

DS04:

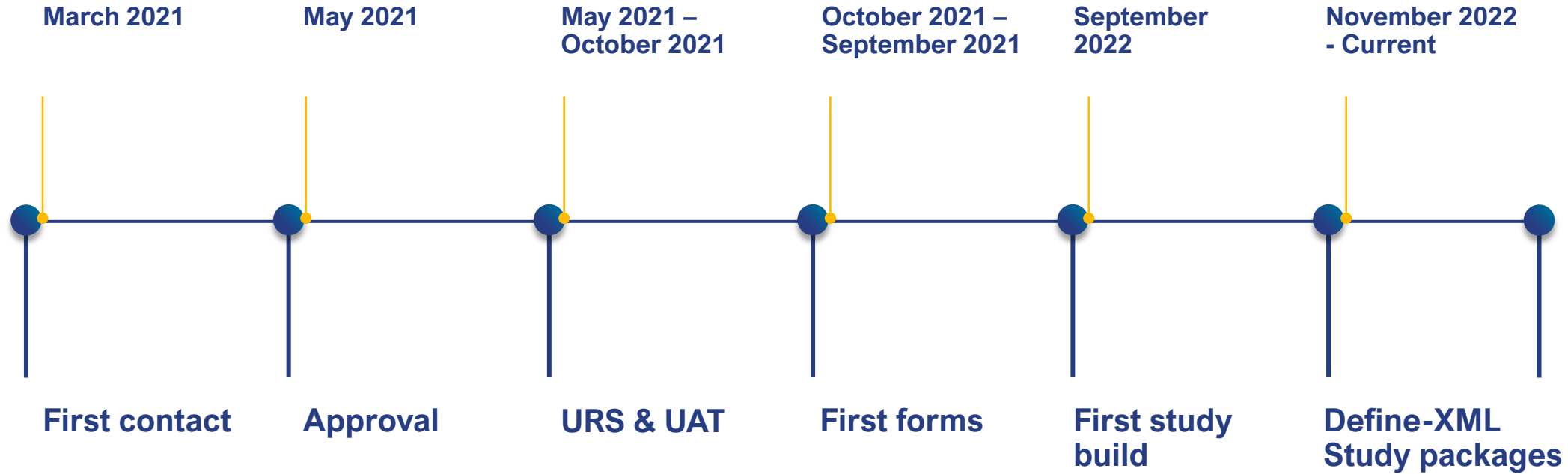
Standardisation in a fast-growing environment; MDR, EDC and other abbreviations.

