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RESEARCH INTEGRITY AND ETHICS CHALLENGES IN ACCELERATED CLINICAL TRIALS, AN INTERVIEW STUDY.

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BACKGROUND

The COVID-19 outbreak affected both pre-existing clinical trials and new accelerated clinical trials working on potential COVID-19 treatments or vaccines. Acceleration of clinical research can be highly beneficial for several stakeholders, but it can also generate specific and exacerbated common challenges, including research ethics and integrity challenges.

METHODOLOGY

Research question: What are the research ethics and research integrity challenges associated with the acceleration of clinical trials according to clinical trial experts? Semi-structured interviews were performed online with 25 key stakeholders in the clinical development field to answer the research questions. Participants included: professionals working at pharmaceutical companies, the European Medicines Agency, national competent authorities, non-governmental organizations and the World Health Organization, among others. Interviews were analysed using a thematic approach with a combination of inductive and deductive coding.

RESULTS: THE CHALLENGES

THEME 1 ETHICAL CHALLENGES ARISING FROM ACCELERATED PROCESSES AND ADAPTED METHODS

Challenges related to accelerated methodology:

- Experts not immediately able to identify ethical challenges
- Exacerbated challenges common in all clinical trials (e.g. representativeness of samples, informed consent processes)
- Specific issues e.g. overlooked secondary effects

Ethics during the research process:

- Accelerated trials do not carry particular ethical issues as long as they are reviewed by a REC
- But during COVID-19, RECs had to improvise due to the reduced time frame

THEME 2 PUBLIC COMMUNICATION AND TRUST

Public trust and distrust:

- Hesitancy in the context of the COVID-19 outbreak due to accelerated methodologies

Responsible actors:

- Public communication in COVID-19 was better performed by some organisations such as EMA
- Political leaders influence social contexts in which scientific information can be adequately communicated

THEME 3 LACK OF GLOBAL RESEARCH GOVERNANCE

Fragmentation of research efforts in COVID-19:

- Urgency to find effective treatments → duplication in trials → competition for resources and structures → underpowered trials & inconclusive results

Economic driven acceleration:

- COVID-19 urgency allowed rapid access to vaccines, but delayed progress on other treatments' development
- Acceleration normally only occurs for diseases affecting high income countries → justice concerns and health inequalities

RESULTS: POTENTIAL SOLUTIONS

*How to **address and improve** these challenges?*

*Experts suggested **participants and public involvement** as a common potential strategy to:*

- Improve participant recruitment and sample representativeness
- Ensure public trust and promote better scientific communication
- Improve the relevance of research, reduce waste of research efforts and include voices from LMIC

CONCLUSION

Clinical research has a trust-dependency relationship towards the general public. Thus, clinical trial-related actors should look at the social and epistemic considerations of its work: without joined and coordinated efforts, robust and sound methodologies and open and transparent communication accelerated clinical trials might fail one of the major pillars of research ethics and integrity.

The relevance of research and trustworthiness of conduction of trials in emergency times becomes even more central for succeeding not only in great and highly needed therapeutics and vaccines, but also in progressing towards a landscape of epistemic and social just clinical research.

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