

# TRIALSTAT



Learn how innovative life sciences companies are using powerful, integrated technologies such as TrialStat EDC, SimpleTrials, and Fuji Teramedica to manage their entire portfolio of studies in a cost-effective, scalable, dynamically linked ecosystem designed to overcome the complexities of today and future-proofing their investments for the challenges of tomorrow.



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EXHIBITING AT



**DIA** GLOBAL  
2020 ANNUAL  
MEETING  
JUNE 14-18

**LEVERAGING THE  
POWER OF  
INTEROPERABLE  
ECLINICAL  
TECHNOLOGY TO  
RUN EFFICIENT  
CLINICAL TRIALS**

# TRIALSTAT

## Agenda

- ✓ Introductions & Overview
- ✓ EDC
  - ✓ Panel Discussion
- ✓ Imaging In Clinical Trials
  - ✓ Panel Discussion
- ✓ CTMS
  - ✓ Panel Discussion
- ✓ Group Panel Discussion and Closing Remarks
- ✓ Wrap Up

**LEVERAGING THE  
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# Interoperable EDC Platform

**TRIALSTAT**



## Company Overview

- ✓ **Founded in 2003**
- ✓ **Offering:**
  - ✓ Electronic Data Capture – SaaS
  - ✓ Study Design & Validation
  - ✓ Project Management
  - ✓ Custom Validated Software Development
  - ✓ Designer Training & Certification

## Premium Features

- ✓ **Randomization / IWRS**
- ✓ **Medical Coding**
- ✓ **ePro**
- ✓ **eSource**
- ✓ **AE / SAE / MedWatch**
- ✓ **Real-Time Reporting & Analytics Portal**
- ✓ **Vendor Neutral Imaging Archive & Adjudication**
- ✓ **SimpleTrials CTMS**
- ✓ **3rd Party Systems Integration**

## All Phases of Product Development:



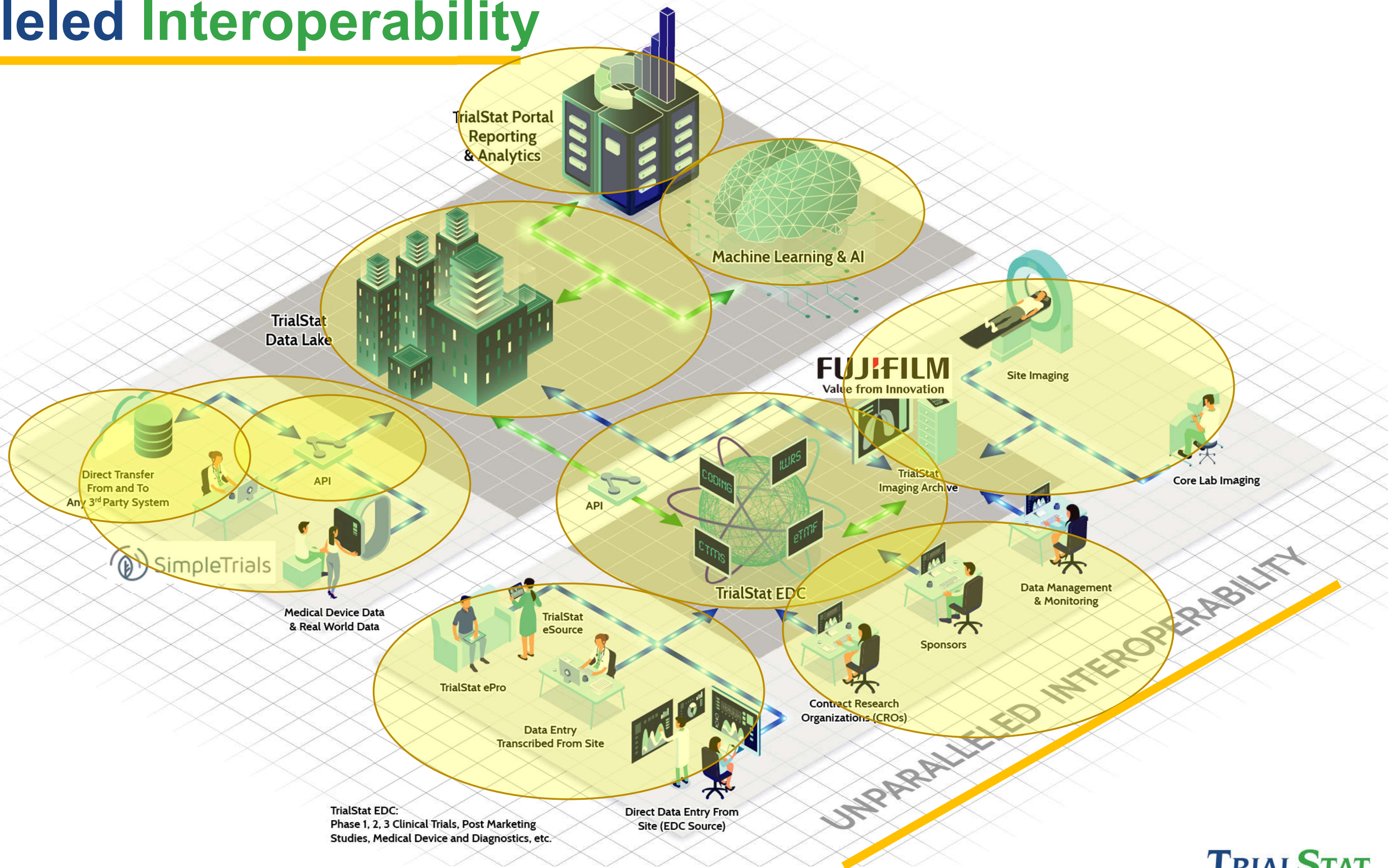
## International Capabilities:



*Engineering a New Generation of EDC Technology.*



# Unparalleled Interoperability



TrialStat EDC:  
Phase 1, 2, 3 Clinical Trials, Post Marketing  
Studies, Medical Device and Diagnostics, etc.

## Panel Discussion

**TRIALSTAT**

# Imaging In Clinical Trials

**FUJIFILM**  
Value from Innovation

 **TeraMedica**<sup>®</sup>



TERAMEDICA

The recognized leader in medical imaging **informatics and interoperability.**

- Focused on imaging interoperability and informatics for nearly 20 years.
- A division of Fujifilm, a company recognized as one of the world's most innovative.
- More than 1,000 installations on six continents, managing more than 15 billion imaging objects annually.



A FEW DEFINITIONS

# Concepts that can change your world.



## Medical Imaging Informatics

The discipline focused on improving efficiency, accuracy, usability, and reliability of medical imaging services. Devoted to the study of how information about, and contained within, medical images is retrieved, analyzed, enhanced, and exchanged.



## Interoperability

The defining characteristic of a product or system able to work with other products or systems without restrictions.



## Imaging Liquidity

The state of being able to work with stored images — and the associated metadata — from any system.



## The Synapse Vendor Neutral Archive (VNA)

Your gateway to interoperability, imaging liquidity, and all the business-building benefits they offer you and your clients.

