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Could 'Challenge' Trials Speed Development of a COVID-19 Vaccine?

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While many, if not most, research compliance officials are at least partially familiar with how vaccines (and drugs and devices) are approved by the Food and Drug Administration (FDA), they may be less acquainted with some of the more uncommon types of trials gaining prominence today, such as so-called "challenge" trials.

As Art Caplan, professor of bioethics at New York University (NYU) Grossman School of Medicine and director of the Division of Medical Ethics, explained during a recent webinar, a challenge trial may be a way to speed up vaccine development, but such studies are also "highly controversial."[1] Still, in the case of the COVID-19 pandemic, Caplan said he has "advocated" for such trials. In other remarks at the webinar, Caplan and Alison Bateman-House, an assistant professor at NYU, discussed their thoughts on how the pandemic has spurred a flood of publications that may be of questionable scientific quality and increased the number of nonapproved medications being used outside of standard clinical trials.[2]

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