

ANA  AMERICAN NURSES ASSOCIATION
INNOVATION

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American Nurses Association Innovation

**medical technology and
devices innovation
advisory committee (iac)**

vision

Nurses practicing in all facets of care are an integral part in the patient care technology and device ecosystem - acting as leaders in the research, design, development, selection, implementation and improvement of such technology and devices.

Committee Members

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general resources

General Resources

Biodesign

- Innovation Process Tech + Device Development [[website](#)]
- Stanford Center for Biodesign [[website](#)]

Human Factors

- Human Factors and Ergonomics Society [[website](#)]
- How to Validate A Need – Jobs To Be Done Theory [[website](#)]
- US FDA Human Factors [[website](#)]
- US FDA Human Factor Considerations [[website](#)]

Nurse Engineer

- Health Care Innovation: Embracing the Nurse–Engineer Partnership [[article](#)]
- Teamwork Between Engineers and Nurses Triggers High-tech Healthcare Inventions [[website](#)]
- The nurse+ engineer as the prototype V-shaped professional [[article](#)]
- Nurse-scientists and nurse-engineers: Nurse- driven device innovations and inventions can improve patient care [[article](#)]

Health Technology

- Conceptual Model for Technology, Nursing, and Patient Safety [[website](#)]
- Digital Technology's Promise for Better Health Care Delivery [[ebook](#)]
- Exploring the Technology Trends That Will Define the Future of Healthcare [[article](#)]
- Health Tech: SnapNurse's Technology Can Make an Important Impact on Our Overall Wellness [[article](#)]
- How Women Are Reimagining The Field of Health Tech [[article](#)]
- Making Sense of Health Technology [[article](#)]
- Nursing Apps and Technology to Optimize Patient Care [[article](#)]



general resources

General Resources (cont.)

Pediatric Resources

- Children's Hospital Association Supply Chain Services [\[website\]](#)
- KidsX Accelerating Pediatric Innovation [\[website\]](#)

Robotics

- Robotics and The Impact on Nursing Practice Case Study and Pilot Site Analyses [\[article\]](#)

Websites

- AAMI Standardization [\[website\]](#)
- AccessGUDID [\[website\]](#)
- Adva Med Medical Device Industry Facts [\[website\]](#)
- American National Standards Institute [\[website\]](#)
- International Organization for Standardization [\[website\]](#)
- ISPI [\[website\]](#)
- Medical Device & Diagnostic Industry [\[website\]](#)
- Medical Device Innovation Consortium [\[website\]](#)
- Medical Device Network [\[website\]](#)
- NEST Coordinating Center [\[website\]](#)
- United States Patent & Trademark Office [\[website\]](#)

Podcasts

- Tech Vitals ([podcast](#))



government

Government

- Advanced Research Projects Agency for Health (ARPA-H) biomedical and technology health research [[website](#)]
- CFR – Code of Federal Regulations Title 21 [[website](#)]
- Classify Your Medical Device [[website](#)]
- How to Determine if Your Product is a Medical Device [[website](#)]
- ISO Standards for Medical Devices [[ebook](#)]
- MAUDE – Manufacturer and User Facility Device Experience [[website](#)] (reporting device suspected death/injury/malfunction)
- Medical Device Identification—Access GUDID [[website](#)]
- Network of Digital Health Experts [[website](#)]
- Regulatory Requirements Overview: Medical Devices [[website](#)]
- Rapid Acceleration of Diagnostics (RADx) COVID Testing [[website](#)]



legislation + policy

Legislation + Policy

- Policy for Device Software Functions and Mobile Medical Applications – Guidance for Industry and Food and Drug Administration Staff [[report](#)]
- Overview of Regulatory Requirements: Medical Devices [[transcript](#)]



universities + academia

Universities and Academia

- Duquesne University – Nurse Engineering Program [[article](#)]
- Med Tech Innovation + Entrepreneurship [[website](#)]
- UMASS Amherst – Nursing Engineering Laboratory [[website](#)]



organizations

Organizations

- Association for the Advancement of Medical Instrumentation [[website](#)]
- American National Standards Institute [[website](#)]
- Avatar Group [[website](#)]
- Avatar Vascular Device Types [[website](#)]
- Azure Health Bot [[website](#)]
- GE Healthcare [[website](#)]
- HIMSS [[website](#)]
- International Organization for Standardization [[website](#)]
- MakerNurse [[website](#)]
- Mass Device [[website](#)]
- Medical Device Academy [[website](#)]
- Medical Device and Diagnostic Industry [[resource](#)]
- Medical Device Innovation Consortium [[website](#)]
- Medical Device Network [[website](#)]
- Medical Tech Startup Resources [[website](#)]
- National Capital Consortium for Pediatric Device Innovation [[website](#)]
- National Pressure Injury Advisory Panel [[website](#)]
- NEST Coordinating Center [[website](#)]



