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Big Steps Towards Streamlined, More Efficient and Innovative Clinical Research: The UK Plan

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CRGo World 2023 & ICN Symposium 2023

CCTU
Cambridge Clinical Trials Unit

Presentation outline

- Academic perspective
- Changes to Regulatory landscape – streamlining
  - Several Government Policy papers, outline the Future of UK Clincial Research Delivery
- Efficient & Innovative Trial design
- Considerations for future clinical trials
- Future direction
  - *Current commercial focus*

Current UK landscape

- Single Research Ethics review system across UK – UK Research Ethics Service
- UK Policy Framework for Health & Social Care
- Health Research Authority
  - REC review
  - HRA approval
  - Coordinate & standardise regulatory practice
- Medicines & Healthcare Products Regulatory Agency
  - Drugs
  - Devices
- NHS R&D approval, community & social care research…

Clinical Trials Legislative Framework

- UK Medicines for Human Use (Clinical Trials) Regulations 2004 as amended
- Proposals for Legislative Changes for clinical trials: Medicines and Medical Devices Act 2021
  - Reframe UK legislation for clinical trials
  - Streamline the regulation of clinical trials
    - Combined review service
  - Encourage innovative trial design & delivery
  - Focus on transparency

Combined Review

- Single application via IRAS (online system)
- MHRA, REC & study wide review at same time
- Review in parallel
- Initial review with 30 days
- 14 days max – respond to request for further info
- 16 days max – final outcome
  - *Previous aim for 60 days*

Progress?

Lord O'Shaughnessy review

Independent review of clinical trials landscape, 26 May 2023

- Unlock growth, investment opportunities & challenges
- Key focus on commercial trials, but principles for all
- Current increased demand for trials = backlog
  - Typically 7000 CTA applications per year
  - 1000 cleared in months to September 2023
  - Resource issue at MHRA

Progress?

Lord O'Shaughnessy review cont'd

- Increased Government funding to achieve goals and boost trials
- Flexible, risk proportional approach to trials
- Data sharing essential
- 27 recommendations to be reviewed

New – National approach to costing commercial trials

Press release

New streamlined notification scheme for lowest-risk clinical trials marks start of MHRA overhaul of regulation

The scheme will see the lowest-risk clinical trials processed by the MHRA in less than 14 days.

From: Medicines and Healthcare products Regulatory Agency
Published 12 October 2023

UK patients, the healthcare system and the life sciences sector are set to benefit from a new scheme that will see the time taken by the Medicines and

NEW MHRA Notification Scheme

- New scheme for Phase IV and certain Phase III trials
- Phase III trials – only those deemed to be lower risk
  - Specific criteria for both
  - No-ongoing safety concerns with drug
  - Existing data profile
  - No innovative designs, ATIMPs, paediatrics etc

NEW MHRA Notification Scheme

- Submit via IRAS as usual
- Acceptance within 14 days
- Aim to reduce approval time by 50%
- 20% UK trials likely to be eligible
- Outcome from clinical trials consultation

https://www.gov.uk/government/news/new-streamlined-notification-scheme-for-lowest-risk-clinical-trials-marks-start-of-mhra-overhaul-of-regulation

Efficient Trial design

Platform trial opportunities (Covid 19)

- Streamlined ethical and regulatory approvals
- Considered data collection
  - Only necessary, not “nice to have” data collected
  - Use of linkage to collect routinely collected data
- Straightforward patient information sheet and consent form
- Trial participation integrated into routine care
- Early discussion with key stakeholders
- Collaboration

