Building the National Evaluation System for Medical Devices

The Role of MDEpiNet PPP

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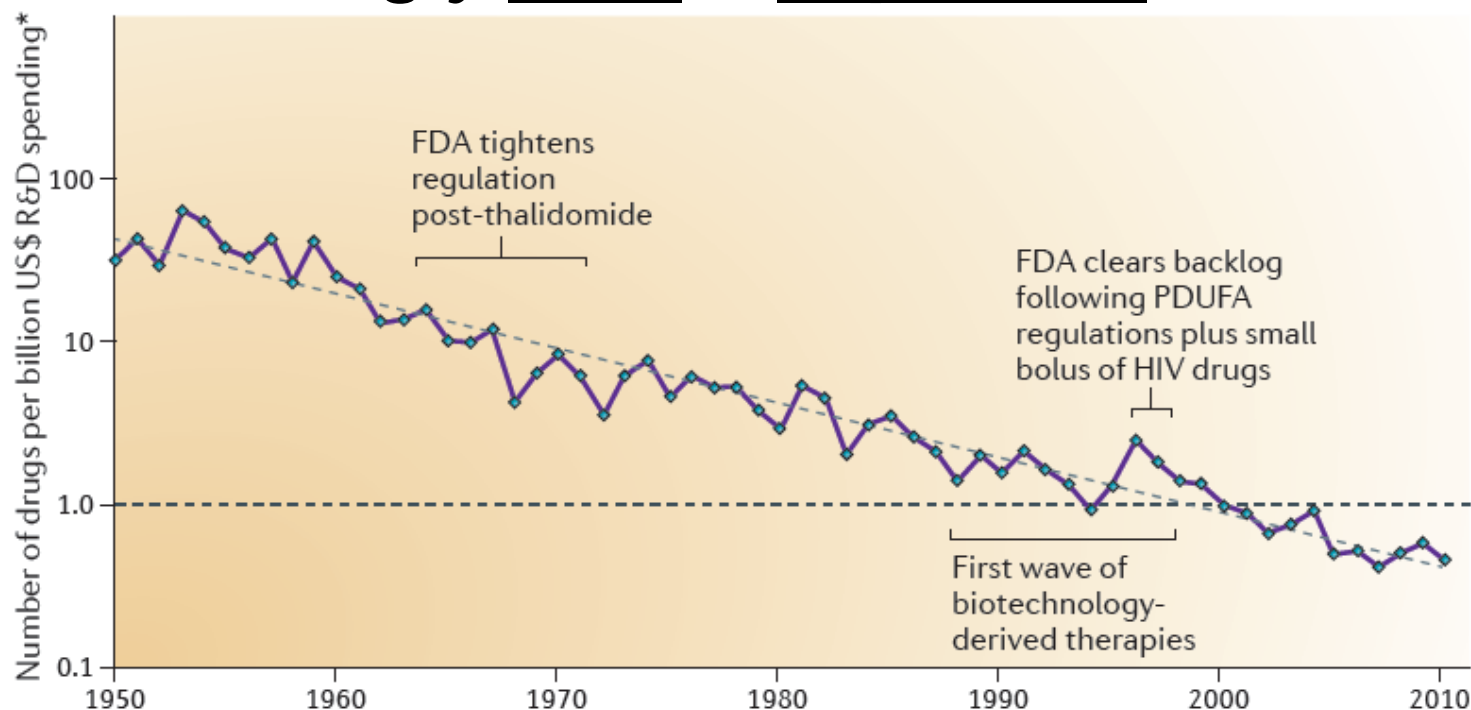Duke University School of Medicine

Overview

- **The Digital Revolution: An Opportunity to Transform**

- **The National Evaluation System for Medical Devices**

- **MDEpiNet: A Catalyst**

  - *What is MDEpiNet?*

  - *The Mission*

  - *The Building Blocks*

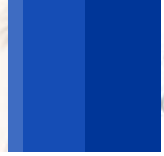 - *Tangible Steps to Change*

- How can you get involved?

Product Development in the U.S.
Increasingly <u>Slow</u> & <u>Expensive</u>

Eroom's Law. The number of new drugs approved by the FDA per billion US dollars (inflation-adjusted) spent on research and development (R&D) has halved roughly every 9 years since 1950.

