

Image Analysis Group Achieves SOC 2 Type II Certification, Setting the Enterprise Benchmark for Global Imaging CROs

DYNAMIKA™ delivers SOC 2 Type II-certified, AI-driven imaging workflows, giving pharma and biotech secure, compliant oversight of imaging data in global trials.

LONDON, UNITED KINGDOM, March 17, 2026 /EINPresswire.com/ -- [Image Analysis Group \(IAG\)](#), the world's leading specialist Imaging Clinical Research Organization (iCRO) and developer of the [DYNAMIKA™](#) clinical trial imaging platform, announced the successful completion of its [SOC 2](#) Type II audit. The independent certification, conducted under standards established by the American Institute of Certified Public Accountants (AICPA), validates that IAG's systems, platform infrastructure, and operational controls meet the highest levels of data security, availability, and confidentiality, reinforcing IAG's position as the trusted imaging partner of choice for the world's most demanding multinational clinical development programs.



Image Analysis Group (IAG)



DYNAMIKA™ at IAG

Why This Matters Now: The New Security Imperative in Clinical Imaging

As imaging endpoints move from secondary to primary measures of efficacy across oncology, neurology, autoimmune, and musculoskeletal diseases, the volume, sensitivity, and regulatory significance of imaging data have grown exponentially. A single Phase III trial may generate hundreds of thousands of imaging datasets spanning dozens of countries - each subject to HIPAA, GDPR, ICH E6(R3) GCP, and increasingly strict FDA and EMA data integrity expectations.

In this environment, SOC 2 Type II is no longer a "nice to have", it is a baseline requirement for imaging CROs seeking to partner with major pharmaceutical and biotechnology sponsors. Unlike

SOC 2 Type I, which is a point-in-time snapshot, the Type II certification validates that IAG's security controls were consistently designed and operating effectively across a full 12-month monitoring period (October 4, 2024 to October 4, 2025). This is the gold standard for enterprise-grade operational assurance.

IAG is among a very small number of specialist imaging CROs globally to have achieved this certification - a distinction that reflects the company's decade-long investment in enterprise-class infrastructure, processes, and talent.

What the Audit Validated: Deep Controls Across Every Layer

The AICPA-accredited audit assessed IAG across all five Trust Services Criteria: security, availability, processing integrity, confidentiality, and privacy, evaluating over a continuous 12-month period. The auditors examined:

- **Software Development Lifecycle (SDLC):** IAG's DYNAMIKA™ platform is developed under a rigorous, security-first SDLC with formal code review, penetration testing, vulnerability management, and change control - ensuring every software release meets pharmaceutical-grade quality and security standards.
- **Enterprise Cloud Infrastructure:** The DYNAMIKA™ platform operates within hardened, multi-region cloud environments featuring encryption at rest and in transit, granular role-based access controls, continuous threat monitoring, automated anomaly detection, and tested disaster recovery with defined recovery time and recovery point objectives.
- **Global Operations & Personnel Security:** End-to-end personnel security programs including background screening, role-based access provisioning, security awareness training, and formal incident response protocols govern IAG's globally distributed teams across the UK, US, EU, and India.
- **Data Governance & Patient Privacy:** Comprehensive controls for the handling of electronic Protected Health Information (ePHI) and imaging datasets, including automated de-identification, audit trails, and chain-of-custody documentation to support full compliance with HIPAA, GDPR, and sponsor data management agreements.
- **Regulatory Auditability & 21 CFR Part 11 Alignment:** System-wide audit trails, electronic signature frameworks, and immutable record management are designed to satisfy FDA 21 CFR Part 11 and EU Annex 11 expectations, streamlining regulatory submissions and inspections for IAG's sponsor partners.

DYNAMIKA™: Enterprise Imaging Platform Built for the Global Trials

At the center of IAG's SOC 2 certification is DYNAMIKA™, IAG's proprietary cloud-based clinical trial imaging platform - purpose-built to manage imaging data at enterprise scale across global, multi-center studies from Phase I through Phase III and beyond. DYNAMIKA™ delivers:

- End-to-end imaging workflow management - from site activation and modality qualification through image acquisition, automated transfer, de-identification, quality control, analysis, and regulatory-compliant reporting

- Image analysis tools and validated quantitative biomarker pipelines across oncology (RECIST 1.1, mRECIST, RANO, PCWG3), inflammatory disease, neurology, obesity and musculoskeletal indications
- Full support for the blinded or AI-Radiologist hybrid reads which can support extraction of additional information from Standard of Care images to generate early insight to help linking drug mechanism of action to imaging biomarkers
- Seamless integration with sponsor EDC and data management systems through validated, secure data exchange interfaces
- Real-time trial oversight dashboards providing sponsors with full visibility into site performance, image quality metrics, and query resolution status
- Scalable architecture supporting simultaneous management of global distributed imaging sites, variety of imaging timepoints, and petabytes of imaging data
- Fully validated 21 CFR Part 11-compliant electronic workflows with immutable audit trails and electronic signatures throughout

SOC 2 Type II certification ensures that the infrastructure underpinning every one of these capabilities has been independently verified as operating securely and reliably - giving sponsor quality assurance, IT security, and regulatory affairs teams the documented assurance they require.

