DICOM GRID

Streamlining Electronic Transfer in Image-Based Clinical Trials

A primer for Contract Research Organizations, Pharmaceutical Companies and Academic Research Organizations

How to cut costs, improve delivery time, and reduce human coding errors with cloud-based image eTransfer technology.

DG Suite is the most affordable eTransfer solution on the market. Decrease clinical trial delays, cut costs and reach critical go-or-no-godecisions faster by, improving delivery speed, and reducing human coding errors.

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BENEFITS

- Easy CD Upload Process
- Real-Time Image Transfer
- Centralize Trial Management
- 24/7 Access to Data
- Configurable Workflows
- Workflow Automation
- Customizable Fields
- HIPAA and 21 CFR 11 Compliant

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Introduction

As medical imaging increasingly becomes a major tool in clinical trials, many CROs and other research organizations have turned to cloud-based solutions to streamline the electronic transfer of images between data acquisition sites and research sites. By reading this eBook you will learn how cloud applications differ from the traditional methods used to transfer medical images. You will also learn about the benefits of switching to the cloud, which include cost savings, faster delivery of images, and reductions in human coding errors. Throughout the eBook you will gain tips and insights about what to look for in regards to features, price, and delivery speed when seeking the ideal cloud-based eTransfer vendor for your CRO.

CHAPTER 1:

WHY IS IMAGE TRANSFER DIFFICULT

In this digitally savvy age, it is surprising that antiquated technology for image transfer is often employed by even the most cutting edge organizations. The complex nature of image file formats combined with increasing image volumes and security concerns makes the process of transporting images difficult. The challenges are exacerbated in a multi-site setting, where the choreography needed to move data from disparate locations and into a centralized repository can be especially tricky. These obstacles have caused a big data problem.

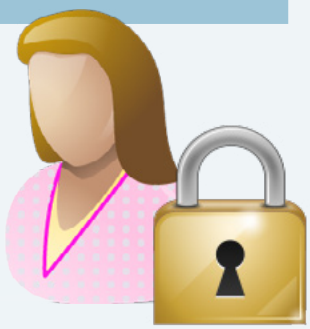
FILE FORMATS

Exchanging medical images is complex due to the extremely large size of these files. As a result, the digital transfer of images can be a daunting and slow process that strains a network and requires an extremely large download window.

DICOM (Digital Imaging and Communications in Medicine) is a core standard for handling, storing, printing, and transmitting information in medical imaging and is the way most medical images are obtained for use in clinical trials. Despite being a universally accepted format among imaging equipment, vendors, and healthcare IT vendors, this standard does have limitations. This format alone is not entirely conducive to image transportation and interoperability. Other standards are often layered on top of DICOM to improve the way systems in healthcare can share medical imaging information.

Non-DICOM images and materials also complicate the way in which imaging data has to be managed. One question confronting researchers is what is the best way to harmonize the different data formats. Options include wrapping other objects in DICOM so that one consistent standard can be used for storage and searching.

SUBJECT PRIVACY



The relationships between patients, investigators, sponsors, and CRO's are governed by a variety of documents and regulations that outline subject privacy, such as patient informed consents, research protocols, and contractual arrangements. Appropriate safeguards protect the privacy of personal health information, and set limits and conditions on the uses and disclosures that may be made of such information without patient authorization. In the case of clinical research, three types of data are allowed to be exchanged for research: identified data with patient authorization, limited data with data use agreement, and de-identified data. In addition, there are strict procedures set by both regulators and commercial contract for how and where data needs to be de-identified.

INTELLECTUAL PROPERTY

Academic institutions and their affiliated investigators are encountering a rapidly changing research environment, in which larger numbers of researchers and universities are competing for increasingly limited government, research trust and industry funding [1]. Keeping data private is often a top concern for parties involved in the research process. In order to protect intellectual property, researchers seek ways to control access and visibility of the image data.

