# Pac* management
# Global harmonization perspectives

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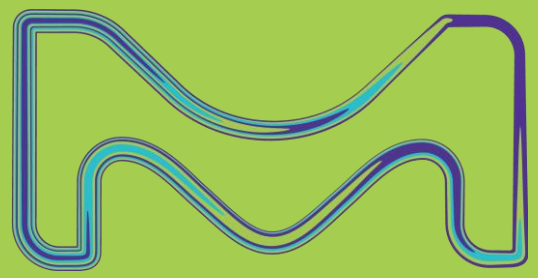

*post approval change

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# Disclaimer

The views and opinions expressed
during this presentation are strictly those of the
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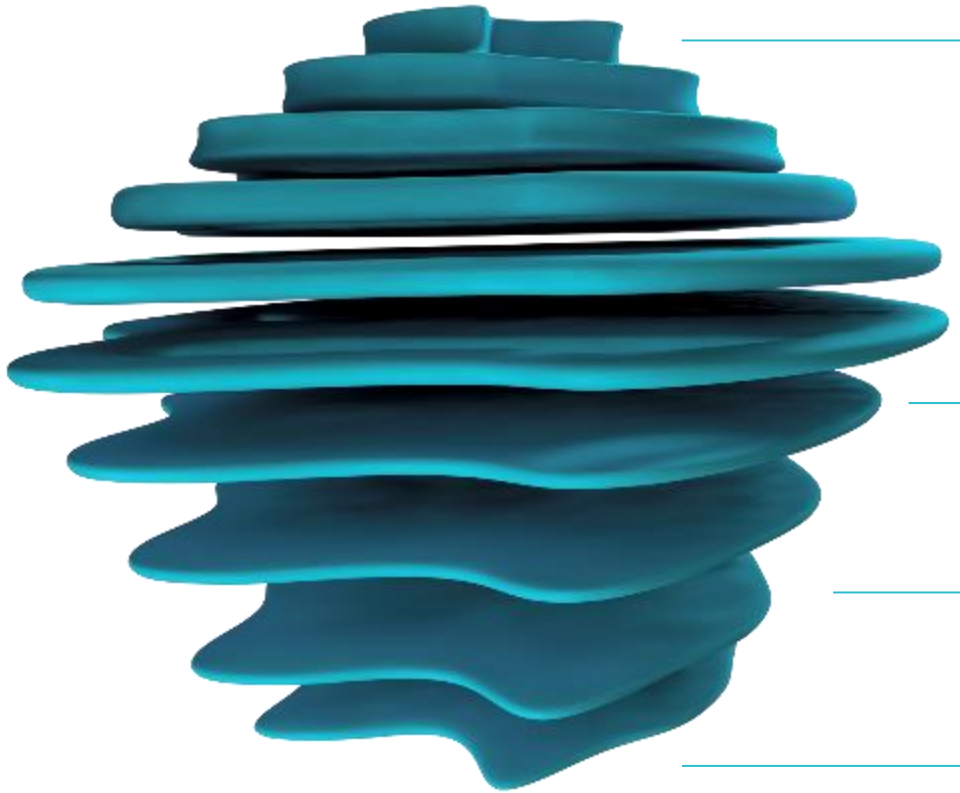
# Post Approval Change Management - Global Harmonization Perspectives
## Presentation Outline



