



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Surgical Robotics: A Call to Action for Policy Advocacy

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Benefits of Robotics in Healthcare

Robotics in healthcare offers substantial benefits, including improved global patient access to care.

By leveraging robotic systems, healthcare providers can theoretically extend their reach and deliver care to patients in remote or underserved areas, ensuring equitable access to quality medical services.



Image: Created with ChatGPT



The Rise of Surgical Robotics

- **SIGNIFICANT GROWTH IN SURGICAL ROBOTICS**

The field of surgical robotics has seen a substantial increase in adoption over the past decade.

- **AI INTEGRATION WITH ROBOTICS**

The integration of AI models with robotics technology is expected to further accelerate the use of surgical robotics.

- **IMPROVED PATIENT ACCESS TO CARE**

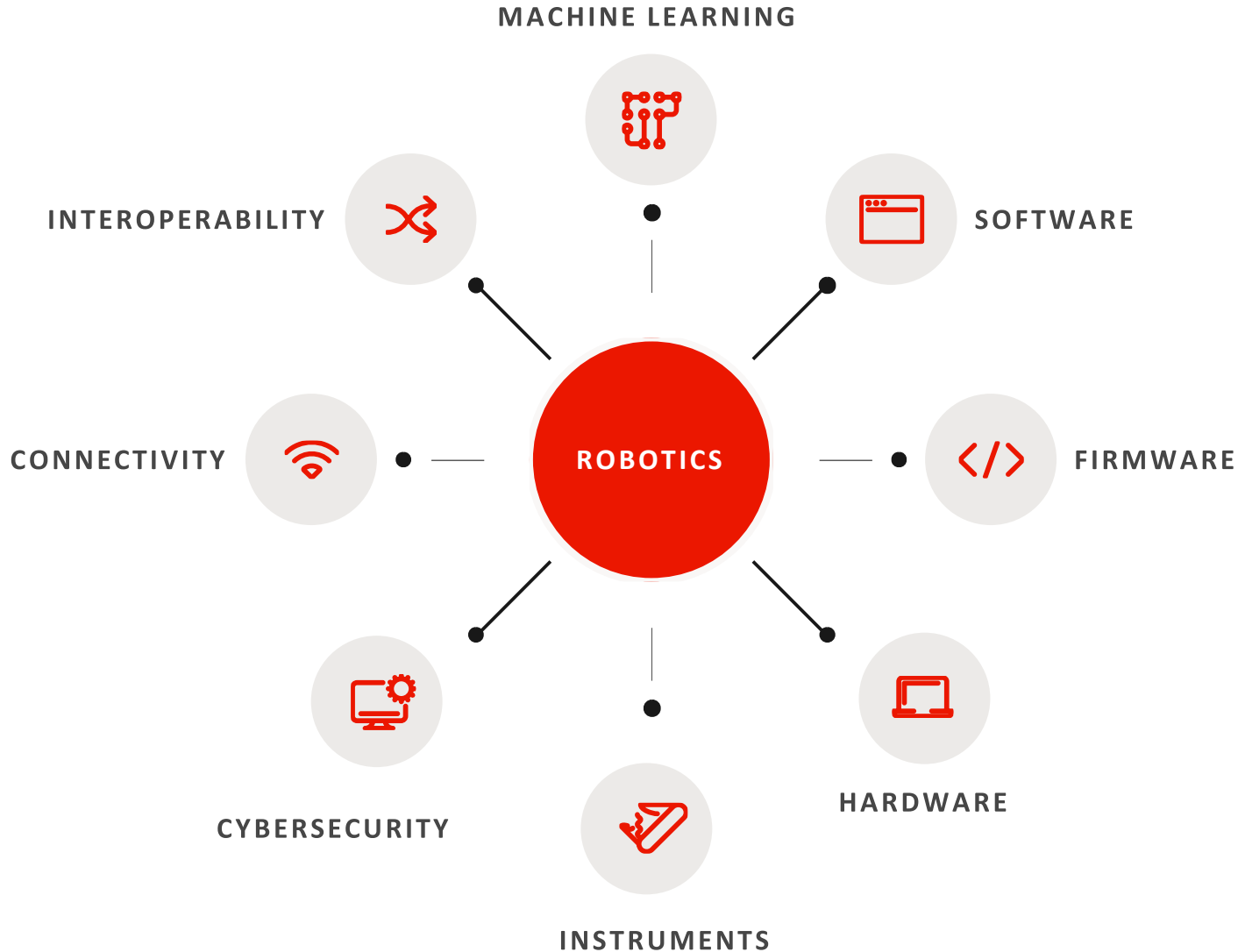
Robotics in healthcare offers significant benefits, including improved global patient access to care.

- **COMPLEXITY OF ROBOTICS SYSTEMS**

Robotic systems encompass software, firmware, instruments, hardware, and involve challenges in cybersecurity, interoperability, connectivity, machine learning, AI, and capital equipment management.