# The value of imaging in drug discovery

Imaging biomarkers play an important role in early and late-phase clinical trials.



In early drug development phases: Imaging helps answer specific questions around whether the new drug candidate reaches the target and, if so, in sufficient quantity or whether the expected mechanism of action can be observed.



Imaging biomarkers help make objective decisions drug safety and efficacy sooner, thus reducing overall R&D timelines and costs through effective early phase trials.



Imaging biomarkers and surrogate endpoints can facilitate small group sizes, quick results and good statistical power, when assessing new drug efficacy.



Imaging can reveal small, subtle changes indicative of incremental progression or regression that might be missed with traditional approaches.



The right imaging biomarker enables much faster assessment of therapeutic efficacy of a new treatment and making early go / no go decisions.



IMAGING LIQUIDITY

# Imaging Liquidity: What is it and why is important to you?

Imaging Liquidity = Being able to work with stored images and the associated metadata from your systems of choice, like TrialStat

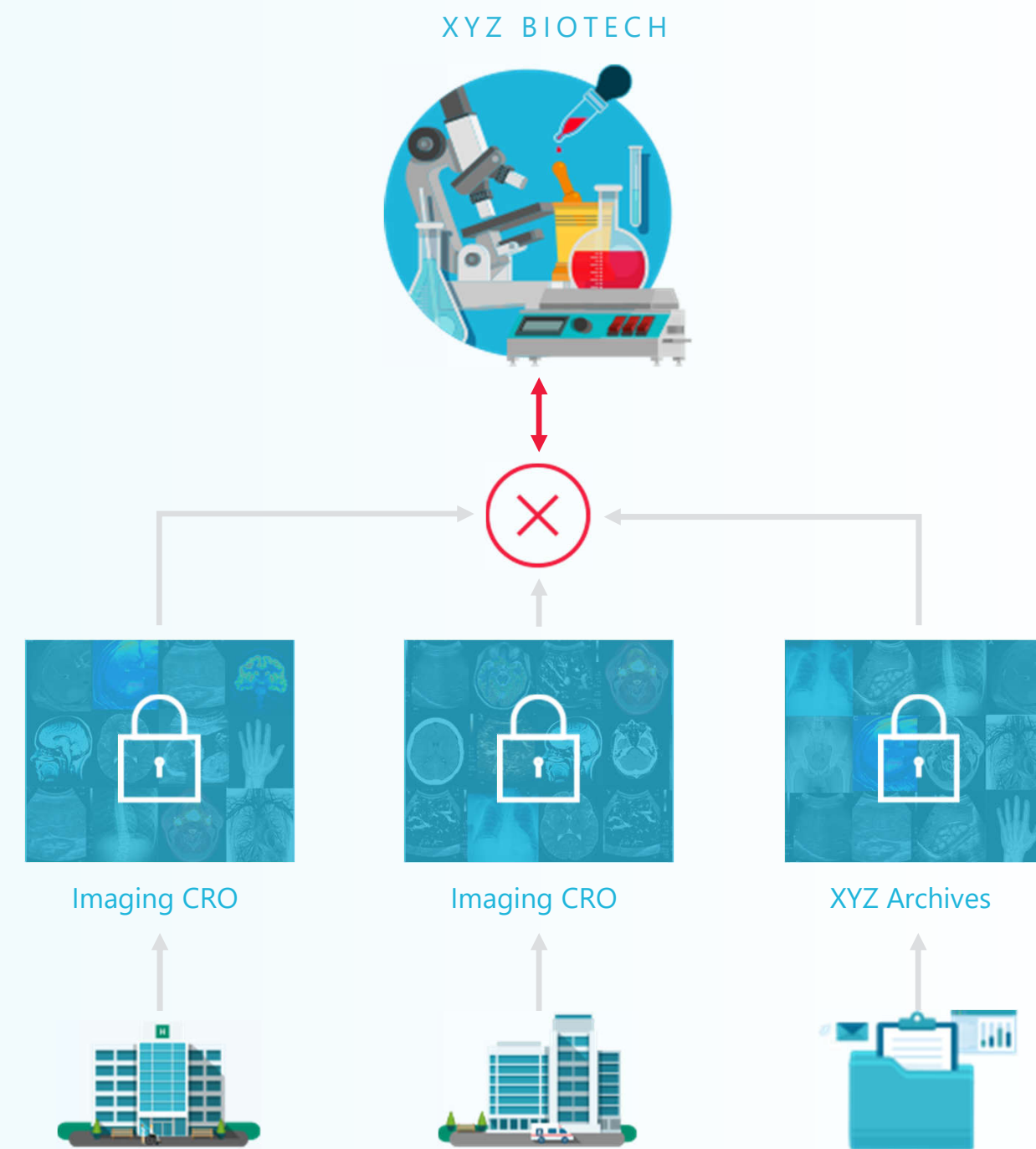
Images and their associated header metadata are extremely rich sources of clinical information, valuable for a wide variety of sponsor use cases within:

- Data Science/Analytics/IoT/Machine Learning
- Translational Medicine
- Clinical Research
- Pharmacovigilance
- Patient Recruitment



# Primary challenges to using imaging for downstream use cases

- Locked in proprietary platforms and devices, archived in silos.
- Saved in multiple formats that can't be used by analytics, AI, and other systems
- A vast multitude of image types
  - MRI, CT, PET Scans, ultrasound studies, etc.
  - Digital pathology
  - Videos, photos, and other non-radiologic clinical outputs
- Metadata is key, but often not available in formats usable by other systems.

