Comprehensive Registry- Based Surveillance

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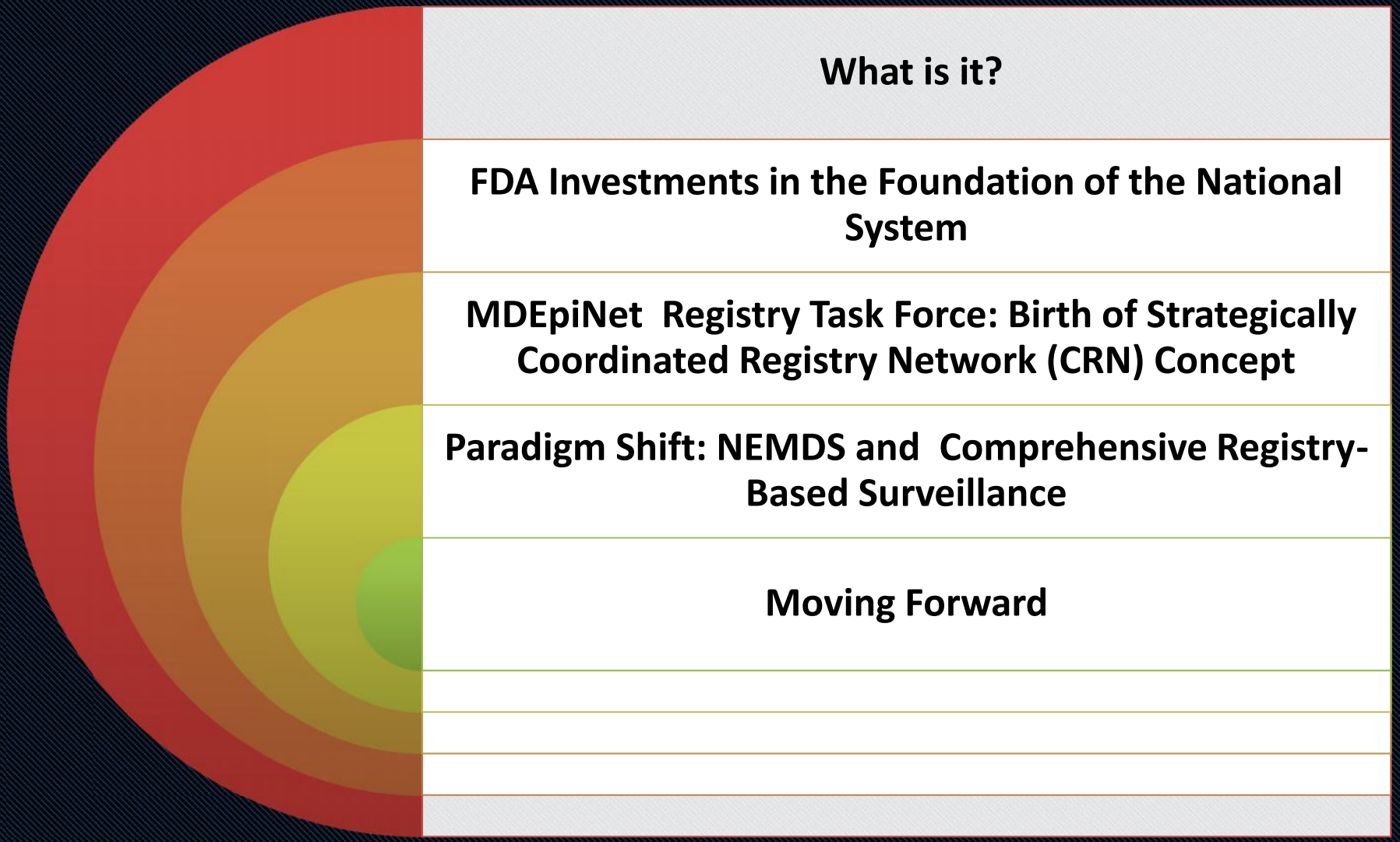

What is it?
FDA Investments in the Foundation of the National System
MDEpiNet Registry Task Force: Birth of Strategically Coordinated Registry Network (CRN) Concept
Paradigm Shift: NEMDS and Comprehensive Registry-Based Surveillance
Moving Forward