1 Canadian Institutes of Health Research Evaluation Unit:
Evaluation of the open operating grant program - final report 2012.
http://www.cihr-irsc.gc.ca/e/45846.html

INCREASE IN IMAGE VOLUMES

Historically, the use of imaging in clinical trials took a back seat to other forms of data (labs, clinical exams etc). Today, medical imaging in clinical trials continues to grow as 1) advances in diagnostic imaging aid in the early go-or-no-go decisions in new pharmaceutical/ biotech product development and 2) the FDA pushes for the use of imaging. As the amount of imaging data being collected increases in volume and complexity, the demand for streamlined image transferring methods becomes apparent.

MANY ACQUISITION SITES WITH LOW VOLUME PER SITE

Another important characteristic is that it is extremely difficult to find subjects to participate in trials. Often the search is global and any given imaging center or research center will only contribute a small number of studies over a long period of time. Given this, it is impractical to install any expensive systems in a given center. It also makes it important to be flexible and agile to accommodate sites that locate and enroll participants.

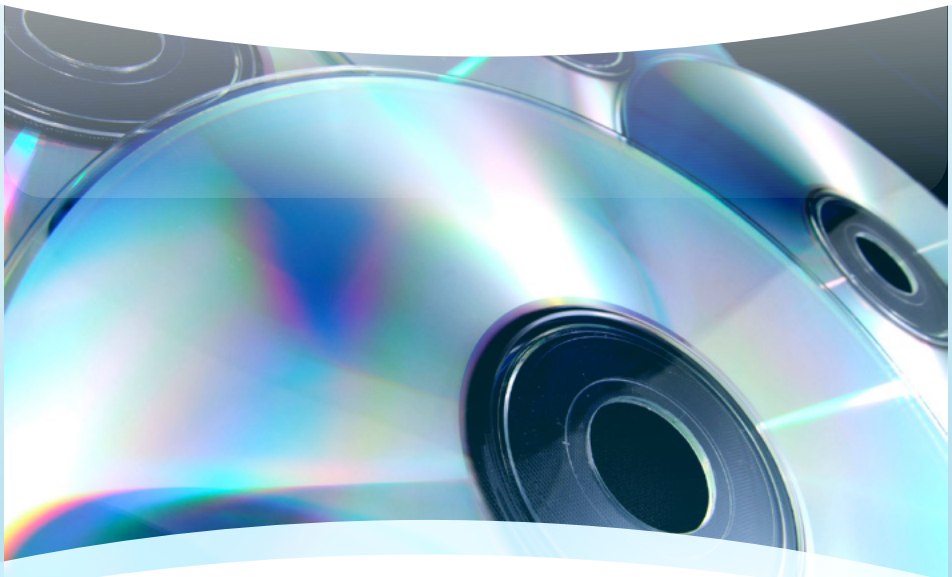
CHAPTER 2:

THE PITFALLS OF TRADITIONAL METHODS FOR IMAGE TRANSPORT

Two common methods used to transfer time points in image-based research are physical media and VPNs.

METHOD 1: PHYSICAL MEDIA

The transfer process using physical media begins by burning the images onto a CD ROM. The CD ROM is then mailed from the acquisition site to the central analysis site. This process has several disadvantages, including the cost associated with using courier services and lengthy delivery times.



PHYSICAL MEDIA PITFALSS

- Scenario 1: Personnel forgets to burn supporting PDF reports onto CD. It takes days to realize CD's content is incomplete. A new CD is burned and sent.
- Scenario 2: CD arrives at the central analysis site and is either scratched or unreadable. A new CD is burned and sent.
- Scenario 3: CD does not arrive to delivery site because it was delivered to the wrong address. Time is spent trying to recover the lost CD. A new CD is burned and sent.

METHOD 2: VPNS

In comparison to CDs, VPNs (Virtual Private Networks) offer a more sophisticated solution for communication between the acquisition site and the central analysis site. However, the design and security implementation for a VPN can be complicated and typically require an IT professional to properly configure and maintain. Reliability can also be an issue. Since VPNs are often remotely contracted, server downtime is not under the user's direct control. Most importantly, VPNs are too costly and complex for most multi-site trials. In large-scale trials, where images are acquired from many sources, the VPN method is impractical, especially if a low number of time points are being collected from each acquisition site.

