Proof-of-concept for a UK federated data network using the OMOP common data model: the UK regulatory 'Study-A-Thon'

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INTRODUCTION

The UK is a rich source of real-world data (RWD) and offers possibilities for supporting and improving the timeliness and robustness of regulatory decisions for medicines and medical devices. However, significant challenges remain around data availability, access, quality, and heterogeneity. Common data models (CDM) have been used to standardise real world datasets and facilitate research across them through federated analytical approaches.

In 2023, a regulatory 'Study-A-Thon' was held to explore the value of a UK federated data network using the Observational Medical Outcomes Partnership (OMOP) CDM in terms of utility, timeliness and data availability.

MATERIALS AND METHODS

The 'Study-A-Thon' was a week-long event attended by six UK data partners in November 2023.

Two study questions of regulatory interest were selected for analysis.

1. **Characterise** the **use** of fluoroquinolones in the UK to monitor the impact of the RMMs.

2. **Increase understanding** on the epidemiology of rectal prolapse & rectopexy (and associated outcomes).

The questions focused on data gaps of interest: secondary care prescribing and medical devices.

Common analytic code was developed prior to the 'Study-A-Thon' and refined during the week.

RESULTS

The 6 UK databases who participated represented over 60m patient lives.

Database	Type of data	Persons
Barts Health	Hospital	2.64m
CPRD Aurum & linked hospital data	Primary care & hospital	44.85m
CPRD GOLD	Primary care	17.05m
GOSH	Specialist hospital (children)	136k
HIC	Primary care & hospital	1.96m
Lancashire Teaching Hospitals	Hospital	1.79m

A set of results was produced for both study questions, and individual manuscripts are underway for each of these. Of note, fluoroquinolone prescribing was described for the first time in secondary care, and unique device identifiers (UDI) discovered and incorporated into the CDM during the 'Study-A-Thon.

Key learnings from the 'Study-A-Thon'

- Data partners took different approaches to OMOP conversion. Efforts to standardise this process will reduce variability that could potentially lead to error.
- Local, ideally including clinical, input to interpret results is essential. For instance, the impact of local prescribing policies leading alongside regulatory advice on rates.
- Careful curation of datasets is required to ensure representativeness across key demographic variables and care settings.
- Because of the time needed for data conversion, development and testing of analytics and interpretation of results this method is currently better suited to less time-sensitive regulatory processes. For instance, evaluation of risk minimisation methods rather than signal detection.
- Ongoing work to develop OMOP to better capture certain data will enhance the value of this model e.g. use of devices.
- UDIs have largely been recorded by hospitals for administrative reasons and safety concerns. During the Study-A-Thon it was possible to incorporate UDI data into the CDM. This would be valuable for future regulatory purposes
- Lack of patient-level data linkage is problematic when trying to capture medicines/device exposure and outcomes that are managed in 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

The UK regulatory 'Study-A-Thon' successfully produced novel insights into two areas of high regulatory interest, with hitherto unseen data on secondary care prescribing and implanted devices explored.

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 buy-in 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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