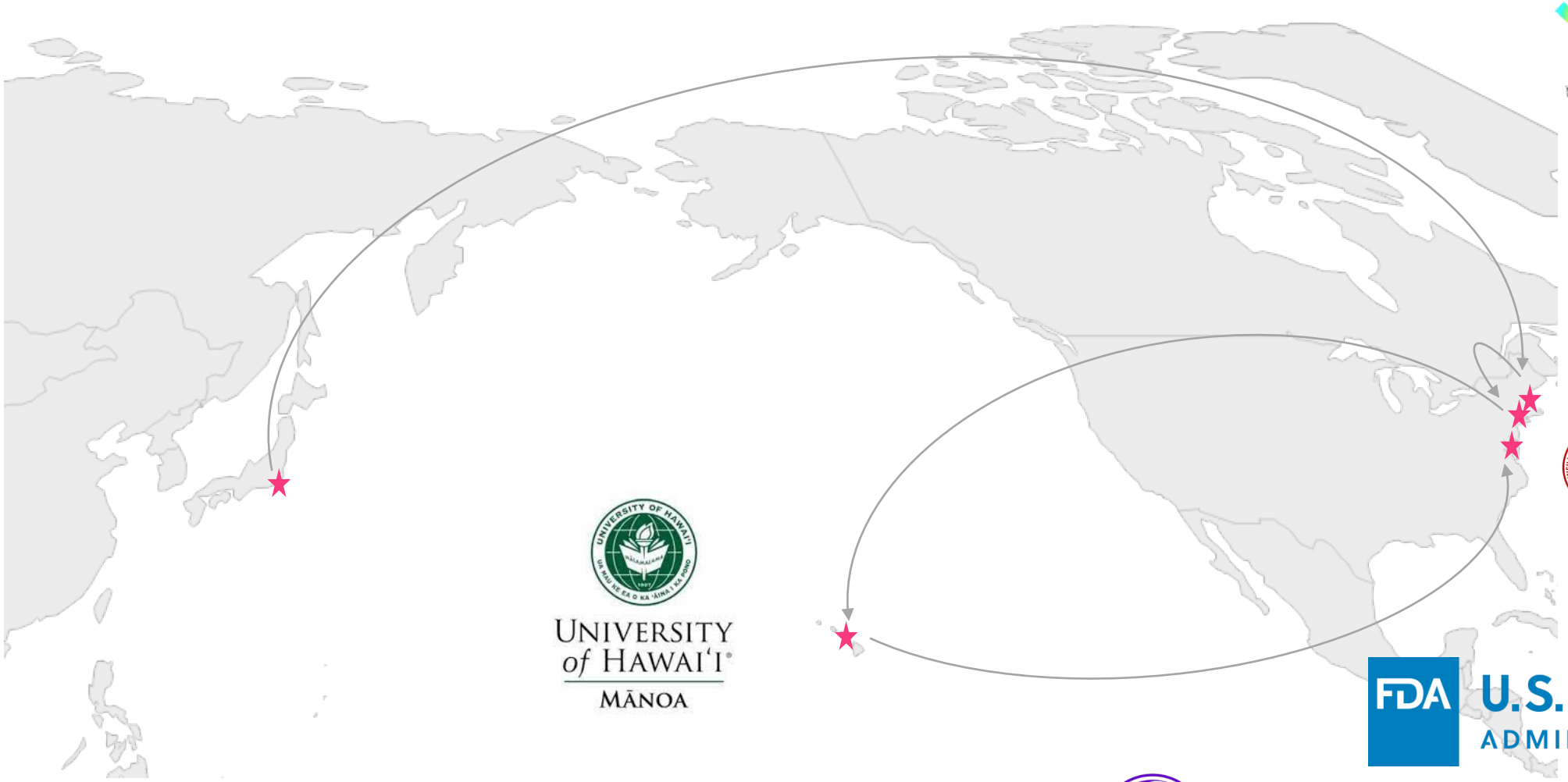
ANALYSIS OF US LEADERSHIP IN MEDICAL IMAGING: RESEARCH & DEVELOPMENT TO MARKETING PATHWAY

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A LITTLE ABOUT ME...



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GE HealthCare



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THE INNOVATION STEPS FOR MEDICAL DEVICE



WHAT SUPPORTS US LEADERSHIP IN MEDICAL IMAGING?

