

Experience

Managing Data

A magazine by ERNI.
March 2018



Focus topic
medical technology



At ERNI, we work hard like climbers to find the best route to take you to the top.

Miloš Karas, Professional Test Engineer

From data to information to valuable assets



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A trend over the past few years is that more and more of our customers are starting to think about how they can make a profit out of their data. Installed devices, executed business processes and customers all typically generate large pools of data. And the technologies to capture, analyse and transform this data into information that eventually creates value for businesses are already out there.

ERNI supports its customers from the very beginning of such projects. We guide them through the creation of appropriate business models, and help them define what data to collect and why, and how to transform this data into valuable information. We run innovation workshops together with our customers, develop the first prototypes or minimum viable products and prepare and run pilot projects. With more than 600 software experts all across Europe and Asia, ERNI implements the resulting products and applications on time and in a cost-efficient manner.

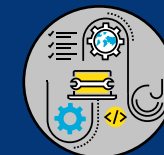
The business model might need to be adapted, the processes changed or an urgency for new departments or whole divisions might arise.

Data-driven projects in medical technology are the special focus of this issue of Experience magazine. We've shared our experiences from some of our recent data-driven projects and analysed them from the innovation and implementation perspectives. Medtech is a typical example of a hardware-intensive industry in which experience with software-intensive projects is still limited. The featured case studies showcase when and how ERNI expertise can significantly support C-level executives and project managers who are new to data-centric projects.

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Analyst, Data
Science & Machine
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The medical industry is not fully accustomed to working with data yet – what can we do about it?



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Senior Principal
Consultant

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The transformation to a data-driven company can take many shapes. Where do you start when you have no experience? And what do you do next when you already have several data initiatives in place?



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Lab Manager and
Test Manager

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Lab Manager Nuria Lluch walks us through ERNI's own medical laboratory in Barcelona.



About ERNI

ERNI believes in the impact of Swiss Software Engineering to create customer value. Our mission is to boost people & businesses in the innovation of software-based products and services.

The global platform for Swiss Software Engineering combined with a deep market understanding provides the framework for customer success. Our crew manages the complexity of projects, enables people and delivers customer solutions fast. A Swiss mindset with behaviours like consensus-building, pragmatism, integration, reliability and transparency have been deeply rooted in the ERNI culture since 1994. Together with our great crew, they are the basis for successful software projects. Today, the ERNI Group has more than 600 employees at 13 locations.

About Experience magazine

In the magazine, published triannually by ERNI, we share important lessons learnt in collaboration and technology.

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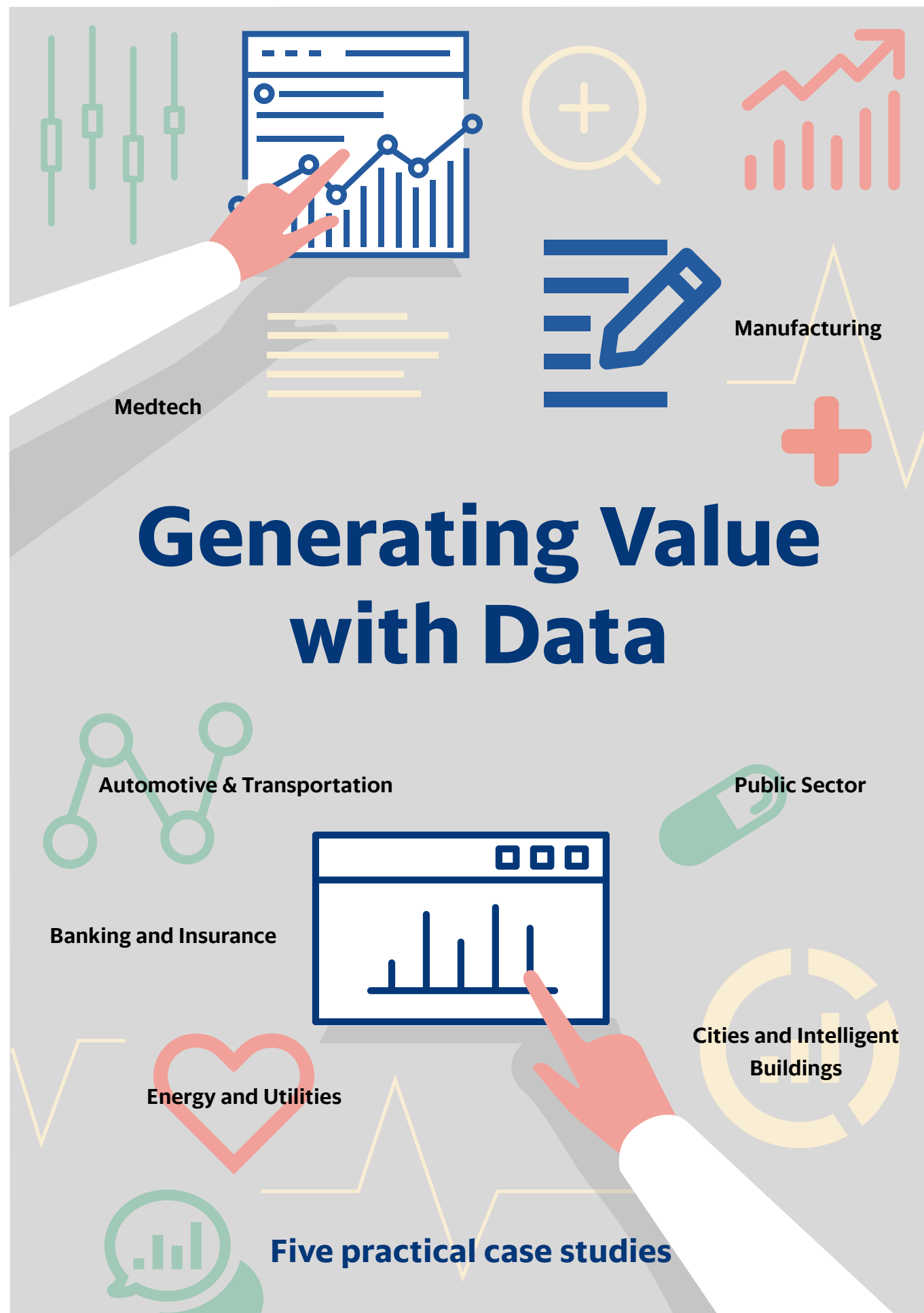
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How ERNI Uses Data to Generate Value

Five practical case studies

Data on its own is meaningless. What matters is how the data you collect is analysed and evaluated, and which of your business processes and products can be improved through data.

