Bring Complete Imaging Value to Your Clinical Trials

Introducing Synapse® VNA for Pharmaceutical Companies and Contract Research Organizations.

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Contents

1. Introduction: Realizing the Potential of Imaging Data

All phases of drug discovery, from early phase target identification to post-marketing activities, are increasingly reliant on imaging as the approved standard of care for tracking clinical trials. This trend is set to continue as new imaging techniques and combinations emerge, offering a non-invasive way to monitor disease progression and treatment efficacy. Medical imaging is used to measure everything from anatomical size and shape to nerve cell loss and tumor cell growth. As a result, the average clinical trial generates a multitude of image data types.

These images are tremendously valuable not only during the trial study period, but in a variety of use cases spanning drug development phases. However, because images are generated from multiple sources at various locations, the images and their corresponding data often end up in separate, siloed repositories. They're also often stored in proprietary formats with varying user interfaces. As a result, it is almost impossible to access imaging data in a logical format from one location.

A vendor-neutral archive (VNA) that is uniquely focused on clinical-trial images is critical for enabling fast, secure, and seamless access to specific imaging sets. Enhancing clinical trial research with a VNA allows pharmaceutical companies and contract research

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organizations (CROs) to have unfettered access to images and associated data while keeping the content's original security settings in place. This is especially critical when it comes to clinical trial submissions and similar imaging use cases. Synapse® VNA, from the TeraMedica Division of Fujifilm, was designed for this exact purpose.

2. The Challenge: Enabling Imaging Access, Wherever and Whenever Needed

Today's clinical trials are generating a multitude of image types and associated data. These range from images obtained through different specialties and imaging modalities (see Table 1) to the associated image metadata input into different databases or systems. This also includes data from more common resources, such as point-of-care ultrasounds and remote monitoring devices, as well as uncommon resources, such as optical coherence tomography (OCT) and fundus photography from ophthalmological indications.

Table 1.

SPECIALITY	Clinical Digital Objects Generated				COMMON TYPES
	DICOM	A/V, MPEG, WAV	JPEG, PDF	Other clinical	
Cardiology	√	√	√	√	VMR, CVCT, CV Cath, CVUS, CVECG/HOLTER/STRESS/PACE
Dermatology			√	√	Photos
Emergency Medicine	√	√	√	√	X-ray, CT, ECG
Endocrinology	√		√	√	SPECT/CT, PET CT
Gastroenterology	√	√	√		Barium X-ray, CT, NM, Endoscope
Nephrology	√	√	√	√	US, MR, Angiography, Scintigraphy
Neurology	√	√	√		Renal Scan, SPECT/CT, PET CT, Renogram
Nuclear Medicine	√	√	√		Bone Scan, Renal Scan
OB/GYN	√	√	√		X-ray, CT, US, Fetal Strips
Oncology	√		√	√	FOG-PET, CT, X-ray, Densitometry, Biograph Report
Ophthalmology	√	√	√		Ophthalmology Laser Image
Orthopaedics	√	√	√	√	Arthrography, X-ray, CT, MRI, Ultrasound, Bone Scan
Pathology	√	√	√		Digital and Scanned Pathology
Pulmonology	√	√		√	CT Gamma, SPECT, PET
Radiology	√	√	√	√	MR, CT, XR, US, NM
Rheumatology			√	√	US, MR
Surgery	√	√	√	√	In-department X-ray, Endoscope
Urology	√	√	√		MR, XR, Digital Fluoroscopy Report

All these images are generated from different locations, most of which rely on proprietary software. Images and associated data are then stored in a variety of places, from imaging platforms to external archives. Imagine the sheer volume of disparate data that is likely to be generated from, and associated with, the average multicenter, international clinical trial, all of which contains invaluable information for research, study planning, and training. While you may have the fundamental information from the primary data source, the actual images are no longer available after they are archived in a nonuseable format and locked away as “cold storage” by the imaging core lab or a local archive bank.

