The Guild
of European Research-Intensive Universities

Statement on the Clinical Trials Regulation and the Accelerating Clinical Trials in the EU (ACT EU) initiative

On 29 March 2022, the EPSCO Council will discuss how to best coordinate responses to cross-border threats to health. It is crucial to draw lessons from the COVID-19 pandemic which has highlighted the need to reduce fragmentation of clinical trials. While acknowledging the recent initiatives of the European Union on large and multi-country clinical trials, The Guild contends that the European Union could be even more ambitious and highlights that some crucial enabling factors are still missing. Therefore, we urge the member states and the European Commission not to lose the momentum and to pursue their efforts, via the meetings of the EPSCO Council and of the Working Party on Pharmaceuticals and Medical Devices the day after, for facilitating larger and multinational clinical trials.

On 31 January 2022, the Clinical Trials Regulation[1] officially entered into force with the ambition to facilitate the conduct of larger clinical trials in the European Union and EEA countries. In January 2022, the European Commission, the Heads of Medicine Agencies and the European Medicines Agency additionally launched the Accelerating Clinical Trials in the EU (ACT EU) initiative to "*further promote the development of high quality, safe and effective medicines, and to better integrate clinical research in the European health system*"[2]. The Guild endorses the ambition of the European Union to ensure that, via these initiatives, European citizens have access to safe, effective, and innovative medicines.

The Guild also praises the establishment of the Clinical Trials Information System (CTIS) and its game-changing potential to significantly facilitate multinational clinical trials in Europe.[3] Clinical trials sponsors will no longer need to submit clinical trials applications to the competent authorities and ethics committees in each country where the clinical trials are expected to be conducted. Instead, they will use CTIS to submit streamlined and single applications.

While CTIS will help the conduct of multinational clinical trials, it will nevertheless be insufficient to address all existing obstacles. The Guild has already highlighted that the General Data Protection Regulation (GDPR) and the mis-harmonized interpretations of its provisions across countries impose limitations on the sharing and reuse of health data for research purposes.[4] The European Health Data Space must therefore complement CTIS by providing solutions for the exchange of health data. This is just as crucial as CTIS to the feasibility of multinational clinical trials.

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[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[2] EMA (2022) *Accelerating Clinical Trials in the EU (ACT EU): for better clinical trials that address patients' needs*. Press release published on 13 January 2022. https://www.ema.europa.eu/en/news/accelerating-clinical-trials-eu-act-eu-better-clinical-trials-address-patients-needs

[3] The Guild (2020) *Proposals for the Pharmaceutical Strategy for Europe*. The Guild of European Research-Intensive Universities and Bern Open Publishing. DOI: 10.7892/boris.146527

[4] The Guild (2021) *Proposals for the European Health Data Space*. The Guild of European Research-Intensive Universities and Bern Open Publishing. DOI: 10.48350/156905

While recognising the positive changes introduced by the Clinical Trials Regulation and CTIS, The Guild urges the European Commission to pursue its efforts to address remaining obstacles to the conduct of clinical trials, such as the poor user-friendliness of safety reporting via EudraVigilance; the 25-year retention of the trial master files (which also creates legal uncertainties in terms of its consistency with GDPR); the lack of guidelines and templates for documents to be implemented in the applications; and, unharmonised national requirements in the documents for the assessment part II (evaluation of the applications by each member state concerned).

Finally, while praising these recent initiatives and their objectives, The Guild encourages the European Union to be even more ambitious. Their scope should be enlarged to include medical devices, as their assessment is equally crucial to ensuring that European citizens have access to innovative and safe health care.