ERNI helps many customers that are leaders in their industries. The most pervasive data trend that can be observed across all sectors is the collection of data focused on value (smart data), rather than sheer volume. You can sometimes stumble upon something meaningful or discover an occasional gem by drilling down into unstructured, large sets of data. However, some of the most successful data projects we've participated in do the exact opposite.

Data science initiatives can cover a very broad spectrum. At the lower end of expectations, you can simply aim to improve your processes in order to introduce fact-based and informed decision making to fuzzy areas. On the higher end of data science initiatives, you can kick-start major product innovations, introduce new business models and even venture into uncharted

business territories and new industries (but ERNI makes sure you have a scalable and sustainable solution).

This article showcases some of the recent data projects we've worked on. For newcomers to data science, this is a useful starting point that will help you navigate the possibilities of data analysis or AI and cognitive services. For seasoned data practitioners, we aim to introduce expertise and inspire new ideas and projects and foster discussion.

Whatever your background, look at the value generation process as a whole and understand your data from the perspective of business processes and value chain management. This way, you'll make sure every data point you collect actually matters.

ANALYSING DATA



1. Prediction of Air Quality Based on Traffic

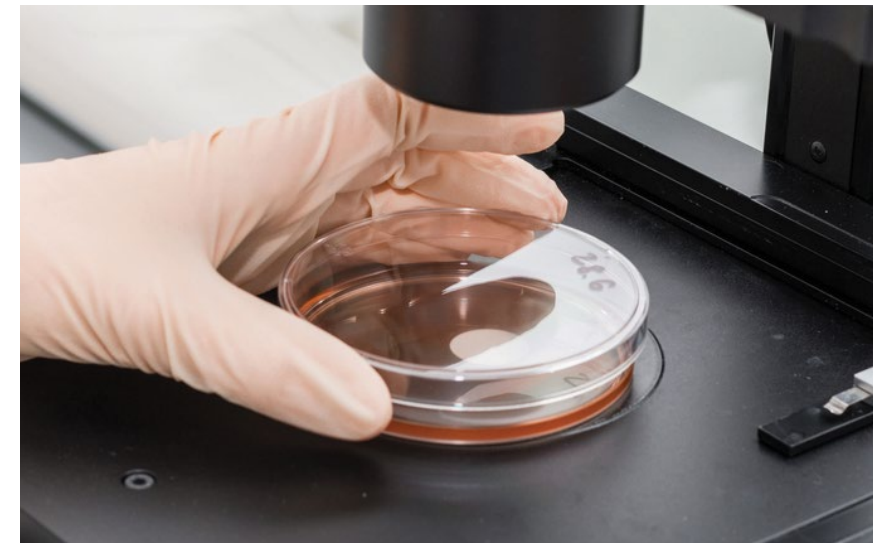
ERNI was asked to use current road traffic information in order to provide a weather station with predictions about air quality (particulate matter PM10).

The biggest issue was collecting up-to-date traffic data from a reliable source. Our team evaluated numerous approaches on how to separate road traffic from secondary data (e.g., delays, traffic jams or historic counts).

The information collected was combined to generate a local traffic rating. In order to establish a model that could predict air quality, we used tools such as **Microsoft Azure Machine Learning** and **Google TensorFlow**, along with **pandas** and **Python**.

Results: As a pilot study, this model accurately predicts air quality in a vicinity of 10 km and our cloud-hosted predictor facilitates simple integration into the weather station's software or alternative applications.

PREDICTIVE MAINTENANCE



2. Operating 10 000 instruments around the world through smart use of data

Our customer sells analytic instruments to laboratories all over the world. Its customers expect no less than minimal downtime, proactive maintenance, flexible support and robust data security. Maintaining and operating close to 10 000 instruments worldwide is a highly demanding task for this customer.

We assisted in building a state-of-the-art infrastructure for predictive maintenance and operational excellence.

1. Standardisation

In the beginning, we captured and standardised all worldwide maintenance processes to the widest extent possible.

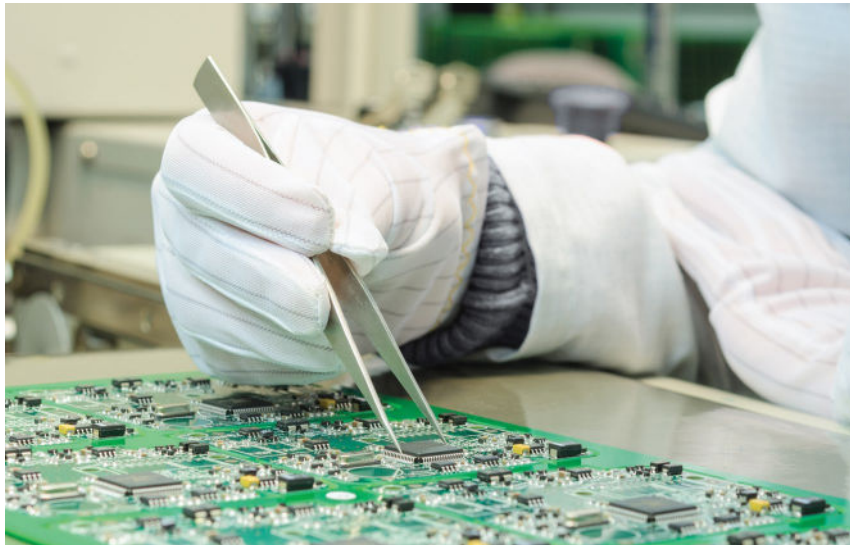
2. Requirements engineering

The standardisation allowed us to derive concise requirements for a data collection platform that aggregates and centrally stores valuable data from instruments located all over the world.

3. Pilots

Several pilot studies on predictive maintenance were carried out to determine the most beneficial scenarios that would guarantee operational excellence and simplify our customers' maintenance processes. A machine learning and artificial intelligence platform is being established as the next step. The platform will allow prompt local analysis of instruments and enable central processing using the complete data set.

PREDICTIVE ANALYTICS



3. Predicting failures in Semiconductor Manufacturing

The next customer is a global manufacturer of semiconductors. Its product, chips, are sent out in reels of 5 000 – 10 000 pieces, and if there are too many faulty pieces per production lot, the whole reel is rejected by the buyer. That can be a big issue for the manufacturer as the cost of the raw material is very high and the margin is low. On top of that, rejections are bad for a company's reputation.

Error detection in semiconductor manufacturing is based on simple statistics. Our customer gave us the task of inspecting the results of the final tests carried out on individual chips to detect the lots/reels with a high probability of rejection.

