Medicines & Healthcare products Regulatory Agency

Proof-of-concept for a UK federated data network using the OMOP common data model: the UK regulatory studyathon

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Who we are

We are the Medicines and Healthcare products Regulatory Agency (MHRA).

We improve and protect the health of millions of people every day by making sure healthcare products in the UK **meet the highest standards** and are safe to use.

We are the UK regulator of medicines, medical devices and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality and efficacy.

Our responsibilities

Ensure medicines, medical devices and blood components for transfusion **meet** applicable standards of **safety, quality and efficacy (effectiveness).**

Enable innovation and research and development that is beneficial to public health.

Communicate with transparency to the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use.

Promote testing, international standardisation and harmonisation to assure the effectiveness and safety of biological medicines.

Ensure safe supply chains for medicines, medical devices and blood components.

Collaborate with partners in the UK and internationally to support our mission to enable the earliest access to safe medicines and medical devices and to protect public health.

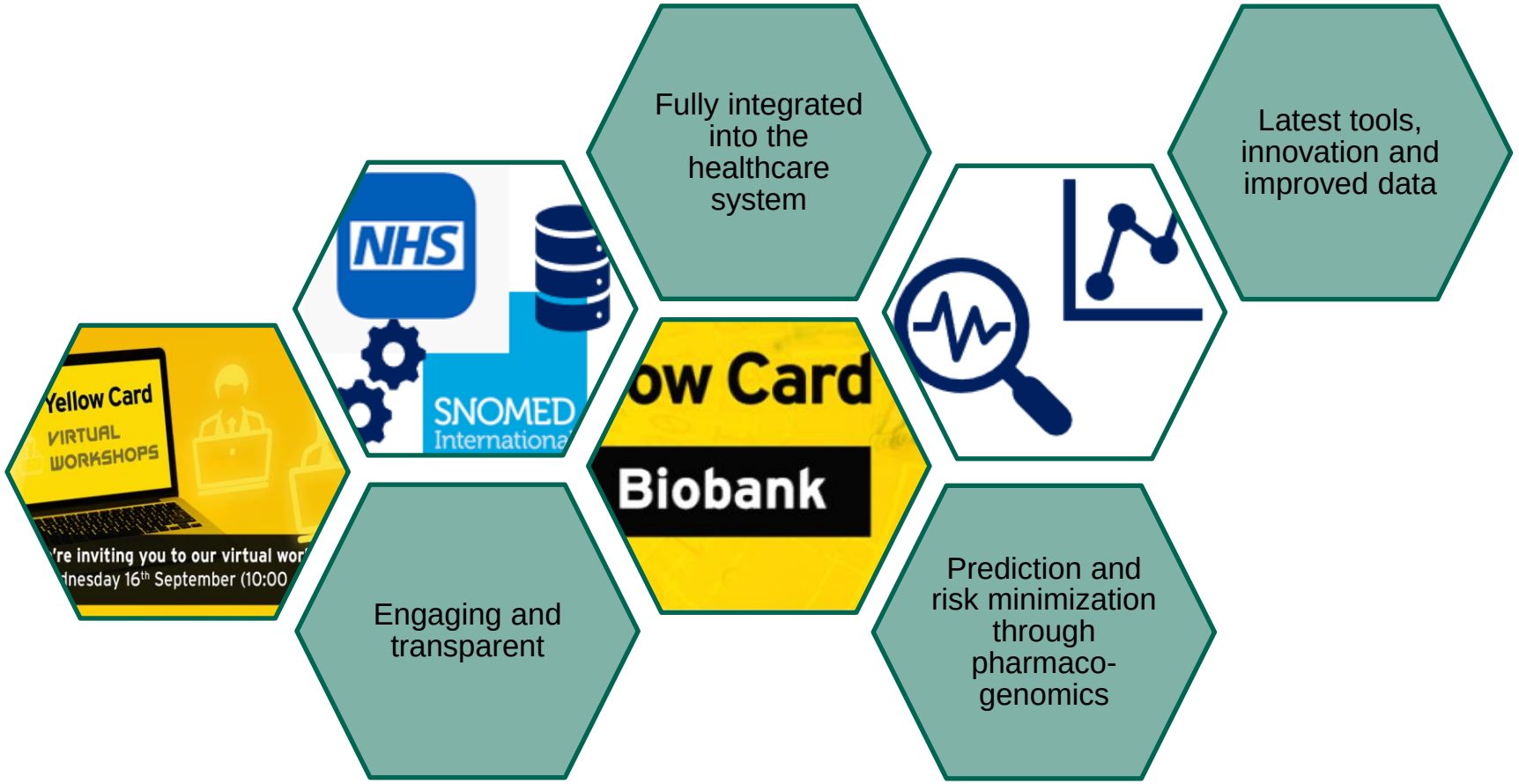
Changing environment

- Growing patient expectations for rapid access to medicines and information
- Changing demographics and disease patterns
- Rapid development of potentially transformative medicines
- The digital and data age

