



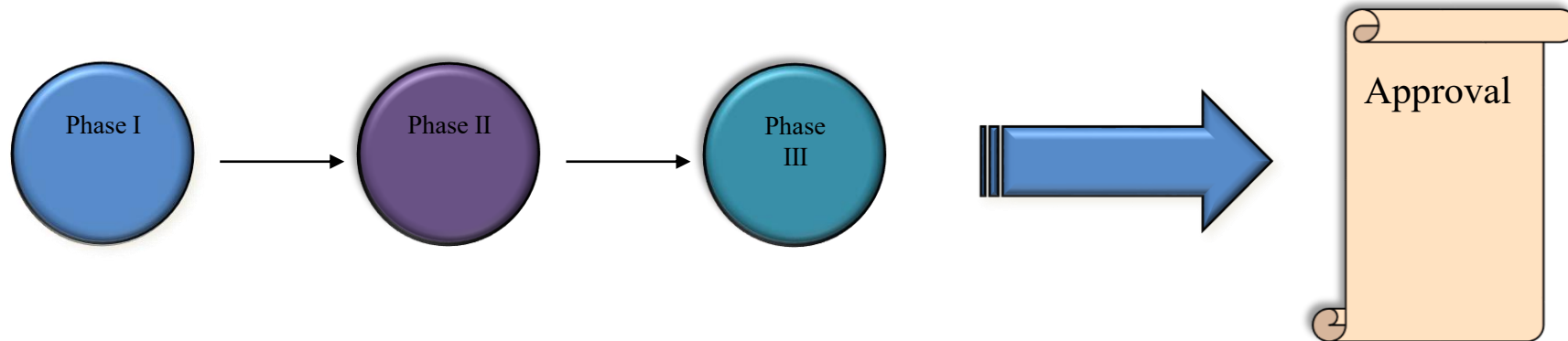
Global Solutions from the World's Largest Data-Focused CRO

