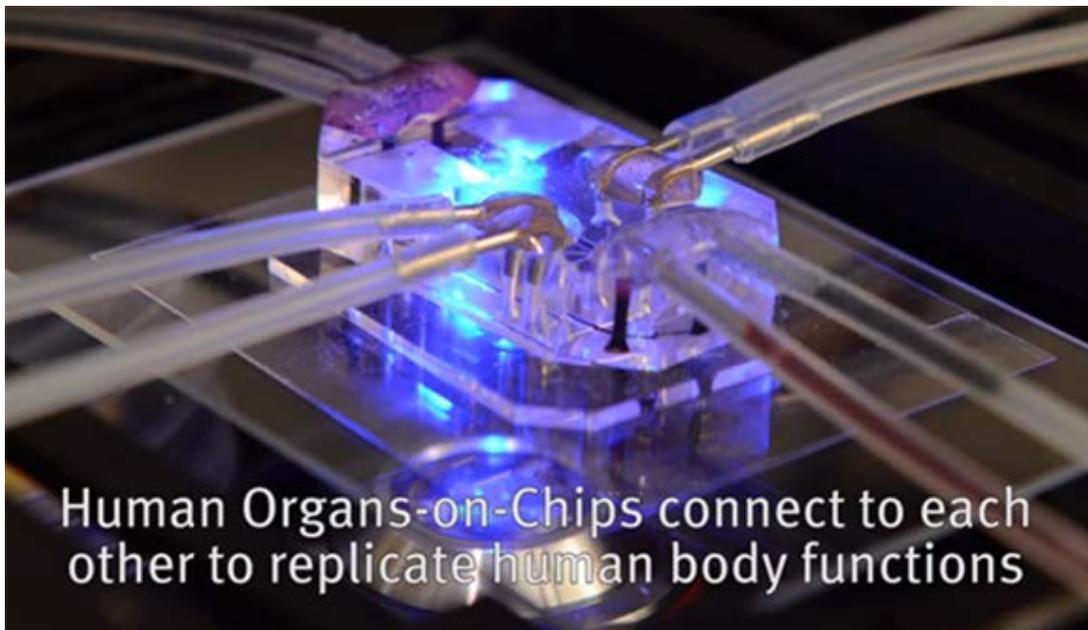


October 17, 2018

## MCM regulatory science news

### FDA expands study to analyze differences in sex-specific responses to radiation



Organs-on-chips mimic the structure, function, and interactions between living tissues within human organs – such as the lung or intestine – on chips the size of a thumb drive. Scientists can use these chips for drug research, including supporting development of medical countermeasures (MCMs).

Under an FDA contract awarded in 2013 to support development of MCMs to treat acute radiation syndrome ([ARS](#)), Harvard University's Wyss Institute for Biologically Inspired Engineering demonstrated that its bone marrow chip produces human red and white blood cells for up to one month in culture. The chip also faithfully mimics human bone marrow responses to ionizing radiation as well as effects of known chemotherapies and radiation countermeasure drugs.

Because scientific evidence indicates that sex differences may play a major role in how bone marrow responds to radiation, FDA's [Office of Women's Health](#) and Medical Countermeasures Initiative (MCMi) have awarded a follow-on study to this project to enable the Wyss team to create male and female human bone marrow chips to analyze differences in sex-specific responses to ionizing radiation and a chemotherapeutic drug.

[Read more about this project](#)

Image: Human Organs-on-Chips connect to each other to replicate human body functions. Image of organ-chip, courtesy Wyss Institute.

#### Related links:

- [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
- [Organs-On-Chips Technology Infographic](#) (PDF, 389 KB) - Information about organs-on-chips research from FDA's Center for Food Safety and Applied Nutrition
- [Radiological and Nuclear Emergency Preparedness Information from FDA](#)

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## FDA and NASA sign agreement

FDA and the National Aeronautics And Space Administration (NASA) have signed a [Memorandum of Understanding](#) to provide mutual support to biomedical research on drugs, biologics, and medical devices, and for medical countermeasure development.

