

*“Stay Ahead of the Game:  
Transformation in Clinical Trials  
in the Age of Artificial Intelligence.”*

**ANNUAL  
CLINICAL TRIALS  
SYMPOSIUM**

**November 8<sup>th</sup>, 2024**

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# Revolutionizing Drug Development: AI a Game Changer in Clinical Research for Contract Research Organization

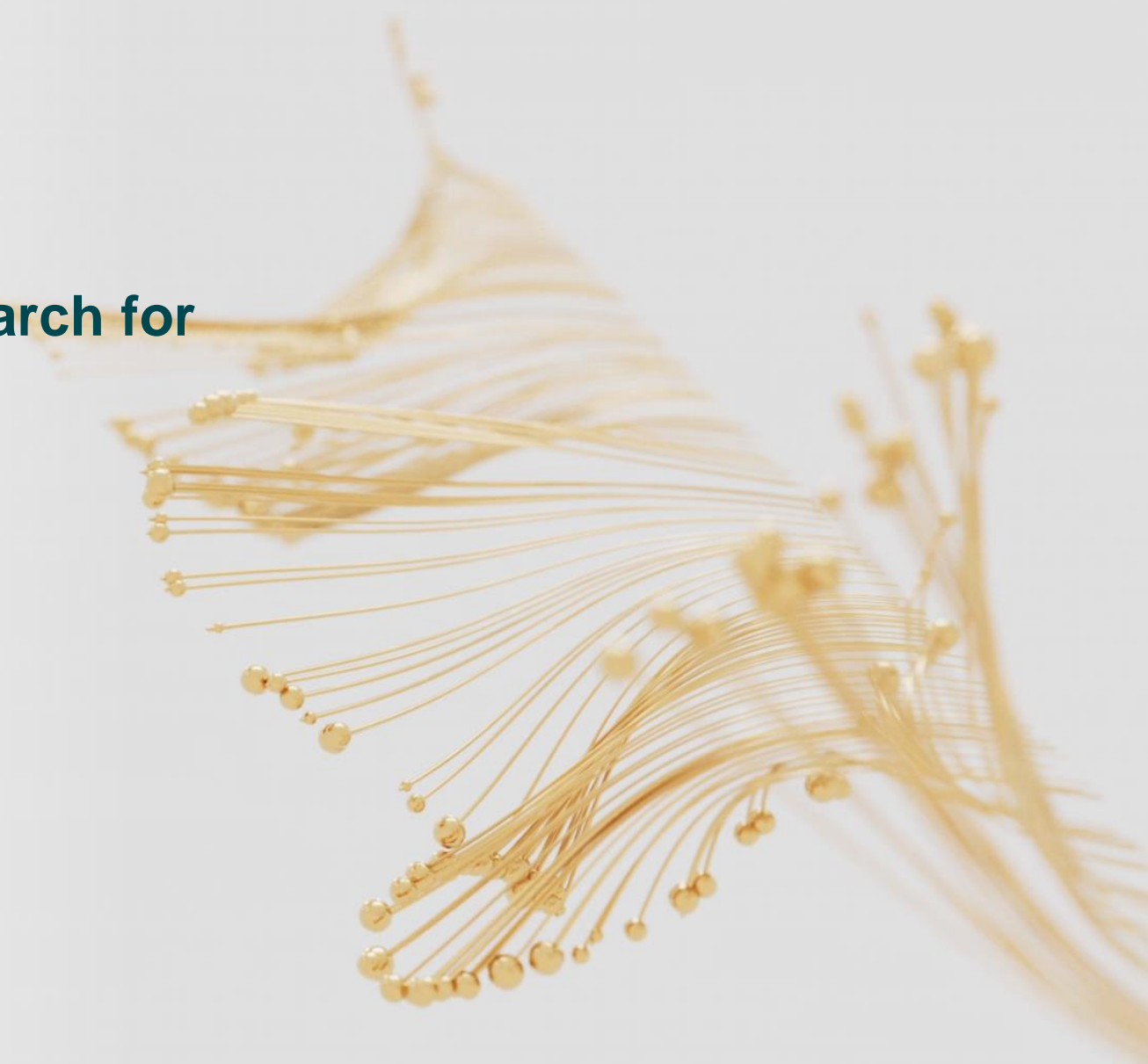
Dr. Alexandre Malouvier, PhD  
*Senior Director Scientific Affairs & Digital Innovation*  
eClinical Development & Commercial Solutions  
ICON plc



