

United States Department of

Health & Human Services

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



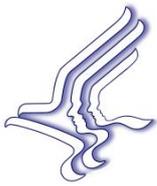
Regulatory Points to Consider For BARDA CBRN Diagnostics

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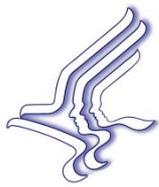
Regulatory and Quality Affairs (RQA) Division

HHS/ASPR/BARDA



Points to Consider

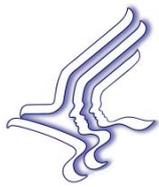
- 1. Regulatory Basics**
- 2. BARDA Medical Countermeasure Development Specifics**
- 3. FDA Interactions During The BARDA Contract**



Regulatory Basics: Two Critical Elements



- **Draft an Intended Use Statement...*Begin with the end in mind***
- **Develop a Regulatory Strategy...*Know where you are going***



Develop An Intended Use Statement

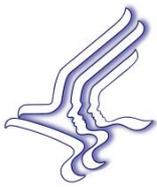


❖ Understand Regulatory Significance of Intended Use Statement

- **REGULATORY STRATEGY** – Draft your intended use statement early in the regulatory process. It helps define your path to ‘market’ and impacts decisions in strategy.
- **REGULATORY PATHWAY** – The level of FDA regulation of an IVD is influenced by the level of regulatory risk. This influences your regulatory pathway.

❖ Draft Intended Use Early in the Regulatory Process

- Define what you are working toward.
 - Apply sound scientific evidence in support of your Intended Use Statement.



Developing A Regulatory Strategy



Step One: Ask Questions About Your Device

- Device description? Intended Use? What data is necessary to support desired claims? Lifecycle issues? Plans for Manufacture and GMP compliance?

Step Two: Do Some Regulatory Information Gathering

- Gather regulatory information and available data. Evaluate what could impact your strategy.

Step Three: Create a Draft Strategy Document

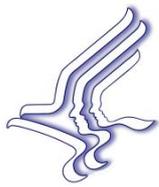
- Key elements of the document should be:
 - Defined objectives and potential regulatory pathway
 - Plans for preclinical testing and clinical investigations
 - Lay out a strategy for communicating with FDA

Step Four: Present and Confirm the Strategy

- Circulate the draft strategy document for input among the cross functional project team. This will provide feedback on if the strategy is sound and if it addresses objectives. Is it a reasonable and practical strategy?

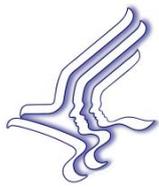
Step Five: Consider It a Living Document

- Set a schedule for periodic review of the Regulatory Strategy Document and update it as necessary to reflect current status of development.



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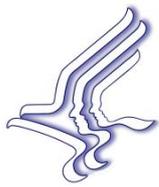
Regulatory in BARDA Product Development



- ❖ **Regulatory Expertise on the Project Team**

- ❖ **Regulatory Specifics in the Contract**

- ❖ **Emergency Use Authorization**
 - *Provide for data needs in strategy and in the contract*



Regulatory: Integral To The Project Team



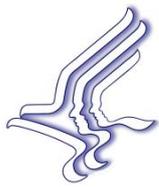
❖ The BARDA Team:

- Project Officer, Contracting, Program Management, SMEs, Regulatory

❖ The Sponsor Team: **Build Your Team Wisely**

- Have skilled regulatory team member(s) available from the outset.
- Build a strong regulatory foundation on your team and integrate into the development cycle.
 - Take time to develop and discuss team regulatory processes.
 - Establish ground rules for regulatory processes and communications within the project team.
 - Realize there are consequences of weak teams. Regulatory should not be an afterthought!

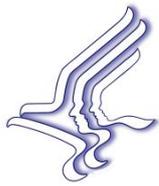
Smart allocation of regulatory resources can maximize probability of regulatory and programmatic success.



Regulatory in the Contract



- ❖ **Regulatory Strategy, FDA Interactions, Submissions**
- ❖ **Understand Document Requirements**
 - BARDA document review process
 - Consider mechanisms needed during all phases to assure appropriate levels of quality and compliance (SOPs, protocols, submissions, etc.)
- ❖ **EUA Elements for BARDA**
- ❖ **Compliance to Other Requirements**
 - Clinical Studies: OHRP Requirements and Federal Wide Assurance
 - Nonclinical Studies: Office of Animal Laboratory Welfare (OLAW) Assurance requirements
- ❖ **Subcontracts**
 - Regulatory components of subcontracts
 - Quality Agreements with subcontractors

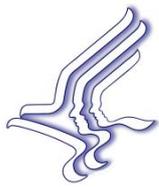


Emergency Use Authorization (EUA)



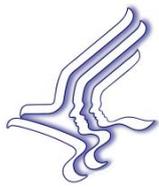
- ❖ **EUA is NOT a regulatory pathway to market**
- ❖ **Always refer to FDA Guidance and BARDA input for EUA**
- ❖ **BARDA expertise is available for navigating the EUA process**
- ❖ **Online course Emergency Use Authorization developed by FDA and CDC – A Great Resource**

<http://emergency.cdc.gov/training/eua/index.html>



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FDA Interactions During the Contract



❖ Novel Products

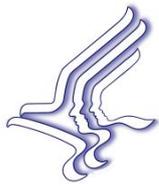
- Plan for early and frequent communication between BARDA, sponsor, and FDA

❖ Intended Use/Indications for Use

- Important for BARDA and required for discussions with FDA
- Influence on determination of regulatory pathway, study designs, and overall project management

❖ Pre-IDE Process and Regulatory Submissions

- Dealing with these as deliverables - Integrate this into your timeline for planned interactions with FDA.



THANK YOU!

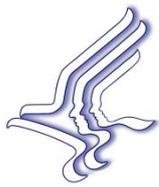
Remember, BARDA RQA is here to help!

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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

