Building a National Capability

to Monitor and Assess Medical Countermeasure Use in Response to Public Health Emergencies

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NASEM Workshop

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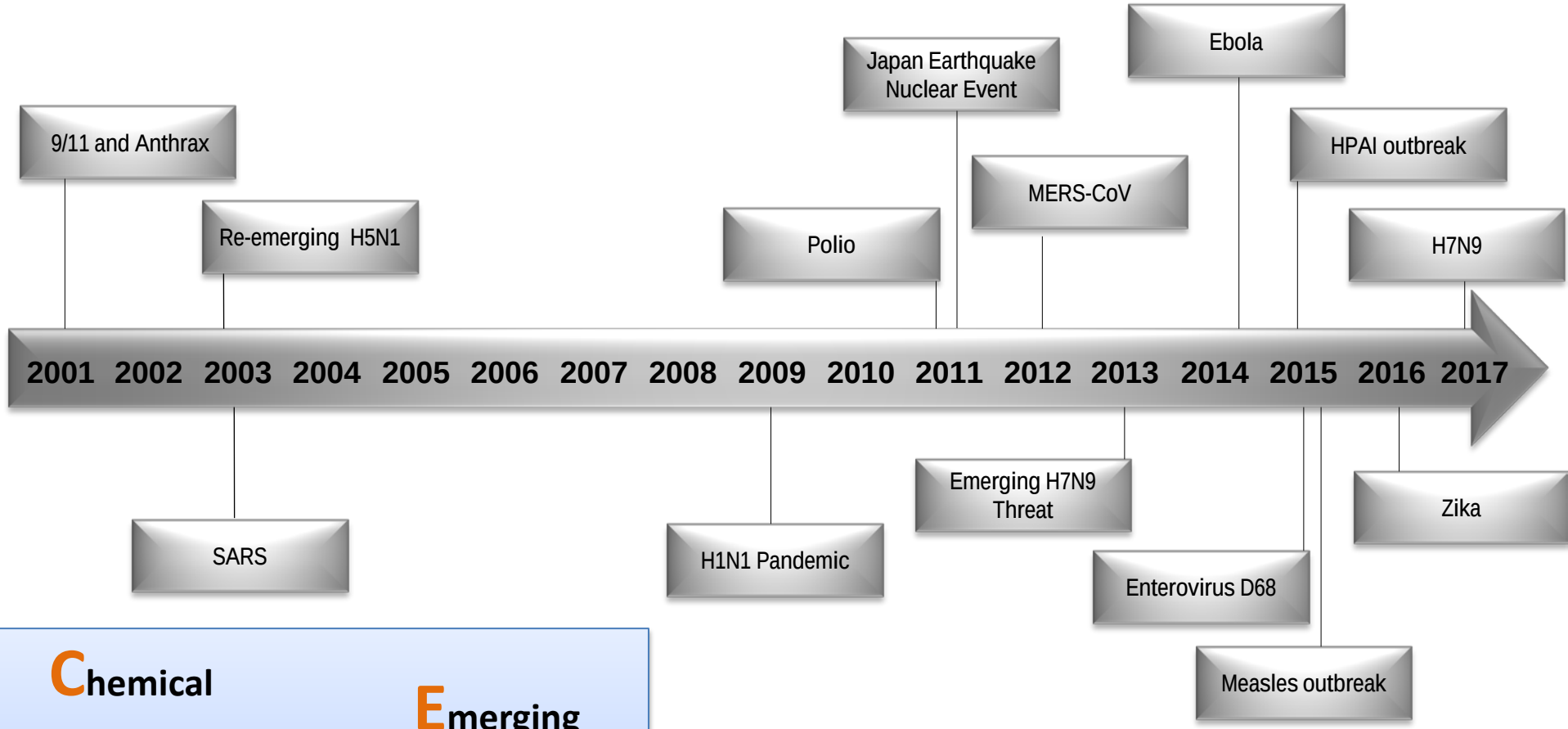
Public Health Emergencies (PHE)



Chemical
Biological
Radiological
Nuclear

\+

Emerging
Infectious
Diseases

Timeline courtesy of HHS/ASPR

The Problem

The U.S. government has a limited capacity to rapidly collect and analyze PHE medical countermeasure (MCM) safety and effectiveness data, especially during a PHE response.