IAG operates as a truly global imaging expert and operational partner to pharmaceutical and biotech clients, with experienced clinical imaging teams embedded across the United Kingdom, United States, European Union, and India. This footprint enables IAG to provide:

- 24/7 follow-the-sun operational support for study sites, ensuring rapid response to imaging queries, data transfer issues, and quality holds across every time zone
- In-region clinical and regulatory expertise to navigate country-specific imaging requirements and health authority expectations in the US, EU, UK, and Asia-Pacific
- Localized vendor qualification and site support capabilities that reduce the burden on sponsor study teams while ensuring protocol compliance at every imaging site
- Multilingual operational teams with deep therapeutic area expertise serving oncology, autoimmune disease, neurology, cardiovascular, and rare disease programs

The SOC 2 Type II audit scope encompasses IAG's entire global operational footprint - not just its technology systems. Sponsors can be confident that the same rigorous security standards governing DYNAMIKA™ extend to IAG's global workforce, processes, and third-party vendor relationships.

Regulatory & Clinical Trial Readiness: A Complete Compliance Framework

IAG's compliance posture extends well beyond SOC 2. The company has built an integrated regulatory readiness framework that aligns with:

- ICH E6(R3) Good Clinical Practice - updated GCP guidelines with enhanced data integrity requirements now directly applicable to imaging CRO operations

- FDA 21 CFR Part 11 & EU Annex 11 - validated electronic systems for audit trails, electronic signatures, and records management
- HIPAA & GDPR - comprehensive privacy controls for patient imaging data across US and EU jurisdictions
- FDA Guidance on Imaging Endpoints - qualification and validation of imaging biomarkers as primary and secondary endpoints in regulatory submissions
- ISO 27001-aligned information security management principles embedded within IAG's SOC 2 control environment

This integrated framework directly reduces sponsor risk at regulatory inspection and supports accelerated market authorization applications by providing sponsors with independently audited, documented evidence of imaging data integrity.

Leadership Commentary

"Achieving SOC 2 Type II is not merely a compliance milestone - it is a statement of who IAG is and the standard we hold ourselves to as the imaging partner for the world's leading pharmaceutical programs. Our multinational clients operate under the most stringent regulatory and security requirements on earth. This independent certification confirms that DYNAMIKA™ and our global teams are built to that standard - today and as clinical trial complexity continues to grow."

— Olga Kubassova, PhD, CEO & Founder, Image Analysis Group

"Sponsors and CRO partners trust IAG with the most sensitive imaging data in clinical development. SOC 2 Type II gives them documented, independently validated assurance that our systems operate with the security, reliability, and compliance required for the most demanding global trials. It also reflects the extraordinary investment our engineering and operations teams have made in building an enterprise-class platform that is genuinely fit for the next decade of clinical imaging."

— Jon Himoff, Chief Product Officer, Image Analysis Group

About Image Analysis Group (IAG)

Founded in 2007 and headquartered in London, Image Analysis Group (IAG) is the world's leading specialist Imaging Clinical Research Organization (iCRO). IAG partners with the world's top pharmaceutical, biotechnology, and clinical research organizations to design, execute, and deliver imaging-based clinical trial endpoints across oncology, inflammatory disease, neurology, musculoskeletal, cardiovascular, and rare disease indications.

IAG's proprietary DYNAMIKA™ platform is the most advanced cloud-based clinical trial imaging management system available, integrating AI-driven image analysis, centralized quality control, regulatory-compliant reporting, and real-time trial oversight across global multi-center studies. IAG's global teams — spanning the United Kingdom, United States, European Union, and India —

combine deep medical imaging science, therapeutic area expertise, and regulatory intelligence to accelerate drug development timelines and strengthen the evidentiary quality of imaging endpoints in regulatory submissions.

IAG is certified to SOC 2 Type II and operates in compliance with HIPAA, GDPR, 21 CFR Part 11, EU Annex 11, and ICH E6(R3) GCP.

For more information about Image Analysis Group (IAG):

Website: <https://www.ia-grp.com>

LinkedIn: <https://www.linkedin.com/company/image-analysis-ltd>

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