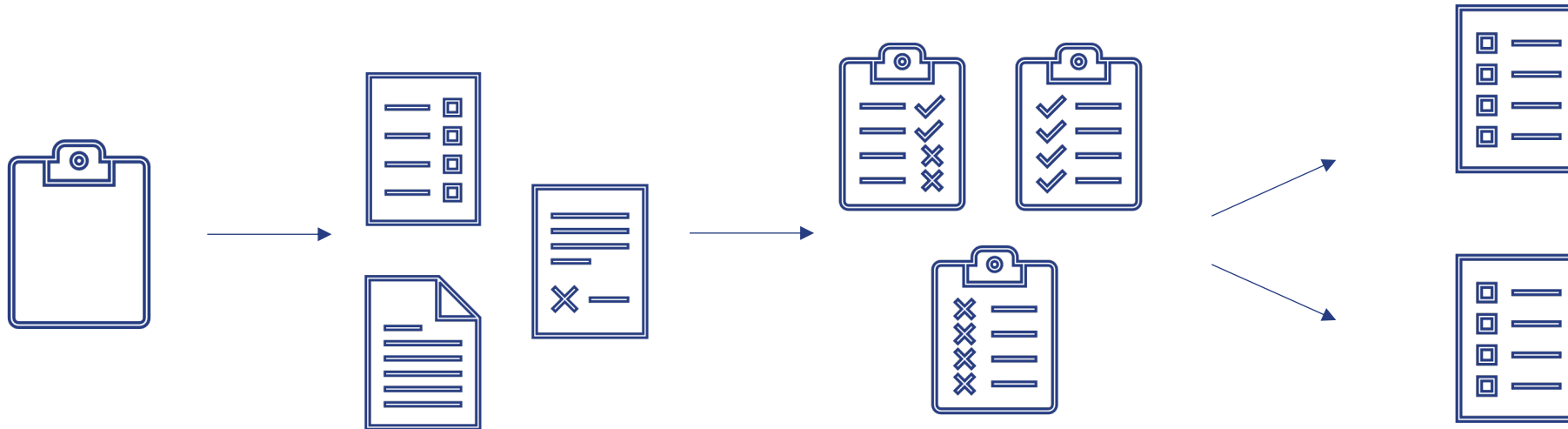
Jasmine Kestemont & Louella Schoemacher

- **Re-cap of MDR Implementation**
- **Current activities**
- **Learnings**
- **Integration and Standardisation in other DM processes**

Re-cap of MDR implementation

MDR implementation from start until today





DM (Demographics)

