U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

February 13, 2019

A new approach for understanding Ebola virus pathogenesis

MCMi regulatory science update

In late 2018, FDA awarded a contract to the Broad Institute to conduct the largest Ebola virus and host gene expression study to date. Researchers will use the latest sequencing technologies to assess how Ebola virus evolves and spreads within the body.

This work will help fill significant gaps in the scientific community's understanding of how Ebola virus disease progresses at the molecular level, which will help identify biological pathways and mechanisms that could be useful biomarkers to assess the efficacy of Ebola medical countermeasures, or advance development of potential therapeutics.

Read more, in the new project profile

Related links:

- Ebola preparedness and response updates from FDA
- MCMi extramural research (including BAA information - also see below)

Funding deadline reminder

Submit BAA white papers for FY19 by March 29, 2019

Extramural MCM regulatory science is primarily funded through a Broad Agency Announcement (BAA) for research and development to support regulatory science and innovation, under area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security.

The current BAA announcement will remain open until further notice, but proposers are encouraged to submit white papers by **March 29, 2019** for current fiscal year (FY19) awards.

Electronic data standards for Animal Rule studies

Notice of upcoming comment periods and webinar

FDA has been working with the Critical Path Institute and the Clinical Data Interchange Standards Consortium (CDISC) to develop electronic data standards for the natural history and efficacy studies conducted in animals that support Animal Rule applications.

CDISC SENDIG-AR comment period
The draft Standard for Exchange Nonclinical Data (SEND) Implementation Guide for Animal Rule studies (SENDIG-AR) will be available for public review and comment on the CDISC website by **February 25, 2019**, with the comment period closing on **April 12, 2019**.

CDISC SENDIG-AR public webinar
A free webinar providing an overview of the SENDIG-AR is scheduled for **March 5, 2019, 11:00 a.m. – 12:30 p.m. (ET)**. **Register** by March 5, 2019.

Controlled terminology comment period
Critical to the development of data standards is the development of appropriate controlled terminology. A major portion of the controlled terminology associated with the new SENDIG-AR has already completed its public comment period. It is anticipated that the remaining portion of the controlled terminology will be posted for public review and comment from **March 22 – April 19, 2019**, at CT-P38-Link. (The preceding link will be activated on March 22, 2019, and will not work until that date.)

Events

- **New! February 28 - March 1, 2019:** Disaster Research Response (DR2) Tucson Workshop (Tucson, AZ), hosted by partners including the National Institute of Environmental Health Sciences (NIH), and the University of Arizona College of Medicine - Tucson. FDA representatives plan to attend. Registration will close **February 15, 2019**, or when capacity is reached.
- **New! March 6-7, 2019:** Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting (Silver Spring, MD and webcast) - Topics include discussion and recommendations on the selection of strains to be included in the influenza virus vaccines for the 2019 to 2020 influenza season.
- **New! March 14, 2019:** Webinar - The Least Burdensome Provisions: Concept and Principles Final Guidance, 1:00 - 2:30 p.m. ET. This final guidance describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to the regulation of medical devices.
- **New! March 26-29, 2019:** Preparedness Summit (St. Louis, MO) - Hosted by NACCHO; FDA is a sponsor. This year's theme is "Preparedness Summit 2019: The Evolving Threat Environment." *(fee)*

Information for industry

Devices

- FDA's Center for Devices Radiological Health (CDRH) Experiential Learning Program (ELP) is seeking sites to participate in 2019 training site visits. The 2019 Spring ELP submission period is open through **March 4, 2019 at 12:00 p.m. ET.**
- Guidance - The Least Burdensome Provisions: Concept and Principles (PDF, 483 KB) - Describes FDA's use of the least burdensome approach to medical device regulation to remove or reduce unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. FDA will host a webinar about this final guidance on **March 14, 2019, 1:00 - 2:30 p.m. ET**. *Also see FDA In Brief: FDA takes new steps to modernize the 'least burdensome' concept and principles applicable to its medical device regulatory framework to advance beneficial innovations to patients more efficiently while improving assurance of safety (February 4, 2019)*
- Guidance - Breakthrough Devices Program (PDF, 586 KB) - Describes policies that FDA intends to use to implement the new Breakthrough Devices Program, established by the 21st Century Cures Act. *Also see: Statement from FDA Commissioner Scott Gottlieb, M.D., and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on new steps to promote innovations in medical devices that help advance patient safety, and Breakthrough Devices Program (December 18, 2018)*
- Guidance - Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices (PDF, 438 KB) *Also see: FDA in Brief: FDA takes new steps to advance development of antimicrobial susceptibility test devices that help identify appropriate drug treatments for infections and reduce overuse of antibiotics (January 17, 2019)*

