DIRECCION NACIONAL DE
VIGILANCIA SANITARIA
PARAGUAY

The Future of Medical Devices' Regulation

DINAVISA's strategic vision towards agility, Artificial Intelligence and continuos surveillance.

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Our vision towards the future

Regulatory agility
Accelerated pathways and global harmonization

Artificial intelligence security
Auditable and transparent algorithms

Digital health
Expansion of connected medical technologies

Continuos surveillance
Real-world data-based monitoring

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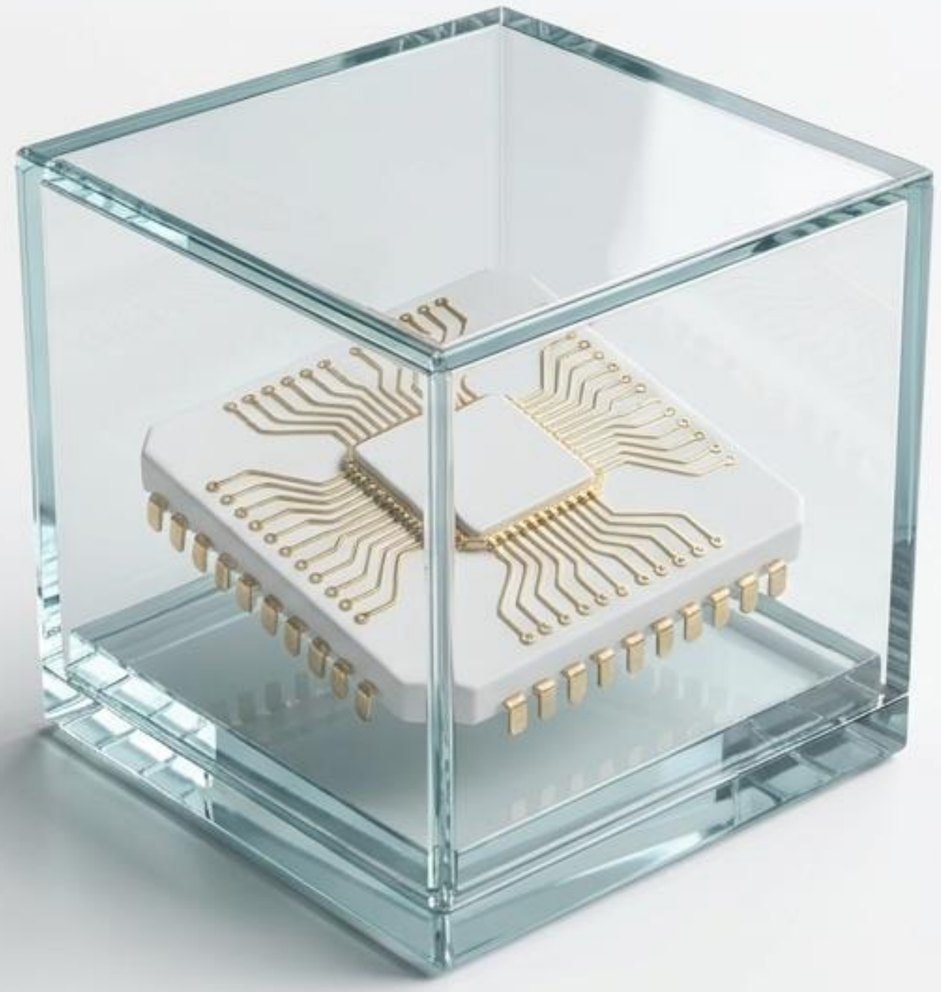
Pillar I: From the “Black Box” to total transparency in AI



Modern regulation on software and artificial intelligence requieres health algorithms to be fully **auditable**, **free** from **bias**, and capable of consistently **justifying their clinical efficacy**.

