GAPS AND BARRIERS	
GAP 1: Lack of common and well shared definitions and classifications of Medical Devices and eHealth	• There is no unique and unified international classification • It is difficult to identify which Health Technologies are implemented in different research projects; and which technologies are used for the diagnosis, treatment, management and surveillance of different diseases.
GAP 2: Limited calls for projects on Healthcare Technologies	• Calls are often generic or directed towards the management of medical diseases and not specifically oriented towards Heath Technologies. • Limited coordination between funding agencies • SMEs have limited human resources, are not aware of all existing facilities offered and prefer to concentrate on their immediate needs. • Lack of information on the budget for research in Health Technologies
GAP 3: Limited number of multidisciplinary projects	• Health Technologies are multi-disciplinary and necessitate the collaboration of different teams. Given the complexities associated with a multi-disciplinary project, further and significant consideration must be done to ensure that evaluators and industrials have the necessary and specific expertise to ensure every part of the project is properly assessed.
GAP 4: Regulation: lack of knowledge, lack of experts, differences between countries	• Regulations are different from one field of Health Technology to another (e.g. concerning risk classification and implementation of regulations). • Different approaches and interpretations amongst certified bodies that participate into the CE Marking process • There is a lack of experts capable to undertaking the requirements of the very complex standards applied to Health Technologies.
GAP 5: Problems with patents and intellectual property rights	• The cost of the patenting or IPR procedure is important for both academic institutions and SMEs, and is even much higher when patents need to be defended. Besides the money-back issue for public institutions, other criteria should be considered such as long-term effects (employment, taxes paid, leverage effect).
GAP 6: Limited regard of applied and translational research on the evaluation of researchers and academics	• For academics and researchers, their evaluation criteria need to include applied translational research and entrepreneurship.

GAP 7: Difficulties on Technology Transfer	• Organizations that support technology transfer activities in a variety of ways do exist but academics and industrial companies often suffer from a paucity of certain information which would ensure successful and rapid transfer of technology such as:
	  ◦ Lack of information on mentoring facilities
	  ◦ Guidelines on “how to conduct technology transfer”
	  ◦ Support and knowledge of good practices

GAP 8: Delayed involvement of industries in the process	• Technology transfer occurs late in prototype/product development • There are difficulties for accessing funding of prototypes, to develop business plans and to perform market studies and post market studies.
GAP 9: Methodological difficulties and limited funds for clinical trials on Healthcare Technologies	• The methodology of clinical trials for Health Technologies is different from those in pharmaceutical trials and necessitate specific competencies. • The industrial companies are mostly SMEs or VSMEs and support with difficulty the cost of randomized multi-centre clinical trials.
GAP 10: Difficulties in obtaining reimbursement	• Rules and procedures differ from country to country • Lack of transparency on the necessary requirements for obtaining a decision of reimbursement • SMEs do not have a clear understanding of the reimbursement process
GAP 11: Lack of education	• In educational curriculums (M.Sc., MD, PhD), engineers, researchers and healthcare professionals interested in the domain of Health Technologies should be trained in all aspects of the idea-to-market process.
GAP 12: Recognising the importance of usability / user experience / usages / ergonomics	• Lack of awareness in stakeholders regarding the requirements for Human Factors Engineering in the regulatory process • There is no specific funding for Human Factors (HF) or usability activities for Medical Devices and eHealth. • Lack of methodological support to implement usability harmonized standard (e.g. IEC 62366).