conferences

Conferences

- AIDH Med Info 23 [\[website\]](#)
- CES [\[website\]](#)
- Heart Rhythm Society [\[website\]](#)
- Healthcare Design Conference [\[website\]](#)
- HIMSS Global Health [\[website\]](#)
- Medical Intelligence & Innovation Institute Summer Internship Program [\[website\]](#)
- Reuter's Digital Health [\[website\]](#)



articles + research

Articles + Research

- Digital Technology and Nursing Care: A Scoping Review on Acceptance, Effectiveness and Efficiency Studies of Informal and Formal Care Technologies [[article](#)]
- Innovation In Nursing: 6 Ways The Field Is Propelling Forward [[article](#)]
- Medical Device Industry Facts [[article](#)]
- Nurses' Perceptions of Technology Used in Language Interpretation for Patients with Limited English Proficiency [[article](#)]
- The History of Technology and Innovation in Nursing [[article](#)]
- Patient Care Technology and Safety [[book](#)]



transdisciplinary + interprofessional

Transdisciplinary

- Interdisciplinary and Innovative: A Nursing and Computer Science Collaboration to Create a Barcode Medication Administration System [\[article\]](#)
- Teamwork Between Engineers and Nurses Triggers High-tech Healthcare Inventions [\[article\]](#)

Interprofessional

- Moving Nursing Innovation To Prime Time Through Creative Partnerships [\[article\]](#)



jedi

JEDI (Justice, Equity, Diversity, Inclusion)

- Designing for inclusivity: How and why to get started [\[website\]](#)



definitions

Definitions

Term	Definition
Human Factors/	<p>There are multiple definitions for different fields. However the FDA defines human factors as the science of “Understanding how people interact with technology and studying how user interface design affects the interactions people have with technology”</p> <p>And the Human factors and ergonomics society states that the goal of Human factors is to “reduce human error, increase productivity, and enhance safety and comfort with a specific focus on the interaction between a human and the thing of interest.” (technology or device in this case)</p> <p>Human Factors and Ergonomics Society</p> <p>Human Factors and Medical Devices - FDA</p> <p>https://www.fda.gov/medical-devices/human-factors-and-medical-devices/human-factors-considerations</p>
Minimum Viable product	<p>The smallest thing that you can build that delivers customer value</p> <p>Minimum Viable Product (MVP) and Design - Balancing Risk to Gain Reward Interaction Design Foundation (IxDF) (interaction-design.org)</p>
Intellectual Property	<p>Creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.</p> <p>IP is protected in law by, for example, patents, copyright and trademarks, which enable people to earn recognition or financial benefit from what they invent or create.</p>



definitions

Definitions (cont.)

Term	Definition
FDA Medical Device Regulations	<p>The FDA defines a medical device as:</p> <p>"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,</p> <p>intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or</p> <p>intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."</p> <p>How to Determine if Your Product is a Medical Device FDA</p>
Medical Device Event Reporting	<p>Houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.</p>
MAUDE Database FDA:	<p>Houses medical device reports submitted to the FDA by mandatory reporters 1 (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.</p> <p>MAUDE - Manufacturer and User Facility Device Experience (fda.gov)</p>



definitions

Term	Definition
FDA Predicate Device	<p>"The FDA may look at a "predicate device" to determine the steps required for regulatory approval of a medical device. This is a device that has already gone through the FDA and can provide a template for necessary testing, data collection, and other steps before FDA regulatory registration or approval can be completed."</p> <p>How to find and effectively use predicate devices - FDA</p>
General Wellness Device	<p>"Products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons. General wellness products may include exercise equipment, audio recordings, video games, software programs⁴ and other products that are commonly, though not exclusively, available from retail establishments."</p> <p>General Wellness: Policy for Low Risk Devices FDA</p>
Virtual Care and/or Telehealth	<p>"Allows for health care provider or nurse to provide care over phone or video."</p> <p>What is telehealth? Telehealth.HHS.gov</p>
Remote patient monitoring	<p>"The use of technology that allows health care to be provided to patients at a distance. In other words, RPM simply entails using technology to collect, transmit, and analyze patient health data. Data can be uploaded to patient EMR for provider review. Goal to keep patients at home vs hospitalization Weights, Blood pressure, spirometry, Heart Rates, etc."</p> <p>Home - Cognosante</p> <p>Vital Sync™ Rapid Remote Monitoring Medtronic</p> <p>(e.g., smart watches, Enso Ring)</p>
Patient care technology	Equipment and devices to deliver direct care to patients.
Stakeholder	Anyone involved in the design, development, research, implementation, and evaluation of healthcare tech & devices, including patients.