We began with a thorough analysis of available literature and with an assessment of data quality. The tight deadline meant we distributed the analysis among three international teams and synchronised them in an iterative and agile manner. Every week, they were to exchange problems and findings.

The teams made use of the different analytic tools and approaches. Some of

the tools applied were Microsoft Azure Machine Learning Studio, Scala and Apache Spark, RapidMiner, KNIME and Dataiku. On the algorithmic side, we used simple statistics, k-means clustering, artificial neural networks, tree ensembles for classification and different types of anomaly detectors.

When the analysis was finished, we suggested to the customer a predictor for failing lots based on tree ensembles and a 1-SVM (one-class support vector machine) for anomaly detection. The predictor includes expert feedback and updates itself based on new data.

The following steps will include industrialisation and integration of the classifier and anomaly detector into the manufacturing engineering system, as well as using a more sophisticated analysis from earlier production steps for the detection of issues; this should be applied not only during the final test but also much earlier in production. Ultimately, this approach will reduce costs and save resources needed for testing.

PERFORMANCE



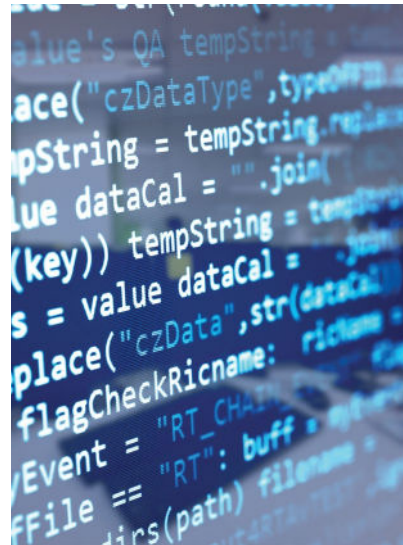
4. Performance Optimisation for an IoT System

The increasing connectedness of devices drives a manufacturer of ventilation systems to extend its proprietary bus system for its embedded actuators with Cloud access. The new system suffers from bad control performance and disturbances on the bus, which are neither reproducible nor able to be analysed.

The ERNI solution collects and evaluates (Python) 1 Mio. system values and bus telegrams for 20 systems daily. The data is filtered, reduced and stored in a time-series database (InfluxDB). Grafana is used as a flexible, powerful and user-friendly tool to visualise and correlate data as well as to define KPIs and set up alarms.

ERNI supported our customer in detecting error patterns and analysing suspicious trends. Ultimately, the bus performance could, in certain situations, be increased tenfold, the control algorithms became predictable and stable, and 90% of the known bus disturbances were eliminated.

VALUE PREDICTION



5. Business-Value Prediction

Our customer connects sellers and buyers of SMEs. In order to optimise its portfolio and marketing investments, it wants to predict the value and popularity of any given company.

ERNI carefully selected significant data from its complex database, and cleaned and simplified historic data. The team used a model based on the Microsoft Azure Machine Learning platform to predict time-to-sale and selling price.

The results are visualised and integrated into a mobile app. This lean and easy-to-use app significantly helps the customer evaluate an offer quickly.

ERNI and IoT projects

Many of our customers' data projects are subsets of larger Internet of Things initiatives. Although the IoT produces data, the scope of the IoT projects is usually more extensive and covers a broader pool of activities. This illustration describes/shows the ERNI collaboration model for IoT projects.

Vision

Through a series of workshops, we reach a common understanding of your needs and **objectives**. We then **develop a vision** showing you how to reach your business objectives with the help of cutting-edge digitalisation technology.



- 1. Stakeholder analysis
- 2. Create overall vision

Use Cases

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



- 3. Identify use cases
- 4. Select 'low-hanging fruit'

Architecture

Next, we **outline the architecture** and the realisation of the vision for achieving identified objectives.



- 5. Identify building blocks
- 6. Identify technologies and rate them

Rapid prototyping

We evaluate platforms and **implement prototypes**. In later stages, ERNI supports your teams or carries out a full-scale implementation on its own.



- 7. Deliver prototypes
- 8. Validate

Throughout the first stages, ERNI can offer proven consulting patterns for innovation workshops, gap analysis and fast prototyping. In the implementation phase, a global shoring platform with more than 500 people is available, enabling cost-effective custom software solutions.

DID YOU KNOW?

As part of wider plans to revitalise their economies, countries across the globe are incorporating legislative initiatives to capitalise on big data. For example, the Japanese government is developing intellectual property protection and dispute resolution frameworks for big data assets in a bid to encourage data sharing and accelerate the development of domestic industries.

(Source: SNS Research, The Big Data Market: 2017 – 2030 – Opportunities, Challenges, Strategies, Industry Verticals and Forecasts)

Data Science Conferences 2018

AI Expo and IoT Expo

London, April 2018

<https://www.ai-expo.net/global/>

<https://www.iottechexpo.com/global/>

Strata Conference

London, May 2018

<https://conferences.oreilly.com/strata>

SDS 2018 – 5th Swiss Conference on Data Science

Bern, June 2018

<https://www.data-service-alliance.ch/sds2018>

Deep Learning in Healthcare

London, September 2018

<https://www.re-work.co/events/deep-learning-in-healthcare-summit-london-2018>

AI and Cognitive Services

As an extension of data solutions, ERNI offers AI and cognitive services built upon Microsoft Azure Stack. Acting upon your needs, we can enhance this by working with open source libraries, IBM Watson, Amazon Web Services or Google Cloud Services.

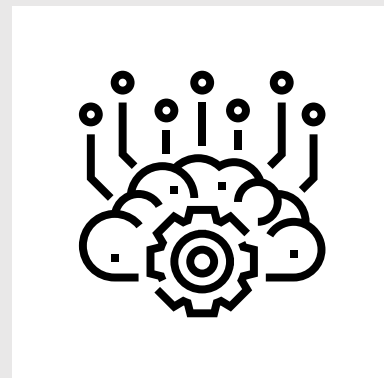
How can cognitive services help?

1. Vision recognition – we help your systems and applications understand images and video.
2. Speech recognition – your applications and systems can hear and talk to users.
3. Language processing – you can process and understand text in large quantities, or extract knowledge from the web, academic papers or your own data.

EXAMPLES

Translate Application

The translate application features optical character recognition, and Microsoft Azure Cognitive translates the API to recognise text on pictures that is then translated into a selected language. The service can easily be integrated into different applications and software solutions.



Optical Character Recognition for Invoicing

We developed an automated invoicing system based on optical character recognition (OCR) which seamlessly integrates with our customer's SAP system. The application can reduce manual processing time for a single invoice from 90 seconds to parallel invoicing of 8 bills in the same amount of time.

