MCRA
an IQVIA business

Empowering FDA Clearance of United Imaging Intelligence Technology in Under 60 Days

Integration Means Acceleration

info@mcra.com • 202.949.4108 • mcra.com

MCRA
an IQVIA business

A case study of expertise, efficiency — and zero deficiencies.

MCRA's AI & Imaging Center team collaborated with its Clinical and Regulatory Affairs divisions to deliver accelerated FDA clearance of a groundbreaking radiology technology from United Imaging Intelligence. **MCRA's operational expertise and seamless integration ensured the study had zero deficiencies** — resulting in the approval of their client's uAI Easy Triage ICH software in under 60 days.

info@mcra.com • 202.949.4108 • mcra.com

MCRA
an IQVIA business

Advancing life-saving AI technology.

uAI Easy Triage ICH uses AI technology to quickly identify and flag potential intracranial hemorrhages in CT scans. This intelligent alert system helps healthcare professionals prioritize treatment for stroke patients — when every moment counts.

United Imaging Intelligence, a global leader in advanced medical imaging and radiotherapy equipment, retained MCRA's AI & Imaging Center to lead their device performance study with the goal of receiving an expeditious 510(k) clearance.

info@mcra.com • 202.949.4108 • mcra.com

MCRA
an IQVIA business

Navigating a challenging submission process.

Achieving FDA clearance of Computer Aided Triage (CADt) technology is particularly challenging. Due to their targeted application, these submissions typically involve multiple rounds of review phases to address key concerns — and can take as long as 100 days. Companies rarely receive clearance on their first submission, and it's even less common to do so without deficiencies.

info@mcra.com • 202.949.4108 • mcra.com

Providing expert insight and seamless integration.

United Imaging Intelligence relied on MCRA's deep FDA insight for all aspects of their study. Bringing together study design, protocol development, data sourcing, biostatistics analysis, report generation, and knowledgeable expertise, MCRA played a crucial role in the study's efficiency and accelerated their FDA clearance.

Alex Cadotte, Ph.D.
Vice President, Digital Health, AI, and Radiology Regulatory Affairs

Former FDA team lead for imaging software review with expert knowledge of computer-aided devices

Nima Akhlaghi, Ph.D.
Director, Digital Health & Imaging Center Lead

Former FDA medical device lead reviewer with a deep understanding of regulatory requirements

Jenny Treiber
Senior Manager, Imaging Operations

More than 14 years of specialized CRO imaging operations expertise

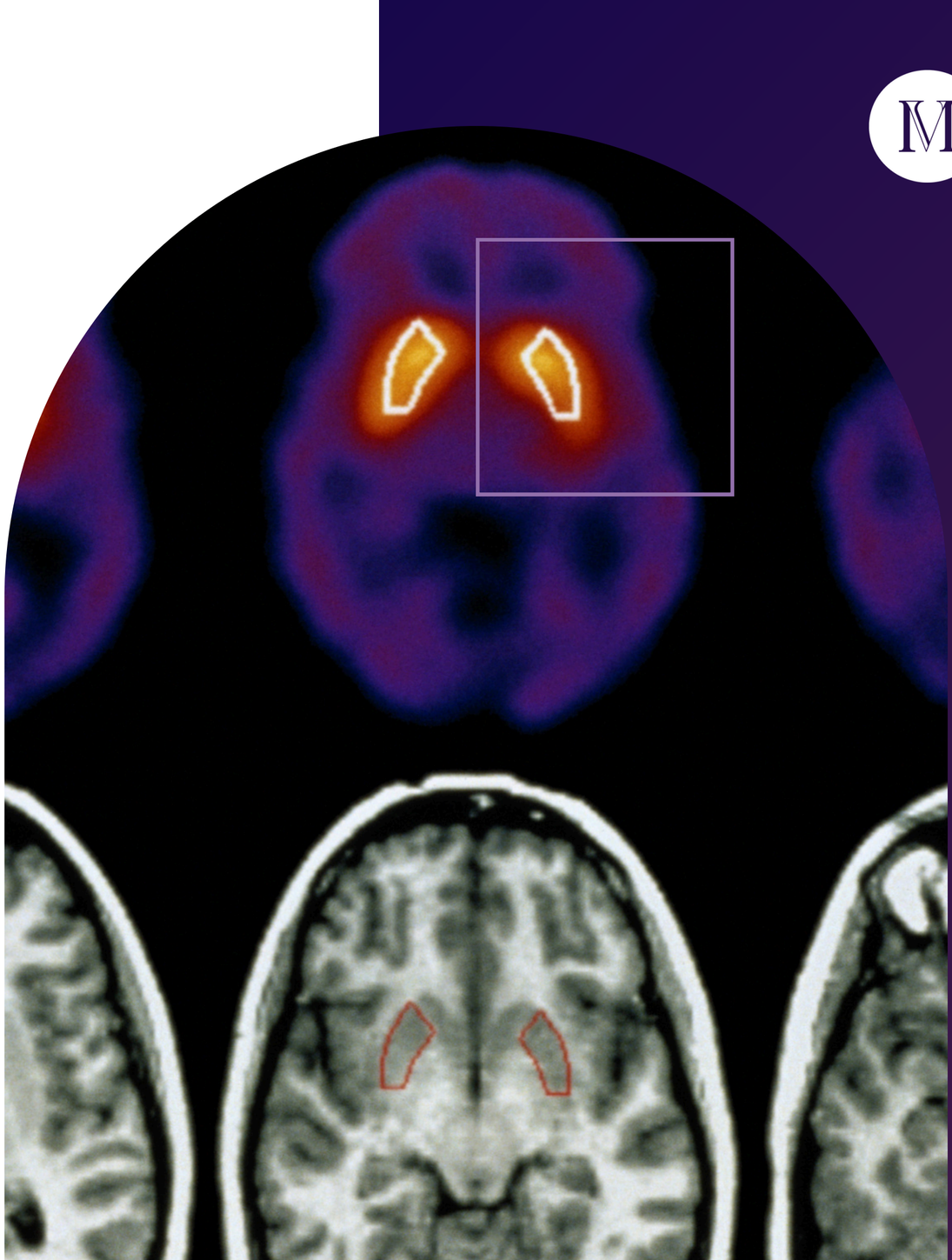
MCRA
an IQVIA business

info@mcra.com • 202.949.4108 • mcra.com

Exceeding expectations and encouraging optimal outcomes.

Drawing on their extensive knowledge of all aspects of FDA clearance, MCRA's cross-functional team ensured United Imaging Intelligence received their 510(k) clearance for uAI Easy Triage ICH in less than 60 days and with zero deficiencies — all while remaining under budget.

"MCRA consistently provided clear guidance on the best steps forward. Their support and responsiveness were crucial in navigating the process smoothly and efficiently."
- Terrence Chen, CEO of United Imaging Intelligence (U.S. Office)



MCRA
an IQVIA business

info@mcra.com • 202.949.4108 • mcra.com

MCRA
an IQVIA business

Talk to MCRA's AI & Imaging Center experts today.

202.949.4108
info@mcra.com
mcra.com