Current activities

- **Consistency check**



- **Managing expectations**

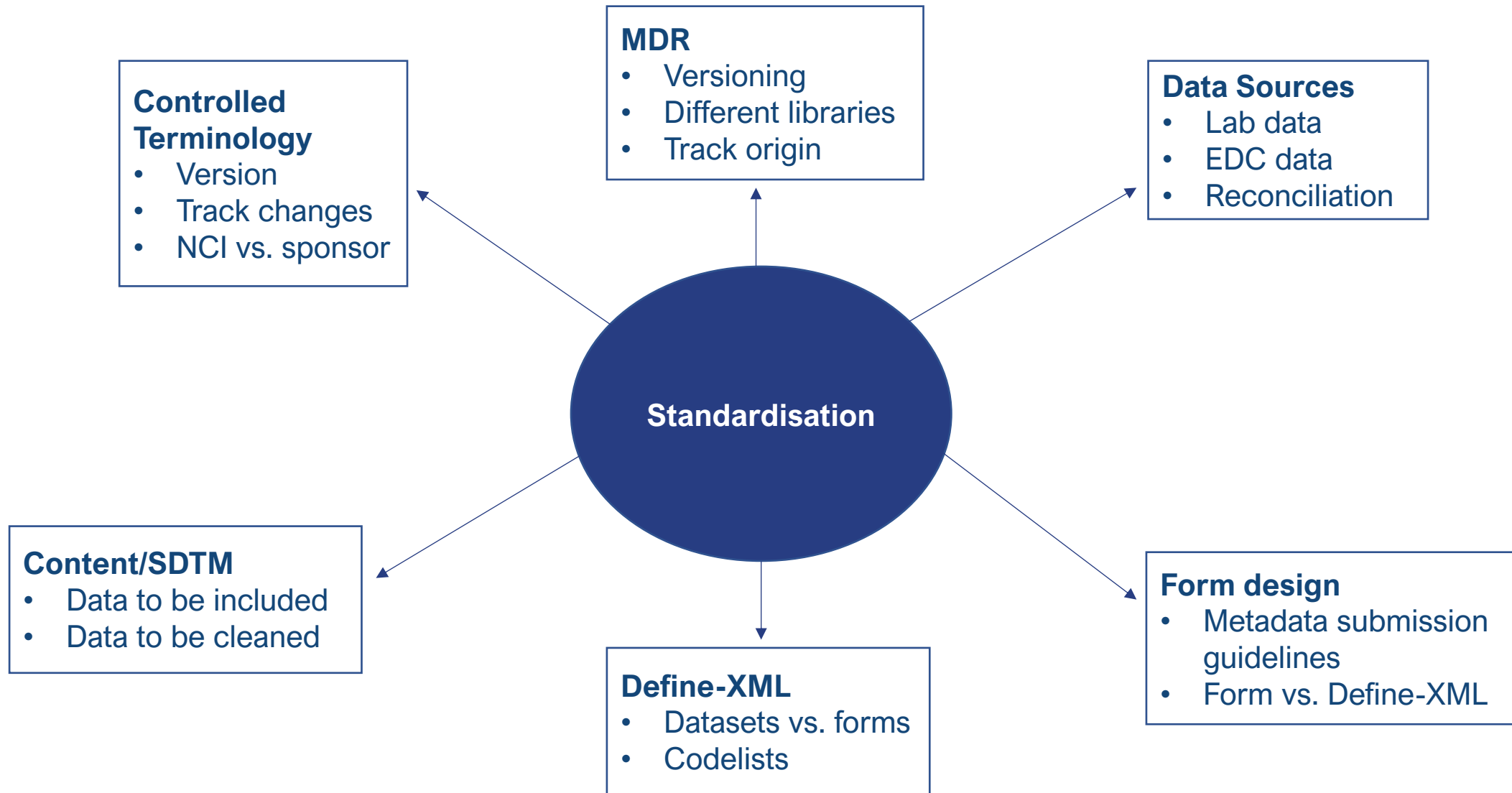


- **QRS**



- **Impact analysis**





Learnings

- Finding a balance
 - Variants
