

Vision: Create a culture of clinical evaluation, both quantitative and qualitative, of Health Technologies.

Recommendation	Actions or action plan	Responsible actor	Other stakeholders	Desired impacts
<p><u>Medical Devices</u> Make researchers, developers, academics, industrials, pharmacists, hospitals professionals, aware of the different steps conducting from a prototype to a CE marked product and from a CE marked product to a reimbursed product.</p>	<p>1. Provide a methodological guidance for the clinical evaluation of Medical Devices, including: - regulation of clinical trials - methodologies of clinical trials - management of confidentiality and security of medical records. - bio statistical analysis - clinical trials for CE marking - clinical trials for Reimbursement 2. Consideration should be given to methodologies that facilitate the harmonisation of clinical trial procedures across Europe. 3. Identify centralised facilities which could be used as a harmonisation vehicle to improve the communication practices and strategies (between payers, providers and manufacturers)</p>	<p>Scientific societies, EAMBES, Academics Industrials ECRIN</p>	<p>Patients organisations Professional organisations</p>	<p>As in other domains of medicine, the use of Medical Devices and eHealth applications must become evidence-based.</p> <p>This will contribute to a safer usage of Health Technologies improving the quality of care and participation and empowerment of patients.</p>
<p><u>eHealth</u> Make researchers, developers, academics, industrials, pharmacists, hospitals professionals, aware of the different steps conducting from a prototype to a CE marked product and form a CE marked product to a reimbursed product. Evaluate the “general public” products sold for welfare, wellbeing and better health.</p>	<p>Provide a methodological guidance for the clinical evaluation of eHealth applications including: - regulation of clinical trials; - methodologies of clinical trials: the clinical investigation must be not only quantitative but also qualitative; - management of confidentiality and security of medical records; - bio statistical analysis; - clinical trials for CE marking when necessary; - clinical trials for reimbursement when possible; - clinical trials for clinical evaluation of a ‘general public’ market.</p>	<p>Big companies working in this sector (e.g. Orange, SFR, Google, Biotronik, Medtronic, Sorin) National eHealth platforms when existing Universities – research organisations Scientific societies ECRIN</p>	<p>Patients organisations Professional organisations</p>	<p>As in other domains of medicine, the use of Medical Devices and eHealth applications must become evidence-based.</p> <p>This will contribute to a safer usage of Health Technologies improving the quality of care and participation and empowerment of patients.</p>
<p>Increase the number and quality of clinical trials in Health Technologies</p>	<p>Delineation of well-defined funding sources to cover the large research costs on evidence development on Health Technologies.</p>	<p>Europe Member states Industry</p>	<p>Academics Start-ups/Industries Research organisations Hospitals</p>	<p>As in other domains of medicine, the use of Medical Devices and eHealth applications must become evidence-based.</p> <p>This will contribute to a safer usage of Health Technologies improving the quality of care and participation and empowerment of patients.</p>