Dr Lucy Buckley, Dr Angus Prosser and Dr Phil Jewell

Hurdles or assets? A new perspective on healthtech regulation

THE DIGITAL HEALTH ASSURANCE COMPANY

THE ROYAL SOCIETY

NHS University Hospital Southampton NHS Foundation Trust

SETT

NHS
University Hospital Southampton
NHS Foundation Trust

SETT

Accelerating innovation research for patient impact

Clinical trials expertise, focused on Medtech, data/AI and advanced therapies
Single point of entry for advice, at any stage of technology development
Support for research design, review, setup, delivery and implementation
Advice on regulatory standards, research governance and ethical guidelines
Access to infrastructure, including clinical samples, data and populations
Identification of clinical leads, PIs, PPI groups and multidisciplinary collaborators

SETT@uhs.nhs.uk

Research data science unit

Supporting clinical research at scale with automated and reproducible data extraction & analytics

Faizan

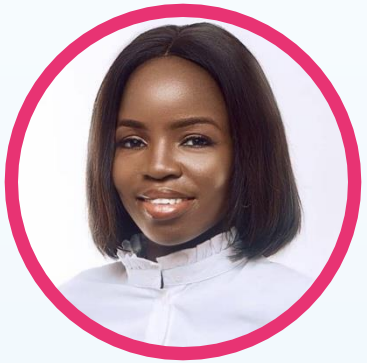
Ananya

Michael

Ashley

Matt

Cai



Kehinde

Jamie

The “hurdles”!

Medicines & Healthcare products Regulatory Agency

FDA U.S Food and Drug Administration

UK CA

CE

CLINICAL TRIAL REGULATION EU NO 536 2014

European Commission
Medical Devices Regulation
EU MDR

Commission on Human Medicines

FDA 510(k)

GDPR

Data Protection Act 2018

HIPAA Health Insurance Portabi & Accountability Act

GCP Good Clinical Practice

GOOD MANUFACTURING GMP CERTIFIED PRACTICE

WHO-GMP

NHS National Institute for Health and Clinical Excellence

ISO

British Pharmacopoeia

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

ICH harmonisation for better health

NHS Health Research Authority

THE DIGITAL HEALTH
ASSURANCE COMPANY

Our mission is to create an innovative healthcare landscape where the highest quality patient care and sustainable business growth coexist harmoniously.

DiCE

Driving digital clinical excellence

Supporting clinical care improvement and safety in digital healthcare to develop excellence in digital care standards.

UoM School of Health Sciences

Providing support and expert advice on promoting innovation and the translation of research, as well as research and development.

THE DIGITAL HEALTH
ASSURANCE COMPANY

Hurdles or assets?

A new perspective on HealthTech regulation?

How do regulation and compliance make you feel?

THE DIGITAL HEALTH ASSURANCE COMPANY

Restricted

Bored

Expensive

Scared

Not my responsibility

Overwhelmed

Complex

Slows me down

THE DIGITAL HEALTH ASSURANCE COMPANY

THE DIGITAL HEALTH
ASSURANCE COMPANY

Why is regulation and compliance important?

Opportunity

Competitor advantage

Trust in innovation

Investor confidence

Credibility

Patient Safety

Quality and reliability

Strong Foundations

Creates a revenue generating asset

Market access

Operational efficiencies

Ethical use of technology

THE DIGITAL HEALTH ASSURANCE COMPANY

Regulation vs Compliance

THE DIGITAL HEALTH ASSURANCE COMPANY

Regulation = The Rulebook

Formal rule or law set by a government or regulatory body

"what" you're required to do by law or policy

Traffic laws

Compliance = Playing by the Rules

Your actions to meet those regulatory requirements

"how" you make sure your product or service meets the rules – the fun part

Driving within the speed limits

What can go wrong?