Evolution of Biometrics & Pathway to Future

Deepu Joseph, VP & Global Head of DM

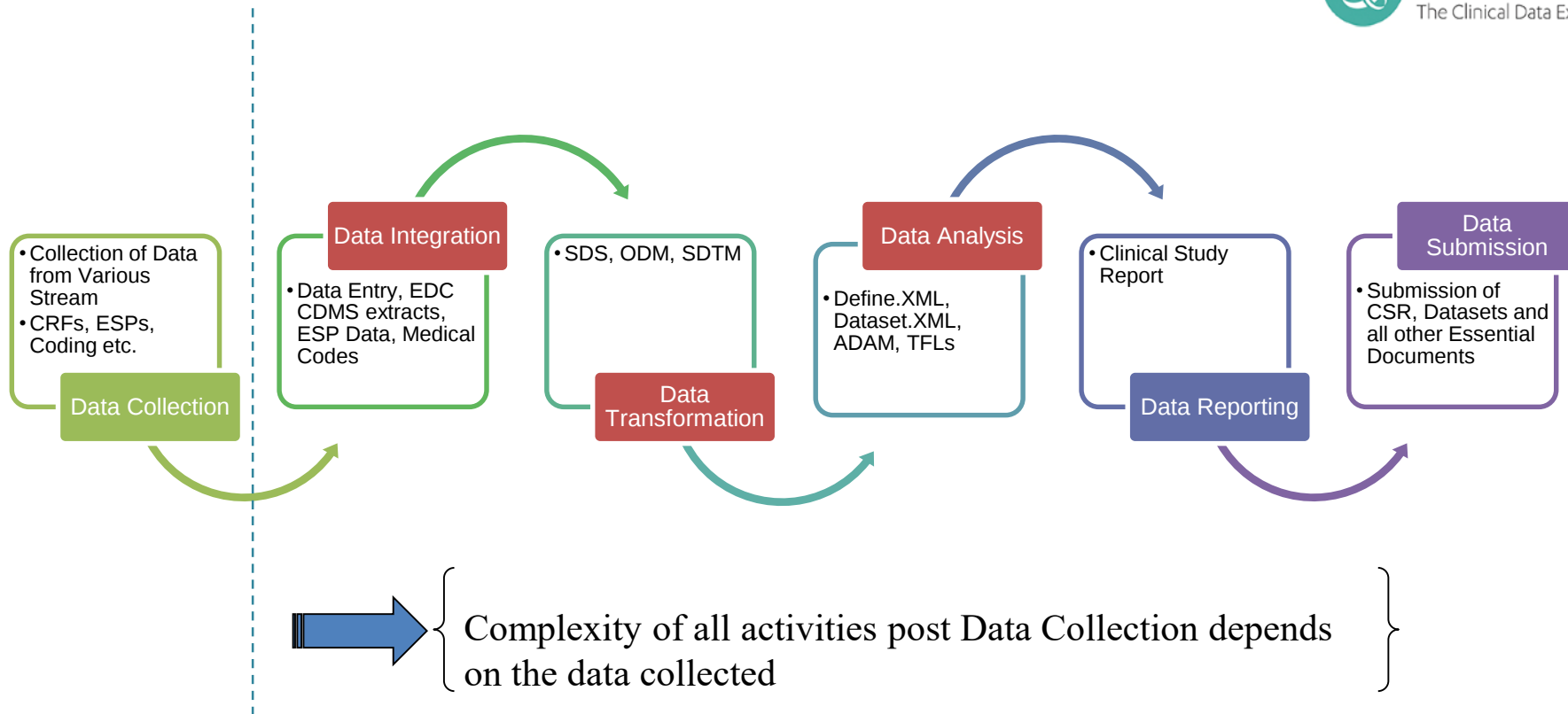
Need for Faster Drug Development

Why faster trials are critical for pharma companies?