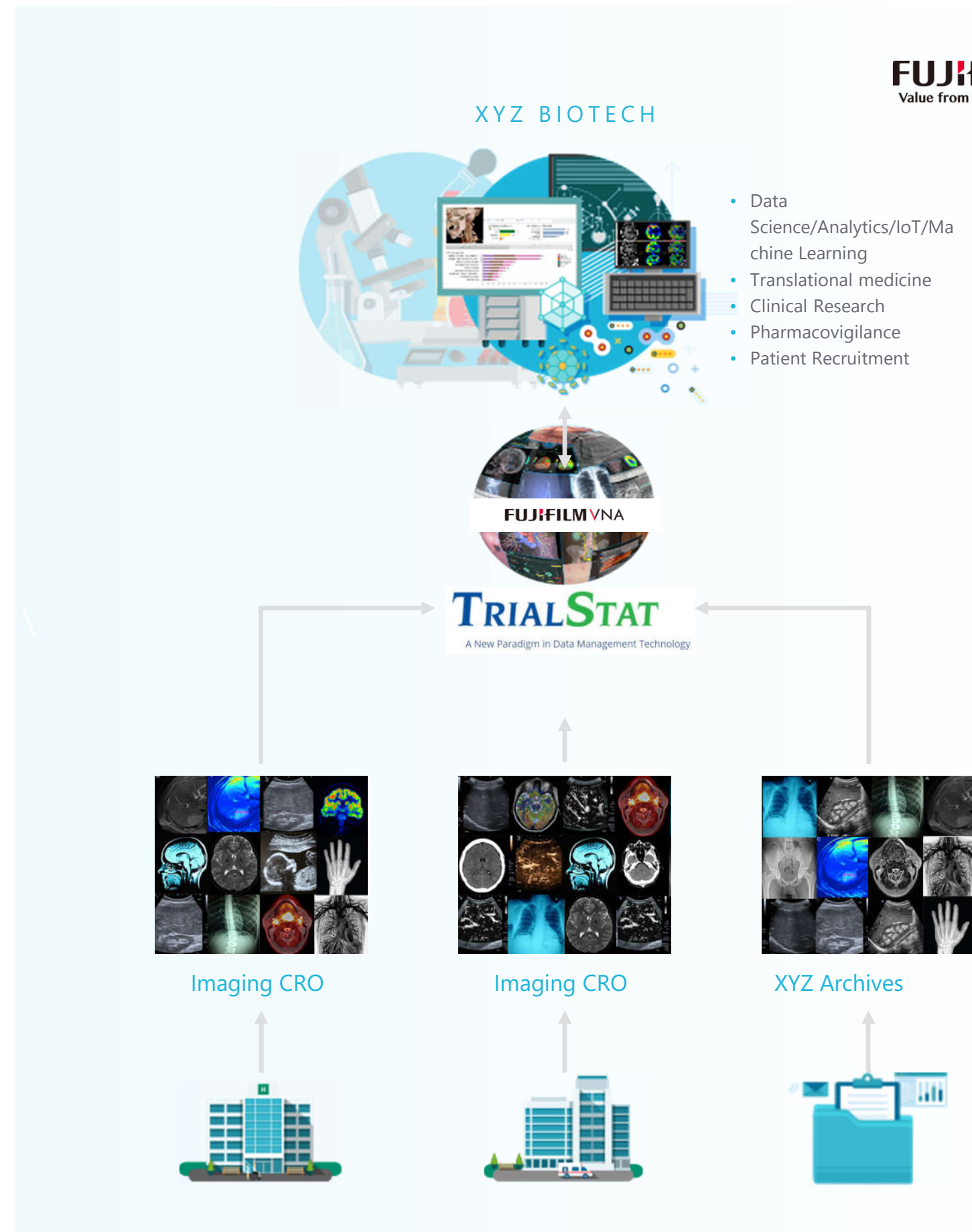


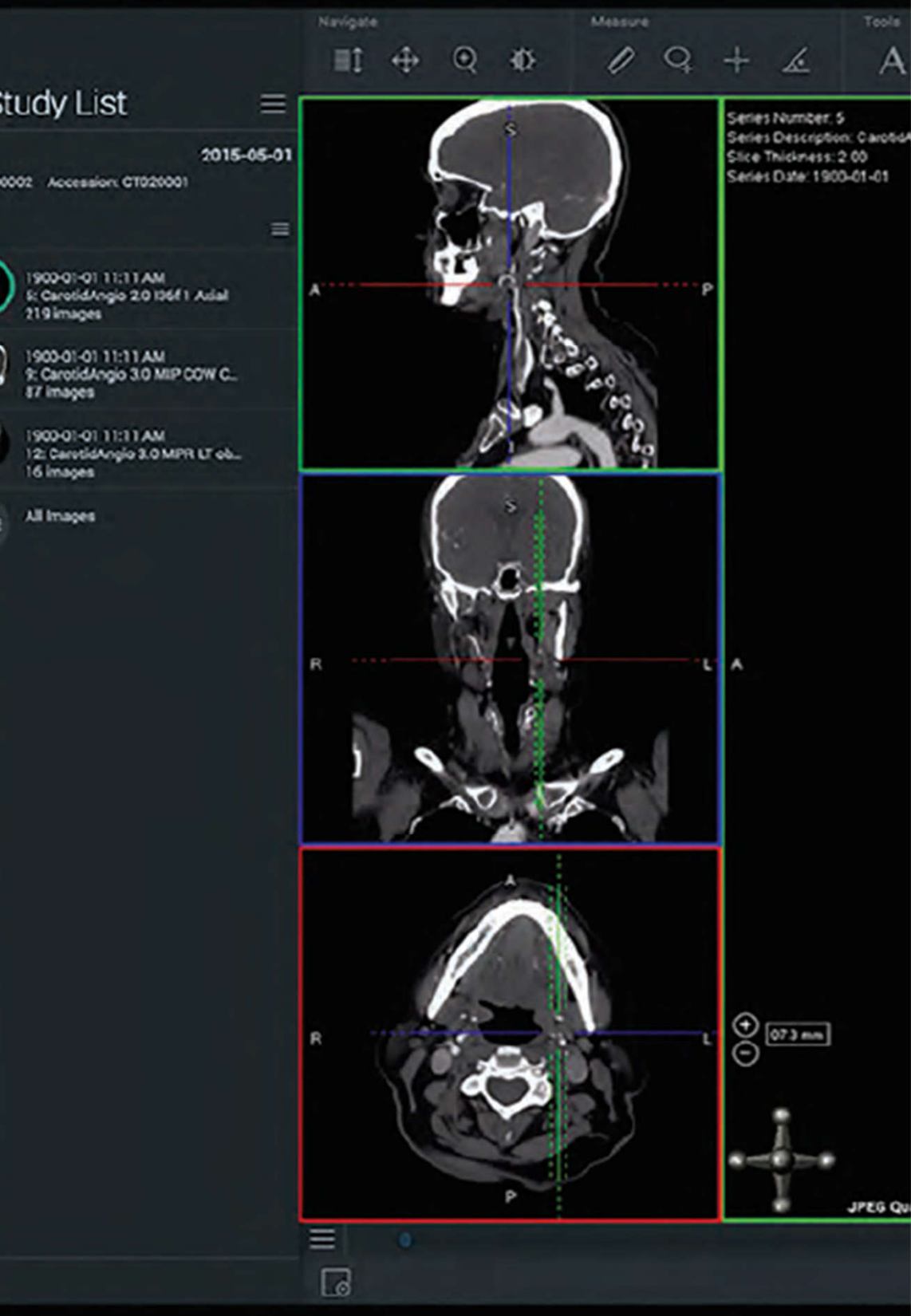
Proprietary, non-interoperable platforms can prevent sponsors from accessing their images and associated data.

SOLUTION

# Imaging Liquidity via the Imaging Vendor Neutral Archive (VNA) for Biotech + TrialStat

- Copies of the images and header metadata are extracted and stored from the source systems & archives by the VNA.
- Stored in formats that make them usable by downstream systems.
- Stored in easily searchable hierarchies for quick find and use.
- Now, you and your colleagues have full use of their images and imaging data for other use cases, from TrialStat and other systems of choice.





