

APPLYING USABILITY DESIGN CONCEPTS TO CLINICAL DEVELOPMENT:

A Conversation with Paul Boyd



Overview

Oracle offers the world's broadest set of integrated life sciences solutions, enabling biopharmaceutical organizations to automate and streamline their entire clinical development process. To make these solutions as intuitive and easy-to-use as possible, Oracle Health Sciences user experience group applies the latest in usability design principles to its clinical research product line. The user experience group is one of the only exclusive usability design teams in the industry and has been instrumental in advancing the capabilities of Oracle Health Sciences users while minimizing product complexity.

As Senior Manager of Software Development, Paul Boyd oversees and helps create all usability design improvements to Oracle's clinical data management and safety solutions. Mr. Boyd has managed the group for the last three years. Here, Mr. Boyd discusses the latest in usability design concepts and how they have been applied in the development of the Oracle Health Sciences' suite of life sciences solutions.

Frequently Asked Questions

Since electronic data capture (EDC) has become the industry standard how have usability needs evolved?

Clinical trials have substantially changed over the last several years. They're longer than they used to be. They are more complex and hence require more information. And they are more virtualized with multiple partners accessing common data using different technologies and systems. That means more subjects, more sites, more visits, more forms, more items, more queries, and more easily overwhelmed users, despite their increasing adeptness with the technology. Clinical development solutions, therefore, must scale their interfaces to these increasing demands, but still need to be efficient.

What has Oracle done to ease the increasing burden on users of clinical development software?

Now that users are very comfortable with EDC technology, and our society in general has become more technologically savvy with the proliferation of the internet and home computers, we were able to rethink how our users

actually interact with our solutions. We completely redesigned the user interface (UI) for our industry-leading EDC product, Oracle Health Sciences InForm GTM, to help users make quicker decisions, reduce errors, and simplify navigation. We also extended much of this UI to other complimentary life sciences solutions—such as Oracle Health Sciences IRT On Demand, Central Coding, and the Clinical Development Center, for example—and deepened product integrations so there's a seamless and familiar transition between tasks and programs.

Whom did you think about when working on the design for Oracle Health Sciences E-clinical solutions?

We targeted three key user communities: clinical research coordinators (CRCs), clinical research associates (CRAs), and data managers. We then launched an “input wanted” program to conduct research with each of these groups before we even started to think about the design of the user interface. We wanted users to tell us what they wanted from Oracle Health Sciences e-Clinical solutions. Over 250 participants from pharmaceutical companies, contract research organizations (CROs), medical research sites and hospitals in 12 countries contributed to our research. We took those results and focused on some key usability and user efficiency issues.

What did you learn from site users?

We learned just how sophisticated they really are. CRCs have a million things up in the air; they use multiple technologies across multiple trials and multiple sponsors. Truly, their challenge is staying on top of what needs to be done across a number of trials, each with their own different processes and expectations. When a patient arrives for an appointment, they need to know the trial they're participating in; what data needs to be collected in what technology; whether they are in their visit window; and once the data is entered, whether there were any queries on it. The result is often repeated tasks with the same data being captured more than once.

What did you learn from sponsors?

CRA's are looking across wide swaths of data and need to be able to quickly see what requires attention—not just what has been done. What needs to be frozen or verified is, in some ways, more interesting than what has been frozen or verified. In addition, not all sites are the same and it makes sense for CRA's to visit some sites more often than others.

Data managers work with the largest sets of data of all these roles. For them, getting a view of the status of the trial across all sites and subjects is integral. Providing project-style progress reports is often a key part of this role.

Being able to gracefully stroll through huge amounts of data and viscerally understand what is happening in a trial and what has changed is very valuable. Yet this remains challenging because of all the individual point systems employed to collect data. Transparency between systems is often minimal and communication is manual and labor intensive. Data managers really need better access to integrated data.

Once you completed your research, what usability design principles did you apply?

There are three basic guidelines that were applied to the new design: signal-to-noise ratio, information proximity, and streamlined workflow. Or more simply: See, Decide, Act.

Signal-to-noise ratio basically means that in any given message, there's signal (what you want to hear) and noise (background distraction from the signal). When dealing with large sets of information, we wanted to make sure that the important information (signal) stood out from the areas of the user interface that weren't conveying any information (noise).

Information proximity ensures that when the user needs a set of information to complete a task, it is grouped in a useful and meaningful way. This allows users to make extremely fast conclusions about what is happening, reduces errors, and all but eliminates the need to navigate in the first place.

Streamlining workflow is simplifying the progression of documents and forms, forms, as well as task delegation, from employee to employee or from sponsor to site.

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For more information, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.



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Hardware and Software, Engineered to Work Together

So what does the Oracle Health Sciences E-clinical interface offer users?

Succinctly, role-based summary worklists and streamlined workflows are customizable to specific users to keep them focused on what's truly important to them, enabling actionable insights for quick decisions; new controls make it easier to navigate and filter; and friendly page layouts allow for more information to be viewed per page without scrolling.

What else is the user experience group working on?

We just completed a follow-up version to Oracle Health Sciences InForm GTM that incorporates data review displays with real-time actionable data listings; customizable review workflows; and support for partial source verification.

We redesigned the Oracle Health Sciences IRT On Demand user interface to consolidate workflows and improve navigability within our interactive voice/Web response system.

Oracle Health Sciences Central Coding has been updated and now includes integrated query workflows with Oracle Health Sciences InForm GTM; auto query and propagation functionality; as well as customizable flags and statuses to help users stay on top of their tasks and studies.

Oracle Health Sciences Clinical Development Center has been redesigned to improve workflows and the UI so it requires minimal training to gain familiarity with the program.

The user experience group has also been conducting extensive research and design work on our latest ground-breaking release, Oracle Health Sciences Trial Center—a game-changing solution and completely new class of application for clinical research. Through a single point of access, users can nimbly navigate across multiple systems and trials to determine what needs to be done across all their studies. Sites and sponsors can now more easily understand the true status of a study in real-time.

We are continually working on improving the usability of all Oracle Health Sciences E-clinical and safety solutions and strive to give our clients the best user experience in the industry.