**Current Landscape and Blue Sky Thinking**

**Post Approval Change Management – From the Manufacturer to the Patient**

**Post Approval Change Management – Challenges**

**Post Approval Change Management – How Can Industry and Regulators Act Together ?**

**Concluding Perspectives**

# Current Landscape

Increased complexity and speed to patient access

Compliance with evolving regulation

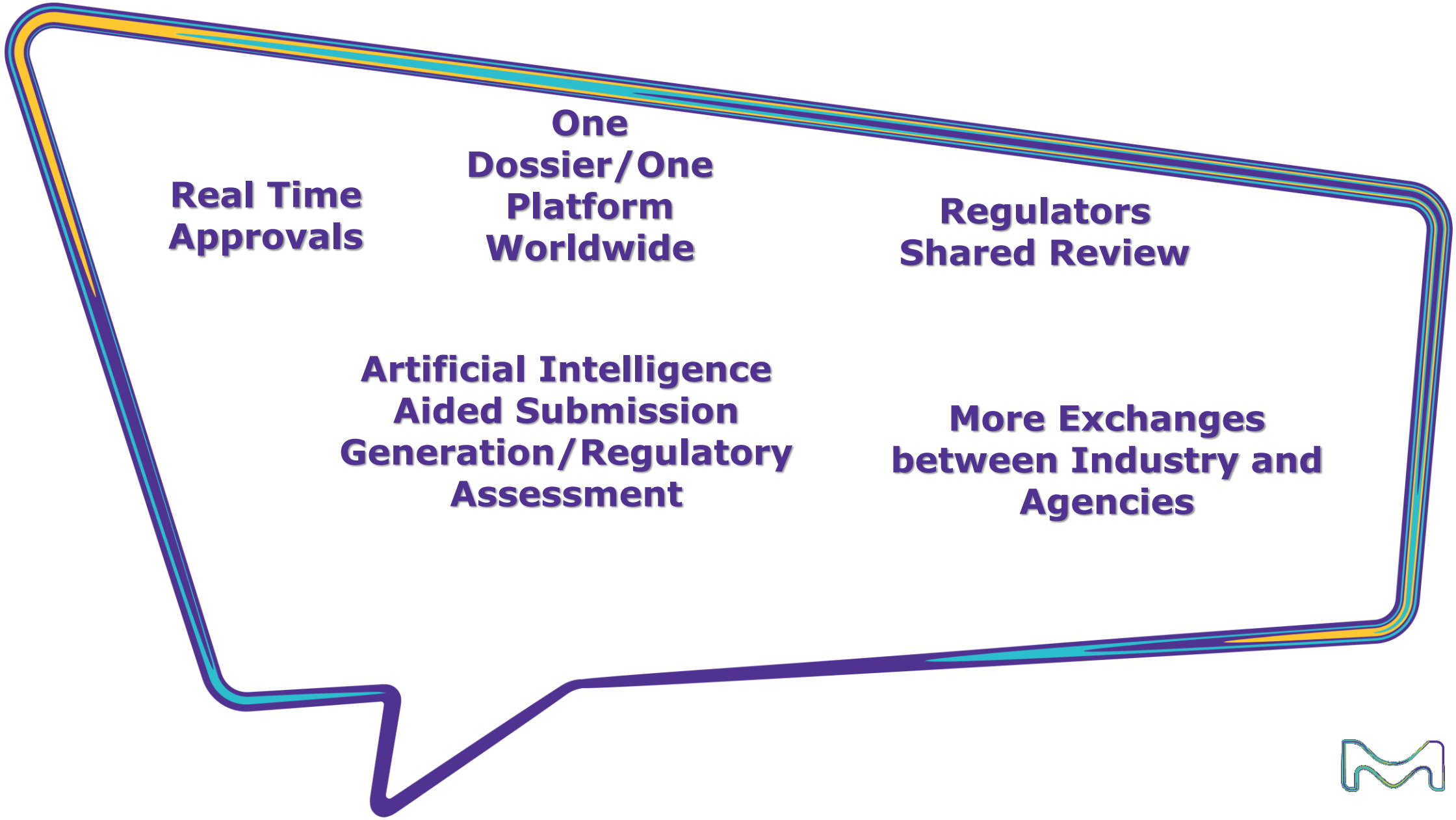
Technology evolution

Market demand

High number of post approval changes

**Evolving Global Regulatory Environment**

# Blue Sky Thinking



# Post Approval Change Management – From the Manufacturer to the Patient

Change initiation and evaluation