Scannell et al., *Nature Reviews Drug Discovery* 11:191, 2012

Product Development in the U.S.

Ineffective

The Digital Revolution
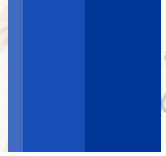## *An Opportunity for Regulatory Reform*
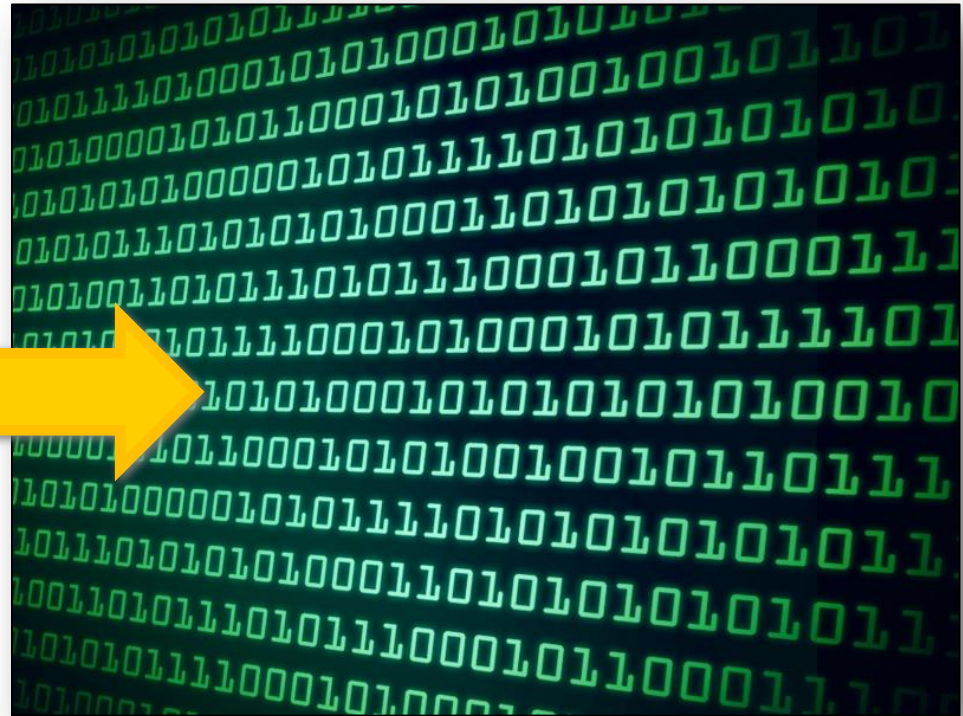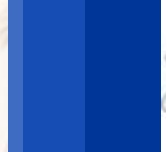
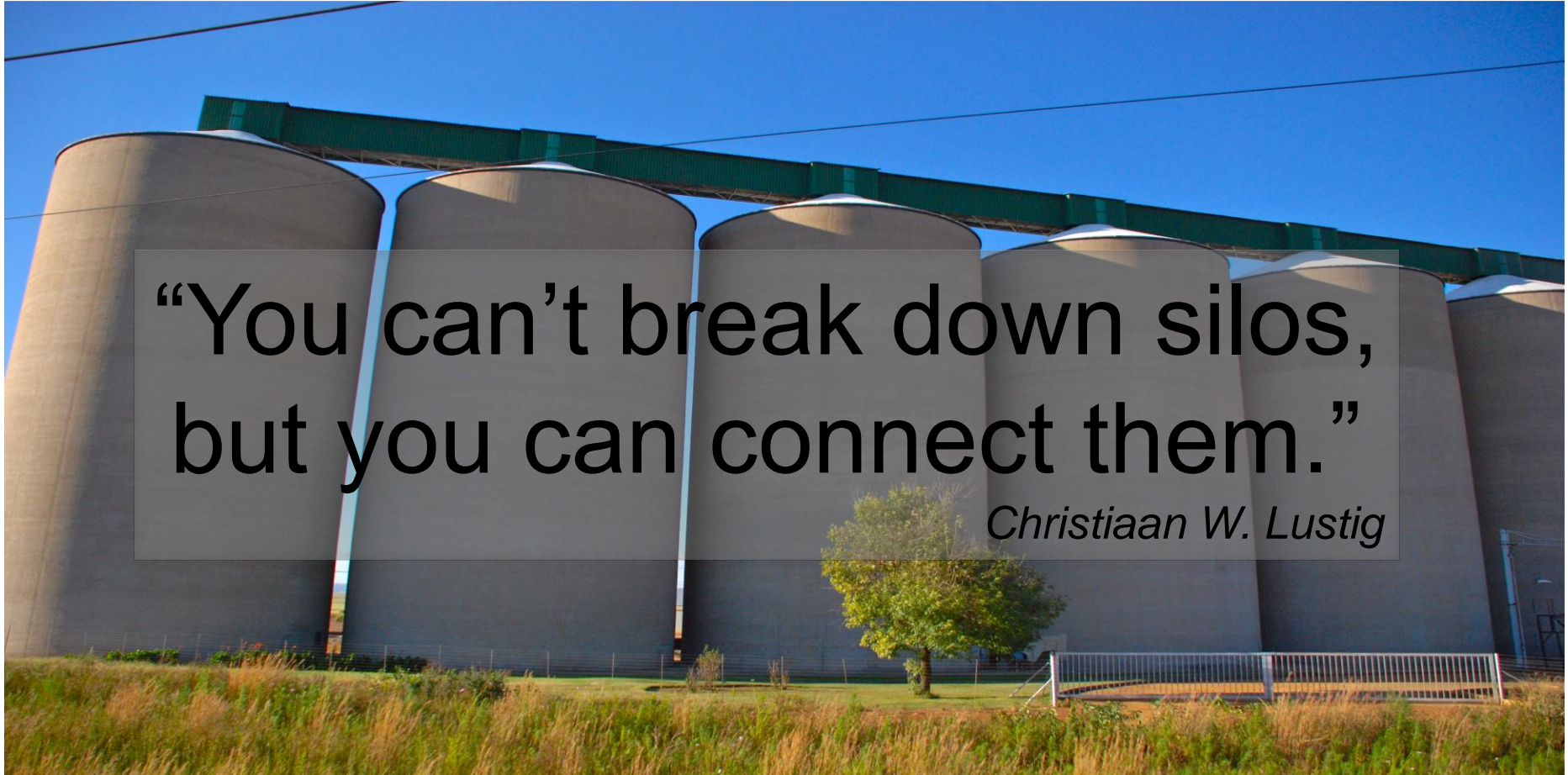# The Digital Revolution
Impediments to Change