**Annual Clinical Trials Symposium**

8<sup>th</sup> of November, 2024

Novotel Bucharest City Center



# Why AI Matters in clinical research



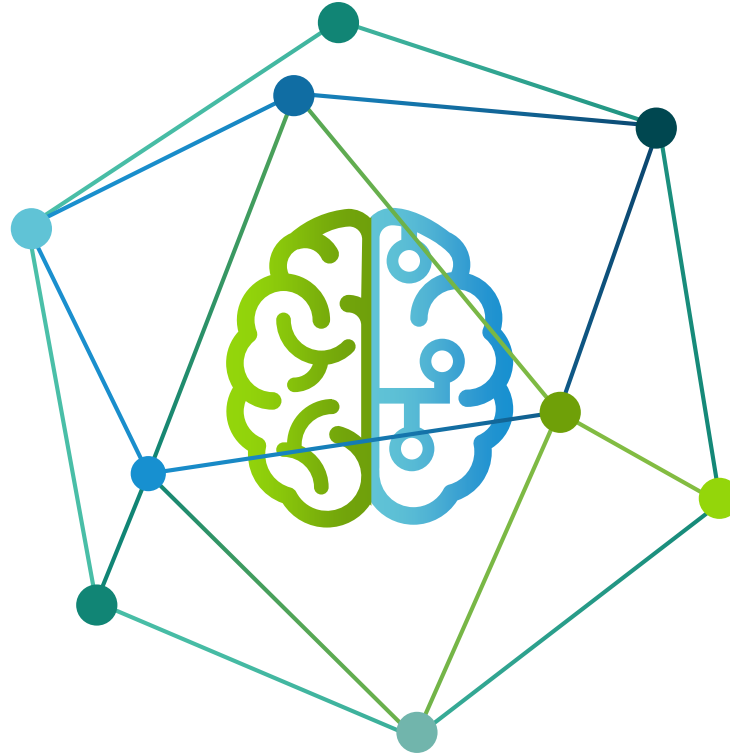
**Speed**



**Accuracy**



**Efficiency**



**Smarter**



**Reliable**



**Streamlined**



In the fast-paced world of clinical research, speed, accuracy, and efficiency are crucial. At ICON, we leverage the power of Artificial Intelligence to transform how trials are conducted, delivering smarter, faster, and more reliable outcomes. Our AI-driven solutions address critical challenges, enabling us to optimise every phase of the clinical trial process—from site selection to data management and beyond.

# Our vision for AI at ICON

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At ICON, our vision is to seamlessly integrate AI into clinical research to:



Accelerate trial timelines by automating and optimising key processes.



Enhance data-driven decision-making with powerful predictive analytics.



Improve patient outcomes by increasing the accuracy and efficiency of trials.



Ensure compliance and ethical governance through responsible AI use.

By pioneering AI solutions, we aim to set new standards in clinical research, ensuring that innovative therapies reach patients faster.

# The AI Center of Excellence



Our AI journey is driven by ICON's AI Center of Excellence, a dedicated team of data scientists, engineers, and domain experts. This team is responsible for developing and deploying cutting-edge AI solutions that are already making a significant impact in clinical trials today. Supported by our AI Governance Committee, which oversees ethical, legal, and data privacy standards, the Center of Excellence ensures that our AI innovations are both responsible and effective.

