FDA Perspective on Latest Regulatory Initiatives and Pathways

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- I have no disclosures.

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Global Innovation

As devices evolve through innovation so to must the regulatory bodies

- Create pathways for innovative devices
- Foster novel areas
- Incorporate patients perspectives
- Build platforms to better evaluate devices across TPLC
- Build global networks

New-ish Pathways

Breakthrough Device Pathway

Intended for medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Safer Technologies Program (STeP)

Intended for medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program

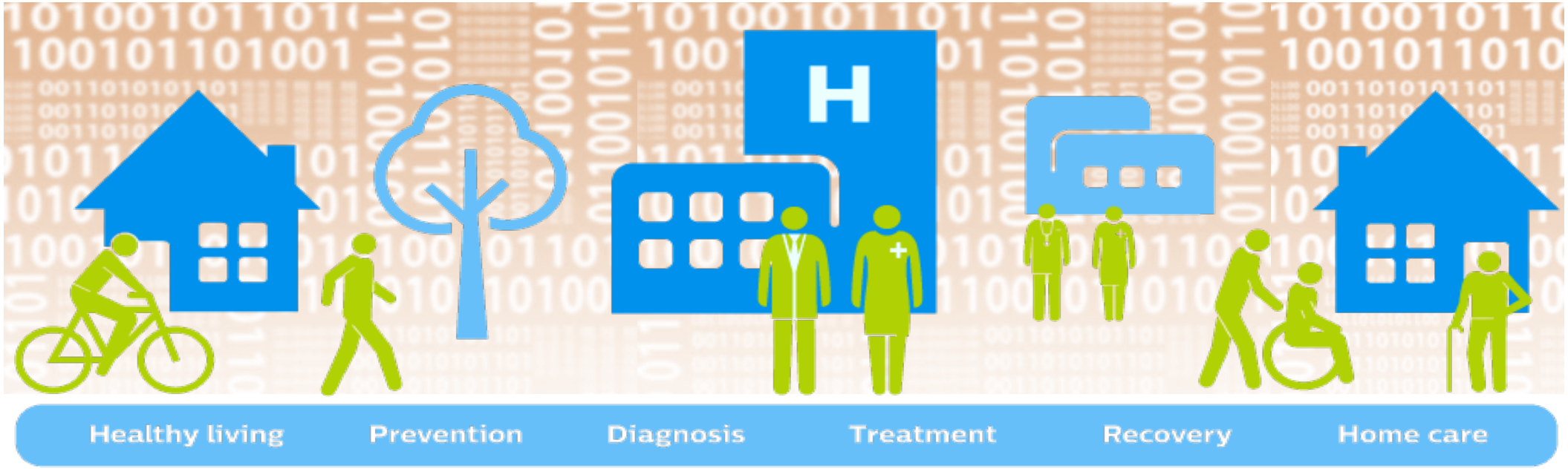
Safety and Performance Based Pathway

For particular devices, FDA develops guidance establishing device-specific performance criteria based on data from existing devices, literature, etc.

FOSTERING NOVEL AREAS
EXAMPLE - DIGITAL HEALTH

Fostering Digital Health

The convergence of connectivity, data and computing power for healthcare and related uses across the life of an individual or a patient.



Moving health care from the Clinic to the Patient

Understanding patient's behavior and physiology *"In the wild"*

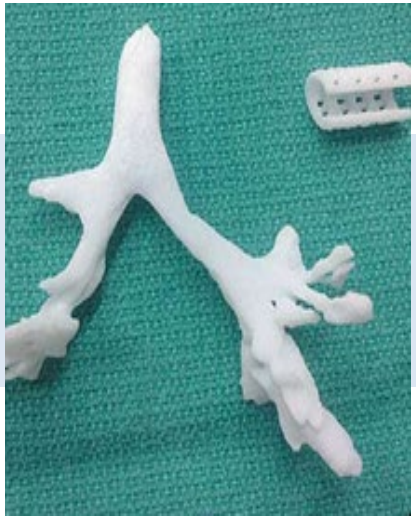
Focusing on prevention for early/smaller interventions

