Internet of Medical Things
Healthcare is facing numerous challenges

As our population ages and the cost of care increases, the healthcare industry must find innovative ways to solve operational, clinical, and financial challenges.

Health expenditure will outpace GDP growth over the next 15 years in almost every OECD country, according to new OECD forecasts. Health spending per capita will grow at an average annual rate of 2.7% across the OECD and will reach 10.2% of GDP by 2030, up from 8.8% in 2018, according to a new OECD report.

Global spending on health is expected to increase to $18.28 trillion worldwide by 2040. More resources are expected to be spent on health in the future with a projected 9% of GDP globally allocated to health spending by 2040.

The percentage of people aged 65 and over is expected to double by 2050.

The IoT is not coming; it’s already here

127 new devices are connected to the internet every second.

It is expected that there will be 75 billion IoT devices in the world by 2025.

29.66 billion IoT devices were active in 2019.

30.3% of IoT devices are used in the healthcare industry.

The IoMT will save $300 billion in the near term.
IoT healthcare ecosystem

For health providers, the IoT unlocks efficiencies for clinical staff and equipment:

- Reduces human error.
- Ensures regulatory compliance when exchanging patient health data across systems.
- Coordinates the productivity of medical professionals across clinical facilities.

For manufacturers, the IoT creates new digital feedback loops connecting their employees, facilities, products and end customers. Real-time data can help:

- Reduce costly downtime with predictive maintenance.
- Improve sustainable practices by reducing waste and ensuring worker safety.
- Contribute to improved product quality and quantity.

For the pharmaceutical industry, the IoT provides greater traceability for inventory along a supply chain:

- Improved visibility into environmental conditions.
- Reduced costly inventory spoilage.
- Increased control against theft or counterfeiting.

For end patients, the IoT can improve health outcomes with continuous patient monitoring:

- Reduces the need for unnecessary readmissions.
- Improves treatment success rates by providing continuous data to care professionals.
- Personalises care based on patient needs.
What is the Internet of Medical Things?

From pregnancy testing kits to surgical instruments, artificial joints and MRI scanners, the medical technology (medtech) industry designs and manufactures a wide range of products. Technology is allowing these devices to generate, collect, analyse and transmit data, creating the Internet of Medical Things (IoMT) – a connected infrastructure of health systems and services.

The IoMT and its relationship to medtech is instrumental in helping health care organisations achieve better patient outcomes, lower climbing health care costs, improve efficiency and activate new ways of engaging and empowering patients. The pace and scale of health care transformation will be exponential if medtech can harness the IoMT.

The seven main ways the IoMT impacts healthcare:

1. Improved drug management
2. Decreased costs
3. Improved diagnosis and treatment
4. Enhanced patient experience
5. Remote monitoring of chronic diseases
6. Improved disease management
7. Improved patient outcomes

Global IoMT market value

<table>
<thead>
<tr>
<th>Year</th>
<th>Global Market Value (billion USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>44.5</td>
</tr>
<tr>
<td>2019</td>
<td>55.5</td>
</tr>
<tr>
<td>2024</td>
<td>188</td>
</tr>
<tr>
<td>2026</td>
<td>254.2</td>
</tr>
</tbody>
</table>
ERNI customer cases

Enabling communications for laboratory instruments

ERNI provides support to enable the communication between medical devices and Laboratory Management Software solutions.

We develop pieces of software to allow communication between laboratory instruments and Laboratory Management Software. ERNI develops the communication layer that allows any sample preparation instruments and diagnostic instruments in the market to connect to these IT Solutions.

We are currently supporting all kind of laboratory sizes and types, and also hospital solutions. We have deep and solid knowledge in all standard communication protocols in the medtech domain such as HL7, ASTM and POCT1A. And we are also able to integrate any proprietary protocols.

ERNI designs and develops solutions, based in .NET core, which are host operating system independent and allow the integration instruments and IT Solutions, which enable us to control end-to-end communications in a diagnostic environment.

Preventive Maintenance Solution

Our customer, a leading company in in-vitro diagnostics and one of the largest pharmaceutical firms globally, wants to integrate some AI capabilities into their medical device, a chemistry analyser.

This device has a throughput of 250,000 tests yearly and it is a compact benchtop system for labs with limited floor space. It is designed to consolidate testing and increase efficiency while reducing running costs for the lab.

The idea is to conceptualise an intelligent solution that can schedule preventive maintenance activities based on data and information available on low-level instruments. Data was gathered with the purpose to find out if such data can be used for predictive maintenance purposes.
Our delivery steps have been:

- Find means for scheduling preventive maintenance
- Implement condition monitoring features for existing instruments
- Research scenarios to determine optimal use of available data
- Use ETLs to capture and transform machine data
- Use cloud-based storage to provision data for predictive maintenance applications utilising machine learning

---

**DevOps Mandate for Swiss Medtech Manufacturer**

The customer is the leading developer and manufacturer of injection and infusion systems for self-medication and a renowned diabetes specialist with 30 years’ experience.

