

# GLOBAL UDI STRATEGY

IMDRF/DITTA Joint Workshop on  
UDI  
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**Medtronic**  
Further, Together

# AGENDA

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



# IMPLEMENTATION FRAMEWORK

Program Management	<b>Interpretation</b> <ul style="list-style-type: none"><li>• Review regulation to understand, document, and communicate compliance requirements and impacts</li><li>• Develop single interpretation for addressing each UDI requirement – drives consistency and efficiency</li></ul>				Change Management & Communication
	<b>Policy Impacts</b>	<b>Function Specific Actions</b>	<b>Process &amp; Systems</b>	<b>Training</b>	
	<ul style="list-style-type: none"><li>• Determine impacts to existing Policies or create new Policy if needed</li><li>• Manage implementation and rollout of Policy updates</li></ul>	<ul style="list-style-type: none"><li>• For each Function (Manufacturing, IT, Labeling, etc.) identify actions required to meet compliance requirements</li><li>• Develop method to track completion of implementation changes</li></ul>	<ul style="list-style-type: none"><li>• Define and implement company wide process and system changes to compile and submit UDI attribute data globally</li></ul>	<ul style="list-style-type: none"><li>• Develop Training Approach</li><li>• Manage updates to new or existing training</li></ul>	
	<b>Governance</b> <ul style="list-style-type: none"><li>• Determine and implement Governance model required for implementation and post implementation operation</li><li>• Includes: Steering Committee, Council, and/or Change Advisory Board</li></ul>				

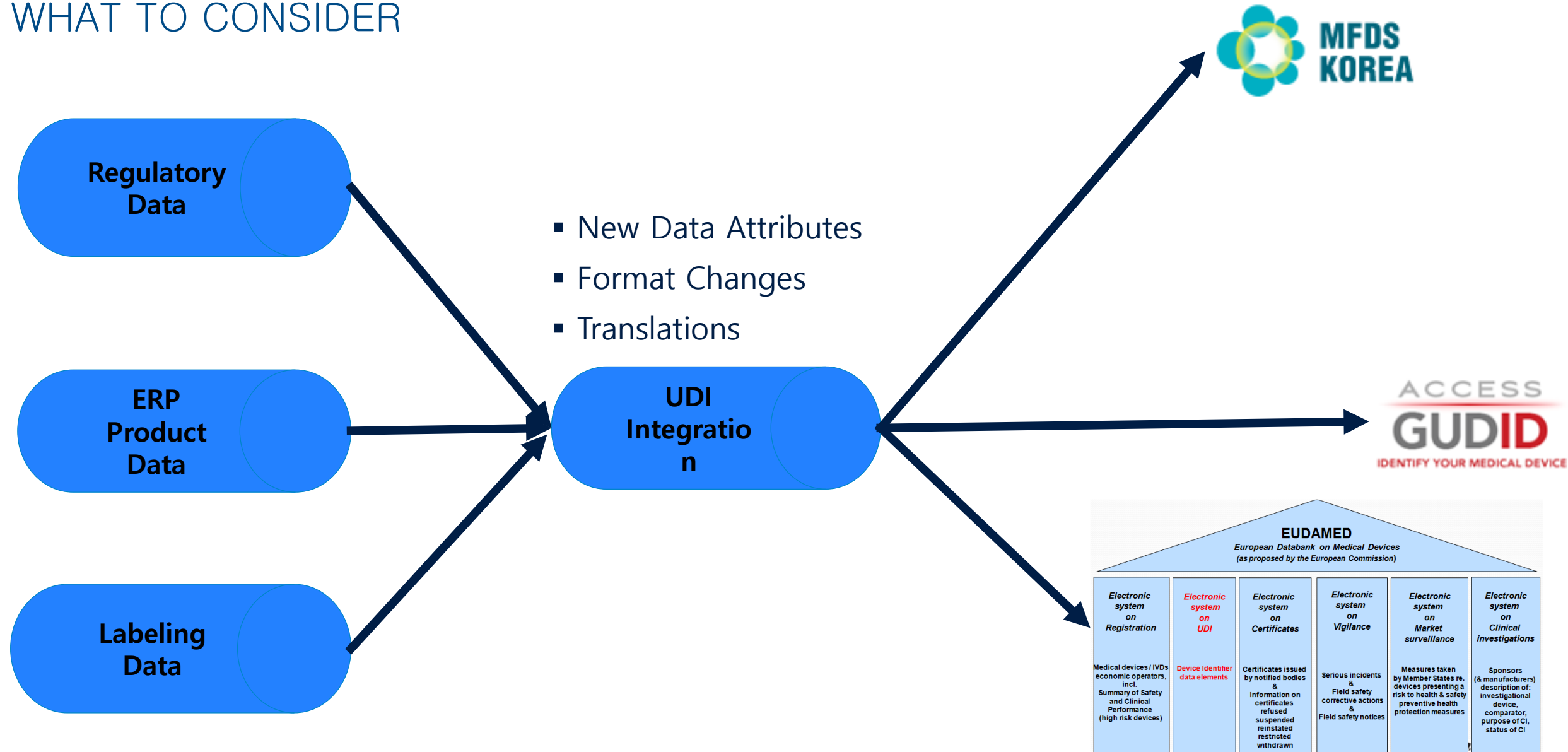
# FLEXIBLE UDI GLOBAL STRATEGY

## 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

# ADJUSTING THE PLATFORM

## WHAT TO CONSIDER



# PREPARING FOR THE FUTURE



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

# THANK YOU!

**Tania Pearson**

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**LET'S TAKE HEALTHCARE  
FURTHER, TOGETHER**