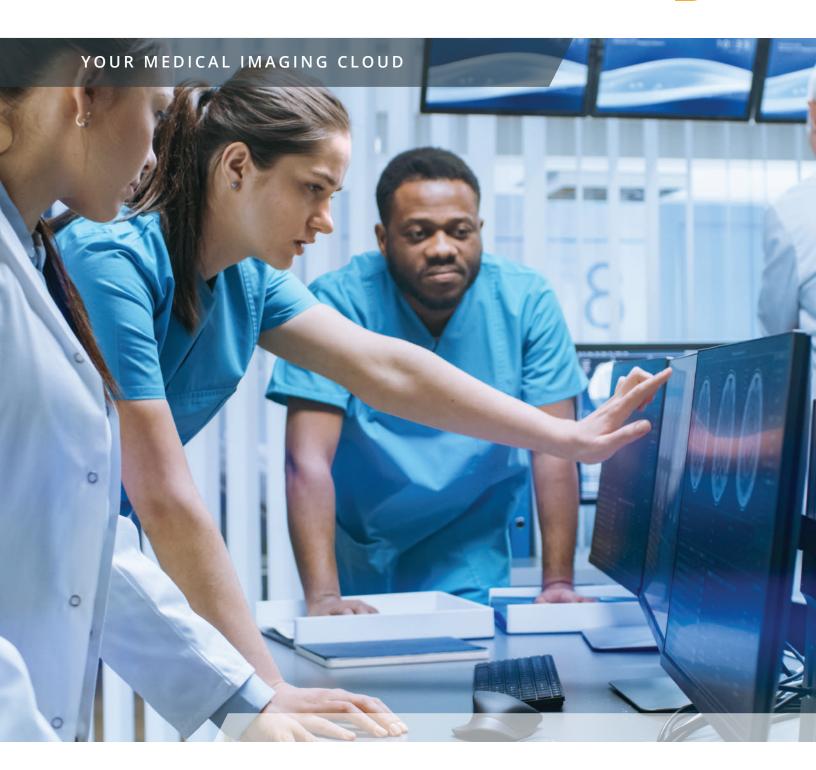
Δ MB Δ



EBOOK

Launching Research Initiatives in the Cloud



Introduction

The 21st Century Cures Act emphasizes a renewed focus on using real world data to power the decisions behind clinical trials. The FDA and Congress define real world data as, "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials." This idea was once unfathomable due to excessive data blocking. The 21st Century Cures Act seeks to remedy the practice of information blocking, which can be simply defined as healthcare technology companies restricting the ability to share information outside of their platforms. While progress remains to be made, the widespread adoption of FHIR as a new standard for information exchange has pushed vendors towards greater interoperability.

This data can be collected from a wide variety of sources ranging from electronic health records, billing data, surveys, and even mobile applications. Previously, the ability to collect and organize huge amounts of data was impossible, but today, machine learning and artificial intelligence tools make it possible.

Yet, imaging is often the forgotten piece of the puzzle in establishing a holistic patient health record. It is not possible to establish strong research programs without imaging, much of which may already be available in the real world due to screening programs. However, the organization and anonymization of imaging often act as a pitfall. Traditionally, medical imaging is still often exchanged on CDs leading to time wasted mailing CDs, uploading and burning, and manually entering patient information. The process is dangerously error-prone and often delays progress in trials due to the slow input of data. Variations in imaging viewing systems and radiology reporting can also cause inconsistent data.



Rapidly indexing through billions of images and data requires complex IT infrastructure. When looking for solutions, a facility must consider tooling that provides capabilities around searching for all relevant data and then appropriately anonymizing and de-identifying data, including the meta-data at the pixel level in the case of medical images.

Working together, vendors and facilities can establish strategies for gathering real-world evidence, including imaging and diverse data, successfully. The data can then be securely anonymized, shared, and even run through additional processing for the acceleration of clinical trials. The future of trials is bright, and we look forward to the patient care improvements that will be made along the way.



Why Cloud?

ELIMINATE RISK WITH ANONYMIZED STUDY HANDLING

The process of anonymizing and de-identification can be dangerously erroneous. Ambra Health's automation removes DICOM tags client-side before the study leaves the sending facility, eliminating the risk of accidentally leaving patient information tags in place. Ambra also has a pixel de-identification tool to even remove identifiable information from the DICOM itself.

Centrally managed and automated workflows enable studies to be routed to end destinations including local file directories, research repositories, third party viewers, and post-processing systems. Ambra's custom eCRF module supports configurable upload and reporting on necessary clinical information for a given project. Managing the flow of incoming studies from sending sites can be a daunting process, but Ambra seamlessly manages the process as incoming studies are routed through configurable workflows, and ultimately to your facility, with automated sharing to organizations, locations, groups, and users like QA personnel and investigators.

