Opportunities for registry-based post-approval studies: FDA View

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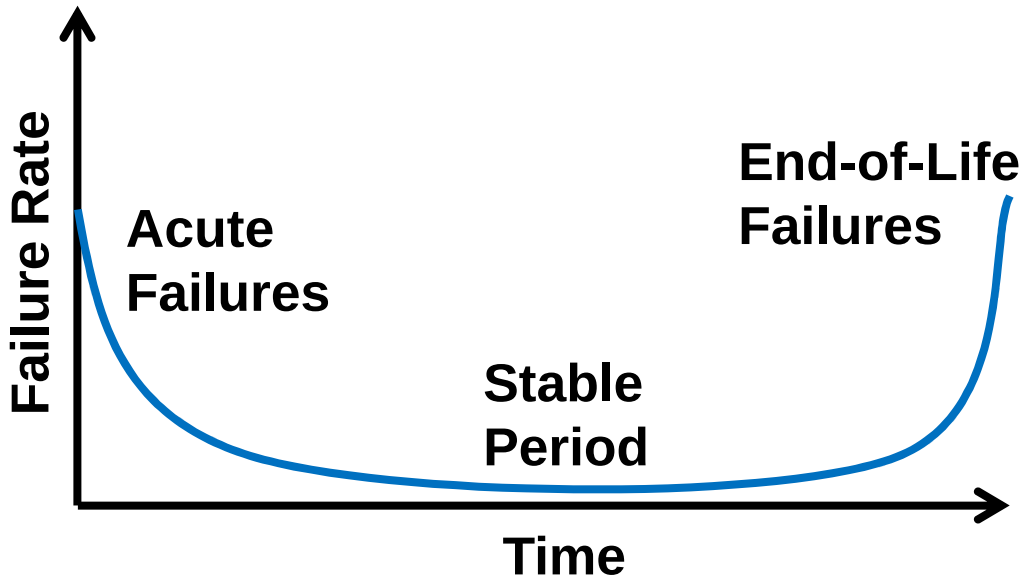
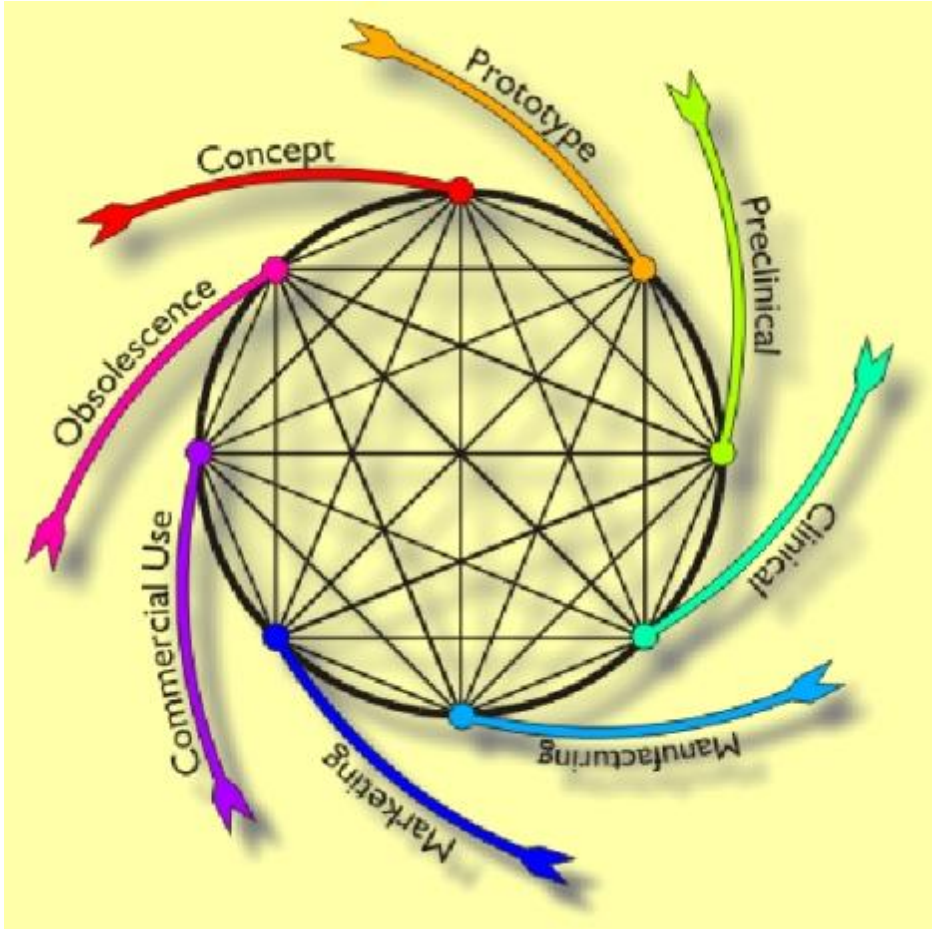
Post Approval Studies (PAS)

- High voltage ICD and left heart leads
- Reduces burden of pre-market data collection



PAS Drawbacks

- Pace and difficulties of enrollment
- Time to completion
- Next generation is already on market before “lessons learned”



Registry-Based PAS Concerns

Extra Cost / Resources

Adding to Burden
rather than
Replacing / Reducing

Overly-complicated “nice to have” data collection

PAS Key Metrics

Traditional PAS		PASSION Data Sources
– Demographics	→	– ICDR
– Adverse Events	→	– ICDR, CMS Claims
– Effectiveness Measures	→	– Home Monitoring
– Mortality	→	– National Death Index
– Returned Products Analysis	→	– Manufacturers

