# Transforming Clinical Business with an Enterprise Approach to EDC

## The Challenge

In 2005, Abbott sanctioned an executive-sponsored governance body to drive the development and implementation of enterprise-wide study build, data capture and trial management processes using a single electronic data capture (EDC) vendor for all clinical studies. The objective was to quickly move the lion's share of studies to electronic capture means while maximizing site acceptance.

Until that point, a vast majority of Abbott's research studies used paper forms shipped to investigative sites as the means to collect research and safety data. The small minority of studies that embraced electronic capture did so independently, with each study team outsourcing EDC to a different vendor of choice. This resulted in inefficient and resource-intensive projects that started from scratch without the benefit of standard building blocks, best practices or operating procedures. Study development by supporting functional areas was purely reactive with poor review of study components by key stakeholders. During study conduct, redundant and competing data reviews across functions created duplicative queries that frustrated sites. Metrics related to site performance, data review performance and CRF quality were unattainable. Project teams and sites were often turned off by these less than positive experiences, perpetuating the electronic adoption delay.

## The Solution

Initial process redevelopment started in 2006, and following a couple of pilots and a vendor evaluation process Medidata Rave® was contracted in early 2009 to supply Abbott's enterprise-wide EDC solution. The selection of Medidata technology provided Abbott with an opportunity to rethink some of the ways the organization mobilized for and managed clinical trials. A series of cross-functional workshops with the Data Management, Clinical Program Management, Clinical Field Operations, Statistics and Medical teams concentrated on "lessons learned" and best practices within the industry, addressing study start-up, conduct and closeout.

A Global EDC Office established responsibility for vendor and tool management as well as cross-functional process development, refinement and adherence. For study start-up, improvements included taking advantage of Medidata's Knowledge Transfer program to in-source study builds and drive significant savings and resource transparency. Rigid review milestones with participation of all key stakeholders increased decision making speed and reduced the cycle time between protocol finalization and EDC go-live at sites with first patients enrolled (FPE) to only seven weeks.

## By the Numbers

Enterprise rollout of EDC technology is critical for Abbott to increase execution efficiency and data availability on a growing pipeline of clinical studies, while controlling key cost areas such as those related to site monitoring.

- **Cost effective:** 24 percent annualized ROI is expected from reduced field travel through remote monitoring, in-sourcing of EDC study builds and reduced paper shipping. This is in addition to savings from streamlined eClinical system integration, site reimbursement and study closeout.
- **Fast study starts:** EDC is live and ready to use by sites, and FPE is within seven weeks of protocol finalization.
- **Fast access to data:** Sites enter data within five days of patient visits and study closeout timelines are over two months shorter, allowing quicker post-closeout redeployment of resources. Most studies achieve database lock within 10 days of LPLV to DBL.

## About Abbott

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies.

On the study conduct and closeout fronts, key improvements focused on data-cleaning performance tracking (see inset on left—"Manager's Toolkit") and elimination of duplicate effort by monitors, data managers, clinical safety analysts and biostatisticians. The Global EDC Office introduced an Integrated Data Review Plan (IDRP) that aggregates all the data review and remote monitoring components into a single document. It ensures mutually exclusive, resource-efficient data cleaning efforts—essentially a guidebook to getting the study team to database lock as quickly as possible. Abbott also implemented Rave Targeted SDV, requiring field monitors to perform remote monitoring on a weekly basis and contributing to significant savings in travel costs.

Finally, leveraging Rave Web Services and an Enterprise Service Bus (ESB) architecture to integrate EDC, interactive voice response (IVR), finance and clinical trial management (CTM) systems in a scalable manner helped free key personnel by streamlining processes, such as site reimbursement, and reducing data entry redundancy and reconciliation efforts.

## Business Impact

Adoption of EDC has been exponential at Abbott; by 2010, complete electronic adoption had been achieved by the organization—100 percent of Phase II, III and IV studies use Rave EDC/clinical data management (CDM) to capture and manage investigative site data. Only a handful of legacy, paper-based studies remain and will be ending over the coming years.

Abbott has seen significant tangible financial benefits as a result of transitioning to an enterprise approach to EDC and leveraging Medidata technology, with an estimated annualized return on investment (ROI) of 24 percent, and transformative process streamlining that has allowed clinical and safety data to become available much sooner to decision makers. All told, Abbott has successfully met its objectives of competitively scaling its clinical research business going into the next decade.

## Abbott's Manager's Toolkit

Leveraging an extensive set of "Manager's Toolkit" reports and metrics built on Rave's robust reporting and real-time data access tools, Abbott introduced proactive correction of operational performance across studies. This prevents accumulation of systemic issues that can cause significant database lock delays, for example by ensuring that sites enter data within five days of patient visits and that queries are opened within five days of data entered. This has reduced Last-Patient-Last-Visit to database lock (LPLV to DBL) cycle times by over 85 percent on average from over two months to less than two weeks.

## About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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