 - What can we know up front



- Pilot study build
 - Protocol
 - Feedback collection

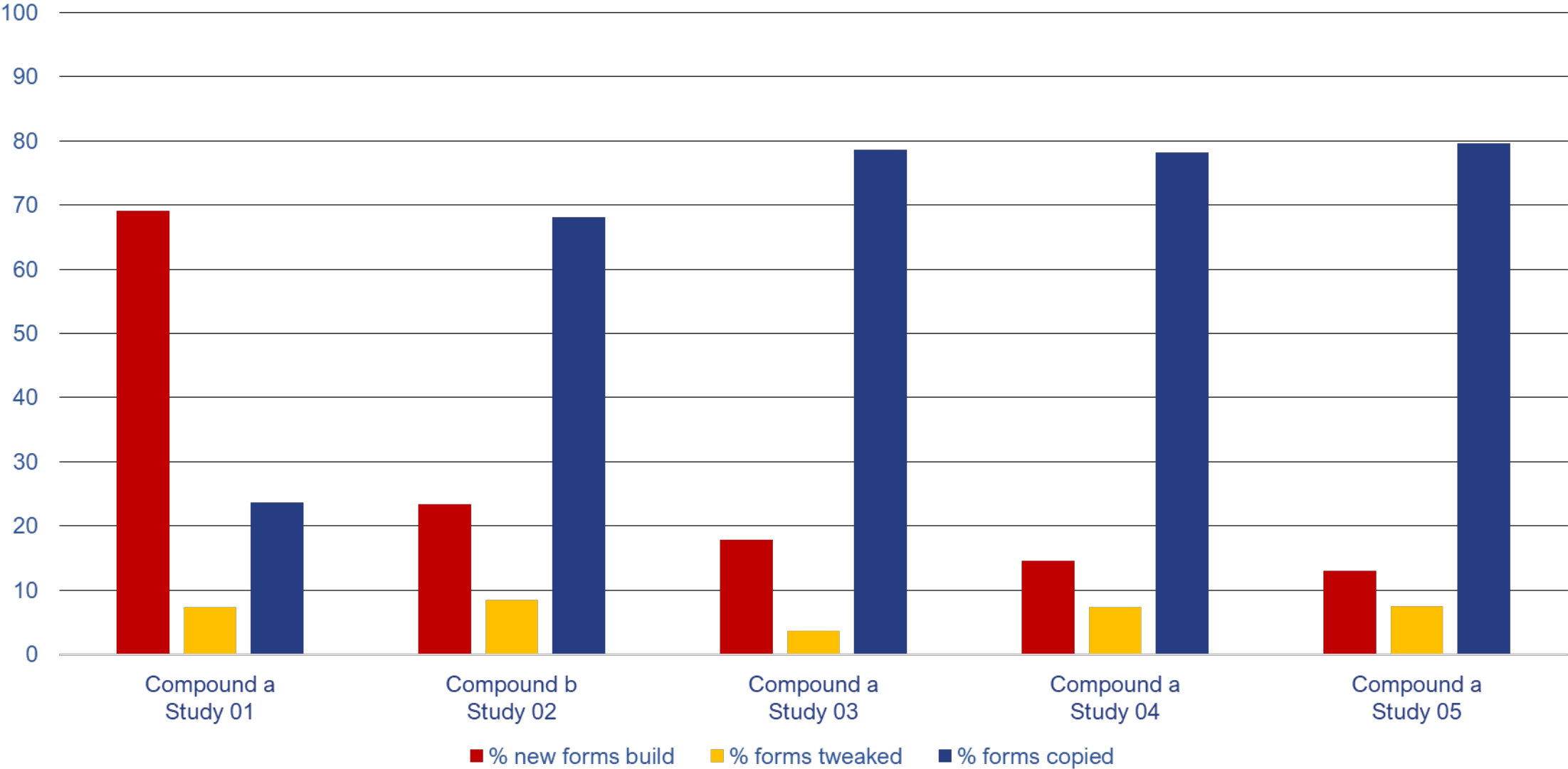


- Training component

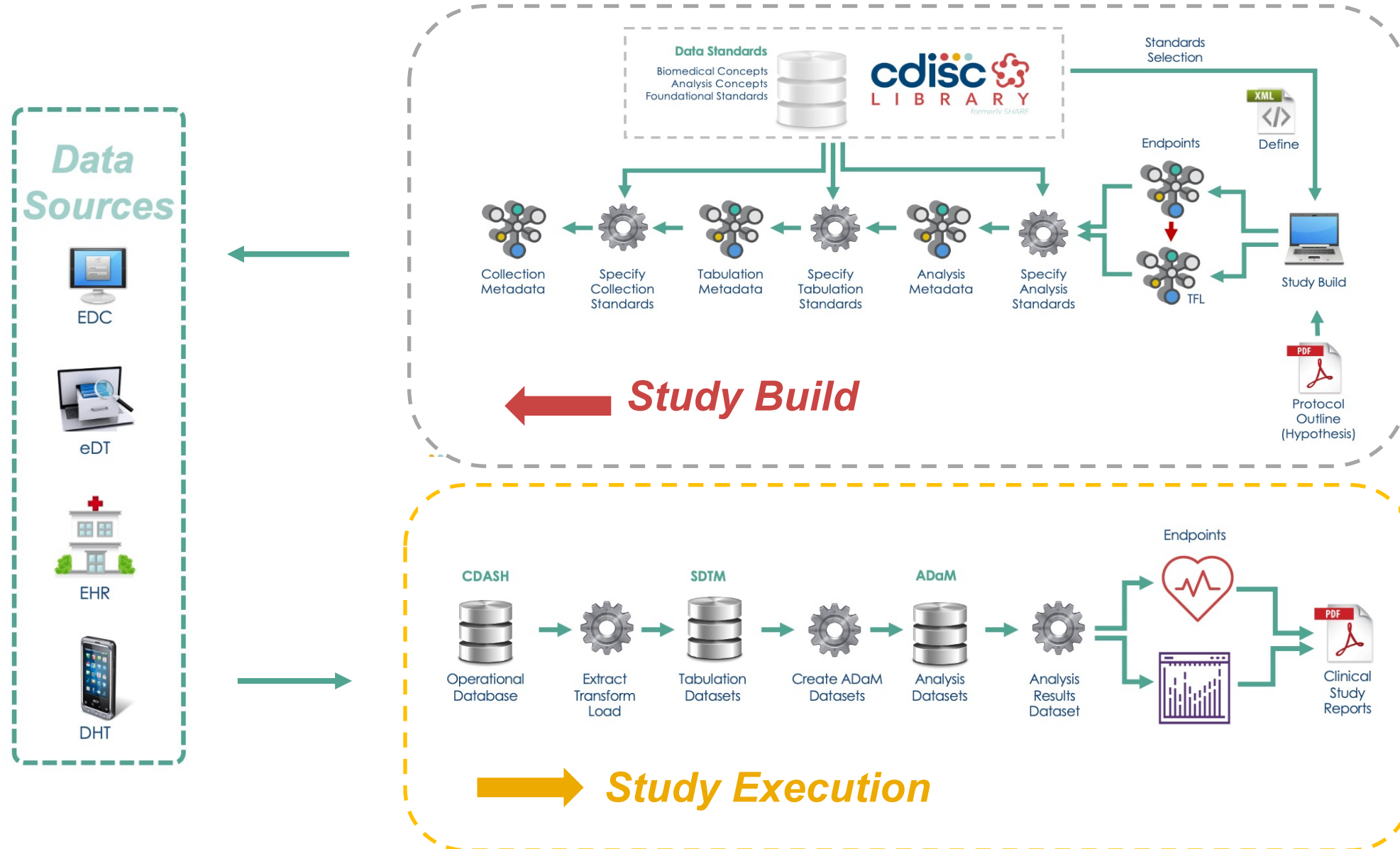


