



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality Control Systems for Secondary Use Data

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Presenter: Peter Berzin, Odysseus



Recapitulation: We have two types of data

Primary use data

Data produced for purpose in a fully controlled process

Secondary use data

Data created for another purpose, and then re-used for ours

Recapitulation: We have two types of data

Primary use data

Data produced for its initial purpose in a fully controlled or regulated process
Quality is woven into these processes and design.

Methods are **Quality Management Systems** (QMS)

Secondary use data

Data used for another purpose, and then re-used for our purpose (regulatory decision making)

Quality needs to be addressed after the fact.

Methods are **Quality Control**

Examples of Data Types for Primary and Secondary use

Primary use data

Drug Research/Pre-clinical Development

- Omics
- Bioanalytical

Clinical Trials

- Clinical Trial data (human/animal)

Manufacturing

- Batch Execution
 - Analog readings (e.g., temp, flow rates, levels, speeds)
 - Product Information (e.g., IDs, batch, raw material lot)
- Purity
- Device Specifications/Quality results

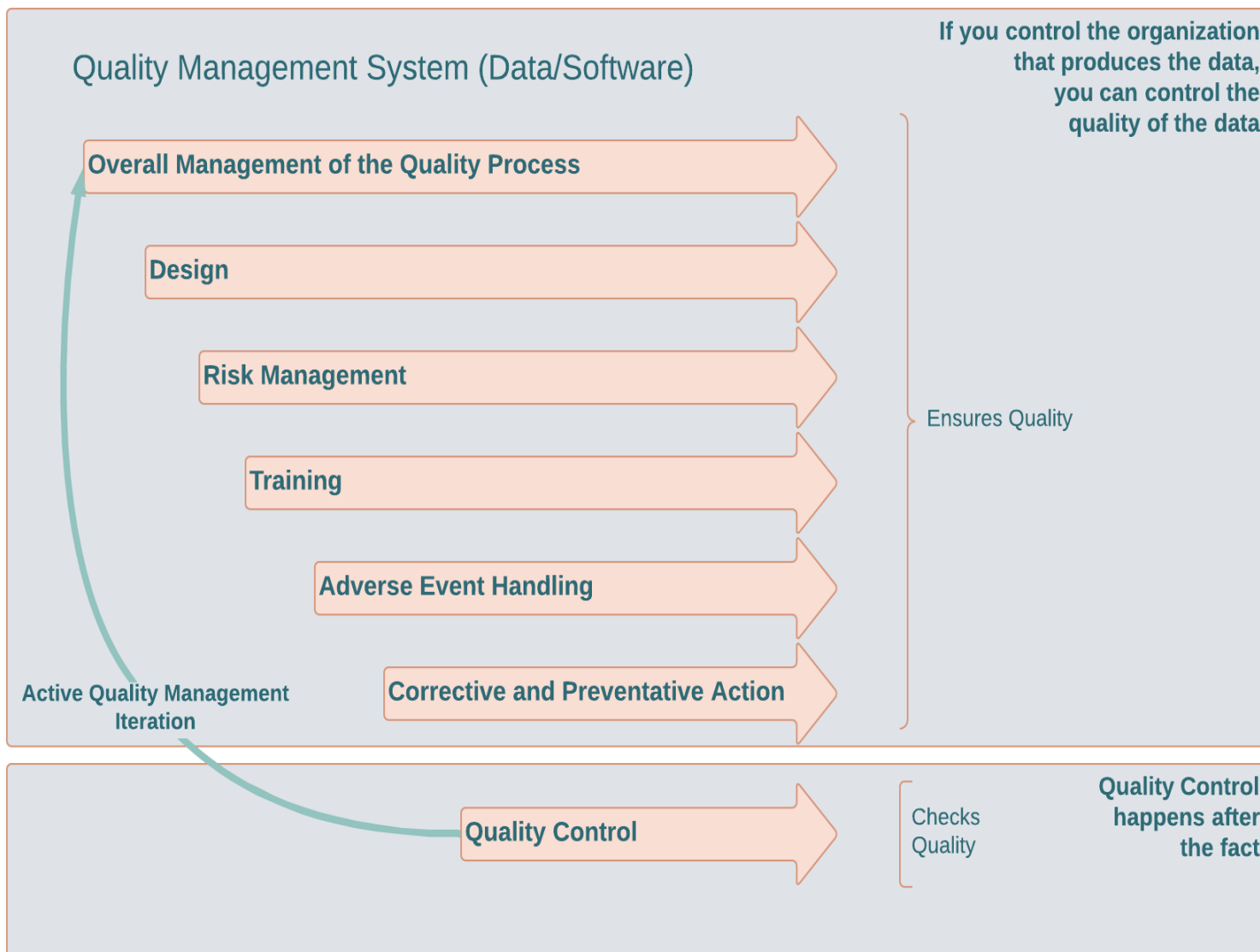
Secondary use data

Patient/Animal-centric longitudinal clinical data

- EHR
- Insurance claims
- Registry data
- Clinical trial data after trial completion

Other person/animal-level data

- Spontaneous AE reports
- Genomic data
- Social media data
- Mobile health data
- Social determinants of health



QMS vs QC:

What is already controlled and what needs to be controlled?