- 89 trusts confirmed they monitored and **logged instances when patients could be harmed** as a result of problems with their Electronic Patient Record (EPR) systems
- almost half recorded instances of **potential patient harm linked to their systems**
- nearly 60 trusts reported **IT problems that could affect patient care**
- more than **200,000 letters were not sent** across 21 trusts
- there were **126 instances of serious harm linked to IT issues**, across 31 trusts

THE DIGITAL HEALTH ASSURANCE COMPANY

When IT failures become headline news

THE DIGITAL HEALTH ASSURANCE COMPANY

Digital Technology Assessment Criteria (DTAC)

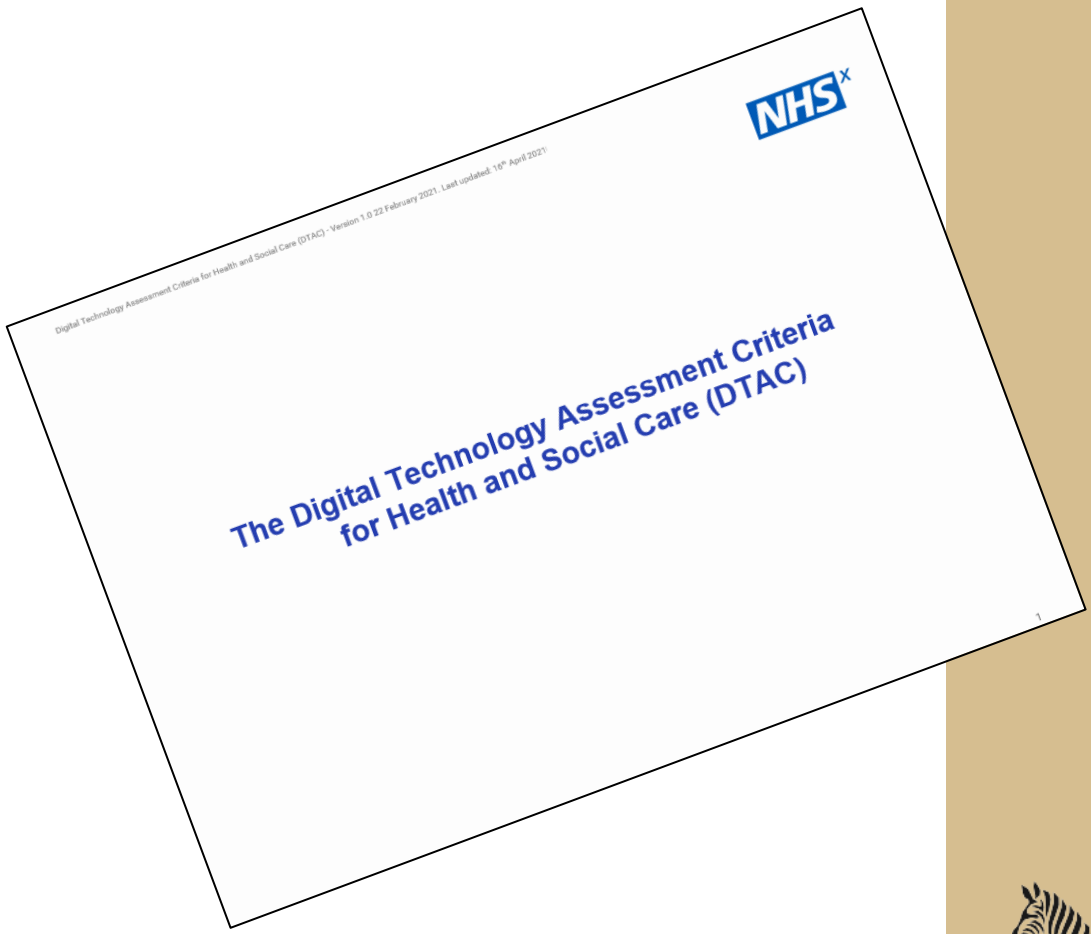
THE DIGITAL HEALTH ASSURANCE COMPANY

Why do we need this?

Unnecessary bureaucracy?

