Regulatory and Reimbursement Overview for Medical Devices

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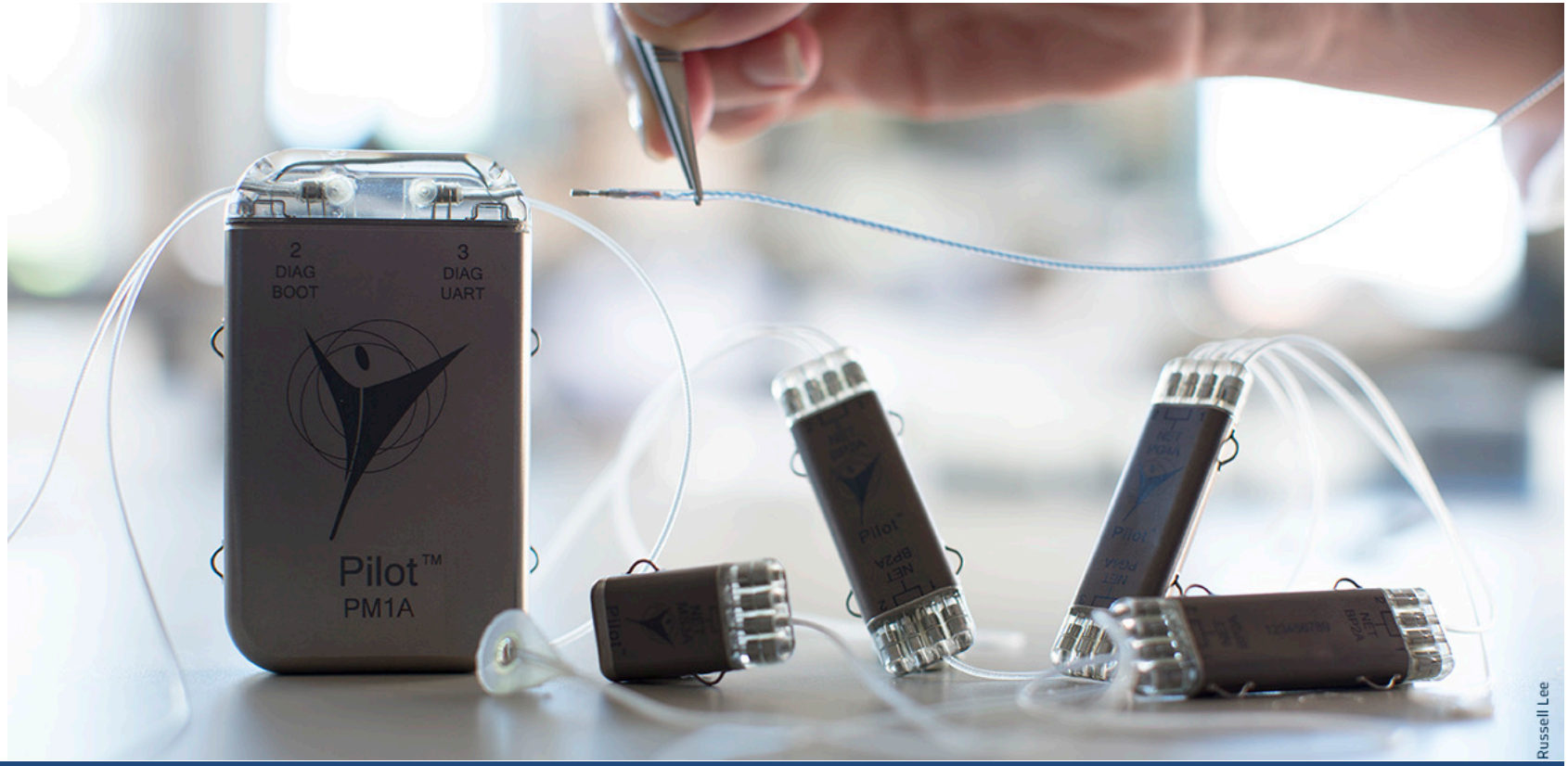
Objective

- Describe the FDA approval process for medical devices.
- Describe the link between FDA approval and CMS coverage for medical devices.



