U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

February 28, 2018

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FDA funding opportunity

Broad Agency Announcement (BAA) to support regulatory science and innovation

In February 2018, FDA revised its BAA for research and development to support regulatory science and innovation. Medical countermeasure (MCM)-related research submissions are encouraged under area 7: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health Security.

The current BAA announcement will remain open until further notice, but proposers are encouraged to submit white papers by **March 30, 2018** for current fiscal year awards.

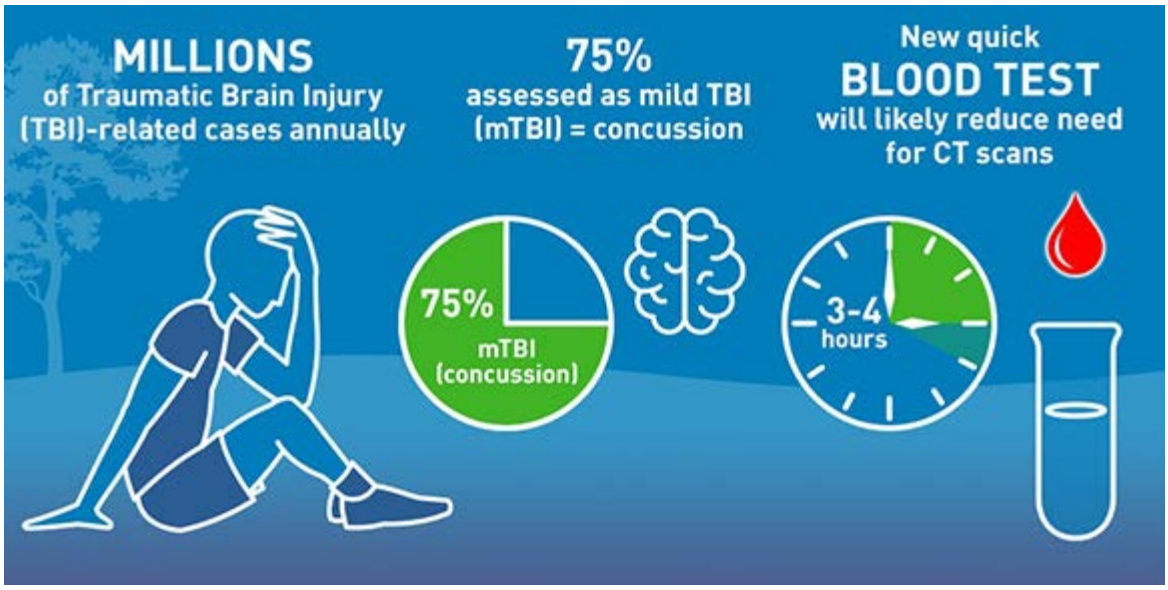
Related links:

- Full BAA PDF (339 KB) - MCM research areas of interest begin on page 19
- MCM-related extramural research from FDA, including current BAA projects
- More MCM-related funding (under Funding opportunities and challenge information)

Image: U.S. Public Health Service officers celebrate as a Liberian man adds his handprint to a "survivors' wall." Each patient who overcame Ebola after treatment at the USPHS mobile hospital outside Monrovia was given a set of clothes and essentials and invited to mark their recovery with a handprint. (Photo: FDA) An FDA BAA project conducted by Stanford University, with U.S. and international collaborations, will help the global scientific community better understand the course of Ebola and Zika virus infections--an important factor in finding new treatments.

Quick concussion blood test

FDA worked closely with the Department of Defense to permit marketing of a quick concussion blood test for adults that can be used by both the American public and U.S. laboratories at home and abroad servicing our Nation's military personnel.

