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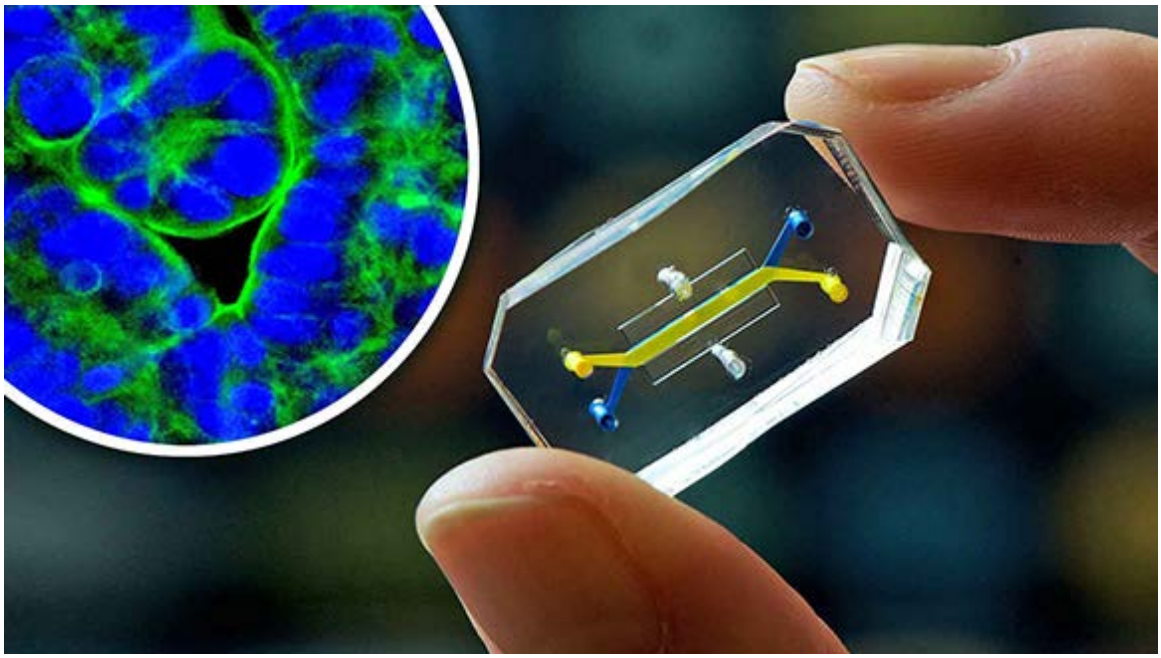
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

December 4, 2019



Human organ chips for radiation countermeasure development

MCMi regulatory science update

Acute radiation syndrome (ARS) is an illness affecting a combination of organs that occurs when the body receives a high dose of radiation over a short period of time, as could occur after a nuclear or radiological incident. The U.S. government has identified a need for safe and effective radiation medical countermeasures (MCMs) for military and civilian applications, as well as to mitigate toxicities associated with medical radiotherapies.

Although animal models are currently used for assessing efficacy of radiation MCMs, they often do not accurately predict clinical outcome in humans. In addition, certain candidate MCMs cannot be effectively studied in animal models because their activity is specific to humans. Thus, there is a crucial need for more predictive *in vitro* models of the effects of ionizing radiation on human tissue and organ function. Closing such knowledge gaps to further MCM development and availability is a key goal of the MCMi Regulatory

Science Program.

In a new MCMi regulatory science project, the Wyss Institute for Biologically Inspired Engineering will build on past FDA-funded work that led to the development of human models of ARS in bone marrow, intestine, and lung organs-on-chips and the application of these tools to the evaluation of ARS MCMs.