… or an essential safeguard?

1. Safety
2. Data protection
3. Technical security
4. Interoperability
5. Usability and accessibility



Governance led Innovation

Using governance, not as red tape, but as a framework that enables faster, safer, and more aligned innovation.

This ensures that what you're building is:

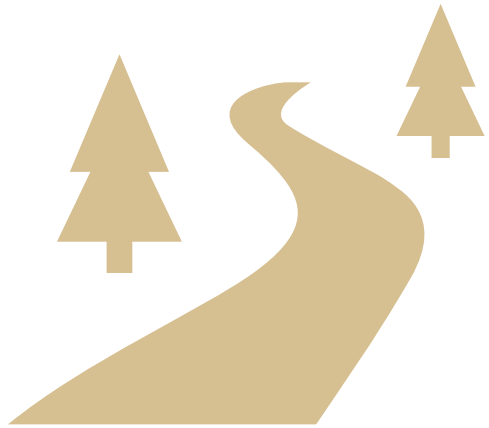
- Safe
- Compliant
- Scalable
- Ethical
- Trusted by stakeholders

If your innovation isn’t safe there is no product market fit

THE DIGITAL HEALTH ASSURANCE COMPANY

Your regulatory Road Map

- Don’t look at regulation in isolation
- Integrate with your commercial, clinical, operational, product development and market access objectives
- Align with your commercial milestones and investment needs
- Build a robust quality management system



THE DIGITAL HEALTH ASSURANCE COMPANY

Be the change

- UK regulation is in a state of flux at the moment with many new initiatives and potential changes – CQC, DCB0129 and DCB0160, DTAC, NHS England
- Being a leader in HealthTech can be lonely, compared to more traditional settings
- Challenge the status quo and be leaders in best practice
- Use leadership and culture as an enabler of strong governance and quality assurance

THE DIGITAL HEALTH
ASSURANCE COMPANY

Case Study

- Secure messaging platform between NHS clinicians and patients
- Designed infrastructure around UK GDPR, NHS Data Security and Protection Toolkit, and Cyber Essentials Plus. Obtained ISO27001
- Published clear, transparent documentation on data processing, information governance, and patient confidentiality.
- Actively collaborated with NHS Trusts and CCGs to ensure local Information Governance) teams were on board.

- Rapid NHS adoption during the COVID-19 pandemic.
- Considered safe, trustworthy, and easy to integrate with existing NHS systems.
- Grew from 20 to 90% GP market penetration in just over a year — thanks largely to its compliance-first approach.

THE DIGITAL HEALTH ASSURANCE COMPANY

Case study

- Online primary care provider rated GOOD with CQC
- Change of leadership - a different changed attitude to compliance and governance
- They resisted and didn't embrace and tried to get away with doing the bare minimum
- Once they started to scale the cracks appeared
- Leading to patient complaints

- Investigations with multiple regulators
- Regulatory fines, product shutdowns, reputational damage, potential criminal liability.
- Company liquidated