- As mentioned in the Landscape Analysis, there is a plethora of regulations and guidelines for Primary Use Data (ISO 900x, 8000, GxP).
- Data can still lack quality when used for regulatory purposes and so needs a framework to ensure quality prior to use

Quality Frameworks depend on the nature of the data and it's use

Quality control for these data are specific for the method of their generation and the purpose of the study

Secondary use data

Patient/Animal-centric longitudinal clinical data

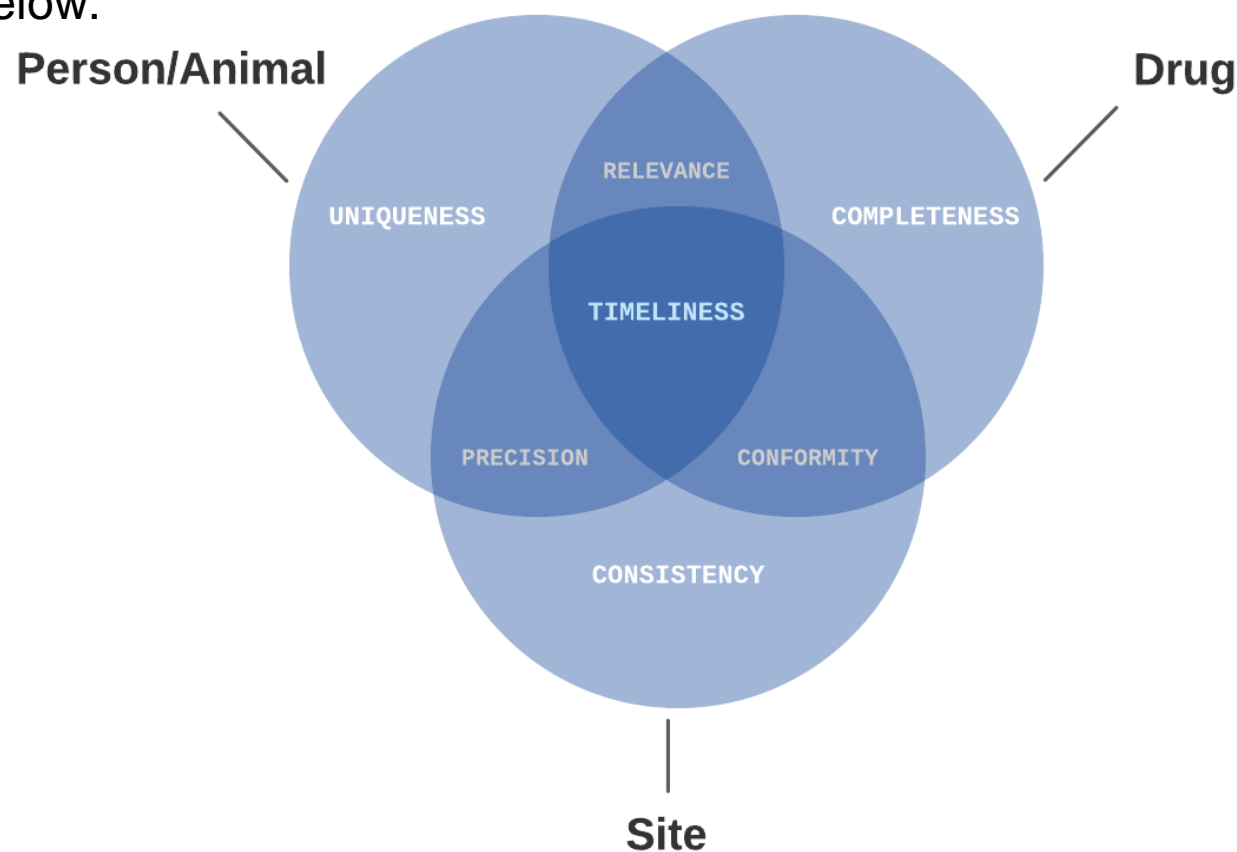
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Quality Control

QC = Data are checked for the degree to which they adhere to the true facts they represent using data quality dimensions as expressed in the example below.



Secondary use data

Data used for another purpose, and then re-used for our purpose (regulatory decision making)

Some Domains Defined for QC

These are overlapping and repetitive

Uniqueness = uniquely identity of a person or medical fact

Completeness = defines the rate at which their occurrence is captured in the data.

Consistence = same information is captured the same way

Accuracy = information is correctly captured

Sensitivity = information is reliably captured if it happened and not missed

Precision = if information is captured it is correctly captured

Relevance = information is captured that matters to the purpose

Conformity = information is captured the correct way

Timeliness = information is captured at the correct time, or is captured without delay in the capture process

Summary

- Analysed Data Quality Frameworks have slightly different foci on quality dimensions
- Data Quality is controlled for Primary Use Data through existing QMS and regulatory guidelines
- Quality Control is possible and needed for Secondary Use Data
- Quality Dimensions are applied depending on the purpose of data

	ACCURACY	COMPLETENESS	CONSISTENCY	CONFORMANCE	PLAUSIBILITY	PERSISTENCE	TIMELINESS	UNIQUENESS	VALIDITY	INTEGRITY
TEHDAS	✓	✓					✓			
Kahn's Framework	✓	✓	✓	✓	✓		✓	✓	✓	
Health Catalyst	✓		✓					✓	✓	
BMC	✓	✓	✓		✓				✓	✓
Sentinel	✓	✓	✓		✓				✓	✓
NESTcc	✓	✓	✓	✓			✓			
PCORnet		✓		✓	✓	✓				
Duke - Margolis	✓	✓	✓	✓	✓				✓	

Thank you!

For any question on this presentation, please contact: DataQualityFramework@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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