LAUNCH NEW RESEARCH PROJECTS QUICKLY

Ambra handles everything from quickly setting up individual research folders to large multi-site research trials. Facilities can customize timepoint fields, project users and roles, case report forms, and trial workflows. Imaging on CDs and on-premise archives can create significant risk from lost studies, errors, and unscheduled PACS downtime. Ambra's secure and scalable research Cloud PACS makes it simple to move all research data into one single repository for easy access and viewing.

CLOUD MEDICAL IMAGE VIEWING

The Ambra zero-footprint, web-based HTML5 DICOM Viewer is FDA 510(k) cleared per FDA regulations and can be used through any web browser. You can use Ambra's viewer for QA/QC review or for clinical review. Annotations done in Ambra's viewer can be mapped into case report forms for automatic calculations.

SCALABLE ARCHIVING AND SIMPLIFIED MIGRATIONS

Migrations can be expensive and time-consuming due to the size and complexity of DICOM data and associated reports. Ambra can provide a tailor-made migration offering for your institution with our cloud-based migration capabilities and experienced technical team. Non-DICOM imaging can be stored side-by-side with DICOM imaging for a holistic view of all patient imaging. Ambra provides flexibility to archive and retrieve all DICOM modalities including MR, CT, PET, CR, US, and MG, as well as many multimedia formats including JPEG, TIFF, PDF, DOC, DOCX, and TXT.



Key Features

AMBRA GATEWAY

The Ambra Gateway quickly and securely moves DICOM & HL7 data. The Gateway supports both push and pull workflows to transfer data from the source PACS/server.

DATA MANIPULATION

Ambra can manipulate the DICOM data during the migration using such tools as Dictionaries and tag morphing.

DATA VALIDATION

Validate data using most methodologies, such as SCP command support or Storage Commit, and on various criteria, such as study UID or DICOM data.

DRIVE CONNECTIVITY TO AL

Ambra Health's open API allows facilities to connect Ambra with their health care systems, build custom integrations, or develop innovative new tools. Ambra Health is proud to partner with a broad range of value-added partners who represent healthcare technology innovators and leaders plug into the Ambra platform. It's easier than ever to deploy an integrated application fabric that elevates healthcare efficiency and care. Organizations are also using Ambra to train and develop their own imaging AI algorithms.





Ambra Health is an AWS Partner Network (APN) Advanced Technology Partner. Amazon ElasticSearch Service enables Ambra to quickly index and search through billions of images and studies. Ambra also used Amazon Comprehend Medical and other neuro-linguistic programming (NLP) tools to extract medical information from unstructured reports.



Ambra Research for Academic Medical Centers

Data Intake

- Rapidly deploy new projects with the help of Ambra's responsive team.
- Seamlessly retrieve imaging and report data from PACS using the Ambra Gateway.
- → Allow outside sites to submit imaging using a web-based upload tool or the Ambra Gateway.

Data Clean-Up

Fully anonymize your data with Ambra's manual and automatic anonymization tools:

Anonymize...

- → DICOM tag values
- → DICOM pixel data
- → HL7 & scanned documents

Data Analysis

- → Provide researchers with a centralized repository of anonymized imaging and report data.
- → Grant appropriate access across projects to enable collaboration.
- → View imaging in Ambra's customizable zero footprint viewer.
- → Capture data in Ambra's reporting module with custom-built eCRFs.
- → Uncover deeper insights with Ambra's scripting platform.

Storage & Support



Store and manage your imaging-related research data in the cloud with flexible retention rules.



Export anonymized data sets to third party systems.



Receive 24/7 end-user support from Ambra's award-winning team.



CASE STUDY: HOW ONE ACADEMIC MEDICAL CENTER ELIMINATED CDS



"The Ambra cloud research PACS enables us to integrate our imaging research in a way that wasn't possible before."

ACHALA VAGAL, MD, MS

Vice Chair of Research Associate Professor of Radiology University of Cincinnati Medical Center

KEY METRICS



Study Upload & Anonymization Time Improved by:

3-5X



5 GATEWAYS

Installed for Enhanced Image Sharing

SUMMARY

UC Health is committed to advancing medical knowledge through clinical research. University of Cincinnati investigators have broad clinical research expertise and conduct NIH funded studies, industry sponsored studies, and phase I-IV clinical trials in nearly all therapeutic areas. The university also has an environment that is conducive for numerous investigator-initiated studies that can be retrospective or prospective in nature.

Medical imaging is a key part of a patient's health record and clinical trial workflows. These workflows are complex; they often involve hunting down imaging off a clinical PACS onsite, requesting imaging be sent from an outside facility, or, worse yet, waiting for imaging data disc to arrive by mail. This process can take anywhere from a few hours when imaging is onsite to days and weeks if imaging is mailed or brought by courier service from an outside facility. UC Health sought to automate their process of managing medical imaging for clinical trials and securely upload, anonymize, and match imaging data with non-imaging clinical data. Working with Ambra Health, they launched an academic research cloud PACS at their facility.

