MAY 2022

Medhealth Outlook

Clinical Trial Management Edition

medhealthoutlook.com

Top 10 Innovators
CLINICAL TRIAL MANAGEMENT Solution Providers
Medhealth Outlook
2022

Driving the Future of Digital Clinical Trials

Cal Collins,
Co-Founder and CEO

OpenClinica

$20

Top 10 Innovators
CLINICAL TRIAL MANAGEMENT
Solution Providers
Medhealth Outlook
2022

Driving the Future of Digital Clinical Trials

It's no surprise that the future of clinical trials is becoming more digital and decentralized. Traditional approaches are being replaced with ones that enable more automation, less burden on site staff, and integrations (such as EHR eSource data) that help researchers collect better data, faster. Covid-19 accelerated this need for better tools and solutions due to the necessity of quickly collecting and analyzing data on the virus so that there were less illnesses and deaths. Facilitating these and other unique clinical trial requirements with innovative solutions is OpenClinica, a company that is driving the future of digital clinical trials.

OpenClinica has been transforming clinical research with its unified, core electronic data capture (EDC) platform that simplifies the process of running clinical trials in the cloud. "At OpenClinica, we offer a platform with an intuitive user experience as well as dynamically configurable logic for workflows and integration. This way, clinical trial management becomes seamless," begins Cal Collins, Co-Founder and CEO at OpenClinica. OpenClinica is used across a wide spectrum of clinical research, including drug, device, and diagnostic trials, global health studies involving over 2 million

> At OpenClinica, we offer a platform with intuitive user experiences as well as a dynamically configurable logic for workflows and integration to eliminate duplication of data entry. This way clinical trial management becomes seamless.

Cal Collins,
Co-Founder and CEO

OpenClinica

patients, adaptive platform trials, and clinical trials for some of the first gene therapies to be approved for market. OpenClinica also enables automated clinical trial data management via features and functionalities that empower clinical researchers, ultimately allowing them to spend more time with patients and less time transcribing or managing data.

Proven in over 10,000 studies worldwide, the OpenClinica platform is trusted by leading pharmaceutical and biotech companies, contract research organizations (CROs), academic institutions (AROs), and government agencies.

Most notably, at the peak of the Covid-19 pandemic, OpenClinica built a model for pulling electronic health record (EHR) data into the study database/EDC. Traditionally, this process has required research coordinators to waste hours of time doing transcription work, increasing the likelihood of errors in clinical trial data among other nuisances. "Our ultimate goal is about helping researchers get better data faster. OpenClinica Unite™ is an EHR eSource integration solution that eliminates time-consuming tasks, eases burden on staff, and cuts the need for source data verification (SDV). It can be used in traditional trials, real world evidence (RWE) studies, decentralized clinical trials (DCTs), and more," adds Collins.

We spend a lot of time making sure the patient is central to what we do. When you are sick, participating in a trial is hard. Add in illness and it's even harder. If we can automate the collection of a patient's medication history, demographics, and lab data with our solutions, it's one less challenge that patient needs to overcome. We've all been there: when a doctor asks us to provide our medications list, it can feel like we have told them a thousand times. Now patients don't need to provide that information—because sites have already acquired it from the EHR. So, it saves the trial team time and effort.

The March Toward Greater Integration and Automation

At OpenClinica, the team believes that delivering clinical trial innovations is all about the march toward greater integration and better ways of collecting, managing, and analyzing data in clinical research. As an industry, thinking "beyond the EDC" is something that OpenClinica prioritizes. Helping patients and clinical trial stakeholders overcome challenges is where the company thrives. For example, if patients or clinical researchers are struggling to submit or capture data that already exists in an electronic record, this is something OpenClinica wants to help them automate (for this challenge, it meant creating OpenClinica Unite, the company's aforementioned EHR eSource integration solution). "We spend a lot of time making sure the patient is central to what we do. When you are sick, participating in a trial is hard. Add in illness and it's even harder. If we can automate the collection of a patient's medication history, demographics, and lab data with our solutions, it means more energy that research coordinators and clinicians can focus on the patient, and one less challenge that patient needs to overcome. We've all been there: when a doctor asks us to provide our medications list, it can feel like we have told them a thousand times. Now patients don't need to provide that information—because sites have already acquired it from the EHR. So, it saves the trial team time and effort as well," explains Collins.