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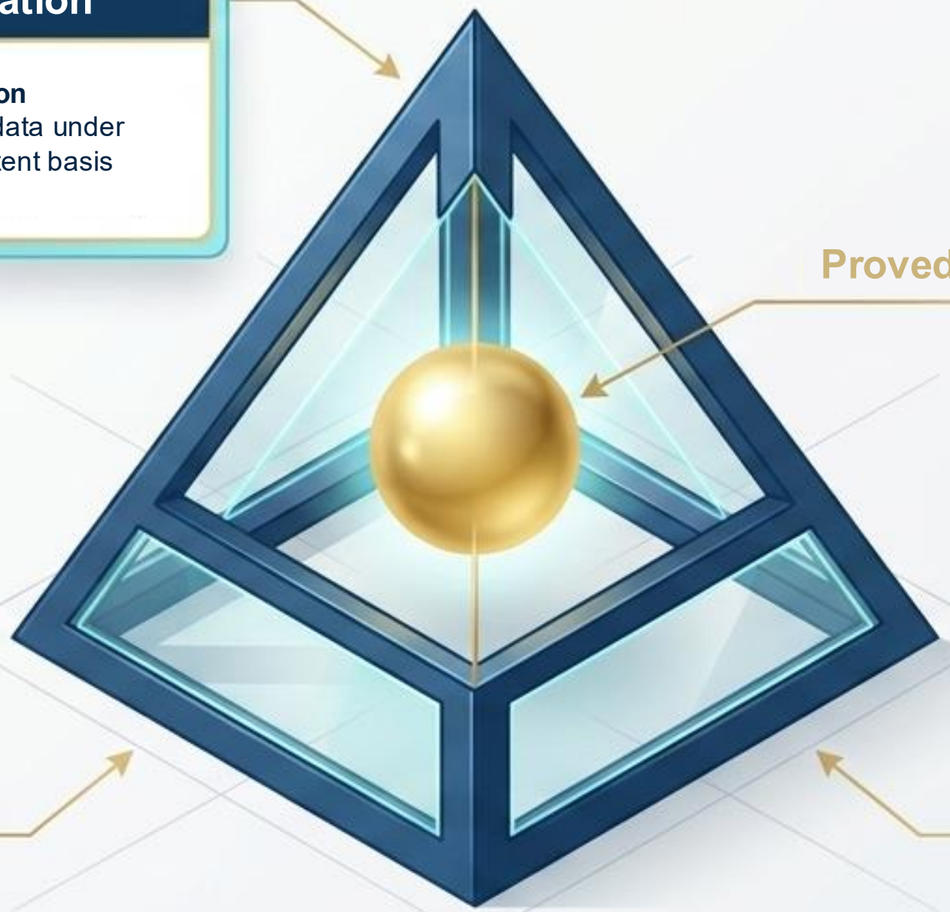
How to justify AI’s efficacy?

Analytical validation

Measures technical precision
The algorithm must process data under standard metrics on a consistent basis (sensibility and specificity)



Impact on workflow

Practical value
Justifies that the tool reduces response times, minimizes errors and guarantees security for healthcare givers.

Clinical validation

Tangible medical outcomes
Demonstrates that real-world environment use, leads to accurate diagnostics and enhances therapeutic decisions.