## Imaging Liquidity via an Imaging Vendor Neutral Archive (VNA) for Biotech

- Multi-Discipline, Multi-Study Enterprise Repository
- Multi-Vendor Interoperability: True Neutrality
- Standards-based and open: Interoperability with source and receiving systems: DICOM, Non-DICOM, HL7, IHE/XDS, FHIR, RESTful web-services, etc.
- Images are stored in native formats to ensure effective repurposing
- Metadata from each image is stored in a database, making fast, accurate searches possible
- Scalable/configurable: Hierarchy by study, program, organization, department.
- Access and re-use can be limited by user role and purpose
- Stored images can be linked by participant IDs and other key identifiers
- Background auditing
- 21 CFR Part 11, HIPAA, and GDPR compliant
- Quick speed to value (weeks not years)
- Augments - not displaces -current systems, providing complete image access



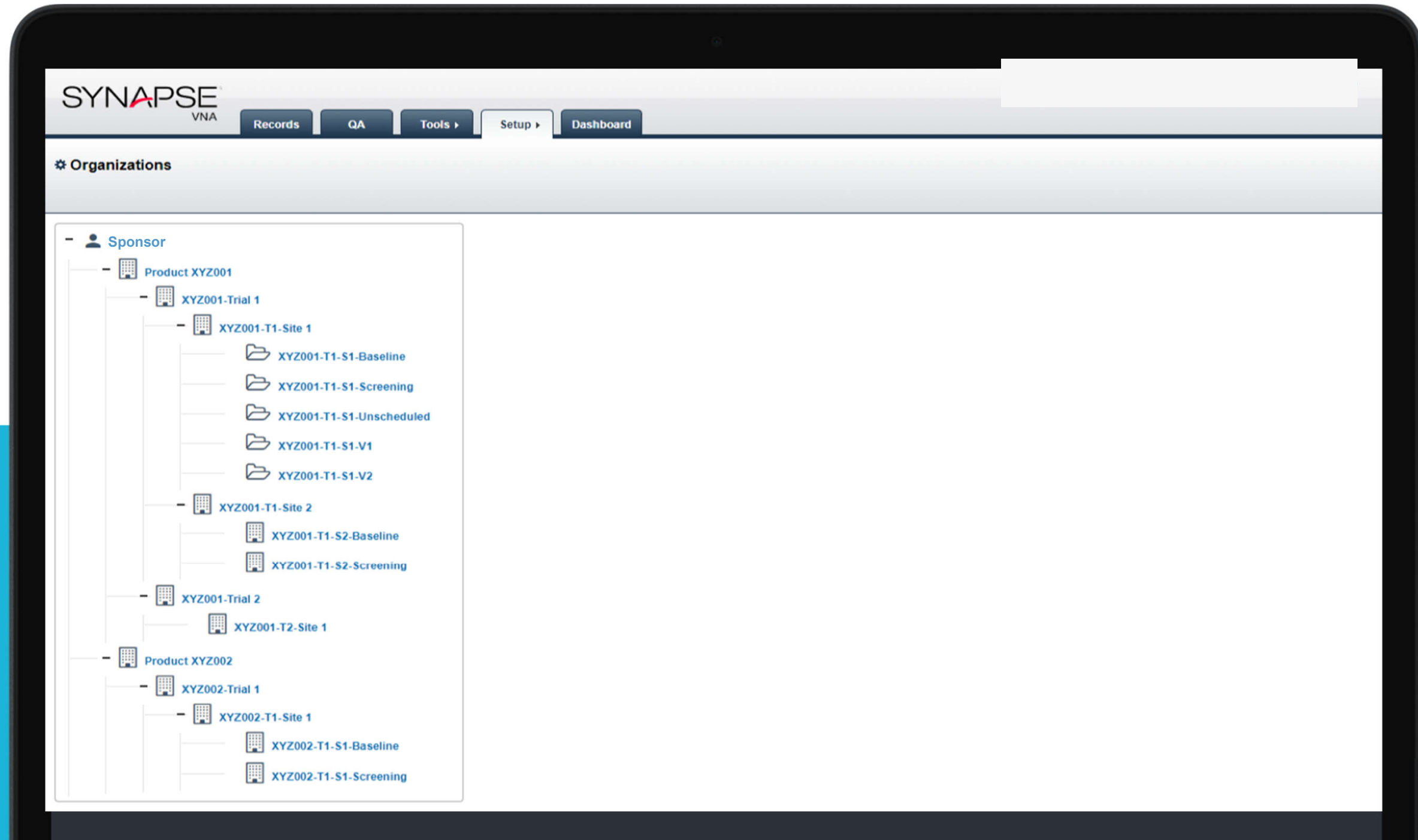
# The wide range of images in use in Clinical trials today.

Your clients want access to all of these — and the associated metadata — quickly, easily, and economically.

Clinical Digital Objects Generated

Specialty	DICOM	A/V, MPEG, WAV	JPEG, PDF	Other Clinical	Common Types
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 S
Radiology			✓	✓	MR, CT, XR, US, NM
Rheumatology	✓	✓	✓	✓	US, MR
Surgery	✓	✓	✓		In-department X-ray, Endoscope
Urology					MR, XR, Digital Fluoroscopy Report

Store your images base on your needs.



Easily search for types of images through any number of metadata keywords.

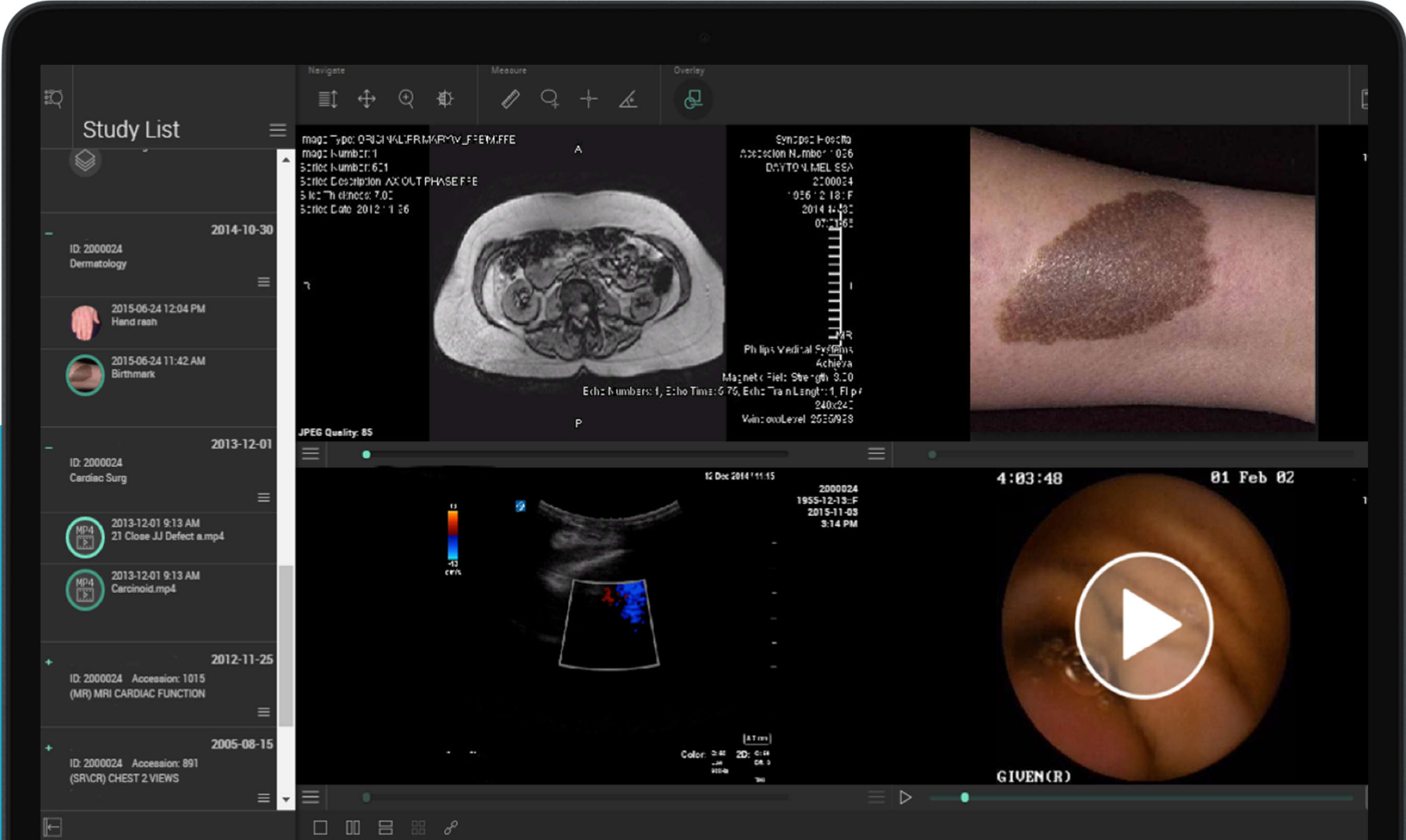
The screenshot displays the SYNAPSE VNA web application interface. At the top, there is a navigation bar with the SYNAPSE VNA logo and tabs for Records, QA, Tools, Setup, and Dashboard. Below the navigation bar, there are search filters for Accession No. and Patient ID. The main content area is titled "Studies" and contains a table with the following columns: Patient ID, Accession Number, Study Date, Modality, Description, STMO, a status indicator (checkmark), and a file icon. The table lists several studies, with the fourth row highlighted in yellow. Below the studies table, there is a section for "Non-DICOM folders" with a "More actions" dropdown and a table with columns for Patient ID, Folder name, Folder description, Stored Date, and Objects.

