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Executive Interview: Chip Jennings CEO, etrial^s

Recently, Q1 Productions had the select opportunity to speak with Chip Jennings the CEO of etrial^s, to discuss his opinions regarding Patient Reported Outcomes collection and management. For information regarding etrial^s, please visit their website at www.etrial.com.

Q1 Productions: It has been over a year since the release of the new FDA Guidance document related to the use and management of Patient Reported Outcomes (PROs). How has this changed the way that industry is utilizing this information? Do you see significant increase in the importance and relevance of PRO collection and management? How is the industry continuing to address the changes in the guidance documents?

Chip Jennings, etrial^s: The FDA’s Guidance on PROs has resulted in greater attention to, and inclusion of, the patient’s perspective of treatment benefits. Throughout the past year, the industry has made great strides to find ways to effectively and efficiently report these “quality of life” measurements, as well as implement them into the drug development and approval process. However, there are challenges and issues that need to be addressed before regulators are able to mandate PROs, specifically electronic submissions.

For instance, the FDA’s plan to evaluate modified instruments just as it would evaluate a new one may be too much of an extreme measure for those common, minor modifications. Additional guidance around this issue, as well as others, will help the industry move toward more seamless reporting of PROs.

I anticipate that further [FDA] guidance will empower electronic PROs, as it is the only way to ensure accuracy and safety for the most effective drugs.

Q1 Productions: New technologies continue to enhance the collection of patient reported outcomes and clinical data, and seem to hold a panacea for the problems that the industry faces in terms of the collection and management of long-term clinical outcomes. What do you see as the emerging trends in new technologies that will continue to assist and improve the utilization of electronic data capture systems?

Chip Jennings, etrial^s: The software and technology is already ahead of the curve, but etrial^s’ application to improve the utilization of EDC is the ability to integrate all technologies and information - interactive voice and Web response, eDiaries, EDC, as well as external lab and device data - into one central database. This integrated platform will house all long-term data and allow for reporting an analytics well into the development process.

etrial^s had prepared for the release of this guidance long before it was published and is committed to continual process and solution improvements; therefore, we haven’t had to make considerable adjustments to our current practices. Our new products, including EDC 2.0 and our trial designer, make it easier to streamline and improve data collection and management of PROs. The full integration of our software platform allows all types of PROs and external (lab) data to be incorporated and validated on one database, which allows for streamlined and ad hoc reporting.

Q1 Productions: As an organization, etrial^s has continued to increase their market share within the industry, fueled by new business, as well as repeat clients. Share with us a success story!

Chip Jennings, etrial^s: We have come a long way, and I believe our true value rests in our ability to provide services and solutions that benefit society as a whole, bringing safer drugs to market quicker, and our ability and dedication to providing top-quality customer service, applying our in-house expertise and creative solutions to solve client problems.

We have grown from 15 employees to nearly 150, and our staff includes some of the most experienced clinical project managers, software developers and technology specialists in the industry. Our employees are the ones on the front line solving customer problems and consequently fueling our company’s growth. Because of them, we are able to fulfill our role as process partners for our clients.

Essentially, etrial^s is in the business of solving customer problems. Our clients have a problem, and we have a solution – if we don’t have the best solution for our clients we will never grow, gain market share or secure repeat business. We have grown because we apply our forward-thinking processes and superior software solutions to solving our customers’ real-world clinical problems.



Executive Interview: Chip Jennings CEO, etrials

A good example of this is our long-standing relationship with The Medicine's Company (TMC), specifically a large Phase III Critical Care Cardiovascular Study, called "ACUITY". Involving nearly 150,000 patients at more than 400 sites in 17 countries, the study required massive mid-study changes due to unanticipated circumstances. As a result, it became necessary for TMC amend protocols and etrials to redesign the eCRFs. Despite the sheer scale of the changes, the ACUITY trial met all objectives in favor of the treatment meeting all levels of testing. The product was approved and is now being marketed globally. Essentially, working with etrials and our EDC solution, enabled TMC to adapt and make those changes quickly. Using paper, this process would have tripled or quadrupled in time.

Q1 Productions: One of the greatest assets of your organization is the ability to provide your clients with a full suite of products that will enhance their data management and outcomes collection. What are some of the challenges you have experienced in bringing together various systems and how have you overcome these challenges?

Chip Jennings, etrials: As with any company experiencing tremendous growth, the integration of people, technologies and operations is challenging. But, proper due diligence and planning is essential in overcoming the expected hurdles that many companies go through.

We brought some of the greatest thought leaders in this business to our team to implement rigorous quality control initiatives and thorough beta testing. With the team we have in place, we are able to ensure that etrials overcomes any integration issues.

Industry adoption rates are challenged by the varying comfort levels associated with integrated technologies. The industry still has a difficult time trusting multiple technologies from one vendor, but we are making progress as clients begin to achieve their goals.

We see adoption rates increasing year-over-year and expect further growth as clients realize the benefits, become more familiar, and become more comfortable with using multiple technologies. Overall there's no doubt that any challenge stemming from integrating systems is returned exponentially in the abilities, accuracies and efficiencies it supplies to etrials' clients.

Q1 Productions: Throughout your professional experiences you have no doubt garnered a range of skills applicable to your new position. What do you believe from your past endeavors will enable you to create successful results at etrials?

Chip Jennings, etrials: I bring more than 25 years of healthcare experience to etrials, having served in C-level positions at Baxter, SHPS and Matria Healthcare. Having worked at a variety of companies within the industry, from biotechnology to large pharmaceutical companies, I bring a unique perspective to the organization and am able to better understand how to meet the needs of our broad customer base.

etrials is well-positioned for significant growth, and I can easily tap into a significant foundation of experience to lead this company to continued success. My experience includes full P&L responsibility for three operating units at Matria Healthcare, developing and managing a new customer acquisition program and initiating a variety of capital-raising activities.

etrials is ready to be catapulted to the next level, and I, along with a phenomenal and supportive team of experts, plan to lead the company to the next stage of success.