Submission strategy and timelines

Submission preparation

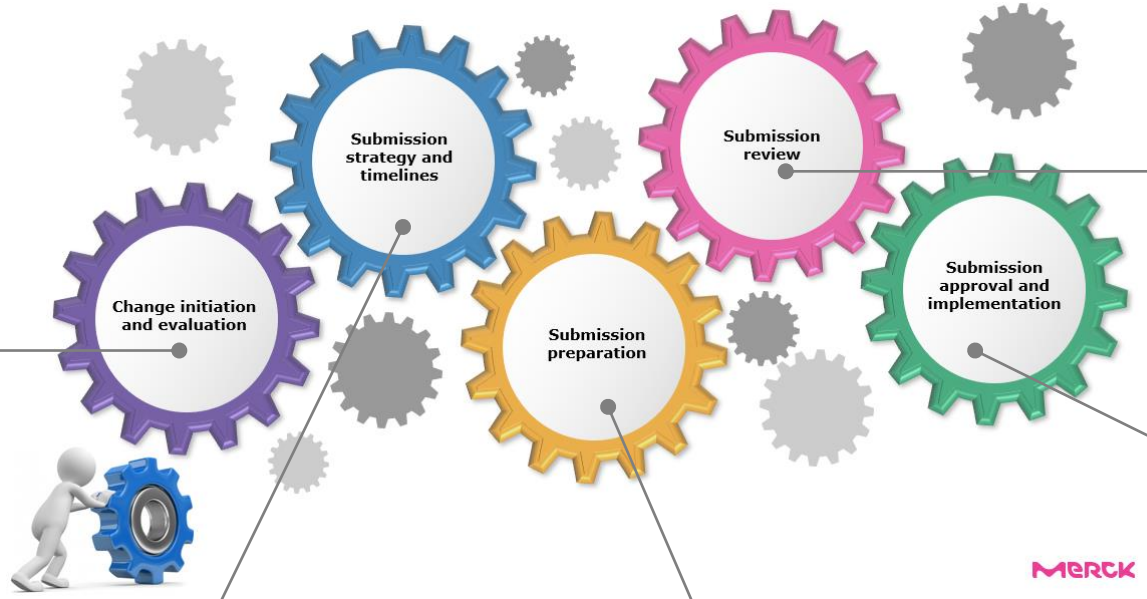
Submission review

Submission approval and implementation

# Post Approval Change Management – Challenges

## Changes Reportability Divergence

*Same minor change (minor quality impact) can be non-reportable for some countries and requiring prior approval for others*




## Heterogeneity in Health Authorities Review Time

*From 2 to 36 months and beyond*

## Heterogeneity in Implementation Transition Periods

## Wide Range of Country Specific Requirements/Languages

*Sometimes redundant with M3 information and GMP related*
*Translation required in several countries*