Further Considerations

- "Study fatigue" at study centers
- Competition for sites and patients within and across companies
- Align data collection with standard of care
- Patients may not be interested in 5-year commitments

Postmarket Linked-Registry Savings

- Study Cost
  - Current post-approval costs around $10 million
  - 40-60% savings based with registry-based
    - Safe PCI in Women and
    - Transcatheter Valve Therapy Registry
- Site Start-up
  - 3 to 6 Months for PAS site recruitment, IRB approval, and initiation
  - Registry based studies reduce this time
- Data Collected More Aligned with Standard of Care


-Clear Regulatory Path
-Data Harmonization and Linkage
-Sustainable Ecosystem

EP PASSION

Implant & Periprocedural Data

Annual Follow-up

Remote Monitoring Data

Five Year Patient Follow-up

EP PASSION

Implant & Periprocedural Data

- Electronic Health Record (EHR)
- Sponsor Registry
- National Registry (extant or new)

EP PASSION



Annual
Follow-up

- EHR
- Administrative Claims
- Direct Patient Contact
- Sponsor Registry or National Registry

EP PASSION

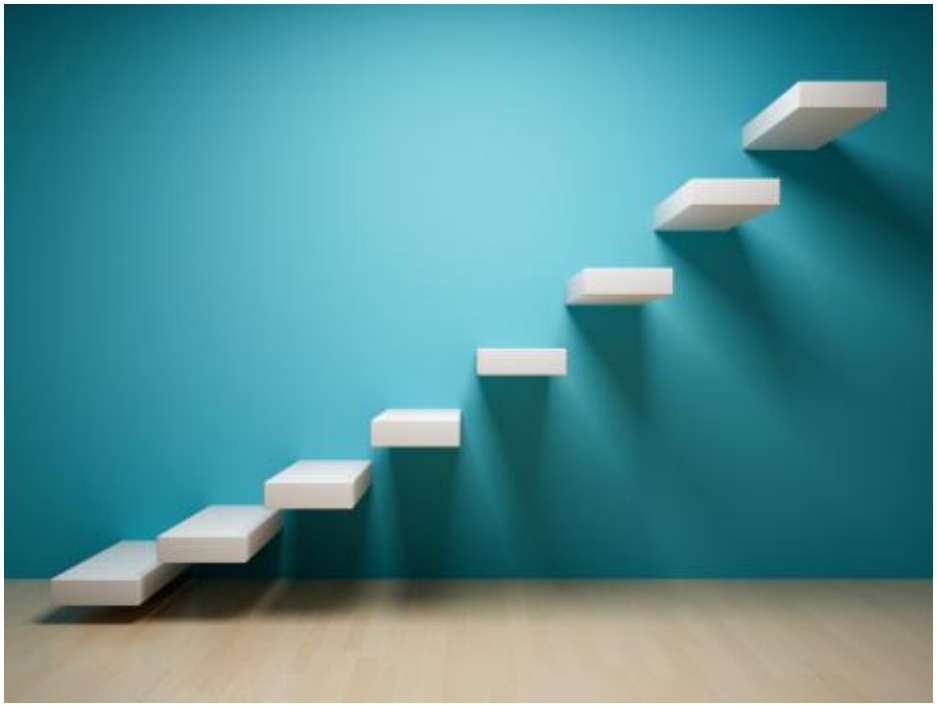
Remote Monitoring Data

- Elimination of 6-month clinic visits
- Standardization of reporting

Proposed EP PASSION Goals

- Transition long-term follow-up and electrical performance assessment in PAS towards a linked-registry approach
  - leverage claims, EHR, remote monitoring, & periodic patient contacts.
- Develop sustainable mechanism to collect long-term chronic performance of new and substantially modified pacing and defibrillation leads.

Possible Phased Approach



1. ID Core Data Set
2. ID & Assess Extant Sources
3. Develop New/ Modify Existing Mechanism
4. Develop linked approach

Phase 1: ID Core Data Set

- Identify data elements collected in recent PAS
- Convene stakeholders to develop a consensus recommendation for core data elements

Deliverable: List of all required data elements of post approval chronic reliability assessment of pacing and defibrillation leads.

Phase 2: ID & Assess Extant Sources

- Identify existing sources for all core data elements e.g. remote monitoring, EHR, claims data
- Evaluate the data sources
  - data integrity, completeness, methodology of collecting data from sources, etc

Deliverable: Evaluation of data sources, methods for evaluation and conclusions regarding quality of data sources including prioritization and assessment of utility of each data source in providing long term chronic reliability data for leads.

Phase 3:Develop New/ Modify Existing Mechanism

- Develop methods for collection for all data elements not obtainable through existing data sources
- Evaluate new data source quality

Deliverable: Detailed listing of which data elements and sources required development or modification

Phase 4: Develop Linked Approach

- Protocol/ Procedures for linking all data sources
  - pre-defined method of addressing conflicting data sets, minimum data requirements, etc
- Acceptance criteria for evaluation of data obtained from all sources

Deliverable: Protocol for collection and evaluation of data required to evaluate long-term reliability of leads

EP PASSION

- Cost savings
- Shorter overall study duration
  - not shorter clinical follow-up
- Sustainable infrastructure
  - Possible future application for regulatory decision making
- Postmarket assessment more consistent with clinical practice
- Data harmonization