Protect public health: Aims of safety surveillance

- To identify previously unknown drug-related adverse events
  - Rapid identification and robust causality assessment
- To learn more about known drug-related adverse events
  - Compare the safety profile seen in clinical trials with that in routine clinical practice
- To ensure continued favourable benefit-risk balance
  - Characterise utilisation and risks across subpopulations e.g by region, ethnicity, etc
- To monitor the impact and effectiveness of regulatory action
  - Assessment of decision-relevant data to inform communication
  - Investigate unintended consequences

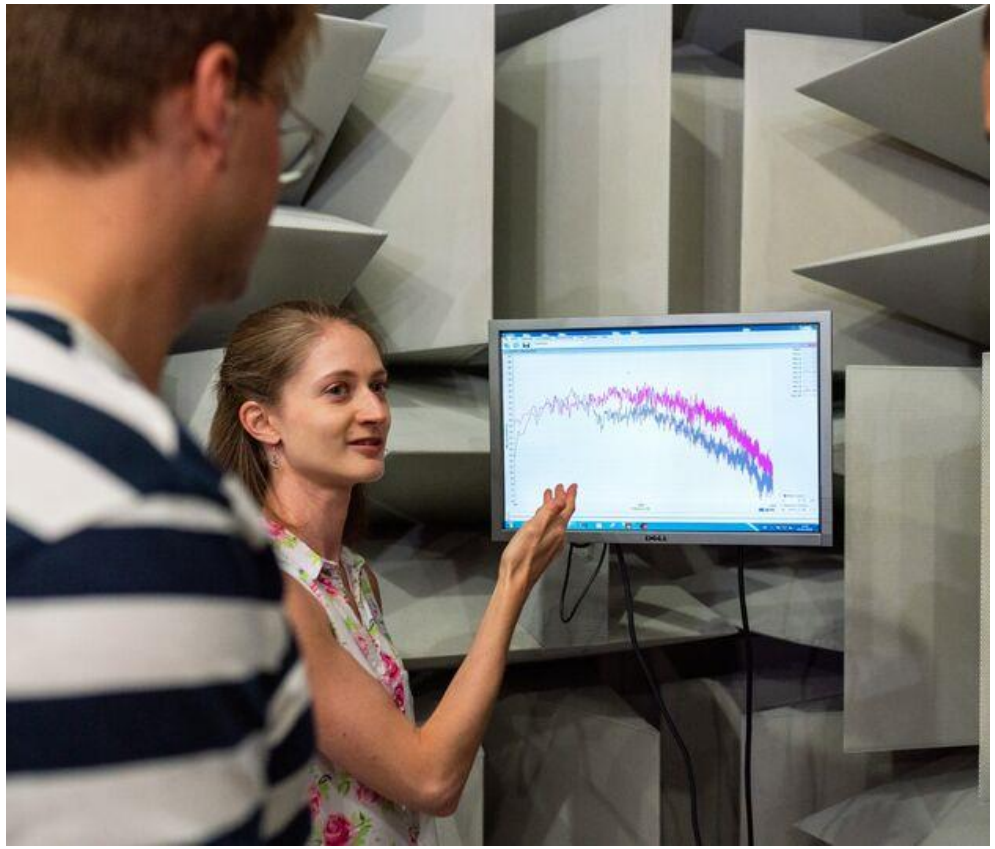
Transforming vigilance: our ambitions



Proactively monitoring and acting on insights across the product full lifecycle

Better use of data to provide insight to inform decisions on medical products but also to improve the efficiency of our operational processes.

Other drivers for increasing access to RWE



Promoting innovation

- Real world evidence to support authorisation
- Innovative licencing pathways and early access