The Digital Revolution
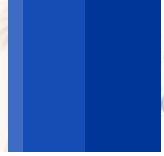## *Impediments to Change*

Clinical Practice

Clinical Research

MDEpiNet Public-Private Partnership

"You can't break down silos, but you can connect them."

Christiaan W. Lustig

MDEpiNet Public-Private Partnership
Who are we?

MEDICAL DEVICES — FDA — FOOD AND DRUG ADMINISTRATION

METHODOLOGY — VE RI TAS — HARVARD

SCIENCE AND INFRASTRUCTURE — WEILL CORNELL

COORDINATING — DUKE

PARTNERS AHRQ, ACC-NCDR, Avalere, Canadian Agency for Drugs and Technologies in Health Cardiovascular European Research Center (CERC), Centers for Medicare and Medicaid Services (CMS), IDEAL Collaboration, Johnson & Johnson, Lahey Health, MedTech Intelligence, Medtronic, Mercy, Northgate Public Services, National Center for Health Research, National Institute for Health and Care Excellence (NICE), Phillips, Phillips Innovation and You, Society for Vascular Surgery Patient Safety Organization, The TMJ Association, LTD…. And, GROWING!

MDEpiNet Public-Private Partnership
The Mission
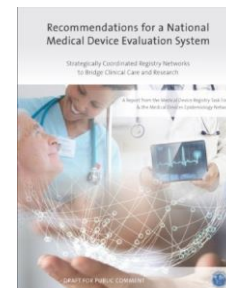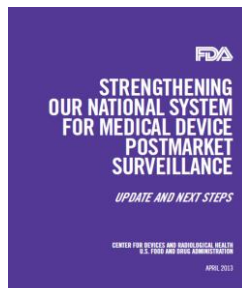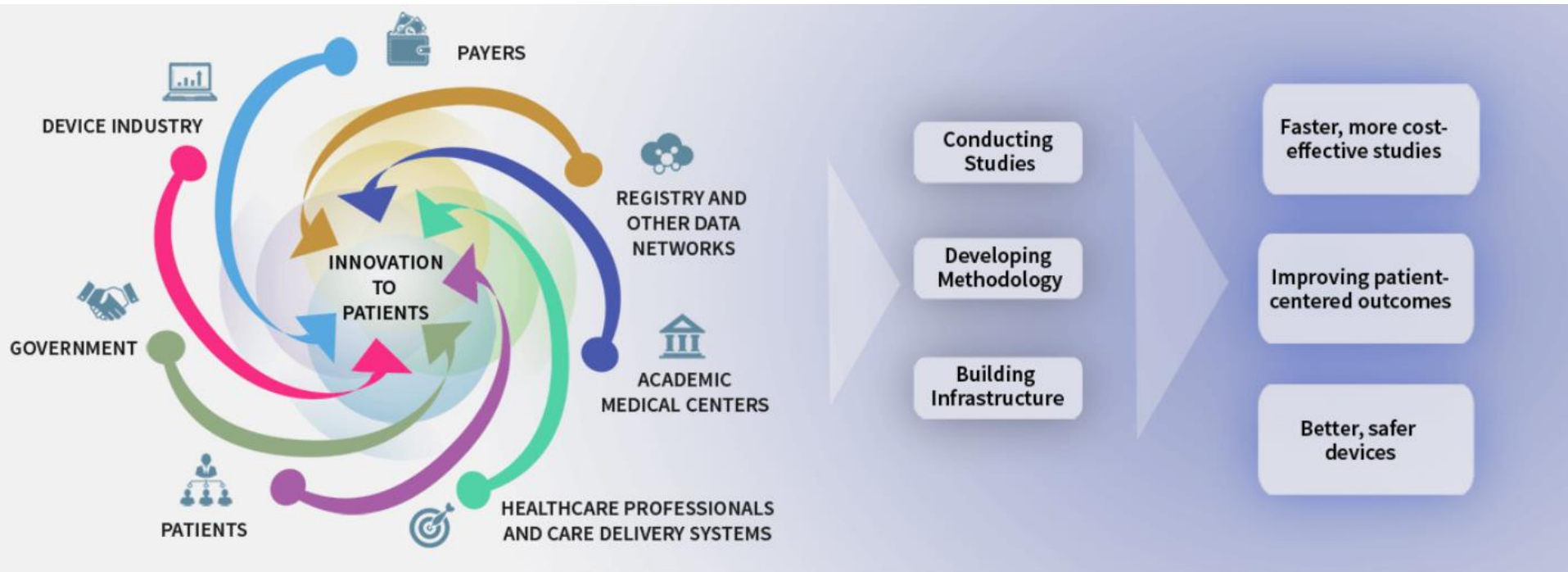
MDEpiNet Organizational Structure

MDEpiNet Stakeholder Council

MDEpiNet Coordinating Center (Duke)

Public Programs Committee

Publications Committee

Executive Operations Committee

International Committee

Stakeholder Engagement and Sustainability Committee

Scientific Oversight Committee

MDEpiNet Science & Infrastructure Center (Cornell)

Disease-Based Working Groups

MDEpiNet Methodology Center (Harvard)