# Ethical and responsible AI

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**Our solutions are developed and deployed responsibly**

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ensuring transparency

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and trust with our partners and clients



At ICON, we recognise the importance of ethical AI. Our AI Ethics Committee and AI Charter guide our efforts to ensure that our solutions are developed and deployed responsibly. This commitment to ethical AI extends across all areas of our business, from data privacy and cybersecurity to ensuring transparency and trust with our partners and clients.

# An Integrated Suite of AI Solutions

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Our AI solutions are designed to address the unique challenges of clinical research. These solutions can be grouped into three key categories:



**Accelerating Trial Execution**



**Enhancing Data and Resource Management**



**Optimizing Operational Efficiency**

Together, these AI-powered tools drive significant improvements in trial speed, accuracy, and overall performance.



# ICON Digital Innovation and Artificial Intelligence





# Digital Innovation & AI Roadmap

## Mature



### OneSearch

AI solution using multiple internal and external data sources to deliver industry leading site and investigator selection. Significantly reduces time to Site ID & non-performing Sites; and increases likelihood of meeting FPI and LPI targets



### Cassandra

AI solution predicting post marketing study requirements to define a mitigation strategy early in the drug development cycle, and this could be critical to the overall success of a new product.



### ICONex

AI targeted solution identifying Key Opinion Leaders globally for all therapeutic areas through publication authorship



### ARCADES – Data Framework

ARCADES Data framework facilitates our data ingestion, transformation & delivery for our AI solutions



### AI Enhanced Clinical Data Science (SmartQuery)

AI/ML solution replacing manual review of clinical data listings (AE-CM-MH) using NLP

## Launch



### iSubmit

Generative AI / LLM solution for the document management on sponsor clinical trials. Reduces resource effort and increases quality



### MRT COA

Generative AI / LLM solution that searches public sources near real-time for comprehensive and latest known/unknown/new clinical outcome assessments and information



### FORWARD+

AI solution that empowers our clinical trial resource forecasting, identification and management processes



### Study Startup Contracts

Generative AI / LLM solution that will create the first draft of all our study startup sponsor / site contracts based on the historical signed contract language and terms



### Operational Metrics AI - OMR

Generative AI / LLM solution that empowers and enables all our operational metrics with large language model search, analysis and reporting capability

## Development



### Resource Intelligence

Combine generative AI and machine learning plan, forecast and tightly couple all stages of study execution

- Patient enrolment
- Resource forecasting
- Resource identification and assignment
- Protocol amendments
- Project risk management



### Intelligent Automation

Use AI to enhance and enable task automation

- Pharmacovigilance case triage
- Site invoice processing
- RFI/RFP processing
- Machine translation (e.g. Trial Documentation)



### Docu Intelligence

Exploit the power of generative AI and large language models to accelerate and drive quality improvements in

- Site activation
- Health authority responses
- Site contract negotiation
- Legal processes

# AI @ ICON – ICON Intelligence program

## ICON Intelligence



### Docu Intelligence

Exploit the power of generative AI and large language models to accelerate and drive quality improvements in:

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- Health authority responses
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# Mature AI Delivered Outcomes

# OneSearch – Identify the right sites the first time



Humans can recognise **key protocol nuances** and identify which study features should be emphasised



**AI can parse a massive amount of real-world data**, evaluate connections and rank the results based on best fit criteria



Find patterns in complex data that are impossible for a human mind to see so we can provide new insight to decision makers and analysts

## One Search combines these two concepts to drive better delivery



Median time for site identification

53% ▼



% Non-enrolling sites

50% ▼



Customer satisfaction scores

24% ▲



First patient in targets

25% more likely



Last patient in targets

21% more likely

# Cassandra – Predict post-marketing requirements



**Machine learning model trained on real world evidence** (trial features and FDA and EMA decisions) can predict post-marketing requirements with **>96% accuracy**



Make accurate predictions to facilitate smarter decision making



ICON commercialisation and outcomes team can ask Cassandra a question, **quickly interpret the answer and devise a smarter strategy informed by AI**