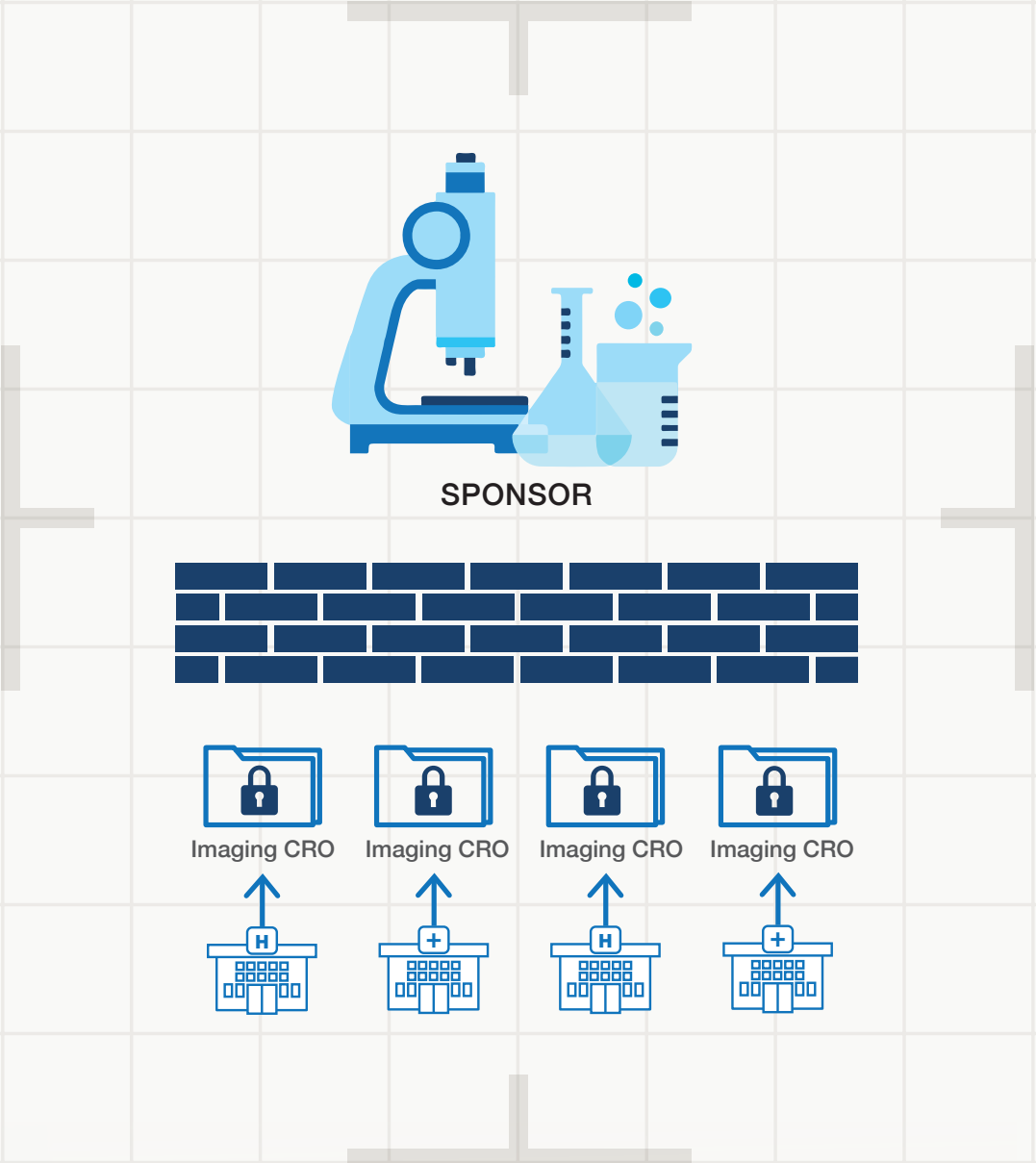


Figure 1.

