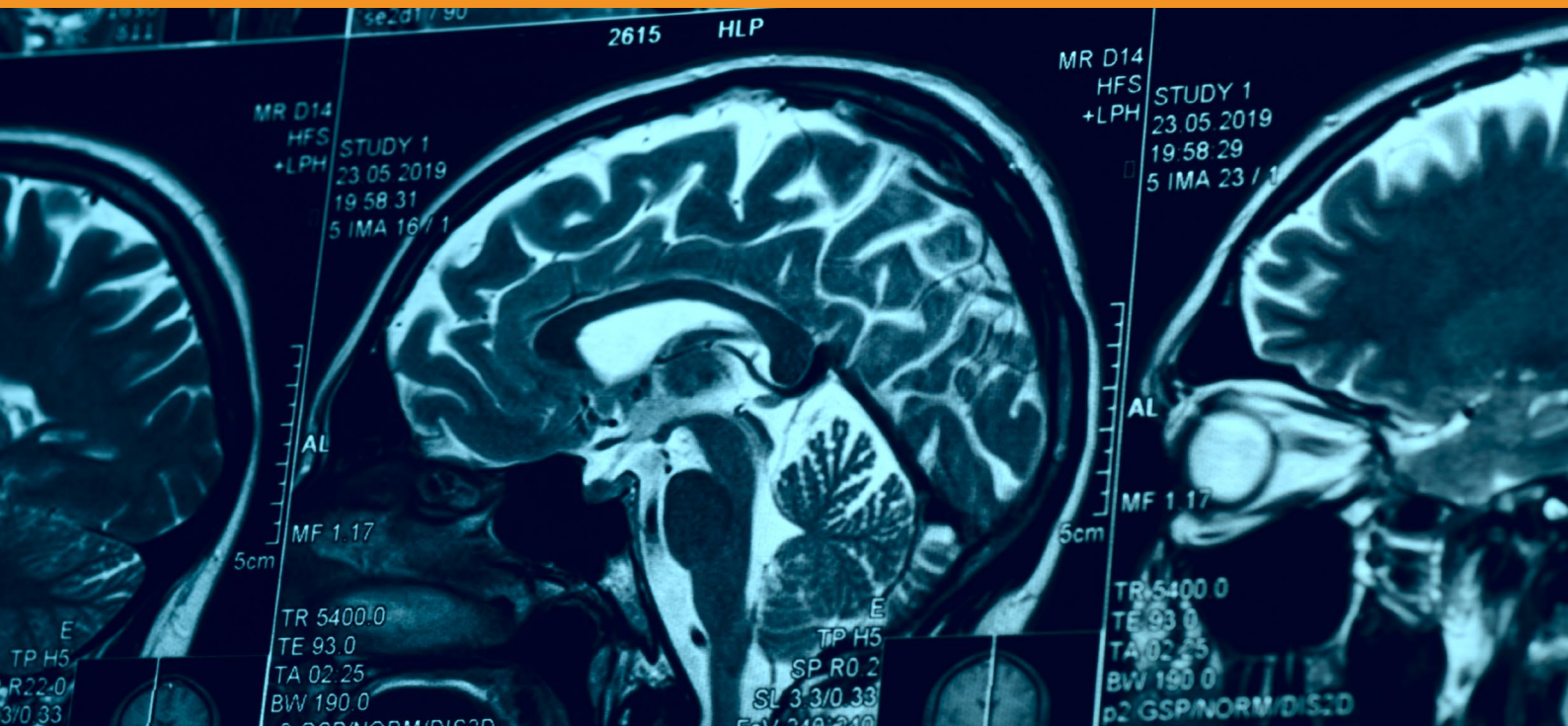




WHITEPAPER

# Anagram CoreLab

*Excellence in  
Medical Imaging  
and CRO services  
for Clinical Trials*



## Introduction

In the dynamic medical research field, clinical trials play a crucial role not only in advancing therapies and technologies but also in shaping public health policies and medical practices. Accuracy and objectivity in the collection and analysis of clinical data are critical, and in some trials the imaging data is key. Anagram CoreLab, a unit within Anagram CRO with over 25 years of experience managing national and international studies, offers a unique perspective by merging advanced technology with meticulously designed processes to enhance the quality and efficiency of clinical studies. Being an integral part of the CRO, Anagram CoreLab not only facilitates the integration of data but also ensures a significant competitive advantage in the market by providing innovative imaging services that comply with the highest standards of safety and international regulation lead by a senior team of clinical researchers.

