Medicines & Healthcare products Regulatory Agency

MHRA approach to innovation in clinical trials

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Six strategic vectors

New Clinical Trial Regulations

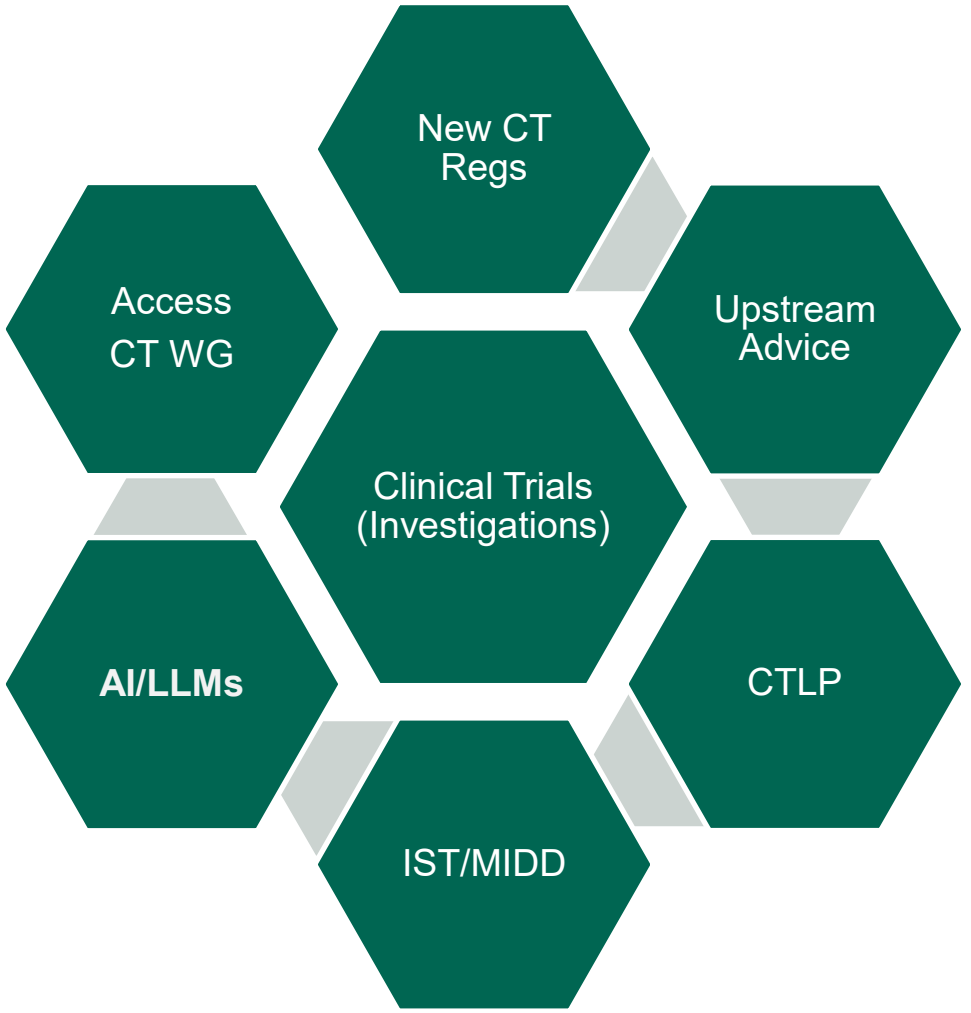
Clinical Trials

Working Group

Scientific advice

Artificial Intelligence /
Large Language Models

Clinical Trial
Lifecycle Package



In-Silico Technology

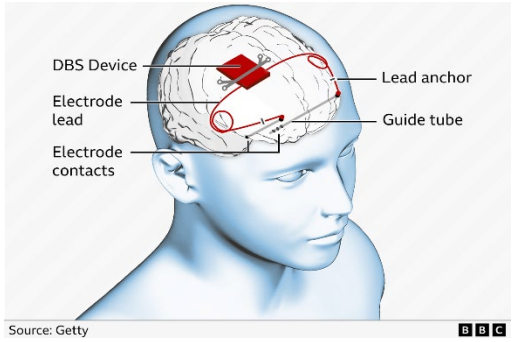
A two-sided coin

Regulate technology	Use technology
Artificial Intelligence (AI)	AI
Software	Machine Learning (ML)
Airlock	Large Language Models (LLM)
Physiologically Based Pharmacokinetic, Quantitative Systems Pharmacology Model Inform Drug Development, Model Inform Evidence	Natural Language Processing (NLP)