MARKET SIZE & TREND

- US medtech annual output exceeds $250B [1]
- The global medical imaging market was estimated at $43.5B in 2025; North America represented 36.3% [2]
- RSNA 2025 brought together nearly 38,000 registrants and 720 exhibitors [3].
- RSNA-reported attendee data showed that 80% seek new or specific products/vendors and 78% play a role in purchasing [4].



[1] AdvaMed, July 2025 [2] Grand View Research, 2026 report
[3] RSNA 2025 Meeting Report [4] RSNA, Sponsorship & Partnership Opportunities 2025

REGULATORY PATHWAYS

Region	Market	Pathway	Published review target
North America	US US [5]	510(k)	90 FDA days
		De Novo	150 FDA days
		PMA	180 FDA days
Europe	EU EU [6]	MDR conformity assessment	No single EU-wide review target
Middle East	AE UAE [7]	Medical Device Marketing Authorization	45 working days
Asia	CN China [8]	Class II	60 working days
		Class III	90 working days
	JP Japan [9]	New device / Standard review	14-month goal at 80th percentile

[5] FDA, *MDUFA Performance Goals and Procedures, FY 2023–2027* [6] European Commission, *Medical Device Classification*, 2026 [7] Emirates Drug Establishment, *Medical Device Marketing Authorization* [8] China SAMR, Order No. 47, 2021 [9] PMDA, *Review and Safety Measures Data*, December 2024

PRIORITIZATION TREND IN REGULATORY PATHWAY

- 62% viewed the US regulatory pathway for standard medical technology as predictable, compared with 22% for the EU [10]

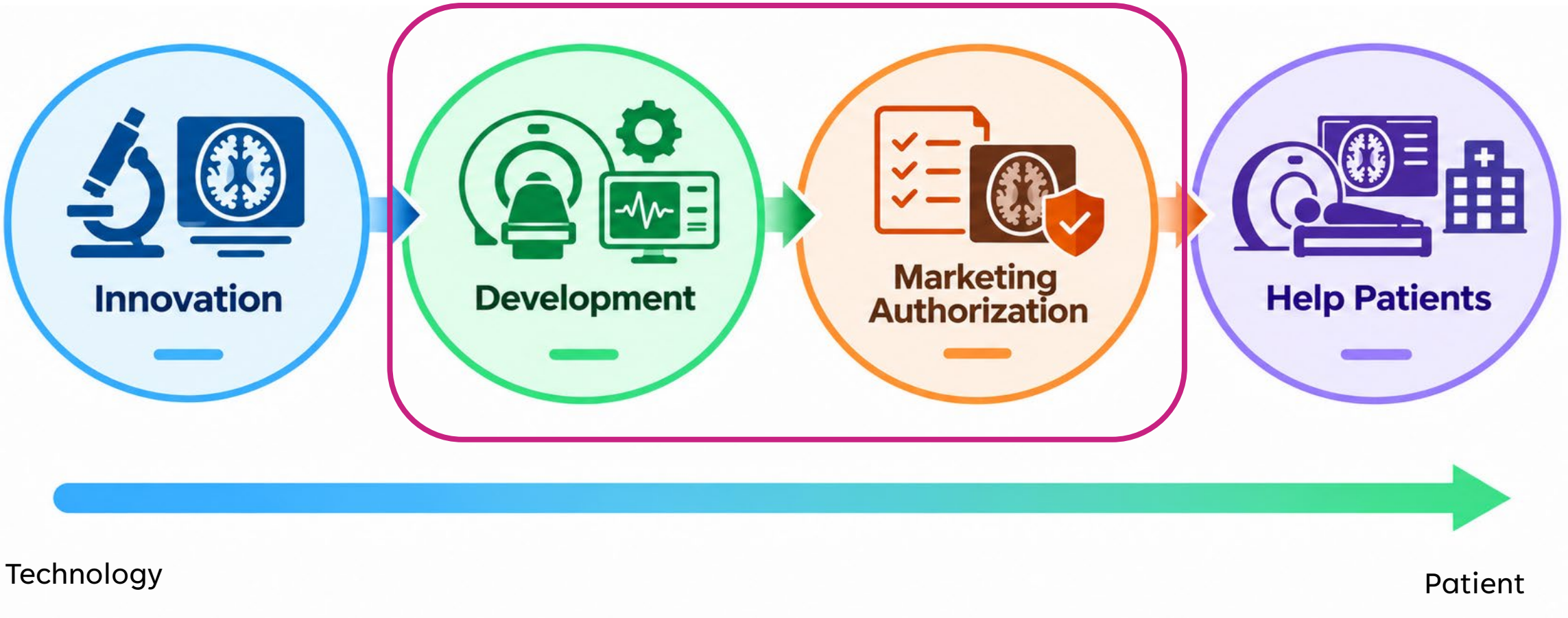
- Among companies with products in Europe, 89% said they would prioritize US regulatory approval going forward [10]

