Case Study: Bayer's Certegra™ Central Application Platform

Bayer HealthCare
100 Bayer Road
Pittsburgh, PA 15205
USA
www.bayer.us
1.800.422.9374

Business Problem

The Medrad® Stellant® CT injection system with Certegra™ Workstation is an integral part of Bayer's CT Imaging solution designed to provide Radiation and Contrast Dose Management. The Certegra™ Informatics Platform originally consisted of individual instances of the Certegra Workstation which had no concept of any other instance and as such provided for no common hierarchical concepts such as MIS reporting of Contrast Usage, Central Applications, Data redundancy, Central User Control, Updates & Upgrades; nor a variety of other concepts that would more readily demonstrate Certegra to be a true "software platform".

Concept Value Statement

Bayer had the desire to increase the value of Certegra to the customer, its partner vendors and within Bayer itself. One of the primary vehicles for this increase in value was the development of an Aggregation Platform which would form the infrastructure necessary to support centralized services, and an Application Platform which would include the application tools, controls and programs developed to deliver additional value once the infrastructure is in place.

Business Considerations

The solution provided should conform to the following technical considerations:

- **Scalability:** The solution should be scalable (monetary and performance) so as to be able to ramp up from an organization with two instances or Certegra and limited interfaces to an enterprise level organization model with several instances of Certegra and extensive interface requirements.
- **Minimal Hardware dependencies:** To the extent possible, there should not be hardware dependencies that will require Bayer to specifically certify, stock and ship servers, routers, data management cables, etc.
- On any hardware/tool/device that Bayer does need to stock, ship or maintain in conjunction with these requirements, all appropriate commercial markings (e.g. RoHOS Compliant, EMC verified, IEC60601 verified, CCC mark, etc.) will be maintained.

Requirements & Constraints

The solution introduced would need to effectively mitigate impacts on existing areas within the existing Certegra Platform. The following impact areas were identified:

- **Certegra Database and User Interface:** Solution would be required to work with the existing database and user interface while introducing new tables, fields and concepts.
- **User Roles and Rights:** While the solution would introduce new users with additional roles and rights to integrate with the new functionality, it should port the users from the existing platform within the context of the new requirements.
- **Data Aggregation:** Data between the individual Certegra workstations and the Certegra Application Platform (CAP) should flow seamlessly with well identified triggers so that the CAP should always have the latest data from all workstations within its purview. Tools need to be provided to handle areas of database inconsistencies such as duplicate records from individual workstations.
- **Central Applications:** Solution should leverage a powerful MIS reporting platform to extract information from the aggregated data.
- **Regulatory:** The solution shall adhere to Bayer established BAA and HIPAA controls and shall provide the flexibility necessary to amend those controls as indicated by business and/or regulatory requirements.
- **Audit:** The solution shall provide for financial and other audit capabilities in accordance with standards set forth and provided by Bayer.

The Solution

The Certegra™ Central Application Platform was developed with SoftLink's domain and technical expertise and with singular effort that allowed the integration of several Certegra Workstations into an aggregated platform that rendered itself to a variety of analytics and information mining.

SoftLink's reusable IPs: SoftLink's database expertise was leveraged to effectively merge duplicate records and several Certegra workstations were able to feed to and from the central aggregation database. The solution was deployed on a web interface that could be accessed from any common web browser so that all data always remained at the users' fingertips. The solution provided tools for Central Administration of users and certegra nodes within an organization, Reporting, Analytics, Exports, Printing, Audits, Licensing and Exception Management. Communication modules were also developed that interfaced with hospital's PACS and the Stellant® CT injection system using DICOM3 and HL7 protocols.

Scalability of solution: The data aggregation platform was designed so that the solution became modality independent. This allowed Bayer to expand the concept so as to encompass not only CT modality but others such as MR, CFD, etc. The architecture was designed to allow the solution deployed

to scale from a small footprint organization with single instance of Certegra to a large organization with several Certegra workstations. The solution also supported a hierarchical distribution of Certegra nodes for flexible and configurable administration and reporting capabilities within organizations.

Safety & Risk Assessment: The solution underwent a rigorous Hazard and Safety Analysis in accordance with Bayer's Hazard Analysis Policy and Risk Priority Guidelines. The implementation and use of the solution was found to introduce no new hazards into the products intended to be used along with it. The solution was assessed to have an acceptable level of safety risks and no analyzed concerns required special mitigations or controls to be developed.

SoftLink thereby provided all the technical expertise required for Bayer to satisfy its business needs adequately. SoftLink's reusable technical components enabled the solution to be developed at an extremely fast pace, consequently reducing Bayer's time-to-market significantly. Through SoftLink, Certegra products today consistently advance how information is generated, mobilized and integrated in contrast-enhanced imaging, delivering new levels of efficiency and patient-centered care in CT imaging.