Read more about this project

Image: The Wyss Institute's gut-on-a-chip constricts and relaxes, just as in the human body, producing finger-like projections called villi, shown at left. (Credit: Wyss Institute at Harvard University)

Related links:

- MCMi Extramural Research
- Radiological and Nuclear Emergency Preparedness Information from FDA
- Acute Radiation Syndrome (ARS): A Fact Sheet for the Public (CDC)
- Human Organs-on-Chips (Wyss Institute)
- Investigating the human intestinal mucus barrier up-close and personal (Wyss Institute)

Events

- **December 5-6, 2019:** Repurposing Off-Patent Drugs: Research & Regulatory Challenges (Rockville, MD) - Hosted by FDA, the U.S. National Institutes of Health (NIH), and the Reagan-Udall Foundation for the FDA, this workshop will explore opportunities and challenges in assessing the safety and efficacy of repurposed drugs; patient experiences; and potential strategies to prioritize certain drugs and diseases for repurposing.
- **New! January 28-30, 2020:** ASM Biothreats (Arlington, VA) - Hosted by the American Society for Microbiology, to offer professionals in biodefense, biosecurity, and biological threats the opportunity to exchange knowledge and ideas, and explore the latest developments and emerging technologies. *(fee)*
- **New! February 25-26, 2020:** Public Workshop - Evolving Role of Artificial Intelligence in Radiological Imaging (Bethesda, MD and webcast) - Through this workshop, FDA is seeking to engage with stakeholders to explore benefits and risks of evolving applications of artificial intelligence (AI) in radiology. Register by **4:00 p.m. ET February 12, 2020**.
- **New! March 3, 2020:** Public workshop - Facilitating End-to-End Development of Individualized Therapeutics (Silver Spring, MD and webcast) - To foster development of individualized therapeutic products for the treatment of one individual or a very small number of patients, based on engineering a product aimed at the specific molecular mechanism underlying a patient's (or small group of patients') illness. To attend in person, register by **February 18, 2020**.
- **New! March 18-19, 2020:** Joint Civil & DoD CBRN Symposium (Alexandria, VA) - Hosted by the Defense Strategies Institute, to provide a forum for CBRN stakeholders to discuss the latest updates in advancing a government-wide approach to improving CBRN defense, readiness and response strategies and capabilities. (*fee)*

- **New! March 31 - April 3, 2020:** Preparedness Summit (Dallas, TX) - Hosted by the National Association of County & City Health Officials (NACCHO), the Summit offers a unique learning and networking opportunity for current and aspiring emergency management, public health, and healthcare professionals, and their partners, to share perspectives and engage in dialogue on key public health preparedness and response issues. *(fee)*

Information for health care providers and emergency responders

- On November 26, 2019, FDA alerted health care providers and emergency responders of expiration date extension updates for certain auto-injector products manufactured by Meridian Medical Technologies (MMT). This posting and FDA's November 18, 2019, memorandum (PDF, 230 KB) provide expiration dating updates for health care professionals and emergency responders for certain lots of MMT AtroPen (atropine), CANA (diazepam), DuoDote, Morphine Sulfate, and Pralidoxime Chloride auto-injectors for use during nerve agent emergencies. This posting and memorandum replace FDA's March 23, 2018, posting and all previous FDA web postings and memoranda notifying health care professionals and emergency responders about the expiration dating of such auto-injectors. Please refer to the table on this page for the new updates. *More about Expiration Dating Extension*

Information for industry

- Final guidance - Adaptive Design Clinical Trials for Drugs and Biologics - Adaptive design clinical trials allow for prospectively planned modifications to one or more aspects of the design based on accumulating data from subjects in the trial. The guidance provides information to sponsors submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics licensing applications (BLAs), or supplemental applications on the appropriate use of adaptive designs for clinical trials to provide evidence of the effectiveness and safety of a drug or biologic. The guidance also advises sponsors on the types of information to submit to facilitate FDA evaluation of clinical trials with adaptive designs, including Bayesian adaptive and complex trials that rely on computer simulations for their design. *(November 29, 2019)*

In case you missed it

- Publication - FDA Zika virus reference panel for molecular-based diagnostic devices supports product testing for Emergency Use Authorization and 510(k) submissions - read the full publication in *The Journal of Molecular Diagnostics* *(November 25, 2019)*
- Remarks by FDA Deputy Commissioner for Policy, Legislation, and International Affairs Anna Abram to the Biocom Celebration of Life Dinner - includes information about medical countermeasures and antimicrobial resistance, among other topics *(November 21, 2019)*

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