



Diagnostic Imaging Network for Clinical Trials

Summary

This paper addresses the efficient collection of diagnostic studies for clinical trials and highlights the success of a current AG Mednet customer.

The four main issues confronting this operational area include:

- DICOM incompatibilities,
- Workflow management at both the sender and receiver sites,
- Costs related to trial completion delays, and
- The difficulty of establishing traditional, direct network connections.

Current methodologies have researchers selecting from one of two sub-optimal alternatives: generating physical media which is then couriered, or *ad hoc* network solutions. For researchers looking to efficiently gather studies from the widest variety of remote sites, AG Mednet is the solution. Unlike couriering or *ad hoc* network solutions, AG Mednet fits effortlessly into the workflow of the sending and receiving institutions, providing rapid, secure transport of lossless studies over a private, high speed DICOM network.

The Current Environment

Collection of Diagnostic Studies from Remote Sites

Clinical trials involving diagnostic imaging often involve a large number of participating sites over a wide geographic area. Site selection is based on factors including local specialized expertise, availability of modalities and patient recruitment capabilities. This process often results in trials where a relatively small number of diagnostic studies come from any one particular site. As a side effect, this process creates an operational challenge for the sites submitting studies, as well as for the researcher to managing their receipt and distribution.

There are four significant hurdles in the process:

1. *Non-standard DICOM formats.* While DICOM is the standard for digital imaging, there are major incompatibilities across vendor PACS. Since one cannot expect every site in a trial to have or deploy the same PACS, the receipt of images generated from a multitude of vendor systems is expensive and fraught with errors.
2. *Difficulty of integration with workflow at participating sites.* In almost all cases, the primary function of the remote site is patient care: the creation and shipping of hard media is never part of a site's every day operation. The harder it is to submit studies to the core lab, the less appealing it is to participate in a study.
3. *High cost of trial delays.* There are two types of costs involved in sending image data for clinical trials. The first is with a study that lasts longer than planned, causing budget overruns and impacting go-to-market strategies. A second type of cost is associated with a researcher's inability to adjust the

overall study program and protocols in a timely manner, based on findings obtained from ongoing results. Sending studies and resending them in the event of errors, or adjustments, needs to be a rapid (and rapidly repeatable) process.

4. *Difficulty of establishing traditional, direct network connections.* Even without the “non-standard DICOM” issues described above, it is problematic to establish network connections between participating locations and the research center using traditional means, such as IEEE/IEC defined Virtual Private Networks (VPNs) and dedicated network bandwidth (e.g. point-to-point T1s or T3s). The management of a concurrent multi-vendor firewall and VPN environment is expensive, and due to the large number of sites and relatively small number of studies from any particular site, sponsors cannot see the return on that infrastructure investment and, therefore, avoid it.

Given these realities, the clinical trials market has been forced to use either manual generation of physical media, which is then couriered to the research site, or *ad hoc* network solutions, such as VPNs or File Transfer Protocol (FTP).

1. *Courier Services.* Whether the studies are transferred to film or to CD/DVD, it involves many expensive steps—from creating and labeling the media, getting the right mailer, receiving the media, opening and retrieving the content and sending it to the proper repository. Missing any one of them has a ripple effect on every subsequent operation.
2. *Ad Hoc Network Solutions.* In some cases, trial managers or sending institutions would like to use a basic electronic transfer mechanism to send or receive study data. Special purpose file transfer protocols based on FTP are used when hospital networks, firewalls and policies allow it. Alternatively, the IT departments may develop a VPN connection between the locations. In these cases, the steps necessary to send patient data do not require the use of mailers or the creation of special media. Those requirements are replaced by a need for resources to set up and manage the connectivity. Sites running or participating in multiple studies and trials will create significant overhead for the studies, as well as their local support resources.

While each provides limited benefits in terms of ease of use (courier) and transfer time (network), neither provide the overall, efficient exchange of studies that is desirable for the management clinical research.

Distribution of Studies to Interpreters

Once the studies are stored in the central repository, researchers and interpreters need to access the images for analysis. More often than not, it is necessary to perform this work on source-quality studies identical to those generated by the modality and not on copies degraded by lossy compression. Trial managers are then faced with the challenge of how to provide investigators access to the studies.

Given the constraints of image size, resolution and data confidentiality, transmission options have been limited and typically require that investigators, and others interested in the data, be present at a central location where specialized access to the repository has been arranged. The restrictions imposed by this requirement are exacerbated by the difficulty in scheduling study interpreters to travel to the central

location. Alternatively, studies can be couriered, or specialized network connections established, with the same aforementioned costs and limitations.