- End to end impact
 - Log forms at site
 - Vendor libraries

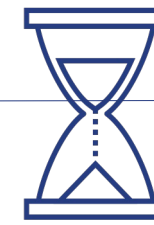




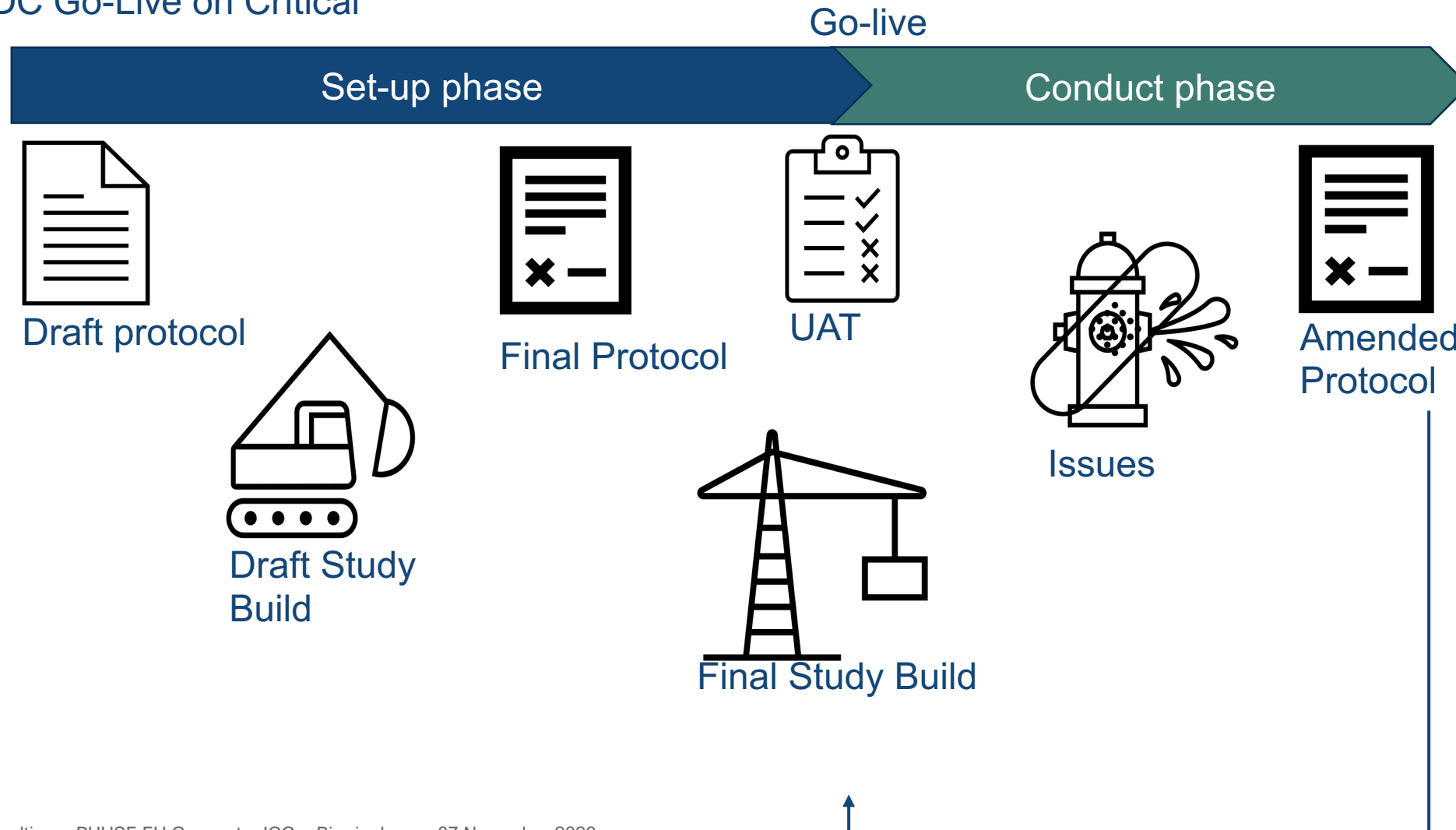
Integration and standardisation in other DM processes