CHAPTER 3:

HOW DOES CLOUD-BASED ETRANSFER WORK

Cloud-based eTransfer is the process of exchanging images using nothing more than Internet access. Authorized personnel can access the service to transport images at anytime, and from any location.

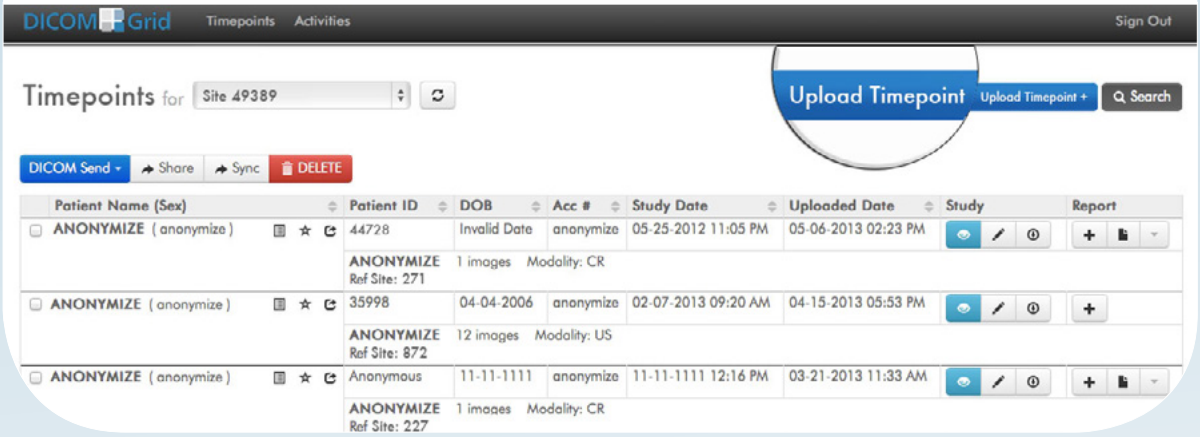
There are two basic ways to transfer images over the Internet. The most basic way is to transfer images from CD, using a Web browser, and then transfer these time points over the Internet to the end destination. The advantage of this methodology is that you can transfer with only a browser and the CD. Images are uploaded from a CD onto a medical image exchange platform where they can be transferred to the Core Lab or CRO online. Images can only be viewed within that system and are not publicly available.

The other method, which eliminates the need to burn a CD, is to enable a software agent to sit on the network of the sending site. Unlike a VPN or a hardware solution, this requires no investment and is similar to enabling a live meeting application or similar small download. This type of gateway approach enables a direct machine-to-machine transfer, so that modalities can send time points directly to the destination site. The set up is no more difficult than other common Web applications.

DG Suite, a cloud-based medical image exchange platform, is the most affordable eTransfer solution on the market. Project managers and site coordinators can streamline the image transfer process and centrally manage the exchange of time points in image-based clinical research using the capabilities outlined in the following pages.

IMAGE UPLOAD TOOL

An image upload tool supports easy Web uploading of images from CDs. The image upload tool guides the investigator through a simple upload process that leverages standard browser technology. In scenarios where high volumes of images need to be transferred, a bulk CD upload tool can be used to rapidly ingest the contents of CDs.



GATEWAY

A gateway is an easy to download and install Windows application that sits on the network of the study site. The gateway enables the acquiring site to transfer time points without burning a CD. Moreover, unlike a VPN or hardware solution, there is no hardware or ongoing cost of maintaining a VPN.

ONLINE IMAGE TRANSFER CAPABILITIES

After a user uploads the contents of the CD onto the system, the images will be automatically routed to the proper destination or central repository based on preconfigured criteria. Project managers or personnel with advanced access to the system can manually transfer images to additional destinations as needed.

