

Experience Reliance for MDs and IVDs

Strategic acceleration on applications
for marketing authorization

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The 3 Pathways for Marketing Authorization

Mandatory health notification (NSO)

**Exclusive target for
Class I**

**Mechanism
Automatic process**

**Requirement
Sworn statement by the
company assuming
responsibility for quality,
safety, and efficacy.**

Simplified process (Reliance)

**Target
Class II, III, IV**

**Mechanism
Accelerated approval
based on reference
authorities**

**Requirement
Authorized products by Annual
List countries (Res. N°148/2024)
or bilateral agreements.
DINAVISA evaluates technical
information without differing
from the source**

Wholesome evaluation

**Target
Class II, III, IV**

**Mechanism
Overall technical and
documentary analysis by
DINAVISA**

**Requirement
For products not covered
by the simplified process
requirements**



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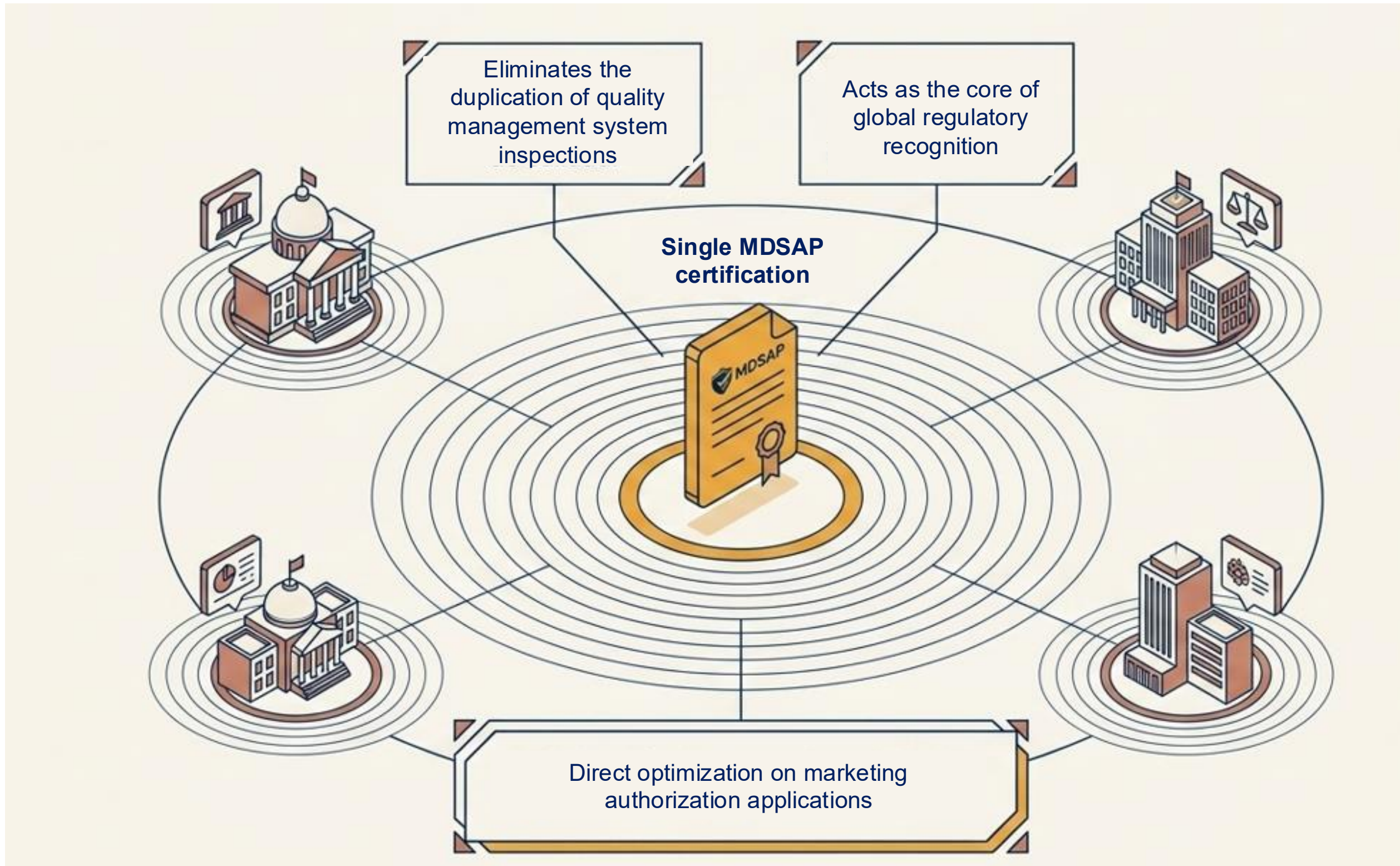
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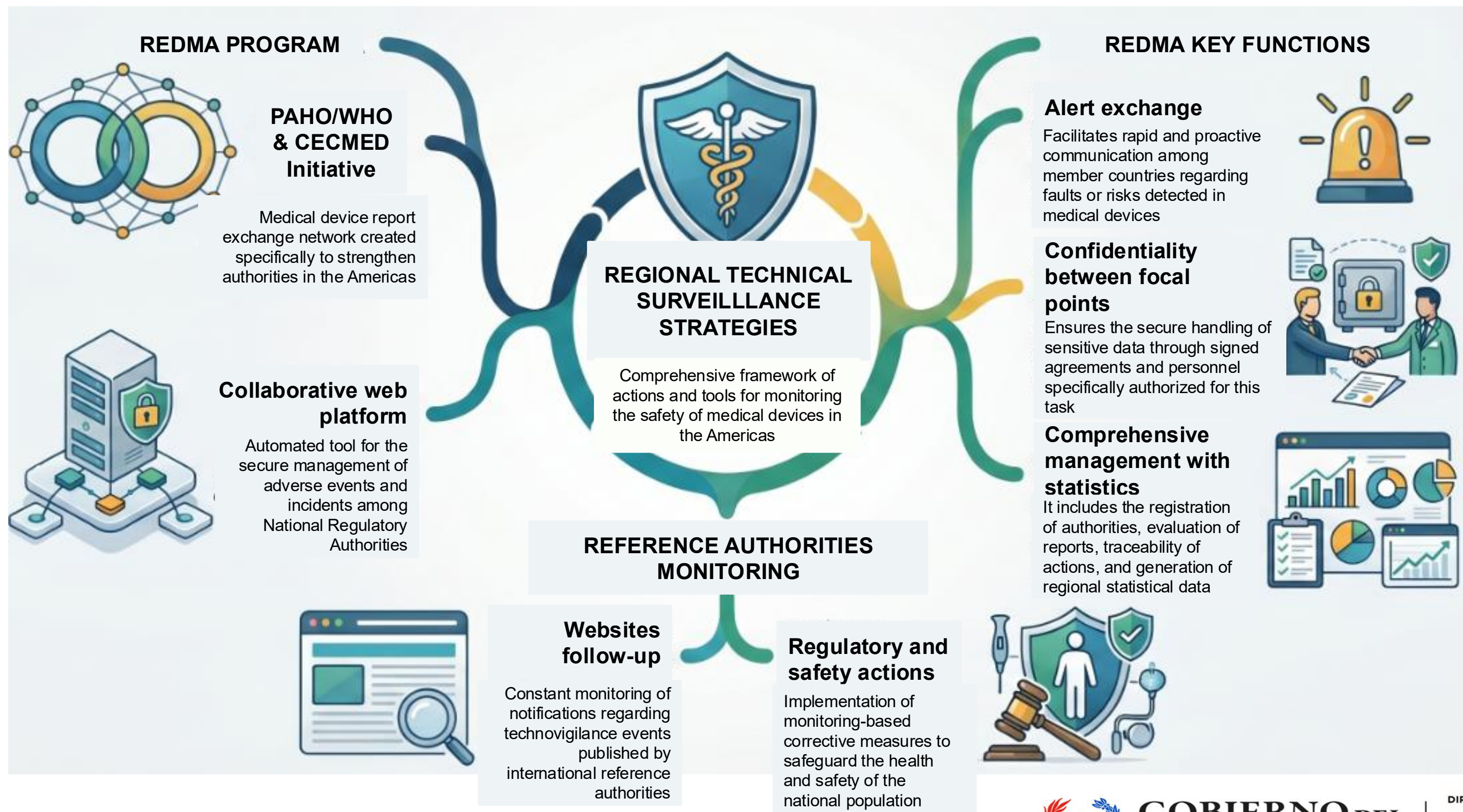
MDSAP certification acknowledgement