Leveraging computing power, sensors, connectivity and software

INCORPORATING PATIENTS PERSPECTIVES

Patients are at the Heart of All We Do

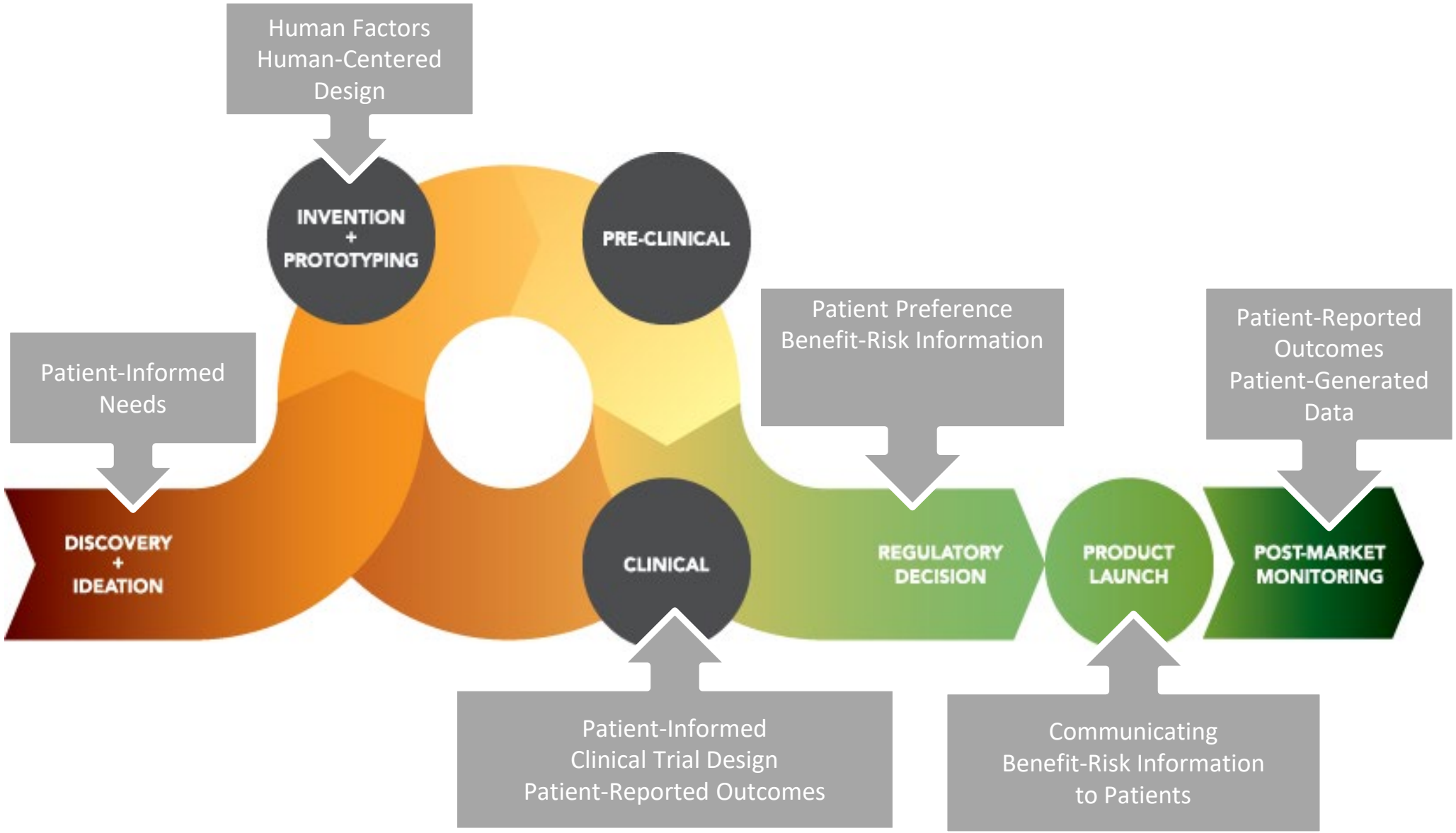