W Health.

OVERVIEW

- Leading academic medical research institution.
- Participant of several completed and ongoing multicenter regional, national, and international studies.
- Needed a streamlined system for uploading, securely accessing, storing, anonymizing imaging data, and sharing the data with other research collaborators.

CHALLENGES

- Legacy method of storing and accessing imaging was very time intensive.
- Mailing discs from other sites was not cost effective.
- Significant administrative burden on staff.

SOLUTION

- Cloud-based research PACS with multiple modes of secure upload.
- For regional studies, imaging is shared within and across different network gateways.
 These gateways are easy to install, and routing rules can be customized according to the needs of the study.
- Secure and consistent viewing experience for physicians including central readers.



Benefits with Ambra:

W Health.

NEW AUTOMATIC WORKFLOW

UC partnered with Ambra Health to electronically share imaging externally and internally. Internally, a lightweight piece of software called a gateway was installed to automatically send imaging from the clinical PACS to the research PACS.

Ambra handled everything from quickly setting up individual research folders to large multi-site research trials. The facility can now customize timepoint fields, project users and roles, case report forms, and trial workflows.

Ambra's automation provides the capability to remove patient health information (PHI) from the DICOM tags client-side before the study leaves the sending facility, eliminating the risk of accidentally leaving PHI tags in place.

Centrally managed and automated workflows enable studies to be routed to end destinations including local file directories, research repositories, and third-party viewers or post-processing systems. Incoming studies from outside sites are routed through configurable workflows with automated sharing to organizations, locations, groups, and users like QA personnel and investigators. Each project may have their own customizable electronic case report form (eCRF) that allowed the gathering of radiological data that can be later exported and linked to their associated clinical data.

SUCCESS ACROSS TRIALS

Assessing Population-based Radiological Brain Health in Stroke Epidemiology (APRISE) Study: This NIH funded population based study is focused on stroke recurrence in the greater Cincinnati area and utilizing imaging variables in addition to clinical and demographic data to build prediction models of recurrent stroke.

This is a large study with multiple clinical imaging studies that are being gathered from various facilities. Today, 5 gateways have been set up to automate sending of patient imaging from facilities in the area that are participating in this study.

OVERCOMING UNIQUE ANONYMIZATION CHALLENGES

One of the key challenges for APRISE during the deployment was conserving subject IDs of approximately 4000 patients from the parent study that has been going on for many decades. The parent study had all the clinical data that needed to be lined up with the imaging data from the study that was setup using Ambra. Ambra needed to create a custom workflow to conserve imaging IDs from the parent study, anonymize all the imaging data (CT, MR, CTA, MRA) coming in from numerous regional hospitals, collect all the radiological data generated by the radiologists from viewing the images, and export radiological data in a way that would allow lining up with the clinical data as specified by the statisticians of the parent study. Ambra was able to successfully configure a workflow that allowed seamless integration from multiple sites and made the imaging available for central interpretation.

66 Ambra's engineering team was able to setup an infrastructure and customize a workflow that met all the needs of a very complicated study."

VIVEK KHANDWALA PHD

Research Associate Department of Radiology University of Cincinnati



Ambra Research for Clinical Research Organizations

Data Intake

- Rapidly deploy large, multi-site trials with Ambra's cloud- based platform.
- Enable site users to submit imaging and report data using web-based upload tools.
- → Collect additional information about the Subject, Scan, and Visit from site users upon upload.



- → Anonymize DICOM tags and pixel data using manual and automatic tools.
- Modify DICOM tag values to match site number or subject ID.
- → Automate and enhance quality control checks with rules-based and Al-driven data validation.

Data Analysis

- → View imaging in Ambra's zero-footprint diagnostic viewer, equipped with dedicated tools for research.
- → Capture data in Ambra's reporting module with custom-built eCRFs.
- → Uncover deeper insights with Ambra's scripting platform and third-party Al tools.

Storage & Support



Provide flexible cloud storage options and data access to study sponsors.



Store and manage imaging in the cloud with flexible retention rules.



Export data at any time using Ambra's export and migration tools.



Receive 24/7 end-user support from Ambra's award-winning team.

About Ambra Health

Ambra Health is a medical data and image management SaaS company. Intuitive, flexible, scalable and highly interoperable, the Ambra cloud platform is designed to serve as the backbone of imaging innovation and progress for healthcare providers. It empowers some of the largest health systems such as Memorial Hermann and New England Baptist Hospital as well as radiology practices, subspecialty practices, and clinical research organizations to dramatically improve imaging and collaborative care workflows. As expert partners, we listen to our customers, understand their needs, and apply our extensive knowledge to deliver innovative medical image management solutions for the future of healthcare, now. Discover what the Ambra medical imaging cloud can do for you at ambrahealth.com.