Cardiovascular WG

Orthopedic WG

Additional WGs

From D Marinac-Dabic

National Evaluation System (NESMD)
Building Blocks

Implementation

Analytics
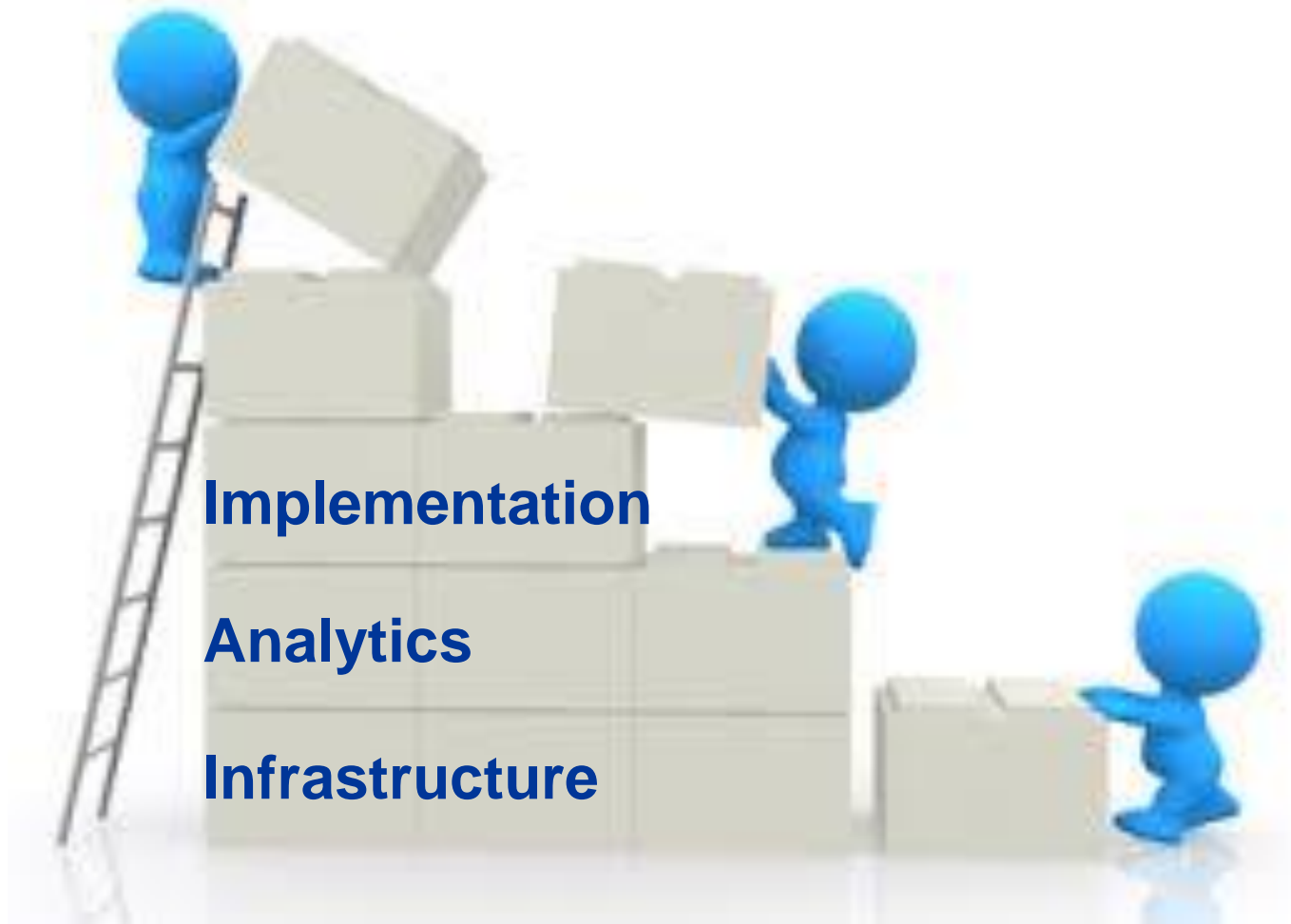
Infrastructure

National Evaluation System (NESMD)

Infrastructure

Identify & Access Global Data Streams

Coordinated Registry Networks (CRNs)

