International Collaboration In Times of Public Health Crisis

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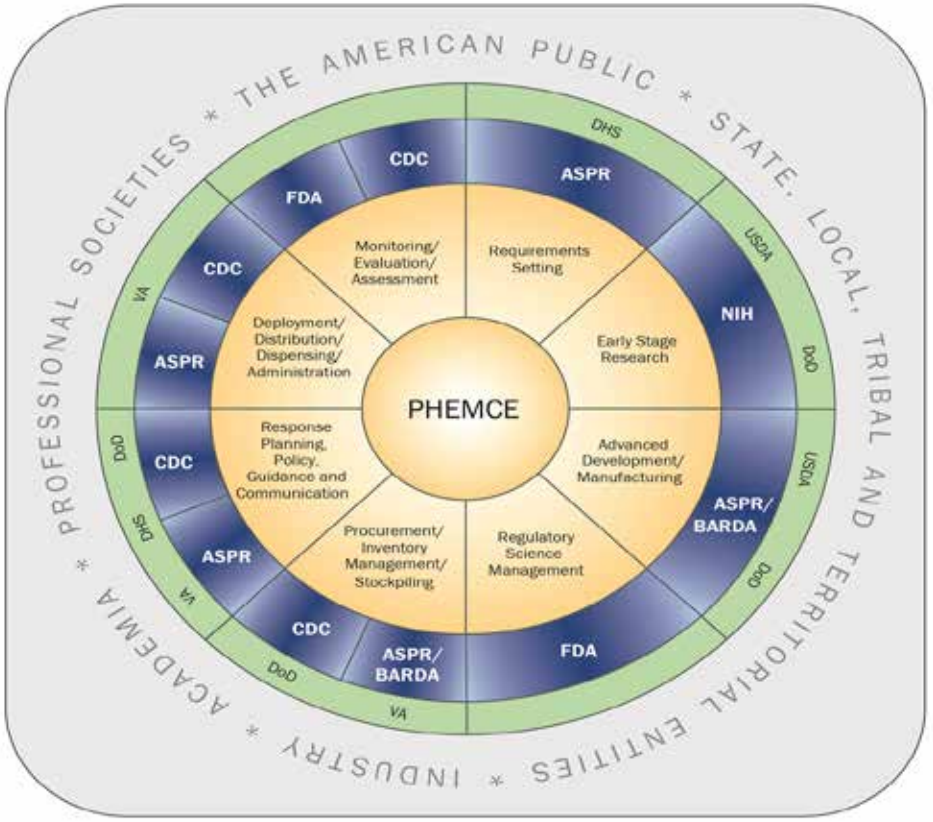
FDA's MCM Mission

- Facilitate the **development** of and **access** to safe and effective medical countermeasures (MCMs) to counter high-priority chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats (e.g., Zika, Ebola, pandemic influenza)

FDA's MCM Roles

- Facilitating development of MCMs; approving, licensing, clearing, and regulating MCMs
- Using legal mechanisms to prepare for and facilitate emergency use (e.g., EUAs, other emergency use authorities)
- Ensuring consumer protection against fraudulent claims; enforcing against misbranded and adulterated products
- Collaborating with domestic and international partners for preparedness and response
- Monitoring MCM use for adverse events (e.g., MedWatch, VAERS) to ensure safety and efficacy of FDA-regulated products

Public Health Emergency Medical Countermeasures Enterprise



Key

- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

Acronyms

PHEMCE: Public Health Emergency Medical Countermeasures Enterprise
DHS: Department of Homeland Security
DoD: Department of Defense
USDA: U.S. Department of Agriculture
VA: Department of Veterans Affairs
HHS: Department of Health and Human Services
ASPR: Assistant Secretary for Preparedness and Response
BARDA: Biomedical Advanced Research & Development Authority
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
NIH: National Institutes of Health

Stakeholders

Sharing Information

- Frequent communication and collaboration
  - Internal (FDA agency-wide)
  - HHS partners (BARDA, CDC, NIH/NIAID) and DoD
  - International (e.g., World Health Organization)