Identity Application

The mobile application uses image recognition to match a picture from either a gallery or a camera with a database, e.g., your company's Active Directory; the application then provides information about the matched person.

Smart Shop

Smart Shop is a joint mobile application and web application to simplify web shop maintenance and product reviews. The user can take pictures of new items that will be placed in the shop and the application automatically classifies and tags each new item. In turn, users can review shop items by taking a picture of themselves expressing an opinion about the article. The feedback system extracts the user's sentiment and provides the opportunity to adjust and complement the automatically generated review. The web shop is based on Microsoft Azure image recognition and emotion APIs and ASP.NET.



New markets. Better decision making.

Many industries stand on the verge of a new era driven by data science. Vast amounts of inputs need to be transformed into a brand-new variety of information: smart data instead of big data.

The transition to smart data may significantly change the nature of your business processes. ERNI supports your business in bridging management, data and technology.



Managing Stakeholders in Data Science Projects

Innovation can be hard to implement if there is no common understanding about it between the organisation's stakeholders (colleagues, partners and leadership). For a project manager, stakeholder management is not only important but it can also often make or break the project.

Words by Richard Bumann

Data Science Consultant at ERNI

Manage expectations, prove and challenge results, communicate outcomes. In each stage of your data science project, these are some of the unspoken expectations your team and leaders will have of you.

Navigating these challenges is not easy, so let's take a closer look at what pitfalls to avoid, what tough decisions to make and whose engagement is the most important during each stage of a data science project.

The individual stages of your data science project as described below don't necessarily happen in a strictly sequential order. You can move back and forth between them or repeat the cycle a number of times to tackle new challenges. Always make sure you take a conscious and well-founded decision when proceeding to the next stage, as with this change, you'll have a change of the stakeholders themselves and their management.

Business understanding: Make sure all stakeholders understand the business goals of your project

During the initial stage, people should not only understand the benefits of the project but it's also just as important to make them understand what the project cannot deliver. Be careful when defining and limiting the scope of the project.

Stakeholders in this phase:

Business end users, business analysts and data scientists.

Obstacles:

If the vision or idea of what should be achieved is too broad, it has to be narrowed down. Keep in mind that business end users and framing conditions are multifaceted and include more than just people, e.g., legal bodies or security regulations.

Difficult but correct decisions:

Abort the project if the business idea is not feasible or the benefits are not viable.

Engagement of stakeholders:

Illustrate the possibilities with well-designed examples and set realistic expectations.

Data understanding: Let's discuss available data

In this phase, you'll be mapping the data landscape and discussing data storage and possibilities to integrate and merge data. It is also important to assess the quality and completeness of the data.

Stakeholders of this phase:

Business analysts, data scientists or analysts, data engineer, IT.

Obstacles:

a Miscommunication between business analysts and data analysts; **b** miscommunication between data scientists and the data engineer, leading to poor identification of necessary and available data sources; **c** bad relationship between IT and the data team because of different goals; **d** missing out on opportunities to uncover poor data quality and data gaps.

Engagement of stakeholders:

Picture the benefits of the data project. When working with IT, engage them in the process so they don't feel left out and you won't end up with requests such as "extract data for us immediately".

Data preparation:

Getting the data in shape

In this phase, make sure you have the right data in the best quality possible.

Stakeholders in this phase:

Data scientists, data analysts and data team, business stakeholders.

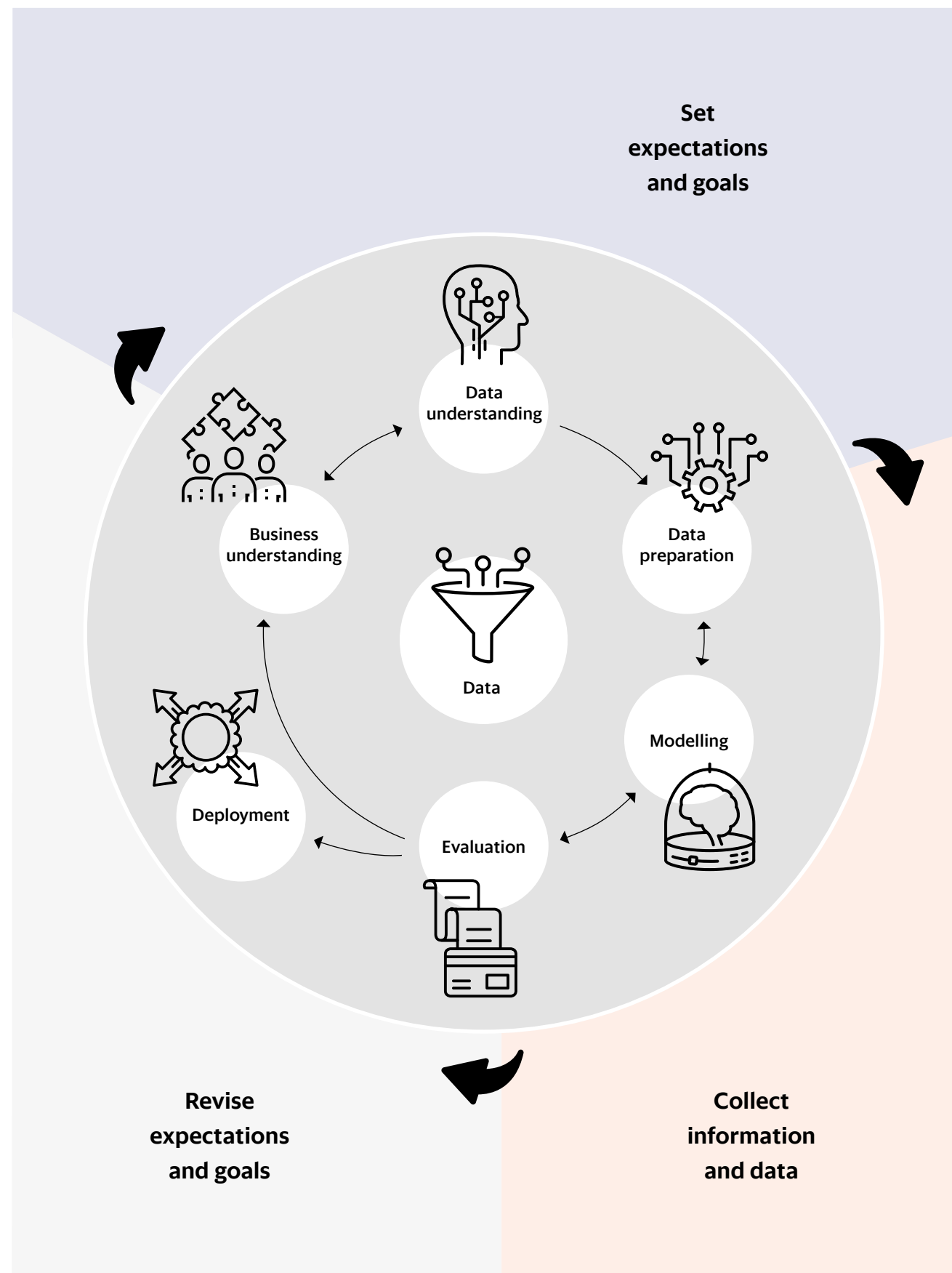
Obstacles:

Incomplete or 'dirty' data, missing resources from the IT department, or missing engineering that could help access data and improve its quality.

