

The thick and thin of adopting Risk-based approach to Data Management

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Presenter Bio



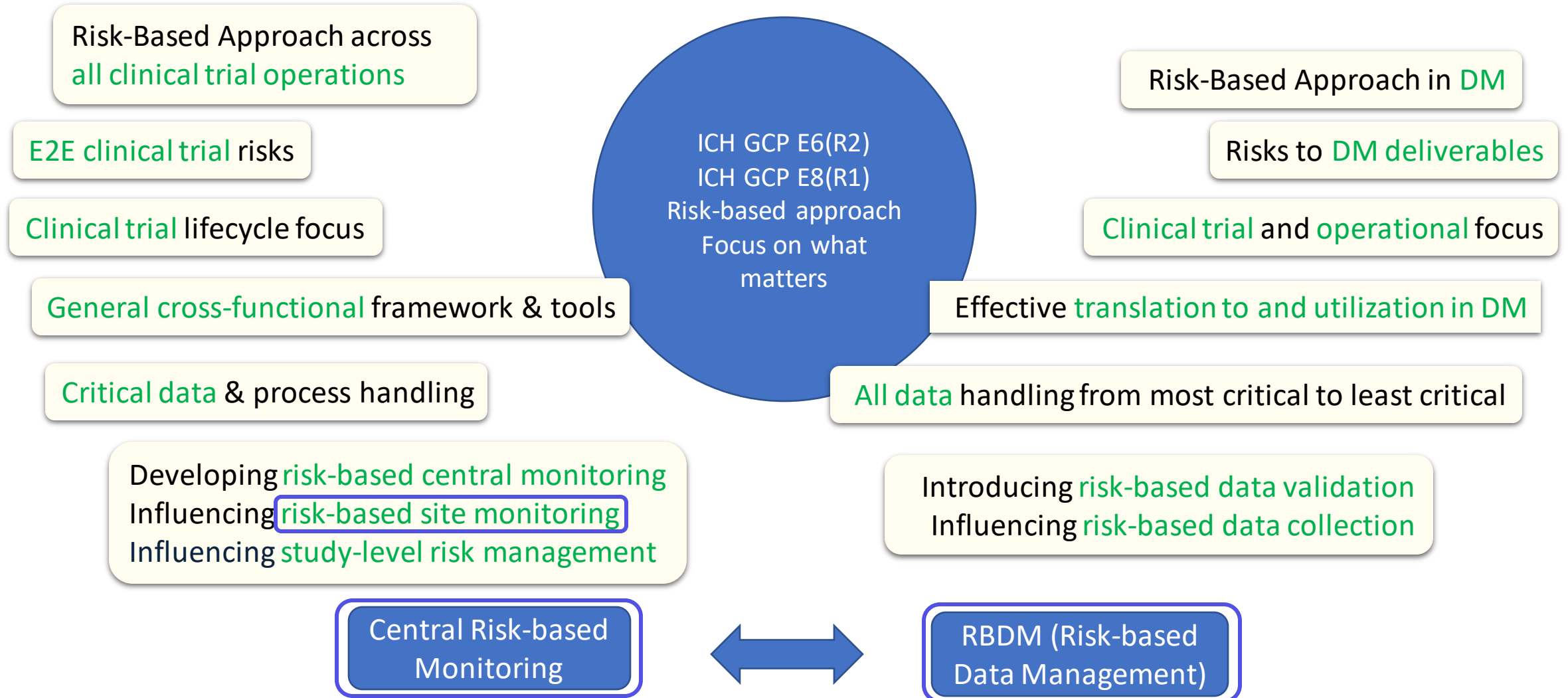
About me

I am Operations Lead in Global Data Operations, Global Data Management & Standards, at Merck Sharp & Dohme Poland.

I started my career in 2013 and progressed through various roles in both expert and people management pathways, while supporting strategic and operational goals around processes, metrics, standards, IT and innovation, as well as the Oncology portfolio.

During recent years, I have been participating in and leading initiatives on innovative, risk-based, and quality-by design approaches to data management (DM), and am now involved primarily in business and technology transformation and modernization efforts.