THE DIGITAL HEALTH ASSURANCE COMPANY

Investment

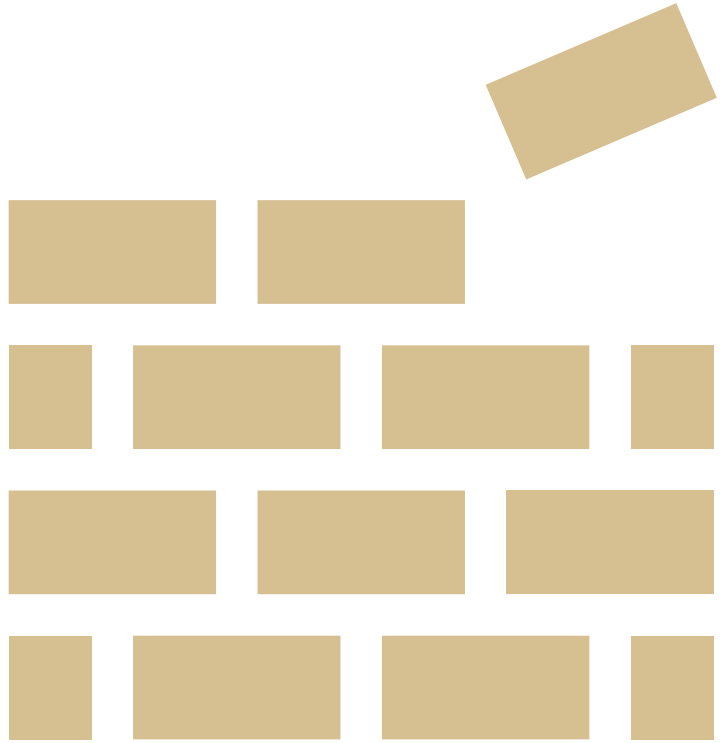
THE DIGITAL HEALTH ASSURANCE COMPANY

- Regulation and compliance are a core asset when raising investment
- De-risks the investment
- A company with strong compliance is seen as **"execution ready“**
- Sloppy compliance **raises red flags** about the whole business
- Compliance unlocks growth and gives a competitor advantage
- Can increase your valuation
- Investors very keen to protect their own reputation

Building strong Foundations

Integrated governance

- Clinical
- Corporate
- Finance
- Technology
- HR
- Information



Governance shouldn’t be a final gate but built into the innovation lifecycle right at the start of development