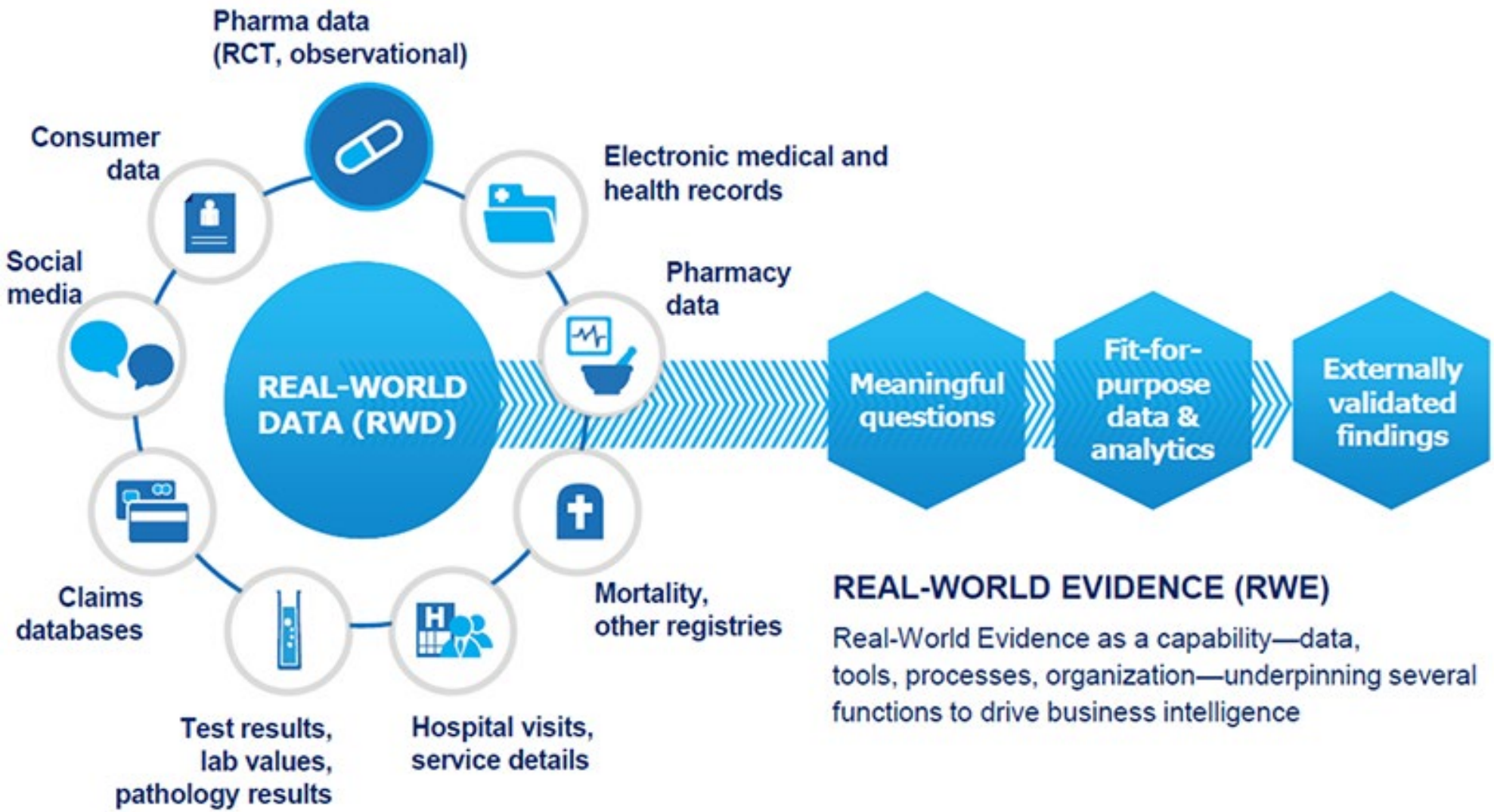
CDRH Vision:
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world.

https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-science-and-engagement-program

