



MERS-CoV Regulatory Questions

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U.S. Food and Drug Administration
Medical Countermeasures Initiative





Disclaimers

- The views expressed in this presentation are those of the presenter and do not necessarily represent those of the U.S. Food and Drug Administration nor should they be interpreted as official Agency policy
- Product specific questions should be discussed with relevant medical product center review staff

Affiliation

- Office of Counterterrorism and Emerging Threats (OCET) is in the Office of the Chief Scientist under the Office of the Commissioner
- Mission of OCET
 - Facilitate the development and availability of safe and effective public health emergency medical countermeasures (MCMs)
 - Identify and resolve complex scientific and regulatory challenges facing MCM development, approval, availability, and security
 - Coordinate the Medical Countermeasures Initiative (MCMi)
 - Working closely with other FDA Offices and the Medical Product Centers

Regulatory challenges...not questions!

- Diagnostics
- Approval pathways
 - Randomized clinical trials (RCTs)
 - Animal Rule?

Diagnostic challenges

- Availability of clinical samples from patients with viremia
- Availability of reference standard panels for assay validation
- Ongoing commercial interest?

What we DO have: EUAs, review templates

EUA Diagnostics

- CDC Novel Coronavirus 2012 Real-time RT-PCR Assay
 - EUA issued 05 June 2013, reissued 10 June 2014
- RealStar MERS-CoV RT-PCR Kit U.S.
 - EUA issued 17 July 2015, reissued 12 February 2016

Potential Medical Product Approval Pathways

- RCTs
 - Robust, flexible
 - Rapidly pick ‘winners’
 - Decrease potential harm
- Animal Rule?
 - Only applicable if other approval pathways aren’t feasible or ethical
 - Need good animal models and human data for comparison

RCT for MERS-CoV

- Limited geographical distribution of disease
- Confounding patient factors
- Statistical challenges
 - Enrollment criteria
 - Appropriate controls
- What is the desired clinical endpoint?
 - Survival?
 - Time on ventilator?
 - pO₂?

Animal models

- Supportive or definitive?
 - At this point...probably supportive
 - Still critical for evaluating which products to move forward
- How well do the animal models recapitulate human disease?
 - Is there adequate clinical data to inform?
 - Endpoints (survival or major morbidity)
- Uncharted territory re: transgenic models

Universal Logistic Challenges?

- Assay development
 - Access to outbreak strains
 - Access to clinical samples
- Development of clinical trial networks
 - Prepositioning of protocols
 - Multiple study arms
- Import/export issues

Things to consider

- Phase 1 studies....commonality across all medical product approval pathways
- Incentives (orphan product, fast-track, priority review...)
- EVERYTHING IS ON THE TABLE, e.g. approval pathways open for discussion w/Agency



Thank you!

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