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Technology Alliance  
*Innovating for a Healthier World*

# Regulatory Reliance

IMDRF Stakeholders Session

13<sup>th</sup> September 2022 – Sydney, Australia

*“The future of medical products regulation is in convergence/harmonization, collaboration, and networking based on reliance and trust.”*

# Presentation Outline



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- Greater Reliance
- Observations and Recommendations
  - Medical Device Single Review Program
  - Medical Device Single Audit Program
  - Electronic Labelling

# Greater Reliance



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The global pandemic emphasized the value of regulatory cooperation and highlighted the opportunities to

Modernize regulatory systems to create efficiencies, avoid redundancies, and reduce unnecessary complexity

Enhance regulatory capacity.

Promote expedited patient access to important innovative technologies in order to ensure global health equity.

# Greater Reliance



## Convergence

A voluntary process whereby regulation and standards across countries and regions are aligned to internationally recognized best practices to include standards. Convergence is not required to practice reliance but it is a strong enabler to facilitate reliance adoption

## Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to decisions made by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.<sup>2</sup>

1. IMDRF (2018), [IMDRF Terms of Reference](#)  
2. WHO (2016), [Good Regulatory Practices Guidance](#)

# Medical Device Single Review Program (MDSRP)



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Following the governance model of MDSAP,  
Develop a work item that includes a pilot for MDSRP

Allow submissions to be used by other regulators for decisions on marketing applications

Strengthen the confidence and consistency in the regulatory decision-making process

Strengthen standards development by promoting the use and development of international consensus standards

Support patient access to innovative medical technologies

# MDSRP – Universal dossier



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## Universal Dossier

- Results of the single review can be leveraged for improved patient access to medical devices and IVDs in multiple jurisdictions, without the need for multiple reviews

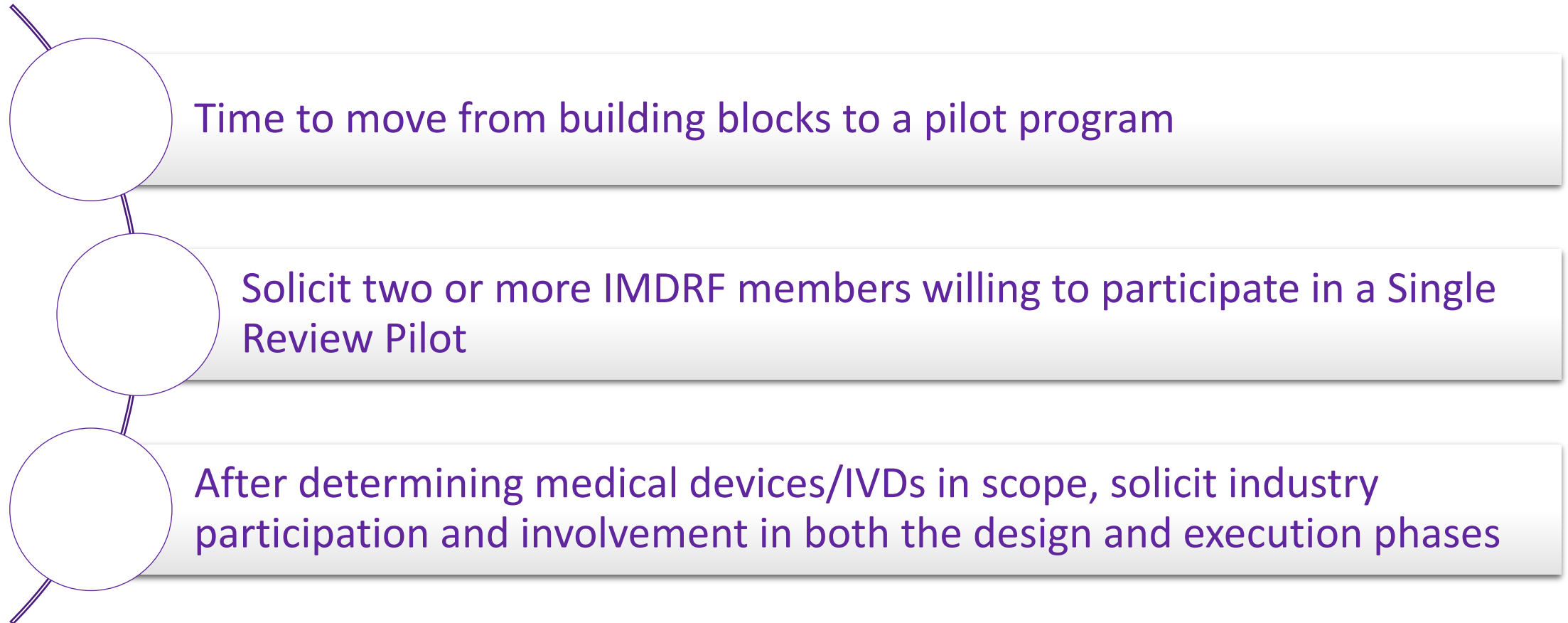
## Non- participating agencies

- Potential to also allow non-participating agencies to rely on the output of the participating agencies; specifically, their pre-market review decision