Patient ID	Accession Number	Study Date	Modality	Description	STMO	✓	📄
523-90-3232	56889752	08/09/2010 10:52 AM	CT, OT	Computed Tomography - Abdomen	Lakeshore University...	✓	2-41
523-90-3232	22546658	06/29/2010 10:42 AM	CT	Computed Tomography - Abdomen	Lakeshore University...	✓	1-45
523-90-3232	#16813	03/16/2010 02:28 PM	CT	Computed Tomography - Chest w/ Lung	Lakeshore University...	✓	4-52
▶ 523-90-3232	11312869	01/01/2007 02:44 PM	CT	Computed Tomography - Abdomen W/WO Contr...	Lakeshore University...	✓	1-80
523-90-3232	9087741	08/31/2006 01:08 PM	US	Ultrasound	Lakeshore University...	✓	1-88
523-90-3232	345098	09/20/2004 07:12 AM	CT, SR	Gastrointestinal Study	Lakeshore University...	✓	2-47
523-90-3232	203845	08/11/2000 10:05 AM	XA	XA - Cardiology	Lakeshore University...	✓	1-8



THE SYNAPSE VNA AT WORK

Use our viewer of yours – even collaborate!



Access to images and metadata is secure, encrypted, and role- and rule-based.

The screenshot displays the SYNAPSE VNA interface. At the top, the logo 'SYNAPSE VNA' is visible. Below it, a navigation bar contains buttons for 'Records', 'QA', 'Tools', 'Setup', and 'Dashboard'. The 'Setup' button is selected, leading to a 'Security' section. Under 'Security', there are sub-sections: 'User Accounts', 'User Roles', 'LDAP And Active Directory', and 'Authentication Options'. The 'User Roles' sub-section is active, showing a table with columns for 'Name', 'Description', and 'Organization Access'. The table lists various user roles such as 'techuln', 'lakeshoreadminuln', 'enterprisesuperuseruln', 'SuperUsers', 'fmadmin', 'iviz', 'HIPAA', 'VNA Administrators', 'ConnexOnly', and 'tadmin'.

Name	Description	Organization Access
techuln	Enterprise Techs	enterpriseorguln
lakeshoreadminuln	Lakeshore Admin Users	enterpriseorguln
enterprisesuperuseruln	enterprisesuperuseruln	enterpriseorguln
SuperUsers	Evercore Super Users	enterpriseorguln
fmadmin	Mountain Spring user group	mountain springuln
iviz	iviz	ivizuln
HIPAA	Admin, No access to patient data	enterpriseorguln
VNA Administrators	VNA Administrators	enterpriseorguln
ConnexOnly	Connex User Only	enterpriseorguln
tadmin	tadmin	enterpriseorguln

# Summary

- TrialStat + Fujifilm VNA = True Imaging Liquidity
- You CAN have control of your images and imaging data, and access them when you want to.
- DICOM and Non-DICOM image types plus all metadata.
- Search, find and work with images in seconds.
- Cloud-based, scalable, and flexible to meet your needs, now and in the future.
- Augments - not displaces - current systems, providing complete image access



# Panel Discussion

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Value from Innovation

 **TeraMedica**<sup>®</sup>

# Benefits of An Integrated CTMS





SimpleTrials is the Flexible, Affordable and Compliant Clinical Trial Management System (CTMS)

### What is CTMS?

A specialized, comprehensive project management application that takes the study team from startup, through enrollment and monitoring, to study close.

The screenshot shows the 'Study Chooser' interface in SimpleTrials. The left sidebar contains a navigation menu with categories: Portfolio, Study, Sites, Subjects, CRA Lounge, and Administration. The main content area displays a list of studies for 'Twist Therapeutics • PII-T2DM-2017'. Each study entry includes its ID, sponsor, status, TMF model, description, and progress metrics for countries, sites, screens, and enrolled subjects.

Study #	Sponsor	Study Status	TMF Model	Description	# Countries	# Sites	# Screens	# Enrolled
CNS-ONC-PII	Twist Therapeutics	Startup	SimpleTrials TMF Reference Model v1	DIA webinar demo study - do not use	2 (target: 2)	4 (target: 5)	0 (target: 20)	0 (target: 15)
FLU-2020	QA Pharma	Planned	SimpleTrials TMF Reference Model v1	generic	1 (target: 0)	1 (target: 0)	0 (target: 0)	0 (target: 0)
Oncology Template	SuperPharm	Planned	SimpleTrials TMF Reference Model v1	Template to be used for oncology study creation	2 (target: 0)	2 (target: 3)	4 (target: 5)	4 (target: 3)
PIII-T2DM-2018	Twist Therapeutics	Planned	DIA TMF Reference Model v3.0		5 (target: 0)	8 (target: 0)	1 (target: 0)	1 (target: 0)
PII-T2DM-2017	Twist Therapeutics	Enrolling	SimpleTrials TMF Reference Model v1	(FOR CRO/SPONSOR DEMO) - A Phase II multi-center study of Tariflozin and exercise in Type II diabetes	2 (target: 2)	13 (target: 10)	51 (target: 100)	39 (target: 75)



# Company Facts



- Trial By Fire Solutions (TBFS) founded in 2008, based in Oakland, California, USA, is a clinical software leader focused on CTMS
- Our team has decades of direct industry experience managing clinical studies and developing innovative software
- 12+ years developing and supporting CTMS products.
  - SimpleTrials is our 2<sup>nd</sup> generation CTMS, released in 2016
  - Global footprint of users in 40+ countries; validated and compliant
- Through our CTMS support team, professional services and leadership, our goal is to collaborate with our clients to make study management easier.

