BIOCLINICA

DICOM DE-IDENTIFICATION:
Using the right tool for the job

A Bioclinica White Paper

bioclinica.com/contact

DICOM DE-IDENTIFICATION: USING THE RIGHT TOOL FOR THE JOB

Summary: The main objectives of this document are to (i) inform research sites why relying on in-house de-identification methods can be problematic and, (ii) explain how the use of professional services can assist in conformance to de-identification standards.

De-identification of a DICOM image is not as simple as removing patient names or birth dates. In order to meet regulatory requirements as well as ensure data integrity, proper de-identification methods must be employed. The process of de-identification is complicated by DICOMs large file size, complexity and fragility – and as a result contains many pitfalls. Incorrect or incomplete de-identification will lead to repeated rejection of your images by core labs, but it could also lead to incorrect patient treatment due to identity mix-ups.

Incomplete de-identification: There are dozens of patient identifiers in the DICOM tags of every DICOM file – and the average DICOM has 1,000 to 10,000 files. Often, the identifiers are burned directly into the images themselves. By using in-house de-identification methods that only remove the obvious identifiers on the surface, all other levels of identifiers are left intact. During a recent project Bioclinica received 12,000 DICOM cases which were believed to have been properly de-identified using 'in-house de-identification" by the site or core lab, less than 20 of these 12,000 cases had been properly de-identified.

Corruption due to de-identification: Research sites often attempt de-identification using their DICOM workstations, 3rd party software, or even PACS. Bioclinica analytics show that this approach results in a 6-fold increased risk of your images being rejected for image quality issues.

Unsanctioned tools commonly cause incomplete de-ientification as well as create the following issues:

- Obscuring important anatomical regions of the image
- Creating imperceptible image quality issues on the local machine that are only detectable at the core lab
- Complete case corruption
- Accidental truncating of the case (this is especially problematic as the lab might not know that the additional images ever existed).

The other major pitfall using in-house de-identification is that these methods typically fail to meet FDA and other health authority regulations. The regulations require that all data modifications generate an unalterable audit trail. Bioclinica's de-identification software has been validated under FDA requirements and generates an unalterable audit trail at all times.

Premature or over de-identification: If you are generating a file for teaching, then simply anonymizing the case is fine for that purpose. However, for submission of clinical data to a regulated clinical trial the proper labeling of the DICOM data is absolutely critical to the integrity of the trial data, as is ensuring the correct patient is receiving the correct trial intervention.

Over de-identification resulting in too much information being removed from the images prevents the lab from being able to effectively interpret the image. When this happens, the lab rejects the case and the site has to restart the entire image submission process.

The biggest concern about over de-identification is that it is very easy to get patient's images mixed up when working with multiple image data sets at the same time. By prematurely removing key identifiers from the case, Bioclinica, the imaging core lab and the sponsor do not have the ability to verify that the data you entered on the upload form really corresponds with the patient's images. By prematurely de-identifying the case, neither Bioclinica, the imaging core lab, nor the sponsor can that the image data you submitted is indeed associated with the subject stated in the upload form.

In 2014, Bioclinica has been alerted to a surprising number of instances where images were mixed-up due to pre-mature de-identification. This simple mistake is extremely dangerous as it could lead to incorrect patient treatment or death. Even with a low probability this is an unacceptable risk when a superior system exists.

DE-IDENTIFICATION USING SMART SUBMIT BY BIOCLINICA

SMART Submit is registered with the FDA, validated to FDA standards, and certified as fully HIPAA compliant.

Bioclinica guarantees 100% proper de-identification of all DICOM processed by SMART Submit. The research site simply loads the original DICOM into the application and enters the case trial identifiers, and SMART Submit handles the rest.

SMART Submit initially screens the case to ensure the correct imaging procedure, the correct trial, and the correct patient for the DICOM. It then checks file integrity as well as other known corruptions of DICOM images. When issues are uncovered, Bioclinica will query the site regarding the issue and then advise the research site on how to resolve the immediate problem as well as identify a fix for the underlying cause.

CONCLUSION

Unlike typical lab data in the form of text or numbers, working with DICOM can be complicated at times and is generally highly regulated. By relying on SMART Submit instead of in-house methods, research sites will reduce their data clarification rate to negligible levels and avoid potentially dangerous outcomes for the patient.