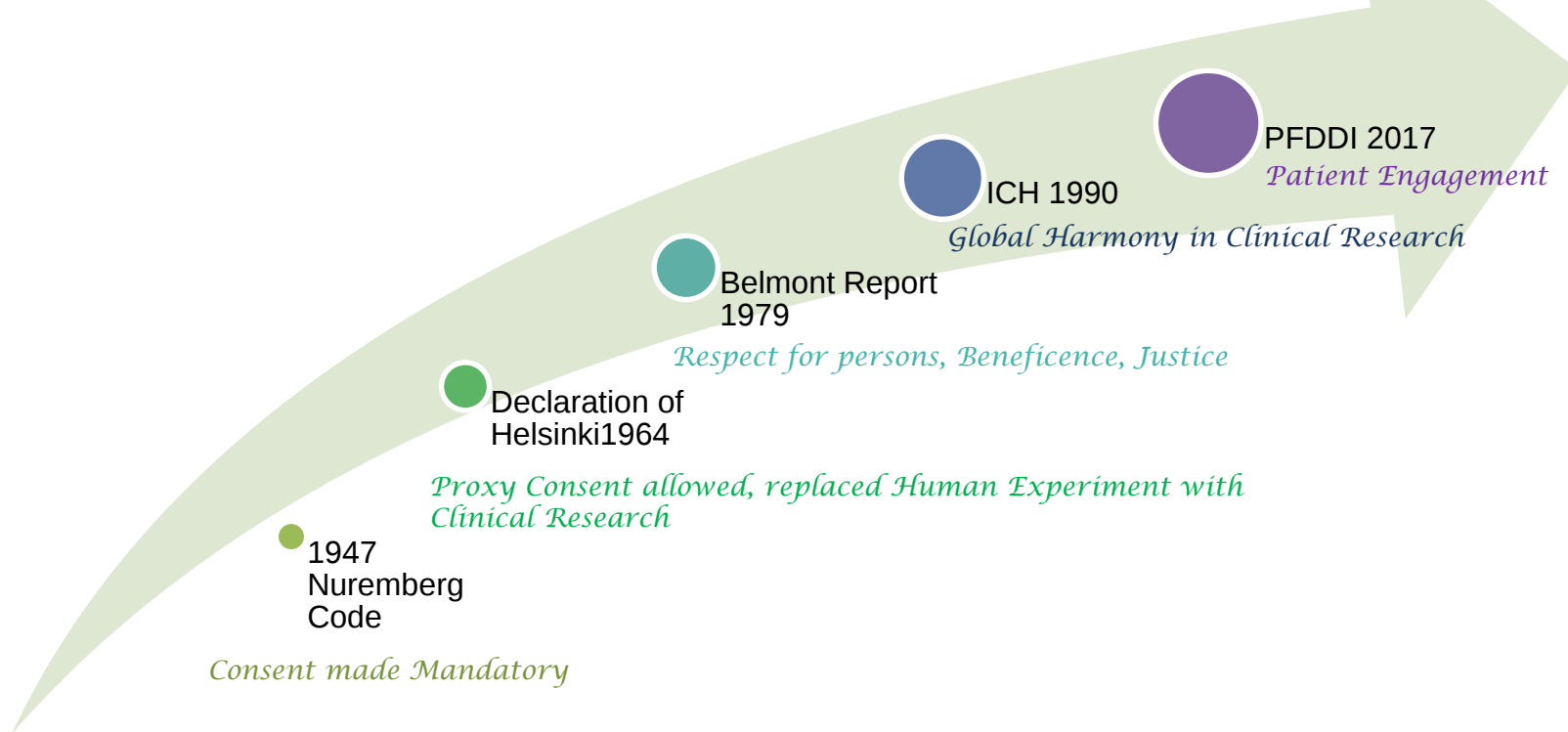


7.5 Years Average per drug
\$161M — \$2B in costs
Only 1 in 10 from Phase I gets approval
High R&D Costs affects healthcare prices

Pre & Post Data Collection



Patient Centricity- Core to Evolution



Evolution from Patient's Perspective

Rights



Respect



Engagement



The 21st Century Cures Act (Cures Act) -2017

21st Century Cures Act and The Food and Drug Administration Reauthorization Act of 2017.

Incorporates the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process.

Cures enhances our ability to modernize clinical trial designs and clinical outcome assessments.

21st Century Cures



Guidance as part of FDA's PFDD efforts in accordance with Cures Act

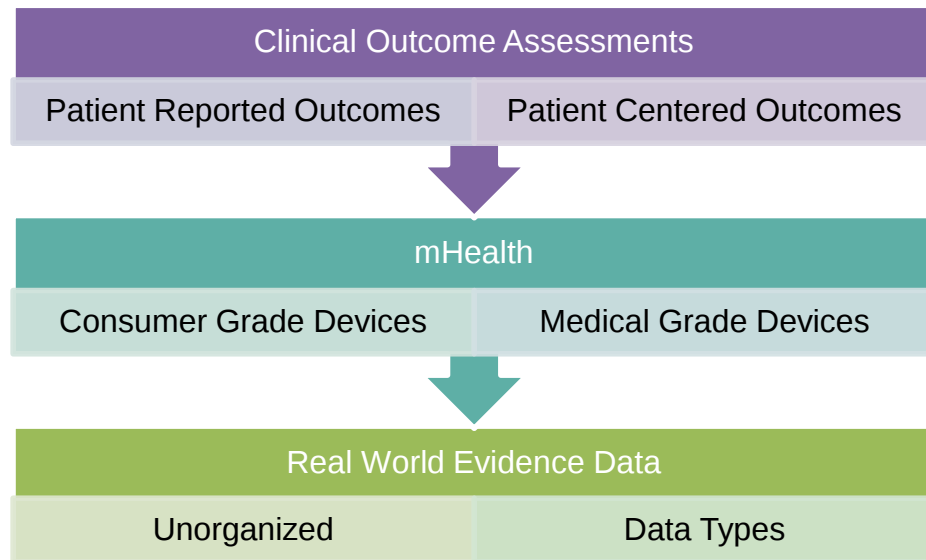
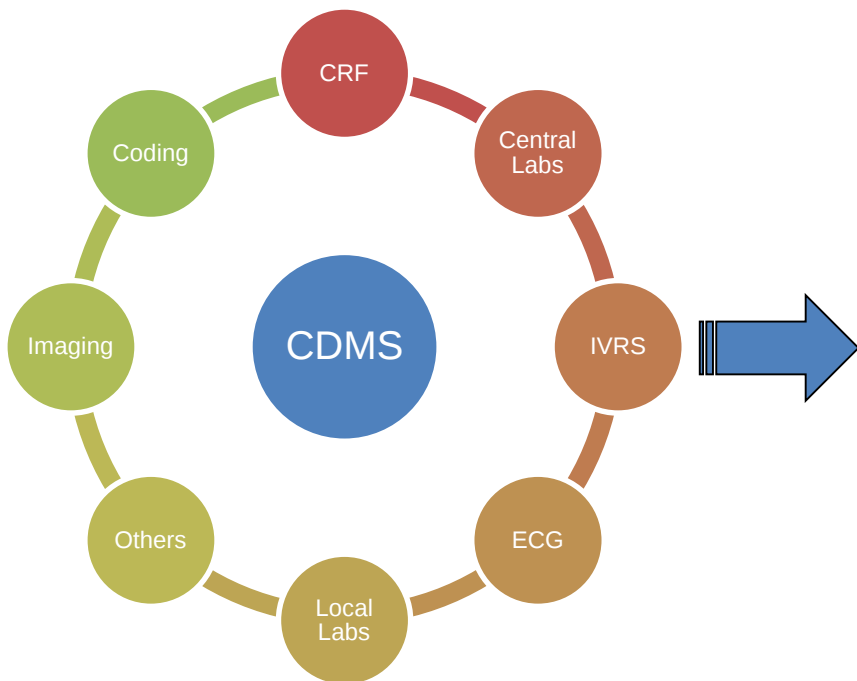
Guidance 1: Collecting Comprehensive and Representative Input