## What is an Imaging CoreLab?

An Imaging CoreLab is a specialized lab that provides objective and independent evaluation of medical images in the context of clinical trials. This type of laboratory uses advanced imaging technologies and specialized software to ensure anonymization of data, accuracy and consistency in image data interpretation. CoreLabs are equipped to handle large volumes of image data, ensuring standardization and quality across various sites and studies. Anagram's Imaging CoreLab, with its cutting-edge technology and standardized protocols, ensures reduced variability in medical image interpretation, facilitating consistent and replicable results. This level of precision is crucial for all types of clinical trials, but is especially important in areas such as oncology, neurology, cardiology, and medical devices, where image interpretation plays a vital role, as the main variable is often assessed using imaging techniques.

# The Importance of an Imaging CoreLab in Clinical Trials

Imaging CoreLabs are crucial in clinical trials because:

## OBJECTIVITY

By operating independently from clinical research teams, they play an essential role in mitigating biases. This independence ensures that medical image interpretations are made without external influences, which is crucial for maintaining the integrity of the study. By minimizing personal or institutional biases, CoreLabs significantly contribute to the objectivity and independency of the trials, providing more reliable and replicable results.

## ENSURE QUALITY AND CONSISTENCY

An Imaging CoreLab establishes and maintains standardized protocols for all phases of medical image management, from acquisition and anonymization to final analysis. This standardization is vital for multicentric trials, where variations in image handling among different sites can influence study results. By ensuring that all image data are processed and evaluated uniformly, CoreLabs ensure the quality and consistency needed for the findings to be globally valid while respecting study timelines.

## COMPLY WITH REGULATIONS

They ensure that methods and processes comply with international regulatory standards, facilitating the acceptance of trial results by health authorities.

These aspects not only impact the scientific quality of the study but also its viability and operational efficiency, which can significantly influence the success and overall cost of the clinical trial.

Reducing variability in a clinical trial can decrease the number of patients needed to detect statistically significant differences between treatment and control groups. When variability is lower, the actual differences between groups become more apparent, even with smaller sample sizes.

# Advantages of Integrating the Imaging CoreLab into the Anagram CRO

Having an experienced CRO as Anagram integrating and managing the Imaging CoreLab activities offers unparalleled benefits:

## **OPERATIONAL EFFICIENCY**

Creates a seamless workflow, where coordination between different phases of the clinical trials is more direct, eliminating redundant stages in data management and analysis, speeding up trial's timelines. This time savings often have a significant impact in reducing total operational costs.

## **QUALITY CONSISTENCY**

Maintaining consistent quality throughout all aspects of a clinical trial is essential to ensure the validity and reliability of the results. The integration of the CoreLab facilitates the standardization of procedures from data capture to interpretation, ensuring that all study elements consistently meet international and regulatory quality standards.

## **INNOVATION AND CONTINUOUS IMPROVEMENT**

The integration facilitates the rapid implementation of new technologies and advanced methodologies in image analysis thanks to the CRO extense experience in most therapeutic areas. This not only enhances adaptability to the changing needs of clinical trials but also fosters a culture of constant innovation where lessons learnt and feedback is exchanged on an ongoing basis.



## Innovations at Anagram CoreLab:

In our ongoing quest for excellence and efficiency in clinical trial management, Anagram CoreLab is proud to introduce **Smile**<sup>®</sup>, a management platform (CRM) that exemplifies our commitment to innovation. **Smile**<sup>®</sup> not only optimizes traceability but also enhances and empowers our advanced technological capabilities in medical image analysis, reinforcing our commitment to precision, data security, and continuous improvement in the field of clinical trials.