- A notable US Regulatory Pathway:
  - 510(k) provides a defined route based on demonstrating substantial equivalence to a legally marketed predicate device [11]
  - FDA's performance goal is a decision within 90 FDA days for 95% of submissions [5]

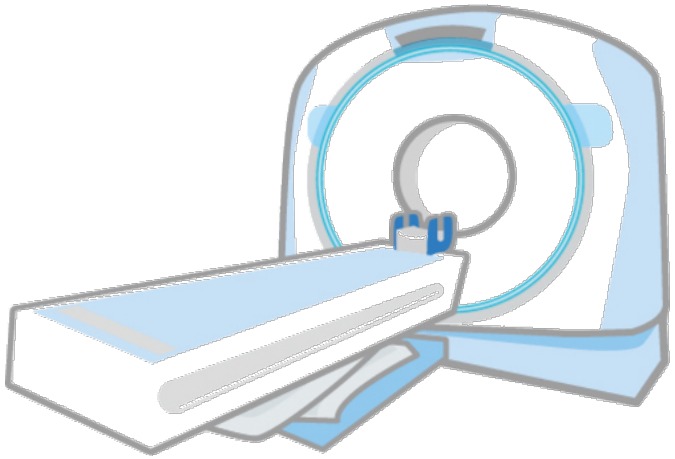
→ Regulatory predictability can influence where companies seek market entry first.

[5] FDA, *MDUFA Performance Goals and Procedures, FY 2023–2027*
[10] BCG and UCLA Biodesign, *Interstates and Autobahns*, March 2022 [11] FDA, *Premarket Notification 510(k)*

BRIDGING INNOVATION AND PATIENT



RECOGNIZED STANDARDS FOR AN MRI SYSTEM



IEC 60601-2-33 Ed. 3.2 b:2015 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

IEC 62464-1 Edition 2.0 2018-12 - Magnetic resonance equipment for medical imaging Part 1: Determination of essential image quality parameters

IEEE Std 3333.2.1-2015 - IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling

NEMA MS 3-2008 (R2020) - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images

NEMA MS-1-2008 (R2020) - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging

NEMA MS 6-2008 (R2014) - Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging

NEMA MS 2-2008 (R2020) - Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images

NEMA MS 4-2010 - Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices

NEMA MS 11-2010 - Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging

NEMA MS 9-2008 (R2020) - Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images

NEMA MS 10-2010 - Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging

NEMA MS 12-2016 - Quantification and Mapping of Geometric Distortion for Special Applications

NEMA MS 8-2016 - Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems

NEMA MS 5-2018 - Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging

NEMA Standards Publication MS 14-2019 - Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

RECOGNIZED MR SAFETY STANDARDS FOR IMPLANTABLE DEVICES



Image from FDA's MRI safety poster

ASTM F2052 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

ASTM F2119 - Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

ASTM F2213 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

ASTM F2182 - Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

ASTM F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ISO/TS 10974 - Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