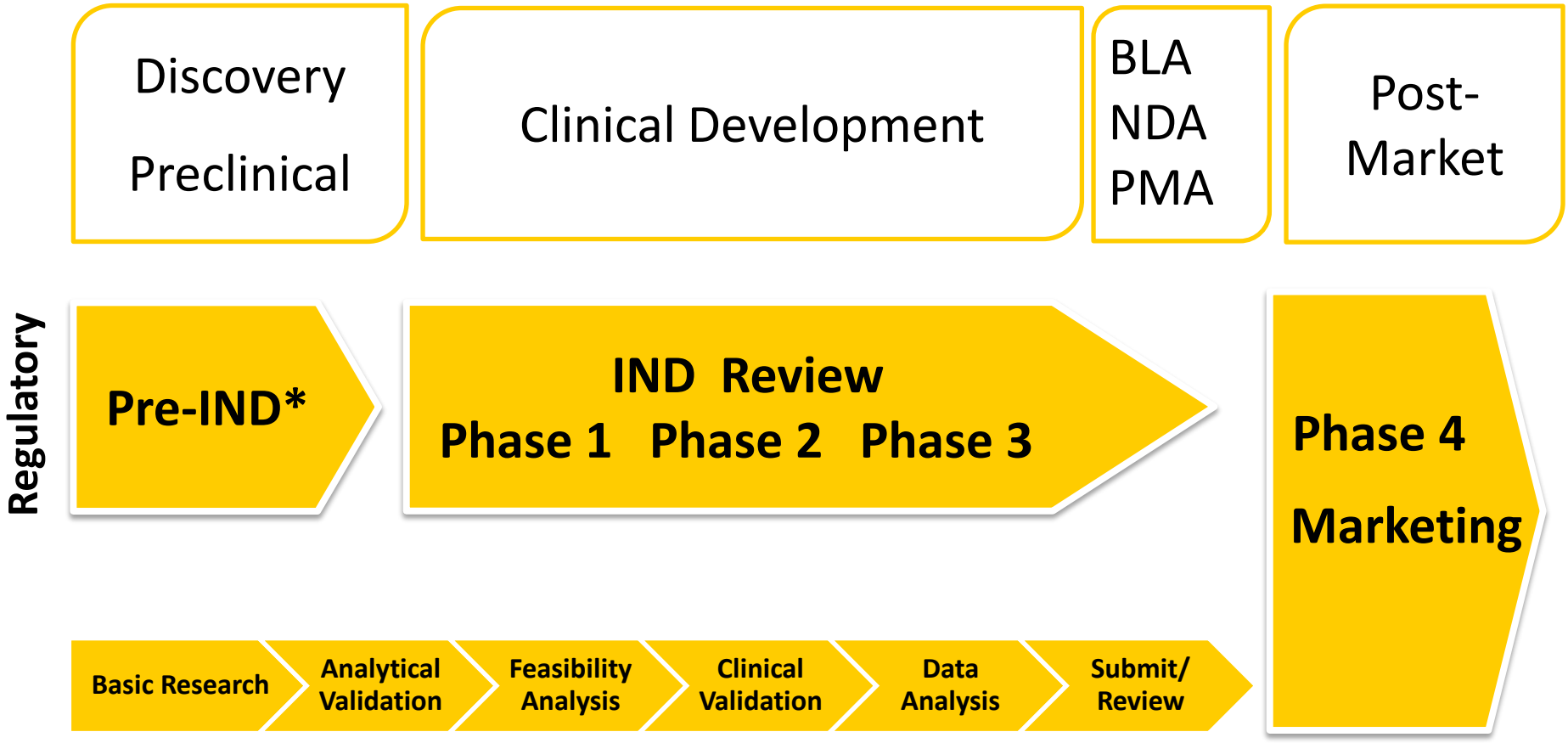
...now what?