One challenge is that most imaging systems used in clinical trials were not built to securely enable easy access to images from other systems, such as data analytics platforms, artificial intelligence programs, or marketing software. Most imaging platforms use proprietary software rather than universal standards-based software that can communicate with other programs. They are not designed to be vendor-agnostic or interoperable to work seamlessly with other software platforms (Figure 1).

There are also unique challenges surrounding the requirements for handling imaging data. In addition to ensuring that all equipment, platforms, and software that handle imaging data are FDA-compliant, there must also be a secure documentation and tracking system for data transfer. The data must be archived and managed in a way that creates an acceptable audit trail for sponsors and regulators to follow.

When you want to use your trial images for a specific purpose, such as further analysis or sharing with your trial participants, accessing those images is often impossible. Additionally, those images are highly unlikely to be usable in anything other than a flat file format. Even if you can locate the right images, you still may not have the necessary permissions to access them. You may also find that the original data format isn't fit-for-purpose. Altering the image to meet your specific needs runs the risk of potential interference with the original file formats or source materials, and risks jeopardizing the data's integrity.

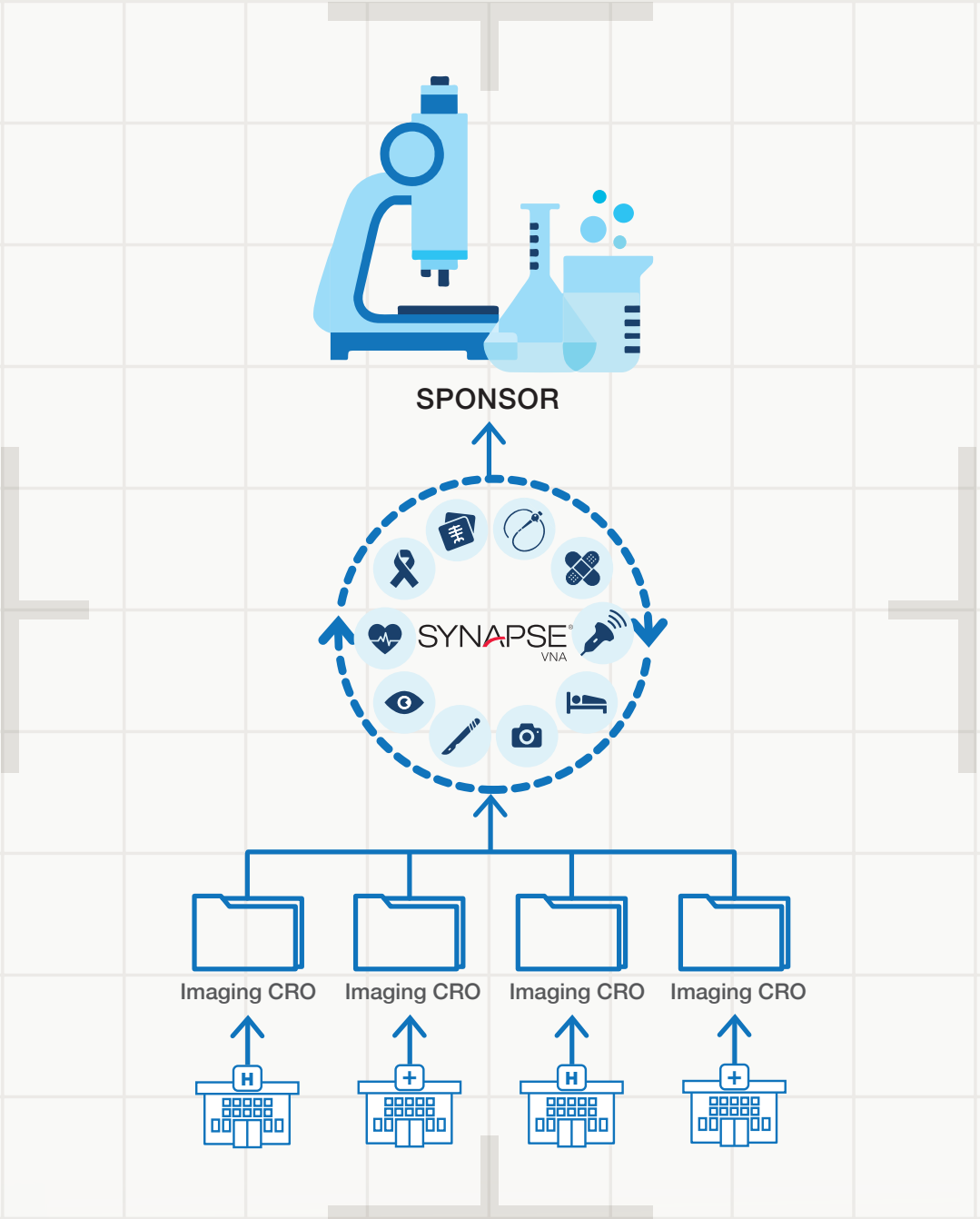
These are precisely the problems that Synapse VNA was designed to solve. Unlike other VNAs, Synapse VNA augments imaging platforms, facilitating access to any and all images and associated data, regardless of location, source, or format.

