A modular and flexible Solution-On-Demand model for clinical development

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Introduction

The recent breakthroughs in drug discovery have increased the pressure on the clinical development to bring the results of drug discovery to therapeutic applications. The traditional paper-based approach to clinical development is a slow and ineffective process (Figure 1 and 2). New designs for clinical trials and new tools are in urgent demand for both biotech and pharmaceutical companies. However the investments required to gain access to new technology for clinical development are out of reach for a small and medium-sized biotech pharmaceutical and biotech company. A business model which reduces up-front investments is required to bring the benefits of modern e-Clinical technology to biotech companies. We propose a modular and flexible approach for applying software technology to clinical development.

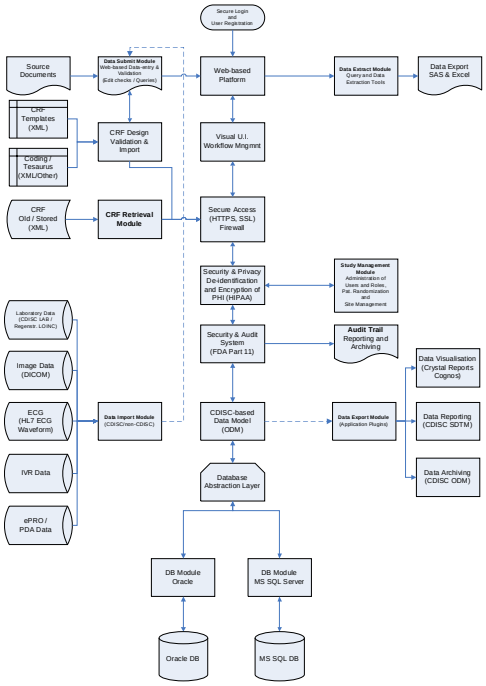

Figure 3: Architecture of an Electronic Data Capture (EDC) system, which takes into account guidelines and regulations (e.g. FDA Title 21 Part 11, HIPAA).

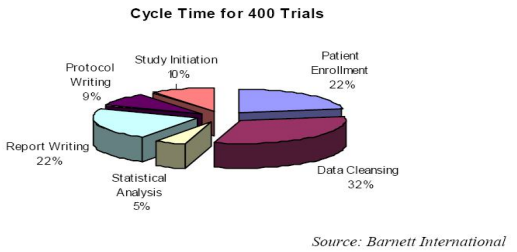

Figure 1: The time spent during different sages of a clinical trial indicate that errors made during data entry (no edit checks, duplication) contribute 32% to the total time spent.

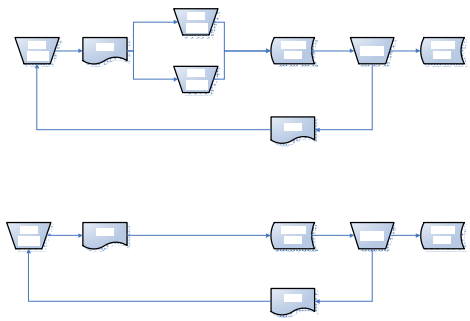

Figure 2: Fewer steps to a clean set of clinical data lead to an increase in data quality.

Approach and System

Building on our own experience in clinical development we have designed a business model which lowers the threshold for biotech companies to enter clinical development. An Application Service Provider (ASP) model allows small and medium-sized biotech companies to access state-of-the-art technology for clinical development. Web-based technology, 24/7 support and service allow the biotech company and/or CRO (Contract Research Organization) to focus on their patients and their data. The near real-time data capture allows for close monitoring of the critical metrics of a clinical trial.

The ASP model provides a biotech company with a "Solution-On-Demand" when it is ready to enter clinical development for a new drug candidate. The "Solution-On-Demand" approach allows for a stepwise implementation of new technology throughout the clinical development path from Phase I to Phase III.

The system provides built-in quality, facilitation of process, improvement of communication and coordination, improved project management and standardization (Figure 3). The system uses open standards (CDISC) for date exchange which allows for easy integration with other technologies and with regulatory authorities (EMEA, FDA). From eProtocol and eCRF (Case Report Form) to research report, the entire data chain is under control and can be monitored. Quality control, security and validation (FDA Title 21 Part 11, HIPAA) are built into the process technology, reducing the need for costly human intervention and sources of errors (e.g. double-data entry).

Conclusion

By providing access to a modular and flexible Electronic Data Capture system, through an Application Support Provider business model, we make EDC available to medium-sized pharmaceutical companies and biotech companies.

With the "Solution-On-Demand" model in combination with modern technology we are able to support the biotech industry to bring their innovations to the market, both faster and cheaper. The combination of innovation in technology, a modern business model and clinical development expertise assists the biotech industry to improve the critical path of clinical development.