



# REAL WORLD DATA (RWD)

# Real World Data: Definition



**RWD** include data derived from electronic health records (EHRs), claims and billing data, data from product and disease registries, patient-generated data including in home-use settings, and data gathered from other sources that can inform on health status, such as mobile devices.

# Real World Evidence: Definition



**RWE** is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.

# RWE: What are the Goals?



Maximize the opportunities to have regulatory decisions incorporate data/evidence from settings that more closely reflect clinical practice

- Increase the diversity of populations
- Improve efficiencies
  - Population identification/selection
  - Reduce duplicative capture of data

# RWE: What are the Expectations?



## 21<sup>st</sup> Century Cures



FDA shall establish a program to evaluate the potential use of real world evidence (RWE) to support:

- approval of new indication for a drug approved under section 505(c)
- satisfy post-approval study requirements

# Real World Data Uses for Clinical Trials

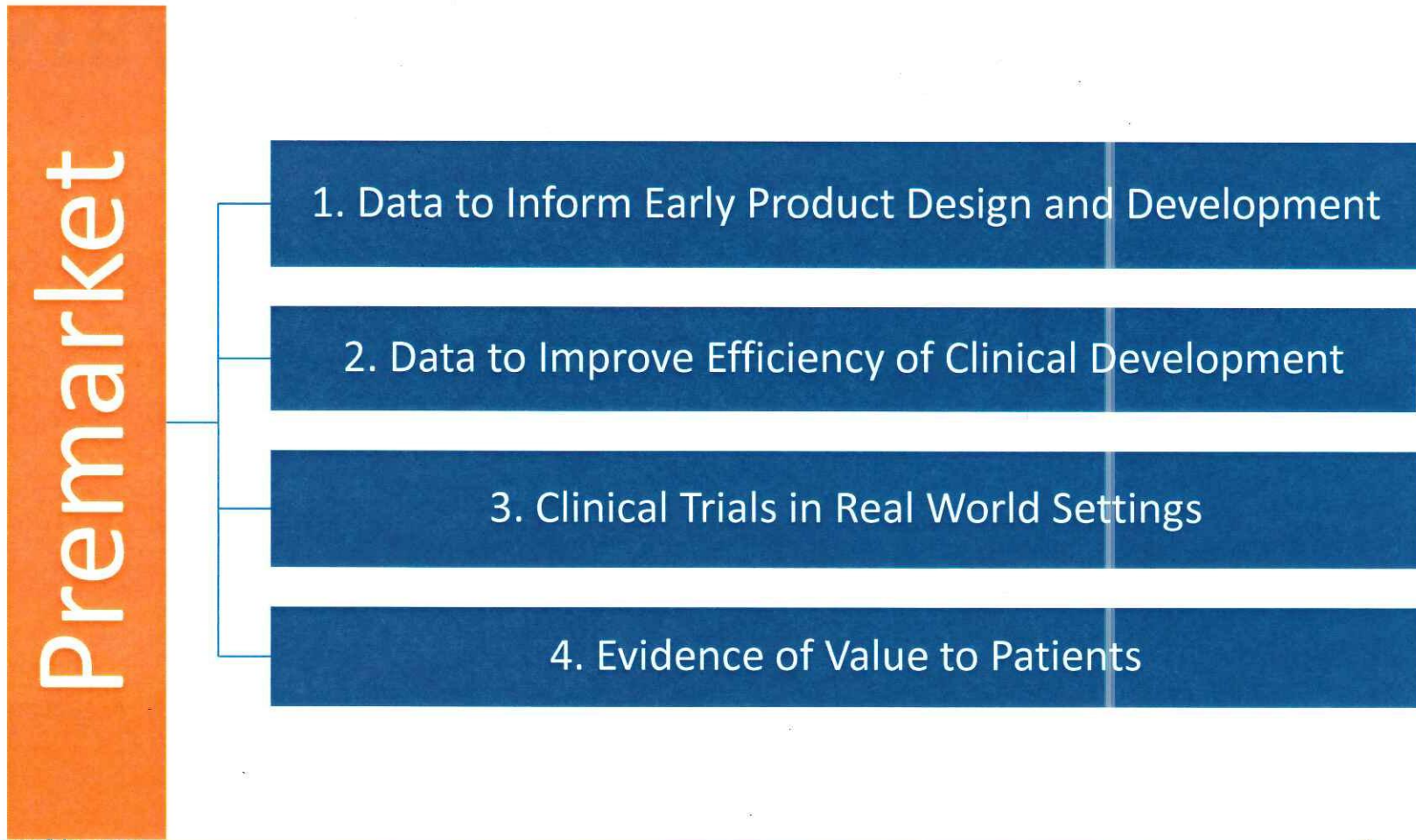


- Rapidly find large numbers of possible participants with all requirements for clinical trial study:
  - Health history
  - Treatment history
  - Medicine history
  - Range of demographics
  - Range of geographies and rural/urban
- Rapidly identify sites/clinical investigators
- Savings of time and money for manufacturers, clinical investigators, and other stakeholders
- Potential to identify additional “off-label” uses for approved drugs