And don’t forget about evidence generation…

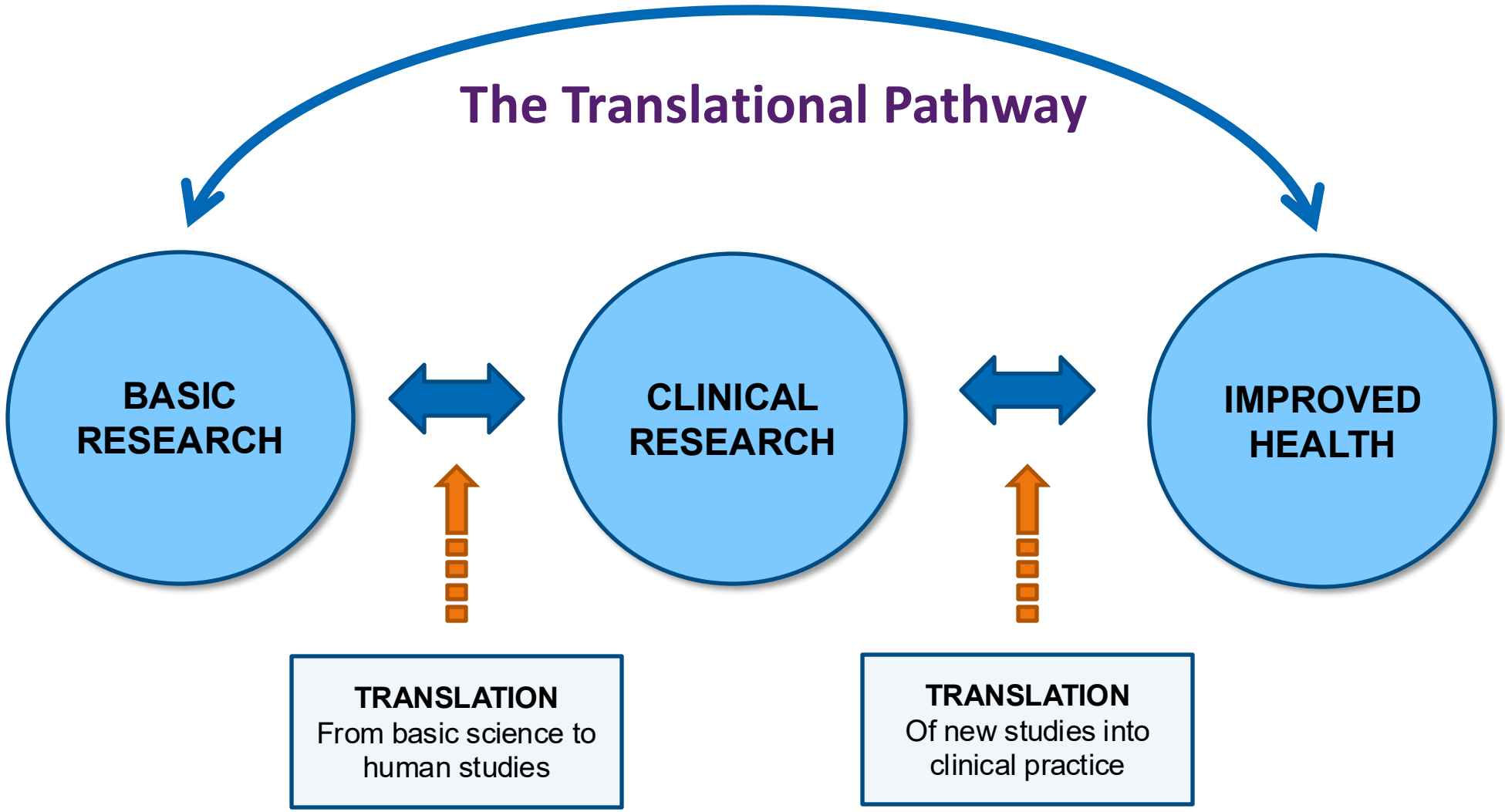
THE DIGITAL HEALTH ASSURANCE COMPANY

Hurdles or Assets? A new perspective on healthtech regulation

Clinical trials as a critical step in healthtech innovation

Dr Angus Prosser

SETT

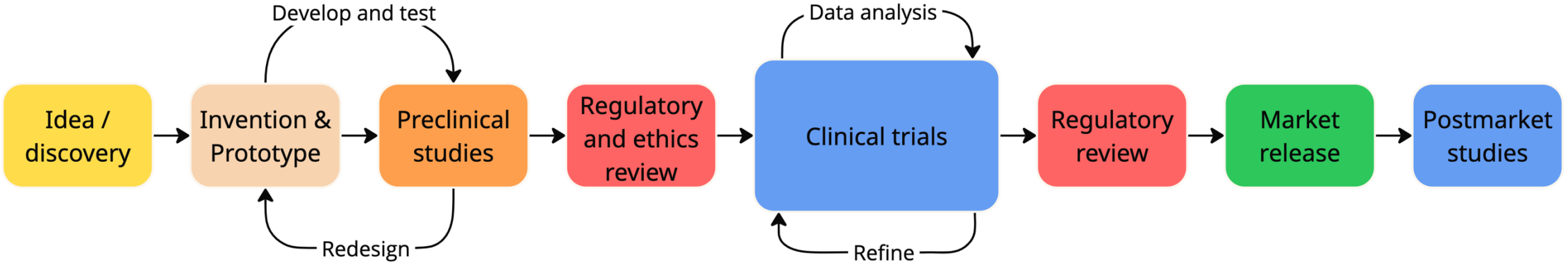

The Translational Pathway
BASIC RESEARCH
CLINICAL RESEARCH
IMPROVED HEALTH
TRANSLATION
From basic science to human studies
TRANSLATION
Of new studies into clinical practice

The role of clinical trials in Healthtech

- Provide evidence on **safety** and **effectiveness** (efficacy)
- Comparison against current standards
- Can also produce evidence for:
  - Cost-effectiveness
  - Usability
  - Patient / clinical acceptance
  - Implementation feasibility