Its main features include:

**Compliance with 21 CFR Part 11 and ISO 27001 certification:** Ensures that Smile <sup>®</sup> adheres to critical regulatory standards for data protection, traceability, security and quality management, essential for operating in an international context and meeting legal requirements.

### **Protocol setup and planning**

Ensuring systematic set up and management of clinical trial protocols, ensuring that each study phase is planned and documented properly, which is vital for meeting study objectives.

### **User registration**

Addition of new site and sponsor users to the system is easy, allowing the configuration and access control based on specific roles, which facilitates task delegation and protects information integrity.

### **User-friendly interface (drag & drop) – Web-based**

This feature is essential as it allows users to interact with the system efficiently and effortlessly. The intuitive interface facilitates navigation through the platform, optimizing the management of clinical trials thanks to its accessible and easy-to-use design.

### **Image upload and anonymization**

All medical images are easily uploaded by site personnel and automatically anonymized by Smile <sup>®</sup> platform to protect patient privacy, essential for complying with privacy regulations.

### **Integrated query management module**

Facilitates the creation, tracking, and resolution of imaging queries. By integrating directly with other components of Smile <sup>®</sup> platform, such as image review and report generation, this module ensures that all interactions are properly recorded and linked reducing the

possibility of errors in communication and data processing.

### **Integrated image review and reports**

Centralizing image review and report generation in one single platform, like Smile <sup>®</sup> offers significant advantages in terms of traceability and accuracy. Other CoreLabs who have different platforms face a high risk of errors such as reporting and entering patient data at the wrong image and / or site. This integration ensures that each image and its corresponding report are unequivocally linked, avoiding discrepancies and facilitating clear and consistent tracking throughout the clinical study.

### **Statistics module**

Provides tools for the statistical analysis of data collected, offering valuable insights for interpreting results and evidence-based decision-making.

### **Dashboard (quality indicators)**

Offers a visual panel of key performance indicators that helps monitor and manage the quality and effectiveness of the clinical trial, providing a clear view of progress and areas for improvement.

### **Data collected accessible to sponsors, CROs, etc. in real time**

**Smile**<sup>®</sup> platform is very appreciated by the sponsor, as they have instant access to all clinical trial data, significantly improving the oversight of the study. Having data available in real time enables sponsors to continuously monitor the progress of the trial, make quick adjustments if necessary, and ensure compliance with study objectives. And more importantly, to show regulatory agencies and auditors that the sponsor is providing effective oversight.

# Commitment to Security and Regulatory Compliance

Anagram CoreLab ensures the security and confidentiality of protected health information (PHI) through a segregated network and the use of encrypted data transmission, adhering to the standards of ISO 27001 and 21 CFR Part 11. Our cloud platform infrastructure surpasses traditional data storage systems in terms of security, offering:

## ISO 27001

This international standard confirms our adequate information security management systems, protecting data from unauthorized access and ensuring data integrity and availability.



## 21 CFR Part 11 of the FDA

We comply with FDA regulations for electronic data management, ensuring our electronic records and electronic signatures are authentic, reliable, and as valid as paper records, crucial for FDA-regulated studies.

## Cloud Provider Infrastructure

We use cloud infrastructures that meet leading industry security certifications, ensuring data compliance and security.

## Rigorous Access Control

Only authenticated users can access, browse, or upload data. Each user session is secured with temporary access tokens and two-factor authentication as needed.

## Advanced Encryption

All data communications are secured with TLS 1.2 encryption, using secure key exchanges and strong ciphers (AES\_256\_GCM), ensuring data protection in transit and at rest.

## Data Anonymization

We implement automatic data anonymization processes to remove personal identification information from uploaded DICOM images, maintaining privacy and compliance with regulations like GDPR and HIPAA.

These security measures not only protect against unauthorized access and data breaches but also ensure that Anagram CoreLab's platform aligns with the highest standards of security and international regulations, supporting the integrity and confidentiality of each study.