What can go wrong:

a If the scientists don't talk to the business and other professional stakeholders, they might miss some important facts needed to prepare and clean the data for a proper analysis; **b** if cleaning is needed, there might not be enough resources to clean data for the project (which →

ERNI and data projects



should be done by professionals). Data teams need to include cleaning in their planning, and occasionally involve data engineers to clean data at the source.

Engagement with stakeholders:
Clearly communicate how important it is to have a clean database for a correct analysis. Assign resources from IT.

Modelling: Creating the right structure and flow

Modelling is an integral part of analysis and provides actual results.

Stakeholders in this phase:
Data scientists, development team.

Obstacles:
Building complicated models that don't satisfy business needs (accuracy, legality, speed) or can't be transferred into an integrated software solution (communication with the IT team about feasibility).

Dangers:
Situations where you have a nice model but it is not applicable or has no real value.

Engagement with stakeholders:
Data scientists must be aware that they need to share their thoughts with business and IT teams.

Evaluation: Present and visualise results, and assess benefits

What works best in this stage is great data visualisation and simple, clear results. You need to know how to present the results and communicate honestly no matter whether your goal was achieved. ERNI has developed evaluation frameworks that can be used in this stage.

Stakeholders in this phase:
Data scientists, visualisers/UI experts, business analysts, business end users.

Obstacles:
a The communicated outcome is too complicated to understand; **b** the result might not be satisfactory and data scientists may try to hide it.

What can go wrong:
a Results can't be communicated appropriately, and the business does not see the benefit or success of the project and stops it; **b** the reverse might also happen: the failure to properly communicate that the experiment has produced negative results with respect to the business goals and that another iteration is needed can lead to the implementation of an unsuccessful application.

Difficult but correct decisions:
Communicate bad results and openly say when it is not worth it to investigate further.

Engagement with stakeholders:
Engage early, show results regularly and visualise in an appealing and simple way.

During the evaluation stage:

1. Present results in a clear, targeted and simple way.
2. Communicate failure.
3. Promote the benefits.

In this stage, your team makes a decision to operationalise a data product (or moves from an offline analysis to the pilot, or from the pilot to a large-scale solution), or even makes the hard decision to put an end to the project.

Make it work in real life

What makes a successful implementation? Good old project management, system integration, process integration and a wisely chosen interdisciplinary team with broad technology know-how.

Stakeholders in this phase:
Data scientists, visualisers, UI experts, development team, data engineers.

Obstacles:
a Poor integration of the data component into the existing software system; **b** a good model but a resulting integration that is not user friendly; **c** poor visualisation can make even a good model and its results hard to understand; **d** you get stuck during the introduction and training of the new tool.

What can go wrong:
A project that, despite a successful start and promising results, must be stopped because of operational failures, or when the outcome is not accepted by the end users.

Engagement with stakeholders:
Show early pilots of the final solution to business stakeholders. Build one team out of data scientists and software developers. →

Ready to take a step towards data?

An overview of the skills needed for both small- and large-scale projects

Competition in key medtech industry markets gets fiercer every year, not to mention all the regulations that businesses must cope with that affect approximately 90% of the Swiss medtech industry. Data science or data products can be a smart move to optimise costs and diversify into areas with more opportunities and less competition.

This can't be done without the right people who possess the right skills. The following illustrated guide is an overview of what types of data people ERNI employs and relies on. We don't look for the 'one to solve it all' kind of scientist in a white coat. We think in a broader context of building a capable team composed of employees with various types of roles and skills that are of strategic importance for our customer's path towards embracing data science.

Generally speaking, Swiss companies are well positioned on the market with their premium technology, but technology today is gaining traction – especially in the context of data. That not only brings more features and advantages to end users but also boosts the medtech industry as a whole. Its total value is now estimated at more than €100 billion in Europe. The potential for further growth with the right use of data can significantly increase this figure. However, companies that are unprepared when it comes to HR could easily end up as bystanders in this game. ✕

Smaller projects

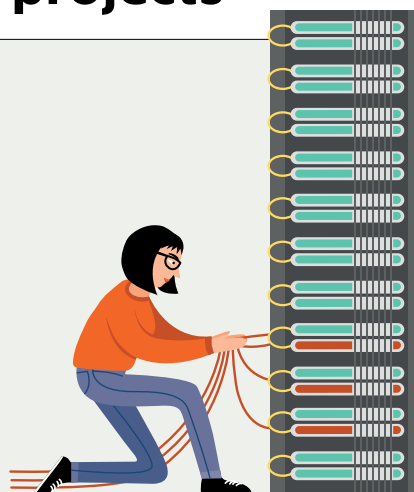
Data engineer

Job responsibilities:

- Capturing and storing data
- Developing, testing and maintaining data architectures
- Keeping a company's data ecosystems up and running
- Consolidating and cleaning data and structuring it for further processing

Skills:

- Excellent understanding of various storage architectures
- Programming
- Industry knowledge



Data scientist

Job responsibilities:

- Cleaning, analysing and visualising data
- Applying statistics, machine learning and analytical methods to solve business problems
- Exploring and examining data for patterns
- Applying algorithms
- Explaining the results to stakeholders in a comprehensible form

Skills:

- Programming
- Mastering data visualisation techniques
- Excellent understanding of mathematics and statistics, machine learning and other related disciplines
- Keeping pace with and applying the latest methods and technology
- Understanding industry and business goals
- Problem-solving



Business analyst

Job responsibilities:

- Identifying and addressing business issues which can be solved with data
- Analysing and documenting requirements
- Aligning communication between IT and business stakeholders
- Creating use cases and user stories

Skills:

- Problem solving
- Strong analytical skills
- Industry knowledge
- Technical writing
- Empathy