# Study Management Features

- Contacts & Organizations, eTMF and Document Management
- Study Project Planning, Sites & Study Teams and Study Startup
- Calendar, Site Visit Tracking and Action Items
- Subject Enrollment, Subject Visits and Protocol Deviations
- Electronic Visit Reports, Template Builder, Contracts & Payments
- Study Dashboards, Performance Analytics and Data Reports
- 21 Part 11 support: Audit Trail, User Controls, Electronic Signatures
- Built-In trackers, workflows and reports, easily customizable

## Navigation

### – Portfolio

Home / Study Chooser  
Contacts  
Organizations  
Calendar  
Documents  
CTMS Reports  
eVisit Report Templates

### – Study

Study Dashboard  
Study Profile  
Milestones & Tasks  
Study Teams & Contacts

### – Sites

Sites & Contacts  
Startup Tracking  
Site Contracts  
Site Payments

### – Subjects

Screening & Enrollment  
Subject Visits  
Protocol Deviations

### – CRA Lounge

Site Visit Tracking  
Action Items

### – Administration

User Management  
Subscription & Settings  
Customize Picklists  
Customized Trackers  
Audit & Activity Log  
Compliance Portal

# How is SimpleTrials Different?



- Easy to Use, Easy to Adopt
  - Integration & Imports
- Innovative Customization:
  - Expand Trackers with Custom Fields
  - Build-Your-Own Tracker Views
- Transparent, Subscription Pricing
- Compliance Portal
- Bring Our Extensive CTMS Expertise to your Team & Study

**Documents**

Manage Folders Manage Documents Auto-Expand Folder Track Site Docs Customize Columns Download Zip

**Folder Tree**

Folders and Document Records	Posted File	Document Status	QC Date (Custom)
12 : MedicalOne : USA : Shah, Ming			
01. General Study Documents			
04. Site Specific Documents			
04.01 Legal Documents			
04.01.01 CDA / NDA			
04.01.02 Clinical Trial Agreement - fully ex...			
04.01.03 FDA Form 1572			
1572	FAQ_FDAForm1572.pdf	Received	15 Feb 20...
04.02 Investigator Documents			

**Track Site Docs - PII-T2DM-2017 - 12 : MedicalOne : USA : Shah, Ming - //PII-T2DM-2017/BY SITE/12 : MedicalOne : USA : S**

Manage Documents Filter/Search Reset Export to Excel Reload Edit On

Folder Name ↑	Required for Site Activation	Required for Study End	IRB/EC Approval Required	Document Title	Posted Filename
04.01.01 CDA / NDA	YES	YES	No	Confidentiality Agreement	(none) Upload...
04.01.02 Clinical Trial Agreement - fully executed	No	No	No	Updated CTA for amendment	(none) Upload...
04.01.02 Clinical Trial Agreement - fully executed	YES	YES	No	Initial contract	DrugInventoryForm.docx
04.01.02 Clinical Trial Agreement - fully executed	YES	YES	No	Initial contract	FAQ_FDAForm1572.pdf
04.01.03 FDA Form 1572	YES	YES	No	1572	FAQ_FDAForm1572.pdf



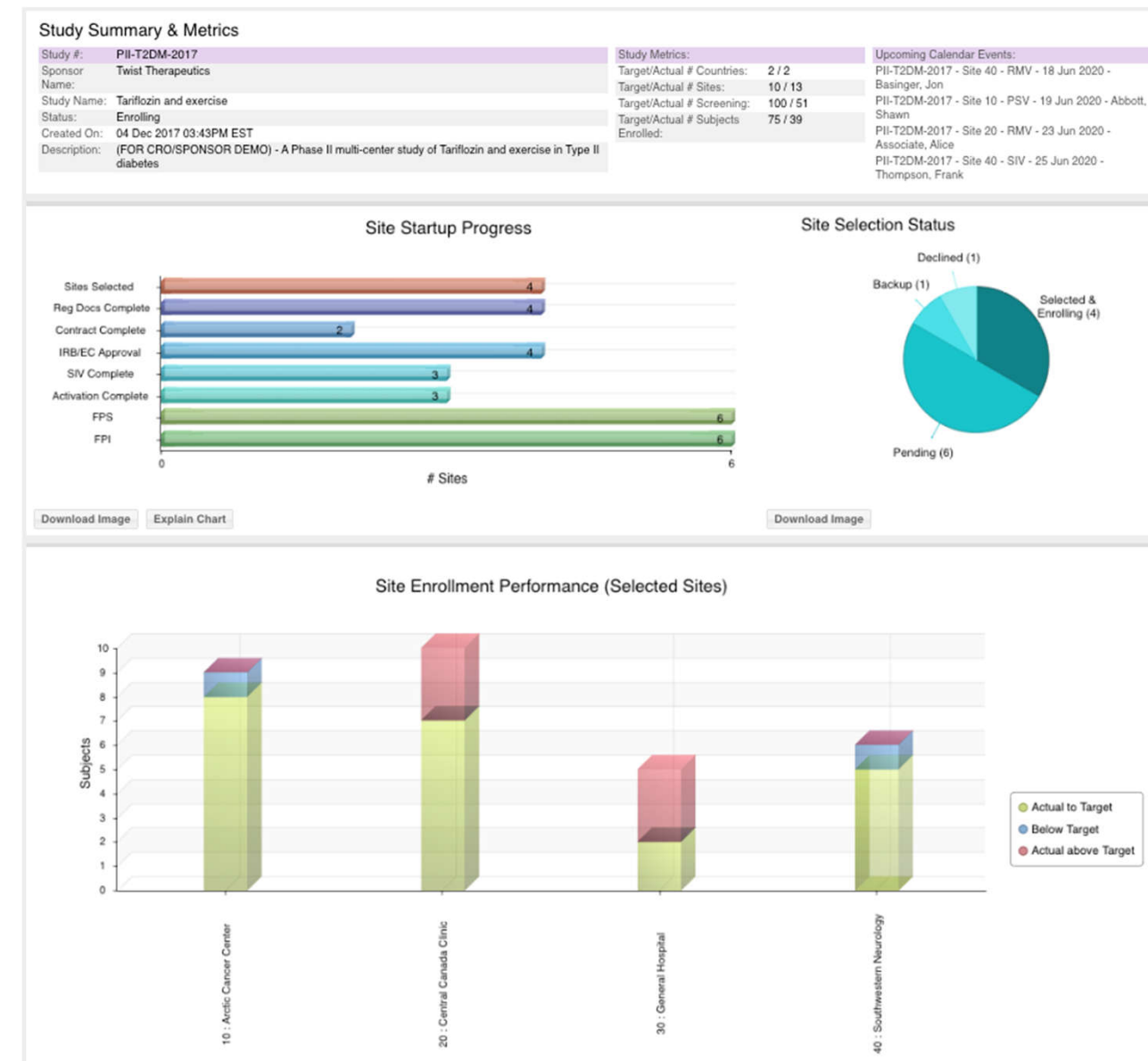
# EDC Integration



**GOAL:** Populate the CTMS with Subject & Visit data from EDC, which can be leveraged for efficient Study Management and Oversight.

