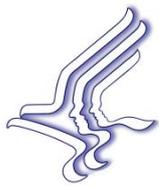




Emergency Use of Medical Countermeasures

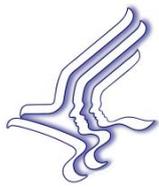
Debra A. Yeskey, Pharm. D.
Director, Regulatory & Quality Affairs Division
HHS/ASPR/BARDA



Mechanisms to use Medical Countermeasures



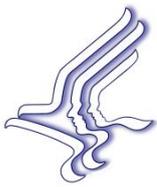
- **“Contingency Use” protocols under Investigational New Drug (IND)**
 - Same requirements as 21 CFR 312
- **Emergency IND: 21 CFR 312.36**
 - Requires IRB approval- 72 hours post use
 - Case by case basis
- **Emergency Use Authorization (EUA)**
 - Requires Declaration of Emergency



Contingency Use” IND Protocol

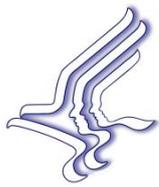


- **Purpose:**
 - An application for exemption from the Food, Drug, and Cosmetic Act
 - Permits distribution of a product during an investigational period
 - A mechanism to obtain safety and efficacy information
- **Requirements**
 - Sponsor Responsibilities
 - IRB approval
 - Informed Consent
 - Patient Parameters
 - Record Keeping
 - Follow-up



Emergency IND

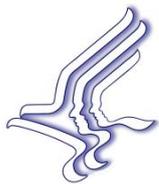
- **Purpose**
 - Exemption from FD&CA and allows distribution
 - Individual patient access for serious disease
 - Need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in accordance with 21 CFR 312.23 or 312.34
 - FDA may authorize shipment of the drug for a specified use in advance of submission of an IND
- **Requirements**
 - A request for such authorization may be transmitted to FDA by telephone or other rapid communication means
 - Provide 1572 and IRB approval within 72 hours of authorization
 - Record keeping



