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# The Time Is Now For Transformation In Clinical Data Collection

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WHITE PAPER

*When the COVID-19 pandemic began, many clinical trial teams were forced to quickly find remote methods for collecting data and conducting visits so they could keep patients safe and enrolled in trials that were already underway. This swift transition to virtual clinical trials demonstrated that these approaches are not only possible but can bring real benefits to research studies. It also showed that many of the necessary technologies are mature enough to support these approaches in a practical way.*

Importantly, the pandemic also forced pharmaceutical companies, which are understandably careful about making changes that might affect drug approval or increase cost, to look beyond the risks and embrace these new technologies. Regulatory agencies are also now more accepting of changes to how clinical trials have always been done. Together, this creates a climate that is ideal for examining the best way forward for virtual clinical trials and new types of data collection.

The pandemic, together with advances in science and technology, is driving the pharmaceutical industry to move ahead with new methods for collecting and using clinical trial data. Today, data collection needs to be set up quickly, and study teams want to control and adapt to changing protocols. These new approaches require a completely different way of working and thinking and new technology for managing and using data. Using the latest platforms for data collection and clinical trial management can help overcome the barriers to implementing new data collection methods and make it easier to move to digital strategies for clinical trials.



## More Real-World Data

As clinical trials incorporate more virtual and digital components, data collection is changing dramatically. Mobile phones and wearable devices – collectively known as mHealth – provide around-the-clock data that comes in various forms. For example, a simple app can be designed to track daily physical conditions while also reminding patients to enter foods they eat at each meal and record any side effects they experience during the day.

This type of technology produces huge volumes of interrelated information that creates a real-world picture of how a patient is responding to a drug. It also provides clinical trial teams with faster and more realistic information about how well a drug is working. For instance, if a patient has been taking a drug during a six-month trial, the clinical team can see everything that occurred during that time instead of relying on tests and patient information provided at a few office visits.

mHealth devices are also helping to solve the critical challenge of increasing patient participation and retention. Today, only 5% of cancer patients take part in clinical trials, a number so low that some trials are forced to stop early if too many participants withdraw. Remote data collection coupled with telemedicine means that patients don't need to come to the clinic as often, or sometimes not at all. This eliminates or greatly reduces what patients often identify as the most inconvenient part of clinical trials.

Genomics information is another new area of data collection being incorporated into more clinical trials. This information can reveal how certain genes' mutations or patterns of gene expression affect the efficacy of a drug to determine who should receive certain treatments. The hope is that one day genomic data can be used to develop personalized medicines that work best for an individual's genetic makeup.

## The Time Is Now

Embracing new types of data can provide more knowledge about the safety and efficacy of a new treatment and help clinical trial teams make better decisions. More data means that drug benefits as well as safety issues will be apparent faster, helping pharmaceutical companies focus efforts where they are most likely to be successful.

While new and valuable data sources such as wearables, apps, and other devices exist, electronic data capture (EDC) systems have not evolved to support them. Most EDC systems used today were designed 20 or more years ago and are based on paper forms and paper-based



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processes. Because form entry is very structured, these EDC systems don't allow clinical research teams to collect new types of unstructured data from these new sources. They also aren't designed to collect large volumes of data or to handle various data in one place.

Integrations have been built to allow EDC systems to collect other types of data, but trying to make new types of data fit into old systems causes many problems because systems were designed to capture data based on paper entry and were not designed for the volume and veracity of new data types that need event-based collection. For a single trial, sites and study teams may work with up to 30 different systems, all with separate credentials, training, interfaces, support, validations, upgrades, and builds. This makes it extremely difficult for sites to get a complete picture of a patient to effectively use the data.

## A New Paradigm

As clinical trials incorporate more virtual components, new tools are needed to help change the way these trials are designed and make it easier to collect any type of data from any source. Oracle's Clinical One platform was built to make it easier for everyone involved in clinical trials to think and act differently by enabling fast setup, harmonizing data from any source, and streamlining workflow.

The platform supports data collection as well as randomization and trial supplies management (RTSM) from the same platform, bringing together what were previously completely separate systems to create a unified clinical trial workflow for sites and study teams.

In addition to form data, Clinical One also enables data collection from EHR systems and wearable mHealth devices as well as genomics data. Study teams can simply select what data they want to collect and when. Managing wearable devices in a large clinical trial can be daunting, but Clinical One has built-in features for managing devices and how they get to patients.

Clinical One allows data to be effortlessly brought in from various sources. The clinical trial team can select when and where the data is coming from, how it's going to come, and configure it themselves. This means that what was previously a time-consuming IT effort can now be done by a data manager in an intuitive self-service environment. What's more, the platform integrates easily with other systems, electronic patient-reported outcomes systems, electronic health records, mHealth devices, and electronic trial master files.

Because Clinical One uses the latest Oracle hosting facilities, it remains functioning and accessible 24 hours a day, seven days a week. The system doesn't have to be brought down to introduce new capabilities



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or to make upgrades. This is extremely important for global clinical trials that might take place in differing time zones and on weekends.

The intuitive user interface was built so that everybody can work together easily. While it typically takes six to eight weeks to set up a study, Clinical One is cutting that down to an average of three weeks or less. For COVID-19 studies, where time is of the essence, Clinical One has helped companies get clinical trials running in 10 days or less. The faster a study can get up and running, the faster safety and efficacy results can be obtained, and the faster treatments can get to the patients who need them.

The complexity of clinical trials means that mid-study protocol changes are often inevitable. These changes are not only tough to implement but can be costly and cause significant delays. Making such changes traditionally takes one to two weeks and sometimes requires bringing down EDC and other systems. With Clinical One, changes can be made in real time and be deployed in minutes by dragging and dropping out old protocols and replacing them with new ones.

### Embracing Future Change

Healthcare and technology are rapidly changing, making it important to adopt tools that are ready to handle today's needs but can also adapt to tomorrow's innovations. Clinical One is built for new ways of thinking and to incorporate new tools that can help the pharmaceutical and healthcare industries now and in the future. All this information will come together to produce lifesaving therapies faster and more effectively.

Embracing modern approaches has the potential to completely change the future of clinical trials. Today, only a small number of physicians participate in clinical trials, but as the new virtual approaches are implemented, it will be easier for doctors to work with patients to collect the necessary data. It will also be possible to use EHRs to automatically identify patients who qualify for trials and get this information to their physicians. This means that one day patients will be able to simply select participating in a clinical trial as a care option during a routine doctor visit.

By making it easier to incorporate new types of data collection and virtual components into trials, Oracle's Clinical One can help companies embrace new technology and new ways of thinking that will help them conduct better clinical trials today while also being well-positioned for clinical trials of the future.

## About Oracle Health Sciences

As a leader in life sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the life sciences industry to improve patient outcomes.

Build a study once,  
enter data once,  
do everything in  
one place.

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