Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

I declare no competing interests.

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Decentralised elements in clinical trials: recommendations from the European Medicines Regulatory Network

Clinical trials of investigational medicinal products (IMPs) increasingly use procedures conducted outside the traditional clinical trial site—a concept referred to as decentralisation. The COVID-19 pandemic highlighted the importance and usefulness of decentralisation when visits to hospitals and other health institutions were restricted. In addition, interested parties, such as from the pharmaceutical industry, issued general plans to introduce more decentralised elements in clinical trials (eg, the Association of Clinical Research Organizations' decentralised trials toolkit[1] and Trials at Home). The aim is to increase the accessibility of clinical trials by bringing the trial to the patient, thereby including a more diverse and remote population.

Decentralised elements in clinical trials bring opportunities and new challenges not only for clinical patient care, but also for ethical, legal, and technical aspects of trial conduct. Thus, an EU and European Economic Area harmonised approach on the use of decentralised elements was needed. A task force was formed with experts from regulatory bodies, ethics committees, investigators, Good Clinical Practice Inspectors, patient organisations, and health-care professionals.[2] This task force resulted in a recommendation paper,[3] which addressed general principles in the conduct of clinical trials with decentralised elements. This paper included the roles and responsibilities of the sponsor and investigator, remote informed consent process and electronic signature, delivery of IMP to the trial participant, procedures at home, data management, and trial monitoring. In addition, an overview of the current national provisions per EU member state is outlined in an appendix to the paper.

The paper's focus is to ensure a participant-centric and risk-based approach to implementing decentralised elements. The objective is to ensure the safety, rights, dignity, well-being, and data reliability of trial participants while not hindering innovation. The appropriate use of decentralised elements depends on many factors, including the type of clinical trial, the trial population, the disease, the condition of the trial participant, the type of assessments, and the characteristics and stage of development of the IMP, including its efficacy and safety profile. General medical rules to protect the safety of trial participants should be upheld, particularly when patients are separated from their traditional care centres.

The paper outlines recommendations for implementing decentralised elements in a clinical trial and the information that should be included in the trial protocol and related documents. A risk-proportionate approach should be practised and explained transparently to allow for a proper review and to balance the potential advantages of decentralised elements with potential risks for the trial participants, trial integrity, and reliability of trial results.

We declare no competing interests. Members of the Decentralised Clinical Trials Task Force are listed in the appendix.

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See **Online** for appendix

Rare diseases: democratising genetic testing in LMICs

Although infections are the leading cause of morbidity and mortality, rare diseases are an unexplored burden in low-income and middle-income countries (LMICs). Despite the similar prevalence of autosomal dominant and X-linked conditions in LMICs and in high-income countries, the prevalence of recessive monogenic disorders is higher in LMICs because, in these countries, consanguineous marriages in minority ethnic groups are more frequent.[1]

Human genomic sequencing has potential diagnostic, prognostic, and therapeutic value across a wide spectrum of clinical disciplines.[2] Next-generation sequencing (NGS) has the potential to increase understanding

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