IEC 60601-2-33 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

BRIDGING INNOVATION AND PATIENT

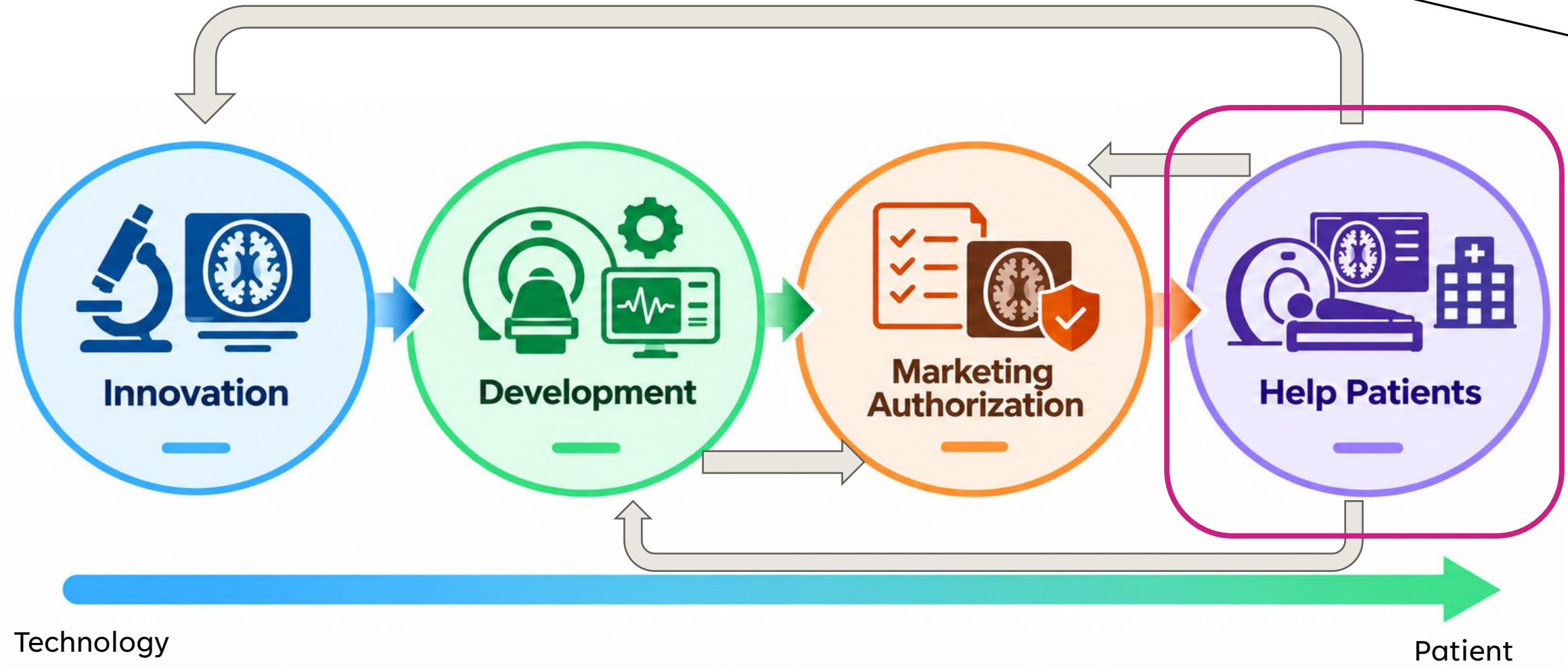


ACCELERATING WITH TOOLS AND MEASUREMENT

- Calibration: *e.g. CT density reference [12] and MR phantom [13]*
- Test Methods – *Performance metrics and protocols*
- Evaluation Criteria – *Cybersecurity, AI performance*
- Reference Data – *AI training, validation & benchmarking*
- Interoperability – *e.g. DICOM [14]*

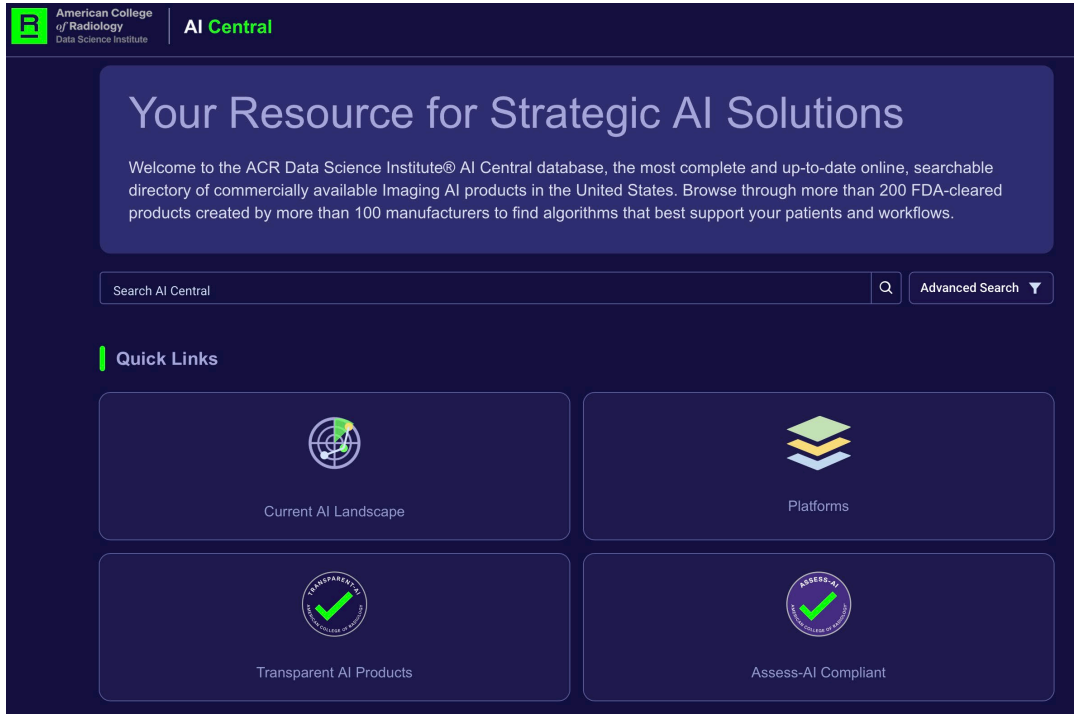
[12] NIST, *SRM 2088: Density Standard for Medical Computed Tomography*, 2013 [13] NIST, *A Standard System Phantom for Magnetic Resonance Imaging*, 2021
[14] NEMA, *DICOM Standard*

