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HORIZON-HLTH-2021-DISEASE-04-02 - Building a European innovation platform for the repurposing of medicinal products

Expected Outcomes: *This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:*

- Researchers continue to use the platform as an effective and sustained approach to coordinate and manage their efforts on the repurposing of medicines, making the best use of scientific knowledge and resources.
- Patients have new and effective therapeutic options addressing unmet medical needs, both for communicable and non-communicable diseases.
- Health care systems and payers have available more cost-effective treatments that reduce the financial burden in the medium- to long-term.
- The public sector and the pharmaceutical industry engage in new models of sustainable collaboration, at European level and beyond.
- Policy-makers adjust the EU's regulatory landscape for pharmaceuticals towards further harmonisation and increased fitness for purpose.

Scope: Development of therapeutics is a lengthy process that requires a large amount of efforts, time and financial resources. It is often burdened by delays and barriers that account for an average of almost 15 years until a promising candidate molecule becomes an approved medicine. It is therefore of paramount importance to define strategies that facilitate the reduction of timeframes, decrease costs and improve the success rate of this complex and lengthy process. One efficient strategy towards this direction is the repurposing of already approved medicinal products[1] and repositioning of investigational products[2] beyond their original indication. This approach has already proved successful[3] in several instances but its potential is far from having been fully exploited.

Proposals should address all of the following:

- Set up a platform[4] supporting an innovative repurposing model with a harmonized and sustainable dimension in the EU, attracting investments and taking a position of leadership at global level. This model should integrate the scientific, methodological,

1 Medicinal products with a market authorisation in the EU.
2 Investigational products without a market authorisation in the EU.
3 Notable examples are thalidomide and sildenafil.
4 Platform built around innovative concepts and comprising the components and expertise necessary to create a solid foundation on which to build a sustainable EU infrastructure to overcome the bottlenecks and fragmentation in the field of medicine repurposing.

financial, legal, regulatory, and intellectual property aspects of the repurposing approach.

- Provide robust and transparent selection mechanisms for prioritising already approved medicinal products or investigational products for repurposing, based on recognized unmet medical needs and sound preliminary data, and identify research priorities for the better understanding of mechanisms of action.

- Leverage, pool and share existing high quality data assets in the European repurposing landscape, also by using pharmacogenomics, in silico, and artificial intelligence (AI) approaches, and deliver new computational tools.

- Resolve the fragmentation and lack of ownership of the repurposing approach that greatly impedes the efficient exploitation of its potential, networking existing projects[5] and initiatives in the field. Particular attention should be given in supporting and strengthening academic driven research.

- Devise and test a European innovation platform to enhance the collaboration among relevant European stakeholders, including academia, non-profit organisations, patients, health-care professionals, regulators, health technology assessment bodies, payers, industry, and European Research Infrastructures.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. This could also involve networking and joint activities with projects funded under other clusters and pillars of Horizon Europe, or other EU programmes, as appropriate. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider to cover the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Commission may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

In order to achieve the expected outcomes, international cooperation is encouraged.

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[5] Particular attention should be given to already EC funded repurposing projects and regulators initiatives in the field.