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#### Events

- **October 22, 2018:** [Science Board to the FDA public meeting](#) (Silver Spring, MD and webcast) - The [Science Board](#) will hear a response from the Center for Veterinary Medicine (CVM) to the recommendations made by the Science Board's 2017 review of CVM's [National Antimicrobial Resistance Monitoring System](#) program. The Science Board will also discuss potential hazards and nutritional considerations in the production of food derived from animal cell culture technologies.
- **New! October 22, 2018:** [The Keys to Success in Clinical Research: Becoming a Trusted Entity in Diverse Communities is the Key to Success in Clinical Research](#) webinar, 2:00 - 3:00 p.m. ET, presented by Dr. Fabian Sandoval, and hosted by the FDA Office of Minority Health - Dr. Sandoval will present on strategies to increase Hispanic enrollment in clinical trials. CE credits available for physicians, pharmacists, and nurses. Please register in advance.
- **New! October 23-24, 2018:** [FDA & MHRA Good Clinical Practice Workshop: Data Integrity in Global Clinical Trials – Are We There Yet?](#) (Silver Spring, MD and webcast) - This workshop will provide FDA Center for Drug Evaluation and Research (CDER) and Medicines and Healthcare products Regulatory Agency UK (MHRA) perspectives on the importance of quality management practices on data reliability. Early registration is recommended due to limited seating.
- **October 29-30, 2018:** [BARDA Industry Day](#) (Washington, DC) - Engage and network with members of BARDA, ASPR and other government and industry stakeholders. [Register](#) by **October 19, 2018**.
- **New! November 8, 2018:** [Vaccines and Related Biological Products Advisory Committee meeting](#) (Silver Spring, MD and webcast) - The Committee will meet in open session to hear an overview of the research program in the Laboratory of DNA Viruses (LDV), Division of Viral Products (DVP), Office of Vaccines Research and Review (OVR), CBER, FDA.
- **New! November 8, 2018:** [Webinar - Special 510\(k\) Program Pilot](#), 3:00 - 4:30 p.m. ET - *See Information for industry below for additional details*
- **November 13-15, 2018:** [Clinical Investigator Training Course](#) (Silver Spring, MD) - Experts from FDA, the University of Maryland, and the University of Pennsylvania will provide training in all aspects of clinical studies: preclinical and clinical science, statistical structure of trials, ethical requirements, and regulatory considerations. Registration closes on **November 6, 2018**, or when registration is full.
- **November 27, 2018:** [Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions public meeting](#) (Washington, DC and webcast) - This meeting will give stakeholders the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. To attend in-person, [register](#) by **November 21, 2018**.

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## Information for industry

- **RFI (reminder):** [Development of New Antibacterial Drugs Active Against Multi-Drug Resistant Bacteria](#) - The FDA Center for Drug Evaluation and Research (CDER) [Office of Antimicrobial Products](#) issued a Request for Information (RFI) on September 11, 2018, to solicit informal input from the public and private sectors to obtain external input into developing an annual list of regulatory science initiatives specific for antimicrobial products. Respond by **October 31, 2018**.
- Draft guidance - [Adaptive Design for Clinical Trials of Drugs and Biologics](#) (PDF, 623 KB) - To help sponsors of investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), or supplemental applications develop appropriate adaptive clinical trial designs to support the effectiveness and safety of a drug or biologic. [Comment](#) by **November 30, 2018**. (September 28, 2018)
- FDA [launched the Special 510\(k\) Program Pilot](#), which aims to simplify how manufacturers submit certain 510(k)s. The program pilot allows the FDA and industry to test an expansion to the Special 510(k) Program. The goal of the pilot is to determine whether updated factors for eligibility in the Special 510(k) Program will improve the FDA staff's efficiency in reviewing 510(k) submissions. The FDA would like to increase the number of 510(k) submissions that are appropriate for the Special 510(k) Program. All Special 510(k)s received on or after October 1, 2018 will be included in the program pilot. [Comment](#) on the draft guidance [The Special 510\(k\) Program](#) (PDF, 697 KB) by **November 27, 2018**. On November 8, 2018, FDA will host a [webinar](#) about this pilot. (October 1, 2018)
- [Guidance for Sponsors, Investigators, and Institutional Review Boards: Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations](#) (PDF, 95 KB) - Revisions to HHS' Federal Policy for Protection of Human Research Subjects (45 CFR 46, Subpart A) have created certain differences between FDA's human subject regulations and HHS' human subject regulations. While FDA intends to undertake rulemaking to harmonize, to the extent practicable and consistent with other statutory provisions, its regulations with the 2018 Requirements consistent with Section 3023 of the 21st Century Cures Act, we recognize the potential for confusion in the interim for sponsors, investigators, and IRBs who are involved in both HHS-regulated research and FDA-regulated clinical investigations. This guidance is intended to clarify the impact of certain provisions of the 2018 Requirements on FDA-regulated clinical investigations. (October 12, 2018)
- Draft guidance - [Rare Diseases: Early Drug Development and the Role of Pre-Investigational New Drug Application Meetings](#) (PDF, 132 KB), to assist sponsors of drug and biological products for the treatment of rare diseases in planning and conducting more efficient and productive pre-investigational new drug application (pre-IND) meetings. [Comment](#) by **December 17, 2018**. (October 16, 2018)

**More:** [MCM-Related Guidance by Date](#)

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## In case you missed it

- [FDA approves a new antibacterial drug to treat a serious lung disease using a novel pathway to spur innovation](#) - FDA approved a new drug, Arikayce (amikacin liposome inhalation suspension), for the treatment of lung disease caused by a group of bacteria, Mycobacterium avium complex (MAC) in a limited population of patients with the disease who do not respond to conventional treatment (refractory disease). This was the first drug granted approval under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, instituted to spur development of antibiotics for

unmet medical needs. (September 28, 2018)

- [FDA Fast Facts: Hurricane Michael Response Efforts](#) (October 11, 2018)
- Statements from FDA Commissioner Scott Gottlieb, M.D.:
  - [FDA's efforts to strengthen the agency's medical device cybersecurity program as part of its mission to protect patients](#) (October 1, 2018)
  - [Preparations for the upcoming flu season and vaccinations](#) (September 27, 2018)
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](http://www.fda.gov/jobs).



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