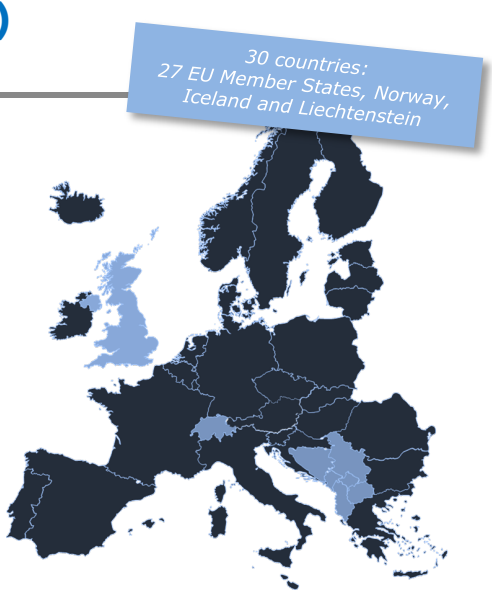
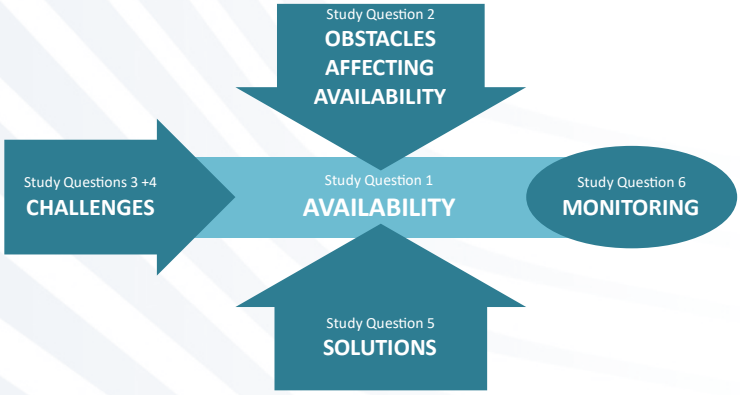
Study supporting the monitoring of the **availability of medical devices on the EU market (MD Availability)**



Medical devices (MD) and in vitro diagnostic medical devices (IVD) are essential for a working healthcare system and have a crucial role to play in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illness and diseases as well as rehabilitation. Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) are fully applicable by 26 May 2021 and 26 May 2023, respectively. **They aim to improve the quality, safety and reliability of medical devices, strengthen transparency and information for patients and enhance vigilance and market surveillance.**

Both Regulations provide for transitional periods during which devices that are in conformity with the previous Directives can still be placed on the EU market. In case of medical devices this is also subject to specific conditions. In order to ensure a smooth transitioning, it is essential to regularly apprise the situation on the ground and gather concrete data on the activities currently performed by relevant stakeholders.



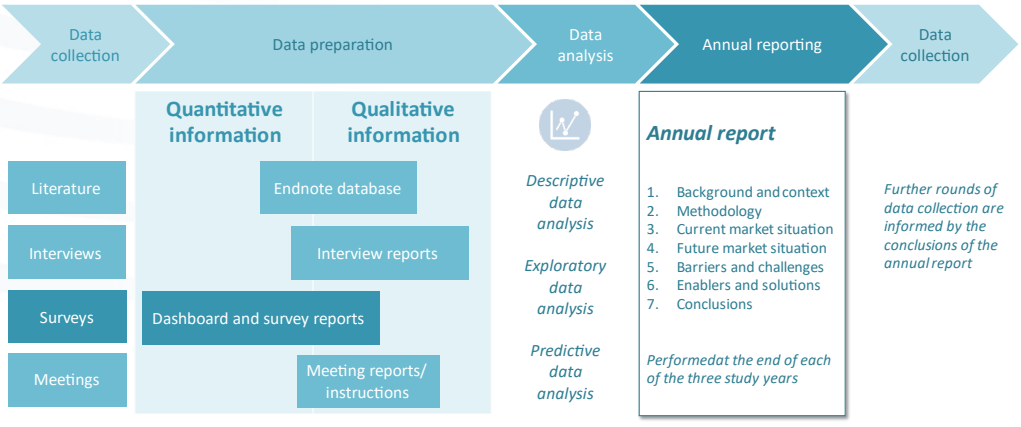
A study was commissioned by the European Commission (via its European Health and Digital Executive Agency / HaDEA) from Gesundheit Österreich GmbH (Austrian National Public Health Institute), Civic Consulting and Areté supported by experts from the medical devices sector **to monitor the availability of medical devices on the EU market.** The study will last 36 months starting from December 2022, examining the **context of the implementation of regulations for medical devices** and contributing to identify potential challenges to be addressed as well as possible solutions.

*For this purpose, the study team will collect information and data through **targeted surveys with key stakeholders** which play a crucial role in the availability of medical devices including:*

- *designated Notified Bodies (according to the old and new EU regulatory frameworks),*
- *manufacturers and other economic operators, including authorised representatives, importers and distributors as well as in a later stage also*
- *health service providers and patient representatives.*

*A **dashboard** will be created to display relevant indicators derived from the data collection. Findings of the study are expected to become publicly available on the dashboard in quarterly cycles beginning in July 2023.*

The study will utilise a **mixed-methods approach** (literature review, data analysis and stakeholder involvement) to create the **dashboard and annual reporting**. In addition to the yearly analysis in the annual reports, the study will provide a **final report** summarising all the activities performed during the study and the results and conclusions found from the study.



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May 2023

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