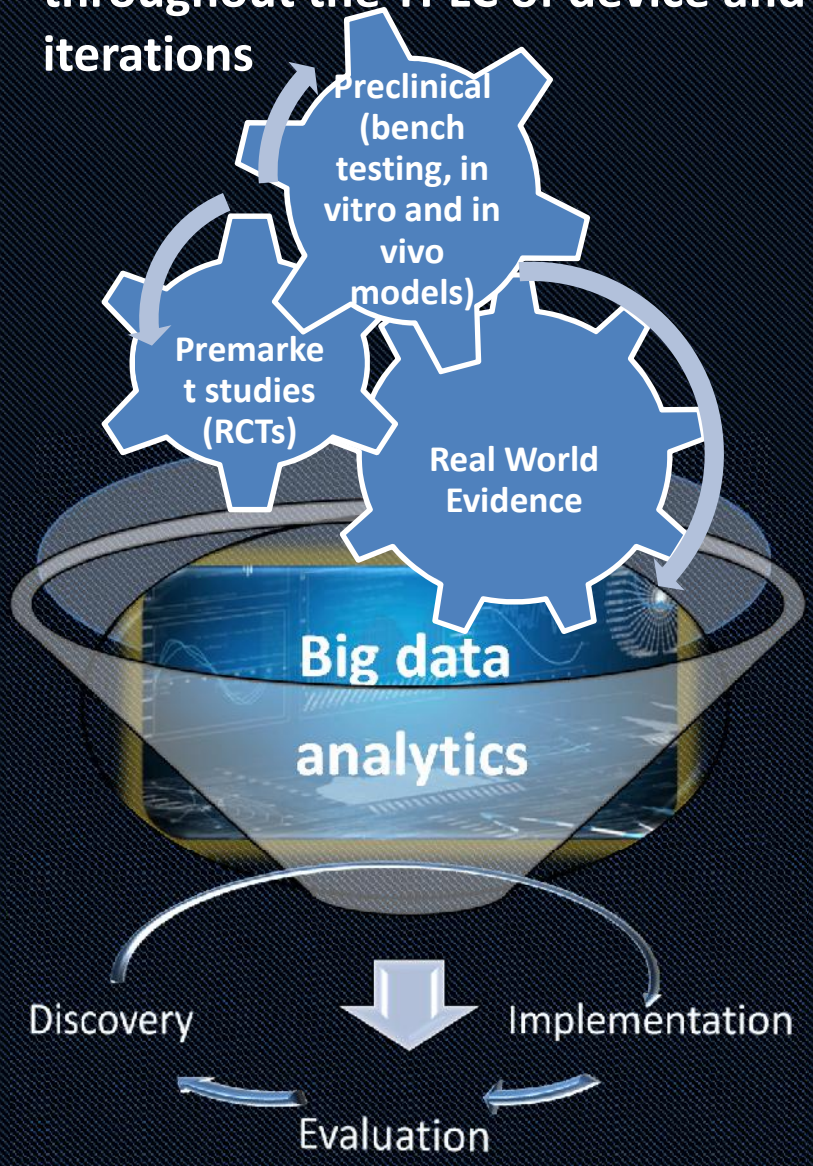
What is it?

- Surveillance Arm of Comprehensive Evidence Evaluation
- Registry-Based (registry, consortia, CRN)
- National/International
- Embedded in the Health Care System
- Shared Responsibilities
- Mandated – vision to evolve into non-mandated

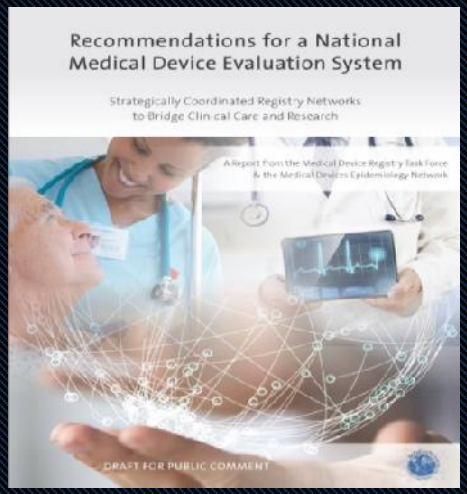
Changing Evidentiary Paradigm for Development and Evaluation of Medical Devices