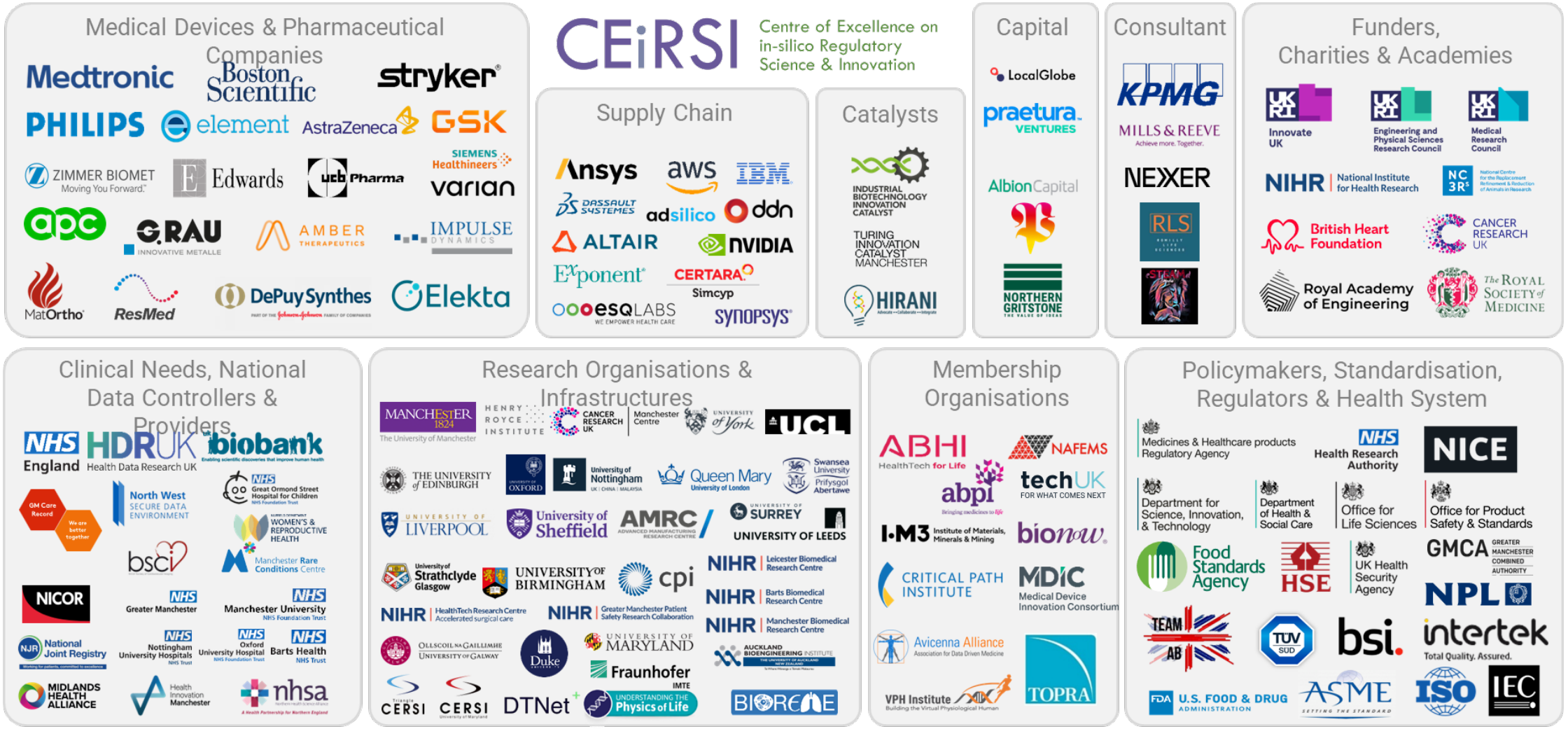
World first device fitted in a UK boy's skull to treat epilepsy

Oran Knowlson is a young patient who received the world's first implant of a new deep brain stimulation (DBS) device in his skull to treat his severe Lennox-Gastaut syndrome (LGS).

LGS is a severe, rare epilepsy syndrome that begins in early childhood and involves multiple seizure types, cognitive impairment, and characteristic slow spike-and-wave patterns on an EEG.