Traditional Set-Up Path Prior to MDR Implementation



- EDC Go-Live on Critical

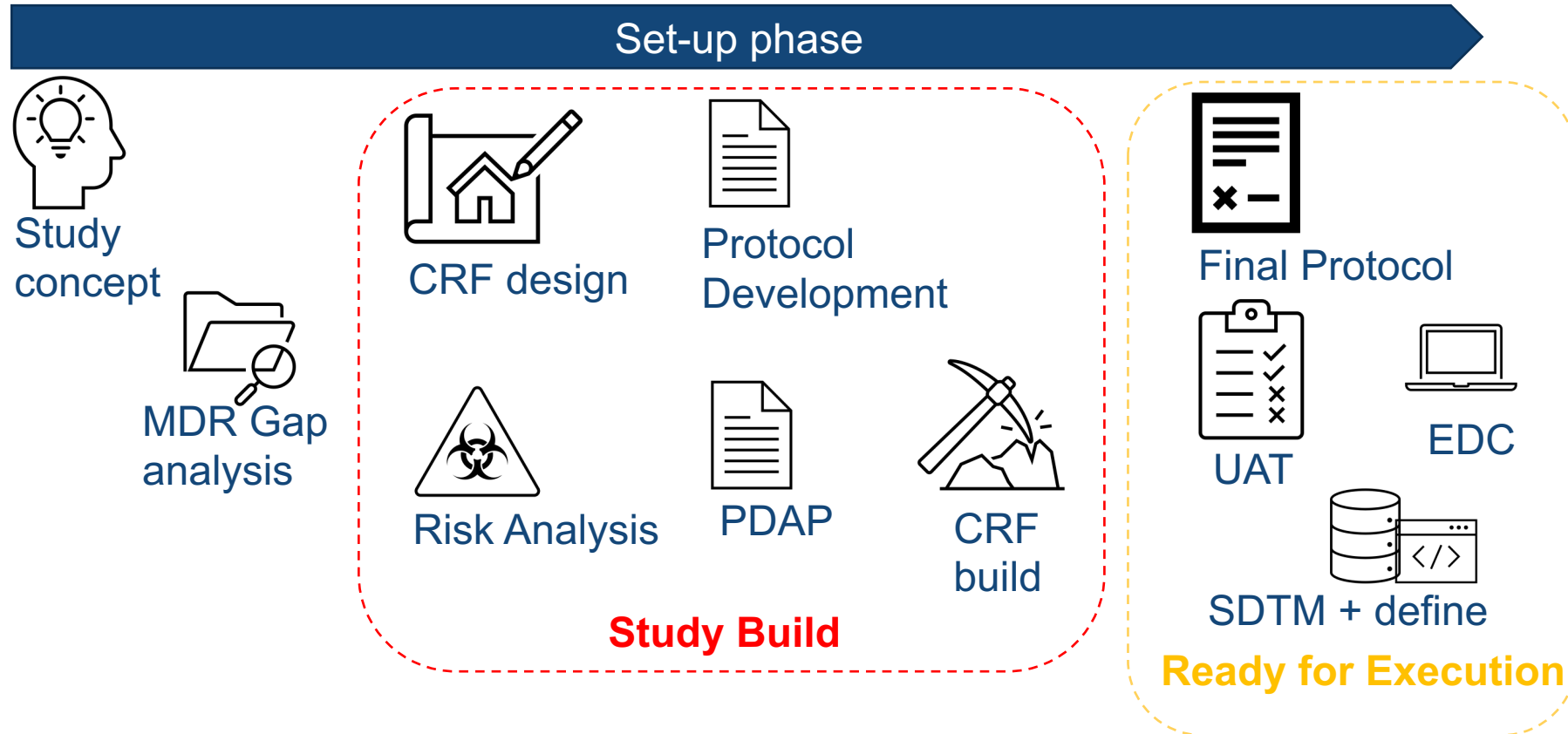


A large green arrow pointing to the right, containing the text 'Conduct phase'.