From:
One-directional Evidence Stream

To:
Multidirectional Evidence Streams throughout the TPLC of device and its iterations



Foundational Work: 2010-2016



FDA Investments 2011-2015

UDI Established a Unique Device Identification (UDI) System

50 Completed or engaged in over 50 projects, including the creation of new RWE data sources, demonstration of proof of concept for use of RWE, development and use of advanced analytics

$20,000,000 Invested over $20 million to stand up MDEpiNet

MDEpiNet Efforts

Infrastructure

- Registry Development
- National/International Consortia Development
- Electronic Device Data Capture (UDI)
- Task Force -Coordinated Registry Networks
- PASSION Initiative

Methods

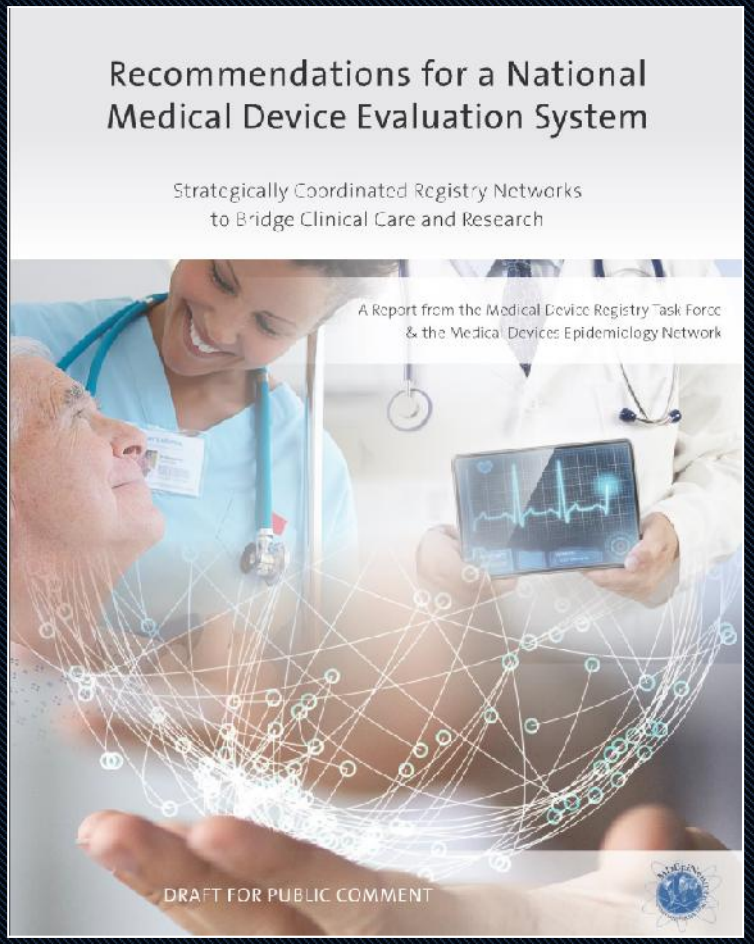
- Active Surveillance
- Distributed Data Analysis
- Evidence Synthesis
- Claims Validation
- Linkage with other Data Sources
- Big Data Analytics