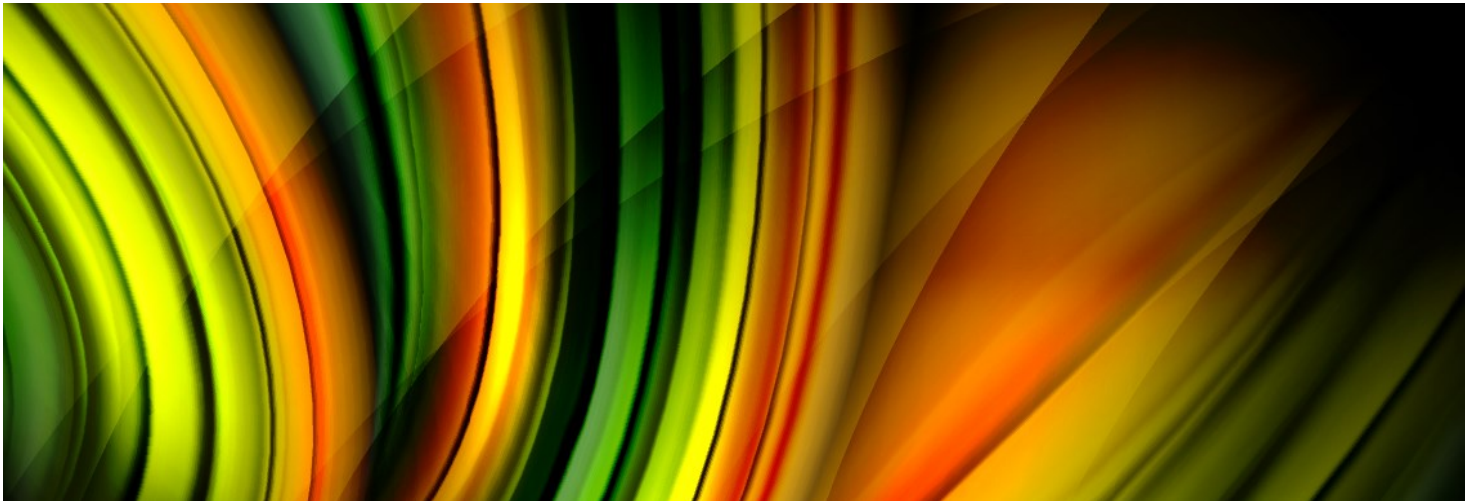


definitions

Definitions (cont.)

Term	Definition
Value Proposition	<p>“A statement of the benefits someone will receive as a result of the technology. May refer to benefits to users as well as investors.”</p> <p>Lehoux, P., Miller, F. A., Daudelin, G., & Denis, J. L. (2017). Providing value to new health technology: the early contribution of entrepreneurs, investors, and regulatory agencies. <i>International Journal of Health Policy and Management</i>, 6(9), 509. doi: 10.15171/ijhpm.2017.11</p>
Return on Investment (ROI)	<p>“Estimation of the potential commercial viability of a technology or device.”</p> <p>Markiewicz, K., van Til, J. A., Steuten, L. M., & IJzerman, M. J. (2016). Commercial viability of medical devices using Headroom and return on investment calculation. <i>Technological forecasting and social change</i>, 112, 338-346. https://doi.org/10.1016/j.techfore.2016.07.041</p>
Healthcare innovation	<p>“a new or improved solution with the transformative ability to accelerate positive health impact.”</p> <p>World Health Organization https://www.who.int/teams/digital-health-and-innovation/health-innovation-for-impact</p>





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med tech + devices

The views and opinions expressed within these resources may not reflect the positions or policies of the American Nurses Association. The resources are provided for the sole purpose of highlighting innovative work across the nursing profession. Listing of links to organizations or groups shall not be construed as an endorsement of said organizations or groups. If you have any questions or concerns, please contact us [here](#).