# STRATEGIC PRIORITIES FOR HEALTH IT

# Health IT Strategic Interests and Premarket Environment



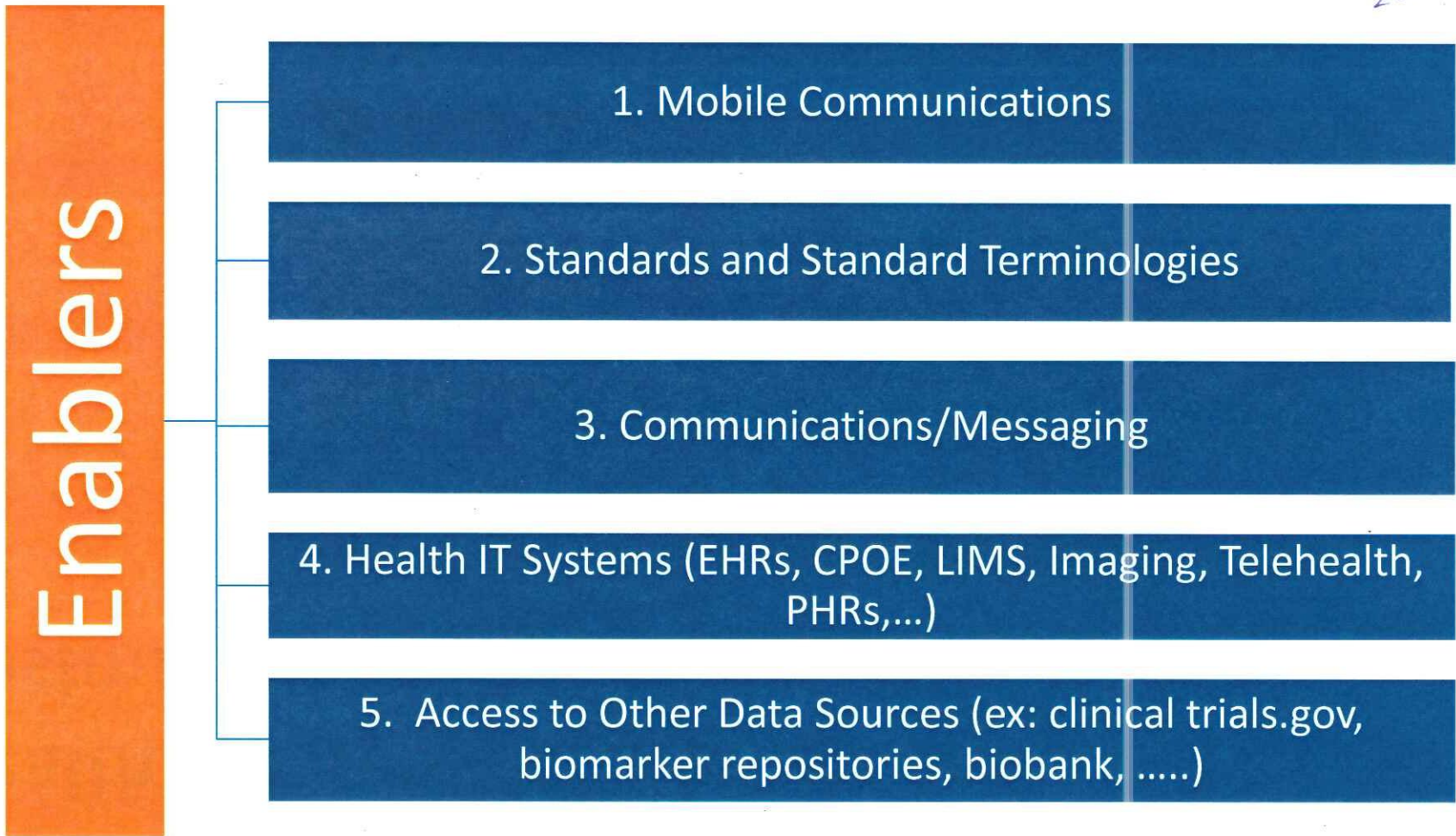


# Health IT Strategic Interests and Postmarket Environment



# Health IT Enablers

2016



# HEALTH IT 2018 VISION

Leverage Health IT to Facilitate Regulatory Decisions

Educate stakeholders on CDER Health IT strategic priorities

Communicating Effectively with our Stakeholders

Governing Health IT within CDER

Supporting Agile Development for Demonstration Projects Leveraging Health IT

Build our own prototyping/integration platform

Right Drug... Right Dose... Right Outcome...

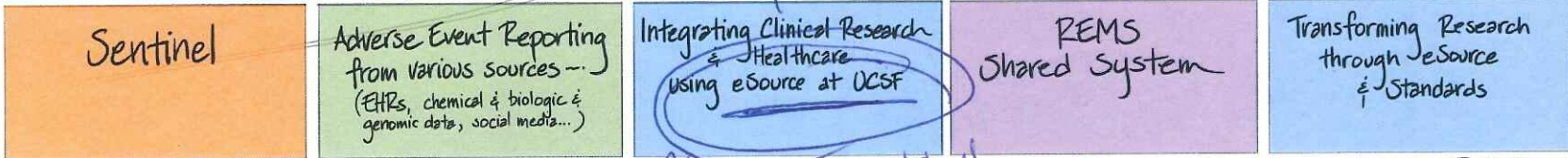
Demonstrate accelerated product development & safety interventions

Streamline Health IT integration into product development & regulation

EHR pilots & other information sources

HL7 FHIR

## CURRENT PRIORITIES



HL7 FHIR epic  
Breast trial buddy eCRF directly into EHR @ UCSF

