Hunsaker Ballroom on the 3rd floor of the hotel.

8am to 9am Breakfast

9am to 9:50am Keynote address from Dr. Regina Barzilay

From every pixel of their MRI scan to each word in their medical chart, patients bring a wealth of data to their clinical trial or care journey. What can we learn from this data? It may not be obvious to human minds, but neural networks trained on historic data and outcomes can produce models that predict, for new patients, everything from future morbidity to treatment fit. The potential benefits to research and care are massive, but some questions, from the statistical to the logistical, remain open. Peel back the many layers of machine learning as your hear from Dr. Barzilay on her own pioneering work in this field.

Dr. Regina Barzilay is a Delta Electronics professor in the Department of Electrical Engineering and Computer Science and a member of the Computer Science and Artificial Intelligence Laboratory at the Massachusetts Institute of Technology. Her research interests nclude natural language processing and the applications of deep learning to chemistry and oncology. In 2017, she received a MacArthur fellowship, an ACL fellowship and an AAAI fellowship. She received her Ph.D. in Computer Science from Columbia University, and spent a year as a postdoc at Cornell University.

10am to 10:50am Plenary address from Cal Collins

Running Tomorrow's Trials Today on OC4
Cal Collins, CEO, OpenClinica

"The story of OpenClinica is a story of customer-driven innovation." This remains as true today as it was last December, when we first released OC4. Hear how the story has continued over the last ten months, and how emerging study designs and new data management needs are shaping the future of our solution.

11am to 11:50am Morning sessions (choose one)

Form Magic
Paul Bowen, Senior Product Owner, OpenClinica

Astound your sites and participants with forms as intelligent as they are dazzling. We'll share examples of form crossing, auto-completing, score calculating wizardry you can use to make your eCRFs more powerful and engaging.

Your Site Engagement Starter Kit
Bryan Farrow, eClinical Catalyst, OpenClinica

After participants, the hard-working investigators, coordinators, and clinicians at your trial sites are your most valuable study resources. How do you keep your study top of mind with this key audience? How do you instill a sense of excitement and ownership that will translate to the best possible enrollment, protocol compliance, and data anagement performance? Attend this session to learn strategies and tactics you can implement today, using free Web-based tools and resources. You'll learn: how to build and send high-impact, metrics-driven, customized emails to all site personnel; bring the science of your study to life with video; make procedures and processes clearer; and recognize your high achievers. A more vested, happier, and productive trial team awaits!

12pm to 12:50pm Lunch, with "Birds of a Feather" topic tables

Please join peers with similar interests and questions as yours at one of the topic tables below, where an OpenClinica representative will facilitate discussion and take notes on the concerns and suggestions raised. We will report out the findings of each table at the 2pm sessions.

Content Libraries
From the global standards offered by CDISC to OpenClinica's own repository of common forms, you have access to content that can save you time and keep you speaking the same language as other systems. But that's only the beginning. How do you develop and manage your own content libraries? (And how would you like to?) Do you every rely on tools such as KoboToolBox to help design, standardize, and share your forms? Grab your library card and check out this discussion.

Getting to eSource
The adoption of eSource won't arrive with the flip of a switch, but by incremental innovation. OpenClinica is well on its way down this path, with mobile-friendly ePRO, tablet-friendly eCRFs, and powerful REST-based API calls. What's the next milestone? What does data capture look like in 3, 5, or even 10 years? Join us on the leading edge at this table.

The Community Spirit: The Future of OC3 and Migrating to OC4
OC4 represents a generational leap forward in how you capture, manage, and utilize your research data. What does this mean for OC3? OpenClinica is committed to its large base of OC3 users. We are working on pathways that ease adoption/migration to OC4, and eager to engage about the future of the community and ways to more tightly integrate the two platforms. Come share your ideas, needs, and questions on these important topics.

Show Me the Data
You've just captured a wealth of thoroughly cleaned data. Now what? From data warehousing, to extracts, to visualization in tools like our own Insight, how we store, move, and review data is just as critical as gathering it in the first place. What's your process, and how well do the tools in OpenClinica support you? Is your organization embracing new approaches to data science, and how is that impacting your job? Extract some best practices here.

1pm to 1:50pm Customer Spotlight

Making the Leap from OC3 to OC4
Alecia Peterson, Manager, Clinical Data Management, University of Utah &
Melissa Pederson, Clinical Data Manager III, University of Utah
in conversation with OpenClinica's solution and services team

Change isn't always easy, but often worthwhile. First-time users of OC4 do face a learning curve, with a new form engine and study building module presenting new skill sets to master. But the power, possibilities, and efficiencies gained represent a tremendous "ROI" on the time spent by users to develop these skills.

Of course, like any change in the real world, bumps are inevitable. So are unexpected delights. In this session, hear from some of your peers on what to anticipate when making the transition from a great solution to our best yet.

2pm to 2:50pm "Birds of Different Feathers, Flocking Together"

Hear the results from each of our lunch hour working groups.

3pm to 3:50pm Afternoon sessions (choose one)

Is eConsent Right for Your Study?
Brittany Stark, Project Manager II, OpenClinica

Informed Consent is a multifaceted process that goes far beyond obtaining a signature. Genuine consent involves providing potential participants with adequate information about the research to allow for an informed decision to participate, facilitating and verifying comprehension of the information, and allowing adequate opportunity for questions and consideration.

Electronic informed consent (e-Consent) must accommodate all these requirements. Done well, e-Consent can maximize patient understanding, engage non-English speakers with multilingual tools, improve documentation and reporting, and standardize the consent process across sites, all while reducing cost and administrative burden. Attend this session to learn how to determine the suitability of e-Consent in light of your study's setting, participant profile, and indication (among other attributes), as well as the best way to adapt the principles of fully informed consent in its usual, paper-based context to one where the process is electronic.

Handling Data in a GDPR World
Ben Baumann, Chief Operating Officer, OpenClinica

This past May, the EU enacted sweeping new laws, called the "General Data Protection Regulation," which redefine the handling of personal data. GDPR has far-reaching implications for all entities collecting or storing data, even those beyond the physical borders EU/EEA, and stiff penalties for non-compliance. This session will provide an overview of GDPR and the principles and requirements which pertain to data subjects, data controllers, and data processors. Emphasis will be placed on breaking down GDPR into practical takeaways that can be implemented for groups running clinical studies.

4pm to 4:50pm Afternoon sessions continued (choose one)

What's New at the FDA? A Review of Recent Guidance
Laura Keita, Director of Training and Compliance, OpenClinica

If you're looking for guidance on procedural and technological compliance, the FDA has you covered. But if you're looking for specifics and how-to's for implementation, well, you'll need to ask around. Your team at OpenClinica is a great source of intepretation and insight. In this session, we'll present recent FDA guidance in plain language, without simplifying the requirements for auditor-friendly practices and system standards.

How to Secure Your Clinical Data
Ben Baumann, Chief Operating Officer, OpenClinica &
Warren VanDeventer, Senior Cloud Infrastructure Engineer, OpenClinica

In the wake of numerous high profile data breaches, data security is a hot topic these days. Security is not something that can be addressed by software features alone–adequately securing your clinical data is a complex undertaking requiring numerous technical and procedural safeguards across varied technology systems and business functions. This session will provide a framework for considering risk and ensuring security of your clinical research data in a holistic way, with an emphasis on practical steps.

On Tuesday evening, join us for a gala dinner at the Museum of Science from 6 to 9pm. Bus transportation from Le Méridien to the Museum and back will be provided.