



2023

Medical Device Connectivity



ZEISS

What are Opportunities
and Challenges.

Connected Health. A growing market.

Connected health market is growing at tremendous pace of CAGR 25.2%¹ worldwide and is heavily dependent on the ability of various medical devices to connect to each other and to other health and medical information systems.

Telemedicine growth stimulated by COVID lockdown and limitations for face to face visits proved that many patient care workflows might be easily moved to remote care scenarios. Which in turn again raised the need for remotely connected medical devices with the ultimate goal to bring as many patients to home-based care as possible.

For the inpatient care other drivers stimulate the connectivity of devices. On average 10 to 15 medical devices² accompany one hospital bed, and some of them are really critical for the continuity of care and for the stability of clinical workflows.

The management of these devices, which is known as asset or fleet management, is a pressing challenge. In case of a city or regional clinic or hospital this amounts a fleet of hundreds or even thousands of medical devices. Managing and maintaining such a big fleet requires understanding device conditions, their servicing intervals, software update requirements, and general lifetime of the device before replacement. Without proper connectivity and interoperability such tasks are very hard to execute.

You will find in this document a summary of key challenges as well as opportunities in this growing market.

**25,2%¹
Globally
Worldwide
CAGR**

Definitions:

Medical Device Connectivity

The ability of medical devices to exchange information with other medical devices, electronic medical records, or other information systems, often via wired or wireless connections.

(American Hospital Association)

Connected Medical Device

A medical device that is equipped with the ability to connect to other devices or systems, such as electronic medical records or other healthcare IT systems, in order to transmit or receive data.

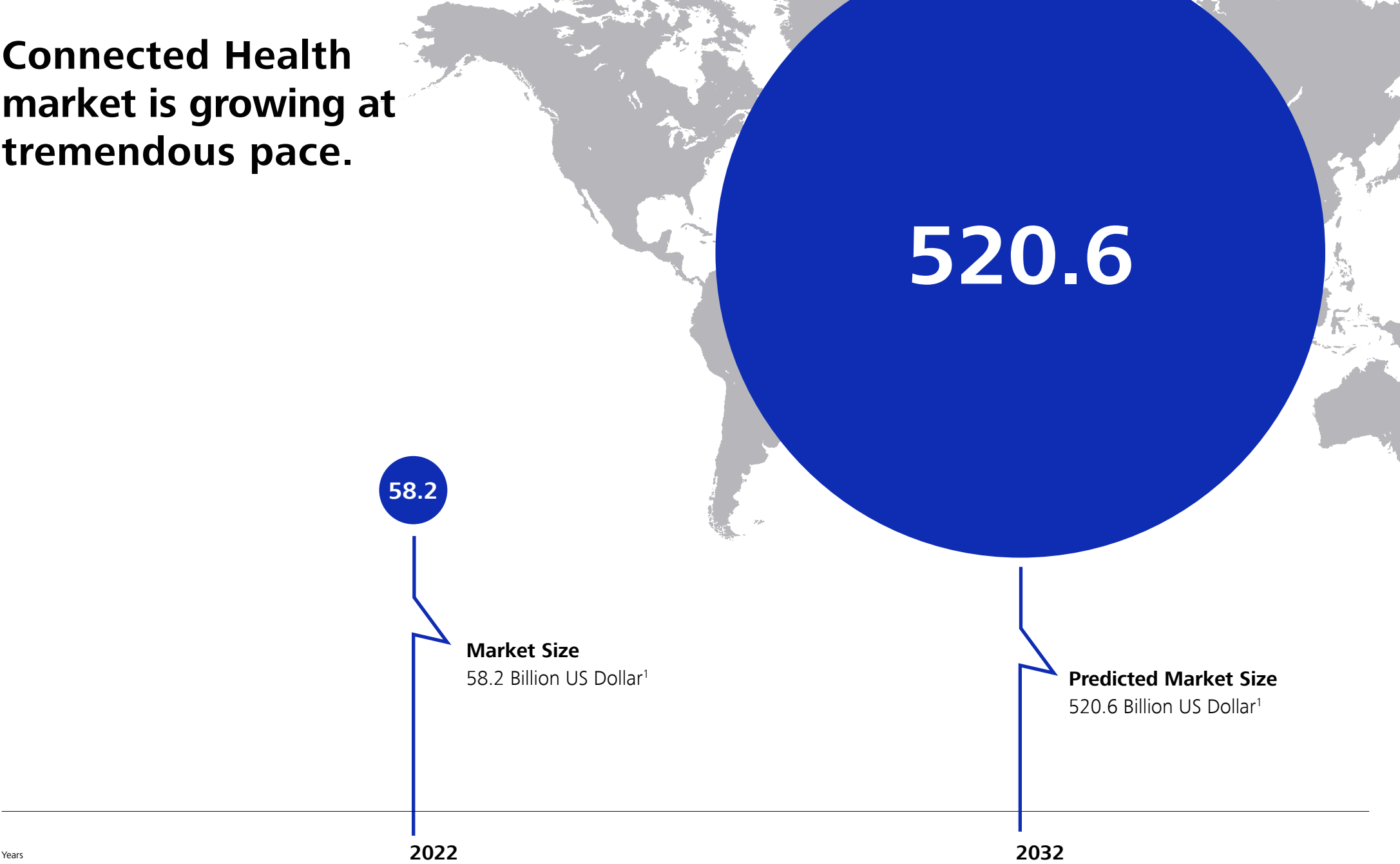
(US Food and Drug Administration)