MCM 101
3M 1860
N95
NIOSH
HEALTH CARE PARTICULATE RESPIRATOR
AND SURGICAL MASK

FDA's MCM Roles

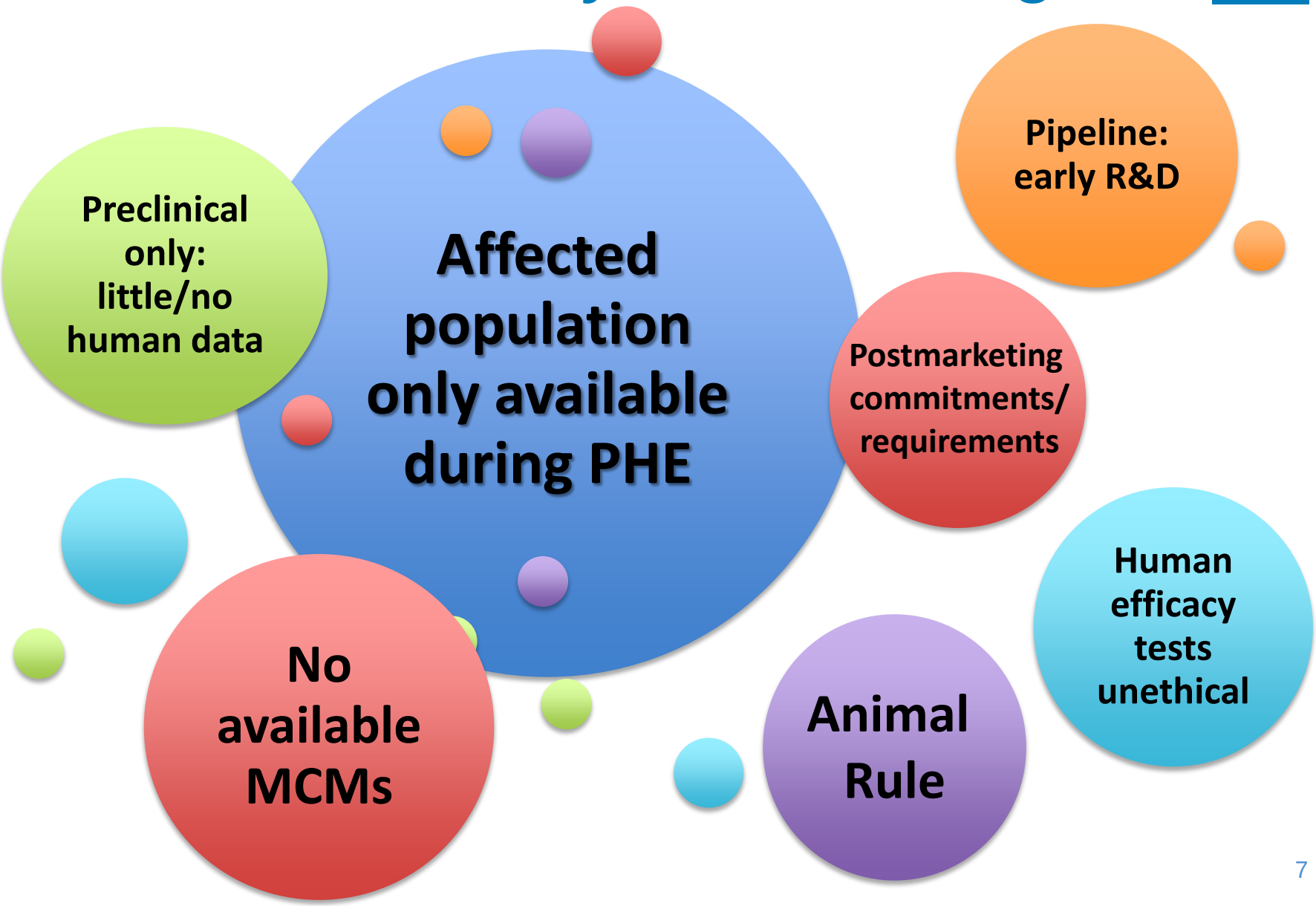
- Facilitating development of and access to MCMs
  - e.g., Animal Rule
- Legal mechanisms (e.g., EUA, IND, IDE, Expanded Access)
- Consumer protection
- Collaboration
- **Monitoring MCM use for safety and effectiveness**