Guidance 2: Methods to Identify what is important to Patients

Guidance 3: Selecting, Developing or Modifying Fit for purpose Clinical Outcome Assessments

Guidance 4: Title Forthcoming (expected early 2020)

Shift in Data Sources



COAs

More than 2000 COAs are comprehensively described in the PROQOLID™ database

Mapi Research Trust created the PROQOLID™ database in 2002 as a tool to help you find the COA that is right for your needs and to provide a better knowledge and understanding of the relevant use of COAs, as well as to extend access to PCO resources for the scientific community.



Clinical
Outcome

Patient
Reported
Outcome

Patient
Centered
Outcome

Non 24 hr Sleep-Wake disorder

- Researchers developed a sleep diary to document and quantify sleep and waking behaviors

Voice-of-the-Patient Meeting held in 2014: Hemophilia & Other Heritable Bleeding Disorders

- Patients expressed that joint pain is one of the most significant symptoms associated with their disease

Voice-of-the-Patient Meeting held in 2013: [Chronic Fatigue Syndrome](#)

- Patients expressed they would like to have a biomarker for their disease. It would convince their families, friends and colleagues that they really have an illness and remove the stigma associate with the disease

Real World Evidence (RWE)

RWD Sources

- Electronic health records (EHRs)
- Claims and billing activities
- Product and disease registries
- Patient-generated data including in home-use settings
- Data gathered from other sources that can inform on health status, such as mobile devices

Non Traditional & Hybrid Clinical Trials

- Minimal Incl/Excl criteria
- Participant characteristics less-precisely defined

Pragmatic Clinical Trials

- Clinical Trial designs includes elements close to routine clinical practice

Observational Studies

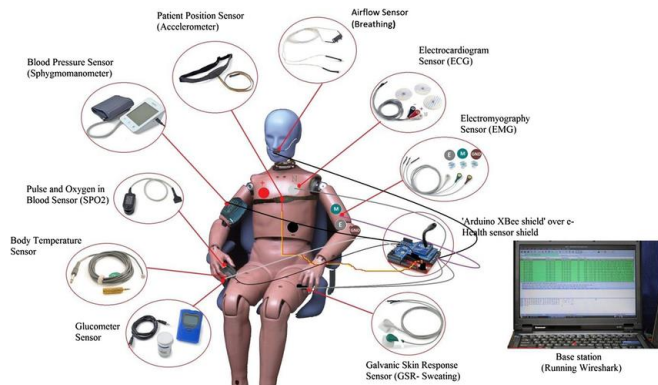
- Non-Interventional Clinical Study Designs