Internet of Medical Things (IoMT)

A subcategory of the Internet of Things (IoT) that refers specifically to connected medical devices and other healthcare technology that are capable of transmitting data.

(Frost & Sullivan)

Connected Health market is growing at tremendous pace.



Key Challenges for Device Connectivity

Variety of standards and proprietary interfaces of devices (especially for clinics and hospitals with significant legacy technologies) leads to interoperability issues in clinical setup, compliance and workflow management, and is not allowing for proper implementation of security mechanisms when there is a mixed fleet of devices.

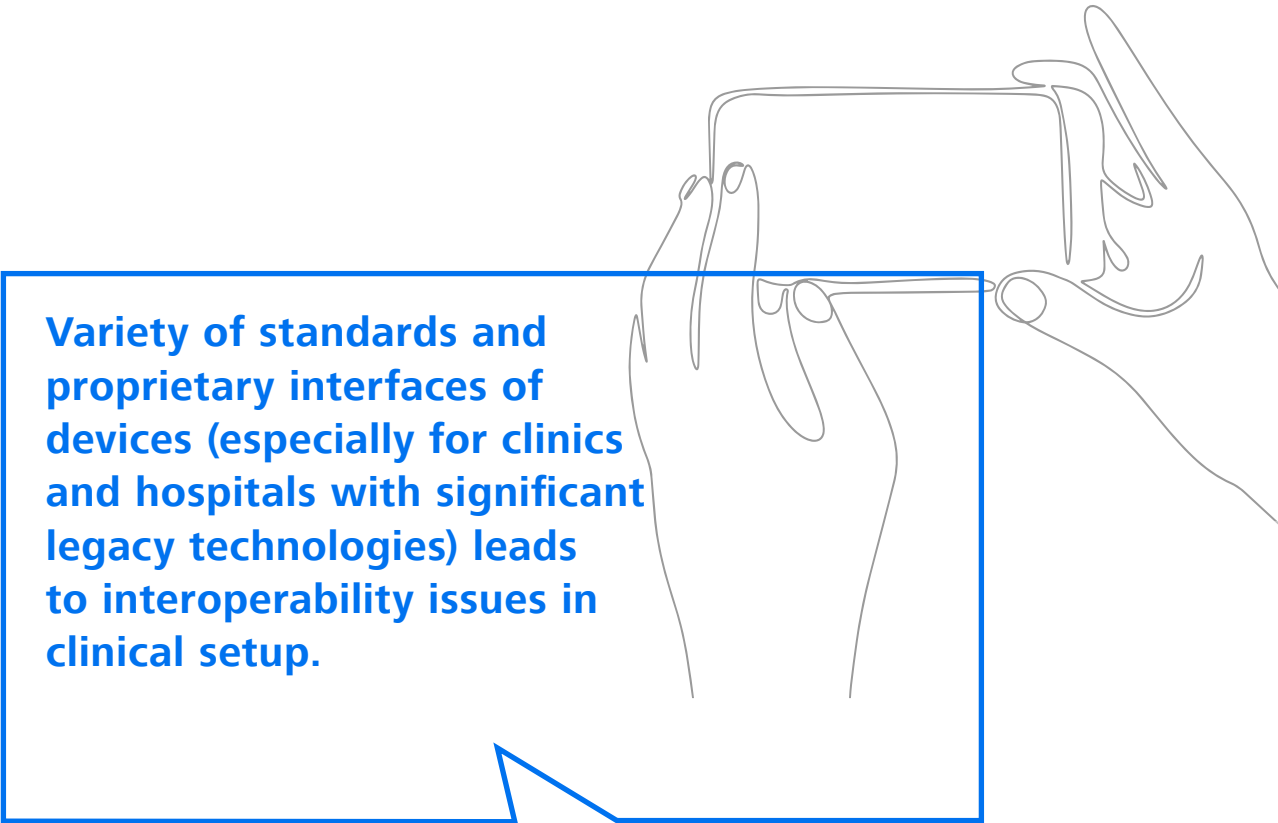
01
Interoperability

02
Security

03
Workflow

04
Regulatory Compliance

01
Interoperability