MEDICAL DEVICES

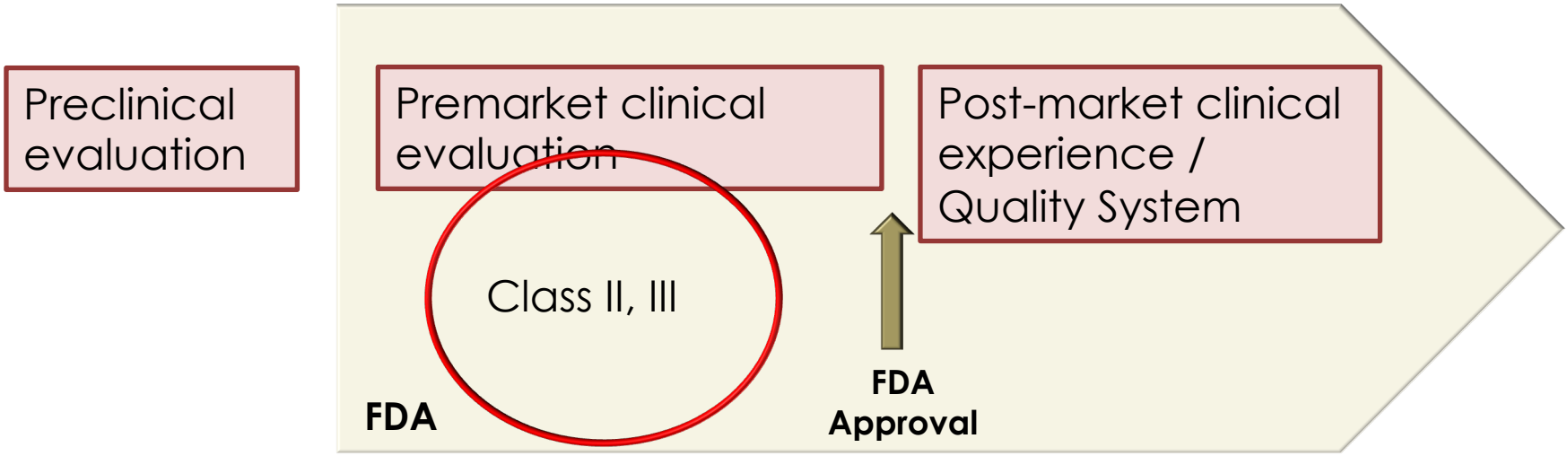
Medical Devices Vary Widely

- FES neuromodulation
- Epidural stimulator
- Implantable scaffold
- Spine stabilization hardware
- Baclofen pump
- Wheelchair
- MR imaging system
- EMG evaluation system
- Surgical implant tools
- Ventilators
- Colostomy systems
- Urinary catheters
- Blood tests
- Hospital beds

Devices are not drugs (or biologics)

- Effect is **local**, not systemic
- Effect is **biophysical**, not pharmacokinetic
- Effect is **predictable and deterministic** based on the design of the device.
  - "Physics of failure" explains much of anticipated safety.
- Devices are expected to be **modified** over time through company's Quality System practices.

Medical Device Approval Process



Risk-based classification of devices

- Class I – low risk devices, typically exempt from premarket review.
- Class II – moderate risk devices: Comparison to predicate(s) must show **substantial equivalence**
  - ME TOO: Traditional 510(k) Pathway – **predominant pathway**
  - NEW: De Novo 510(k) Pathway
- Class III – high risk devices: Establish **reasonable assurance of safety and effectiveness**
  - Premarket Approval (PMA)

Reasonable Assurance of Safety and Effectiveness / Substantial Equivalence

Safety

- Sterility
- Biocompatibility
- Electrical safety
- Software robustness
- Mechanical reliability
- Electromagnetic compatibility
- Cybersecurity
- **Safety profile in the intended population**

Effectiveness

- **Clinical outcomes in the intended population**
- Bench performance, for "me too" devices.