Scope of RWE Program Under 21st Century Cures Act

- ✓ Generating hypotheses for testing in randomized controlled trials
- ✓ Identifying drug development tools (including biomarker identification)
- ✓ Assessing trial feasibility by examining the impact of planned inclusion/exclusion criteria in the relevant population, both within a geographical area or at a particular trial site
- ✓ Informing prior probability distributions in Bayesian statistical models
- ✓ Identifying prognostic indicators or patient baseline characteristics for enrichment or stratification
- ✓ Assembling geographically distributed research cohorts (e.g., in drug development for rare diseases or targeted therapeutics)

To efficiently process RWD and submit it for evaluation to FDA, appropriate data standards are necessary

mHealth



300+ sensors in the market

Differentiating Consumer & Medical Grade Devices

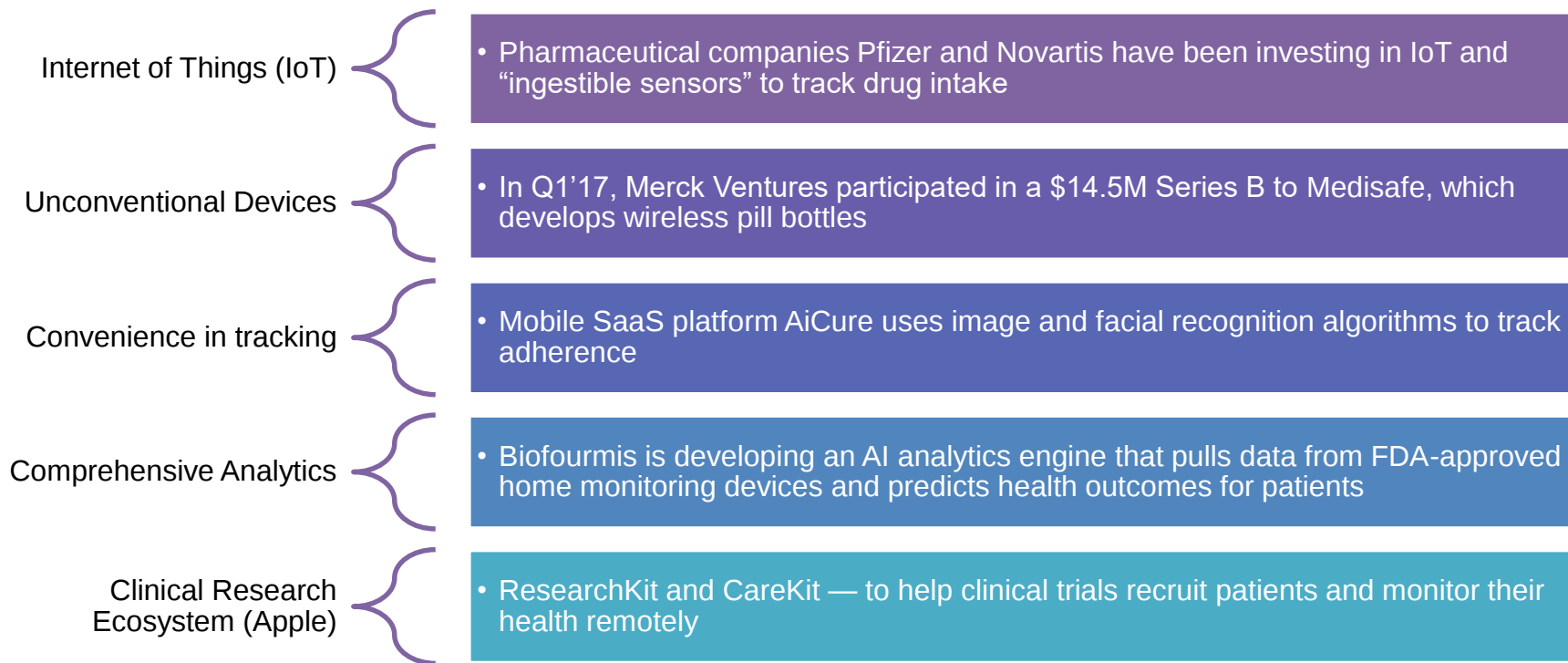
FDA and other regulators are open to see this data

Enrollment
Support

Medication
Adherence

Precise
Monitoring

Artificial Intelligence & Machine Learning



Pathway to Future