RECOVERY
Randomised Evaluation of COVID-19 Therapy

PROTECT-V
PROphylaxis for paTiEnts at risk of COVID-19 infecTion

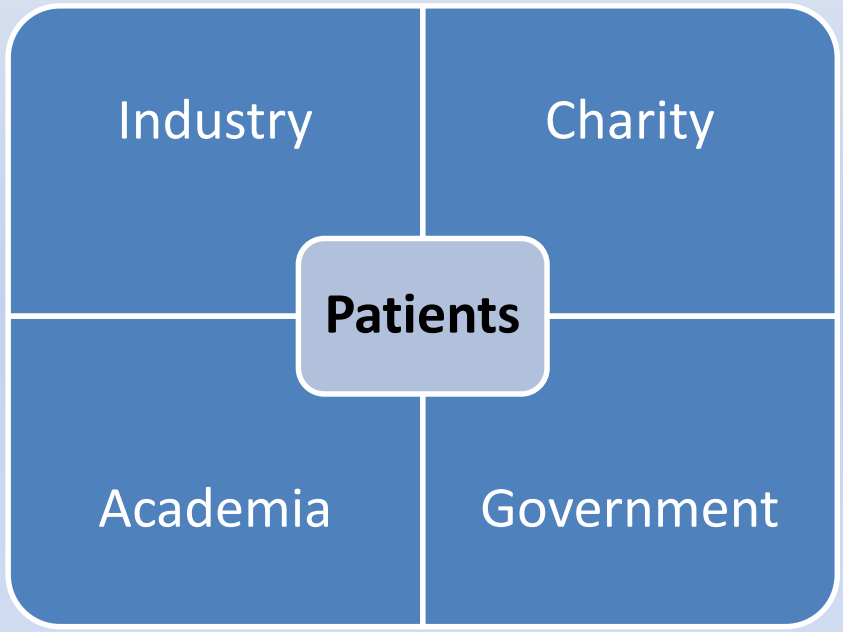
Efficient Trial design

Multi Arm Multi Stage Trials

- **STAMPEDE** (Prostate cancer) – completed this year, 20 year project
  - http://www.stampedetrial.org/participants/about-stampede/
- **OCTOPUS** (Progressive MS) – just started
  - https://ms-octopus.mrcctu.ucl.ac.uk/
- Test multiple drugs/treatments at same time
- Flexibility to drop arms
- Add arms via amendment process rather than new trial
- Rapid analysis, also during trial
- May take time to set up, but quick to add arms
- Patient Involvement key to success