Drugs and biologics

- Guidance - Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway (PDF, 85KB) - To assist applicants in developing the Indications and Usage section of labeling for human prescription drug and biological products approved under the accelerated approval regulatory pathway, specifically indications for drugs approved via accelerated approval on the basis of a surrogate endpoint or a clinical endpoint other than survival or irreversible morbidity. *(January 23, 2019)*
- Draft guidance - S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines (PDF, 1.4 MB) This guidance, which was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), recommends international standards for the nonclinical safety studies recommended to support the development of pediatric medicines. Submit comments to FDA by **April 2, 2019.** *(January 23, 2019)*
- Guidance - Immunogenicity Testing of Therapeutic Protein Products--Developing and Validating Assays for Anti-Drug Antibody Detection (PDF, 372 KB) Provides recommendations to facilitate industry's development and validation of immune assays for assessment of the immunogenicity of therapeutic protein products during clinical trials. *(January 23, 2019)*
- FDA issued two guidances that aim to bring clarity to the assessment of risk evaluation and mitigation strategies (REMS) programs. These guidances, REMS Assessment: Planning and Reporting Guidance for Industry (PDF, 590 KB) (Federal Register notice) and Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry (PDF, 463 KB) (Federal Register notice) will assist sponsors in assessing the effectiveness of REMS programs. Comment by **April 2, 2019** using the Federal Register notice links for each draft guidance. *Also see: FDA statement from Commissioner Scott Gottlieb, M.D. announcing efforts to improve the quality of the information used to assess the effectiveness of REMS programs in supporting the safe use of medications (January 24, 2019)*

Combination products

- Draft guidance - Principles of Premarket Pathways for Combination Products - Presents the current thinking of the FDA on principles for premarket review of combination products, including how to determine which type of premarket submission is appropriate, including new drug applications or abbreviated new drug applications for drug-led combination products; stand-alone or biosimilar biologics license applications for biologic-led combination products, and 510(k), De Novo or premarket approval applications for device-led combination products. Comment by **May 7, 2019**. *Also see: FDA in Brief: To advance efficient development and review of combination products, the FDA outlines principles to promote a more predictable premarket review pathway (February 5, 2019)*

Research

- FDA is extending the comment period for the proposed rule Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations that appeared in the Federal Register of November 15, 2018. FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit comments. Comments on the proposed rule may be submitted at https://www.regulations.gov (Docket No. FDA-2018-N-2727) and are now due by **February 13, 2019**. *Also see: FDA In Brief: FDA takes steps to allow greater flexibility for clinical investigators about informed consent in minimal risk situations (December 19, 2018)*

More: MCM-Related Guidance by Date

In case you missed it

- FDA issued the Sentinel System Five-Year Strategy: 2019-2023 (PDF, 1.7 MB). This plan lays out the major goals associated with the future of the Sentinel System and FDA Catalyst. It is intended to serve as a roadmap to guide the development of Sentinel over the next five years. *(January 9, 2019)*
- The National Association of County and City Health Officials (NACCHO) and the U.S. Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) are accepting applications for the fourth annual National Health Security Award. This award recognizes local health departments that have demonstrated significant accomplishments in implementing health security-related initiatives within their jurisdictions. Apply by **April 26, 2019**.
- From HHS - ASPR has released an updated quadrennial strategy to safeguard the nation's health in times of crisis. The 2019-2022 National Health Security Strategy (NHSS) provides a vision to strengthen the nation's ability to prevent, detect, assess, prepare for, mitigate, respond to, and recover from disasters and emergencies. It includes strategies to improve readiness and adapt operational capabilities to address evolving threats such as the use of chemical, biological, radiological, and nuclear (CBRN) weapons; cyber warfare; emerging infectious diseases that could lead to a pandemic; and catastrophic natural disasters and human-caused incidents. *Also see: National Health Security Strategy Overview (January 15, 2019)*
- From NIH - Investigational monoclonal antibody to treat Ebola is safe in adults - The investigational Ebola treatment mAb114 is safe, well-tolerated, and easy to administer, according to findings from an early-stage clinical trial published in *The Lancet*. *(January 24, 2019)*
- You want to make a difference. FDA wants to hire you. Follow @FDAJobs on Twitter, or visit www.fda.gov/jobs.

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