Not all devices need a clinical trial

- **Almost all Class III** devices will require clinical trial
- About **10-15% of Class II devices** will require clinical trial
  - Safety and effectiveness are better evaluated on bench
  - Comparison to predicate more easily evaluated on the bench

Not all clinical trials require IDE

- "IDE Exempt" studies
  - Studies of investigational diagnostic devices using human clinical samples, e.g., blood, urine, stool, etc.
  - Studies of investigational "algorithms" (image identification, cardiac rhythm, EMG, ENG) using archived signals.
- Non-Significant Risk studies
  - Studies of investigational devices that are assumed to be Class I or Class II.
  - Studies of approved moderate- or high-risk devices used according to their label.

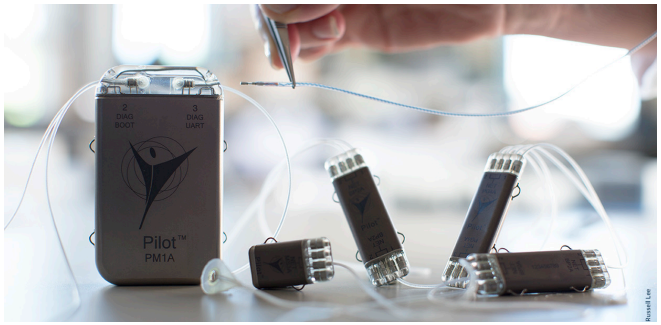
Investigational Device Exemption

- Not formally "phased" as for drugs, biologics
- Early Feasibility / First-in-Human
  - Allows for quick entry to human clinical trials
  - Device may be in early form / modifications allowed
  - Limited to ~5-30 subjects
- Pivotal Clinical Trial
  - Sized to support a marketing application (10's – 100's of subjects)
  - Device in near-final form

Other Premarket Programs

- Humanitarian Device Exemption ← **marketing application**
  - **Orphan populations** not exceeding 8,000 / yr incidence
  - Establishes "**safety and probably benefit**" of the device.
- Breakthrough Medical Devices ← **pre-submission designation**
  - Innovative medical devices
  - Address unmet clinical need
  - Provides companies with additional access to leadership

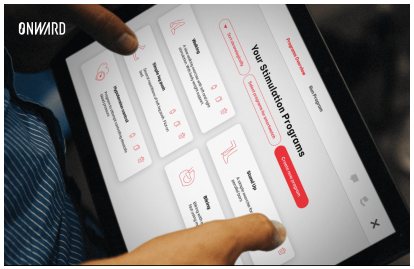
FDA Breakthrough Designations in SCI



Case Western Reserve University Networked Neuroprosthesis (2017)

PathMaker MyoRegulator™, Treatment of muscle spasticity (2021)

USMIMA Mowoot™ bowel management for neurogenic bowel (2021)



Onward Medical, ARC^{IM} (2020) and ARC^{EX} (2021) for movement restoration in SCI.

