Ethical, administrative, regulatory and logistic bottlenecks and solutions for pandemic-relevant clinical research in Europe: findings from PREPARE WP1

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PREPARE is an EU-FP7 funded European network for harmonized large-scale clinical research studies on infectious diseases, providing evidence for the clinical management of patients and informing of public health responses. PREPARE WP1 is examining ethical, administrative, regulatory and logistical (EARL) barriers and solutions to pandemic-relevant research.

REGULATING PANDEMIC-RELEVANT STUDIES IN EUROPE: ARE WE READY?

- National Competent Authorities (NCAs) and Research Ethics Committees (RECs) across Europe are not uniformly ready to expedite review of clinical research in a public health emergency[1,2].
- NCAs and RECs support the need for clinical research in an infectious disease outbreak and for swift review. However there is variability across EU member states regarding the availability of expedited review and lack of clarity regarding the standard operating procedures for such review[1,2].
- Guidance needed regarding expedited review under the forthcoming Clinical Trials Regulation.

WHAT DO POTENTIAL RESEARCH PARTICIPANTS THINK ABOUT RESEARCH IN A PANDEMIC?

- Potential research participants consider it important that medical research is done during an influenza pandemic[3,4]: 84% of 6804 respondents thought clinical research should be done in an influenza pandemic and 75% thought that "special rules" should apply to make it happen[3].
- We also found support for more proportionate research protection procedures for publically funded, low-risk comparative effectiveness research[4,5].
- We need to bring people with us in our efforts to integrate research into response. Wider public dialogue is needed, particularly initiatives to build research literacy[3].

ADPATIVE PLATFORM TRIALS: A CLOSER LOOK

Novel trial designs offer promise for delivering clinical research in an ID outbreak. However, little is known about stakeholder experiences of these designs[4,5]. PREPARE WP1 is leading a qualitative study embedded within the REMAP-CAP clinical trial. As part of this study, we will evaluate the effect of a novel audio-visual intervention designed to enrich information exchange about the multifactorial component of the REMAP design and about response adaptive randomisation. This audio-visual intervention will be shared with patients or proxy decision makers during the consent process for this trial.

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