Central & Site Risk-Based Monitoring & Risk-Based Data Management



Risk-based approach in Data Management – opportunities & challenges

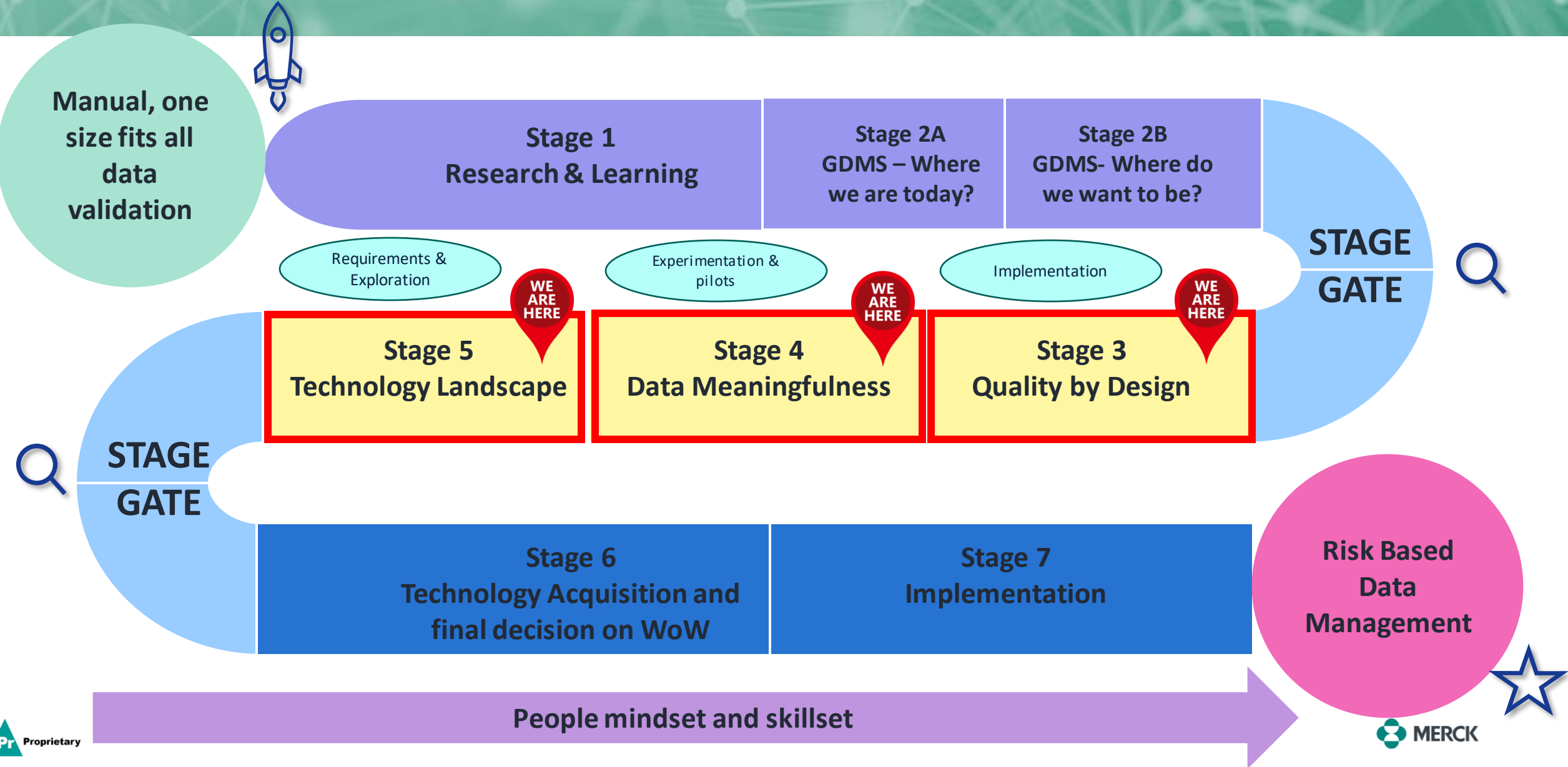
Why Thick?

- Targeted, focused data validation
- Anticipate and prevent vs. react and fix
- Less burden for both sites and sponsor (data validation & queries)
- Job satisfaction – focus on meaningful insights
- Acquiring new skills (big data, data analytics, Quality by Design)
- E2E risk-based approach – central, site, data management

Why Thin?

