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Hill, PA

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Denver, CO
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18th Annual Partnerships with CROs
April 28-30
Rosen Shingle Creek Hotel, Orlando
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61st AAN Annual Meeting
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Extracting Greater Efficiency From Clinical Trial Processes

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Extracting greater efficiency from clinical trial processes can have tangible and significant benefits to sponsors, core labs and investigator sites alike. In the case of imaging intensive trials, an important source of increased productivity is embodied in the image workflow. This starts at the modality, where the images are created, and continues all the way to populating trial repositories used to complete the necessary analysis of the trial data. If we can see this as a continuous workflow, as opposed to three discreet steps—image acquisition and burning of media; shipping of media and extraction of data; initial data QA and queuing of cases for analysis—opportunities abound to reduce time, queries and cost for all parties involved.

Until now, linking the workflow steps carried out by the three principal actors (i.e., investigator sites, courier companies and core labs) was close to impossible. All their individual systems are focused on local, internal efficiencies, without regard to the next or previous steps in the overall process. For example, FedEx is not “aware” when images were taken, whether transmittal forms are correctly filled or whether the slice thickness of the exam meet the protocol standards. By the same token, until the data has arrived at their facility and has been processed, a core lab is not aware that it will receive data which has not been properly de-identified or that the exam sent does not correspond to the requirement defined in the trial protocol. All of these are only examples of the myriad of issues that arise in the image-gathering process, all of which generate numerous queries, increases the QA process load and give rise to the cost and time it takes to close a trial database.

Recently, a powerful platform has become available that links site, data transfer and core lab workflows. **AG Mednet's** Diagnostic Imaging Network provides a top down view to trial managers, and through its embedded tools, is able to reduce the number of queries and time it takes for submitted images to be analyzed. Bio-Imaging has been at the forefront in adopting this platform and has embed it into its data acquisition processes. From the start, we have begun to see important benefits for our sponsors in three areas:

1. **Data Integrity:** The simple, web-enabled site interface to **AG Mednet** provides a powerful exam de-identification capability, as well as an electronic transmittal form, both of which are configurable by trial. These capabilities have powerful validation mechanisms which guide CRAs, and ensures that all necessary data is entered, and all entered data is within proper parameters. The system can also perform remote database queries which can be used to give CRAs visibility into the subset of parameters they need to fill a form, thus pruning data entry options and simplifying the data entry processes. This functionality ensures that exams are properly anonymized before submission and double data entry is eliminated, putting an end to most queries related to data integrity.
2. **Data Submission:** **AG Mednet** has a global telecommunications infrastructure used to transfer images and ancillary data from sites to trial repositories. For the first time, the capability is based on a

far reaching network and not the old file transfer protocols that failed in the past. A very tangible benefit of the platform is the transfer efficiency, as eligibility trials are suddenly closer at hand. In addition to the speed of delivery, the network is monitored 24/7/365 by a Network Operating Center which ensures that data transfers occur efficiently at all times.

3. Alerts, Notifications And Delivery: Another advantage of the imaging network is its capability to provide real-time notifications of events, such as when an exam was sent or when it arrived at the core lab. Email-based notifications can be sent to multiple interested parties, including submitting sites, trial managers and monitors. Additionally, notifications can be delivered directly to other systems, such as those used by core labs, to trigger internal workflows. While images are delivered directly into the Bio-Imaging repositories, transmittal form data, as well as data elements found in the image meta-data files, can be delivered directly to other data systems. This reduces redundant data entry and any mistakes that can happen when data is re-keyed.

The use of the largest imaging network is proving to be a great development that will improve clinical data management efficiency. The service is easy to deploy and can be operated globally by any staff member at the investigator site. There is minimal or no training required. The platform has been validated for Part 11 and GxP compliance. Its architecture has been designed from the start to be extensible in a variety of ways and Bio-Imaging is already considering the possibility of adding new quality assurance functions to reduce even more the number of queries to sites. This will go a very long way towards better, faster and less expensive image-intensive clinical trials.

[Bio-Imaging announced a partnership with AG Mednet](#) in December 2008.

This partnership offers a complete imaging solution for clinical trials that enhances trial efficiency and data quality. The unique solution from Bio-Imaging offers a completely electronic process from the site to your trial database and is available immediately. If you would like more information, please [contact](#) your Bio-Imaging Business Development Representative.