## Combining AI and human expertise substantially de-risks drug development



Proactively plan for post-marketing requirements



Define mitigation strategy early in the drug development lifecycle



Implement additional early safety monitoring to avoid post authorisation safety studies

# ICONex – Finding rare disease experts



**Network graph that builds a comprehensive picture of expert publication, peer relationships and influence**



Find patterns in complex data that are impossible for a human mind to see so we can provide new insight to decision makers and analysts



**ICON consultants can quickly identify the best key opinion leaders and geographic locations for any rare disease opportunity**

## Combining AI and human expertise accelerates study start up



**Quicker path to study design**



**Identification of disease indication networks**



**Key insights for feasibility plans**

# SmartQuery – AI enhanced Clinical Data Management

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The use of **Natural Language Processing (NLP)** has greatly reduced the human data review time for AE-CM reconciliation - (AE=Adverse Event; CM=Concomitant Medication).

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## AI / ML solution replacing manual review of clinical data listings using NLP

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Standardised  
programming for all  
studies



Manual review focused  
on AE-CM anomalies only



Human error associated  
with high data review  
volumes reduced



# **AI Initiatives Launch 2024 / 2025**



# iSubmit – Auto-filing; improved compliance



## Machine learning models trained on eTMF documents

- Autoclassify type, subtype and filing level
- Extract metadata required for filing
- Detect document formatting issues
- Impute associated filing requirements

Automate processes that are either trivial but long to execute or complex and difficult or impossible for a person to execute



**Simple but repetitive eTMF filing tasks can be automated, and complex determinations for eTMF document dependencies can be made through AI insight**

## AI can automate a process and raise the quality threshold



Decreased burden on study teams



Automated indexing and indexing QC



Reduced audit findings because of AI coherence checks



Expert hours repurposed for advanced coherence checks

# MRT COA – AI-powered outcomes intelligence

Mapi Research Trust



**Natural language processing and fine-tuned large language models auto-update our existing eCOA database and add new eCOAs to the repository based on published resources**

Find patterns in complex data so we can provide new insight to decision makers and analysts



The ICON commercialisation and outcomes team, in association with ICON's Mapi Research Trust, can **recommend optimal outcomes strategies for protocol design and execution**

## Generative AI takes outcomes consultancy to a new level of insight and effectiveness



**Near real-time sync with published outcomes research**



**Gather intelligence on outcomes trends and effectiveness**



**Build new commercial opportunities in healthcare intelligence beyond clinical research**

# FORWARD+ – Resource forecasting and identification



**AI enabled** visibility and management of all core resources - demand, allocation and forecasting – in a single solution



Integrated demand and forecasting – working in synergy to deliver efficient resourcing and accelerate revenue.

## FORWARD+ AI enablement drives better delivery



Integrated demand and forecasting



Proactive control of potential and actual resource overrun



Visibility and management of all core resources



Decreased burden on study teams

# Study Startup Site Contracts – AI Enabled Site Contracts



**AI enabled SSU Site Contracts are trained on the historical corpus of ICON site contracts so that the model can quickly recommend what is most likely to work for a particular combination of site, sponsor and country**



**SSU contract analysts will be able to provide an evidence-based, near-final draft of a contract as a starting position**

## AI can drive efficiency into the site contract process



**Decreased burden on study teams**



**Automated creation of sponsor / site contract**



**Site Contracting cycle time improvement**



**Increase in efficiency in site contracting process**

# OMR AI – AI-powered operational metrics reporting

Operational Metrics Reporting



**Generative AI / LLM** are trained to search and interrogate operational metrics, thereby providing natural language responses to business queries

Find patterns in complex data so we can provide new insight to decision makers and analysts



**Operational Metrics** evidence-based insights will be obtained quickly and intuitively for even the most specialised and nuanced scenarios

## Generative AI takes outcomes consultancy to a new level of insight and effectiveness



Apply consistent and in-depth business intelligence to decision making



Gather intelligence quickly across operational metrics



Ease of access to extracting full value from our operational metrics

# ICON



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