UK CEiRSI Community of Interest



In Silico Regulatory Airlock: Implementation Phase

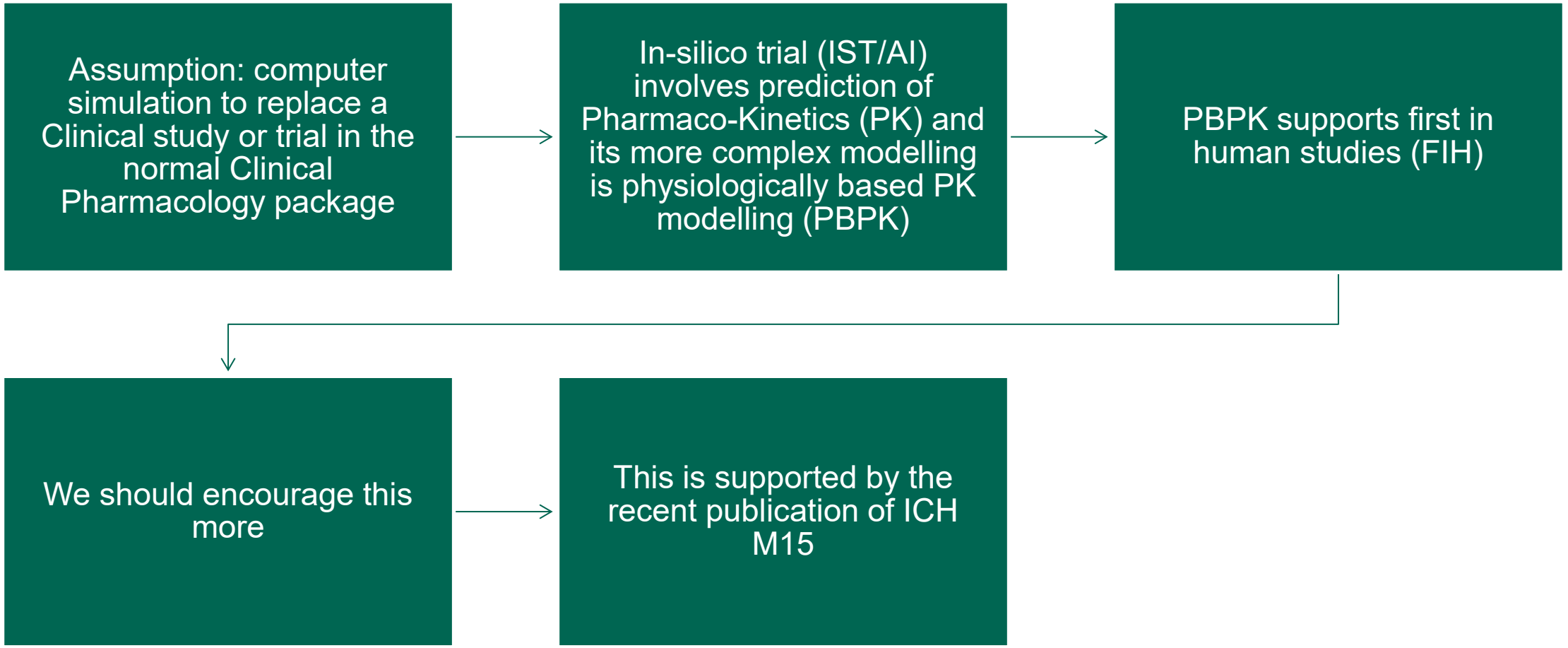
Pilot Convenors	#	Theme
Resmed	1	CPAP Mask Evaluation: CO2 Venting and Rebreathing Performance Using In-Silico Techniques for Regulatory Compliance
stryker	2	Flow-Diverter Device: Pre/Post Implantation Intracranial Aneurysm Blood Flow & Clotting Models for In-Silico Trials
Boston Scientific	3	Transcatheter Aortic Valve Implantation: Conditional Generative Virtual Populations of Heart Anatomy for Targeted In-Silico Trials
Edwards	4	Transcatheter Aortic Valve Implantation: Frame Release and Pre/Post Implantation Blood Flow Models Predicting Aortic Stresses and Valve Leakage for In-Silico Trials
AMBER THERAPEUTICS	5	Deep Brain Stimulation: Closed-Loop Physiological Bidirectional Control System Model for Early Safety/Performance Assessment
DePuy Synthes PART OF THE Johnson & Johnson FAMILY OF COMPANIES	6	Spinal Pedicle Screw System: In-Silico Bench Testing for Confirming System Integrity after Introduction of a Cannulation
MatOrtho	7	Total Hip-Joint Replacement: Computational Simulator for Patient-Centered Wear Testing of Orthopaedic Device
ZIMMER BIOMET Moving You Forward.	8	Total Knee Replacement Device: Augmentation of National Joint Registry with Data Derived from In-Silico Trial Insights
GSK	9	Vaccines: Quantitative systems pharmacology (QSP) computational models for finding optimal dosing regimens
SIEMENS Healthineers varian	10	Radiotherapy treatment system: in-device integration of treatment data and models of radiobiology for optimised radiotherapy performance

- Support assessment
- Support training
- Support sponsors

Input from our assessors (part I)

(Pharmacology & Toxicology)	(Pharmaceutical)	Clinical
How representative are the AI models?	Is the Investigational Medicinal Product (IMP) used by AI sufficiently representative of the IMP proposed in the trial?	Modelling and simulation can be used as ‘supportive’ tools but would not replace the need of real clinical data to support a CTA
Could AI models 'over-simplify' biological systems?	How would the validity of the AI method be assessed for the situation it is intended to model?	Modelling can be used to optimize the design of clinical trials, and to calculate a proposed dose in subgroups (e.g. paediatrics, elderly, renal impairment)
Are AI models reliable?		From safety perspective, adequate assessment of an IMP’s safety should be conducted in humans which can only be performed in well controlled clinical trials.

Input from our assessors (part II)



Opportunities

Innovation Area	Technology Used	Regulatory Impact
MIDD	Simulation, modeling	Improves trial efficiency
In Silico Trials	Digital twins, Virtual Humans	Reduces patient risk
NLP for Submissions and Assessment	Automation, AI	Streamlined documentation
AI in Drug Discovery	Generative AI	Faster clinical entry

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Thank you

Any questions?

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