- **NEED FOR DEDICATED POLICY APPROACH**

A concentrated policy approach is essential for the success of robotics in healthcare, requiring a dedicated focus on regulatory policy and strategic pathways.



Robotics
are greater
than the
sum of their
parts.

Robotics Systems Are Complex



SOFTWARE

Complex software systems that provide the intelligence and control for robotic systems



FIRMWARE

Embedded software that governs the low-level operations and interfaces of robotic hardware



ML / AI

Incorporating advanced AI algorithms to enhance the autonomy, decision-making, and adaptive capabilities of robotic systems



CONNECTIVITY

Enabling remote access, control, and monitoring of robotic systems through secure network connections



INSTRUMENTS

Specialized medical devices and tools integrated into robotic systems for precise surgical procedures



HARDWARE

Sophisticated mechanical, electrical, and electronic components that make up the physical structure and capabilities of robotic systems



INTEROPERABILITY

Seamless integration and communication between different robotic components and with broader healthcare IT systems



CYBERSECURITY

Safeguarding robotic systems against cyber threats and ensuring the integrity and privacy of sensitive data



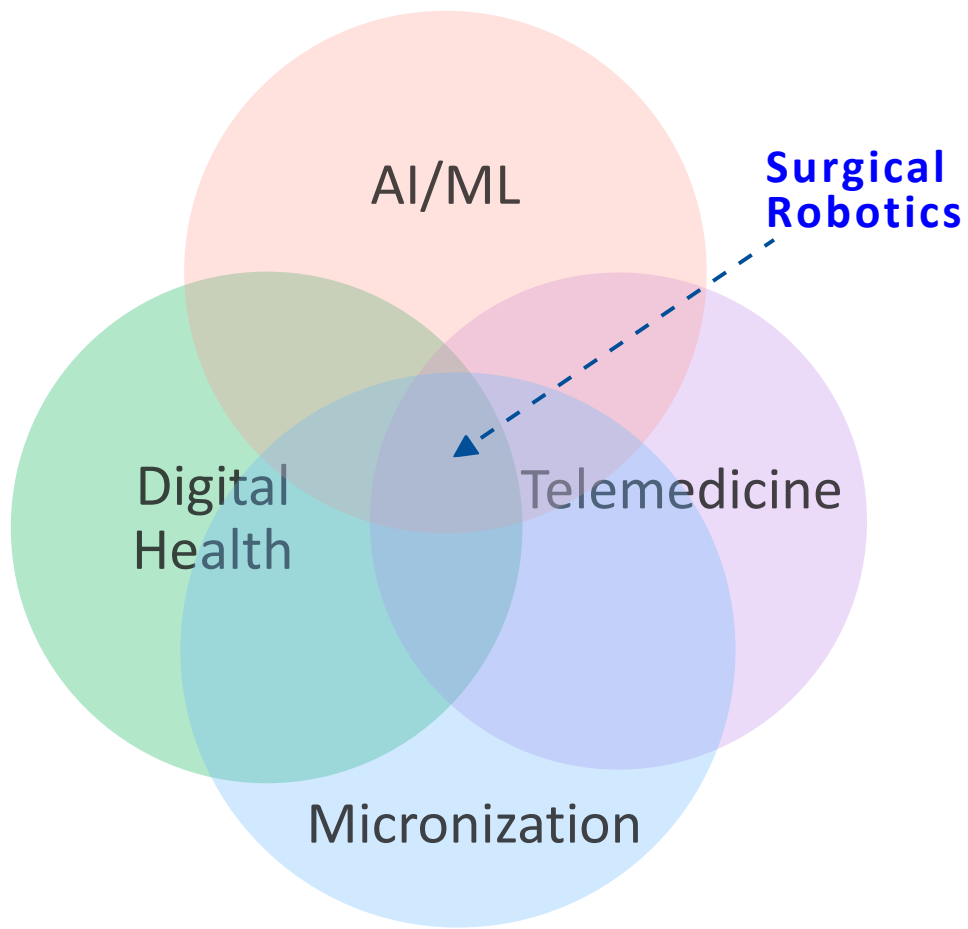
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Robotics Complexity Reflects Technology Convergence

Robotics serves as the forefront for emerging technologies.



Technology is converging in MedTech on robotics, driven by the integration of several advanced technologies:

- **Artificial Intelligence (AI) Integration:** Robotics is increasingly powered by AI, enabling smarter decision-making, real-time navigation, and predictive analytics.
- **Sensor Technologies:** Sensors integrated into robotic systems provide detailed feedback for real-time adjustments, ensuring higher accuracy in procedures
- **Micro-Robotics:** Advances in micro-robotics are expanding the scope of robotics from large-scale surgical systems to tiny, specialized devices.
- **Digital Health and Telemedicine:** Robotics combined with telemedicine and IoT platforms is enabling remote surgical procedures and improving access to care in underserved regions.



