Medical Xpress

World cardiology leaders call for global action to reinvent randomized clinical trials

December 16 2022

Credit: Pixabay/CC0 Public Domain

The current model for randomized clinical trials must be redesigned for the 21st century, according to the European Society of Cardiology (ESC), American Heart Association (AHA), World Heart Federation (WHF) and American College of Cardiology (ACC).

The joint statement is published simultaneously in the flagship journals of all four organizations: *European Heart Journal, Circulation, Global Heart* and *Journal of the American College of Cardiology*.

ESC President Professor Franz Weidinger said, "Randomized trials are the gold standard method for evaluating new therapies and improving patient care. However, the cost and complexity of trials are becoming prohibitive and the current model is unsustainable. Cardiology provided the foundation for an era of highly successful clinical trials and is well placed to lead the way on modernization."

"Without sustained efforts to increase the application of streamlined approaches, and a more supportive regulatory environment for those who do choose to generate randomized evidence (instead of the adversarial approach that is often taken in regulatory audits), patients will suffer from important clinical questions not being addressed reliably, either because trials are too small or, due to excessive financial or bureaucratic obstacles, are never done at all," states the paper.

The COVID-19 pandemic necessitated highly streamlined trials that were easy to administer in busy hospitals. Only essential data were collected and much of the follow-up information was obtained from national electronic health records (EHRs) when possible. In addition, digital advances have allowed app-based data collection, remote monitoring and virtual trial visits which can enhance efficiency while maintaining safety.

WHF President Professor Fausto Pinto said, "The pandemic reinforced the value of digital technology in health care and demonstrated the power of partnerships in global health. It also showed the importance of using digital tools to improve the organization, development, and implementation of clinical trials, essential to drive innovation in care and meet unexpected challenges such as a pandemic. The future of clinical

investigation needs to be carefully tailored to address the several challenges it faces, and digital technology will certainly play a major role."

EHRs have huge potential for trial recruitment and follow-up but remain an underused resource. This is due to restricted access to records and reticence among regulatory authorities to accept EHR-based outcome data. On the other hand, inappropriate emphasis is often placed on observational analyses of routine healthcare data to bypass the challenges of randomized trials.

AHA President Dr. Michelle A. Albert said, "With this document, our societies wish to engage in the development of guidance that allows broader use of real-world data, housed in routine EHRs, to conduct the trials that are needed to improve patient care along with addressing unmet medical needs. Pragmatic clinical trials that allow flexibility while promoting innovation are required to address health care needs for different racial, ethnic and socioeconomic groups. This guidance is also an opportunity to have a close look at the real-world implementation of care practices designed to improve health equity."

During the past 25 years there has been an enormous increase in the rules and related bureaucracy governing clinical trials. The International Council for Harmonization (ICH) guideline for Good Clinical Practice (GCP) aims to ensure the safety and rights of trial participants and safeguard patients impacted by the results. However, the guideline is often over-interpreted thereby prohibiting the conduct of affordable clinical trials.

ACC President Dr. Edward T. A. Fry said, "Clinical trials like the Apple Heart Study, along with many conducted throughout the COVID-19 pandemic, have shown it is possible to conduct high quality trials safely, efficiently and effectively. Importantly they have also highlighted new

opportunities to reach patient populations spanning race and gender, socioeconomic status and geography. As such, the ACC, ESC, AHA and WHF fully support adoption of the revised guidelines put forth by the Good Clinical Trials Collaborative (GCTC) that keep the best parts of existing clinical trial guidelines, while also acknowledging new innovations and technologies available to clinical trial researchers both now and looking to the future.

"In a rapidly changing and increasingly global world, there is no excuse for clinical trials not to keep pace with recent advances and the proposed GCTC guidelines are an important step forward in ensuring we are able to optimize our efforts to provide the best possible patient care and outcomes when it comes to new and emerging medical therapies, devices or treatment strategies."

More information: Louise Bowman, Randomized Trials Fit for the 21st Century. A Joint Opinion from the European Society of Cardiology, American Heart Association, American College of Cardiology, and the World Heart Federation, *European Heart Journal* (2022). DOI: 10.1093/eurheartj/ehac633. academic.oup.com/eurheartj/adv … artj/ehac633/6886997

Provided by European Society of Cardiology