COVID-19: A catalyst for change

- Collaboration
- Innovative trial designs
- Efficient trial processes

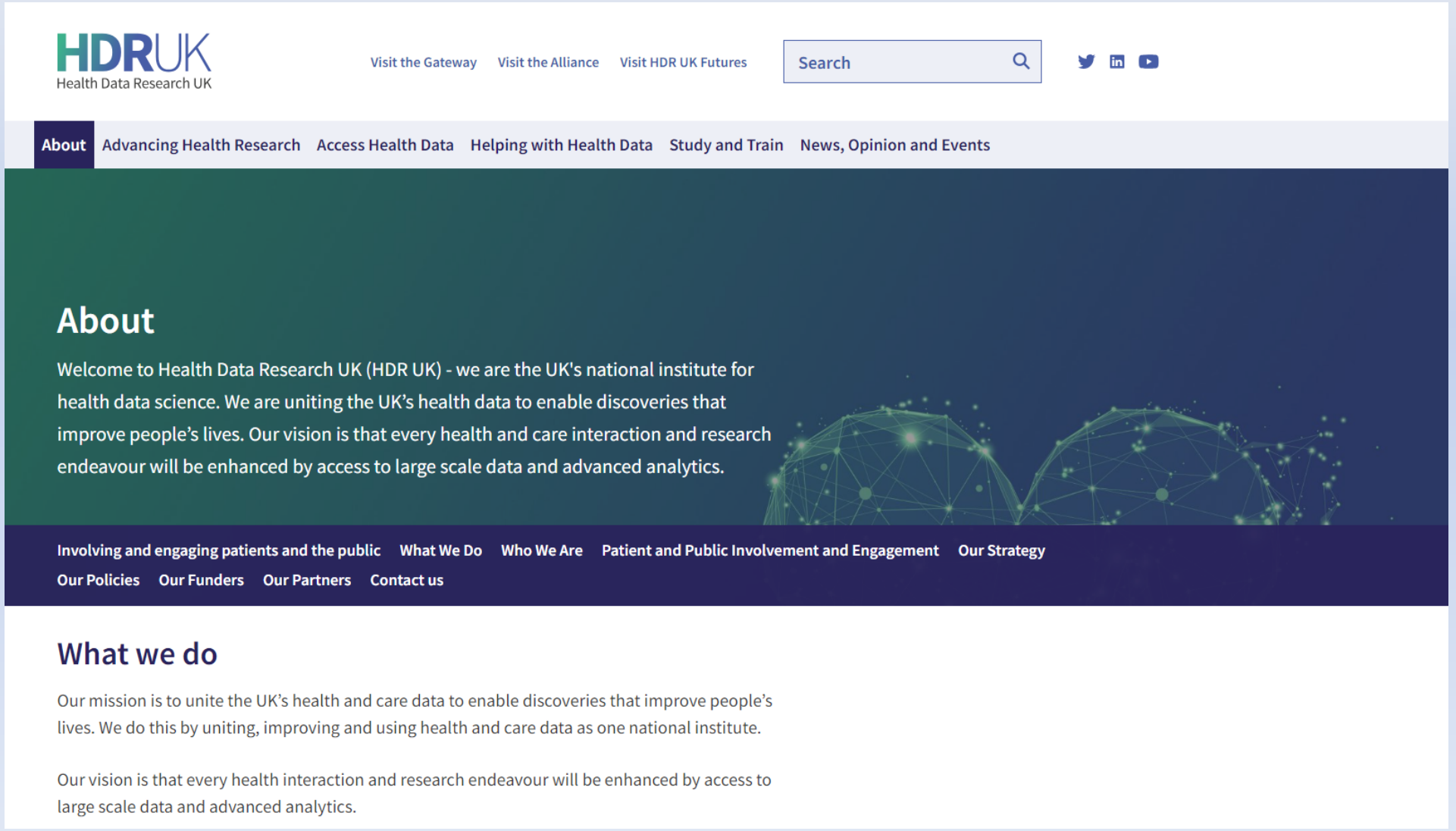


- Beyond Covid-19
  - Utilise available networks
  - Involve all stakeholders – including patients
  - Streamline processes

NIHR Clinical Research Networks - infrastructure

- Comprises of 15 Local Clinical Research Networks (regions)
- Coordinate & support delivery of research
- Increase opportunities to take part in research
- Studies supported to be efficient
- Government strategy, funded by DoH
- Changes coming April 2024 – *Regional Research Delivery Networks*
- But, not UK wide

Health Data Research UK



HDRUK

- National Institute for Health Data, UK Wide
- Aim to make health data available for researchers
- Effective patient and public involvement
- Aim to provide system to help recruitment for clinical trials
  - Participant identification
- Health Data Research Innovation Gateway
  - Appropriate access to health datasets

Decentralised Trials (CTIMPs)

HRA position statement – 17 November 2023

- Trials may take place digitally, participants' home or local healthcare facilities
  - In person visits reduced using technology
  - Reduce burden on participants
  - Involve all in design of trials: patients, family members, carers
  - Still must comply with Regulations and ICH GCP principles
  - Sponsor must risk assess and validate any technology
  - Principles can be extended to other trials…

Challenges

- Great steps forward but…
  - Resources
  - Staffing
  - NHS Capacity issues
  - Competitive funding

Implications for future clinical trials

- **Embed clinical research into routine practice**
  - Much greater public awareness of clinical trials
  - Streamlined regulatory processes
  - Pragmatic approaches: reduced burden to patients

- **Ensure adequate resources**
  - Funding and personnel
  - Time!

Summary

- Combination of various factors
- Improving Regulatory landscape
- Innovative & Efficient Trial design
- Use of routinely collected data
- e-systems
- Patient Involvement
- Future direction for UK

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