Variety of standards and proprietary interfaces of devices (especially for clinics and hospitals with significant legacy technologies) leads to interoperability issues in clinical setup.

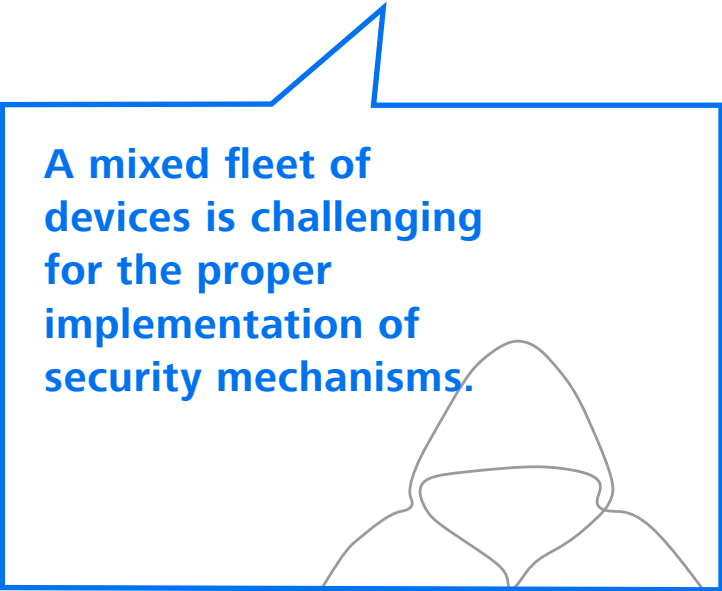
Lack of interoperability between devices and EMR/HER systems.

Proprietary and non standardized data format and exchange protocols of medical devices.

02
Security

Healthcare was the most targeted industry for cyber attacks in 2020, accounting for 79% of all reported data breaches.²

Ponemon Insitute found that 67% of healthcare providers had experienced a cyber attack on their medical devices.²



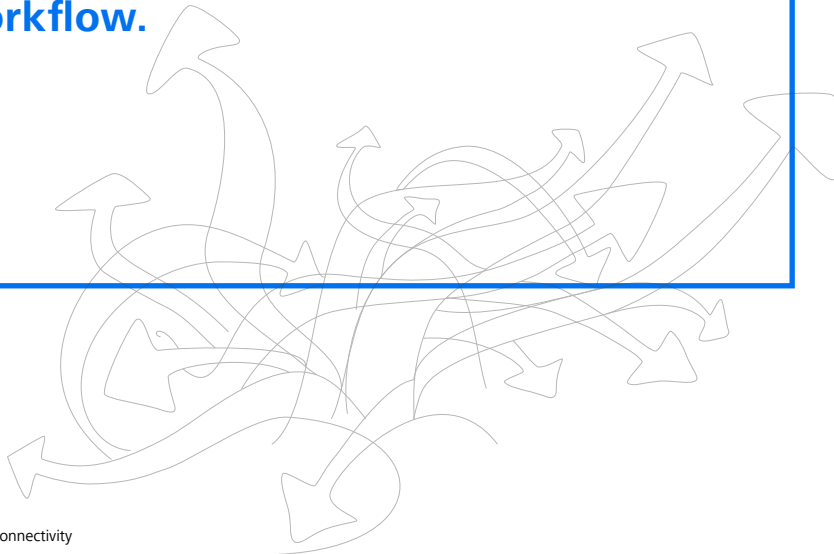
A mixed fleet of devices is challenging for the proper implementation of security mechanisms.

03 Workflow

Healthcare generates large amounts of data, but managing and making sense of that data remains a challenge.