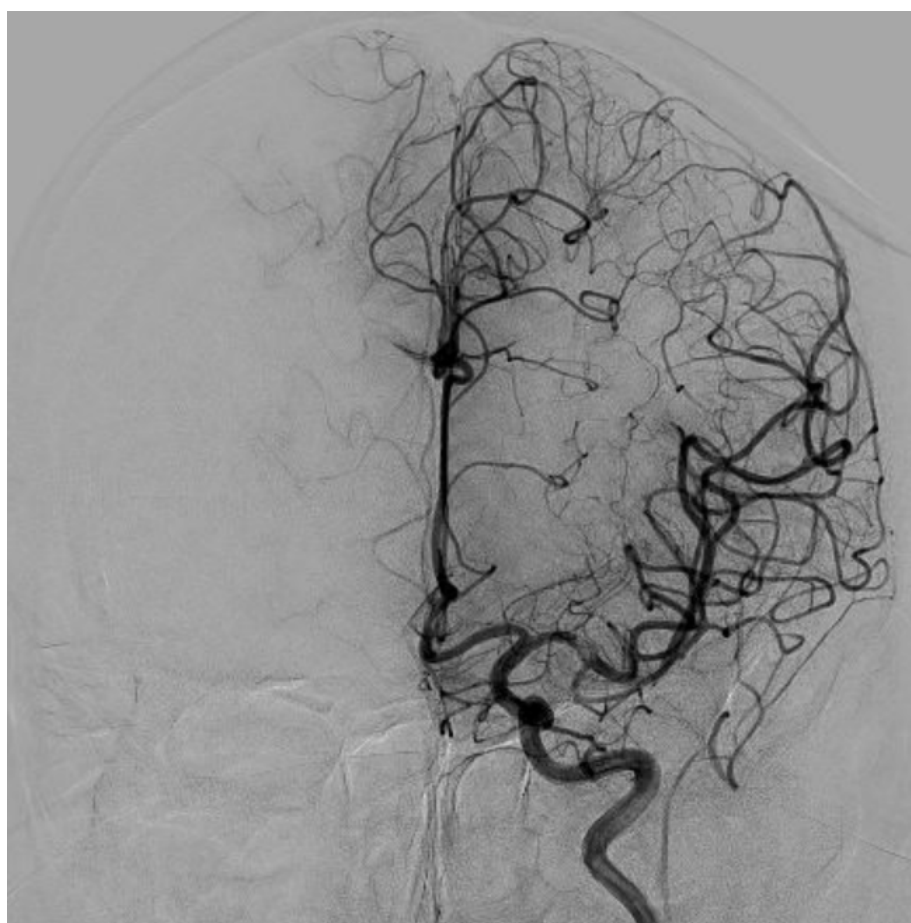


# Experience and Professionalism at Anagram CoreLab

Anagram CoreLab team of radiologists and nuclear specialists have over 15 years' experience in diagnostic imaging and is deeply committed to excellence and precision. Since its inception 4 years ago, the CoreLab has actively participated in multicentric studies across various medical fields such as **Stroke, Oncology, Vascular, Neurosurgery, and Pneumology**, demonstrating its capability and versatility in managing a wide range of medical disciplines.

Our team comprises highly qualified radiologists specialized in different medical areas, ensuring accurate and objective data interpretations. We operate independently and objectively, eliminating any risk of bias and staying up-to-date with the latest research and advancements in the field.

Our rigorous quality control process is carried out in two stages to ensure data excellence. The first stage involves a meticulous review of image quality, while the second stage confirms the radiologists' readings and verifies data completeness. We continuously monitor the data to identify and resolve discrepancies, contributing to the precision and consistency of the results.



*Figure 1. Thrombectomy image that facilitated the exclusion of a patient with initial TIC1 2b.*

# Conclusion

At Anagram CoreLab, we have been at the forefront of clinical trials for over a quarter of a century. Our collective experience, coupled with the innovative use of our Smile® robust platform, allows us to precisely adapt to the specific needs of each study. Our continuous improvement processes enable us to deliver fast, high-quality results, reinforcing our position as leaders in Imaging CoreLab services.

This dedication motivates us every day to exceed expectations and significantly contribute to the advancement of healthcare.

