

July 2022

Call for Applications: External Advisory Group to the European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)

Overview

The European Taskforce for Harmonised Evaluation of Digital Medical Devices pursues the goal of harmonising evaluation procedures for patient-centred Digital Medical Devices (DMDs) within the European Union (EU). The Taskforce has been established in April 2022 under the French Presidency of the Council of the EU and consists of 20 representatives of different European public and academic institutions, including HTA bodies. It is chaired by the Ministerial eHealth delegation of the French Ministry of Health and Prevention and co-chaired by the European Network for Health Technology Assessment (EUnetHTA). The Taskforce's future recommendations are primarily aimed at the HTA Coordination Group (HTAR) of the EU, national competent and HTA authorities, innovators and policy makers. The Taskforce's work comprises three work packages: "Classification and taxonomy", "Evidence in clinical evaluation" and "Healthcare system integration/Socio-economic evaluation". The External Advisory Group will review, challenge, and support the work of the Taskforce and contribute with relevant use cases to underpin the Taskforce's recommendations.

Mission of the External Advisory Group

The mission of the External Advisory Group is to assist the Taskforce with expert perspectives throughout its work. By providing the Taskforce with real world examples, use cases and expert input, the Advisory Group supports the Taskforce in elaborating recommendations for the harmonised evaluation of patient-centred DMDs in the EU. It is crucial to incorporate the input of relevant stakeholders representing the European DMD ecosystem in order to arrive at robust, real-world-ready recommendations for the harmonisation of the evaluation of DMDs in the EU. Therefore, the Advisory Group will act as a sparring partner, which challenges and enriches the Taskforce's work. Especially relevant in this regard will be the sharing of concrete experiences, feedback and use cases, which are able to demonstrate specific regulatory needs and gaps.

Operation of the External Advisory Group

The External Advisory Group will comprise maximum 15 members. The first phase of contribution starts at the end of October 2022, after the European Digital Medicine Conference in Luxembourg on 26-27 October 2022, where the first results of the three work packages of the Taskforce will be presented. The interaction with the Taskforce will consist of different ways, for instance sharing input material (e.g. a use case), online/in-person meetings or giving written feedback. An in-person kick-off meeting will be organised during the week of 14-18 November 2022 at SDA Bocconi in Milan. Moreover, it is planned to hold bi-monthly meetings of approximately one hour, which will predominantly take place online. Those meetings might take place with the whole Taskforce or only with a part of it, for instance the members of one specific working package. Hence, the contributors should expect to devote some time for this project (e.g. a couple of days per month). Further details on the operation of the Advisory Group will be shared at the beginning of the contribution period.

Target group

Invited to apply are representatives of European and non-European organisations that have strong interest as well as great expertise in the evaluation of patient-centred DMDs and its harmonisation within the EU.

Application timeline

4 September 2022	Application deadline
September 2022	Jury evaluates applications and selects candidates
Beginning of October 2022	Notification of selected candidates
26 October 2022	Start of first contribution period (for approximately one year)

Selection process

In total max. 15 representatives of companies, associations or other organisations will be selected based on both, the suitability and relevance of the expected contribution to the Taskforce as well as on balanced representation of different countries, categories (e.g., academia, public agencies, industry, patients, healthcare professionals, etc.), and genders. In the application form the applicant should state clearly which contribution they can make to the Taskforce's work with regards to the evaluation of patient-centred DMDs and its harmonisation within the EU.

The selection committee consists of a representative group of the Taskforce, including the chair of the Advisory Group and the work packages leaders. The committee will review the applications during September and will consequently choose 10-15 members based on the above mentioned aspects.

Compensation

Please note that no financial compensation will be provided to the participants. However, the contributors will be publicly acknowledged within the final recommendation document(s), which will most likely be papers, websites or slides on conferences. The name of the members as well as of their organisations will be stated.

Further notice

Apart from the External Advisory Group, there will be the opportunity for further stakeholders to share ideas and feedback during several public conferences, including the European Digital Medicine Conference in Luxembourg on 26-27 October 2022.

– End of Call –