Patient Engagement

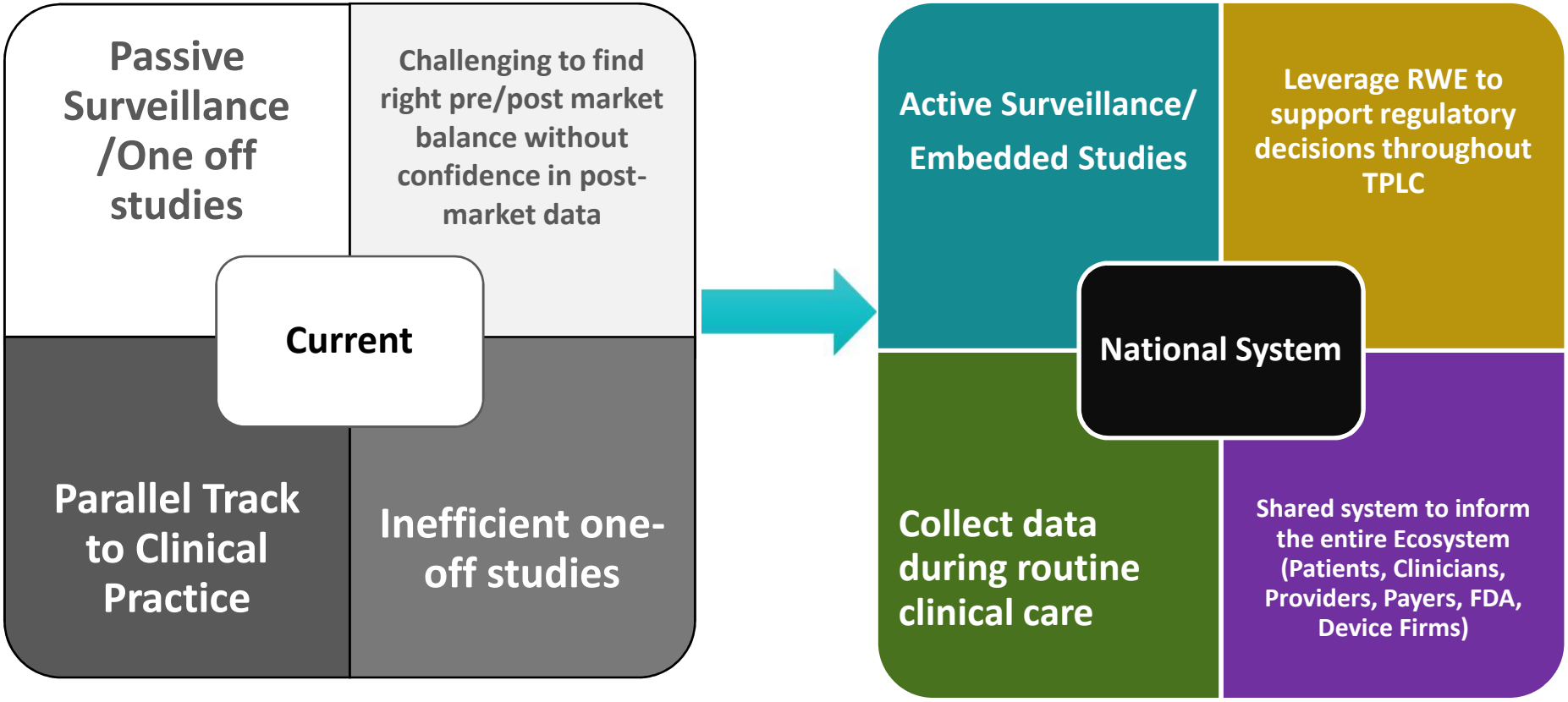
- Augmenting Registries with PROs and Explant Analysis for Precision Medicine
- Assessing Minimally Important Difference (MID) for orthopedics implants
- Patient and Family Engagement Committee
- Patient-led Device/Disease Specific Round Table

National Registry Task Force

- Strategically Coordinated Registry Network (CRN)
- Registry Task Force proposed priority device areas in need of coordinated registry networks (registries linked to other data sources)
- PASSION initiative builds foundation of CRNs



Paradigm Shift



Early Successes

National registries are being leveraged for:

- 15 Post-Approval studies
- 1 Continued Access study
- 1 labeling extension study
- 7 Postmarket Surveillance Studies (522)