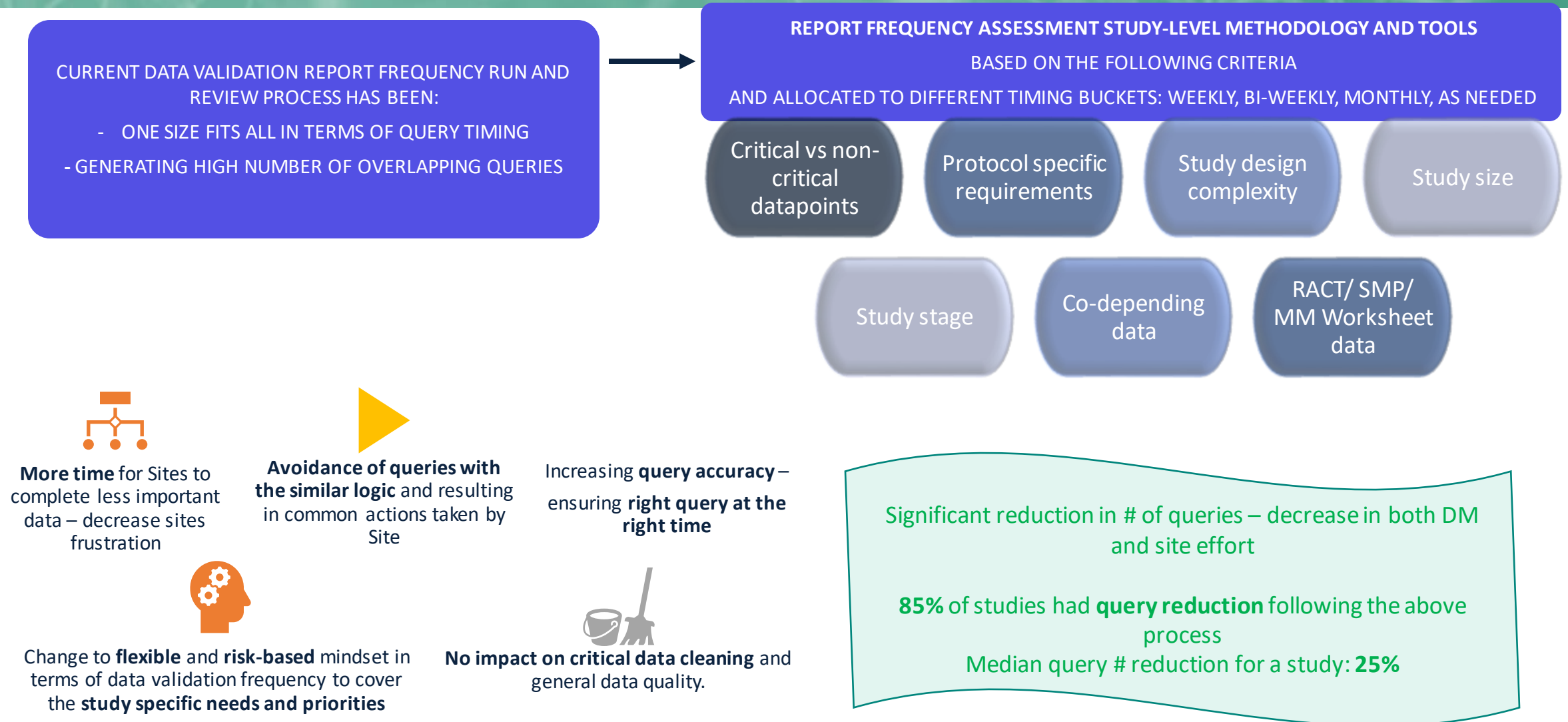
- Concerns with decreasing quality
- Mindset challenge of accepting imperfection
- Need for upskilling (big data, data analytics)
- Challenge with clear requirements definitions at trial set-up
- Translation of analysis requirements to data management
- Cross-functional acceptance and E2E alignment

Mapping the road to Risk-Based Data Management



Examples of risk-based approaches in Data Management processes:

Reports frequency run assessment



Examples of risk-based approaches in Data Management processes: Aggregate data visualization