A. Linked complementary registries

B. Multiple source structured data extraction

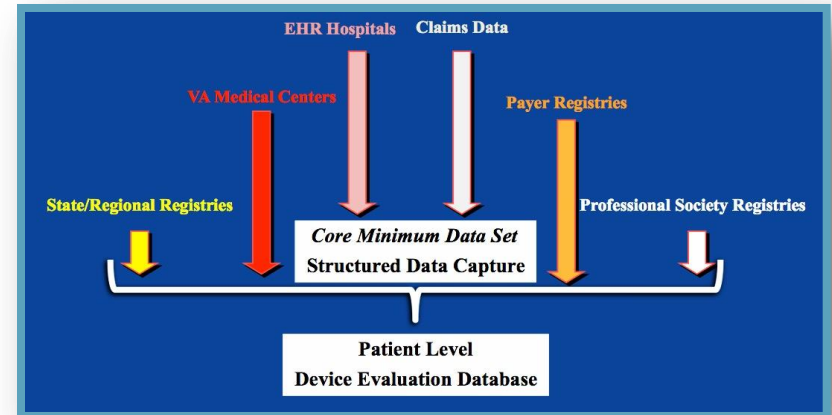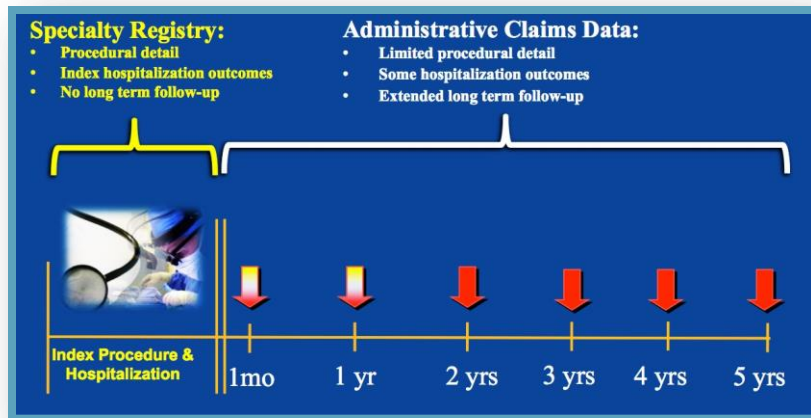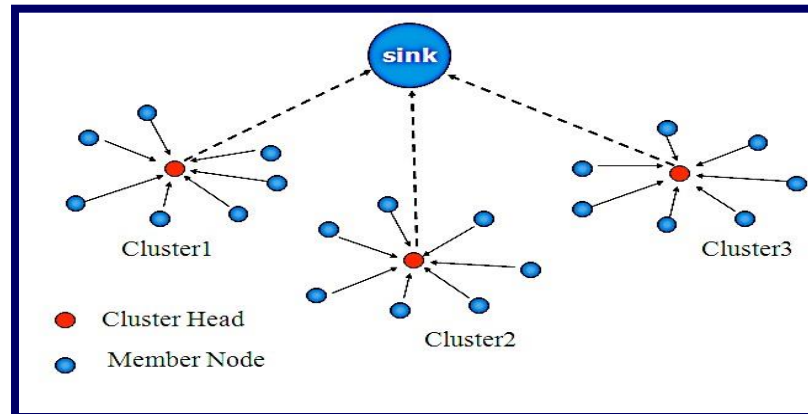**C. Distributed data networks**

Create a Unified Syntax

# Incorporate Unique Device Identifier(UDI)

FDA UDI Timeline

	Final Rule	Sept 24, 2014	Sept 24, 2015	Sept 24, 2016	Sept 24, 2018	Sept 24, 2020
Labels and Packages must contain UDI Dates must be formatted at YYYY-MM-DD Products must be submitted to FDA UDI Database	Final Rule Published September 24, 2013	Class III	Implantable or life sustaining/ supporting	Class II	Class I	
Products intended to be used more once *must have direct part marking*			Implantable or life sustaining/ supporting	Class III	Class II	Class I

Validate Data Accuracy

'Big Data'
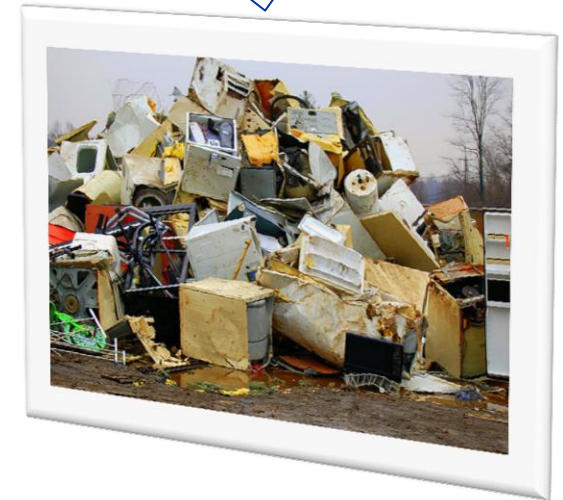
National Evaluation System (NESMD)
Data Analytics