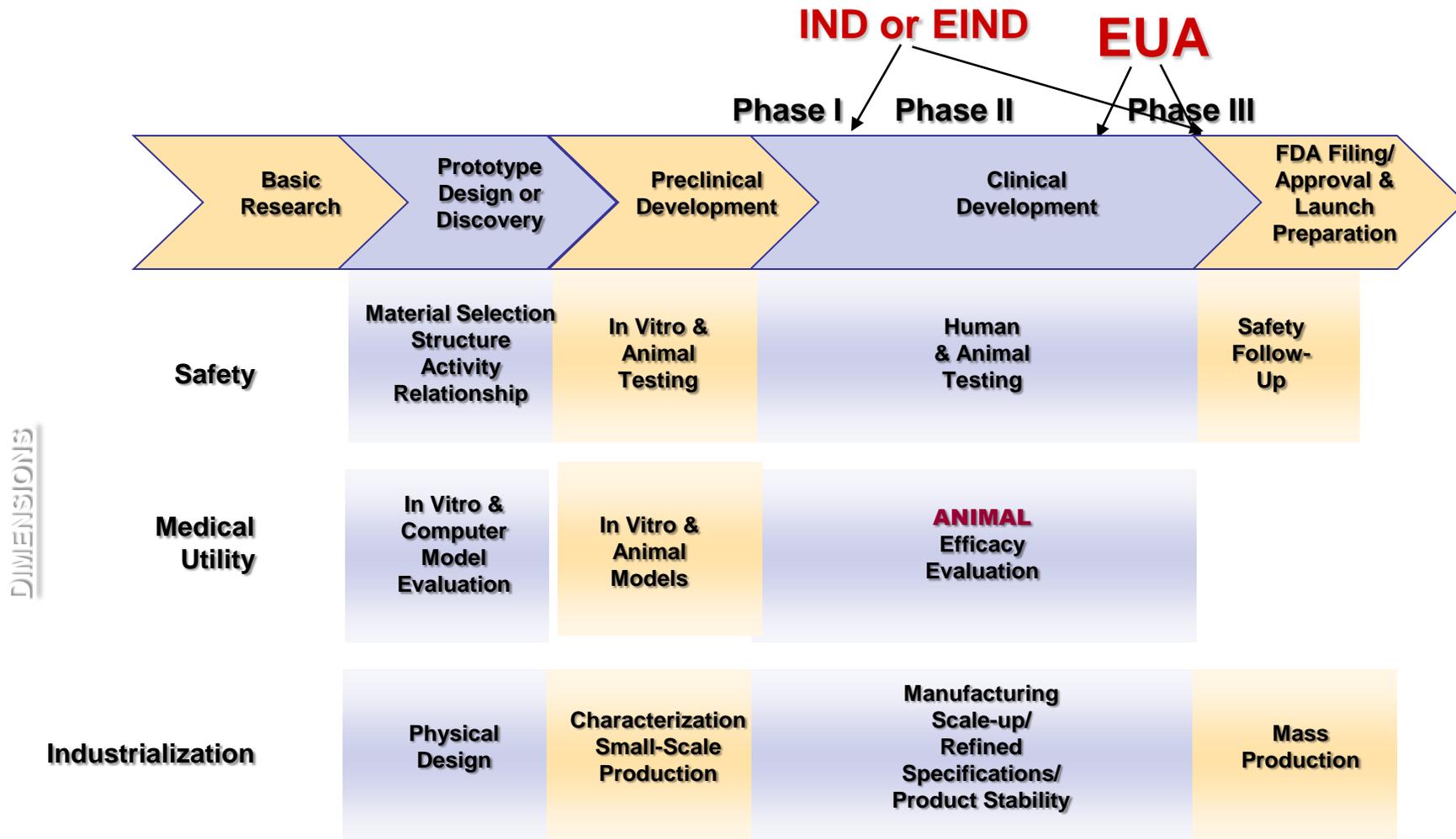
Emergency Use Authorization



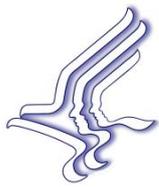
- **Purpose**
 - **Mechanism to use**
 - an unapproved product,
 - an approved product for an unapproved indication, or
 - an approved product with other circumstances
- **Requirements**
 - **Declaration of Emergency**
 - **Adequacy of the data – known and potential benefits must outweigh the known and potential risks**
 - **Information sheets for healthcare providers and recipients**
 - **Conditions of Authorization**



Emergency Use During Product Development



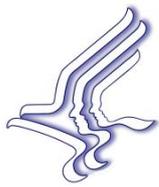
Adapted from the FDA Critical Path Report (March 2004)



Products Authorized for Use Under an EUA



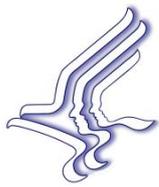
- **January 2005**
 - Department of Defense- AVA Vaccine- expired
- **October 2008- Currently Authorized**
 - Department of Health and Human Services/BARDA
 - Home Antibiotic Kits for USPS
- **April/May 2009- expired**
 - Department of Health and Human Services/Centers of Disease Control and Prevention
 - Antivirals
 - N-95 masks
 - PCR kits



Practical Aspects of a pre-EUA/EUA

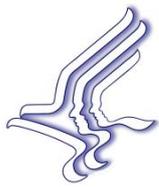


- USG will *likely* be the sponsor of any pre-EUA/EUA
- Formulating the “Request”
 - Cover letter
 - “Executive summary”
 - Fact sheets
 - Other documents requested
- Correspondence with FDA
- Conditions of Authorization
 - Clarity of Roles CDC, State and Local Public Health Authorities



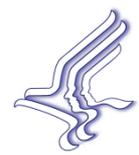
Logistics of an EUA

- **EUA route not a given**
 - Depends on data
 - Depends on the nature of the incident/emergency
- **MCMs in the Strategic National Stockpile**
 - EUAs typically held by CDC
- **Examples where BARDA holds the EUAs**
 - Home Antibiotic Kits for US Postal Service workers under the Cities Readiness Initiative (CRI) – Authorized October 3, 2008
 - EUA's to support the use of pre-pandemic vaccines
 - First Responder “medkit” (in conjunction with DHS)



Other EUA Considerations

- **An EUA is NOT a regulatory endpoint**
- **Do not assume that your regulatory development pathway will be easy with FDA because you have an MCM**
- **Sharing of data with the USG is critical to support use in an emergency...the USG will decide on the best regulatory mechanism for use...IND, EIND, and/or EUA**
- **Work closely with BARDA, CDC, and FDA on your alternative labeling strategy...take the comments from these entities seriously...this is not a slam dunk – it will require work on your part.**



United States Department of

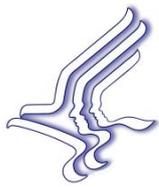
Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)



Thank you!

**Contact Information:
debra.yeskey@hhs.gov**



Interfacing with BARDA



- www.phe.gov
 - Program description, information, news, announcements
- www.medicalcountermeasures.gov
 - Portal to BARDA
 - Register, request a meeting
 - Tech Watch
- www.fedbizopps.gov
 - Official announcements and detailed information about all government contract solicitations