• Conduct phase

- ☐ Third-Party Vendor Set-up (eDT)
- ☐ SDTM Database Design
- ☐ Defining Protocol Deviations

- CRF for Visual Confirmation of the protocol

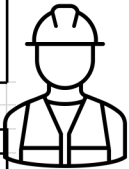


• Conduct phase

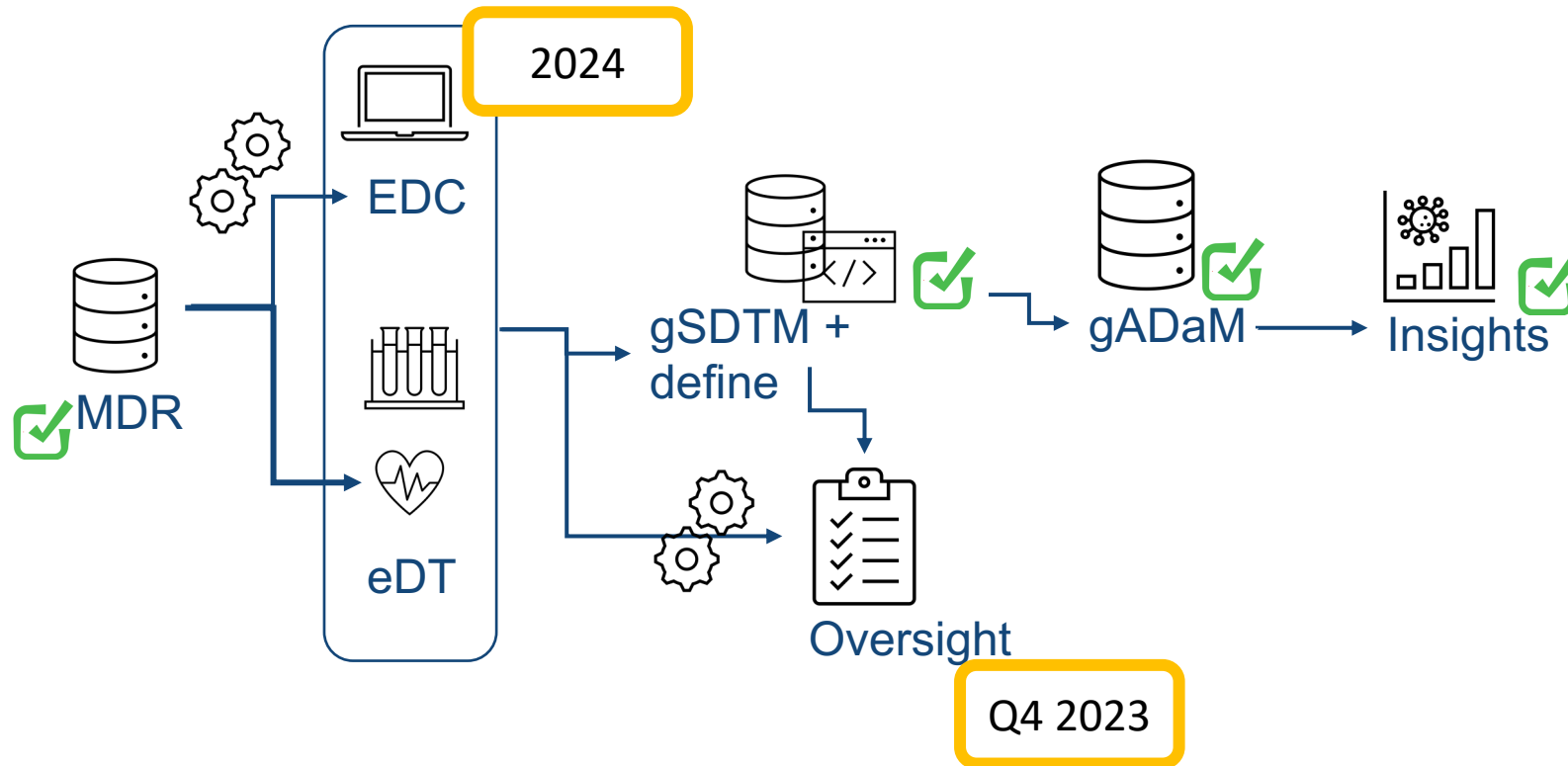
❑ Third-Party Vendor Set-up (eDT)

but

Data Transfer Agreement for PC data for ARGX-XXX-YYYY		
This Data Transfer Agreement (DTA) describes the structure and contents of the data to be provided by the Data Provider to the Data Recipient. The document will be maintained by argenx and will be signed off by the Data Provider and the Data Recipient.		
Version History		
Version Number	Date of Document	Summary of Changes
V0.1		Initial version of the document
V0.2		
V1.0		Final version of the document



Next steps in our roadmap



Thank You!



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Or visit booth 26 after this session!