Another example of greater clinical trial integration would be OpenClinica's commitment to enabling clinical researchers to effectively engage with patients. "OpenClinica ParticipateTM, an electronic patient reported outcomes (ePRO) tool, is an integrated part of our solution that makes the process of sharing their experience frictionless for participants. With OpenClinica, we bring research closer to patients, providing them more information about what's going on, and giving them more control over what information is shared," adds Collins.

In a nutshell, OpenClinica makes the complex work of clinical trials easy and efficient. The company's deeply experienced product team is highly committed to simplifying processes for its customers. This includes maintaining and continuously improving its strong foundation of great user experience. OpenClinica does this by optimizing its EDC for each client's individual needs, whether that is being able to build and design a study by themselves, working hand in hand with OpenClinica to configure their trial for optimal success, or integrating within the study's greater landscape so that their trial is effortlessly conducted (and much, much more). "We have features like auto-save, real-time execution, and the ability to provide data back to the end-user—whether that's visualizations provided in real-time or automated alerts and reminders," points out Collins.

A Unified, Best-of-Breed Platform

OpenClinica started as an open-source solution. It is within the company's DNA to be community-oriented and highly transparent with users. Using this open communication to continuously evolve its products and address the needs of users is a high priority for the company. Today, OpenClinica provides a breadth of modules and functionality, including the leading electronic data capture (EDC) system; an EHR integration solution that pulls data from the EHR into the EDC; ePRO; eCOA, and an advanced reporting solution that provides the insights stakeholders need during and after a clinical study.

Known for building its foundation on the user's experience, OpenClinica is also celebrated by clients due to its regulatory rigor and depth of experience with clinical data management. This experience only comes with supporting clinical trials—including COVID-19 trials—for over 15 years. The team spends lots of time listening to customers and empowering them to streamline their workflows, manage their data, and eliminate manual efforts that do not add value or worse, burden existing resources. "The bottom line is that OpenClinica will always do what is best for its customers and their study participants," Collins commented.

A Pathway to Better Data, Faster

Founded in 2006, OpenClinica has always been an advocate for automating processes so that clinical trial stakeholders can collect better clinical data, faster. Since opening its doors, OpenClinica has been a pioneer in delivering innovative clinical trial solutions and streamlining the way clinical trials flow. The team works closely with its customers and partners to offer the most cutting-edge clinical trial solutions available today. Hundreds of small, midsize, and large research organizations leverage OpenClinica to capture better clinical data faster and to do so in a way that meets the highest standards for security and regulatory compliance (21 CFR Part 11, Annex 11, GDPR, HIPAA).

In the last year, OpenClinica launched its newest product, OpenClinica Unite, which, as part of the OneSource initiative, earned the company the esteemed 2022 Innovative Practices Award from BioIT World. OpenClinica also doubled in size last year, a result of many years of hard work building out the OpenClinica platform. "Right now, we are making investments across the board to expand the breadth and capabilities of our products and services. Some of our highlights are OpenClinica Unite, with which we have an aggressive roadmap to continue expanding. Complimentary to that, we will be bringing technology related to patient-directed data share, which is an exciting and empowering way to get data faster from patients in clinical research," concludes Collins.

OpenClinica is the leader in next-generation clinical research approaches and methodologies, and with even more exciting developments to come later this year, there is no stopping OpenClinica as the industry rides into the "beyond the EDC" era.