CENTRALIZED IMAGE-BASED TRIAL MANAGEMENT

A key benefit of using a medical image exchange platform like DG Suite for eTransfer is the ability to centrally manage the transfer process of numerous trials from one dashboard. A CRO project manager who is responsible for overseeing several trials at one time can easily track the status of each image-based study. Real-time access to reporting provides product managers with a play-by-play or snap shot of trial progress by site.

CHAPTER 4:

BENEFITS OF ETRANSFER IN THE CLOUD

Cloud-based transport is faster, more reliable, and less expensive than courier or alternative electronic methods such as VPNs. In using eTransfer, CROs can decrease clinical trial delays and reach critical go-or-no-go-decisions faster by cutting costs, improving delivery time, and reducing human coding errors.

CUT COSTS

With the financial pressures that researches are facing, many CROs are looking for ways to reduce costs. The traditional methods used to transfer images are expensive. In moving to the cloud, courier charges are completely eliminated. Cloud-based eTransfer employs a SaaS (Software-as-a-Service) business model. With this type of service, there is no hardware to purchase or investments in infrastructure. Users are only charged a one-time fee per trial and small payment per image set uploaded onto the system.

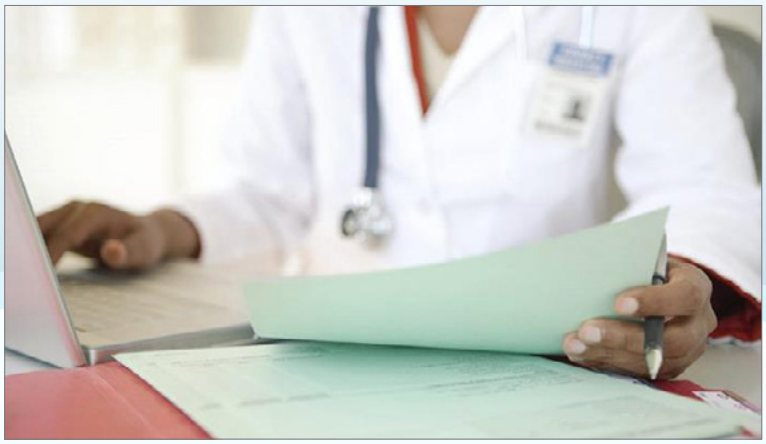
IMPROVE DELIVERY TIME

Sending physical media by snail mail can take days. Cloud-based eTransfer occurs in real-time. It takes under five minutes on average to upload a 100 mb set of radiology images. If any issues are noticed, investigators can be notified right away and the issues can be resolved quickly. For example, if the central analysis site receives an incomplete image set, rather than requesting a modified CD be resent via mail, the amendment can be attached to the image set in minutes with just a few clicks of a mouse.

REDUCE HUMAN CODING ERRORS

Minimizing manual data entry as much as possible helps to reduce errors caused by human miscoding. DG Suite achieves this in two ways.

- Prepopulating the correct values in the de-identification process
- Replacing (without human intervention) tags for which constants for the site or trial can be used



CHAPTER 5:

OVERCOMING ETRANSFER CHALLENGES WITH CLOUD-BASED TECHNOLOGY

In chapter one we outlined why image transfer is a difficult. In this chapter, you will learn how cloud-based technology tackles those challenges to simplify the electronic transport of images.

Overcoming Security Challenges: Addressing Data Integrity and Patient De-identification

DATA INTEGRITY

One of the most secure methods of exchanging patient data in the cloud is split-merge technology. This technology anonymizes image studies by removing protected health information (PHI) from the imaging data. The protected health information is then separately encrypted and stored, creating an Internet-safe image.

PATIENT DE-IDENTIFICATION

A process called patient de-identification, which involves making fundamental changes to the data content to remove any patient identifying information, must be made prior to an image transfer. De-identification typically involves the complete removal of any identifying information. This is straightforward and involves removing DICOM headers that reveal patient names, ID, study date, and any other patient health information. DG Suite removes over 250 DICOM tags locally before the time point leaves the sending computer.