Data Extraction and Longitudinal Trend Analysis (DELTA)

	Uniform	**Stratified**	**Risk Adjusted**
Frequentist	Statistical Process Control (SPC)	Stratified SPC CUSUM	Logistic Models SPRT Propensity Match Survival Analysis
Bayesian	Bayesian Updating System (BUS)	Stratified Bayesian	Hierarchical (Bayesian) Logistic Regression(HLR)

MDEpiNet Strategic Projects
Redesigning the Pipeline

App 1   Late-Phase Pre-Market Clinical Trials

App 2   Label Extension & Post-Approval Studies
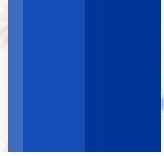
App 3   'Dedicated' Post-Approval Analyses
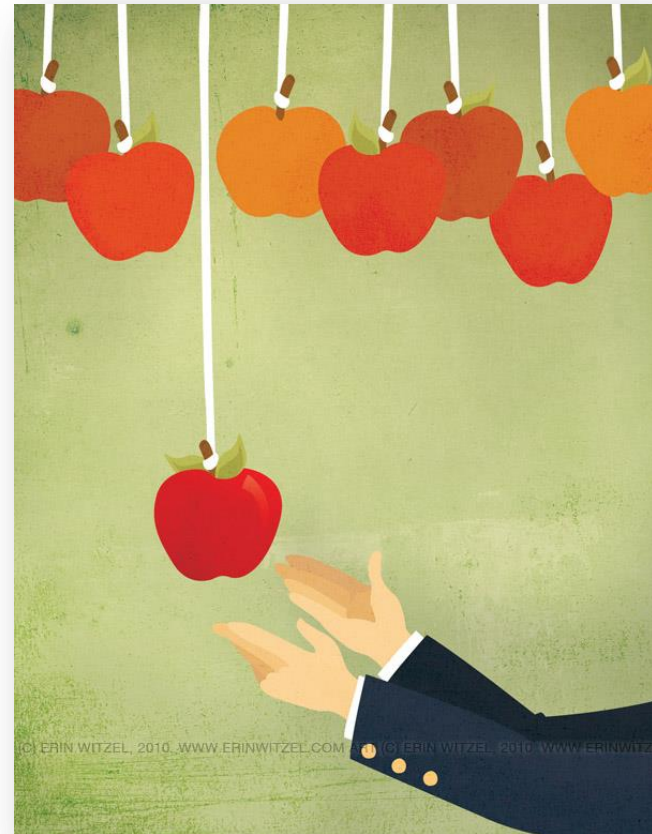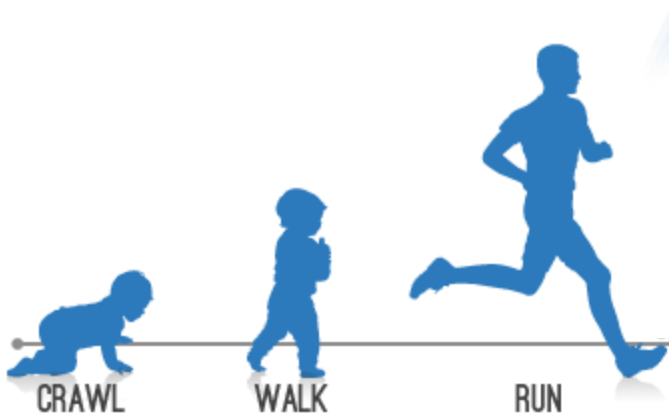
App 4   Claims-based 'Performance Goals'

App 5   Automated Safety Surveillance

National Evaluation System (NESMD)
Redesigning the Pipeline

MDEpiNet PPP
A <u>Shared</u> Philosophy

"FAITH IS TAKING THE FIRST STEP, EVEN WHEN YOU DON'T SEE THE WHOLE STAIRCASE"
- Martin Luther King Jr
kushandwizdom.tumblr

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THANK YOU