PROCESS

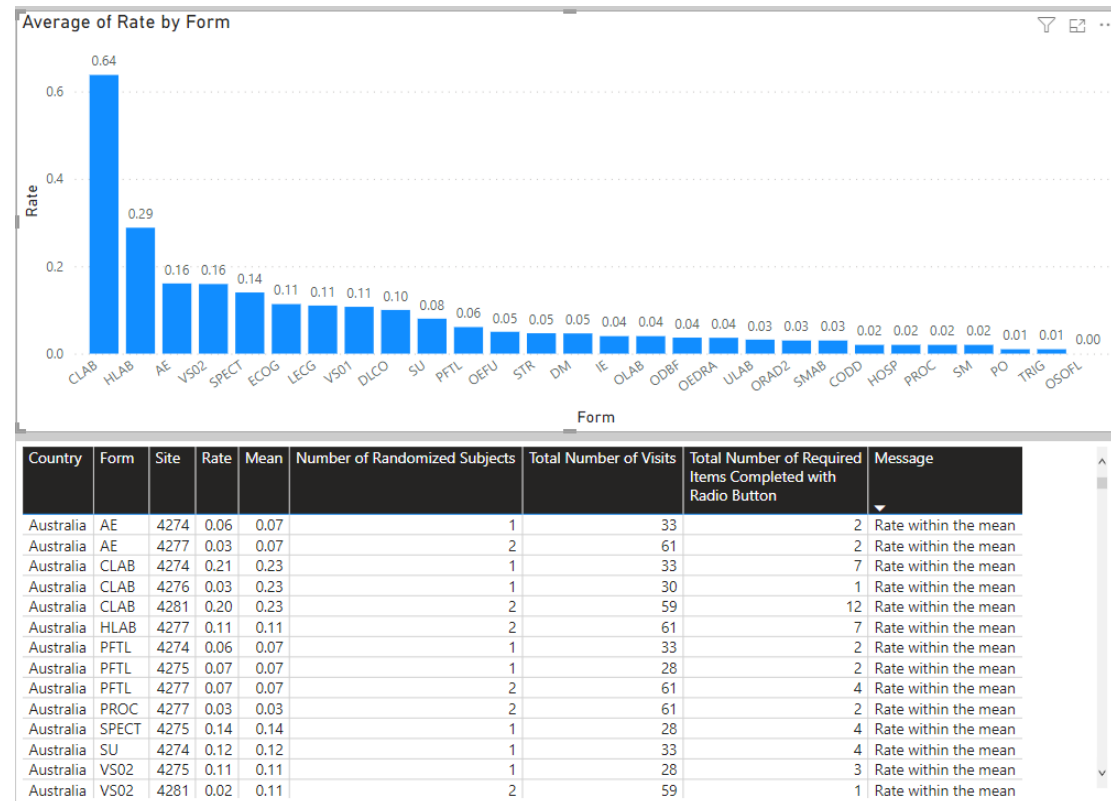
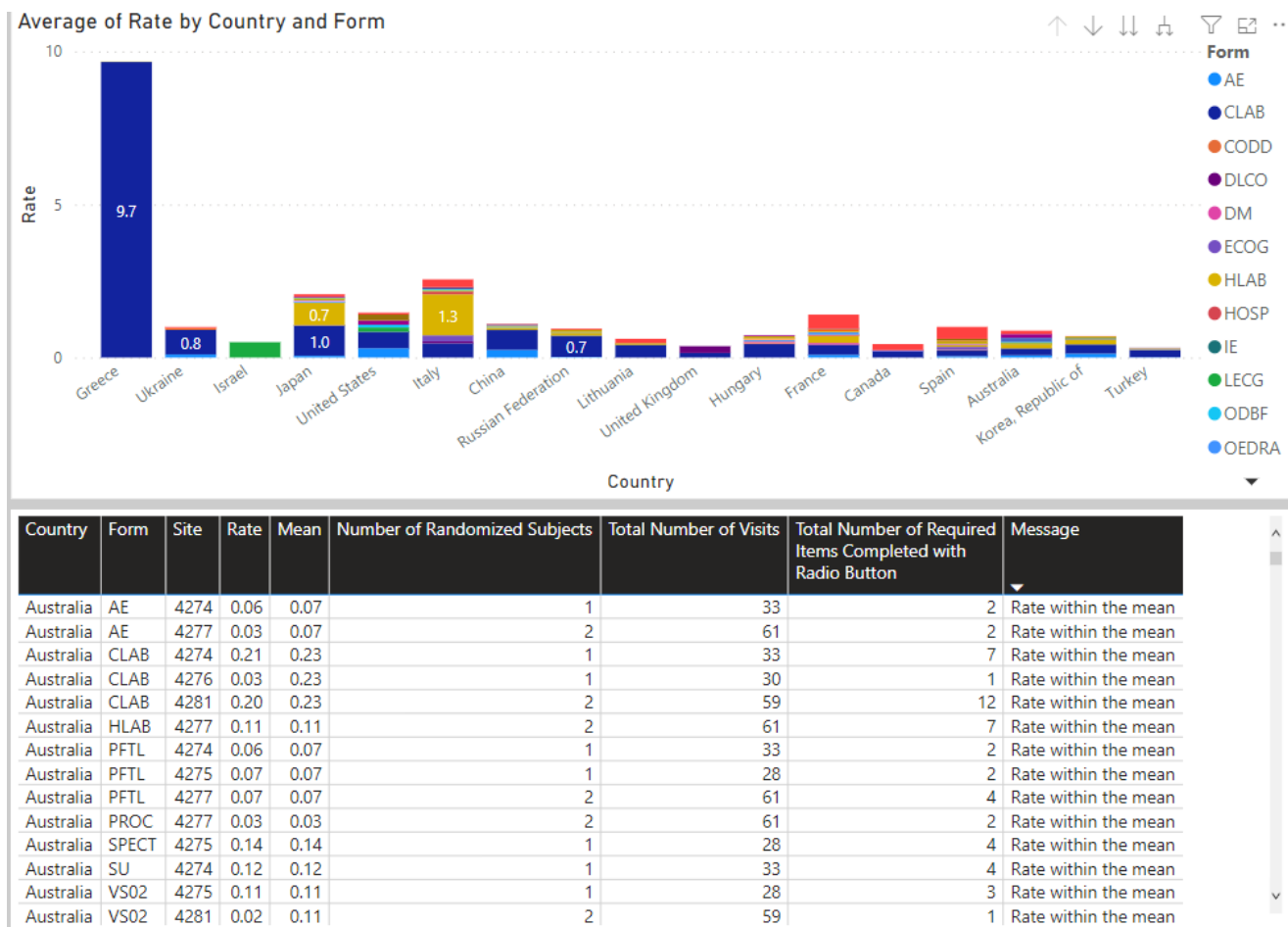
Aggregate data review:

- looking for **trends and outliers** across patients to identify critical data issues:
- high-level **visualization** analysis -> drill-down to detailed issues **where needed**
- e.g. for missing data (blank, and marked as permanently missing), dates before screening,

Examples of risk-based approaches in Data Management processes: Aggregate data visualization (cont'd)

TOOL

FIELDS COMPLETED WITH NOT DONE/NOT APPLICABLE/UNKNOWN RESPONSE



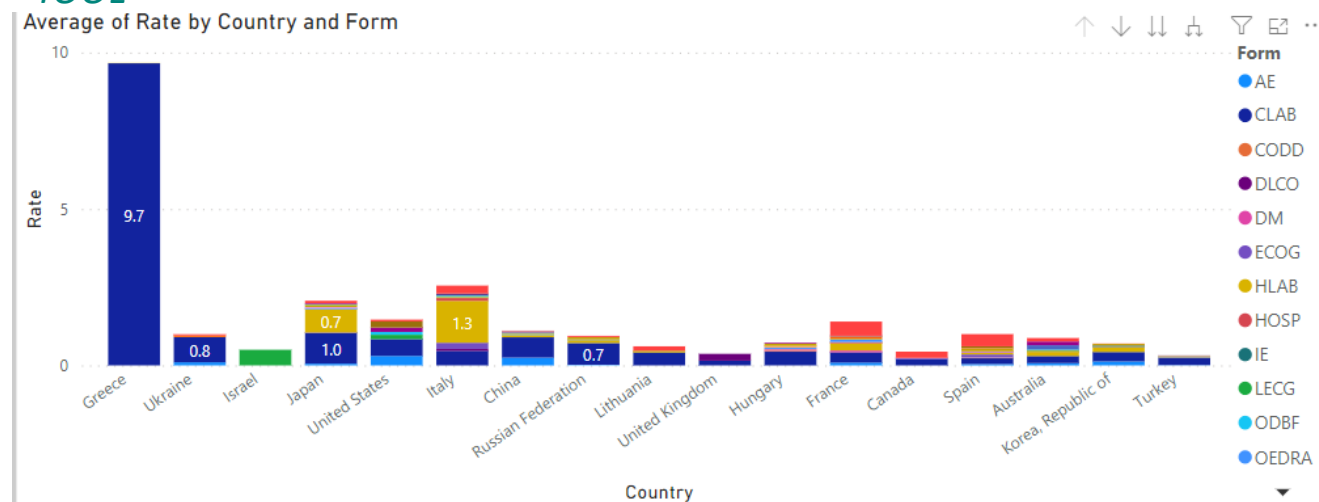
Examples of risk-based approaches in Data Management processes: Aggregate data visualization (cont'd)

PROCESS

Aggregate data review:

- looking for **trends and outliers** across patients to identify critical data issues:
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TOOL



GAIN

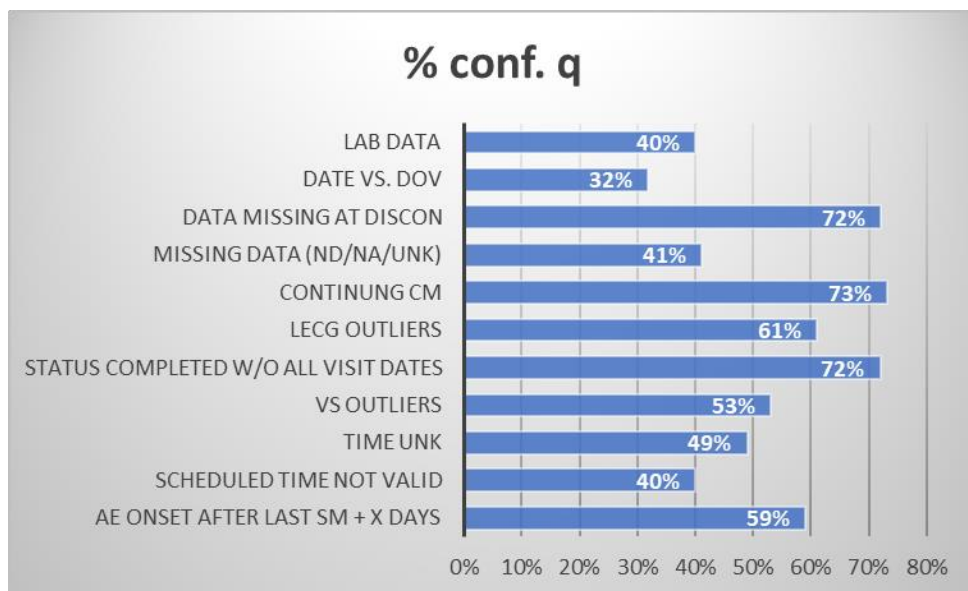
- Time efficiency
- Easier and fast identification of inconsistencies, trends and outliers within the visual graphs than in tables
- Accuracy
- Standardization of presented results
- DV approach by utilization of visualization
- Mindset change towards targeted DV
- Basis for establishing baselines and KRIs leveraging historical data