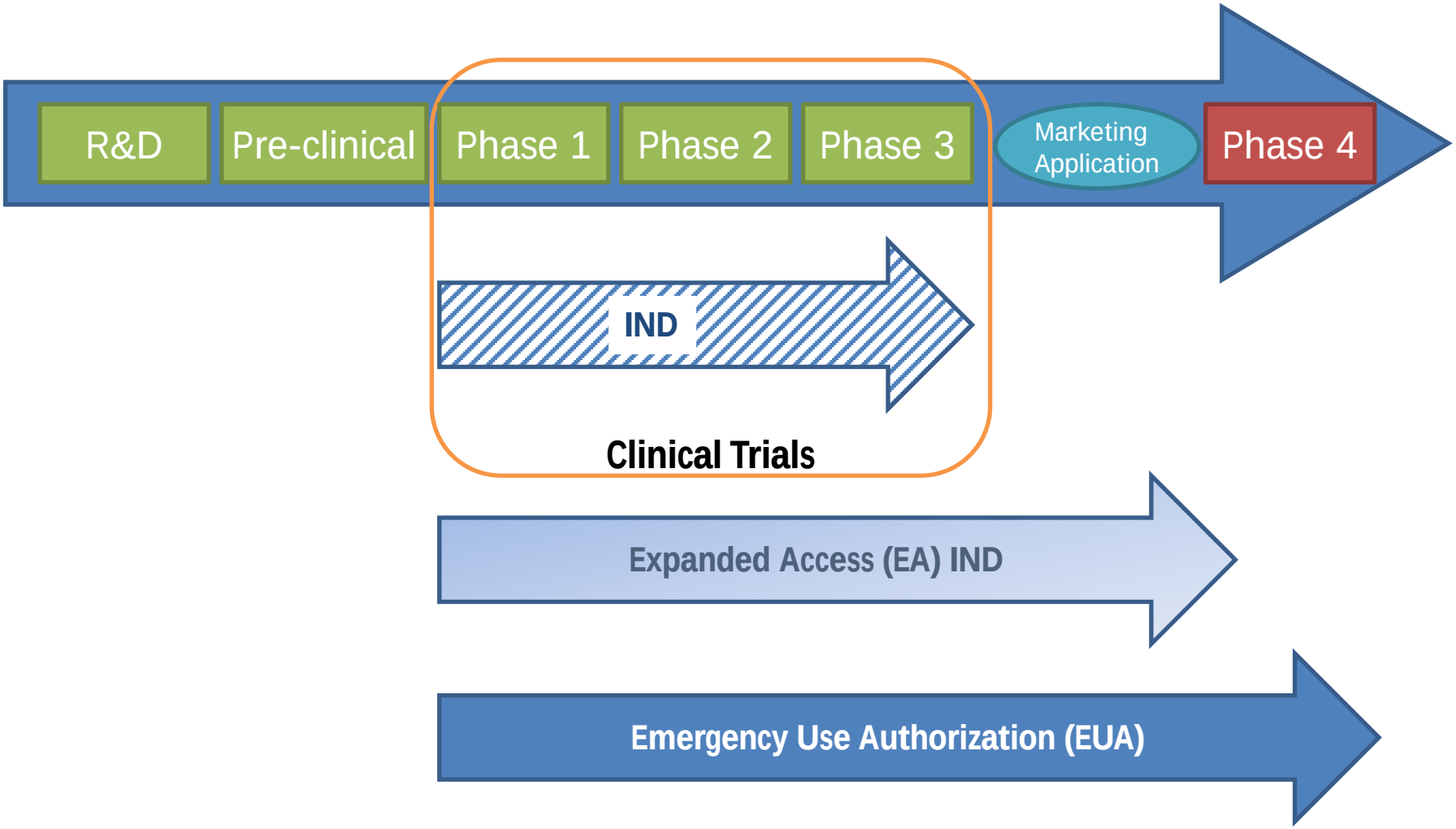
- Product sponsors (active communication)
  - Clarify regulatory requirements
  - Provide input on preclinical and clinical trial designs
  - Expedite review of regulatory data