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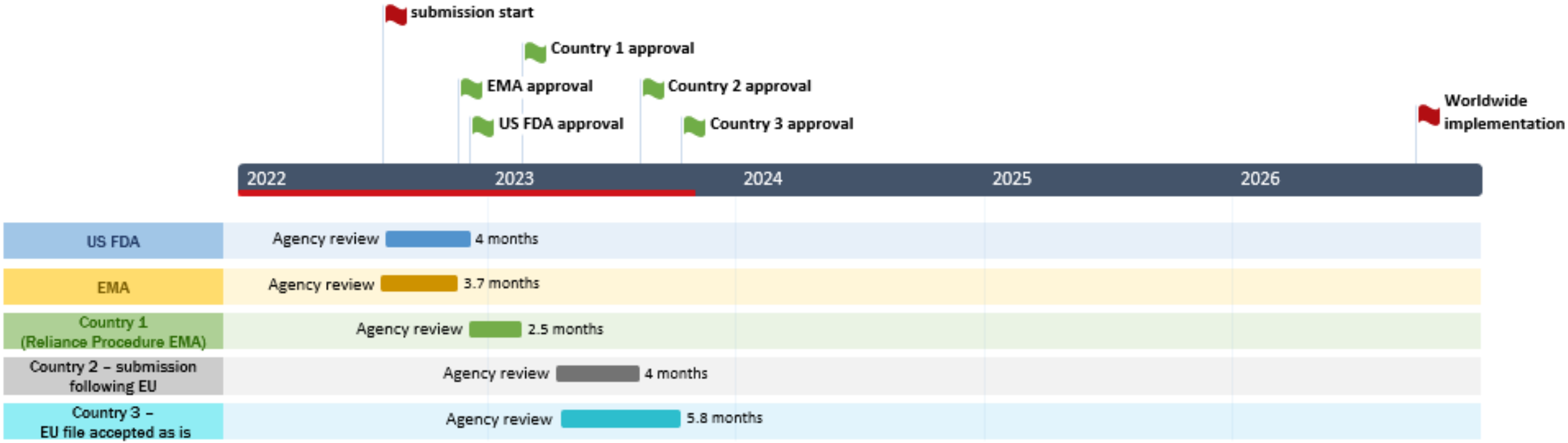
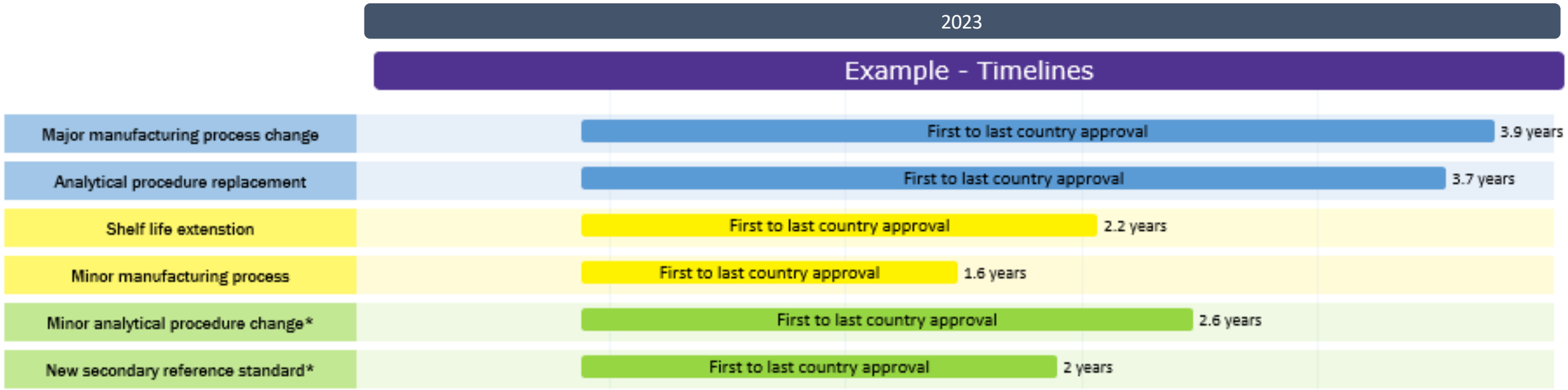
**<u>Direct Impact</u> : Implementation Strategy Complexity and Slow Down Supply/Patient Access**