3. The Solution: A VNA for Clinical Trials

A VNA can automatically extract copies of images from electronic source systems and securely store them in their native (or core lab) formats so they are accessible through other software and systems. It is not a new imaging platform, nor a way of integrating existing technology. Instead, the VNA augments, rather than displaces, current image systems to provide comprehensive image access. It allows systems that are not interoperable to seamlessly work together using a variety of methods, including native APIs, HL7, XDS, FHIR, and RESTful web services. This ensures that you can connect quickly and easily to the systems of choice.

What Does a Great VNA Offer?

Not all tools that claim to allow access or integrate imaging data from different sources are created equal. Many are not truly vendor-agnostic, or may not have the scale required to deal with the immense variety and size of imaging data from today's large clinical studies. When choosing a VNA, the following criteria are essential:



- Standards-based and open
  - Communicates with other imaging and data systems, both source and receiving.
  - Uses industry standards rather than proprietary software.

- Future-thinking
  - Incorporates additional images from new sources in the future, or uses new analytical tools on existing images.
- Vendor and technology agnostic
  - Avoids locking you in to one imaging platform technology or vendor.
  - Allows you to add and change the systems connected to your VNA.
- Scalable and flexible architecture
  - Handles large amounts of data – including petabyte levels and beyond – as well as a wide variety of image types for true imaging interoperability.
    - Digital Imaging and Communications in Medicine (DICOM) standards support to promote interoperability.
    - Non-DICOM support for objects spanning a number of medical image modalities and their associated clinical information. Without this capability, the VNA can never be truly interoperable, as all non-DICOM data would need to be converted prior to use.
- Robust image-search capabilities
  - Searches archived data from past studies to find the exact image needed from the right study and the right participant.
  - Utilizes the image itself and its associated data to facilitate searching.
- 21CFR Part 11 and HIPAA compliant
  - Balances easy access with appropriate data security.
- Optimal setup – including network or cloud-based
  - Allows imaging access for small companies with a few people at the same site, as well as large international organizations with numerous people across multiple sites.

These criteria are a pre-requisite for ensuring images are accessible from any source and remain available for use, while still leaving the data itself unchanged.

4. The Impact: Enhancing Clinical Trial Research with Synapse VNA

Synapse VNA can help you find, review, and reuse images and associated data that are normally stored and locked away in siloes. In doing so, image accessibility is streamlined and simplified. But how can this benefit clinical trial research?