ERNI began a development partnership to support the customer in the DevOps area. We have a validated development tool chain for the development of embedded software based on ISO13485:2016, Computer system validation. We have given support evaluation of artefact management (ALM software), application management of TFS. We have designed cloud architecture to bring patient data from instruments into the AWS cloud and to their customers, enabling device provisioning, device management, re-supply and data analytics across all devices (100+ types).

It allows to our customer build better instruments, deliver supplies and replacements on time and receive insights and analysis of end-user behavior.
**Application for Coagulation Patients**

The mobile application, available for iOS and Android devices, was developed for Oral Coagulation Treatment patients to help them control and monitor their INR (international normalised ratio) level and daily dosage, view historical data, plan medical visits with calendar integration and enable a direct line of communication with the doctor to help the decision making.

This application is designed and developed to securely interact with the hospital network in order to access and manage patient data using Wi-Fi or cellular network; it also implements an offline architecture to allow patients to track their measurements without internet.

Patients can access the application using their credentials or using advanced mechanisms such as fingerprint and face recognition.

Our customer’s external INR measurement device connects with the application using BLE (Bluetooth Low Energy) to allow patients to quickly sync of their INR information.

<table>
<thead>
<tr>
<th>Improved drug management</th>
<th>Decreased costs</th>
<th>Improved diagnosis and treatment</th>
<th>Enhanced patient experience</th>
<th>Remote monitoring of chronic diseases</th>
<th>Improved disease management</th>
<th>Improved patient outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HIV Application for patient support**

It is a system intended to allow patients to be connected to the sanitary network (having a secure communication) and boost the engagement in HIV.

This mobile health application supports engagement in HIV care and viral load suppression.

The mobile health application (app) delivers HIV viral load results, as well as educational and clinical support directly to patients’ smartphones, empowering those living with HIV to remain adherent to treatment and engaged in care. It can provide HIV VL results to users faster than standard of care.

**The software platform was built from:**

- A backend software development based on a single sign-on solution (Oauth2)
- A mobile app which uses the authentication to grant the access to the information
- A cloud-based platform to enable doctors to contribute to the system

<table>
<thead>
<tr>
<th>Improved drug management</th>
<th>Decreased costs</th>
<th>Improved diagnosis and treatment</th>
<th>Enhanced patient experience</th>
<th>Remote monitoring of chronic diseases</th>
<th>Improved disease management</th>
<th>Improved patient outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Mobile Application – Diabetes Management**

The client required a mobile application that allows patients to have tools for diabetes management at their fingertips. It is meant as an aid in the treatment of diabetes patients and recommended by the customer’s physicians and hospitals.

The ERNI solution has been developed to utilise automatic transmission of readings from a glucose meter analyser, and then its bolus suggestion is used to calculate insulin dose. The application sends diabetes info to your doctor via the web account. The users can see diagrams to view gradients and patterns.

Data is synced to the mobile app via Bluetooth protocol, and the app and database are also synced with the cloud.

<table>
<thead>
<tr>
<th>Improved drug management</th>
<th>Decreased costs</th>
<th>Improved diagnosis and treatment</th>
<th>Enhanced patient experience</th>
<th>Remote monitoring of chronic diseases</th>
<th>Improved disease management</th>
<th>Improved patient outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
# Challenges and opportunities of medtech

<table>
<thead>
<tr>
<th><strong>Regulatory</strong></th>
<th>National and international compliance</th>
<th>Regulatory oversight delays</th>
<th>Regulatory adaption</th>
<th>Slow technology adoption</th>
<th>Pressure of delivery vs. compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data privacy</strong></td>
<td>Data protection by design and by default</td>
<td>Collection &amp; storage of patient health information</td>
<td>HIPAA GDPR compliance</td>
<td>Encryption and anonymisation</td>
<td></td>
</tr>
<tr>
<td><strong>Cybersecurity</strong></td>
<td>Attacks, ransomware, intrusions, malware</td>
<td>Software vulnerabilities, lack of upgrade policy</td>
<td>Wireless devices monitoring &amp; protection</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Connectivity</strong></td>
<td>Huge number of devices</td>
<td>Not enough wireless capacity</td>
<td>5G is promising, but won't reach everywhere</td>
<td>Monitoring, battery life</td>
<td>Unreliable network structures</td>
</tr>
<tr>
<td><strong>Interoperability</strong></td>
<td>Many incompatible different devices</td>
<td>Unstructured data</td>
<td>Multiple IOT standards</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Scalability</strong></td>
<td>Massive information datasets</td>
<td>Storage of data</td>
<td>Selection of relevant data to storage</td>
<td>Huge gap from pilots to global solution</td>
<td></td>
</tr>
<tr>
<td><strong>Accessibility</strong></td>
<td>Hospitals &amp; Clinics centralised access</td>
<td>In-home telemedicine</td>
<td>On-the-body wearables</td>
<td>Health insurance companies</td>
<td>Remote and rural areas</td>
</tr>
<tr>
<td><strong>Analytics</strong></td>
<td>Insights from massive information datasets</td>
<td>Need consistent, unbiased data</td>
<td>Detect hidden patterns</td>
<td>Centralised processing</td>
<td>Real-time visibility of quality and performance</td>
</tr>
</tbody>
</table>
**Regulatory**