Traditional Medical Product Lifecycle



* Pre-submission for medical devices

PHE MCM Lifecycle Challenges



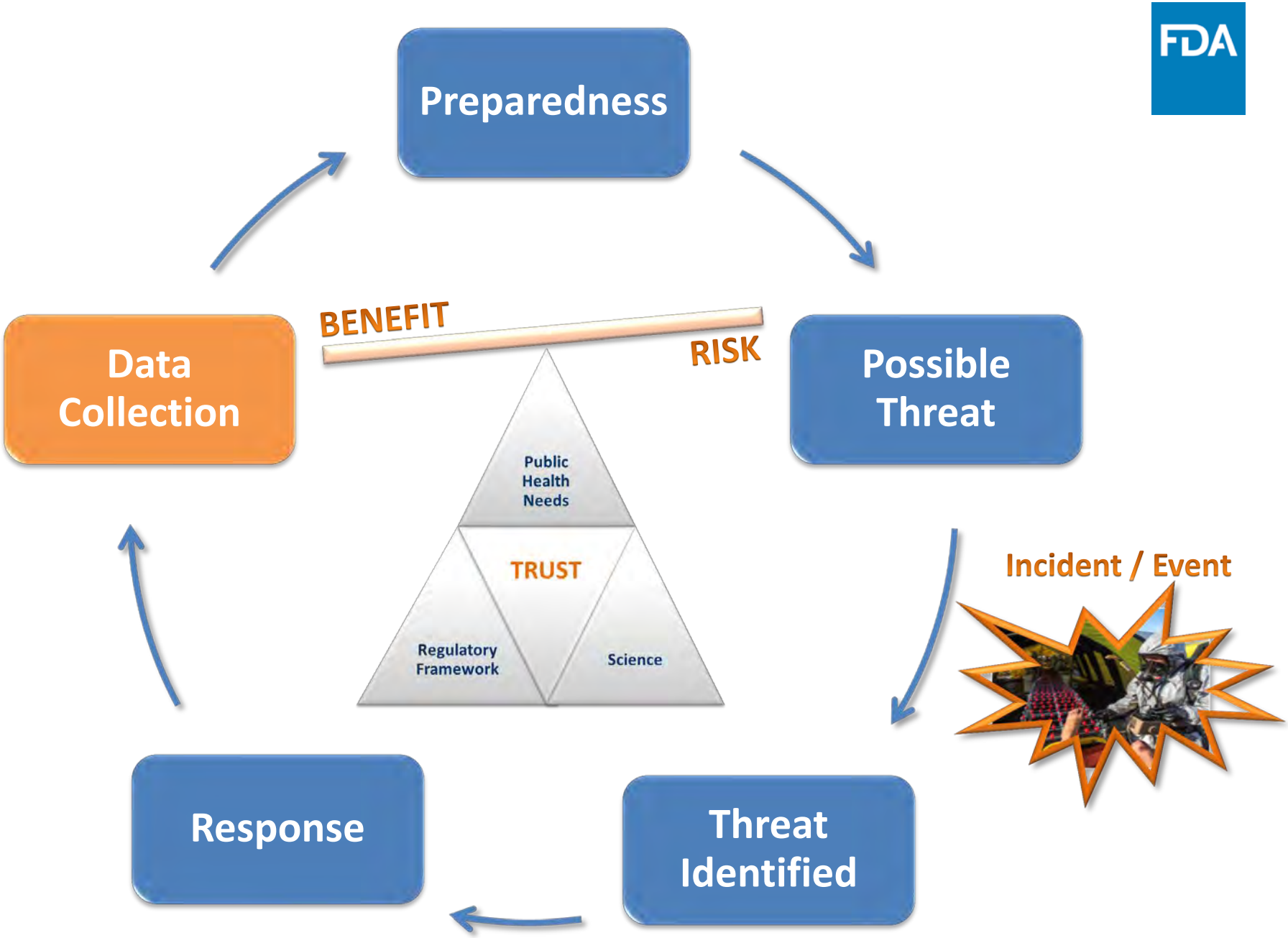
How is assessment different in a public health emergency?

PHE

- Intent – respond and mitigate
- Unplanned / unexpected
- Uncontrolled or no data collection
- Large numbers of individuals
- Simultaneous administration / multiple products
- Rapid decision-making / response
- Little or no tracking / monitoring
  - Lack of primary provider oversight / interaction
- Limited reporting or information dissemination

TRADITIONAL R & D

- Intent – generalizable knowledge
- Planned / deliberate
- Well-controlled clinical trials
- Smaller numbers of individuals
- Stepwise progression / single product
- Careful decision-making / time
- Strict oversight and monitoring
  - Informed consent / process
  - IRB review and approval
  - Adverse event reporting


Preparedness
Possible Threat
Incident / Event
Threat Identified
Response
Data Collection
BENEFIT
RISK
Public Health Needs
TRUST
Regulatory Framework
Science