Essential for regulatory approval of a technology

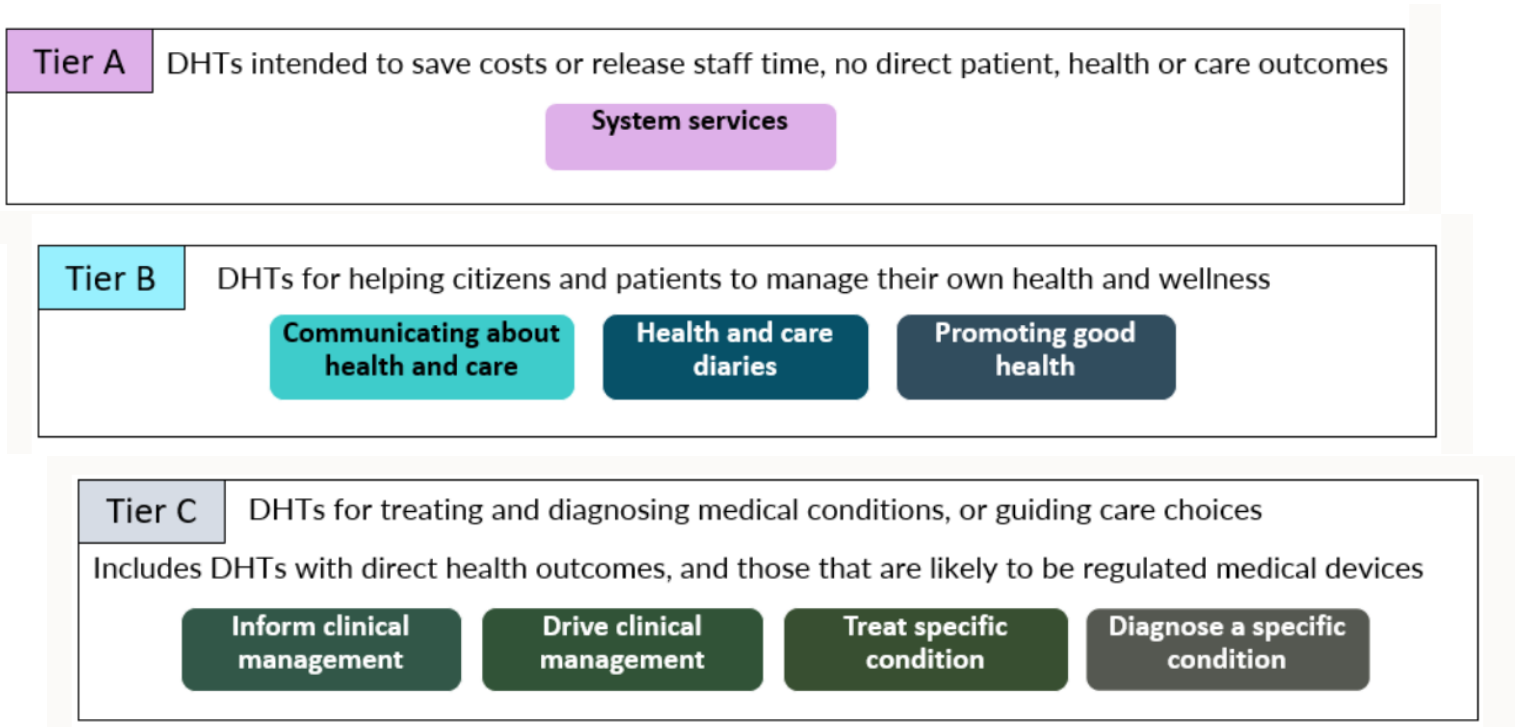
Type of evidence required



- **Pre-market**
  - Feasibility
  - Pilot
  - Pivotal
- **Post-market**
  - Real-world evidence generation
  - Implementation feasibility

Type and extent of trial(s) required can depend on device class

Classification of (digital) health technologies



Understanding your classification and intended use early on is essential

ESF classification group in tier C	UK MDR
Inform clinical management	Class 1 – 2a
Drive clinical management	Class 1 – 2b
Diagnose a condition	Class 2a - 3
Treat a condition	Class 2a - 3

Ethical and practical considerations

- Patient safety, informed consent, and ethics approvals (HRA and NRES)
- Choosing the right population, trial sites and investigators
- Data privacy and security in digital health trials