Technology is moving at a faster pace than the healthcare system and the regulatory system. Unlike the consumer electronics market, the development process of medtech products must be carefully documented, traceable in the case of audits, adherent to international certification standards (like ISO13485 or IEC62304), compliant with existing national and international regulations (like the imminent MDR or IVDR for the EU) to ensure the safe delivery of their products. Additionally, slow and lengthy acceptance procedures by the regulatory oversight further contribute to the challenge: pressure of delivery against regulatory compliance.

Even though the latest regulatory policies in several countries are encouraging the adoption of the IoMT, the slow adoption of modern technologies is going to require entirely new regulations, for instance on medical data sharing platforms and how they handle sensitive information.

**Data Privacy**

Collection and storage of patient health information (PHI) is a very sensitive matter in medtech. Compliance with existing medical privacy laws such as the Health Insurance Portability and Accountability Act (HIPAA) and the California Consumer Privacy Act (CCPA) in the United States and the General Data Protection Regulation (GDPR) in the EU heavily impacts medtech solutions: data protection must be achieved by design and by default.

As no one-size-fits-all standardised platform to handle medical data exists, heterogeneous platforms are used together, which can end in a potential privacy nightmare. Careful selection of PHI to share among devices, proper anonymisation practices and end-to-end encrypted communications are key when handling medical data over the IoMT.

**Cybersecurity**

As the number of connected devices grows, cybersecurity risk increases. Healthcare provider networks are constantly under attack by ransomware, hacks and other threats (incapacitating medical networks, stealing and selling medical records).

IoMT devices can be more difficult to monitor and protect than other wireless devices, significantly increasing the risk of exposure. As no standard operating system for medical products exists, most medical devices use easily compromised off-the-shelf software. Also, if the security software of a device isn’t automatically updated, it can leave further vulnerabilities.

Lack of knowledge or training on secure coding practices and pressures on development teams to meet product deadlines are vulnerability contributors as well: hard-coded passwords or credentials, lack of relevant patching. Intended longevity adds further complications, as many IoMT devices are built to last from 10 to 20 years, and patching medical devices entails regulatory issues.
ERNI and cybersecurity best practices:
IoMT devices and networks must be designed to anticipate, prevent, identify, assess and respond to cyberthreats both known and unknown.

- A risk-based cybersecurity plan
- Device software developed in consultation with IT and medical device experts to avoid known legacy vulnerabilities
- Specific security features such as structured processes for limiting access to devices, proven secure design and communications protocols, secure standard operating procedures and physical barriers
- Regular security updates and software tests
- Third-party cybersecurity testing

Connectivity
Today’s wireless infrastructure does not hold the capacity to accommodate the huge number of growing devices in use. The continuous transfer and exchange of data puts a strain on the network and battery life of devices. And more often than not, hospitals and clinics endure unreliable network structures with spotty coverage and intermittent connectivity.

5G has the possibility to bring faster – near instantaneous – data transfer and zero latency. 5G connectivity can also support more sophisticated tracking sensors when reaction time is critical. But it is unlikely that 5G will be readily available other than in big cities in the foreseeable future. Remote and rural areas will remain a challenge.

Interoperability
Healthcare systems are extremely decentralised. Barriers to widespread medical interoperability exist even without factoring in the complexity of integrating new IoMT systems. Connected medical devices introduce even more data sources, providing unstructured patient-generated data formats that need to be stored, shared and consumed.

Even though open standards such as HL7, DICOM, CMS or FHIR are becoming widely adopted, they are not always implemented in the same way within and between organisations, impacting the chances of interoperability.

Scalability
The massive information datasets produced in the IoMT are usually stored in a cloud infrastructure (Azure, AWS, Google Cloud). Often solution builders struggle when growing their pilot into a globally scalable IoMT solution. This process introduces significant complexity into the whole system architecture, requiring expertise across cloud and device security, DevOps, compliance and more.
The huge amount of patient data generated is often greater than what is actually needed for useful analysis, and each kind of device provides heterogeneous unstructured data. Therefore, only the most relevant data must be collected and stored, discarding duplicate and inaccurate data, maximising the quality and the consistency of the information that will be used for analytics.

