



Case Study: Web Based CRO CARDIOCORE Delivers with Visual Vault



cardiocore

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The global contract research outsourcing (CRO) market exceeds €10B and is growing at 15-18% CAGR, in-line or exceeding R&D spending. The market is increasingly fragmented as CRO's focus on niches and competencies. Cost pressure at pharmaceutical and biotechs continues to be a key driver, and CROs enable conversion fixed costs to variable, while leveraging highly skilled professionals with proven accelerated time-to-market skills.

In this article we introduce Cardiocore, a specialty CRO based in Bethesda, MD and discuss one element of their strategy – using web technologies to augment and accelerate their growing business. Cardiocore offers high quality, centralized electrocardiogram (ECGs) and echocardiogram analysis, Holter monitoring and consulting. Study protocols are developed with clients and all clinical trial procedures are validated with full compliance to 21 CFR Part 11 and associated regulations. All data are reviewed by US board certified cardiologists.

Five years ago, Cardiocore set a corporate goal to establish a web-basis for cardiac ECG clinical research outsourcing. In-house development had created the initial customer facing portal for data delivery. As Cardiocore's customer base and project workload grew, the need for automated and integrated processes and scalability was immediately recognized.

Jennifer Cotteleer, CEO of Cardiocore refers to their growth opportunities at the time as a strategic inflection point. She explains, "Cardiocore's management team understood that pharmaceutical and biotech customers required flawless management of high-volume data to complement the company's top-quality clinical services. We needed to achieve greater efficiencies in handling the scale and precision of information. We made the decision to outsource the development of a data management system and focus on our core competencies in the science of cardiac safety trials."



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Cynthia Casemyr, Cardiocore's Director of Technology and Data Management, led the Cardiocore team in evaluating available products to establish their web based platform. Documentum, OpenText and Sharepoint were each considered before the selection of VisualVault, a web based compliance solution. "VisualVault was the only solution that met our requirements and had the technology for our long term vision", offers Cynthia.

With the selection of **Waypoint Technologies** of Scottsdale, AZ as Prime Contractor for integration services and VisualVault for the technology platform, Cardiocore has established a growing reputation for web-based cardiac clinical studies.



"In addition to the business the convenience and security of on-line access delight many of our clients who are responsible to manage intensive, global drug trials."

**Cynthia Casemyr, Director,
Technology and Data Management**

The process starts with set up of the client's study in the portal. Each client is provided with secure access to their study information, and can monitor progress through direct access.

A typical study involves multiple patients who are screened and tested in various clinics around the world. The digital ECG output includes the waveform as a PDF and an associated index file which contains key measured attribute data.

Using web services, the files are automatically uploaded from their source of origin into VisualVault and measured attribute data are mapped into HTML forms in the database. Cardiocore-defined and empirically validated business rules are applied to rapidly assure the quality of the ECG data before making them available in data dashboard views for review, printing, download or export by study sites and sponsors.

Workflow and process automation moderates Cardiocore's operational cost basis and significantly reduces error-handling, while simultaneously ensuring integrity of the clinical data.

The technical challenges to web based CRO are many. VisualVault provided a controlled repository for user access rights, document storage, workflow and forms processing. Digital ID stamps provide compliance to 21 CFR Part 11 requirements.

One of the unique challenges was to create an automated way to set up each study given that study parameters vary for each. Cardiocore's executives place high importance on molding their service to the customer needs. Each customer, in turn, presents a unique set of business rules and requirements. Communicating and codifying those business rules while still maintaining a rapid flow of data was a challenge.

WayPoint developed a sophisticated "Study Manager" application that utilizes the VisualVault API to configure each specific protocol. One of the important capabilities of Study Manager is the ability to change a business rule on the fly without further application development. As business rules are passed from the customer to Cardiocore, the study set-up process can mold to those new rules. Rules are described in the system in plain language to further reduce the possibility of error.

The second important facet of Study Manager is the automated quality assurance capabilities. Previously, quality assurance was a labor intensive process with several levels of manual checks and reviews. Each new study required staff to perform the QA functions and manage the process. **WayPoint's** Study Manager automates the entire quality assurance process. The result is that Cardiocore staff can now focus on the just exceptions, streamlining the entire QA process while improving data quality.

As measured by clients, the initiatives taken by Cardiocore have proven to be a great success. Jennifer Cotteleer states, "This system will allow Cardiocore to meet the challenges of completing successful clinical trials for many years to come. I can confidently report to our clients that as their needs evolve, Cardiocore has the agility to meet those needs."