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In post-market stage



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Accelerated access to technologies

Reducing waiting times for the approval and availability of critical medical supplies



RELIANCE BENEFITS



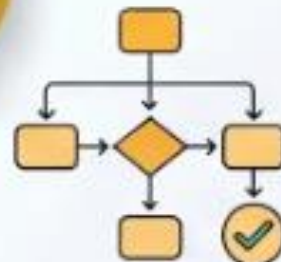
Fostering global convergence

Aligns local standards with international practices to facilitate technical collaboration



Financial resources optimization

Minimizes the duplication of effort and optimizes the use of institutional budget



Reassignment of specialized talent

Enables expert personnel to focus on high-value, complex tasks



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RELIANCE IMPLEMENTATION CHALLENGES FOR MEDICAL DEVICES

Regulatory and operational management



Regulatory misinterpretation

Inadequate understanding of the rules in force for the implementation of reliance models.



Platform use failures

Common mistakes when managing commercialization requests via digital tools

Accuracy and information availability



Lack of transparency regarding critical technical data

Vital technical information that cannot be located or verified in official external sources



Discrepancies in device data

Inconsistencies between the submitted information and the data originally approved by reference authorities



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Next Steps...

Evaluate implementation of reliance mechanisms in post-market authorization modifications for medical devices.



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