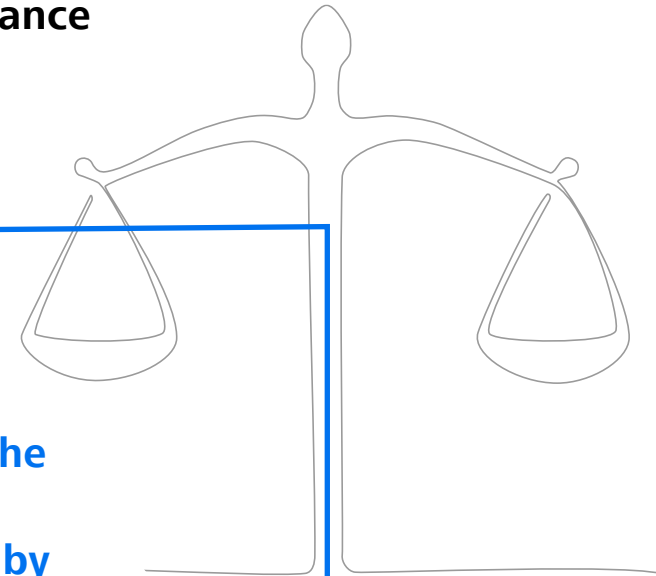
ECRI Institute identified usability issues as a top concern for medical devices, with factors such as poor user interfaces and complex data entry requirements contributing to increased risk of errors and patient harm.

Connectivity disruptions, management of data produced as well as usability issues present challenges to the workflow.



04 Regulatory Compliance

Ensuring proper device software integration into the clinical setup can only be achieved by adhering to current regulation.



Different regulations in the world regions regarding different types of medical solutions lead to extended time to market for innovative products. Major examples include:

- The US Food and Drug Administration (FDA) issued guidance on the cybersecurity of medical devices.
- The European Union's Medical Device Regulation 2017/745 sets requirements for design and production.

Key Opportunities for Device Connectivity

01
**Improved
Patient Care**

02
**Asset or Fleet
Management**

03
**New Business
Models**

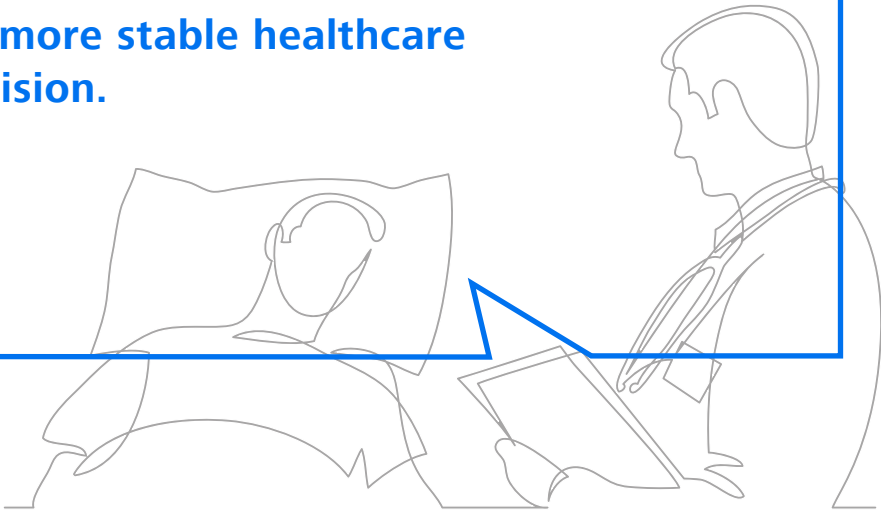
04
**Applied Artificial
Intelligence**

01

**Improved
Patient Care**

Remote patient monitoring is the most critical part of the remote care setup. In a future with fully connected clinical beds more patients can be brought home for care and the cost of remote care will drop significantly. Adding AI to this vision will allow for personalized care.