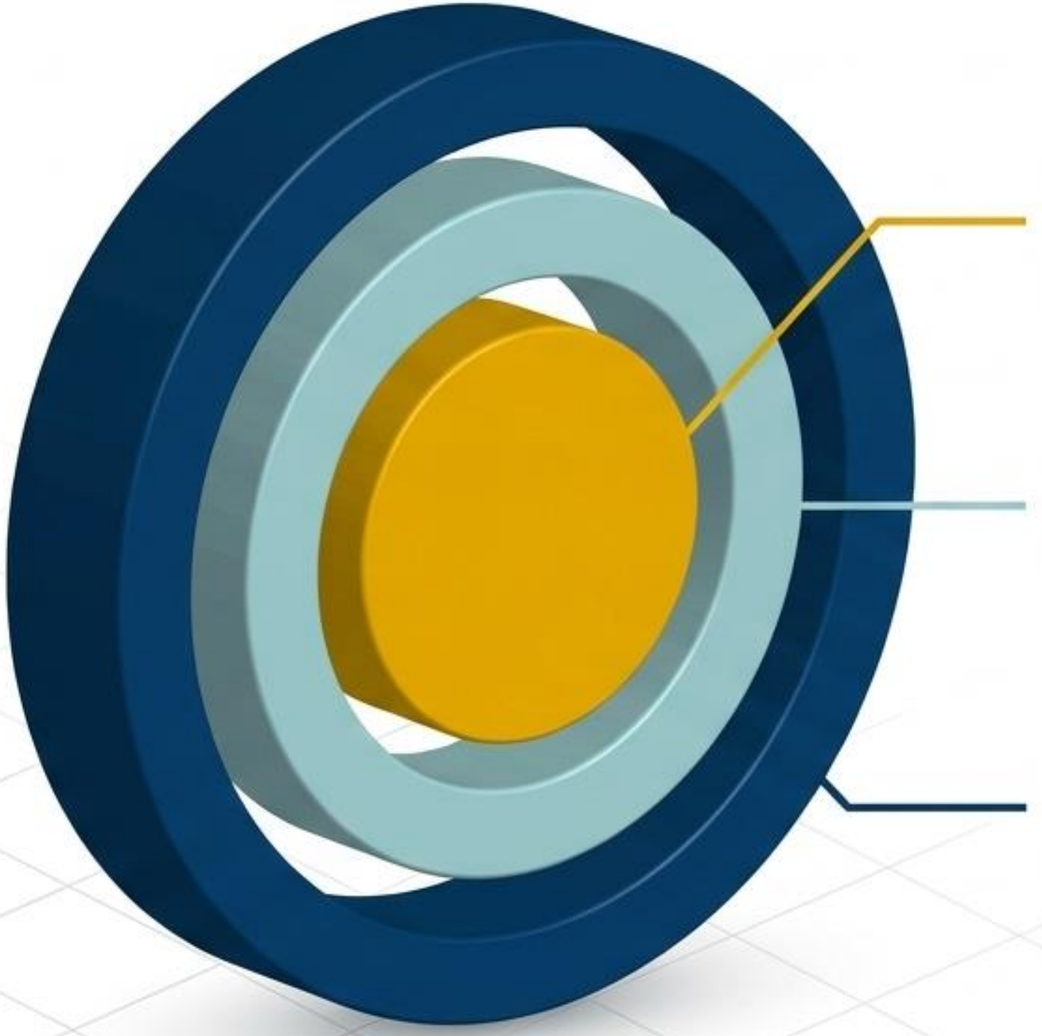
Pillar II: Post-market surveillance

The evaluation does not end with the granting of registration

Granting of Sanitary Registration

Monitoring devices in the real world is now a strict requirement to ensure they maintain their satefy and efficacy throughout their entire operation

Indissoluble integration with the quality system



Quality Management System (QMS) – ISO 13485

Risk management– ISO 14971

Post-market surveillance processes

Surveillance processes have to be directly connected to the QMS core, as well as to the organization's risk matrixes. They are not parallel systems.

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The Operation Cycle of Proactive Surveillance

1. Structured planning
Establish a documented plan to gather data on quality, performance and security in a systematic manner.