21 CFR 11

Title 21 CFR Part 11 of the Code of Federal Regulations deals with the United States Food and Drug Administration (FDA) guidelines and is the de facto standard requirement by leading pharmaceutical companies for eTransfer vendors. You want to work with a partner that has appropriate processes and process controls so that the transfer of time points happens dependably and without surprises. It's important for CROs to partner with a company that adheres to this standard.

User Access Control: Addressing Authorization and Roles-Based Access

AUTHORIZATION

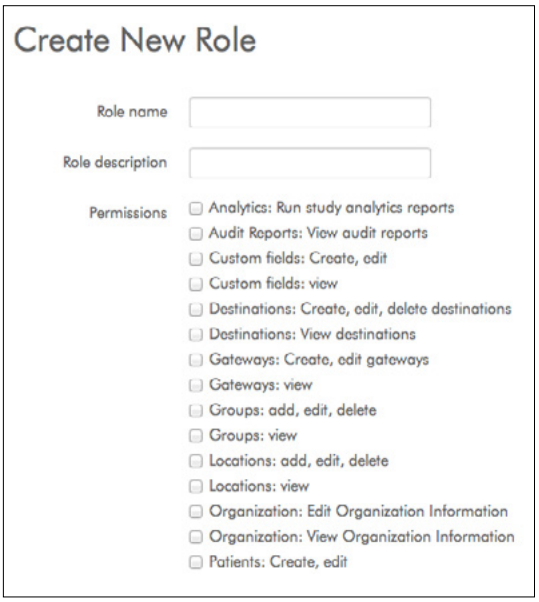
It is important to secure access to the system and to secure the levels of access users have to the imaging data on the system. User authentication methods are put in place to identify the user and verify that the user is allowed to access the eTransfer service. DG Suite leverages the latest in user authentication technology, including session expiration and timeout policies.

ROLES-BASED ACCESS

Once a user is signed into the system, administrative settings control user access to the data and tools in the application. This approach is referred to as role-based access control. System administrators can allow, disallow, or partially allow users the ability to access data on the system and tools within the system.

For example, a researcher whose task is to upload CDs may have limited access privileges, while a project manager may have greater access to system features and data.

DG Suite makes it easy to create users and assign roles to these users. Each role is defined by a set of access permissions (using check boxes like the ones featured in the right image).



Improving Workflow: Addressing Configurable Workflows and Customizations

ROUTING RULES AND AUTOMATED WORKFLOW

The ability to automate the image distribution process is extremely valuable and offers a level of control you won't get with traditional methods of transferring. Site coordinators and investigators may be involved in several trials from various sponsors, each requiring different types of submission to imaging core labs. Some of these trials can span many years. Expecting site coordinators and investigators to remember dozens of submission steps from visit to visit is not always reasonable. It is important to have a smart workflow-based platform that helps eliminate the need for the sender to make manual submissions. Automated routing rules are another key to guarantee images are getting to the proper location based on a certain set of criteria.

With technology like automated routing rules, studies can automatically be pushed into the image management system. Routing rules ensure the appropriate images are being forward to the correct location, while simultaneously unburdening personnel with the monotonous task of manually forwarding images through the system.

CUSTOM FIELDS

Every trial is different and often requires unique descriptors or customized fields to help track data (customizations include unique site numbers, subject number, visit description etc.). System administrators can add custom fields to the image upload process. Corresponding descriptions or responses can automatically be mapped to the DICOM tags within the time point. Without cloud-based eTransfer technology, the process of writing out each response or description and assigning it to the proper image can be very manual.

NOTIFICATIONS

With cloud-based eTransfer, senders, core labs and sponsors can be alerted via automated notifications whenever a submission is made.

CONCLUSION AND RESOURCES

In this eBook, we outlined the challenges organizations in a research setting face when trying to move medical images from disparate locations. We covered the pitfalls of traditional image transferring methods commonly used in clinical research and presented ways to avoid the pitfalls by moving to the cloud. Lastly, we discussed how investigators, sponsors, and CRO's are cutting costs and reducing image delivery time by eliminating the use of courier services and VPNs.

If you are interested in learning more about how you can streamline your image transfer process, contact a DICOM Grid image exchange specialist.

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