Clinical Imaging: Focus on Service

BY ALISSA POH

Novartis' open-source platform, ImagEDC, first rolled out in 2010 (see, "Novel IT Platform Helps Novartis Gain Control of Clinical Imaging Data," *Bio•IT World*, Nov 2010), continues to make waves in the IT and informatics world. It garnered a Best Practices Award (IT & Informatics category) at this year's Bio-IT World Expo, in conjunction with Novartis Image Analysis Interface (NIAI), the company's fully automated image analysis workflow system.

ImagEDC, a nifty combination of service-oriented architecture (SOA) and grid computing, gives researchers greater control and ownership of imaging data across multiple clinical trials. Basically, it enables smooth data transfer between trial partners, using caGrid-enabled Web services for high performance and security.

According to Stefan Baumann, head of Novartis' clinical imaging team, and Josh Snyder, an imaging infrastructure expert at the company, incorporating innovative image processing techniques—even into small, exploratory trials—is currently no easy task. "If you look at other industries, such as travel or banking, interoperability between data sources and consumers has grown tremendously in recent years, and the resulting ease of data exchange has created huge advances in data driven applications," Snyder says. "Not so for imaging; we believe there is significant opportunity in this space."

Meanwhile, there are increasingly complex needs that come with this opportunity—data quality requirements, interface standards, and workflow modularization, to name several. ImagEDC offers the flexibility to adapt as these requirements change. "We've delivered not just a solution for interoperability, but a working, open source reference software package," says Snyder. "Vendors and other sponsors can use this to accelerate their own efforts at implementing infrastructure."

IT & Informatics

Winner: Novartis Institute for BioMedical Research (NIBR)

Project: Novartis Image Analysis Interface and ImagEDC

Until recently, Novartis researchers had to deal with a "closed box" workflow, where several different parties were involved in any one trial. Each—from the imaging CRO to core labs—had its own systems and processes, with no standards enabling decentralized data storage or removal of patient-identifying information. This was an inefficient process, and potentially compromised research quality.

Transparent, Trackable Data

The imaging team at Novartis developed a plan to manage clinical trial data that would be transparent, trackable, and easily configurable, with real-time quality control enabled through faster image transport between study partners. They turned to caGrid, an open-source middleware product capable of supporting partners with different IT proficiency levels and budgets, and compliant with the relevant health care standards, including DICOM and CDISC.

When deployed at clinical trial sites, ImagEDC enables clients to produce images compatible with trial requirements, without additional processing from the responsible CRO. These clean, [patient] de-identified images are then stored in a local repository that includes a tracking service to record their receipt and other workflow events.

One might figure that physical bandwidth for image transfer between Novartis and a study partner could be a bottleneck, but Baumann and Snyder disagree. "Several generic and specialized solutions [to maximize bandwidth] work very well, and we don't seek to supplant these with ImagEDC. Data format and quality issues are far more pertinent." The approach is also cost-effective: with NIAI and ImagEDC replacing manual image reads, Novartis estimates that it has reduced the cost of each applicable clinical trial by about $80,000.

"We were interested to share our success story with NIAI and encourage adoption of ImagEDC, to promote interoperability between sponsor and vendor infrastructures," says Snyder of Novartis' decision to participate in this year's Best Practices competition. "Given the excellent work submitted by our competitors, it was definitely gratifying when the judges announced our win; it's validation that we are working to a valuable purpose."

Snyder, Baumann, and their colleagues at Novartis are also organizing a Pharma Image Exchange interest group to help govern the rapidly evolving landscape of image processing, "We hope that SOA-based tools like ImagEDC will be increasingly adopted, and that we'll see an encapsulation of more image processing and workflow functions as services," Snyder says. "Service-based exchange of data quality requirements, for example, is an important next step." •

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