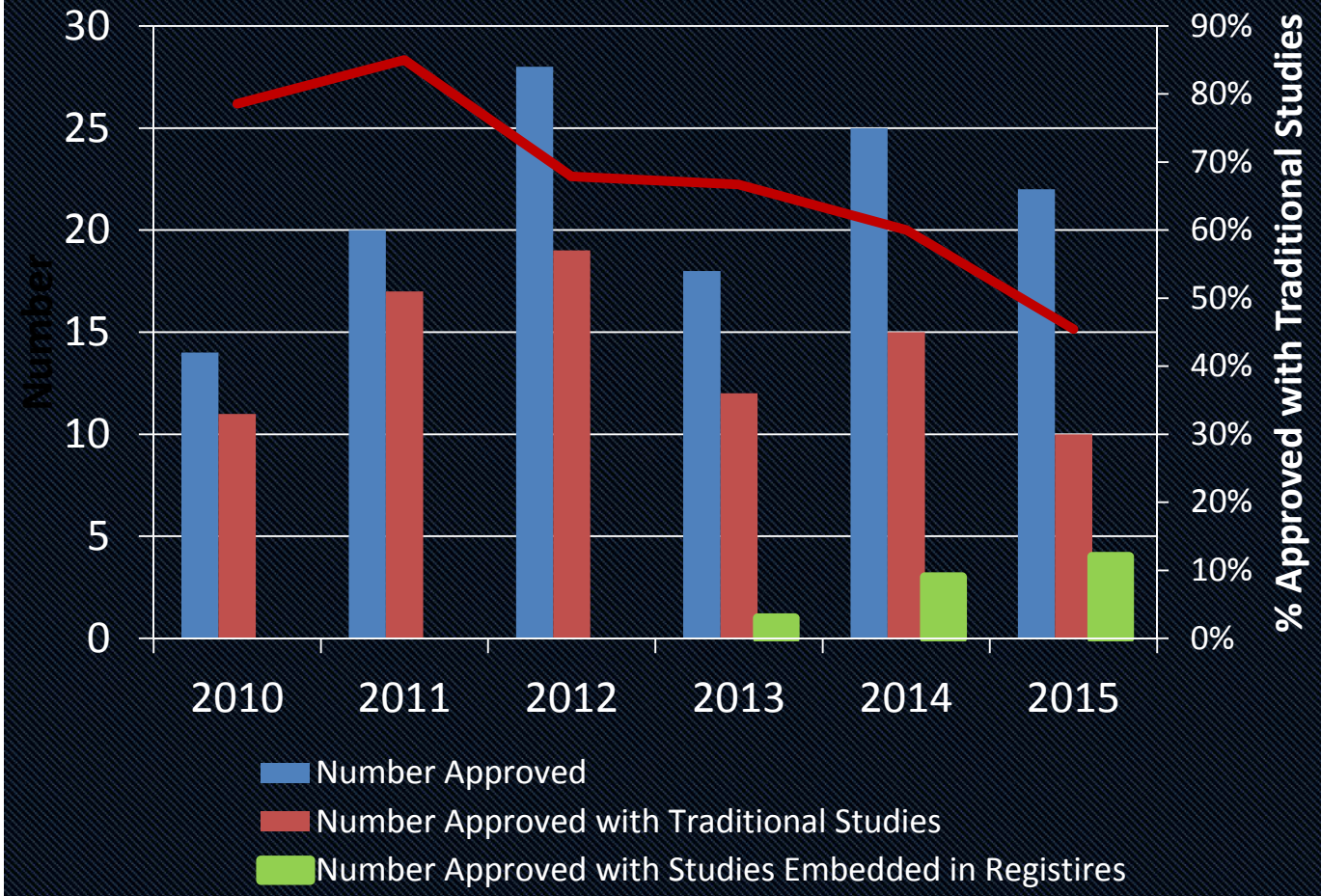
International Registries are being leveraged for:

- 3 post-approval studies

Active review/analysis of data (starting early 2016)

- Example: American College of Cardiology (ACC) will share data with FDA quarterly for review
- Separate studies are no longer required, providing additional value

