

FDA Awards Contract to Develop Promising New Technology to Test Radiation Countermeasures

U.S. Food and Drug Administration

The U.S. Food and Drug Administration has awarded a \$5.6 million contract to Harvard University's [Wyss Institute for Biologically Inspired Engineering](#) [1] to apply its breakthrough [organs-on-chips](#) [2] technology to assess [medical countermeasures](#) [3] for treating acute radiation syndrome (ARS), also known as radiation sickness.

Organs-on-chips are microchips that mimic the functions of and tissue structures present in living organs, such as the lung, heart and intestine. The technology replicates the interactions between the living tissues within human organs on chips the size of a thumb drive. Under the contract, Wyss Institute scientists will develop models of radiation damage in lung, gut and bone marrow organs-on-chips and then use these models to test candidate medical countermeasures.

"Organs-on-chips technology represents the kind of transformational change in the way products are evaluated that is critical to advancing regulatory science, the science underpinning all FDA regulatory decisions," said Luciana Borio, M.D., the FDA's assistant commissioner for counterterrorism policy. "It holds enormous promise for improving our understanding of new medical countermeasures, particularly when it is unethical or unfeasible to conduct efficacy studies in humans; and when available animal models have limited use in accurately predicting human response."

The FDA plays a critical role in protecting the United States from chemical, biological, radiological, nuclear, and emerging infectious disease threats. FDA's responsibility is to ensure that medical countermeasures—such as drugs, vaccines, and diagnostic tests—to counter these threats are safe, effective, and secure.

ARS, an illness affecting a combination of organs, occurs when the body receives a high dose of radiation over a short period of time—as would be expected to occur after a nuclear or radiological incident. The first symptoms of ARS typically are nausea, vomiting and diarrhea. These symptoms will start within minutes to days after the exposure, will last for minutes up to several days, and may come and go. Then the person usually looks and feels healthy for a short time, after which he or she will become sick again with loss of appetite, fatigue, fever, nausea, vomiting, diarrhea, and possibly even seizures and coma. This seriously ill stage may last from a few hours up to several months.

Developing medical countermeasures to treat ARS is a high-priority for the U.S. government, but presents complex scientific challenges. ARS may involve many organ systems, which makes it hard to study candidate medical countermeasures that target the radiation effects on one specific organ system in animal models.

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Also, certain candidate medical countermeasures cannot be effectively studied in animal models because their activity is specific to humans. The Wyss Institute's organs-on-chips offer a unique opportunity to potentially address some of these challenges.

The technology will provide a capability to evaluate candidate medical countermeasures for ARS within the specific context of a target human organ system, which could yield valuable information for facilitating development.

The Wyss Institute contract was awarded through a [Broad Agency Announcement \(BAA\)](#) [4] for the Advanced Research and Development of Regulatory Science, in the area of Supporting Medical Countermeasures Development to Protect National Health and Security.

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Links:

[1] <http://wyss.harvard.edu/>

[2] <http://wyss.harvard.edu/viewpage/461/>

[3]

<http://www.fda.gov/EmergencyPreparedness/MedicalCountermeasures/default.htm>

[4] https://www.fbo.gov/?s=opportunity&mode=form&id=862c0ec16447bad7c7196f5d451ec601&tab=core&_cview=0