Examples of risk-based approaches in Data Management processes: Confirmatory query analysis

Purpose: Analyze queries that lead to no database change, understand rationale and improvement areas, and recommend solutions for increasing query accuracy and reducing query volume

Over **500 000**
confirmatory queries/year
13.0% of all Data Management queries

TOP SCENARIOS
totaling ~200 000 queries/year



Opportunities

Related to global data and scenarios analysis

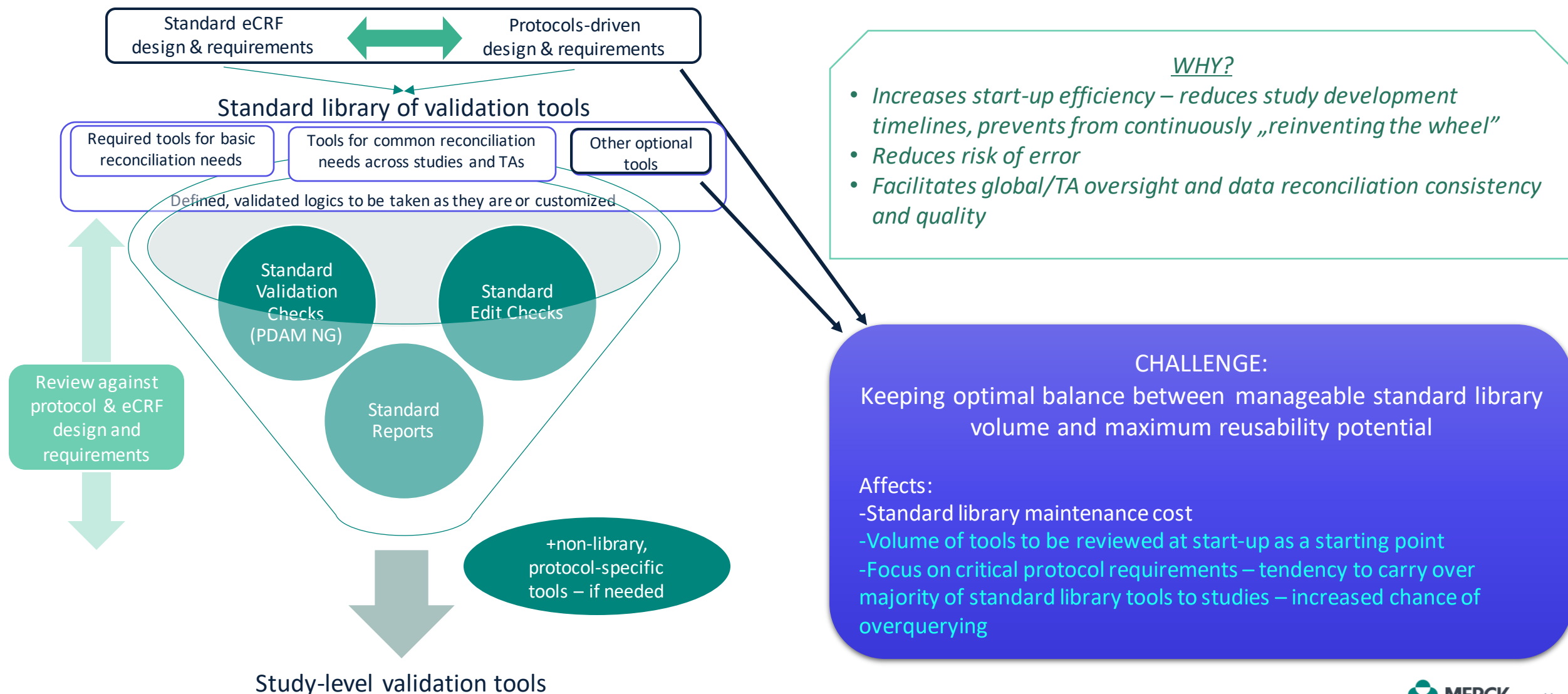
- Remove or condition non- or low-value queries (e.g. data missing at discon)
- Remove duplicate or overlapping data validation (e.g. status completed w/o all visit dates, data missing at discon)
- Improve risk-based, critical-driven data collection and validation set-up (e.g. scheduled time usage, missing data ND/NA/UNK, missing data, lab data)
- Assess tolerance levels and utilize trend/outlier review (e.g. VS/LECG ranges, date vs. DOV)
- Increase specificity (e.g. lab data, time UNK)
- Align between FA plans on scope of review (e.g. data missing at discon, AE/CM review)

Related to study-level quality assurance

- Introduce effective, standardized study-level confirmatory queries monitoring process and visualization tools – improved query analysis

Examples of risk-based approaches in Data Management processes:

Standard library tools reusability analysis



Examples of risk-based approaches in Data Management processes: Standard library tools reusability analysis (cont'd)



Main goals

- Reduce burden resulting from non- and low-value data validation tools development and maintenance at library and study levels
- Ensure ongoing library health assessment for keeping value-added, reusable tools as standards

Query impact

- Reduced risk of introducing non-value, overlapping or duplicating data validation tools and resulting queries in-life
- More space for risk-based, critical-driven discussions on valid tools per protocol requirements towards increasing query accuracy and meaningfulness

Examples of risk-based approaches in Data Management processes: No Process Left Behind app, Data Entry Guidelines (DEG) refresh

NPLB (No Process Left Behind App)

- Aids in DM daily activities tracking and improving quality
- Allows to analyze data from studies around processes execution for risk-based processes evaluation and maintenance
- Together with **Process re-evaluation and monitoring** initiative, contributes to **increasing query meaningfulness, focus and accuracy**

First Patient Enrolled *	25% of Enrollment *	50% of Enrollment *
10/Feb/2021	14/Jul/2021	27/Jul/2021
75% of Enrollment *	100% of Enrollment *	Final DBL *
20/Oct/2021	11/Nov/2021	07/Apr/2023

Name	Assigned To	Target Start Date	Start Date	End Date	Status	Comment
Perform Query Analysis during in life and until final DBL		10/Aug/2022				
Perform Report Efficiency Assessment		10/Aug/2022				
Obtain German PI Signatures		10/Aug/2022				

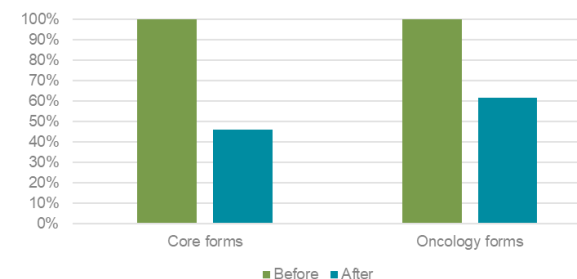
Data Entry Guidelines (DEG) refresh

Feedback on DEG limited ease-of-use, large volume and suboptimal format

- Improvement by:
- targetting guidelines on common data entry problems and exceptions
 - eliminating redundancy
 - optimizing format, content and structure

- Maximizing value vs. volume
- Increasing clarity, guidelines meaningfulness, and ease-of-use
- **Increasing Quality by Design and issues & queries prevention**
- Facilitating consistent, risk-based approach for DEG development, as well as greater flexibility and room in terms of protocol-specific guidelines

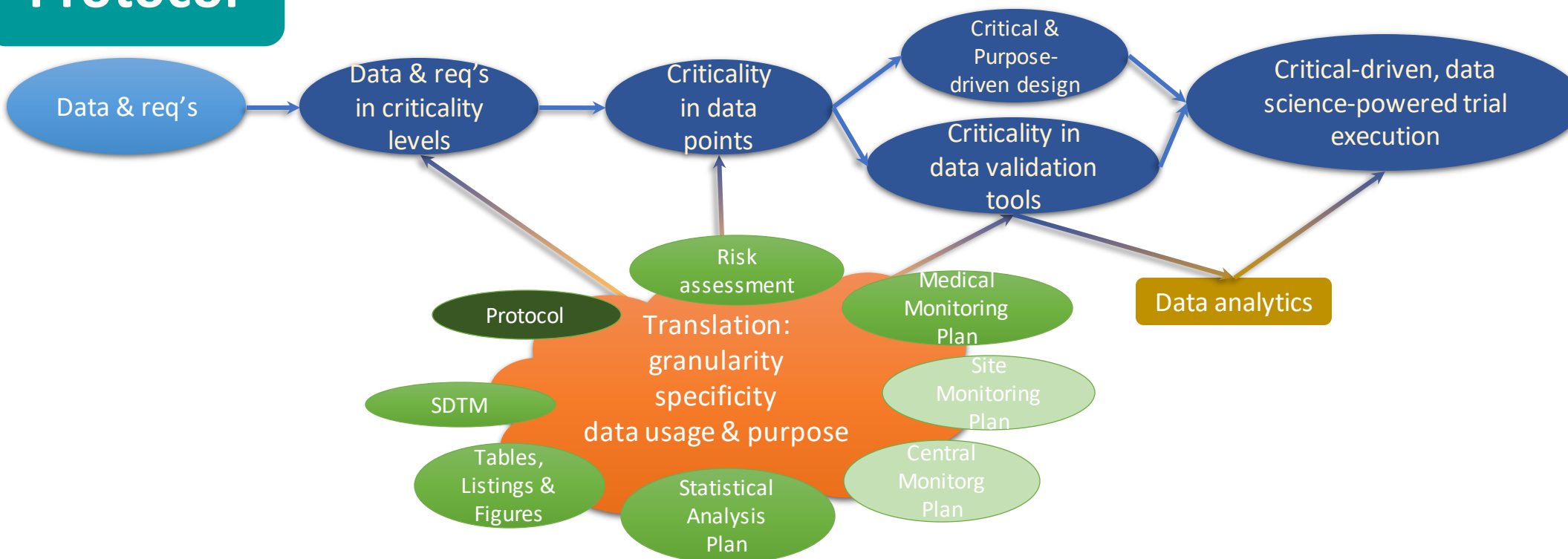
Standard Data Entry Guidelines before and after reduction (based on # of characters)