Impact: Shifts in Cardiovascular Device Post-Approval Studies Since 2010

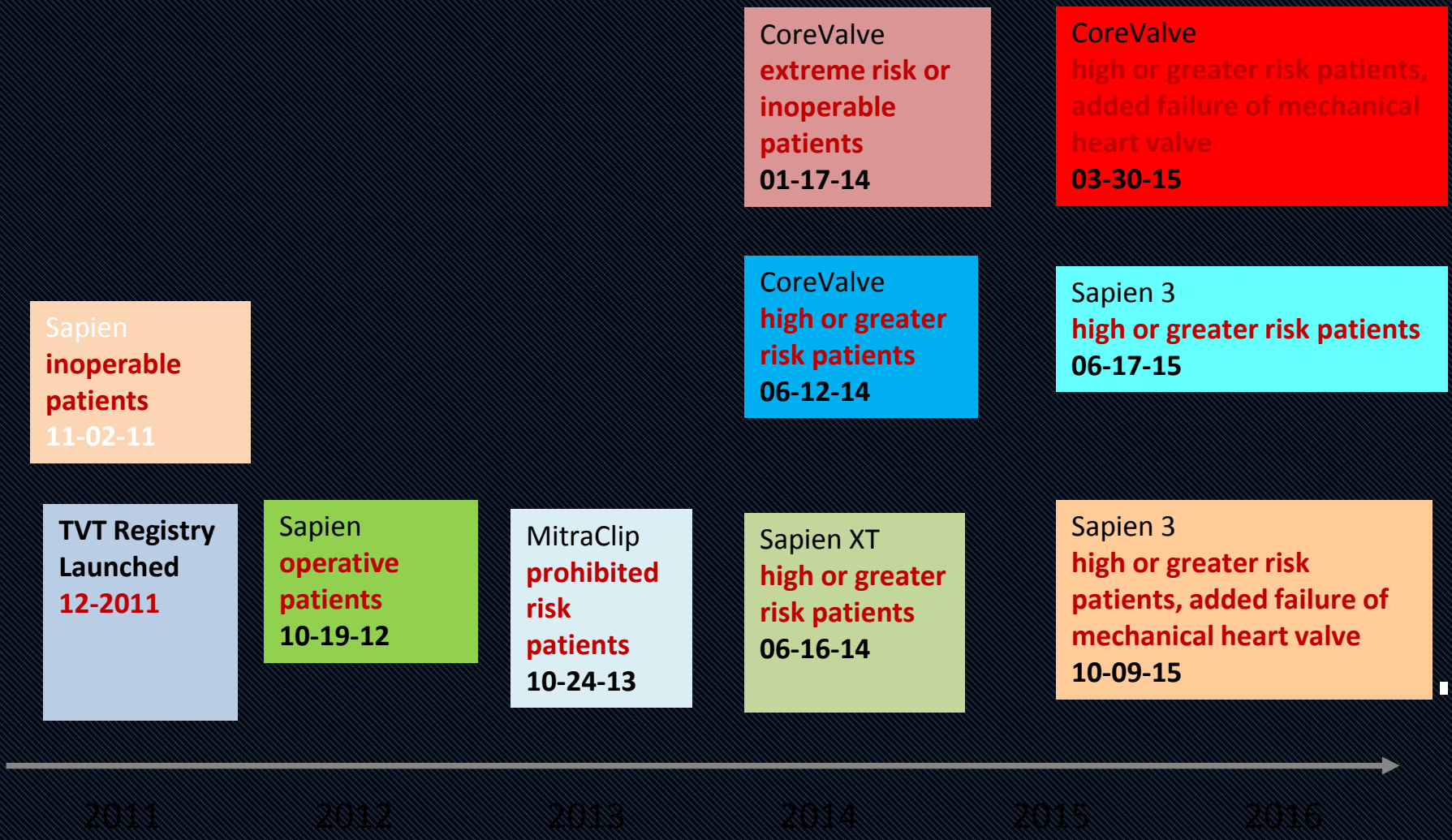


Number of expensive studies is decreasing; replaced by cheaper studies.

Data as of November 30, 2015.

Trans-catheter Heart Valve Approvals and TVT Registry

N = 10 Post-Approval Requirements within Registry



Impact: Registry Data Reduces Premarket Review Time!

P100041 Filed

MDUFMA II Goal

P100041/S039 Filed

MDUFA III Goal

P100041
TVT Registry used for Postmarket Surveillance.
Approved 45 days ahead of MDUFA goal

P100041/S039
TVT Registry data used for premarket approval.
Approved 154 days ahead of MDUFA goal

Moving Forward

- Advance CRN infrastructure via PASSION Initiative
  - More efficient fit for purpose (real and virtual) registries
  - Link registries (national and international) with longitudinal data (claims, EHR, PCORNET)
- Enable use of innovative methodological approaches for studies
  - Registry-derived comparison groups, EHR-driven comparison groups, big data analytics
  - Nesting new clinical trials in registries (e.g., Safe STEMI for Seniors)
- Robust regulatory apparatus that utilizes RWE to streamline device evaluation, ensures nearly real time surveillance and support innovation

Thank you!

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