# Post Approval Change Management – Examples




## How to bring all countries in optimized timeframe to fasten worldwide implementation?

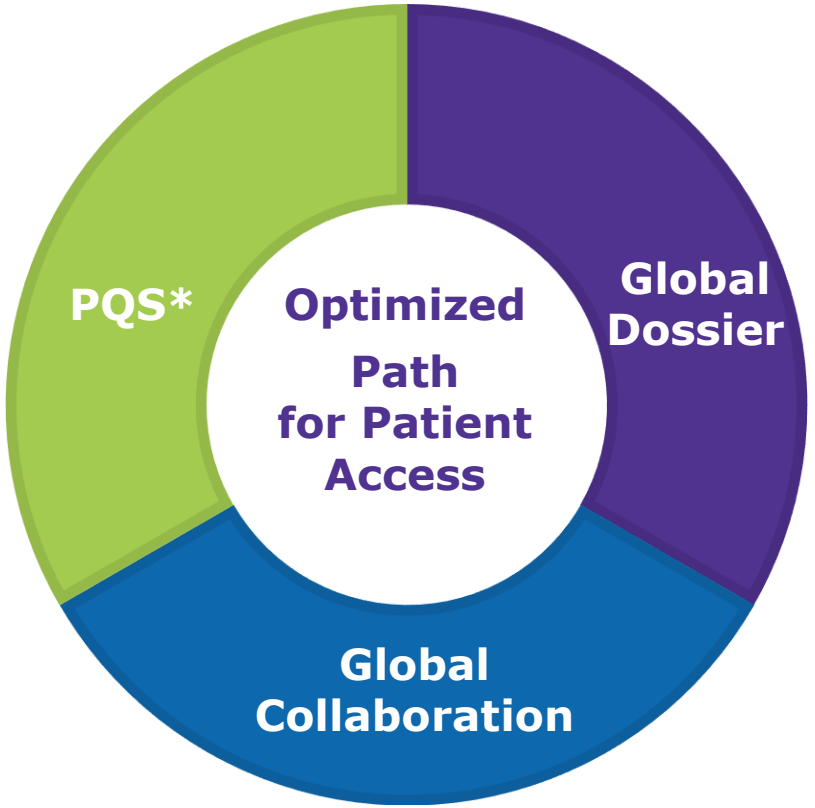
# Post Approval Change Management – Examples






* Annual report for US and Type IA variation for EU

# Post Approval Change Management – How Can Industry and Regulators Act Together ?






*PQS : Pharmaceutical Quality System

# Post Approval Change Management – How Can Industry and Regulators Act Together ?

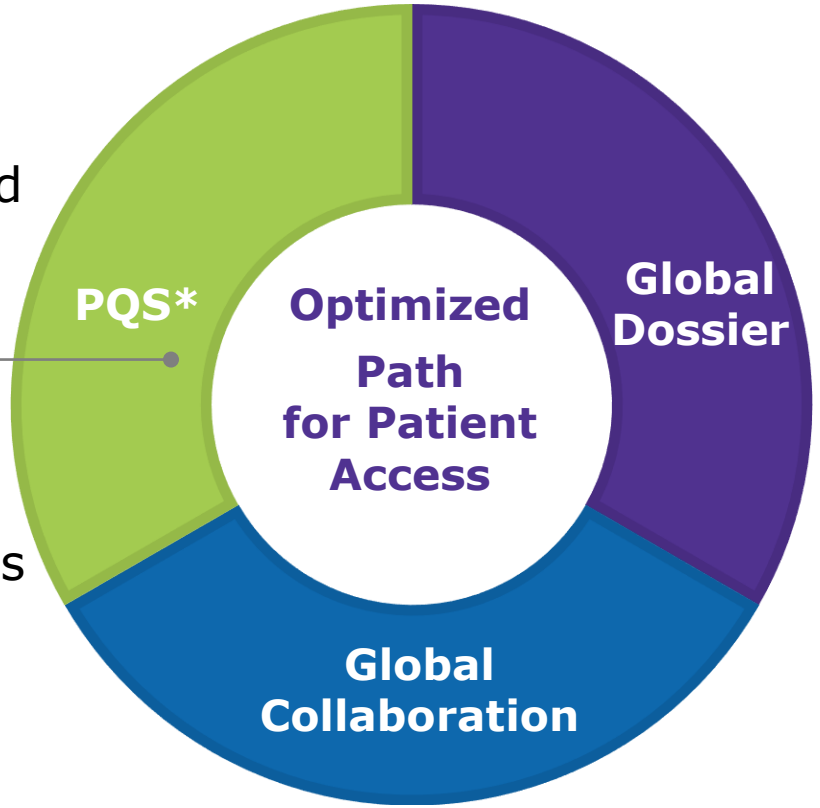
## Challenges:
## Changes Reportability Divergence /Country Specific Requirements /Review Time

