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ARTICLE

Discovering COVID-19 Countermeasures Without Discarding Scientific Method

APR 20, 2020 | KENNETH BENDER, PHARMD, MA

The National Institutes of Health (NIH) and the Foundation for the NIH have [announced](#) the launch of a massive public-private partnership to speed up the development and evaluation of coronavirus disease 2019 (COVID-19) vaccine and treatment options. This initiative is called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

"We need to bring the full power of the biomedical research enterprise to bear on this crisis," Francis Collins, MD, PhD, director of the NIH said in the announcement. "Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic."

The announcement indicates that the ACTIV collaborative is being formed as the research community is trying to sift through more than 100 potential preventives and therapeutics for COVID-19. The program will support simultaneous, rather than serial, testing of multiple candidate products, across what have traditionally been siloed, competitive pharmaceutical and academic laboratories and clinical testing networks.

"ACTIV will aim to provide guidance which can be used to prioritize the plethora of vaccine and therapeutic candidates in development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently," according to the statement.

While the program will hasten research by pooling resources and sharing methods and evaluating models, it should also serve to demonstrate that methodologies can be quickened without compromising findings or invalidating outcomes.

The emphasis on good science is imperative now, according to Jesse Goodman, MD, MPH, Georgetown University, and Luciana Borio, MD, In-Q-Tel, Arlington County, Virginia, in their viewpoint column in [JAMA](#).

"Currently, under intense pressure and based on hope and limited data from poorly conducted clinical trials and observational data, many clinicians are embarking on ill-advised and uncontrolled human experimentation with unproven treatments," Goodman and Borio wrote.

They call for careful assessment of the decisions to seek and evoke emergency use authorization (EUA) from the US Food and Drug Administration (FDA), such as that recently used to open treatment with chloroquine and hydroxychloroquine.

"Not only are there potential negative consequences from uncontrolled use of these drugs based on currently unconvincing data but, equally concerning, the integrity of governmental decision-making is increasingly coming under pressure, risking harm to both patients and to the public confidence needed to respond effectively to this pandemic," they stated.

Goodman and Borio explain that an EUA is intended to follow from the careful weighing of available evidence, and that it represents a de facto government judgment that use of an agent is warranted in a specific emergency. "Although unintended, it is not infrequent to see an EUA portrayed as akin to an FDA approval," they pointed out.

Goodman and Borio urge regulatory and research communities to avail themselves of the most recent results from randomized controlled trials, such as

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those currently supported and/or conducted by the NIH, the World Health Organization and Inserm. In addition, current treatment and support methods should be optimized, and best practices expanded. They also emphasize the importance of protecting the integrity of and resulting public trust in the scientific and regulatory agencies and their advice and decisions.

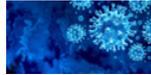
"That trust will be needed once vaccine against COVID-19 become available and in future public health emergencies," Goodman and Borio concluded.

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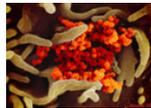
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