

The header features a grid of hexagonal icons on a blue background. The icons include a white cross, a syringe, a pill, a person in a lab coat, a microscope, a brain, an eye, a heart, and a cell. The words 'SCIENCE' and 'MEDICAL' are written in white capital letters within some of the hexagons.

# BARDA INDUSTRY DAY

## Regulatory Considerations for MCM Development: Strategies and Challenges

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October 29-30, 2018 | Grand Hyatt • Washington, D.C.



# Agenda

- Expedited Programs
- Priority Review Voucher
- Development under Animal Rule



# Expedited Programs

| CENTER   | FAST TRACK | BREAKTHROUGH THERAPY/ DESIGNATION | ACCELERATED APPROVAL | PRIORITY REVIEW |
|--|------------|-----------------------------------|----------------------|-----------------|
|  <p><b>Center Biologics Evaluation &amp; Research</b></p>  | ✓          | ✓                                 | ✓                    | ✓               |
|  <p><b>Center for Drug Evaluation &amp; Research</b></p>   | ✓          | ✓                                 | ✓                    | ✓               |
|  <p><b>Center for Device &amp; Radiological Health</b></p> |            | ✓                                 |                      |                 |

# Expedited Programs - Drugs and Biologics



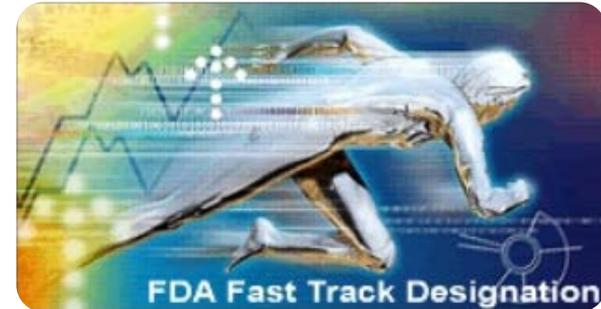
# Fast Track

## QUALIFYING CRITERIA

- Intend to treat a serious condition AND nonclinical or clinical data demonstrate the potential to address unmet medical need OR
- Designated as a qualified infectious disease product (QIDP)

## BENEFITS/FEATURES:

- Expedite development and review
- Rolling review



# Breakthrough Therapy

## QUALIFYING CRITERIA

- Intend to treat a serious condition, AND
- Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints

## BENEFITS/FEATURES:

- Intensive guidance on efficient drug development
- Organizational commitment
- Rolling review



# Accelerated Approval

## QUALIFYING CRITERIA

- Treat a serious condition AND,
- Provide meaningful advantage over available therapies AND
- Demonstrate effect on surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit

## BENEFITS/FEATURES:

- Based on an effect on surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict drug's clinical benefit



# Priority Review

## QUALIFYING CRITERIA

- To treat a serious condition AND, if approved, would provide a significant improvement in safety or effectiveness OR
- To propose a labeling change pursuant to a report on a pediatric study under 505A OR (supplements only)
- Designated as a qualified infectious disease product OR
- Submitted with a priority review voucher

## BENEFITS/FEATURES:

- Shorter review clock: 6 months versus 10 months compared with standard review



# Qualified Infectious Disease Product Granted for Tetraphase

- Xerava (eravacycline)
  - ✓ cIAI are serious life threatening infections requiring new antibiotics, QIDP designation was requested
  - ✓ QIDP granted
  - ✓ Granted Fast track designation
  - ✓ NDA Review cycle was 6 months



# Breakthrough Device Program

## QUALIFYING CRITERIA

- Provide for more effective treatment
- Represent breakthrough technology
- No approved or cleared alternative exists
- Offer significant advantages over existing approved or cleared alternatives
- Availability is in the best interest of patients
- Must be requested anytime prior to the submission of marketing application

## BENEFITS/FEATURES:

- Sprint discussions, Data Development Plans, Clinical Protocol Agreement, regular status updates
- FDA response is within 60 days



# Breakthrough Request Designation



- Spectral MD: DeepView for burn imaging
- Breakthrough Device program suggested by FDA
  - ✓ More effective treatment
  - ✓ Best interest of patients
- Request submitted and designation granted in less than 30 calendar days
  - Currently working on DDP
  - Have regular updates with FDA



# Priority Review Voucher

## QUALIFYING CRITERIA

- May be granted upon approval of a
- Medical countermeasure,
  - Pediatric rare disease therapeutic,
  - Eligible tropical disease therapeutic
  - Indication is to prevent or treat a PHEMCE identified CBRN threat
  - Therapeutic is eligible for priority review
  - Therapeutic is not previously approved
  - Only 1 PRV/application

## BENEFITS/FEATURES:

- Entitles the holder to have priority review on a NDA/BLA Application



# Priority Review Voucher Granted to SIGA

- Ticovirimat treats human smallpox disease
- ✓ Smallpox is on the PHEMCE list of Material Threats
- ✓ NDA review cycle was 5 months
- Priority review granted
- First approval for ticovirimat
- Priority Review Voucher awarded



**Placeholder for Andrea Powell  
(FDA speaker)**

# Resources for Industry

## Guidance for Industry

Expedited Programs for Serious Conditions – Drugs and Biologics  
May 2014

Material Threat Medical Countermeasure Priority Review Vouchers  
July 2018

Product Development Under the Animal Rule  
Oct 2015

## Guidance for Industry & FDA

Breakthrough Devices Program  
Draft Oct 2017



# QUESTIONS?