FDA vs. CMS regulations

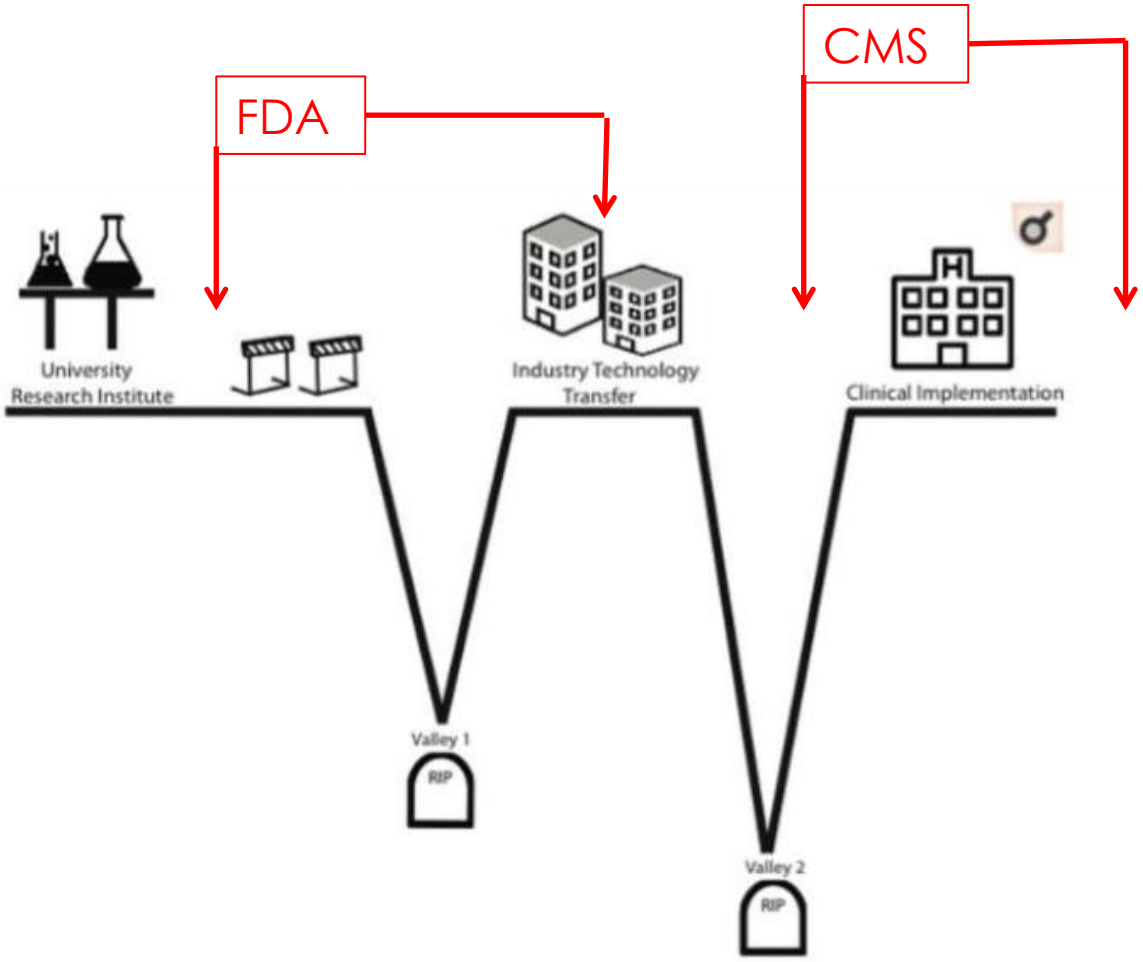
FDA

- **"Reasonable assurance of safety and effectiveness"**
- Clinical evidence presented in FDA application.
- Highly-controlled clinical trials.
- May not always include Medicare population (over 65 and/or chronically disabled)

CMS

- **"Reasonable and necessary" – 2019:**
  - **Safe and effective;**
  - **Not experimental;**
  - **Appropriate for Medicare patients.**
- Clinical evidence from published literature.
- Real-world clinical evidence.
- Must include outcomes in Medicare/Medicaid population.

FDA to CMS "valley of death"



Medicare Coverage of Innovative Technology

- October 2019, *Executive Order on Protecting and Improving Medicare for Our Nation's Seniors (EO 13890)*.
- Applies to FDA-designated Breakthrough Medical Devices:
  - Innovative medical device (assumed: first-of-its-kind)
  - Address unmet clinical need
- Provide **CMS coverage for the first four years** the product is on the market; allows for collection of real-world evidence to support CMS requirements.
- Executive Order rescinded in November 2021.

CONCLUSIONS

FDA → CMS ecosystem

- FDA process for medical devices is different than for drugs and biologics for a reason –
  - Engineered systems whose effects are deterministic
  - Designed to be improved over time
  - Many aspects are better suited to evaluation on the bench.
- Not all medical devices need a clinical trial, and not all clinical trials are reviewed by the FDA.
- Clinical trials to support FDA approval decisions may not be suitable to support CMS coverage decisions.

Thank you!