> "**Whatever the context, the interests of research participants come first**. Those responsible must be satisfied they have taken all reasonable steps to protect the dignity, rights, safety and wellbeing of participants."
>
> Professor Dame Sally Davies
> *Foreword to the Research Governance Framework for Health and Social Care Second edition, 2005*

Navigating Regulatory Requirements

- Consider clinical evidence **early!**
- **Funders and regulators** expect a structured approach to evidence generation
- Designing a **regulatory roadmap** integrating clinical validation saves time and resources

✅ **Early regulatory input** → Better trial design.

✅ **Stronger trial data** → Faster approvals.

✅ **Regulatory compliance** → NHS & investor confidence.

Common pitfalls

❌ Poorly defined outcomes & endpoints

❌ Sources of bias not considered

❌ Insufficient sample size & statistical power

❌ Not considering recruitment strategy

❌ Ignoring data security, GDPR compliance & AI transparency

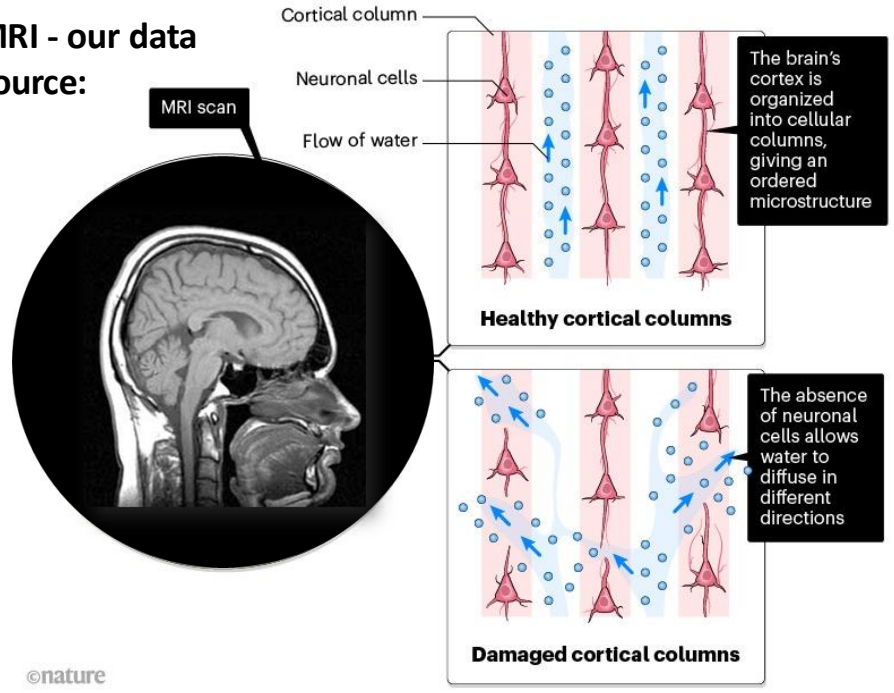
❌ Not considering what regulators, clinicians & commissioners want

Case study:
Improving Alzheimer's diagnosis and prognosis

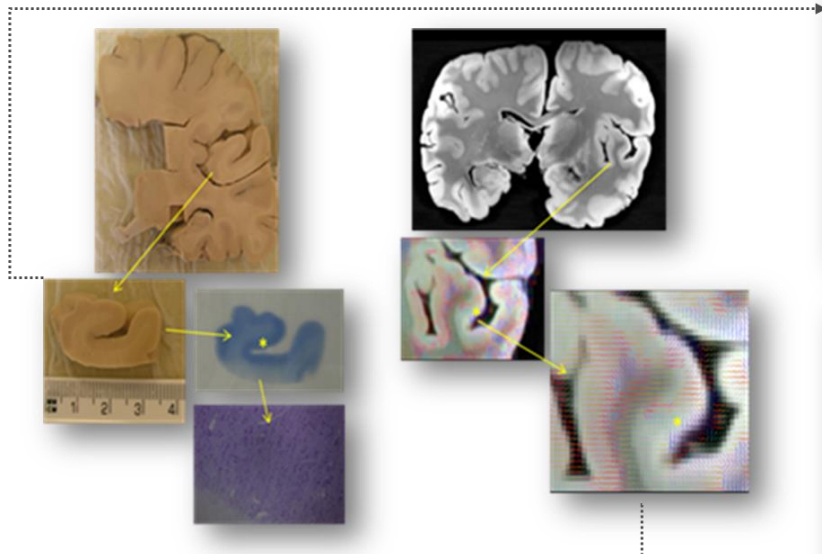
University Hospital Southampton NHS Foundation Trust