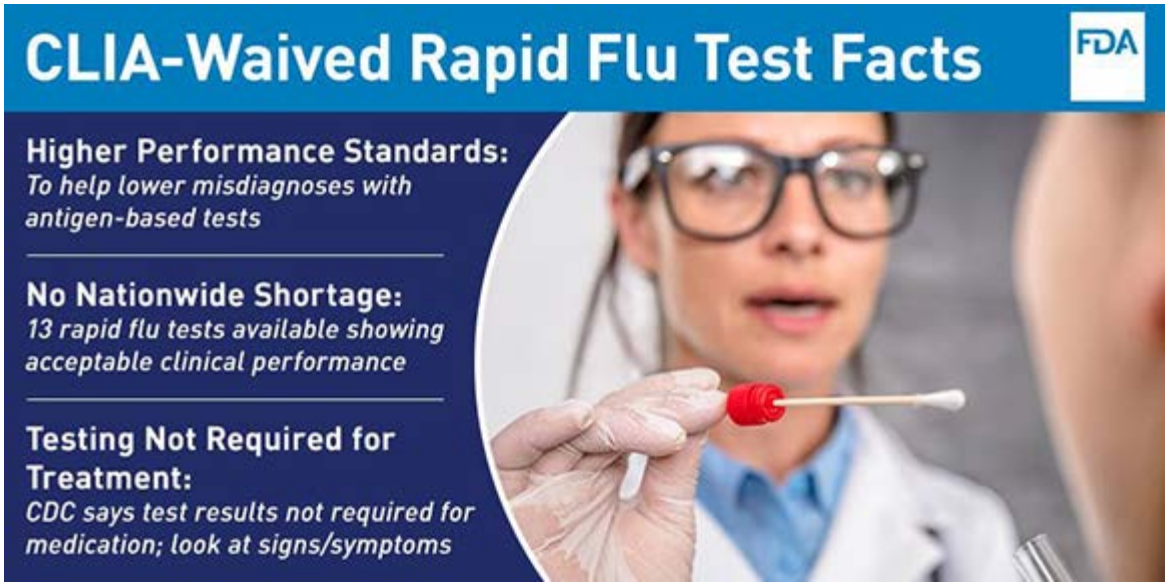


Related links:

- Traumatic Brain Injury: FDA Actions and Research (Consumer Update)
- Biomarkers for Brain Injury Monitoring, an MCMi regulatory science profile
- FDA/DoD work plan (joint program to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel, launched January 2018)

Rapid influenza tests

With higher performance standards, FDA helps lower misdiagnoses with antigen-based rapid flu tests during this year's flu season. Fact sheet (PDF, 112 KB)



Also in flu news, FDA Commissioner Scott Gottlieb, MD, made a **statement on FDA's ongoing efforts to help improve effectiveness of influenza vaccines**. FDA is collaborating with the Centers for Medicare and Medicaid Services (CMS) to use a large database that includes details of the flu vaccines administered to four million individuals along with whether they were hospitalized for influenza or treated with antiviral medications for influenza-like illness. This work, which is still underway, will try to better understand why overall effectiveness with both the cell-based and egg-based vaccines was less than optimal. *(February 26, 2018)*