# MDSRP – Pilot



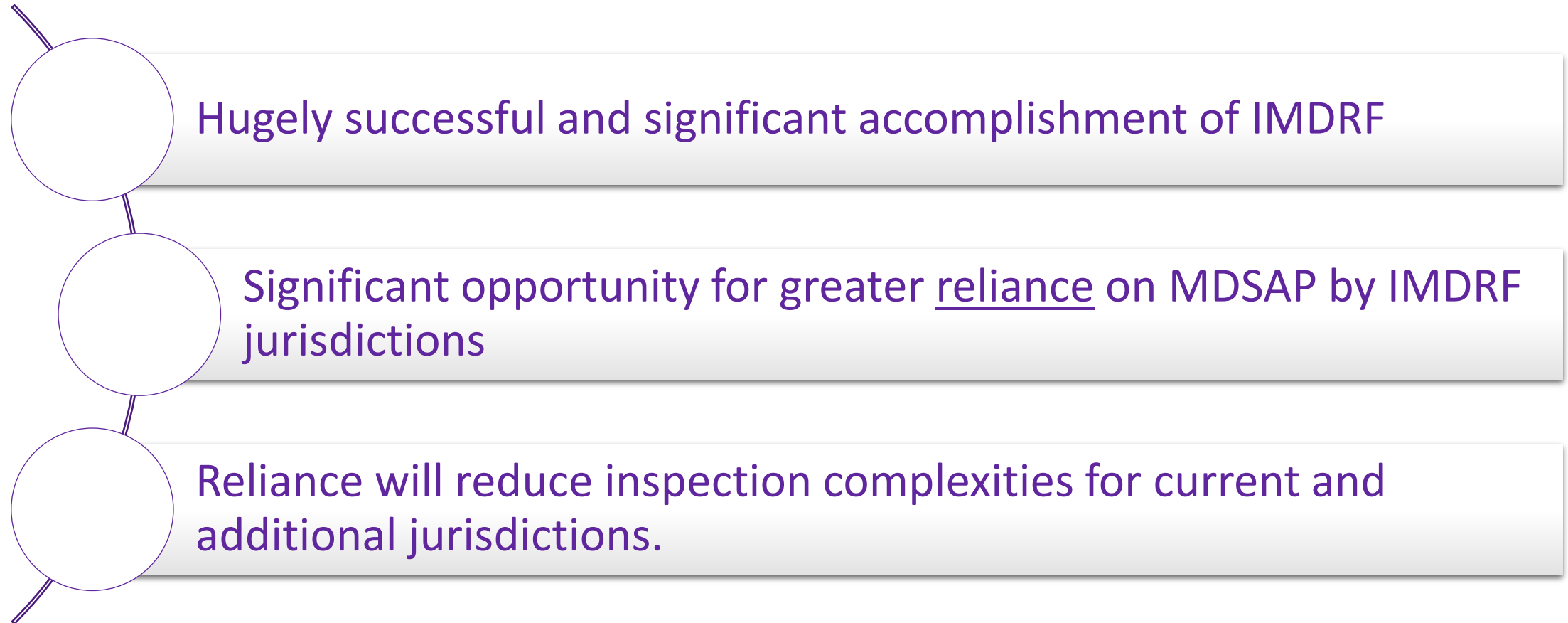
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# Medical Device Single Audit Program (MDSAP)



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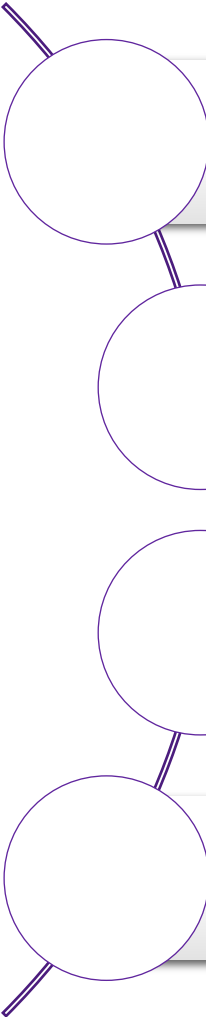




# Electronic Labelling



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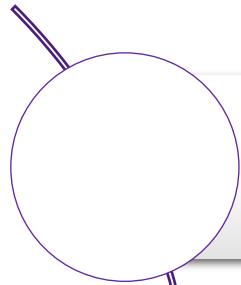
Rapid access to timely labelling, including instructions for use and safety information, even during a pandemic (e.g., stay at home orders).

Rapid access to the most up to date patient use and safety information

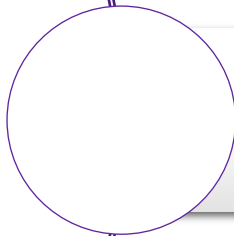
Electronic format enables the ability to easily search and find specific information

Supports global environmental sustainability goals

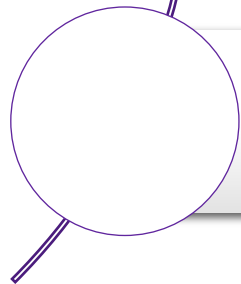
# Recommendations



Develop a work item that includes a pilot for MDSRP and ensures industry involvement in the design and execution



Encourage greater reliance by more IMDRF members on MDSAP



Develop a work item to create an IMDRF guidance encouraging acceptance of electronic labeling under a common format