Derive more Value from Your Images

A VNA supports interrogation of data in a variety of new ways. For example, as more artificial intelligence (AI) algorithms are approved and made readily available, they have the opportunity to be applied to your trial images as well. Not only does this allow novel insights to be gleaned from existing image assets, it also allows future studies to be designed based on these new AI-driven findings.

Easy access to existing images also simplifies training for new readers. For example, the data from the original trial image analysis can help to inform clinicians and scientists on how to optimize treatments and study designs in the future. Unfortunately, having easy access to existing images is not always feasible for some VNAs. Instead, the images are often neglected, leaving this rich source of clinical information and education untapped.

With Synapse VNA, you will be able to extract more value from your imaging data. Discrete clinical data can be paired with images – delivering a comprehensive view of each patient's outcome. By augmenting real-world patient data that is pulled from electronic health records, wearables, and applications containing images, Synapse VNA investigates data linkages to reveal new and impactful findings. While this may not currently be part of your trial schema, the architecture is already available to you in the latest Synapse VNA technologies.

Easy Access and Search Capabilities

One of the key advantages of a VNA is the ability to seamlessly search all stored images and view them in the way that best suits your particular needs. Synapse VNA offers a zero-footprint, web-based viewer that allows users to access images from a wide variety of devices and browsers (Figure 2). The diagnostic-quality viewer enables users to view and manipulate diverse image types on a single screen, providing the unprecedented ability to "see" disease progression and

Figure 2.

therapeutic response. However, if you would prefer to use your own image viewing software, you have that option as well.

Images can be stored in a flexible and personalized hierarchy that is configured to meet your unique needs. This hierarchy can then be automatically streamed or manually downloaded. Synapse VNA's embedded workflow tools allow you to automate workflows and set up alerts notifying you when data is available. The viewing activity of each user is tracked in real time in the background, providing an audit trail that fulfills regulatory requirements for medical image handling.

Speedy Setup and Ongoing Support

Every day that you are unable to locate and access important imaging data risks a reduction in efficiency, an increase in cost, and a delay in your ongoing drug development. Because Synapse VNA augments rather than displaces existing systems, it can be up and running in weeks, not months or years, helping to streamline unfettered image access to fuel your clinical trial initiatives. Following implementation, you will be supported by a team of medical imaging informatics experts to ensure not only adoption, but also sustainment of the Synapse VNA platform.

5. Conclusion

Imaging is increasingly called upon throughout all phases of drug discovery. The advantages are well-documented, as it offers a non-invasive method for monitoring disease progression and treatment efficacy. As new modalities and combinations emerge, imaging will continue to play a major role in bringing new therapeutics to market. With this, it will be essential to easily locate and access all of the data assets generated from these imaging studies.

Synapse VNA from the TeraMedica Division of Fujifilm can help you access the right imaging data, from the right system, at the right time, and incorporates real-world data alongside your trial-acquired data to help enhance research efforts.

A number of factors must be considered when choosing the right VNA for your organization. It must be standards-based and open – a true vendor-agnostic system that supports interoperability. It also must be scalable and configurable to support your unique and evolving needs. Finally, it should balance ease of access with robust security and auditing capabilities. Not all VNAs are created equal, which is why you must consider the pedigree, expertise, and reputation of the vendor chosen to supports your clinical trial goals.

Synapse VNA is purpose-built to ensure you have the images you need, wherever they may be and whenever you may need them. The intuitive platform simplifies adoption, and when you do need support, a global team of imaging informatics experts is available 24/7, 365 days a year. More than a thousand research organizations, hospitals, and imaging organizations across six continents already trust Synapse VNA with capturing, storing, and managing all of their clinical images and content. Available as a cloud-based installation or an on-site implementation, Synapse VNA is fast and cost-effective way to ensure you have unsolicited access to the images you need to fuel your clinical trial initiatives.

To learn more, visit www.teramedica.com.

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TeraMedica®

FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421 (781) 323-5300
www.fujimed.com