H1N1

Cases reported in Mexico
April 2009

CDC starts candidate vaccines
Apr. 21

CDC starts releasing MCMs from SNS
Apr. 26

Discussions well underway:
- Vaccine EUA/lic.
- Vaccine safety
- Antivirals

May 2009

Resistance to oseltamivir & zanamivir found
July 2009

FDA approves 4 H1N1 vaccines
Sept. 2009

Peramivir EUA
Oct. 2009

CDC confirms US cases
Apr. 15

WHO declares PHEIC
Apr. 25

US declares PHE
Apr. 26

FDA issues 1st EUAs for flu antivirals & diagnostics
Apr. 27

Vaccine distribution planning well underway
June 2009

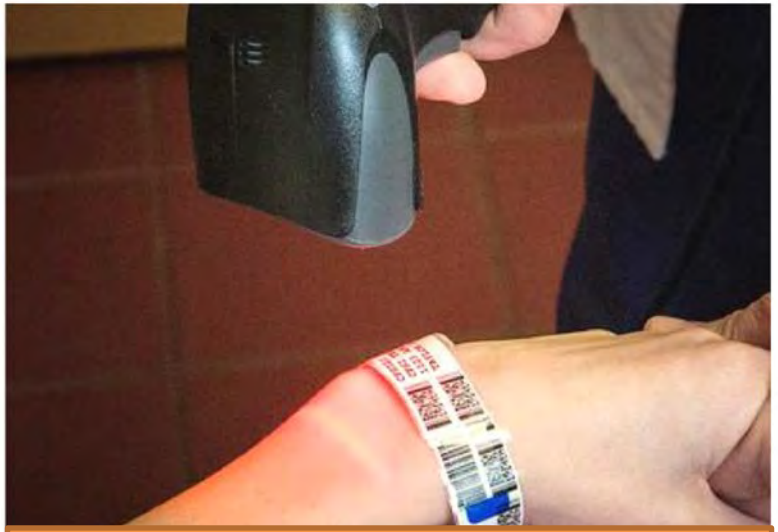
ACIP meeting for recommendations
July 2009

NIH starts clinical trials
July 2009

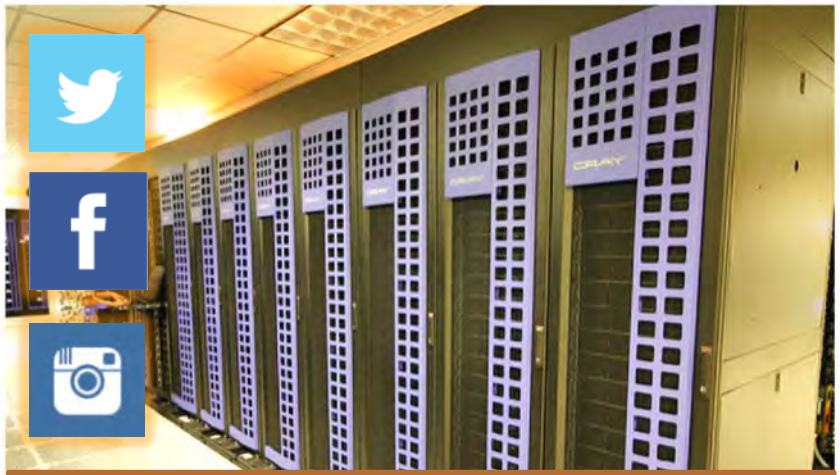
NIH announces trial results
Sept. 2009

Sources:
FDA 2009 H1N1 (Swine) Flu Page (archived)
H1N1 EUAs – Archived Information (FDA)
Historical Information about Device Emergency Use Authorizations (FDA)
CDC 2009 H1N1 Pandemic: Summary Highlights, April 2009 – April 2010 (archived)

