



# Unexpected Mid-Study Updates Put eClinical Solutions to the Test

case study



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## SUMMARY

Author Benjamin Disraeli once said: “Change is inevitable. Change is constant.” Never has that been truer in the world of clinical trials than it is now. When change happens in clinical trials, the benefits of technology show their true colors.

People tend to resist change, but technology doesn't. etrialis technology is adaptive by design.

This case study outlines how etrialis helped one company successfully perform massive unanticipated mid-study changes through the right mix of tools and expertise, ultimately resulting in the company gaining actionable information for faster, more informed decision-making.

## THE CLIENT

The Medicines Company — A company committed to delivering innovative, cost-effective acute care products in the worldwide hospital marketplace.

## THE TREATMENT

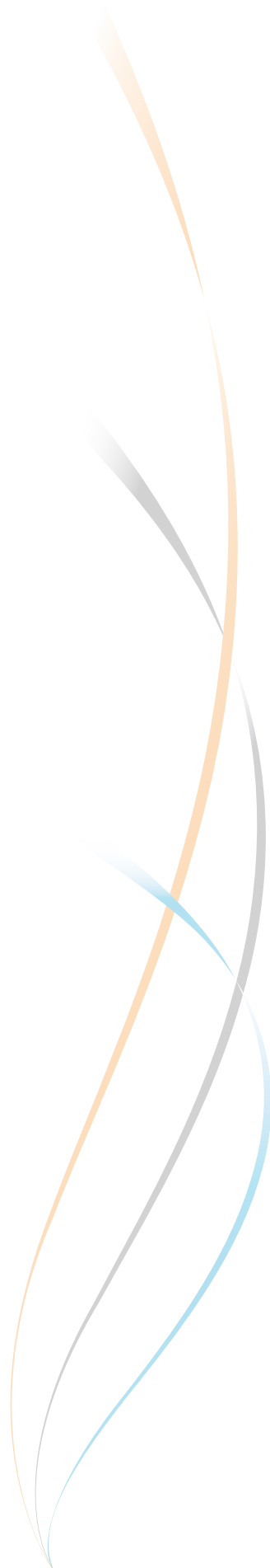
Angiomax® (bivalirudin) for injection, an anticoagulant approved for use in patients undergoing coronary angioplasty procedures.

## THE DETAILS

- Phase III Critical Care Cardiovascular Study; The “ACUITY” Study
- More than 13,800 patients
- 448 hospital-based sites
- 17 countries worldwide
- 3 treatment arms
- Randomized open-label parallel group study
- etrialis' EDC for data capture and data management capabilities
- etrialis' IVR for randomization, drug supply management and logistics

## THE NEED

The Medicines Company (MDCO) was working with a variety of data sources that all needed to be incorporated into the EDC system and populated into the final patient eCRF.



This study was relatively straightforward at the start of the trial. Ultimately, MD-CO's technology and service needs fell into four main categories; all the specialty of etrials as a comprehensive Clinical Information Solution Provider:

1. Real-time data access
2. Seamless data integration from diverse collection sources, including IVR system data
3. Custom reporting tools for increased control and visibility which helped to improve patient enrollment and site compliance
4. Ongoing consultation and customer service before and throughout the trial process

## THE CHALLENGE

Amidst data collection for the final stage of the Phase III ACUTY Study, MDCO discovered a competitive study failed, which made it necessary for MDCO to amend the protocol and etrials to completely redesign the eCRFs.

This required MDCO to halt data entry for six weeks and analyze every element of the trial's design, even down to each screen of the eCRF. Working closely with MDCO, etrials was able to adapt quickly, ensuring changes to the data fields were made using design tools inherent in the EDC system.

“The study kicked off in August 2003 and we had to completely redesign the EDC systems after about 2000 patients were enrolled,” said Judy Sromovsky, Vice President, Data Management and Clinical Systems at The Medicines Company. “It was like putting the study into a metaphorical blender. etrials was able to help us find the solution. In the end the technology worked perfectly.”

## THE SOLUTION

What had to happen to ensure the mid-study updates were performed quickly and accurately:

- Full coordination between etrials' project management team and MDCO to consult on each necessary change and the best approach to the technology backend systems and regulatory requirements, as well as the end-user experience.
- Complete audit trail coordination and verification — audit trails had to match up with all phases of data collection, not just new information.
- Query transfer and verification to ensure no open queries were missed or answered queries lost.
- SAS and Access data updates for proper data mapping for final submission.
- Unlocking and locking of database multiple times, taking only one week for each instance.
- Full-access to customer service team.

## THE RESULT

Despite all of the mid-study changes, the ACUTY trial for Angiomax met all objectives in favor of the treatment meeting all levels of testing, including all six of the main pre-specified endpoints in patients with acute coronary syndromes.

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“As clinical researchers, we change our minds all the time based on new science, new discoveries and new ideas,” said Sromovsky. “Technology, like etrials’ EDC, allows us to adapt and make those changes quickly.”

## ABOUT MDCO

Founded in 1996 and employing approximately 250, The Medicines Company meets the demands of the world’s most advanced medical practitioners by developing products that improve acute hospital care. The Company markets Angiomax® (bivalirudin) for injection, an anticoagulant approved for use in patients undergoing coronary angioplasty procedures. The Medicines Company creates value using its range of clinical and commercial skills to develop products acquired from leading life science innovators. In addition to the approved Angiomax product, The Medicines Company is developing clevidipine, a short-acting calcium channel blocker. The Medicines Company is also conducting significant clinical research to study potential additional indications for Angiomax use. In December of 2003, the Company acquired cangrelor, an anticoagulant that prevents platelet clotting factors from activating, which the Company believes has potential uses in coronary angioplasty and cardiac surgery.

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