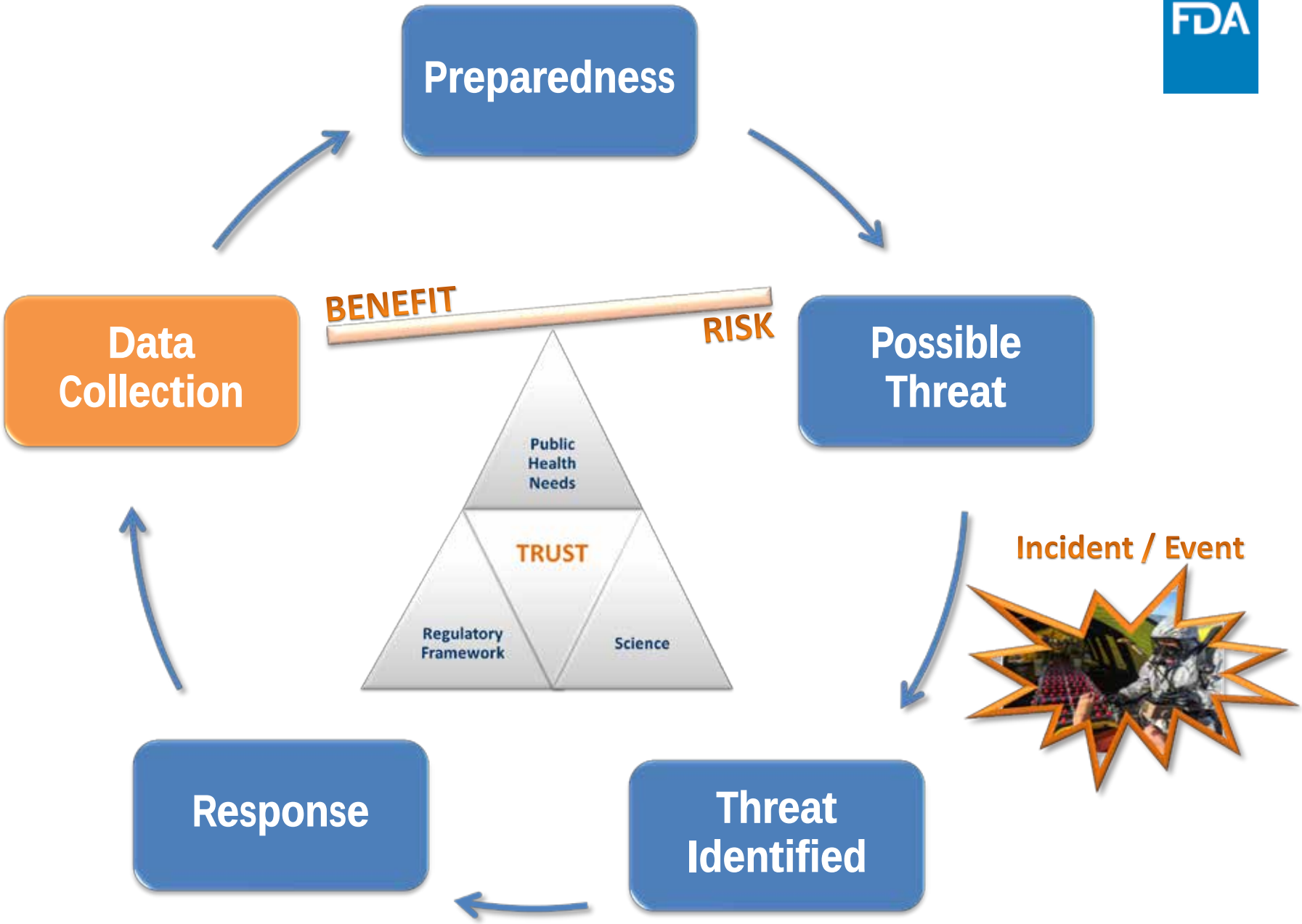
Ebola Epidemic: FDA's Role

- Sharing information about medical products in development
- Communicating our assessment of product readiness
- Clarifying regulatory pathways for development
- Protecting consumers

Help expedite development and availability of treatments, vaccines, diagnostics, PPE

Regulatory Mechanisms to Enable Access to Investigational Products




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

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