Data criticality – translating requirements to Data Management: Desired state

Protocol

Closeout

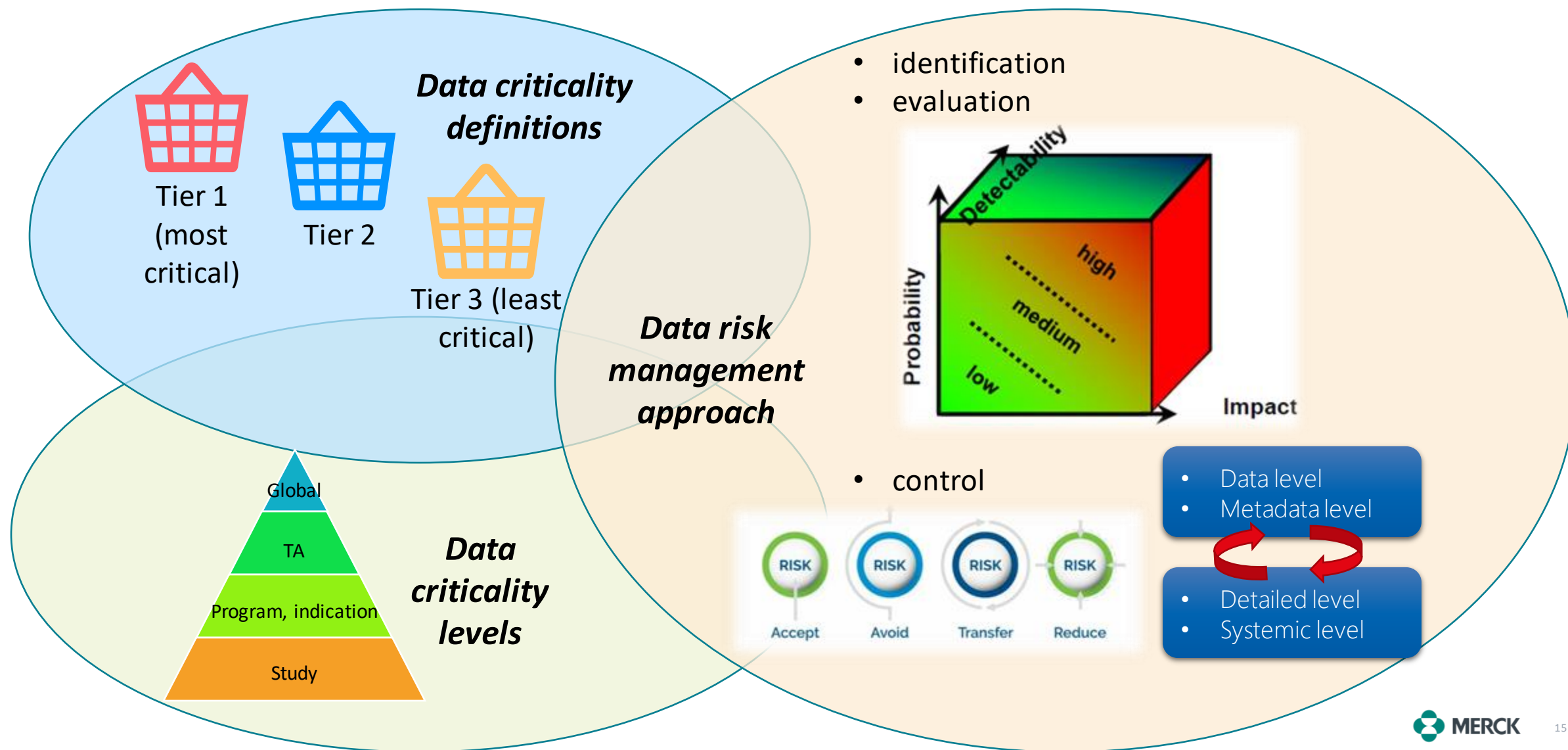


**EDC
Development**

Data Validation

Trial Execution

Data criticality – translating requirements to Data Management: Vision







THANK YOU

The image features a central white rectangular area containing the text "THANK YOU" in a teal, hand-drawn, sans-serif font. Above and below this central area are decorative borders consisting of multiple rows of teal chevron patterns. The entire composition is set against a white background with a subtle, light teal speckled texture.