GLOBAL UDI STRATEGY

IMDRF/DITTA Joint Workshop on UDI September 9, 2021

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AGENDA

- ➤ UDI Implementation Framework
- > Flexible UDI Global Strategy
- ➤ Industry Submission Challenges



Interpretation

- Review regulation to understand, document, and communicate compliance requirements and impacts
- Develop single interpretation for addressing each UDI requirement drives consistency and efficiency

Policy Impacts

Function Specific Actions

Process & Systems

Training

- Determine impacts to existing Policies or create new Policy if needed
- Mange implementation and rollout of Policy updates
- For each Function
 (Manufacturing, IT, Labeling, etc.) identify actions required to meet compliance requirements
- Develop method to track completion of implementation changes
- Define and implement company wide process and system changes to compile and submit UDI attribute data globally
- Develop Training Approach
- Manage updates to new or existing training

Governance

- Determine and implement Governance model required for implementation and post implementation operation
- Includes: Steering Committee, Council, and/or Change Advisory Board

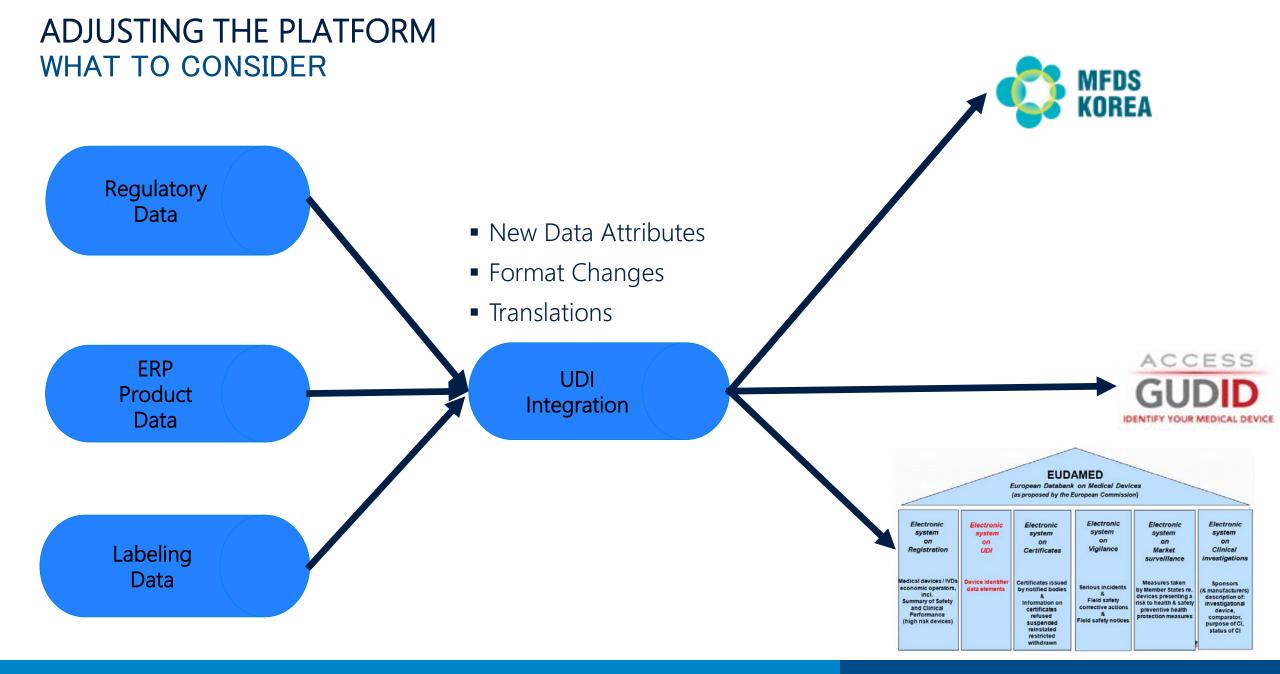
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Manage

Program

FLEXIBLE UDI GLOBAL STRATEGY PROS & CONS

Pros	Cons
Consistent Data across Global UDI Databases	Duplicated Work
Alignment with Internal Processes	Integrated Process
Resources	Maintenance
Funding	Funding
Implementation	Timing of Implementation



PREPARING FOR THE FUTURE



- ➤ Understand UDI requirement differences
- Prepare Organization alignment and change management
- ➤ Enable Process & Technology

THANK YOU!

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LET'S TAKE HEALTHCARE FURTHER, TOGETHER