Cloud storage solutions provide the perfect environments for such hoarding of data, but a careful design is required to guarantee efficient and redundant data filtering and processing while minimising the volume of stored data and complying with regulatory, security and privacy requirements.

**Accessibility**

One of the key objectives of the IoMT is to keep the patient in continuous contact with their health care provider, and to allow their provider to easily access and check patient-generated data. A performant cloud solution that aggregates and stores data from all medical devices, and allows timely access to it for physicians, caregivers, patients, payers or health insurance companies from everywhere in the world and always in a robust and secure fashion is of paramount importance.

In hospitals and clinics, a doctor can view a patient’s lab or imaging results and latest vitals in real time on his or her mobile device. Payers can view patient data more quickly, allowing for claims to be processed accurately and quickly. At home, remote monitoring systems can allow patients suffering from serious diseases to avoid visiting the doctor frequently. Biosensors and wearable medical devices can allow both healthy and sick people to access their information through websites or smartphones.

**Analytics**

Cloud technology is increasingly embraced by the pharmaceutical and healthcare industry as an important channel for computing big data. Mining, managing and analysing a vast array of data from IoMT devices raise the need for developing advanced analytical capabilities able to uncover hidden patterns and trends in information. Accurate and consistent data is key to avoid incorrect conclusions.

From diagnostic accuracy and patient care to medical research and drug development, AI is revolutionising the healthcare sector, leveraging on AI advancements in machine learning, voice recognition, cognitive technologies and digital imaging.

As the AI trend becomes more deep rooted, it gives rise to highly ubiquitous discussions. Will AI replace doctors and medical professionals? What about regulatory concerns? Whereas a non-AI device can undergo thorough testing and gain approval, an AI’s performance may be different the day after it’s undergone testing.
ERNI and IoMT projects

Many of our customers' data projects are subsets of larger Internet of Medical Things initiatives. This illustration describes/shows the ERNI collaboration model for IoMT projects.

Vision
Through a series of workshops, and using our medtech domain expertise, we reach a common understanding of your needs and objectives. We develop a vision showing you how to reach your business objectives with the help of cutting-edge digitalisation technology suitable to a highly regulated environment.

Use Cases
We identify use cases with the highest return and decide on what to implement based on ROI.

Architecture
Following ISO13485 methodologies and procedures, we outline the architecture and realisation of the vision for achieving identified objectives.

Rapid prototyping
We evaluate platforms and implement prototypes. Our agile mindset allows us to have a high productivity team through all the stages of your V&V model or our adapted QMS and V&V medtech model. If required, validate the prototype in a BSL-capable laboratory.

Quality Solutions
All our projects include quality assurance set-up and have been certified in ISO9001 and ISO27001. If required, validate the final solution in BSL-capable laboratory.

Enhance your future solution
The final solution must be able to provide meaningful data to your engineering and data departments to optimise your current solution, improve customer satisfaction and achieve business targets.
Key trends shaping the IoMT industry

**Disruptive technologies can improve the pulse of healthcare**

These disruptive technologies are changing ways of working across the whole IoMT ecosystem. Big data, AI, mobile applications, 3D printing, advanced sensors and other technologies will continue to create new opportunities for medtech companies. Voice technology is being adopted faster than any previous technology, from chatbots and doctor visits, to home health care.

**Additive manufacturing**
(3D printing) is significantly reducing the costs of medical implants and surgical tools, and can enable hospitals to create tools on site.

**Genomics**
is improving our understanding of health conditions, providing patients with more information on their health risks, making health care more personalised and therapies more accurate.

**Smart sensors and materials**
of increasing sophistication can allow products and materials to alter their behaviour based on external conditions such as pH, temperature, electric fields and bacteria.

**Robotics**
is providing surgeons with new and more accurate tools for complex surgeries. It is also making health care operations, such as the delivery of medical goods throughout a hospital more efficient and less costly.

**Advanced digital imaging**
is creating visual representations of internal human anatomy, with pre-, peri-, and post-operative digital images used to obtain a more accurate picture of internal patient anatomy.

**Telemedicine**
enhanced 5G technologies will enable high-resolution connections to remote areas and can also empower remote surgery through the use of robotics.

**Blockchain**
can improve the privacy of sharing data across a large network of users and provide an immutable record of data transactions.

**Pandemic detection and control**
The IoT can help to collect sensory data in real-time. It involves tracking people, health systems and environments. For example, smart thermometers are feeding data in real-time to global medical systems; bench-top analysers are analysing patient samples instantly and sharing data in real-time with disease monitoring tools installed miles away.

**Advanced technologies can improve:**

- patient outcomes
- healthcare related costs
- access to healthcare
- the accuracy of medicines
- the manufacturing of products
- the privacy and security of patient data