

The Seoul Declaration: ^[1]_[2]_[3]_[4]_[5]_[6]_[7]_[8]_[9]_[10]_[11]_[12]_[13]_[14]_[15]_[16]_[17]_[18]_[19]_[20]_[21]_[22]_[23]_[24]_[25]_[26]_[27]_[28]_[29]_[30]_[31]_[32]_[33]_[34]_[35]_[36]_[37]_[38]_[39]_[40]_[41]_[42]_[43]_[44]_[45]_[46]_[47]_[48]_[49]_[50]_[51]_[52]_[53]_[54]_[55]_[56]_[57]_[58]_[59]_[60]_[61]_[62]_[63]_[64]_[65]_[66]_[67]_[68]_[69]_[70]_[71]_[72]_[73]_[74]_[75]_[76]_[77]_[78]_[79]_[80]_[81]_[82]_[83]_[84]_[85]_[86]_[87]_[88]_[89]_[90]_[91]_[92]_[93]_[94]_[95]_[96]_[97]_[98]_[99]_[100]A Manifesto for Ethical Medical Technology

Presented and signed at Grand Wakerhill Seoul, November 10, 2018

The Seoul Declaration on ethical medical technology is founded on the policies articulated in the World Health Assembly resolution WHA55.18 (2002), which urged Member States to “*pay the closest possible attention to the problem of patient safety and establish and strengthen science-based systems, necessary for improving patient safety and the quality of health care*”.

Seoul is capital of Korea where the national ideology has been to “benefit all mankind” and has followed cultural values and norms of harmony, balance, and moderation which are fundamental to Korean culture and prosperity for 10000 years.

We welcome the vision and leadership of countries in building political sponsorship and momentum at the highest levels of government to address the development and deployment of ethical medical technologies globally as well as locally, adhering to the precept that “Ethics is knowing the difference between what you have a right to do and what is right to do.”

We reaffirm our commitment to improving medical technology and patient safety in order to reduce all avoidable harm and the risk of harm to all patients and people during their interaction with providers and health care systems, whoever they are, wherever they live, and endorse the following Seoul Declaration, while:

Recognizing that unsafe health care and avoidable patient harm represents a serious challenge to health care service delivery globally, including the significant level of preventable human suffering, the considerable strain on health system finances and the loss of trust in health systems and in governments;

Recognizing the need to promote and implement new technologies based on human factors design that promote patient safety following medical ethics are fundamental requirements of all service delivery systems, at all levels of health care and in all health care settings;

Recognizing that the latest advances in medical technology, however, are raising many questions relative to ethics. The revolutionary inventions and advancements in the field of medicine have sometimes meant that traditional medical ethics could not be followed.

Recognizing that smart implants, automated robotics, artificial intelligence, autonomous devices represent an ongoing opportunity to expand and support ethical technical innovation;

Recognizing that ethical technologies that promote patient safety are important components of health care delivery and newer technologies are essential to achieve Universal Health Coverage (UHC), and moving towards UN Sustainable Development Goals (SDGs); and that patient safety systems and practices need to be established in all countries as one of the critical health care standards for achieving UHC on a sustainable basis;

Recognizing the roles that information and communication technology play, from data collection and surveillance to monitoring and notification, anticipating risks,

improved service delivery and improved safety and quality;

Recognizing the role of engaging and empowering patients and families in the design and implementation of medical technologies that help deliver safe and quality care and in all aspects in health care - policy development, organizational level, decision making, health literacy and self-care.

We declare that we will:

Pledge to support ethical medical technologies with the goal of “*Primum non nocere*”

. Enable health care institutions, both public and private, from the level of primary care through to referral level care, to implement changes in an ethical and transparent manner, in systems and practices to improve patient safety using new medical technologies, while contributing to achieving UHC and SDGs;

Support collaborative, ethical and transparent biomedical design methodologies working with industry for global health concerns.

Collaboration is essential for successful engineering of complex projects and the biomedical engineering field stands out for the need of multidisciplinary teams capable of systematically addressing the development of medical devices considering medical, social, economical, technical, safety and regulatory issues.

Call on our governments to fund and support development of new technical standards and open-access e-infrastructures for global action.

The development and employment of adequate data management strategies and of methodologies for improved information sharing is intimately connected to the construction of healthy, sustainable, creative, effective and efficient collaborative design environments. Developing user-friendly, versatile, stable and safe open-access e-infrastructures, for supporting these online interactions in the collaborative development of biomedical devices, and following FAIR (findable, accessible, interoperable and reusable) data principles as the right direction for achieving global action towards the democratization of medical technology.

Strive for harmonization of medical devices directives and accessible standards.

Construct a framework for enabling medical technologies to reach everyone and everywhere relies on the use of common design practices and on the fulfillment of broadly accepted regulations that must warrant patients' safety and that should allow for a compliant device to be commercialized and applied worldwide. Establish clinical follow up, post market surveillance and registries of the use of medical devices, if needed in addition to loco regional regulatory demands.

Sign and assume the present manifesto, as a symbol of commitment and deep respect for future collaboration.

We will pursue the aims highlighted in this document, supporting our partners, promoting collaboration with significant stakeholders (from patients, patients' associations, medical professionals and biomedical engineers, to educators, policy makers, manufactures and companies), working towards universally accessible, intrinsically safe and high-quality medical technologies and solving unforeseen issues with a balance between pragmatism and idealism (*pedes in terra ad sidera visus*).