Patient Input Useful Across TPLC

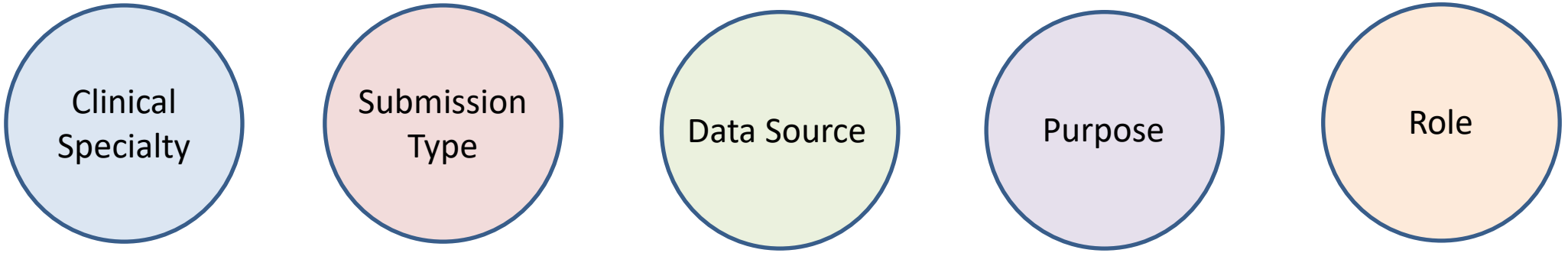


BUILD PLATFORMS TO BETTER EVALUATE DEVICES ACROSS TPLC
EXAMPLE - RWE



from Mike Waters' presentation during MDEPiNet meeting, 2017

RWE Successes



Cardiovascular
Diagnostics
General Hospital
Neurological
Ophthalmic
Orthopedics
Surgical

510(k)
De Novo
PMA
HDE

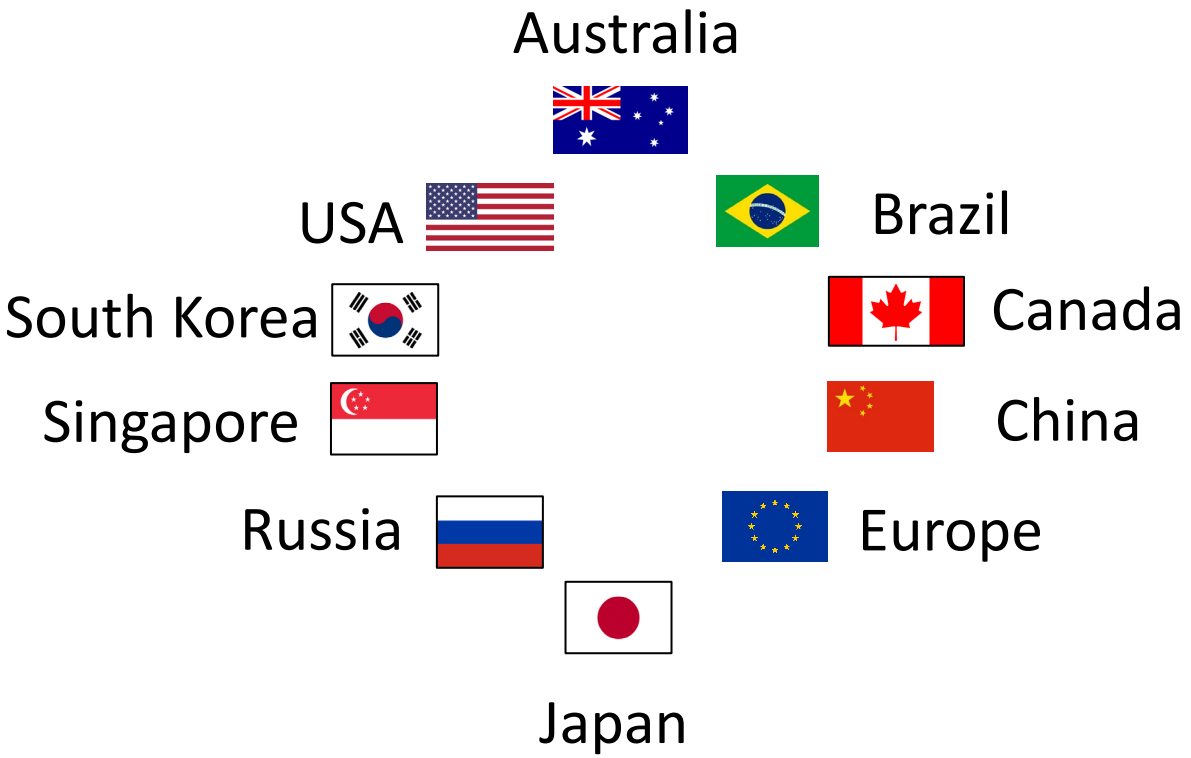
Medical Records or Charts
Claims
Registry
S-I Studies
Literature