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Complexity Requires Innovation Pathways

What Robotics Policy Advocacy Aims to Achieve

Defining Robotics for the future

- Robotics in healthcare encompasses technologies that enhance precision, efficiency, and access to medical services. By leveraging AI, micro-robotics, and advanced systems, these tools redefine surgical procedures, diagnostics, and patient care. A clear definition and scope are essential for shaping standards, policies, and innovation frameworks.

Implementing pathways for technology growth and adoption.

- **Harmonized regulations:** Harmonize global policies to reduce entry barriers for new technologies.
- **Collaboration:** Encourage partnerships between innovators, policymakers, and healthcare providers.

Ensuring the safe and ethical use of Robotics to benefit patients globally.

- **Patient safety:** Develop robust testing and quality assurance protocols.
- **Ethical AI integration:** Address autonomy levels and decision-making authority for robots.
- **Global equity:** Ensure accessibility of advanced robotic systems, particularly in underserved regions.

Why are Innovation Pathways Important to Robotics?



Pre-Authorized Changes

If a manufacturer obtain authorization during the review process for pre-plan device modifications, the changes can be implemented in a timely fashion. This will improve patient access to improved devices.



Innovation Pathway

Mature regulatory bodies are positioned to create innovation pathways (e.g. PCCP).

Canada, UK, EU, Japan, South Korea, and Singapore, and are amongst those developing similar pathways.



Bigger than AI/ML

In some regions PCCP-like pathways exist, but must be expanded beyond AI/ML, bringing in scope devices in general and with it a host of opportunities to re-imagine regulatory approaches.



Novel to Industry

Health ministries and authorities may not have depth of experience with Innovation pathways. This is both an opportunity and a challenge.

Industry/regulatory collaboration is strongly recommended to help better facilitate global harmonization.

Example of Changes an Innovation Pathway Can Support

The following is a non-exhaustive list of potential robotic system changes:

- **AI/ML:** to update an AI/ML algorithm (e.g., improve performance by retraining with a larger data set).
- **User interface or device design:** to modify user interface features such as voice recognition or gesture improvements; or design features or specifications.
- **Modifications to software:** to add new software features.
- **Connectivity:** to support changes to improve devices connectivity, health care setting integration, or interface with other equipment.
- **Operating system:** to make software changes necessary to maintain use of a 3rd party platform.
- **Device components:** to potentially improve performance, or to replace with a functional equivalent.
- **Supply chain management:** to improve supply chain resilience (e.g., proactively identify component replacements) and improve efficiency of the manufacturing process (e.g., additional manufacturing capacity)



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Robotics Complexity Requires Centralized Policy Advocacy

A Targeted Approach is Needed

When examining the current efforts by working groups and collaborations, we observe a focus on various elements that comprise robotics.

It may be more advantageous to establish a dedicated group focused on specifically on robotics policy. Such a group could draw from the work of existing initiatives while concentrating specifically on robotics applications and their unique challenges.

Additionally, inclusion of critical topics like capital equipment, service and repair, and reimbursement—key components for ensuring market access and the sustainability of robotics in healthcare—will drive faster adoption and greater patient access.

Robotic Coverage Currently

A quick glance of IMDRF working groups covering robotic-related topics

IMDRF: Artificial Intelligence/ Machine Learning Working Group

Focused efforts related AI/ML could apply directly to robotics.

IMDRF: Software as a Medical Device

Focused efforts related to software could be leveraged to by robotics technologies.

IMDRF: Regulated Product Submission

Focused efforts related to harmonizing submission requirements and approaches can accelerate multi-country access to robotics.

IMDRF: Good Regulatory Review Practices

Efforts focused on Develop good review practices for pre-market reviews and evaluations can improve patient access to all types of devices, including robotic systems.

Robotic Coverage Currently

A quick glance of GHWP working groups covering robotic-related topics

**GHWP: Work Group 3 -
Premarket: Software as a
Medical Device**

Focused efforts related to software could impact robotics as well.

**GHWP: Work Group 4 -
Postmarket**

Focused efforts related to postmarket could be leveraged to by robotics technologies, such as real-world evidence and training data.

**GHWP: Work Group 5 -
Clinical Evidence and
Performance Safety**

Focused efforts related to establishing and evaluating clinical evidence and performance have significant ties to robotics technologies and their safe implementation.

**GHWP: Work Group 8 -
Standards**

Focused efforts related to robotics standards would be essential in building robotics that are suitable for multiple markets.

Dedicated Policy Helps Ensure Safe and Ethical Use

•Patient Safety:

- Consistency in expectations for pre-market testing to ensure reliability and performance.
- Clear and transparent post-market surveillance to track safety metrics.

•Ethical AI Integration:

- Clear guidelines on autonomy levels to define human oversight.
- Addressing data privacy concerns in AI/ML-powered robots.

•Equity in Access:

- Reducing cost barriers for resource-limited settings.
- Developing scalable solutions for underserved areas.

•Global Collaboration:

- International guidelines for robotics deployment and use.
- Sharing of data and best practices across nations.

Thank you