Events

- New! **March 1, 2018:** Vaccines and Related Biological Products Advisory Committee meeting (Silver Spring, MD) - the committee will meet in open session on topics including selection of strains to be included in the influenza virus vaccines for the 2018-2019 influenza season
- **March 8, 2018:** FDA Grand Rounds webcast - Are Stem Cells Ready for Prime Time? A Look at FDA Research Advances in Regenerative Medicine, 12:00 - 1:00 p.m. ET, presented by Steven Bauer, PhD, Chief, Cellular and Tissue Therapy, Division of Cellular and Gene Therapies, CBER
- New! **March 13, 2018:** Webinar for healthcare professionals - FDA's MedWatch Adverse Reporting Program – Opportunities to Collaborate, 1:00 p.m. ET - advance registration required
- **March 19, 2018:** Public workshop - Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data (Silver Spring, MD and webcast) - register by **March 12, 2018** - *Also see Plan for Issuance of Patient-Focused Drug Development Guidance (PDF, 146 KB)*
- New! **March 19, 2018:** Public workshop - Utilizing Innovative Statistical Methods and Trial Designs in Rare Disease Settings (Silver Spring, MD and webcast) Advance registration required. To view the webcast, register before **5:00 p.m. ET March 18, 2018**.
- New! **March 20, 2018:** Promoting the Use of Complex Innovative Designs (CID) in Clinical Trials public meeting (Silver Spring, MD and webcast) - to (1) facilitate discussion and information sharing about the use of CID in drug development and regulatory decision making and (2) obtain input from stakeholders about the CID pilot program. To attend in-person, register by **March 13, 2018**.
- New! **March 22, 2018:** Patient Engagement in the National Evaluation System for Health Technology (NEST): Lessons Learned and Best Practices (Baltimore, MD), hosted by the University of Maryland and FDA - The workshop will gather lessons learned and best practices for patient engagement in evidence generation (e.g., planning, collection of data and information, analysis, and dissemination).
- **April 16, 2018:** Evaluating Inclusion and Exclusion Criteria in Clinical Trials (Washington, DC and webcast) - register by **April 12, 2018**
- **April 17-20, 2018:** Preparedness Summit (Atlanta, GA) - The theme for the conference is Strengthening National Health Security: Mastering Ordinary Responses, Building Resilience for Extraordinary Events. Registration is now open. *(fee)*
- **April 23-27, 2018:** Achieving Data Quality and Integrity in Maximum Containment Laboratories course (Bethesda, MD) - **Last chance to attend: register by March 2, 2018 (deadline extended)**.

Information for industry

- Today is Rare Disease Day! FDA is taking new steps to meet the challenges of rare diseases. FDA is taking several new actions as part of our ongoing commitment to support and expedite development of rare disease products, including a new pilot for more efficient orphan designation requests, with a new **fillable form** (PDF, 3.1 MB) that will make the submission process easier for sponsors to complete designation requests, and make it more efficient for FDA to review. We have also launched a new **online tutorial** to guide sponsors through the orphan designation process. *Also see Rare Disease Day 2018 (February 28, 2018)*
- FDA updates regulations to better define when studies run outside U.S. can support U.S. regulatory

device submissions; and to improve data quality, integrity, and ensure patient safety - The new rule requires that sponsors and applicants provide statements and information about how the investigations conform with good clinical practices (GCP). *Also see: Final Rule: Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices, and Guidance for Industry and FDA staff: Acceptance of Clinical Data to Support Medical Device Applications and Submissions Frequently Asked Questions (PDF, 115 KB) (February 21, 2018)*

- FDA invites pharmaceutical companies interested in participating in the Regulatory Project Management Site Tours and Regulatory Interaction Program to send proposed agendas to CDER by **April 13, 2018**.
- FDA calls on the food safety and infectious diseases communities to help improve bioinformatics pipelines for detecting pathogens in samples sequenced using metagenomics by launching the precisionFDA CFSAN Pathogen Detection Challenge, February - April 2018.
- Reminder: Comment by **March 20, 2018** on draft guidance Material Threat Medical Countermeasure Priority Review Vouchers (PDF, 174 KB) *Also see: FDA takes steps to spur development of medical countermeasures needed to protect, prepare for emerging threats to public health and national security and 21st Century Cures Act: MCM-Related Cures Provisions*

More: MCM-Related Guidance by Date

In case you missed it

- A gut reaction…on a chip - First study of radiation exposure in human gut organ chip device offers hope for better radioprotective drugs, from Wyss Institute - *Also see Organs-On-Chips for Radiation Countermeasures and Modeling radiation injury-induced cell death and countermeasure drug responses in a human Gut-on-a-Chip (February 14, 2018)*
- Slides are now available from 2018 presentations on FDA roles in supporting the emergency use of MCMs.
- The FDA Center for Food Safety and Applied Nutrition (CFSAN) has transformed its Education Resource Library into a catalog of nearly 300 publications and videos covering food safety, nutrition, cosmetic safety, dietary supplements, and industry information, including food defense. *(February 22, 2018)*

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