Large-scale projects

Data science team lead (might be a thought leader)

Responsibilities:

- Building data products and leading data projects
- Framing and prioritising the problems to solve
- Supervising the data science implementation of data science solutions
- Cooperating closely with engineers and managers

Core skills:

- Conviction in the benefits of data science
- Strong communication and presentation skills
- Creating and managing teams
- Solid knowledge of data processing and analysis



Data visualiser

Responsibilities:

- Making complex data more comprehensible and usable for a broader audience
- Delivering data in a useful and visually refined form
- Transforming and integrating data depending on requirements

Core skills:

- Strong analytical skills
- Ability to see the bigger picture in a huge volume of data
- A sense for aesthetics
- Critical thinking
- Attention to detail
- Creativity



User experience designer

Responsibilities:

- Designing interaction within an application based on data
- Increasing the value of a product for the end user
- Creating a desire to use the product

Core skills:

- Wireframing and prototyping
- UX writing
- Empathy for various types of users



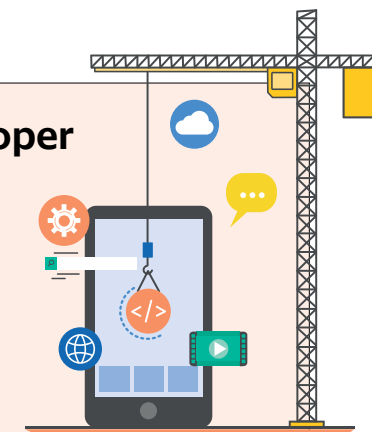
Backend developer

Responsibilities:

- Making product solutions or applications functional
- Optimising products and solutions for speed and efficiency
- Creating a data storage solution
- Implementation of security and data protection

Core skills:

- Proficient knowledge of backend programming languages
- Understanding of frontend technologies
- Integration of multiple data sources and databases into one system



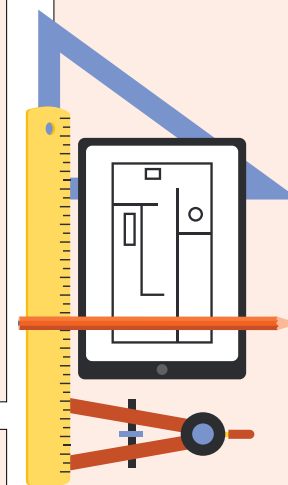
Data architect

Responsibilities:

- Developing database solutions to store and retrieve company information
- Installing and configuring information systems to ensure functionality
- Analysing structural requirements of new software and applications
- Installing and configuring information systems to ensure functionality
- Optimising existing and new database systems

Core skills

- Deep understanding of database structure principles
- Knowledge of data mining and segmentation
- Analytical skills
- Problem solving



B

Briefing

Agile: The Answer to Working with Data

As companies race to digitise their business and shift from hardware to data-enhanced solutions, their internal workflow methodology is undergoing a transformation of its own. Agile and Scrum are finally applicable, opening doors to more flexible ways of collaboration.

How Scrum Helps in the ERNI lab

By Oscar Llorens of ERNI

Scrum is a very dynamic method that is great for meeting tight delivery deadlines. It is especially useful in medtech software development, where, if adapted well, it enables the team to manage their goals and their time in sprints. Our team, for example, runs on two-week sprints, after which we all meet and review the sprint and plan the next one. These cycles, combined with daily stand-up meetings that typically only take 15 minutes, offer a very stream-lined working experience.



Oscar Llorens
Development Lead / Scrum Master at ERNI laboratory, Barcelona

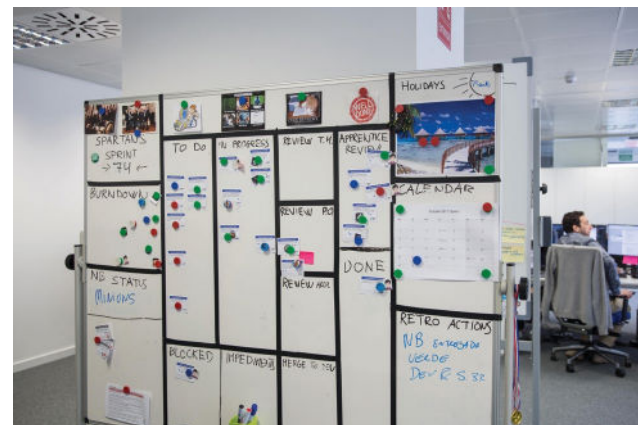
„Agile methods and sprint-based development make our teams more effective, synchronised and focused, enabling us to deliver faster and better solutions.“

Typical Scrum shortcomings and how to overcome them

Implementing Scrum in an established team might not be as easy as it sounds. Methodological oversights often result in shortcomings that lead to delays, confusion and higher error rates. Thankfully, there are ways to overcome them.

Typical reasons for these shortcomings include the omission of certain Scrum principles, alterations to goals during a sprint or a misunderstanding of roles and responsibilities within the team. These issues can usually be overcome through adequate leadership techniques that focus on individual motivation and responsibility.

To start a change of mindset, however, external help is often required. Internal leadership on its own typically has a hard time implementing Scrum fully, because it is influenced by established systems and lacks the experience with similar cases that external experts can provide. Hiring an external Scrum master is therefore becoming the number one choice for effective implementation of Scrum that ensures long-term growth of quality and efficacy.



Scrum also helps keep communication with the customer alive – on top of regular reports drafted by the project lead, we are in touch with the customer on a daily basis. This saves time, as relying on the traditional concept of a single entry point is a lot less effective.

All in all, Agile and Scrum are helpful tools in any software-based business. However, you need to keep in mind that these are only ideas, principles and rules that need to be adapted to the way your team works and what your people need.