New Marketing Submissions
Indication Expansion
Postmarket Study
Signal Detection

Primary
Supplementary
Partnering
Find patients

BUILD GLOBAL NETWORKS

IMDRF International Medical Device Regulators Forum



- Voluntary effort involving medical device regulators from around the world to harmonize various regulatory requirements across their jurisdictions
- Proposed IMDRF documents incorporate public comments prior to finalization and adoption
- Net result: increased global regulatory cooperation and review process efficiency

IMDRF Model for Future Single-Review Program

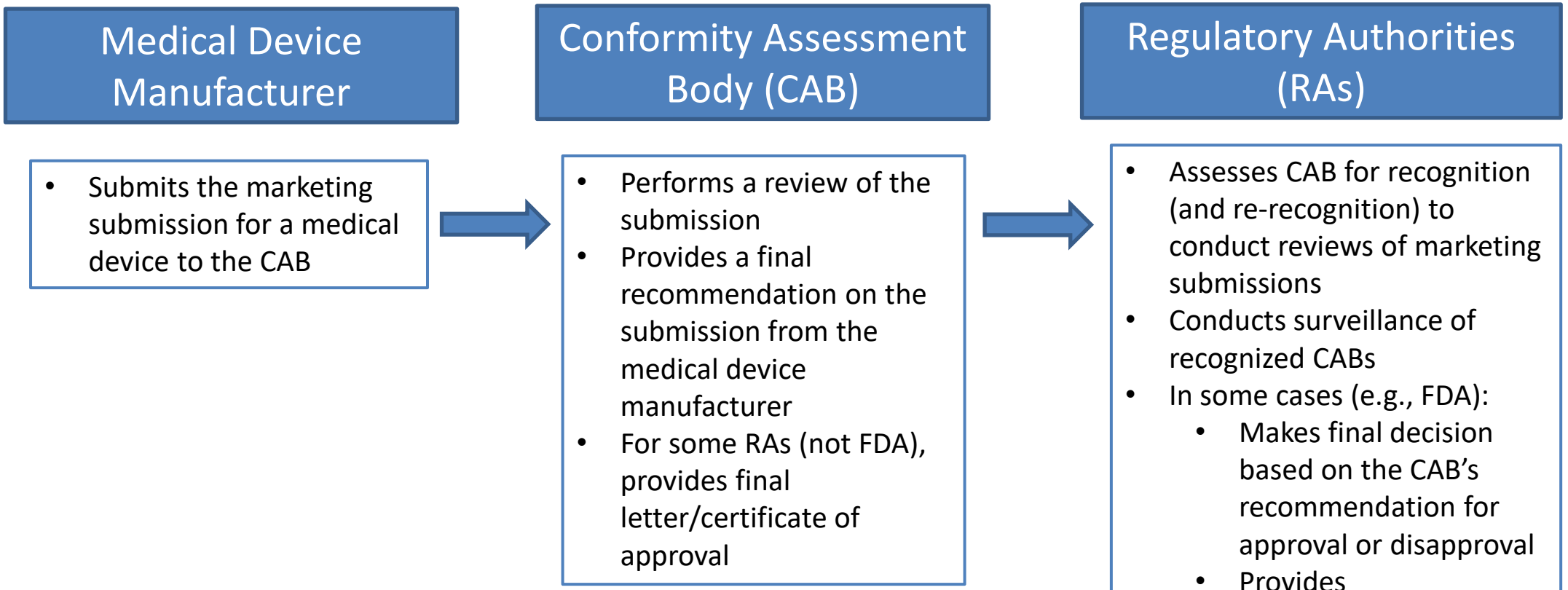


Figure 1 from IMDRF/GRRP WG/N61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