Operations for Response



Electronic Health Data



Unstructured/Big Data

Clinical Networks

Photo credits, from top left, clockwise: CDC, FEMA, NIAID, LLNL

Progress to Date

EvGen Evidence Generation

openFDA

PHEMCE

MDEpiNet

USCIITG

Sentinel Initiative

RAPID

The National Academies of SCIENCES ENGINEERING MEDICINE

Food and Drug Administration MEDWATCH

Innovation in Medical Evidence Development and Surveillance

BD4P

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

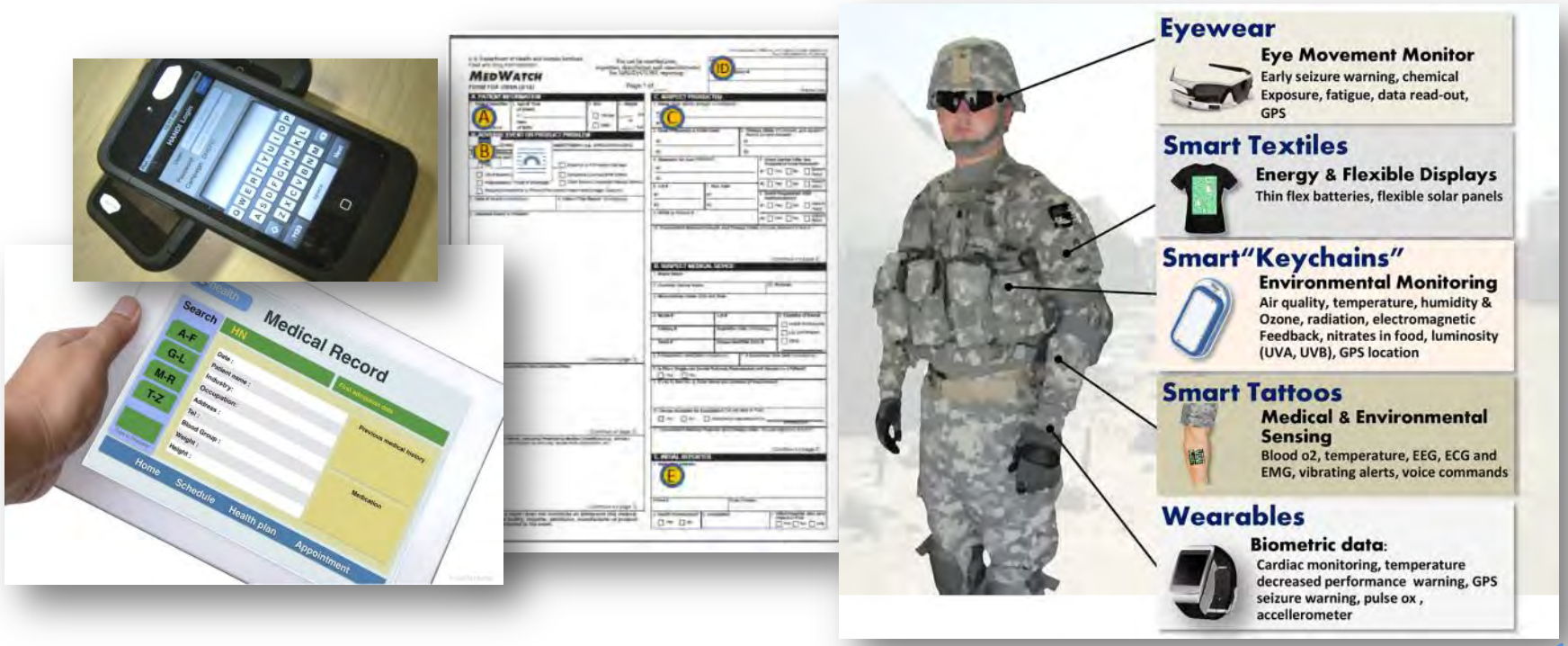
NEST

VAERS Vaccine Adverse Event Reporting System

Image courtesy of BARDA

What more can we do?

- EHR capabilities
- Handhelds
- Linking clinical trial networks
- Machine learning
- Social media / crowdsourcing
- “Smart” tech



Images left to right: CDC, CDC, FDA, ECBC

Our Charge

How do we leverage and coordinate all of this during a PHE response—our only opportunity to collect safety and efficacy data for MCMs?

Resources

- **MCM Monitoring and Assessment (new page)**
  - https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm561377.htm
- **FDA Medical Countermeasures Initiative (MCMi)**
  - https://www.fda.gov/medicalcountermeasures
- **Emergency Use Authorization of Medical Products and Related Authorities – Jan. 2017 Guidance**
  - https://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm
- **PAHPRA (Public Law 113-5)**
  - http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf
- **MCM emergency use authorities (EUA, etc.)**
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411432.htm

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