CORE-MD Recommendations

Recommendations	Exploitation measures
Pediatric devices recommendations: The evidence collected by Task 2.4, and the recommendations prepared in the related workshop, have been presented in D2.5 and published in two peer-reviewed papers. Participants in the task continue to promote its conclusions within their own specialist paediatric communities and in interactions with regulators in many different contexts.	The leader of Task 2.4 in CORE-MD presented its recommendations to the International Medical Device Regulators Forum, in 2023. He and two other members of the expert group which prepared recommendations for the clinical evaluation and regulatory approval of medical devices in children, were active members of the writing group that prepared recent EU regulatory guidance on orphan medical devices (MDCG guidance 2024–10); that document encourages increased use of approval with conditions on the certificate of conformity. Contacts have been made with paediatric regulators within FDA.
Clinical study design recommendations: Recommendations for the conduct of registry-based randomised controlled trials of high-risk devices, have been exposed in D4.3 and submitted for publication; and the recommendations for clinical trials, as a 'hierarchy', are being prepared for publication.	Members of the CORE-MD consortium, in their roles for the Biomedical Alliance in Europe, and as consortium partners the ESC and EFORT, are currently reviewing draft guidance from the CIE Working Group of the European Commission, on "Clinical Evaluation under Regulation (EU) 2017/745". Advice will be provided, as far as possible, to ensure that insights from the CORE-MD project are provided to CIE. A planned second release of this document will consider a "Hierarchy of clinical evidence and level of sufficient clinical evidence for high-risk devices" and also "Clinical evaluation of AI based medical devices". CORE-MD partners will work with regulators through WP28 of CIE to offer its recommendations as a basis for developing appropriate regulatory guidance.

Education roadmap and recommendations: The recommendations gathered in D4.1 were made freely available in an open-access publication, and they were shared with members of the EMA who have been planning educational programmes for expert evaluators in the EU.	The BioMedical Alliance has decided to provide educational resources on EU regulations and standards, for colleagues in its member scientific and medical associations and will incorporate the CORE-MD recommendations in the design of the educational and training contents and materials. The CORE-MD roadmap (D4.1) has been shared with other stakeholders also planning educational and training activities, including TEAM-NB. It was also presented to the NoBoCap consortium – aiming to improve technical knowledge at the NBs - during a dedicated meeting.
Ethics charter: The review and recommendations conducted within Task 4.1 and exposed in D4.2 are being prepared as manuscripts to be submitted for publication.	The recommendations in D4.2 are voluntary but have been shared with the different stakeholder communities represented within the CORE-MD consortium. Possibilities for their endorsement or further promotion will be discussed with EU regulators in MDCG CIE WP28.