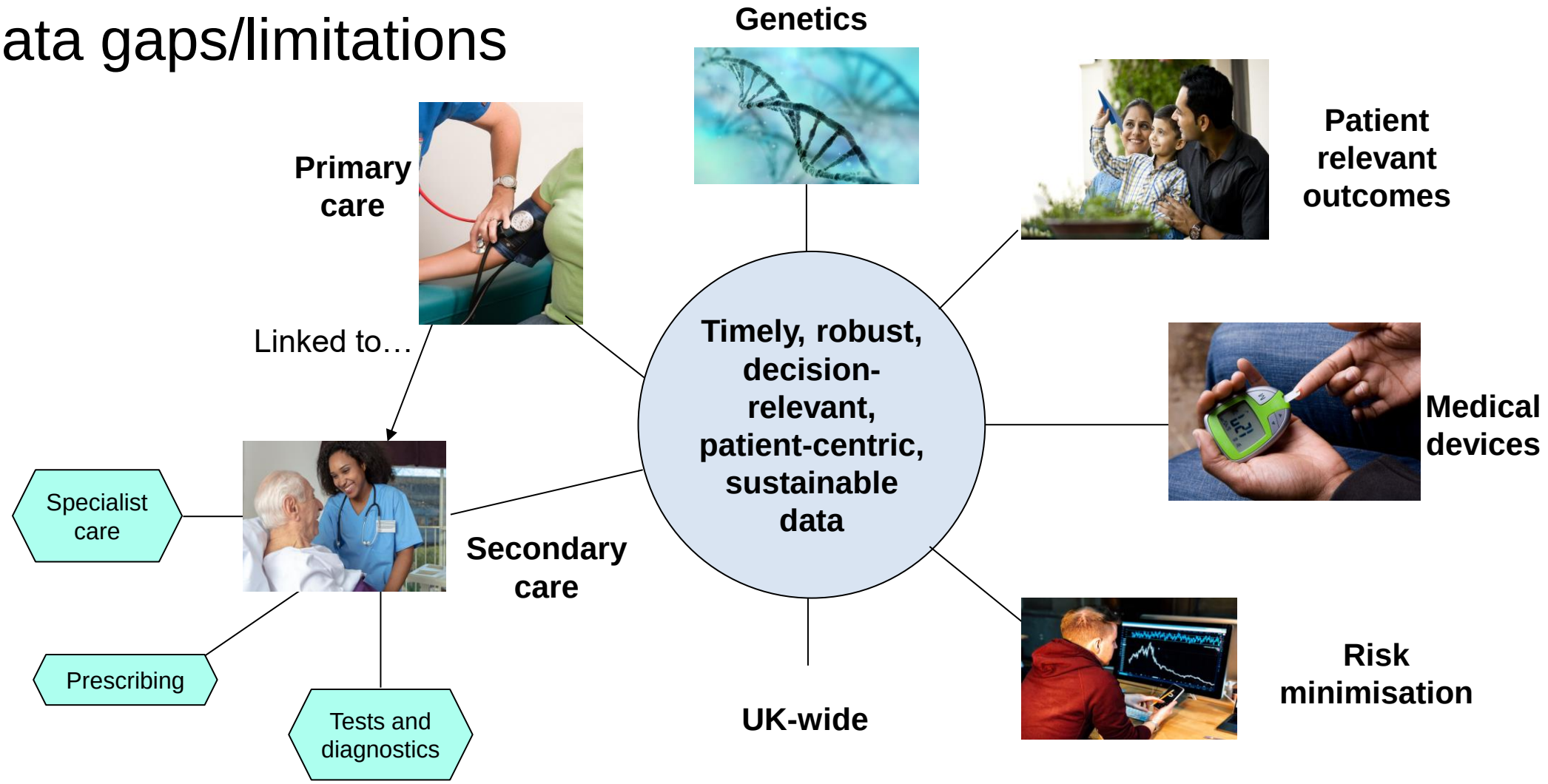
Recognised data gaps and opportunities

- Independent medicines and medical devices safety review
- Life sciences vision
- Opportunity to build around the Clinical Practice Research Datalink

Evolving landscape

- Improvements to data particularly for medical devices
- Advancing analytical methodologies and pipelines
- COVID-19 experience
- Role of regulators promoting robust use of RWE

Data gaps/limitations



Regulatory Study-a-thon

- One week study-a-thon (w/c 27 November 2023)
- Multi-disciplinary team
- Hosted by University of Oxford
- Two regulatory-focused questions
- Using UK databases

Data Partners and Stakeholders

CPRD

Health Informatics Centre

Great Ormond Street Hospital

University of Oxford

NHS Lancashire Teaching Hospitals NHS Foundation Trust

Barts Health NHS Trust

OHDSI Observational Health Data Sciences and Informatics

MHRA Study-a-thon: Fluoroquinolones & Rectopexy Mesh

Aims:

- Increase understanding of utility of **OMOP CDM**
- Understand **implications of CDM** on robustness, timeliness, & availability of data
- Understand contribution to **data gaps** – particularly **devices.**

