

**Nextrials.** San Ramon, Calif.

**An interview with Jim Rogers, founder and president, and Anthony Costello, founder and vice president product development and data services**

**What is Nextrials' background?**

**JR:** We were founded in 1999. Half the founders came from the Genentech Oncology program. We felt that web-based electronic data capture [EDC] was an idea whose time had come. We like to characterize ourselves as more of a next generation EDC company because we're doing more than just electronic data capture—we focus on innovation, integration and customer value.

**Tell me about some of your tools.**

**JR:** Based on the clinical data, our inventory management tool can track how much drug is at the site. It can track control versus active drug in a blinded fashion. It can anticipate shortages and can automatically send an email to either the sponsor or manufacturer to say the site is due to run out of active or control drug. It can also allocate drug that's due to expire the soonest. Another example of what we can do with the clinical data is our laboratory data management tool. We collect all the units and all the ranges for every lab use for every study, so when the sites enter the lab data we can run edit checks against the normal ranges for that specific lab. Instead of giving a broad range for a generic edit check you can now drill down and be specific for each site. We also

do email notification, so any key data point in the study or any calculated value at any data point can generate an email to the sponsor. The sponsor can track an efficacy or safety endpoint and be notified based on that. These innovative tools have led to two industry awards this year.

**What else differentiates Nextrials from other EDC companies?**

**AC:** It's core to our development strategy to have one integrated tool—PRISM. That's a big difference between Nextrials and what other EDC companies are doing. We don't have third-party software tie-ins that we've purchased or that have come to us through mergers or acquisitions. We have one product. We've built it from the beginning to be integrated. We also have patient randomization and tools for exporting data on the other end of the study in formats that are consistent with industry formats such as CDISC that are ready for delivery to the FDA. One other component that differentiates us is that we do offer the associated data management services—data management, SAS programming, statistical analysis.

**JR:** Also, since the beginning we've had an integrated safety database that's directly linked to all the clinical data. So you have an

**Year Founded:** 1999  
**Employees/contractors:** 20  
**Active Projects:** 19  
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opportunity to eliminate the need for reconciliation between your clinical database and your safety database. The safety database takes the adverse event data collected as part of the clinical trial, automatically migrates that into the safety database, allows you to enter the additional information that you need to as part of safety reporting and then can generate a MedWatch report right out of the system.

**What challenges do you face?**

**AC:** The industry is waiting for the FDA to endorse, in a broad-based fashion, the idea of EDC for its abilities to accelerate drug development. If that were to happen there would be instantaneous adoption across the industry.

**What are your plans for growth?**

**JR:** We're self-funded and we've been profitable since 2000. We're actively talking to both CROs and other eClinical vendors in the space both from a recruitment end and an analysis end and looking to expand a lot through partnerships and growth internally through direct sales.

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