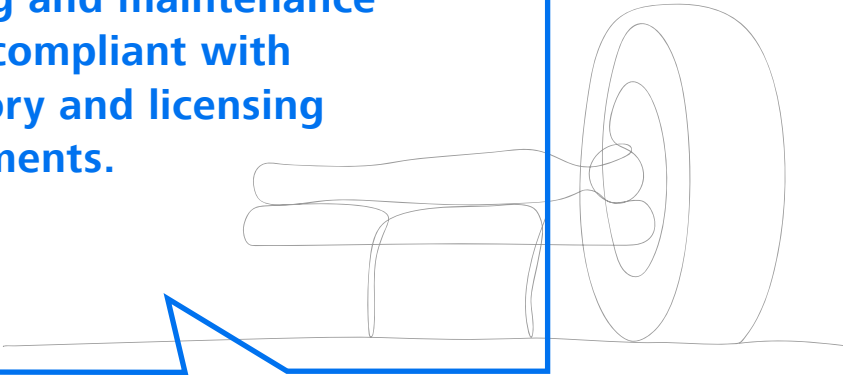
Fully connected clinical workflows will minimize man-made errors and result in a more stable healthcare provision.



02

**Asset or Fleet
Management**

Globally millions of devices require proper and timely servicing and maintenance to stay compliant with regulatory and licensing requirements.



Proper management of the fleet will not only help healthcare providers to comply with regulatory requirements related to device safety and maintenance, it can also address device connectivity and interoperability challenges by providing a centralized platform for managing and integrating data.

If this were to be combined with AI it could mean: automated device performance monitoring, tracking of maintenance needs and even optimization of device utilization.

03

New Business Models

While many³ in the industry are already working on the realization of ideas like value based healthcare, personalized care or individual health risk profiling, one can only imagine how many more will be unlocked when all medical devices and data get connected and properly integrated, analyzed and leveraged.

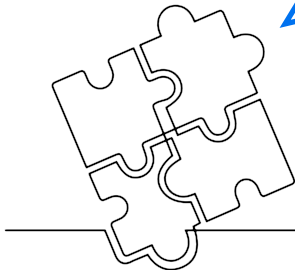
One can only imagine all potential new business models arising when all medical devices are connected and the data from them is properly integrated, analyzed and leveraged.



04

Applied Artificial Intelligence

AI enables many opportunities to process constantly increasing amounts of medical data produced by devices, to extend use cases for existing devices, improve quality of diagnostics or care without investments into changes of device software.



Just imagine what might become possible with AI: Predicting a health risk by drawing insights from the analysis of a pattern in data originated from constant monitoring.



Key Take-Aways for your next connected medical device project

Follow Proven Cybersecurity Practices

The Medical Devices industry is highly regulated to ensure proper security for patients' lives, health and their data. Following secure SDLC cycle for timely identification and elimination of threats at early stages of the solution development and implementation of threat modelling techniques might significantly shorten time-to-market cycles and reduce overall costs, improve brand image and satisfaction of device users.

Make your R&D effective with hypothesis validation prototyping

Effective R&D practices and proper innovation cycle is recommended to ensure proper ideas got prioritized, and to reduce costs and improve time-to-market it is recommended to implement hypothesis validation techniques with early modelling and prototyping in close to real environments before full implementation.

Align with industry standards to ensure regulatory compliance and interoperability

In order to ensure that device software properly integrates into the ecosystem of other information systems in the clinical setup, that it will not create additional risks for information and cyber security, compliance risks and will fit properly and reliably in to the continuity of care it is important to adhere to industry standards (HL7/FHIR, DICOM, SDC, ISO 13485, ISO 27001) and follow important regulations (HIPAA, GDPR, MDR).

Improve understanding of how doctors and patients will use your devices and software in their workflows

Workflow analysis is a critical task to be completed before developing any device connectivity solutions: Understand and capture full clinical user journey and perform context awareness analysis to design a complete clinical workflow and what use cases the device supports.

Rely on the right Expertise

If you want to improve in connectivity of your medical devices and the ecosystem of connected medical solutions, shorten time-to-market cycles, improve quality and interoperability of your medical and health-care solutions, to make use of the innovative technologies - we at Zeiss Digital Innovation Health Solutions would be glad to support you in turning your challenges to opportunities to build a new connected future for medical devices together

Address your digital health challenge with us:

Leo Lindhorst

Head of Innovation Health Solutions at
Carl Zeiss Digital Innovation GmbH
leo.lindhorst@zeiss.com

Author:

Dmytro Batsenko

Senior Consultant Innovation Health Solutions at
Carl Zeiss Digital Innovation GmbH
dmytro.batsenko@zeiss.com



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Carl Zeiss Digital Innovation GmbH

Fritz-Foerster-Platz 2
01069 Dresden Germany

Phone: +49 351 49701 – 500
Email: info.digitalinnovation.de@zeiss.com
zeiss.com/digital-innovation