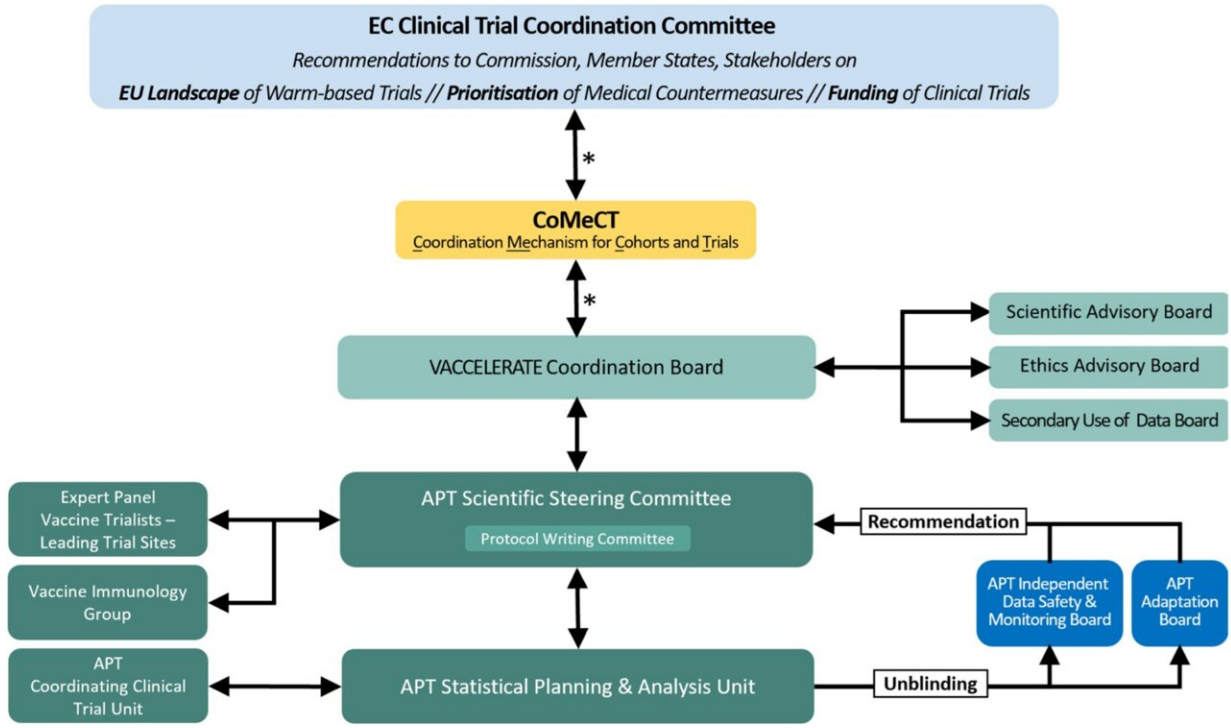
Experts explore new approach to vaccine trials and pandemic preparedness

July 17 2024



Exemplary setup of a VACCELERATE APT on vaccines. Credit: *Infection* (2024). DOI: 10.1007/s15010-024-02347-1

An international consortium of experts led by Translational Research Professor Oliver A. Cornely of the University of Cologne has created a

white paper on innovative approaches for clinical vaccine research in order to be better prepared for future pandemics. The contributing scientists see the future of vaccine research in the field of adaptive platform trials (APTs), a new type of clinical trial in terms of design and implementation.

The new approach was presented under the title "Innovative approaches for vaccine trials as a key component of pandemic preparedness—a white paper" in *Infection*.

APTs are a further development of conventional randomized clinical trials. The APT methodology facilitates a flexible ("adaptive") adjustment of the study design during the ongoing clinical trial. For example, this allows new questions to be added immediately and certain comparison groups of study participants to be used across different research questions (i.e. on one platform). It is also possible to continuously adjust the randomized distribution of study participants to different treatment arms (e.g. receiving vaccine A or B or none).

Mathematical-statistical modeling and artificial intelligence are important tools for using data collected during the ongoing study to optimize the further course of the study. The planning, implementation and evaluations of APTs require specific expertise and diligence; precisely defined decision-making paths and control mechanisms guarantee consistently high scientific quality.

"In the field of vaccine research, methodical approaches such as APTs have not been widely applied yet," said Professor Cornely, Leader of the Institute for Translational Research at CECAD Cluster of Excellence for Aging Research at the University of Cologne and coordinator of VACCELERATE.

"However, COVID-19 made us realize us how important it is to be able

to react quickly to an emergency and adapt vaccine studies to new developments. This can significantly speed up the time it takes to generate the data required for political decision-making. However, this requires a paradigm shift in the field of clinical vaccine research," explained Cornely.

Crucial to the success of APTs is a study infrastructure that enables work free from interruptions in the period between pandemics, but is immediately available for research on possible new and unknown pathogens in an emergency and only needs to be adapted to new questions. In times other than a pandemic, this infrastructure can be used to answer highly relevant research questions that have previously been neglected.

"This enables us to close gaps in research areas and plan long-term studies while being able to respond immediately to imminent challenges in an emergency situation. Implementing the APT approach in vaccine trials would be a great benefit for medicine and a logical consequence of what we have learned from the coronavirus pandemic," said Cornely.

The structures created so far in the VACCELERATE consortium are a prerequisite for the development of vaccine APTs, including the VACCELERATE Volunteer Registry, where European citizens who are interested in taking part in clinical trials can register.

Together with the VACCELERATE Site Network, a platform for clinical trial sites in currently 40 different countries in Europe, a large number of participants can be recruited for APTs at short notice. The VACCELERATE offers are currently being expanded with the establishment of a center of excellence for APT statistics and vaccine and immunology, as well as a forum where internationally renowned vaccine experts discuss.

More information: Ullrich Bethe et al, Innovative approaches for vaccine trials as a key component of pandemic preparedness—a white paper, *Infection* (2024). DOI: 10.1007/s15010-024-02347-1