2. Clinical detection and monitoring
Report compilation, detection of failure trends, and long-term proactive studies

3. Periodic reports
Preparation of formal safety reports (e.g. PSUR)

4. Corrective actions
Immediate implementation of corrective and preventive actions (CAPA) regarding identified flaws.

5. Timely notification
Immediate incident communication to authorities (DINAVISA) and users.

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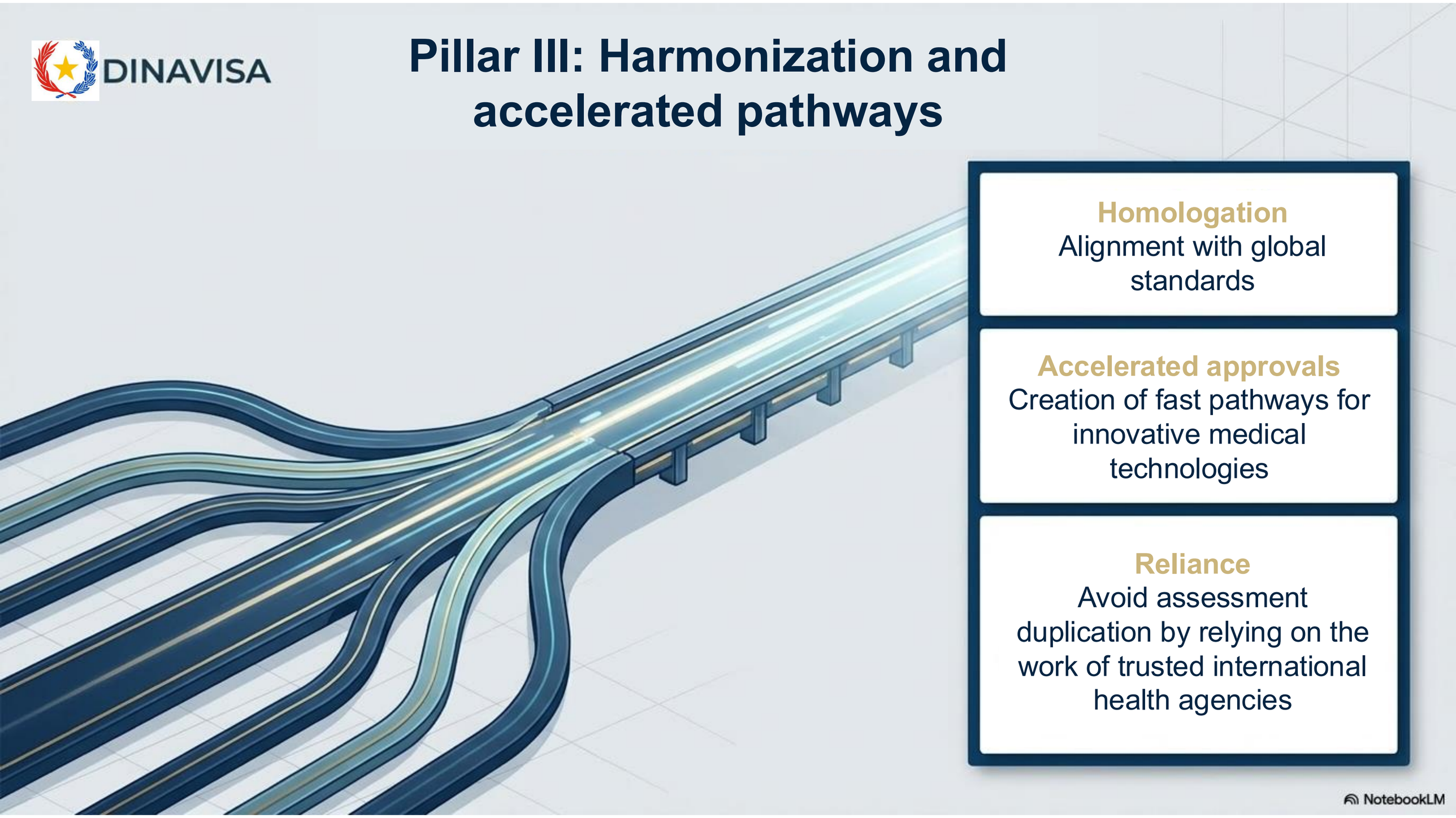
Pillar III: Harmonization and accelerated pathways



Homologation
Alignment with global standards

Accelerated approvals
Creation of fast pathways for innovative medical technologies

Reliance
Avoid assessment duplication by relying on the work of trusted international health agencies

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The New Regulatory Ecosystem