**PQS as major enabler-**
**ICH Q12 toolbox**

Framework for quality risk-based categorization for changes reporting

Established Conditions (EC) – binding information subject to reportability to health authorities (quality risk based reportability level)

PACMP : Post Approval Change Management Protocols






*PQS : Pharmaceutical Quality System – Refer also to ICH Q8, Q9 and Q10

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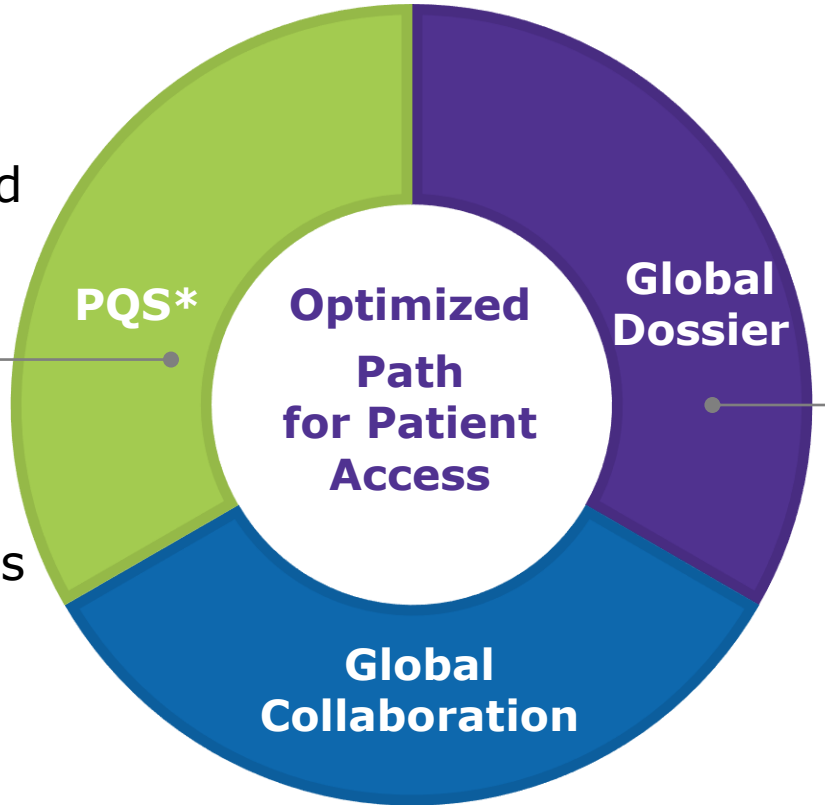


