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ADR Data Quality activities of a non-commercial sponsor

Safety Data Quality activities at EORTC

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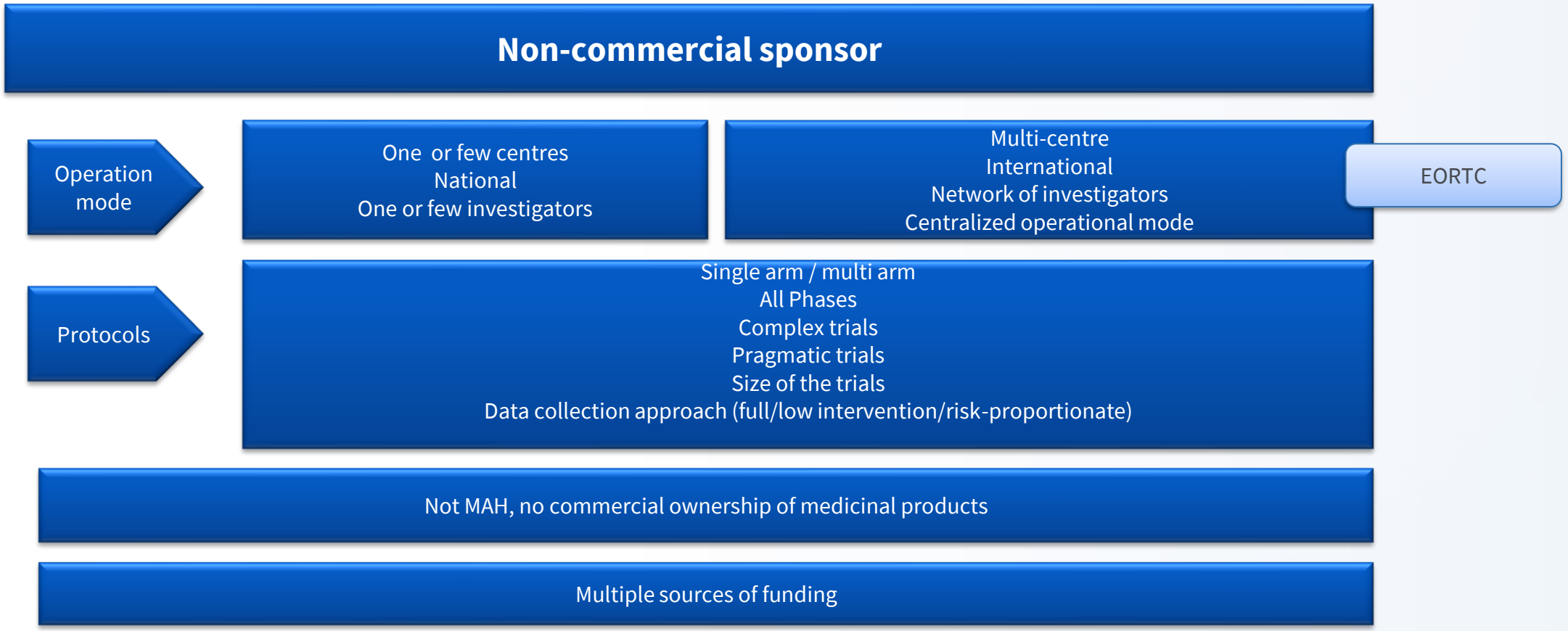
The landscape of non-commercial sponsors



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Clinical Trials Safety Data Quality activities at EORTC
What, when

Safety Data Quality activities - what

- Data
  - Individual Case Safety Reports (SAEs, SARs and SUSARS)
  - AE data
  - Aggregate reports: Development Safety Update Report (DSUR)/ Annual Safety Report (ASR)
- Timeliness
  - data receipt timeliness
  - data reporting timeliness, submission compliance
- Database
  - correct functioning of database(s) - (database testing, validation per project)

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Clinical trial safety data quality activities - when

Before data collection

at database set-up: AE, SAE e-CRF review; db validating, testing

example: check if specific events are to be collected within a specific timeframe

Data collection

AE reviews

SAE , SAR, SUSAR reviews, SAE query reviews

DSUR/ASR QC

TMF QC

Source data verification

Reviews by data management, pharmacovigilance, medical, monitoring

Data quality: accuracy, completeness, consistency, availability, attributability

Data timeliness (data receipt , submission compliance reviews)