Typical Scrum shortcomings

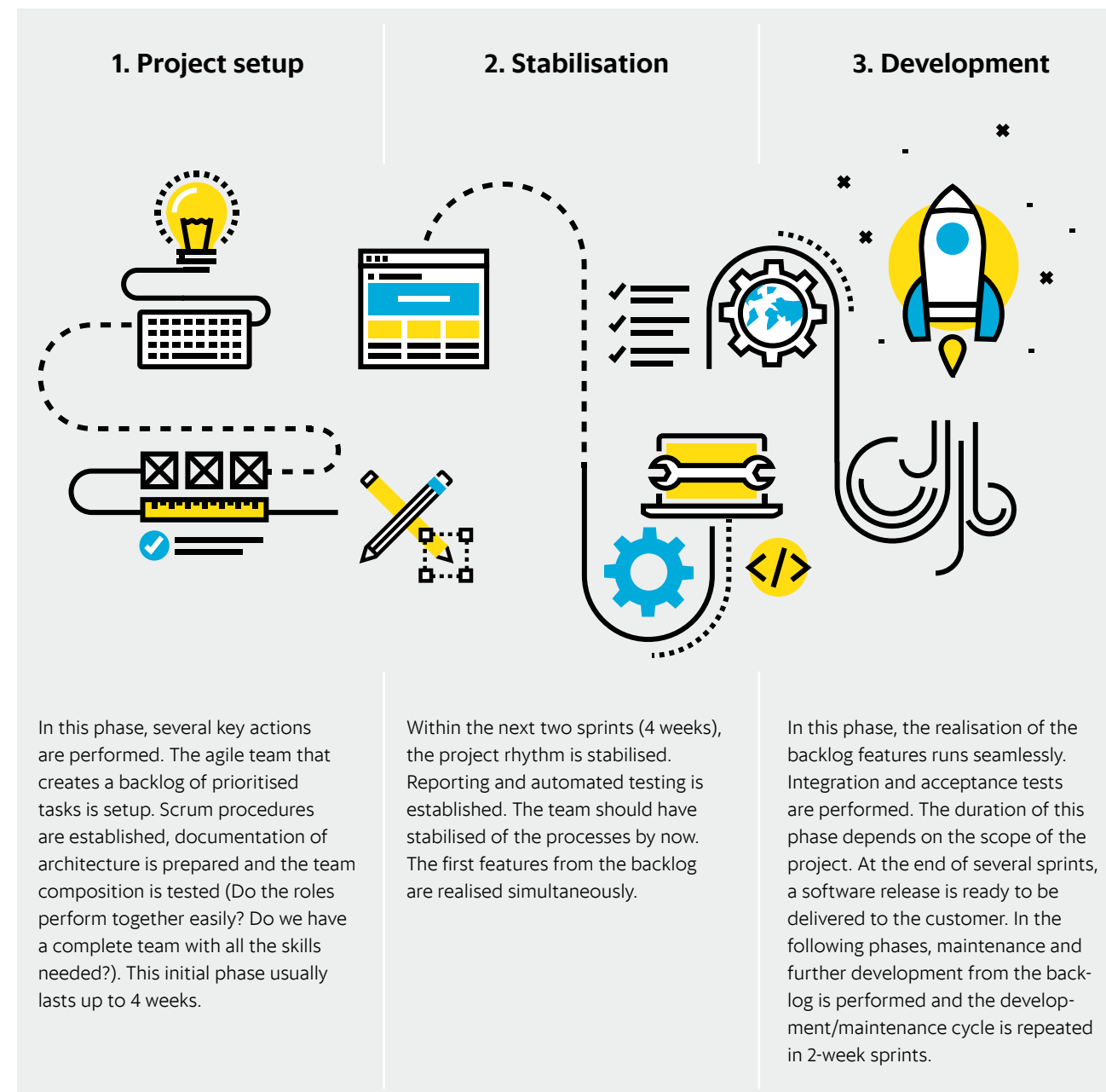
Changes during the sprint. The person in charge sets the specifications for the team or changes the priorities during the sprint, rather than handing over the responsibility.

Quantity over quality. The development of additional features becomes more important than the quality of the primary features.

Superior syndrome. The team does not take over responsibility for the implementation and quality of the delivery and expects coordination from a superior.

Successful Rapid Development through Agile

Agile is a methodology that can be used to launch new software projects efficiently and rapidly. After the initial review phase, which requires reviewing architecture and processes in the company that will be impacted by the project, a typical agile project goes through three main phases.



Two Cases of Agile and Scrum

An External Scrum Master

A medical company realised that the introduction of Scrum had not fulfilled its expectations. After a few months of applying the methodology, the improvements had not materialised to the extent anticipated.

The company decided to hire our specialist as an external Scrum master. His role was to support change management, and clarify competences and duties. In order to anchor the improvements, he also ensured that the continuous improvement process of Scrum was well applied in every development cycle. Progress could be seen after a few months – the quality of the finished components was increasing measurably and the delivery assurances were being met to an ever-growing extent.



A Nearshored Scrum Team

Looking to build new software, but unable to produce internal resources fast enough, a technology manufacturer turned to a nearshore, agile-based contractor. The product owner and Scrum master stayed in Switzerland, and the Scrum team was in Slovakia.

Following initial setup and the definition of goals and procedures at the customer site, the team returned to Slovakia, regularly synchronising with the customer and clarifying all questions instantly via online tools. Close cooperation was key, which is why the team frequently travelled to Switzerland, and the Scrum master and product owner to Slovakia.

Through a regular and open exchange of ideas, intensive collaboration and strict adherence to Agile principles, the Scrum team was able to deliver timely results, with the Scrum master and project owner always up to date on the project status. This not only improved the quality of the output but also made the whole process structured, transparent and efficient.

Special Report on Medical Technology

Internet of Things

Inside the ERNI Medtech
Laboratory

Data Science in Medtech

Innovation

Improvement of Business
Processes

AI, Machine Learning

Regulations and Security

Our Experience and Business
Briefings

Working with ERNI in Medtech

B

The European & Swiss Medical Technology Industry in Numbers

Medical technology is blanket term for:

- medical devices
- in vitro diagnostics
- imaging instruments
- e-health solutions

There are more than 500 000 medical technologies registered around the world. The global medical technology market is worth roughly €340 billion.

340 billion

Computer-aided diagnosis, personalised treatment, pattern recognition

The future of the industry lies in linking a large number of devices and data within a sole robust system, and also in data analysis that is performed on top of the collected inputs.



