Empowering Data Managers

Creating Best Practice Guidance

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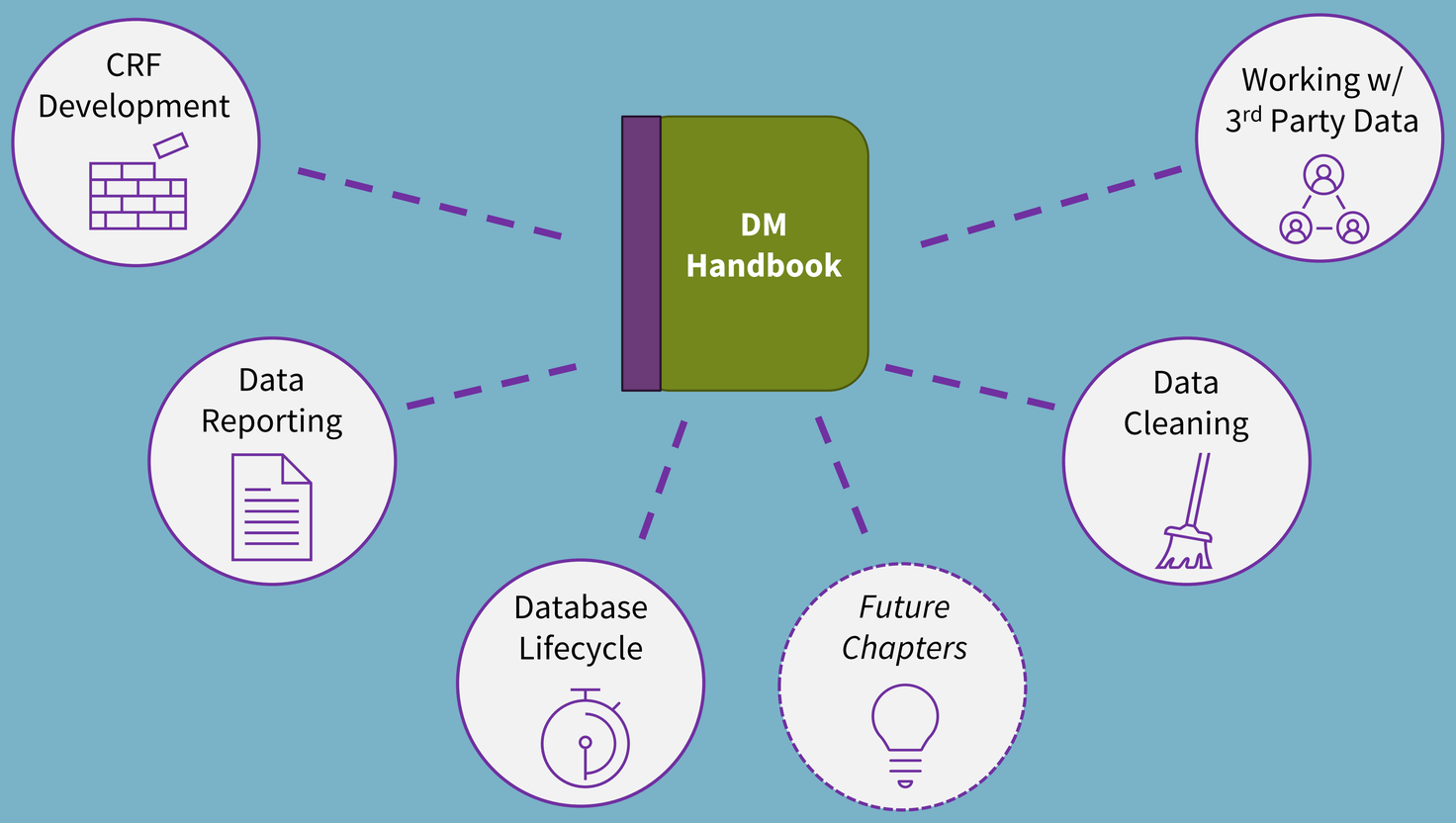
Why is this needed?

Feedback from Data Management (DM) and Information Systems (IS) staff from UKCRC-registered Clinical Trial Units (CTUs) highlighted the need for comprehensive DM guidance to meet the following needs:

- Supporting CTUs in implementing best practice.
- Specifically tailored to the CTU setting, with a focus on maximising efficiency using available resources whilst ensuring regulatory compliance.

How was this achieved?

- Surveyed DM staff to identify preferred areas of focus and prioritise these for initial work packages.
- Identified five key areas: Case Report Form (CRF) development; Data Reporting; Study Database Lifecycle; Data cleaning and Querying; Working with External / Third Party Data.
- Invited DM staff to join working groups within their area of interest.



Who are the UKCRC?

- The UK Clinical Research Consortium (UKCRC) brings together major stakeholders (funders, academia, NHS and others) that influence clinical research in the UK.
- Tackle complex and long-standing issues in clinical research together.
- Support the UKCRC Registered CTU Network.

What is a Clinical Trials Unit?

- Specialist units which design, conduct, analyse and publish non-commercial and investigator-led clinical trials & other studies, both in the UK and overseas.
- CTUs must have systems in place to conduct and deliver clinical trials to the highest quality standards.

Who are we?

- We are the UKCRC Registered CTU Network's Data and Information Systems Operational Group, a small group of DM and IS staff drawn from UKCRC-registered CTUs across the UK.
- Our aim is to identify common challenges, develop solutions and improve efficient trial conduct within DM and IS at CTUs.

Current Progress

- Working groups have been meeting regularly to draft and review content for the initial five subject areas.
- Comprehensive draft guidance documents have been developed for four of the five subject areas, with the fifth still in draft.
- Now collaborating with UKCRC Registered CTU Network Chairs' Group for review and input from operational groups for other functions, including Statistics, Trial Management and Quality Assurance.

Potential Impact

- Provide CTUs with best practice DM guidance focused on the specific challenges faced by these units.
- Reduce duplication of effort in often resource-stretched environments.
- Highlight the significant benefits of collaboration across CTUs, and between functional groups.

Future Work

- Release CRF Development and Data Reporting guidance documents by end of 2024, with remaining guidance documents from the initial work packages released by end of 2025.
- Expand the range of DM subject areas to cover the full trial DM lifecycle.
- Share information on the new guidance via Network website, webinars and meetings.
- Continue to update guidance documents in line with developments in the world of clinical trial data management and related technology, as well as updates to relevant regulations such as ICH GCP.

Contributing CTUs

For more information on the UKCRC Registered Clinical Trials Unit Network

UKCRC Registered Clinical Trials Units

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