

Proposals for the Pharmaceutical Strategy for Europe



The Guild
of European Research-Intensive Universities

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For additional information, please contact Silvia Bottaro (Senior Policy Officer, The Guild office): silvia.bottaro@the-guild.eu.

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The Guild's proposals for the Pharmaceutical Strategy for Europe

Background

The European Union is in the process of launching a novel strategy to improve patients' access to medicines and to support innovation in the pharmaceutical industry of the EU ("Pharmaceutical Strategy for Europe"). Within this framework, one objective is to address how scientific and technological advances are put into practice. Among preclinical and clinical investigators it has long been recognised that it is extremely difficult to pursue industry-independent, multinational clinical studies¹. These are of paramount importance for investigating the safety and efficacy of drugs and interventions, and for supporting more personalised decision-making in health care. The covid-19-pandemic has even further highlighted the

challenges in initiating, coordinating and evaluating multinational studies within the EU. This is mainly due to three reasons:

1. For some innovative treatments there is no interest among industrial shareholders to develop or evaluate new strategies.
2. The existing regulatory framework, both at a national and European level, is not aligned with the rapidly developing innovations in medicine.
3. There is no dedicated framework for international, multicenter clinical studies within the current and upcoming EU Framework

¹ We refer here to the definition of clinical studies provided by the European Commission: "A 'clinical study' is defined as any clinical research involving a substantial amount of work related to the observation of, data collection from, or diagnostic or therapeutic intervention on multiple or individual patients. It

includes but is not limited to clinical trials in the sense of the EU Clinical Trials Directive (2001/20/EU)": https://ec.europa.eu/research/participants/data/ref/h2020/other/legal/templ/h2020_tmpl-clinical-studies_2018-2020_en.pdf

Programme for Research and Innovation (Horizon 2020 and Horizon Europe).

The above-mentioned challenges apply to studies on pharmaceuticals, medical devices, and advanced therapies.

The Pharmaceutical Strategy for Europe represents an opportunity to develop a European Framework for Multinational Clinical Studies - "EU-CLIN". Such a framework, coupled with appropriate research funding in this area under Horizon Europe, would help to tackle existing unmet needs and to foster cutting-edge biomedical and clinical research, which is a crucial stage of the life cycle of medicines and paramount to boosting Europe's competitiveness.

While addressing clinical studies, the proposed framework would need to take into account the specific obstacles for clinical trials. When compared to for example collecting real world data, clinical trials are strongly regulated and require a specific approval process through the current Voluntary Harmonization Procedure as well as the upcoming European Clinical Trials Regulation, registration in EudraCT, access to Eudravigilance, and good clinical practice monitoring. Once it will become applicable, the European Clinical Trials Regulation (EU No 536/2014), will simplify and harmonise the administrative provisions governing clinical trials. The proposed EU-CLIN framework, together with targeted investment to support capacities and innovation in academia, would be instrumental for the successful implementation of the Regulation in independent clinical research.

In this paper we provide an overview of the existing barriers and concrete actions that, if implemented in the context of the Pharmaceutical Strategy for Europe, will effectively support

research and innovation focusing on medicines and diagnostics for the benefit of patients and our societies.

Existing unmet needs

A European framework that supports the rapid and successful conduction of studies on pharmaceutical compounds, medical devices and advanced therapies, using state-of-the-art as well as novel and innovative clinical studies methodology, would need to address the following issues:

1. There is currently no platform at EU level where researchers can announce planned clinical studies and invite researchers from other EU countries to participate.
2. It is difficult for academia to initiate multinational clinical trials. Clinical trials, in contrast to for example collecting real world data, are strongly regulated and involve a complex approval and implementation process.
3. The current GDPR legislation does not provide a clear legal framework for enabling cross-border sharing of sensitive data, and the merging of data from multiple countries participating in a study is often delayed for reasons related to legal uncertainty and bureaucracy. There is for example interest in the academic community to develop a European equivalent to the "UK biobank"², but under the current rules that would be impossible.
4. The existing Horizon 2020 programme does not provide a designated framework for the conduction of clinical studies, nor does it seem that this possibility will be offered in the future under Horizon Europe.

² <https://www.ukbiobank.ac.uk/>

Horizon 2020 has been adapted to better accommodate the implementation of clinical studies, but it was not primarily designed for this purpose. A designated framework would enable addressing the existing shortcomings and also take into account the specificities of these projects (such as the need for more flexible timelines and cost adjustments).

5. There is a need to strengthen collaboration between EU regulators and academia in the regulatory processes. The scientific community plays an important role in providing EU regulators such as the European Medicines Agency (EMA) with expertise on the opportunities and challenges related to transformational research (such as novel clinical trial approaches, the use of real-world data, etc.) and in supporting the evaluation of increasingly complex medicines and trial designs taking into account legal, ethical, methodological and regulatory aspects.

Suggested actions

In light of the above-mentioned needs, we recommend the European Commission to:

1. Create a platform where researchers from all EU countries can express an interest in joining multinational clinical studies. To this end, the Commission could consider expanding the scope of the existing EU study platforms where ongoing trials are already registered (EU Clinical Trials Register³). Existing platforms where planned and ongoing clinical research is supported

(such as ECRIN⁴ - European Clinical Research Infrastructure Network) could also be leveraged further for this purpose.

2. Provide a simplified process, easier access and a more user-friendly interface to databases such as EudraCT and Eudravigilance, as this would greatly benefit investigator-initiated clinical trials.
3. Provide the swift adoption of guidelines and solve issues related to the interpretation of GDPR rules regarding the sharing of health data for scientific purposes. In this context, we welcome the proposal of the Commission to develop sector-specific legislative or non-legislative measures for a "European health data space", including a Code of Conduct for processing of personal data in the health sector, in accordance with Article 40 of the GDPR⁵. We recommend that the Commission extensively consults and engages with the scientific community in implementing these actions, so that the future health data space will truly deliver on its ambition to support scientific and medical research in Europe.
4. Devote funding for the conduction of multinational clinical studies, via the Horizon Europe programme. The EU is the primary source of public funding for multinational collaborative research across borders⁶. Stepping up the EU's support in this area is needed given the limited resources available for this kind of activities at Member States' level. In particular, we call on the European Commission to provide

³ <https://www.clinicaltrialsregister.eu/about.html>

⁴ <https://ecrin.org/>

⁵ "A European Strategy for data", COM(2020) 66 final, pp. 29-30.

⁶ "Building the future of health research. Proposal for a European Council for Health Research", Scientific Panel for Health, May 2018, p. 20. https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/building_the_future_of_health_research_sph_22052018_final.pdf

additional funding for these studies within the Health Cluster of Pillar II.

5. Use the opportunity offered by the European Medicines Agency's (EMA) framework for collaboration with academia⁷ to enhance a dialogue with the scientific community on emerging questions related to regulatory science. The definition of research funding priorities in this area should also be based on the advice and the expertise of academia.

A European framework for conducting multinational clinical studies, including traditional randomized trial designs, observational studies on large-scale biometric databases, and pragmatic adaptive study approaches would contribute to strengthen Europe's position as a global leader in healthcare research. It would, in a wider perspective, help generate new knowledge both on novel pharmaceuticals, medical devices, and Advanced Therapy Medicinal Products (ATMPs). Today, the existing challenges and obstacles can only be solved at the level of the EU.

⁷ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/framework-collaboration-between-european-medicines-agency-academia_en.pdf



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