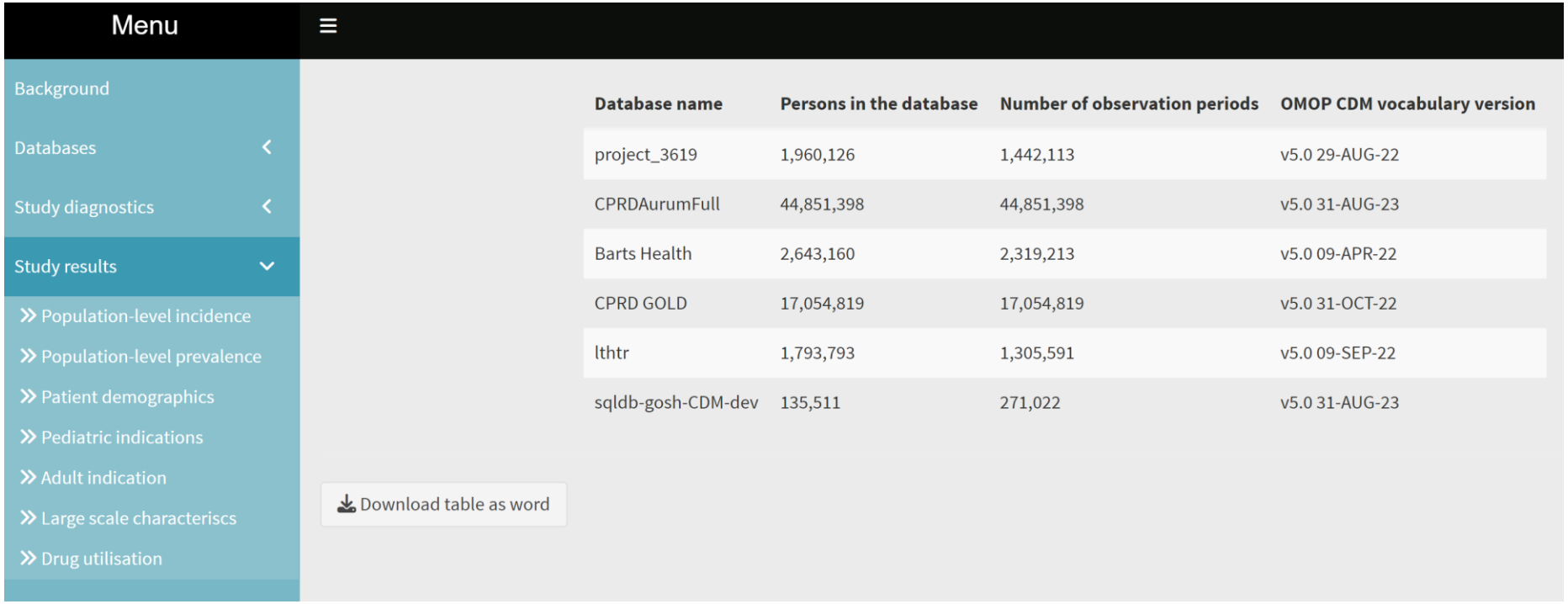
Studies:

- **Characterise use** of fluoroquinolones in UK to monitor impact of RMMs
- **Increase understanding** on epidemiology of rectal prolapse & rectopexy (& associated outcomes).

Format of the studyathon

- Day 1: Presentations from MHRA (on aims), Oxford (on protocols) and data partners (on their data)
- Days 2-4: Running analyses, looking at current results and tweaking analytic code, drafting manuscripts
- Day 5: Finish up. Closed session for MHRA and Oxford to sum up and consider what next

Outputs



- Shiny web apps for each study question presenting results
- ~ 5 manuscripts
- 3 poster presentations at ICPE

Reflections on the studyathon

Need for standardisation of OMOP conversion across data partners to minimise variability and room for errors.

Local, ideally clinical, input is vital for appropriate interpretation of results.

Curation of datasets required to ensure demographic representativeness and ensure coverage across care settings.

Further development of OMOP to better capture data on e.g. devices.

Lack of patient-level data linkage remains problematic when trying to capture exposures and outcomes from different settings.

Signal assessment based on secondary care data is limited by lack of long-term follow-up and absence of an appropriate denominator.

Conclusions and next steps

The UK regulatory studyathon produced novel insights into two areas of high regulatory interest, with previously unseen data on secondary care prescribing and implanted devices.

Nationwide initiatives making use of OMOP CDM will lead to development of expertise in data conversion, meaning improved capacity to harness various datasets over time and with greater efficiency and reliability.

To further develop the use of a federated data network in the UK consideration must be given to financial resource and sustainability to ensure buyin from data partners, including clinician time, for both improved data capture at source and interpretation of results into appropriate actions.

The ‘Study-A-Thon’ demonstrated the feasibility of using a UK federated data network to provide evidence to support regulatory decision-making.

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