Clinical Trials and AG Mednet

The extensive reach of the AG Mednet diagnostic imaging exchange network eliminates the aforementioned obstacles. In addition, clinical trials are complex and time-intensive enough without worrying about the logistics around collecting studies. During Phase II and III clinical trials, hundreds of scans can be submitted daily and their interpretation is often delayed due to outdated or unreliable transmission procedures.

With AG Mednet, pharmaceutical, bio-tech, device and clinical research organizations that utilize imaging technology have added flexibility in protocol design, enhanced workflow integration and site compliance, and efficient transport management, all leading to faster trials at lower cost.

With AG Mednet, clinical trials benefit from:

- Delivery of secure, lossless digital images, 24/7/365, directly to trial repositories anywhere in just minutes.
- Faster, easier access to images and expert interpretation that is far less costly than traditional shipping methods or web-based solutions.
- Faster site setup worldwide.
- Integrated workflow between sending sites and trial repositories.
- Streamlined processes and state-of-the-art technology that does not require capital investment, training or IT administration.
- Easy access to hospitals and radiologists in the trial community for the secure and reliable exchange of diagnostic images.

AG Mednet applies proven telecom principles and patent-pending technologies to deliver a multi-fold increase in image delivery performance and ease of use for clinical trial settings, regardless of the type of modality, PACS or DICOM reader. AG Mednet’s private 10 Gigabit nationwide network meets any scan volume and performance requirements, and is actively monitored and supported 24/7/365.

Capabilities	AG Mednet	Courier Services	AdHoc Network
Fits within existing workflow	✓	✗	✗
Low cost	✓	✗	✓
Easy to deploy at remote site	✓	✓	✗
Easy to deploy at receiving side	✓	✗	✗
Directly from sender to repository	✓	✗	✗
Single send to concurrent recipients	✓	✗	✗

Case Study: SPARC Trial Increases Efficiency and Reduces Burdens

Previously, clinical trials utilizing images as part of the study protocol relied upon traditional mail and delivery services, as well as exchanged images using computer discs, CDs and non-DICOM file transfer protocols. This traditional approach is not only costly and labor-intensive, but can significantly delay the completion of clinical

trials due to slow delivery times, human error and hardware/software incompatibilities.

Clinical trial settings of all sizes have adopted the AG Mednet network to ensure improved delivery of flawless images.

The Study of Myocardial Perfusion and Coronary Anatomy Imaging Roles in Coronary Artery Disease (CAD)—also known as the SPARC trial—is a wide-reaching clinical trial that will enroll approximately 3,700 patients with, and without, a history of CAD who are being referred for routine clinical studies to one of four noninvasive imaging arms (stress SPECT, stress PET or PET/CT, or CTA). The SPARC trial is being conducted by some of the world’s most prominent imaging hospitals and centers, including Brigham and Women’s, Massachusetts General Hospital, The Mayo Clinic, Mount Sinai, New York University Medical Center, Yale University, The Cleveland Clinic and The University of Florida at Jacksonville.

SPARC is using AG Mednet’s diagnostic imaging exchange network to securely and rapidly exchange DICOM images and studies for the comprehensive 40-site clinical trial. SPARC selected AG Mednet to ensure the efficient transfer of studies between locations and the SPARC image repository, as well as to minimize the burden imposed on the different participating institutions.

“We chose AG Mednet in part because of its improved speed, efficiency, strong security model and, in particular, because it does not require any of our participating sites to add out-of-workflow steps in their everyday schedules,” said Dr. Marcelo DiCarli, chief of nuclear medicine at Brigham and Women’s Hospital and associate professor of radiology at Harvard Medical School. “There are other key advantages that made AG Mednet the perfect choice for our trial—all SPARC studies are encrypted and secure without requiring VPNs, and installation at our trial sites was simple, requiring little, if any, IT support.”

Since early 2007, SPARC sites across the U.S. and Canada have been producing and exchanging significant numbers of PET/CT and CTAs with many thousands of images, ranging to more than 10,000 in a single study. AG Mednet easily, seamlessly and efficiently handles these high volume transfers without the clinical study’s participants deviating from their daily clinical workflow, or having to spend time creating and mailing CDs or using primitive file transfer methods.

For more information please visit www.agmednet.com or call 1-888-9-AGMEDNET.