

The Avonex Combination Trial (ACT): An Early Service Oriented Architecture (SOA) Implementation

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Abstract

Although prospectively integrated design of all aspects of clinical trial data handling is generally perceived as scientifically optimal, trends towards specialization and outsourcing increasingly require the integration of data from numerous contributing organizations in diverse prepackaged forms, and the ability to rapidly add or replace system elements. Systems architectures in such dynamic circumstances must be modular, forgiving, and scalable. In the Avonex Combination Trial (ACT)¹, the central data repository received data from six sources within five organizations. Successful integration required an early implementation of service oriented architecture (SOA), driven by the matrix of service data providers and their structurally dissimilar internal software approaches. Consequently, clinical research informatics was more visibly and continuously engaged with the study's scientific and operational leadership than typical in clinical trial management. The ability of the clinical informatics team to bridge technical and administrative gaps between contributing entities proved critical to obtaining high quality data.

Introductions

The Avonex Combination Trial (ACT) was an industry-sponsored investigator-run trial of combination therapies for multiple sclerosis coordinated by Cleveland Clinic's Multiple Sclerosis Academic Coordinating Center (MSACC). The study informatics team was tasked to accept and integrate data from automated randomization, electronic data capture, clinical laboratory, and adverse event coding contractors, a sponsor laboratory serving as the bioassay core, and the MSACC central image analysis facility. A systems engineering approach was used to define clinical research workflow processes, perform gap analysis, identify cross-disciplinary resources, and develop customized yet scalable tools.

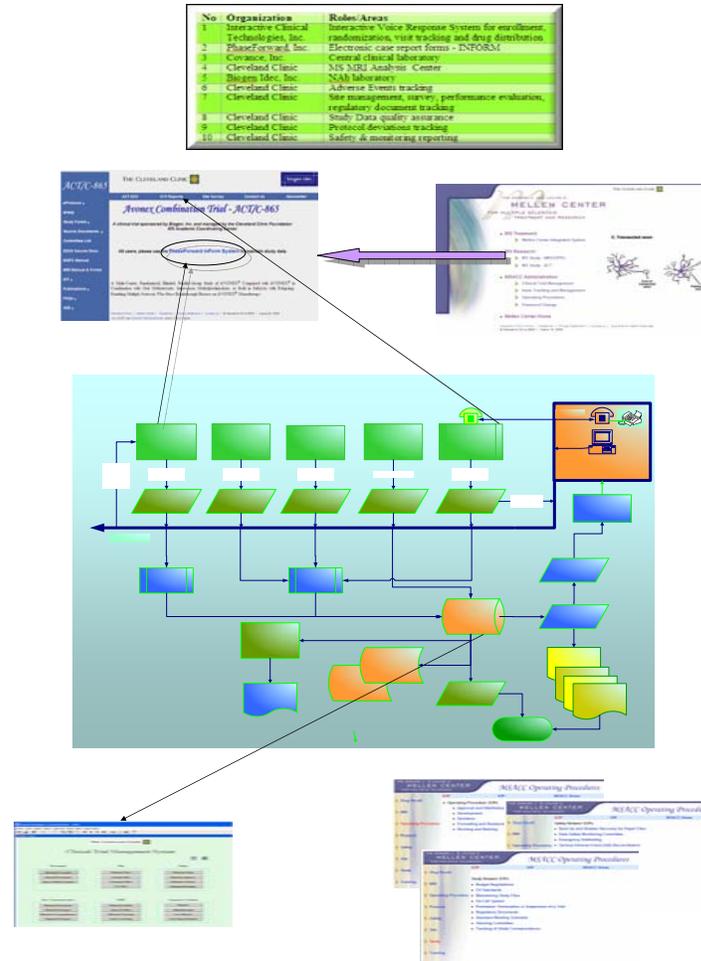
Disease - Relapsing-remitting multiple sclerosis;- RRMS
Study design - controlled, Phase IV trial, 2 X 2 factorial design
Sites - 72 sites in the USA
Start Date - May 2003
End Date - June 2006

Methods

Software engineering methodology played a key role in designing the architecture for integration across multiple vendors and operational subgroups. Capability Maturity Model Integration (CMMI)² process improvement methodology was used to move from *ad hoc* methods to initial process definitions to repeatable, managed processes, and even to optimized processes in particular areas.



ACT Workflow – SOA configuration



Results

Gap-identification in specific areas facilitated a model-driven development approach, leading to replacement of *ad hoc* approaches with mature methods in an integrated system fitting seamlessly with third party vendor systems. Site management and coordination capabilities were enhanced for this and future studies. Interim data monitoring was recognized for timeliness and comprehensiveness. Cross-functional collaboration, originally necessitated by resource constraints, reinforced the benefits of including informatics as a fully collaborative element of study design and management.

Specific Themes	Descriptions	ACT
Service integration	Many services consolidated under the SOA often unglued	✓
Service abstraction	Logic hidden to maintain logical service contracts	✓
Service contract	Adheres to communication agreement pre service-design	✓
Service reuse	Large or divide into services to promote reusability	✓
Service availability	Large or divide into services to promote reusability	✓
Service interoperability	Ability to consume services from assembling from a collection	✓
Service autonomy	Services fully control their respective encapsulated logic	✓
Service explanation	Focus on quality rather than existing processes	✓
Service discoverability	Developers enough for easy search and assessment	✓
Service relevance	Functional granularity for user recognition as meaningful usage	✓

Discussion

The SOA approach proved well-suited to our inherently awkward task of integrating use of multiple compartmentalized software products and manual processes. The disparate elements were synchronized so as to remain independently functional while interacting relatively seamlessly. High level informatics involvement in study management was crucial to achieving trial objectives in this environment. The approach taken allows for the rapid adaptation of modular components to future projects, without commitment to an underlying mega-architecture.

Acknowledgements

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- Capability Maturity Model Integration (CMMI) Software Engineering Institute (SEI) of Carnegie Mellon University <http://www.sei.cmu.edu/cmmi/>
- History of SOA - <http://www.soapatterns.org/>

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