## EDC to CTMS Integration Includes:

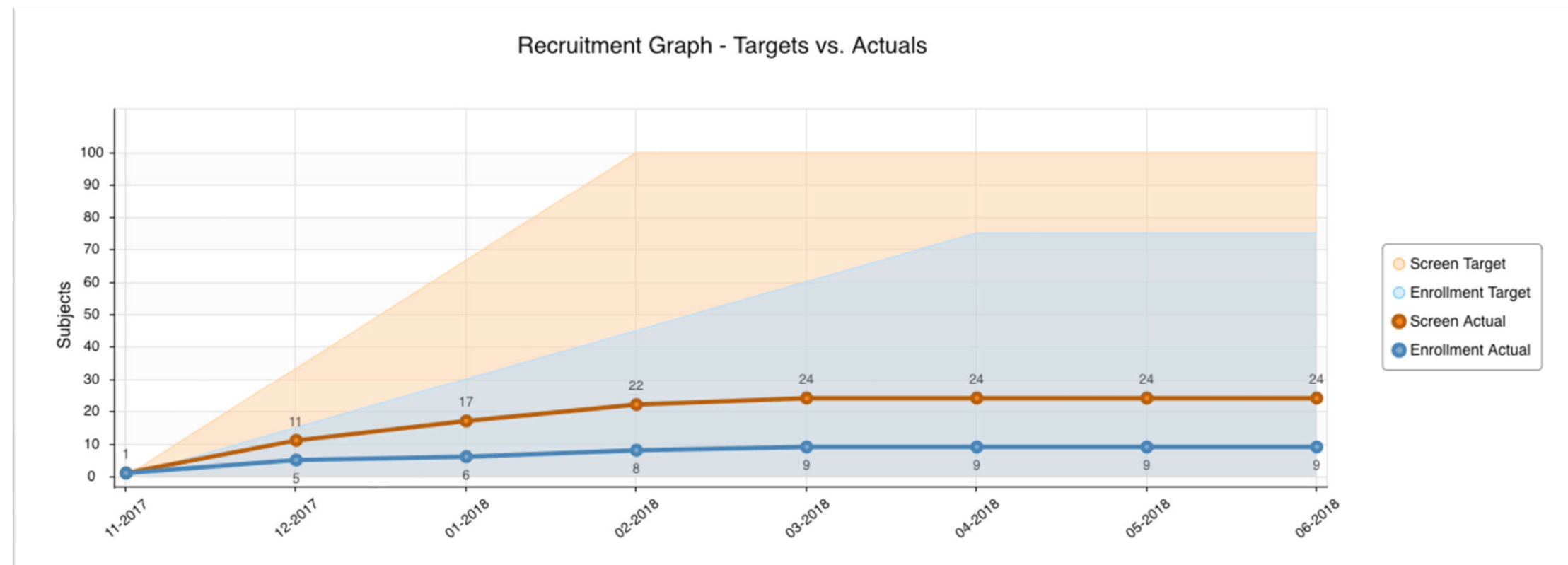
- Subject records: Screened, Enrolled, Completed
- Key Subject Data: Consent & Enrollment, Protocol Version, End of Study Disposition
- Subject Visits: Actual Visit Date, Visit & Data Status
- Protocol Deviations
- Automated Nightly Transfer



