Operational Challenges and Opportunities for Novel Research Infrastructure

Novel Approaches to IDE Studies Using the NCDR: ACC View

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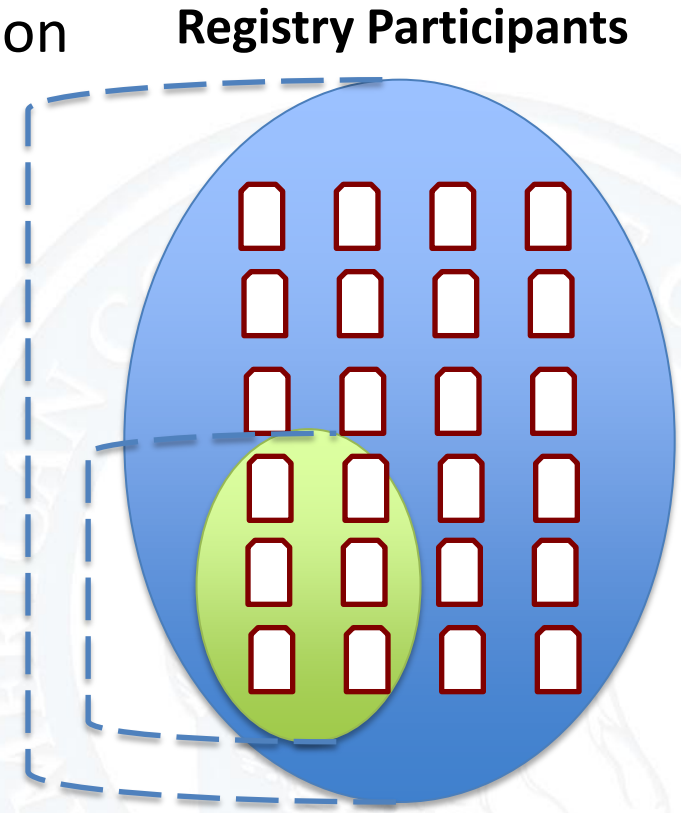
Helping Cardiovascular Professionals Learn. Advance. Heal.

Registries/IDEs

- Access to larger volume of pts
- Eliminate redundant data collection
- Existing data collection
- Granular clinical data
- Data quality procedures
- Clinical support for data interpretation and data capture
- Collect a large amount of data quickly
- Extended surveillance



IDE Sponsor

Regulations
Risks
Funding

	Traditional Approach	Novel Approach
	$$$ Longer	$ Shorter
	A Spectrum of Approaches	
Recruitment	select among existing participants	
Site Training Support	build upon existing training structures	
IRB/Informed Consent	traditional	modified
Site Monitoring	onsite and remote monitoring	registry completeness & select audits
Data Capture	registry + more	registry only
Adjudication	clinical event committee	algorithmic


Time for a Parad


KEEP
CALM
THERE'S A
PARADIGM
SHIFT
GOING ON

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