Medicines & Healthcare products Regulatory Agency

MHRA and the use of RWE

Why an OHDSI study-a-thon?

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MHRA: Who are we?!

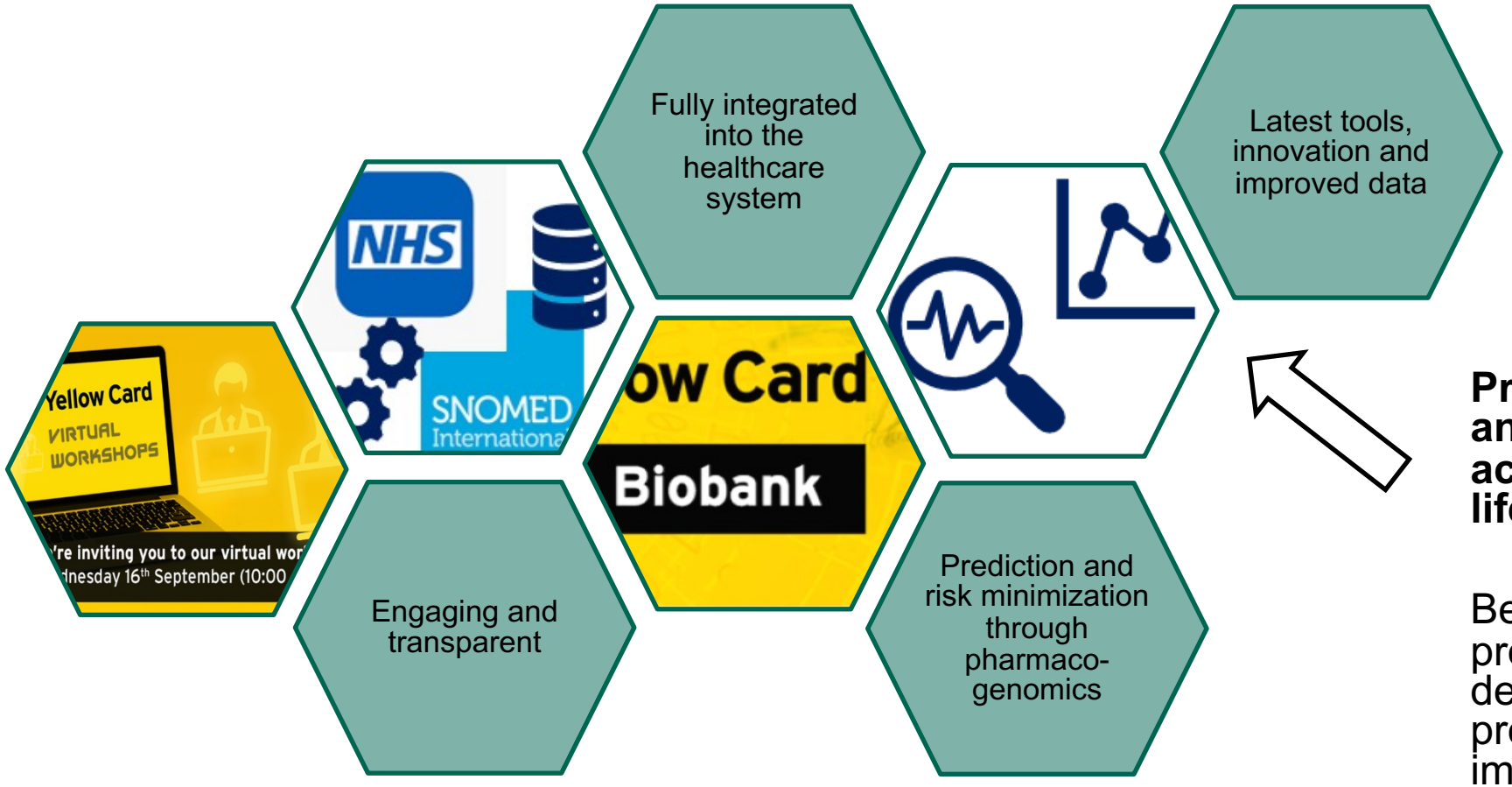
We are the regulator of medicines, medical devices and blood components for transfusion in the UK.

Our responsibilities include:

- ensure medicines and medical devices meet applicable standards of safety, quality and efficacy
- educate the public and healthcare professionals about the risks and benefits of medicines and medical devices and blood components, leading to safer and more effective use
- enable innovation and research and development that is beneficial to public health
- 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

Scientific Research and Innovation	Healthcare Quality and Access	Safety and Surveillance
• Innovation accelerator • Clinical investigations and trials • Research and development	• Enabling access to innovative medicines and devices • Population health	• Robust vigilance • Implementation of evidence-based risk mitigation • Public health

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 and Access Pathway – early identification of RWE needs
  - Early access to medicines scheme – requirements for proactive vigilance

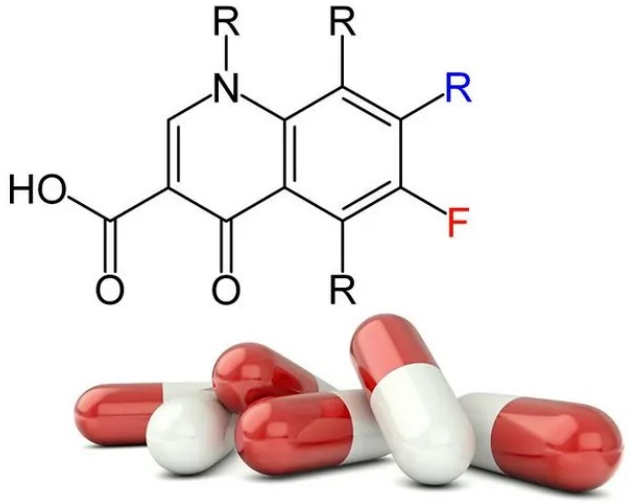
- Recognised data gaps and opportunities
  - Independent medicines and medical devices safety review
  - Life sciences vision
  - Opportunity to build around the Clinical Practice Research Datalink

- 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

MHRA Study-a-thon: **Fluoroquinolones & Rectopexy Mesh**

Aims:

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



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

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