Regulatory Points to Consider
For BARDA CBRN Diagnostics

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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](http://www.phe.gov)**
  – Program description, information, news, announcements

• **[www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)**
  – Portal to BARDA
  – Register, request a meeting
  – Tech Watch

• **[www.fedbizopps.gov](http://www.fedbizopps.gov)**
  – Official announcements and detailed information about all government contract solicitations