FROM CLINICAL SETTING TO NEXT TECHNOLOGY



IMAGING WITH AI: INFORMATION FOR CLINICAL USE

- AI Central: ACR's initiative to gather information on AI-enabled medical imaging related devices
- Voluntary program that gathered more than 200 products; 35 appeared under Transparent-AI (as of this morning) [15]



Standalone Model Performance

Reference Standard (Ground Truth)
Not provided

No. of Cases
Not provided

Age Range (Years)
Not provided

Sex (%)
Female: Not provided
Male: Not provided
Unknown: Not provided

Race (%)
White: Not provided
African American: Not provided
American Indian/Alaska Native: Not provided
Asian: Not provided
Hispanic: Not provided
Unknown: Not provided

Ethnicity (%)
Hispanic or Latino: Not provided
Not Hispanic or Latino: Not provided
Unknown: Not provided

→ The challenge: providing sufficient evidence to assess clinical applicability while protecting intellectual property.

[15] https://aicentral.org/

DIFFERENT CYCLES, SHARED GOAL

COMMUNITY	CYCLE REPRESENTED	ILLUSTRATIVE DURATION
1 Industry	Product and commercial planning	Quarterly
2 Regulators	Pathway-specific submission review	1–3 quarters
3 Academia	Research project cycle	~1.5–3 years
4 Standards community	Consensus development and revision	~3+ years
5 Healthcare systems	Medical-imaging equipment lifecycle	~7–14 years [16]

One shared purpose: turning innovation into better care for patients.

→ Timely and continuous dialogue aligns these different decision cycles around patient needs.

[16] Canadian Association of Radiologists et al., *Lifecycle Guidance for Medical Imaging Equipment in Canada—Summary*, 2013

ISMRM MR Safety Study Group Member Survey

MR Safety Priorities and Practices: Results from an ISMRM Study Group Survey

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Synopsis

Motivation: The ISMRM MR-Safety Study Group aims to understand its community's diverse needs across research and clinical practice. With evolving MR safety challenges, assessing current priorities is essential to guide future direction.

Goal(s): To gather feedback from the MR safety community on priorities and needs to guide strategic planning for the ISMRM Safety Study Group initiatives.

Approach: A survey among ISMRM/ISMRT members assessing clinical relevance, workload, safety benefits, technologies, and resources using Likert-scales and open-ended feedback.

Results: Active implants (4.6/5) and safety education (4.3/5) are top priorities, with 71% citing a need for standardization. Members emphasized implant protocols, training, and guidelines, noting resource gaps.

Impact: This survey reveals the MR Safety Study Group's needs while emphasizing the importance of bridging research and clinical practice. Understanding community priorities across diverse backgrounds will guide future initiatives addressing evolving safety challenges.

[Martinez *et al.*, ISMRM 2025, #1318]



Word Cloud Courtesy of Dr. Jessica A. Martinez

→ **71%** cited a need for standardization



THANK YOU!

QUESTIONS?

Special thanks to Alan Matsumoto, MD and Eriko Yoshimaru, PhD for helpful discussions.