**Single Dossier Worldwide as a Tool for Enhanced Collaboration**

Harmonized content

Support for modernized regulatory AI abled processes

More GMP related documentation managed under PQS



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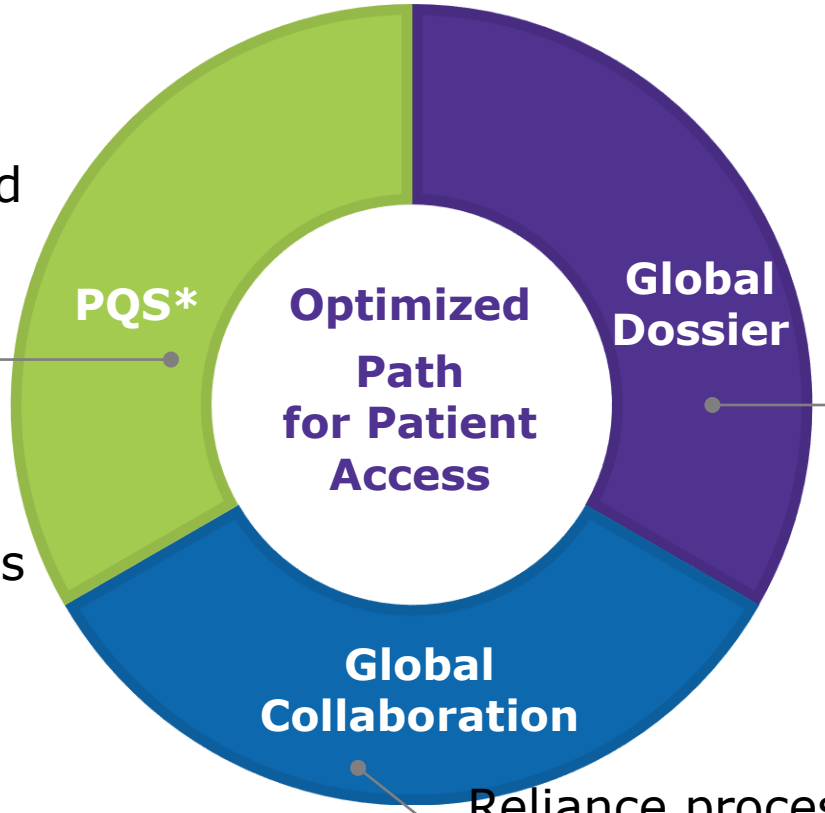


**Single Dossier Worldwide as a Tool for Enhanced Collaboration**

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Support for modernized regulatory AI abled processes

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Reliance processes

Regulators work sharing

Global opportunities for Health Authority/Industry dialog



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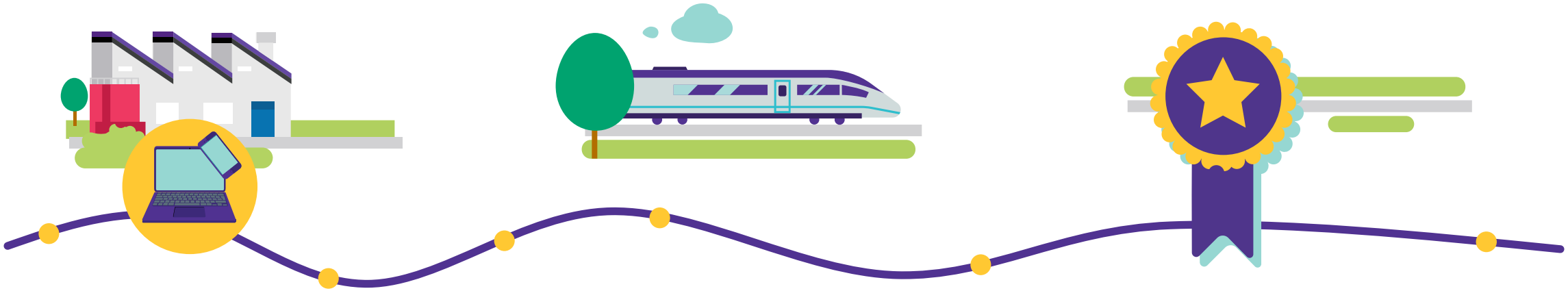
# Concluding Perspectives
## **Road to success**



### More Harmonization

Same change, same data, same quality, same reportability

### More Collaboration

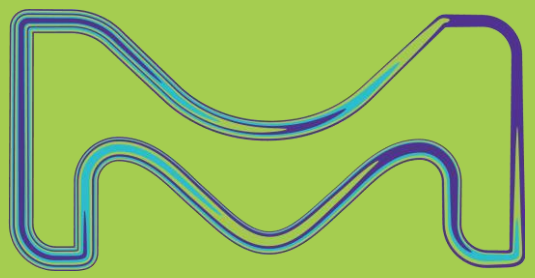
Capitalize on worldwide resources – Reliance Pathways

### Single Source of Truth

Cloud-based data sharing and assessments (e.g. “Dynamic Regulatory Assessment”)

# Thank you

# any questions ?



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