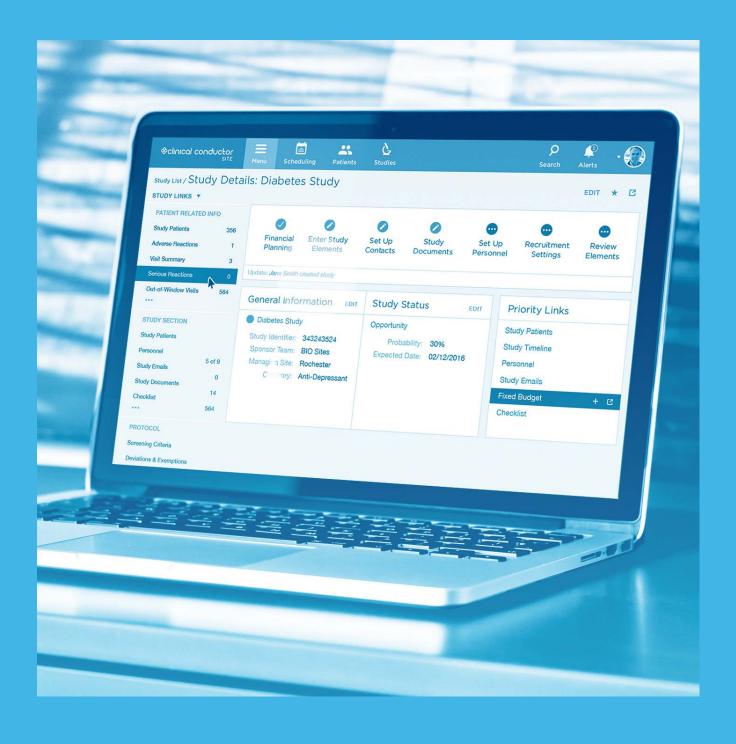


Taking the Tribulations Out of Clinical Trials — Bio-Optronics



Clinical trials, like those for new drugs, are lengthy, complex and expensive exercises, with an average pre-approval cost of over \$40M in 2014¹, so it is no surprise that a whole class of software, called Clinical Trial Management Systems, or CTMS, has evolved to help improve efficiency and accuracy.

 $^{^1\} https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development$

Introduction

Untapped Excellence

Clinical Conductor, from Bio-Optronics of Rochester, NY, is one such solution. Launched in 2007, it has steadily grown in features and market share, becoming a successful incumbent along the way. But by 2015 Dan Kerpelman, President and CEO, realized that the feature-rich depth of the product was coming at the cost of a level of complexity that inhibited some users. Since Clinical Conductor is web-based, they could review and see selective patterns of underuse. He gives the example of financial workflows. "Trials have very involved contracts, with numerous and variable payment triggers, split billing and other characteristics that make each one uniquely challenging" he explains. We could handle all this, but not in a way that customers were using to its full potential." Other hints came from support calls and feedback during sales demos. They also noticed that new competitors coming into the market today inherit the simplicity of newer user interface (UI) design metaphors, even if they lacked Clinical Conductor's functional sophistication. With these factors in mind Kerpelman began looking for a professional services company to guide them through the first, critical phase of redesigning the interface, a process they planned to bring in-house as they gained expertise and confidence.

Bio-Optronics considered several companies to partner with but chose Macadamian for a number of reasons. Lorraine Chapman, Senior Director, Healthcare at Macadamian, is chair of the HIMSS Health IT User Experience Committee, but, busy as she was, she jumped in right away to see how to best help Bio-optronics address their challenges, and remained directly involved throughout the project. Macadamian understood the complex regulatory landscape, the day-to-day challenges faced by healthcare workers, and the specific user experience (UX) characteristics of effective healthcare apps. Perhaps most importantly, if harder to quantify, was the cultural compatibility. Since Macadamian's

experts like Matthew Herlihey, a UX designer, would be embedded in Bio-Optronics development team for several weeks, the strength of the working relationship was a critical consideration, and Kerpelman saw the natural flow and easy rapport he was looking for.

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— Dan Kerpelman, President and CEO, Bio-Optronics

A Business-first Approach

Having formed a partnership, the two companies conducted an intensive two-day user experience strategy workshop to launch the project. A key goal of the workshop for Macadamian was to understand the client's business, which, Chapman explains, is foundational to making technology and design decisions that support overarching objectives. Also important was the transfer of domain knowledge to Macadamian, which is vital to the design process but can also involve an intensive ramp-up, especially in an area as complex as clinical trials. Herlihey recalls the challenges. "There was a lot to learn in a very short period of time but the easy collaboration between the teams really helped ease the learning curve."

Measure Twice, Cut Once

Clinical trials test the efficacy and safety of new drugs and medical devices through rigorous data collection in the real world. So it is somewhat poetic to think that, in the hands of experienced researchers like those at Macadamian, something akin to this goes into the UX design of the software that supports them. This data collection took the form of a comprehensive research phase led by the Macadamian research team. Working assumptions about product usage were tested and refined, user personas were formalized and they confirmed what those users want to achieve, identified

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pain points and generally verified Bio-Optronics' hunches while uncovering any hidden problems and flagging popular characteristics that they should take care to preserve. They spent time at customer sites interviewing users, observing their work in person and remotely via screen sharing, and even assessed the physical work environments. Chapman explains that "there is really no substitute for getting out in the field with users to gain a nuanced understanding of how they use the product, what works and what doesn't. It gives us a wealth of behavioural and contextual information we can use to strengthen features, create efficiencies, remove pain-points and fill gaps." She and Herlihey reviewed the resulting data in parallel with the research, coming up with design recommendations about workflows, wireframes, and visual assets. They also used this review process to prioritize design changes - an important step when the development time available is short, as it was for Bio-Optronics. "Updating all our workflows will be a multi-release process," explains Kerpelman, "so we wanted to identify the ones that would be most advantageous to start off with." He also appreciated the tough love Macadamian provided when difficult choices were needed about project priorities. "We couldn't do everything we wanted in the first release," he recalls, "and we hesitated over Lorraine's advice to focus on visual design and persistent navigation, but seeing the results it's obvious she was right, and I'm glad she prevailed. It provides a unifying umbrella, under which, progressive workflow improvements will be placed, release after release going forward."

When Great Teachers and Great Students Meet

With research data in hand, Herlihey worked with Bio-Optronics' developers through the design phase, using wireframes to give form to the concepts, personas and workflows identified earlier. He collaborated electronically with the Bio-Optronics developers and conducted regular review meetings to help keep everyone on the same page. The success of this interaction was measured not just in the

resulting software update, but in the knowledge and skills cultivated within the Clinical Conductor team. On that front Herlihey could not be happier. "The folks at Bio-Optronics have shown me UX design work they've done on their own for the next wave of workflow enhancements, and I'm very impressed with their uptake of core concepts. I'm confident they'll be able to bring this work in-house in the future."

An update of Clinical Conductor was released in April, 2016 to very positive feedback from users and prospects. It is already easier for users to experience the full richness of today's product, and the phased roll-out of the new UX design metaphor over the next few releases will complete the redesign work, providing the same intuitive elegance for years to come as Clinical Conductor continues to evolve.

Thank you.

m_acadamian

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