Predictive measurement of Neurodegeneration in life, from a single time point

MRI - our data source:



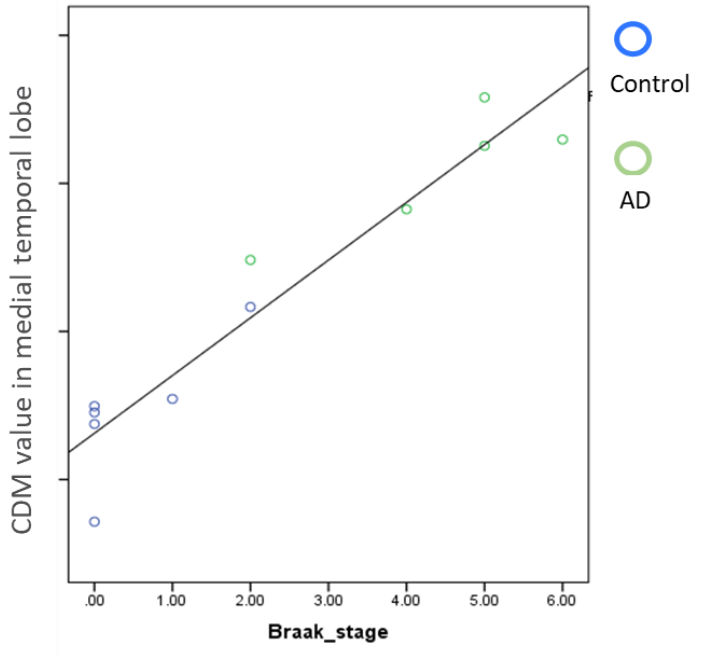
(adapted from Nature, June 2020) www.nature.com/articles/d41586-020-01803-w



Histology section of human cerebral cortex showing neuronal cell bodies in purple

Diffusion MRI measures brain structure from movement of water molecules

Validated against the post-mortem 'ground truth'



CDM strongly correlates with gold standard Braak staging of disease severity, measured by post-mortem examination

SETT

Case study:
Improving Alzheimer's diagnosis and prognosis

An observational longitudinal cohort study to investigate Cortical Disarray Measurement in MCI and AD

- Patient safety, informed consent, and ethics approvals (HRA and NRES)
- Choosing the right population, trial sites and investigators
- Considering clinically relevant outcomes, health economics and clinical pathway
- Data privacy and security considerations in anonymising, transferring and analysing scans
- Patient voice!

Turning trials into an asset

- Clinical trials are an **investment**, not just a requirement
  - ✓ Builds **trust** and ensures **safety**
  - ✓ Helps secure funding
  - ✓ Further understand clinical fit and impact
  - ✓ **Essential for NHS procurement** and NICE favourable assessment

Strong clinical evidence accelerates adoption by the NHS

Trials can drive clinical advocacy and adoption in hospitals

Thank you

THE DIGITAL HEALTH ASSURANCE COMPANY

THE ROYAL SOCIETY

NHS University Hospital Southampton NHS Foundation Trust

SETT

When approached strategically, healthtech regulations become powerful tools for growth, credibility, and long-term success.

Thank you for listening!

Q&A