# Integration Benefits

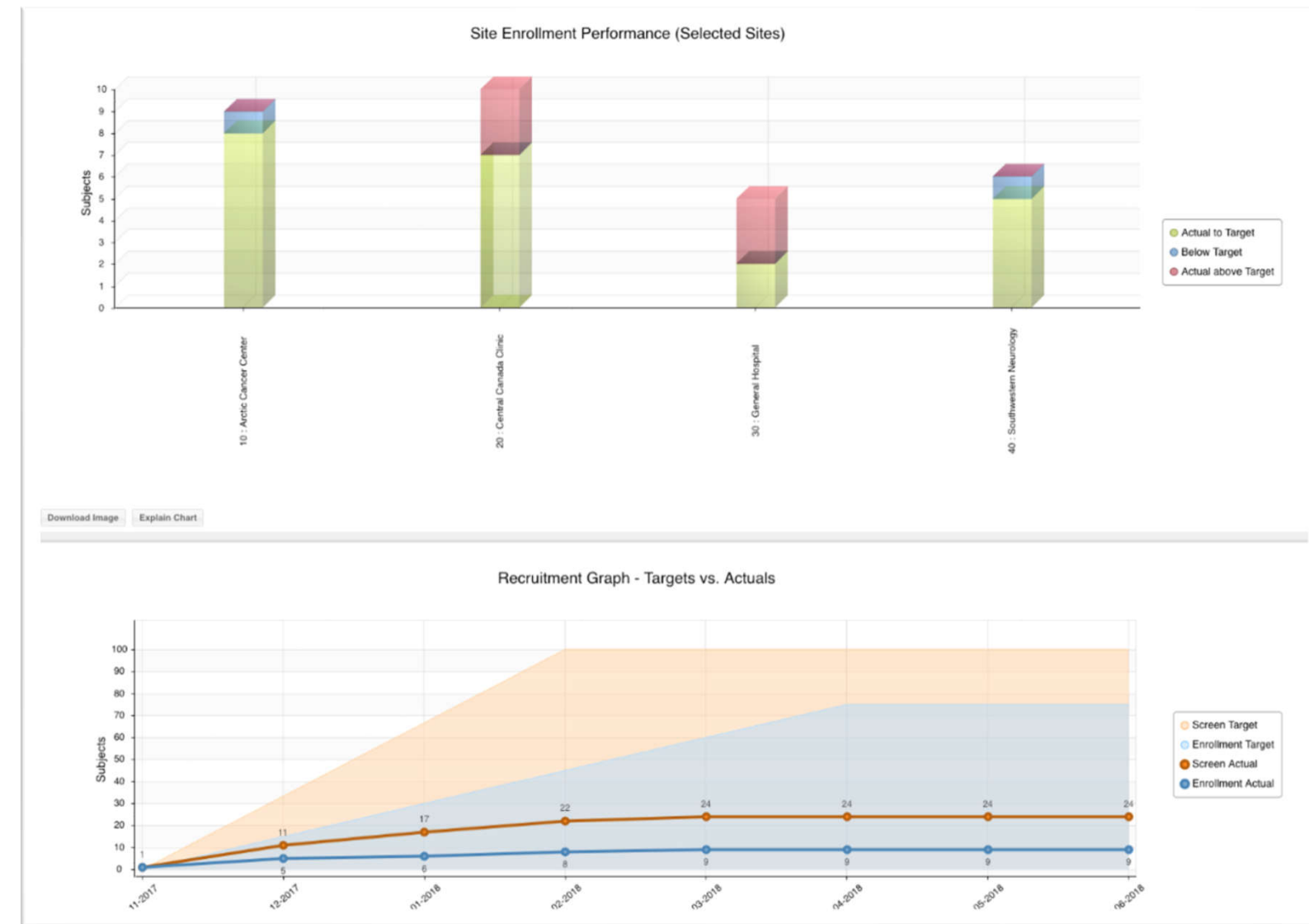


- Automatic Data Population: Eliminate Manual/Duplicate Data Entry
- Subject Payments: Automatic Generation of Qualified Payments
- Site Monitoring: Supports Electronic Visit Reports
- Risk Based Monitoring: Track In-Window Subject Visits
- Insights and Analytics: Enrollment Metrics and Visualizations



# Real-Time Insights

- Enrollment Progress at a Glance
- Always Up To Date
- Targets vs. Actuals
- Actuals Roll-Up from:
  - Subject-level
  - Site-level
  - Study-level



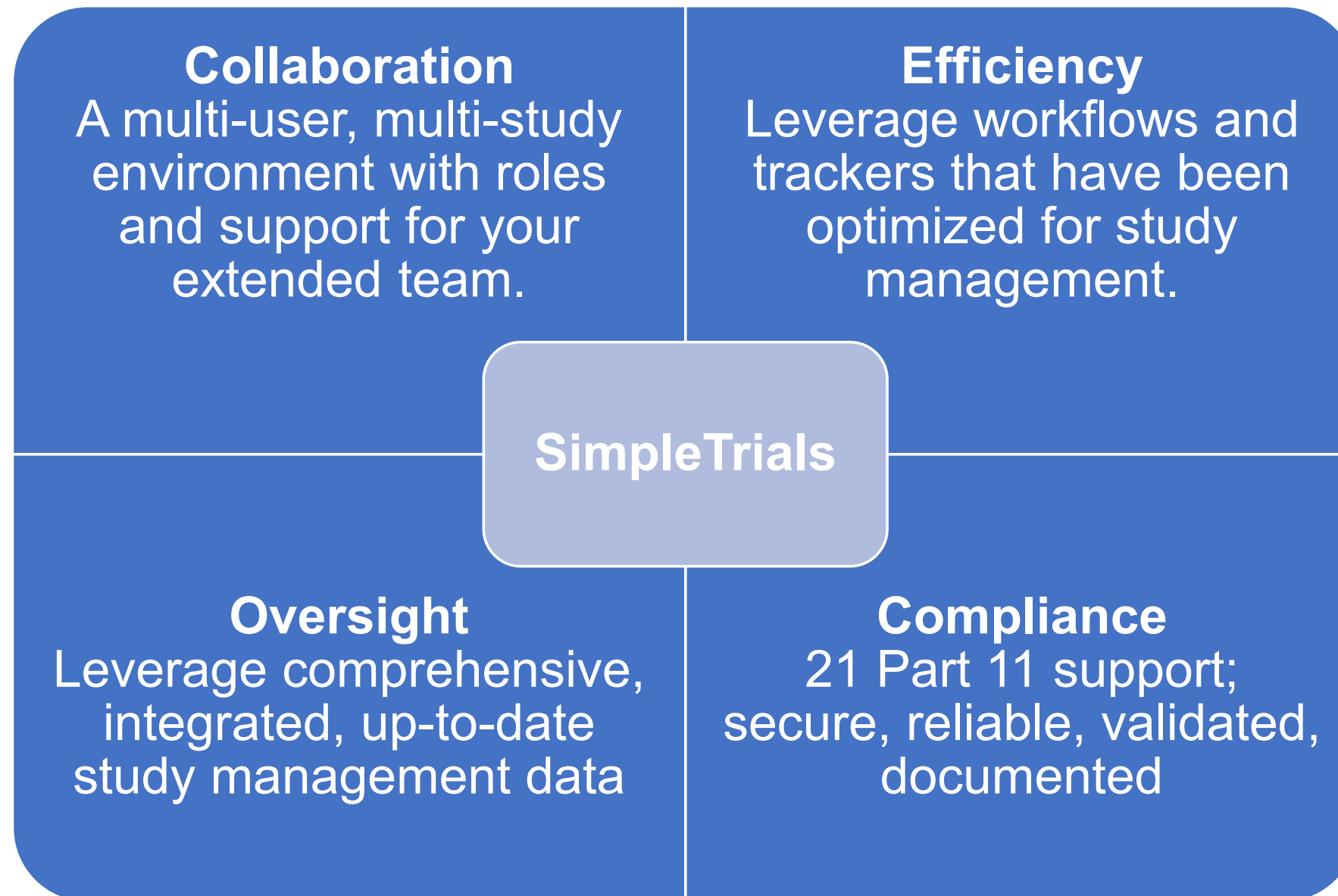
## Startup Tracking

⏪ ⏩ | Page  of 1 | 🔄 Showing 1 - 4 of 4 | 🔍  Clear Filters Sync Actuals Import Export Customize Columns Edit On

Site Description				Enrollment			
Site # ↑	Site Name	Target First Patient Screened (FPS)	Actual First Patient Screened (FPS) (SYNC)	Target # Subjects Enrolled	Actual # Subjects Enrolled (SYNC)	Target First Patient In (FPI)	FPI Actual (SYNC)
10	Arctic Cancer Center	08 Nov 2017	15 Nov 2017	9	7	10 Nov 2017	16 Nov 2017
20	Central Canada Clinic	08 Nov 2017	01 Dec 2017	7	10	10 Nov 2017	19 Dec 2017
30	General Hospital	10 Dec 2017	21 Dec 2017	2	5	12 Dec 2017	23 Dec 2017
40	Southwestern Neurology	10 Dec 2017	10 Mar 2018	6	4	12 Dec 2017	16 Mar 2020



# Conclusion: Simplify Study Management, Reducing Timelines & Costs



## Panel Discussion

# TRIALSTAT



SimpleTrials

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# Wrap Up / Next Steps

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SimpleTrials

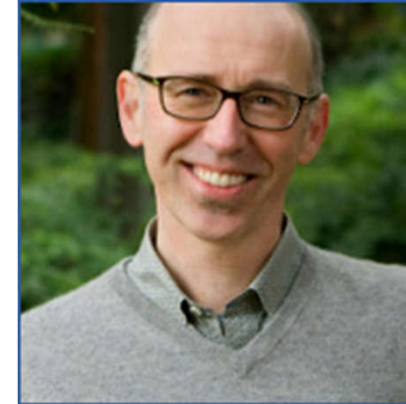
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To download the webinar and supporting materials visit this page

<https://trialstat.com/DIA2020webinar>