End of Trial

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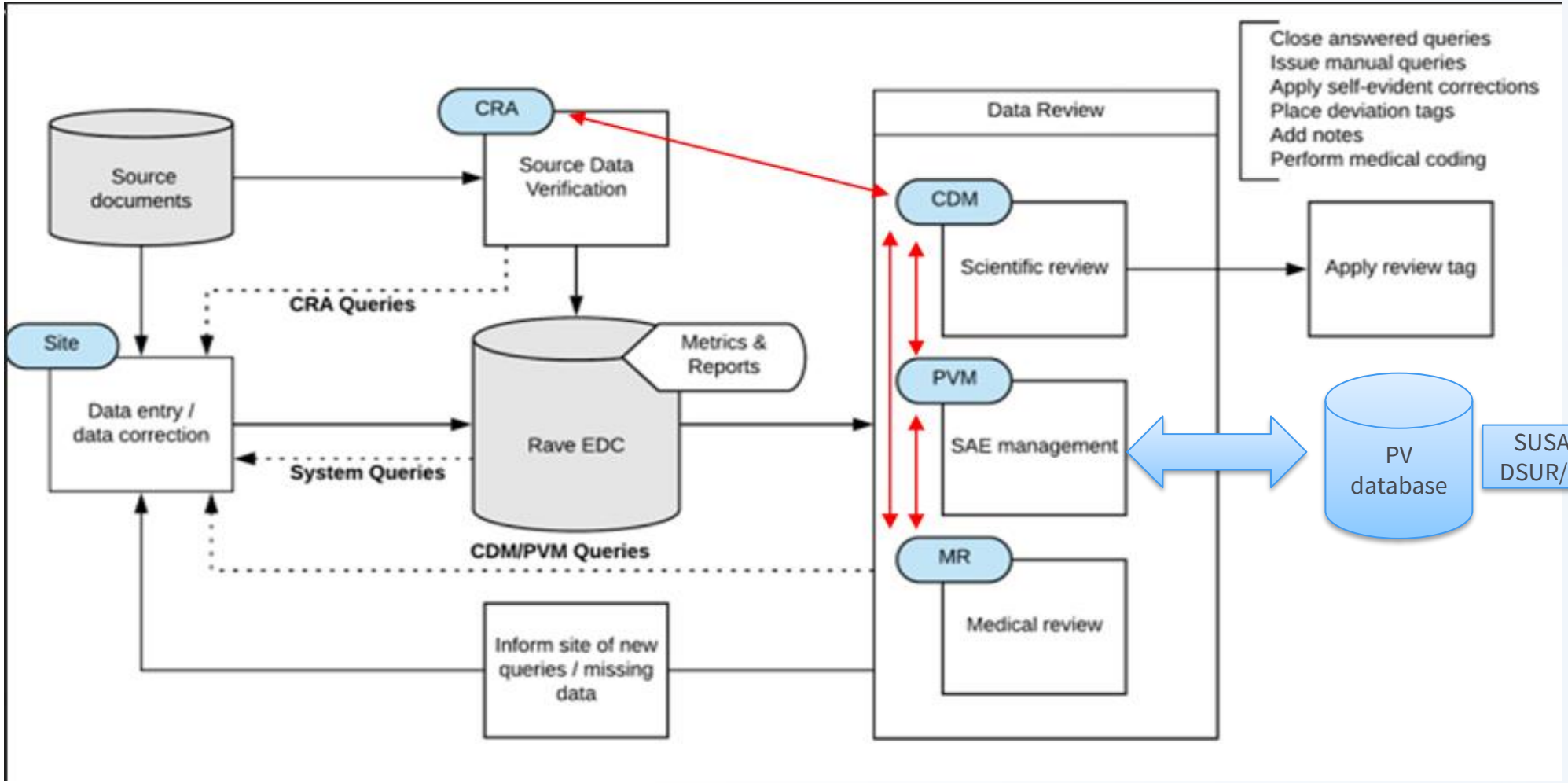
Data flow

Data flow



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Serious adverse events: Data quality activities

- **Database**
  - Testing, validation per trial at database set-up

- **SAE**: individual safety case quality reviews
  - Triage at SAE receipt including duplicate check
    - SAE minimum criteria
    - data completeness
    - Timeliness of receipt
    - -> SAE queries
  - Data entry review
    - Consistency, technical accuracy
  - for SUSARs : submission criteria, content, technical elements (E2B(R3))

- **DSUR/ASR** QC
  - Content and format

Serious adverse events: Data quality activities

- **Reconciliation** activities
  - data consistency reviews, management of discrepancies

- **TMF**
  - Structural, scheduled TMF QC on PV documents
    - SUSARs, DSUR/ASR
    - Other PV documents (Safety Reporting Plans, Reference Safety Information, Note to Files, other safety specific documents)

- **Data timeliness**
  - SAE receipt timeliness, SAE query response timeliness
  - submission compliance of SUSARs and DSURs

Ongoing safety data quality activities	Periodic safety data quality activities
Triage at SAE receipt + timeliness	AE and SAE reviews
Quality review before submitting SUSAR + timelines	Fatal SAR medical review
Quality review before submitting DSUR/ASR + timeliness	Reconciliation activities
Database: testing and validation incl. review of SAE/AE-CRF	SAE query timeliness
	SAE receipt timeliness
	Submission timeliness (compliance) of SUSARs and DSURs/ASRs
	TMF QC
	SDV at monitoring

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Our approach for Safety Data Quality activities

Our approach for safety data quality activities

- Full quality check vs risk-based approach
- Self –checks and independent reviews by a second person
- Trial focus

- Principles for risk-based approach:
  - Justifiable, transparent, documented
  - Focus: related cases e.g. SUSARs, SARs; fatal and life-threatening case reports and DSURs
  - Priority in high-risk trials and in new medicinal products
  - Management of the findings and actions in the quality management system (QMS)

- Internal processes for data quality activities
  - process reviews
  - adequate internal guidelines

- Technology
  - moving towards automated checks: findings review and actions management by experts
  - utilizing metrics by EDC, PVDB and QMS

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Points to consider

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- Diversity of non-commercial sponsors as stakeholders

- Data volumes
    - Impact of data collection/trial approach
        - No change in data quality and timeliness criteria
        - Adjusted data collection may reduce the volume of data quality activities, however minor/no impact to SUSAR and DSUR quality activities

- Data Quality activities
    - What is adequate, efficient and doable

- Guidance for Data Quality activities
    - Current situation: multiple guiding documents
    - On detail level, it may take effort to translate guidance to operational activities

- Training
    - External trainings suitable for a non-commercial sponsor scarcely available

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Thank You

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