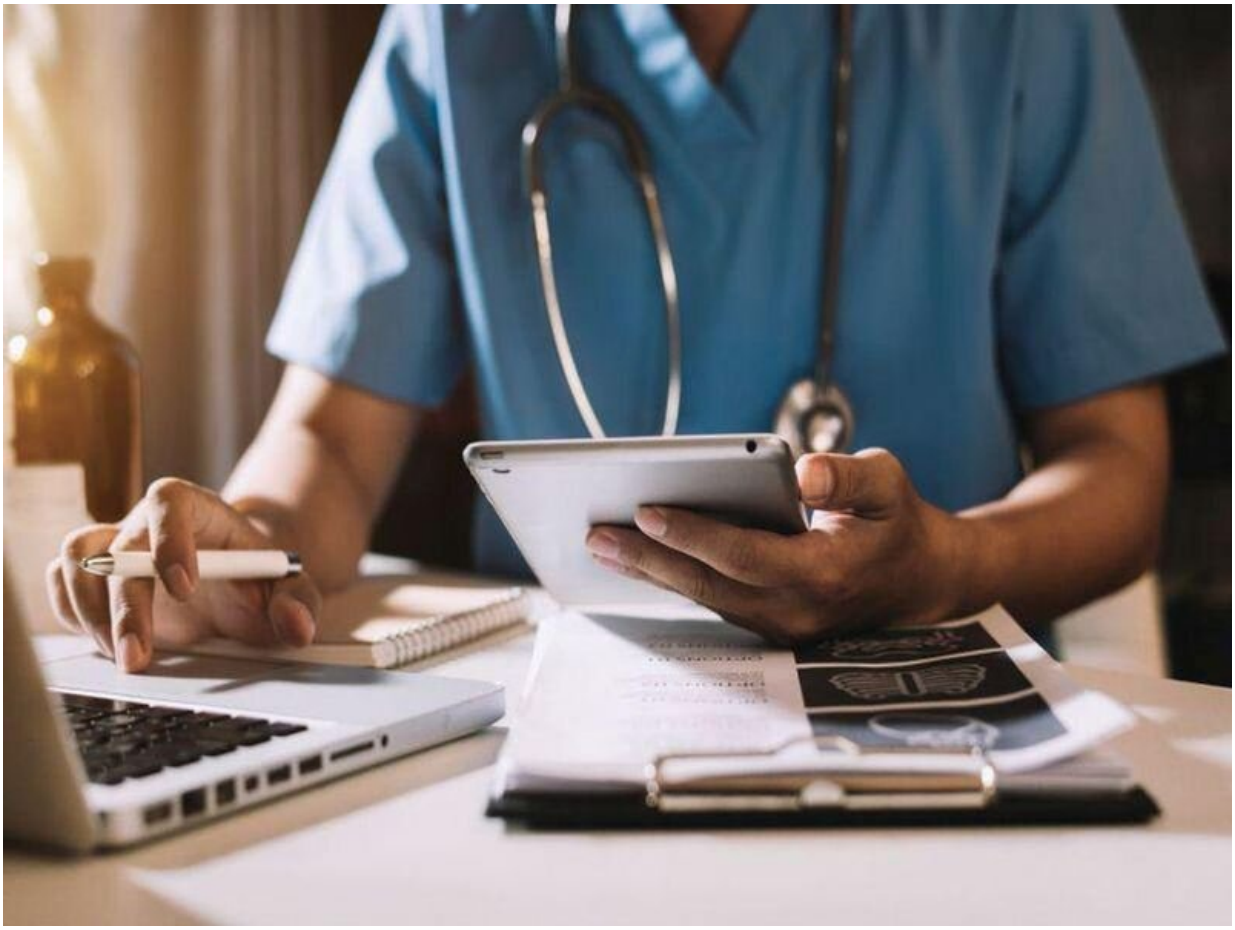
Should changes made to clinical trials during pandemic be kept?

July 22 2021



(HealthDay)—Many of the alterations made to clinical trial procedures

during the COVID-19 pandemic should be implemented in the post-COVID-19 roadmap, according to an article published online July 21 in *Cancer Discovery*.

Keith T. Flaherty, M.D., from Massachusetts General Hospital Cancer Center in Boston, and colleagues describe changes to cancer clinical trials during the COVID-19 pandemic, which were implemented to preserve potential patient benefit while minimizing risk associated with investigational therapies and COVID-19, and address the incorporation of these changes as part of future trials.

The authors note that the requirement for in-person consent was changed to allow for obtaining signed informed consent remotely; making electronic remote consenting permanent is recommended as part of the post-COVID-19 roadmap. The requirement to use clinical trial-specific laboratories and imaging was altered to allow use of alternate laboratories and imaging centers; henceforth, any laboratories or imaging centers that meet specifications should be allowed. Recording of safety and clinical assessments based on in-person visits was changed to allow for alternative methods of assessment; telehealth and other approaches are recommended for routine clinical trial methods. Administration of investigational products exclusively at clinical trial sites was changed to allow alternative delivery/administration methods; post-COVID-19, increased use of community-based network sites is recommended.

"Guided by lessons learned, many of the remote assessments and trial efficiencies deployed during the pandemic can be preserved and improved upon," the authors write. "We strongly encourage use of these streamlined procedures where appropriate in future prospectively designed cancer clinical trials."

Several authors disclosed financial ties to the pharmaceutical industry; one author is employed by AstraZeneca.

More information: Abstract/Full Text (subscription or payment may be required)