Medhealth Outlook

Innovators

TOP 10

CLINICAL TRIAL MANAGEMENT

Solution Providers

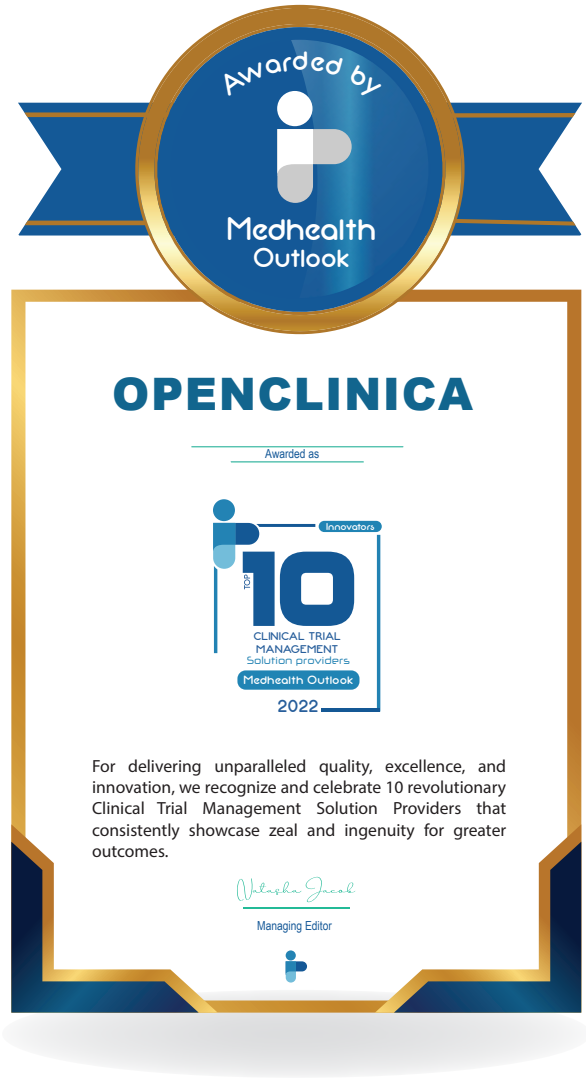
Medhealth Outlook

2022

Clinical trials in a way are quite complex and time-consuming with numerous regulations existing in the industry. The clinical trial management systems space is anticipated to gain noteworthy growth on account of steady adoption among the majority of healthcare suppliers today. Modern and advanced clinical trial management systems and such integrated tools help solve some of the complex problems associated with clinical trials. Today's intelligent solutions enable resolved solutions in a shorter span of time, consequently generating effective results. These benefits have incited the adoption of clinical trial management tools across numerous pharmaceutical and healthcare facilities.

Extensive R&D expenditure on clinical research and life sciences will broaden the business outlook for clinical trial technology providers. The rising focus on developing new drugs has proliferated funding for clinical trials. Companies are also implementing intelligent systems that enable them to automate repetitive tasks to reduce the complexity and processes so that it becomes seamless for people in the healthcare space.

As the industry is filled with numerous solution providers. To help businesses find the right solution provider, we've created this special edition on Top 10 Clinical Trial Management Solution Providers 2022. The companies listed below are selected by our team of researchers, clinical experts, and CEOs to help the healthcare space align with the changing requirements of the clinical trials space.



OpenClinica

Cal Collins, CEO

Ben Baumann, Co-Founder and COO

Headquarters
Waltham, Massachusetts

Website
openclinica.com

OpenClinica is driving the future of digital clinical trials. Proven in over 10,000 studies worldwide, the OpenClinica platform is trusted by leading biopharmaceutical companies, contract research organizations, academic institutions, and government agencies. OpenClinica is used across a wide spectrum of clinical research, including drug, device, and diagnostic trials, global health studies involving 2,000,000 patients, adaptive platform trials, and clinical trials for some of the first gene therapies to be approved for market.