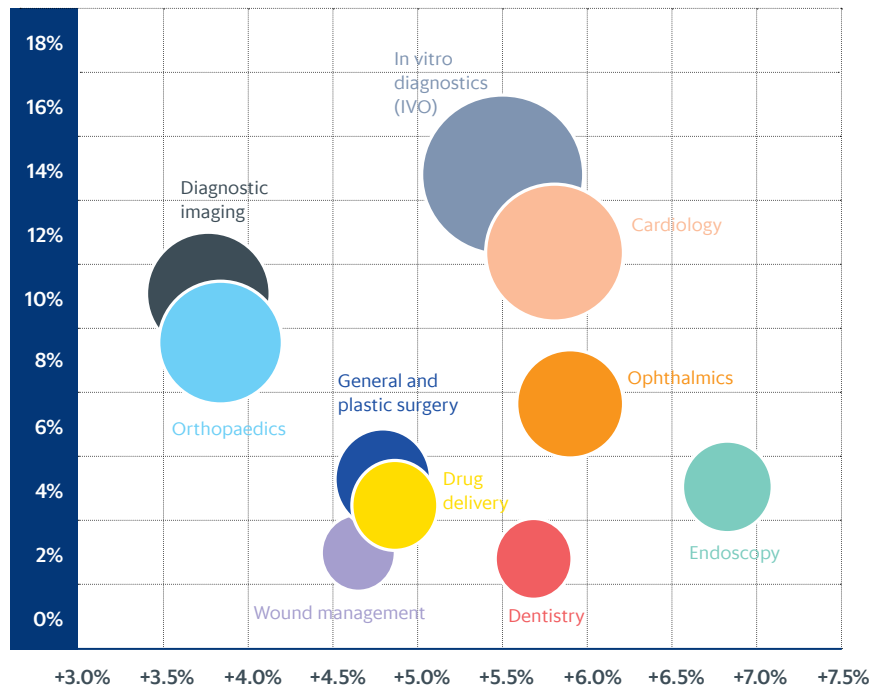
€110 billion market

Based upon manufacturer prices, the European medical technology market's worth is estimated at €110 billion.

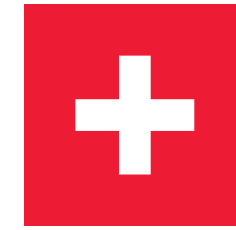
Global Medical Technology Market (by area and sales growth)

In vitro diagnostics will be the biggest growth sector in medtech sales, followed by cardiology and diagnostic imaging.

Market share in 2022



Sales growth: CAGR 2015 - 2022



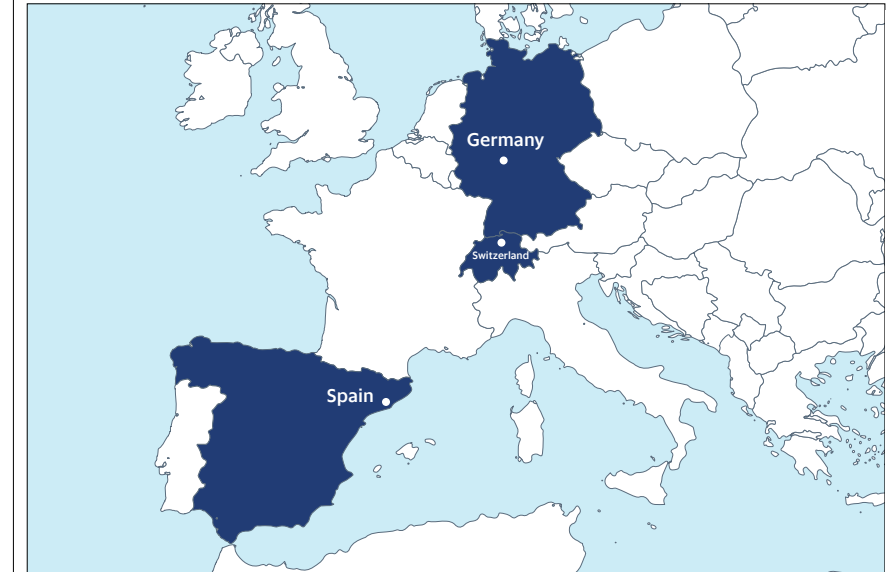
€12.1 billion

Swiss market size

Switzerland's medical technology market stands at some €12.1 billion.

ERNI and medical technology

Our medtech activities are located mainly in Spain (Barcelona), Germany (Frankfurt) and Switzerland (Zurich).



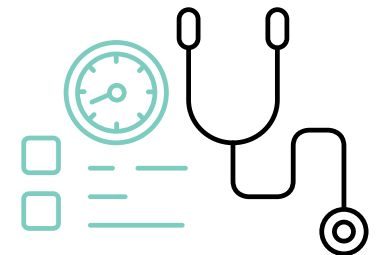
95%

of medtech companies are SMEs*

*"The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 people and which have an annual turnover not exceeding 50 million euros, and/or an annual balance sheet total not exceeding 43 million euros."

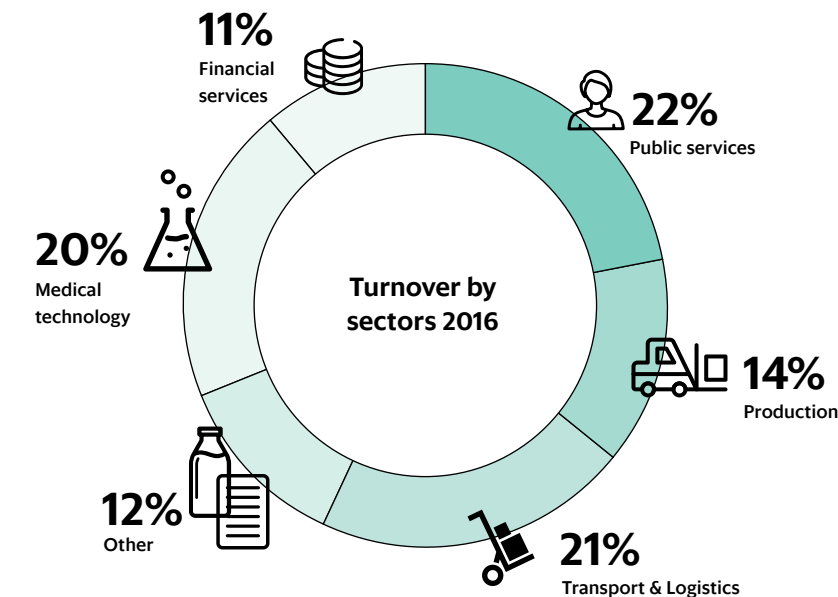
26 000

Number of medtech companies in Europe



Medtech: 20% of ERNI revenue

One-fifth of ERNI's revenue comes from medtech companies. Our other projects cover areas such as logistics, financial services, production and public services.



1 450

Number of medtech companies in Switzerland

Half of all Swiss medtech companies have less than 10 employees, and only 6% of all companies have 250 or more employees.

TOP

10

Largest companies in Switzerland according to number of employees in 2012/2013.

Johnson & Johnson Medical

Roche Diagnostics International AG

Sonova Holding AG

Biotronik Schweiz AG

Medtronic (Schweiz) AG

Zimmer Holdings, Inc.

B. Braun Medical AG

Dentsply International Inc.

Straumann Holding AG

Ypsomed AG



650 000

Number of people employed in the medtech industry across Europe.

54 000

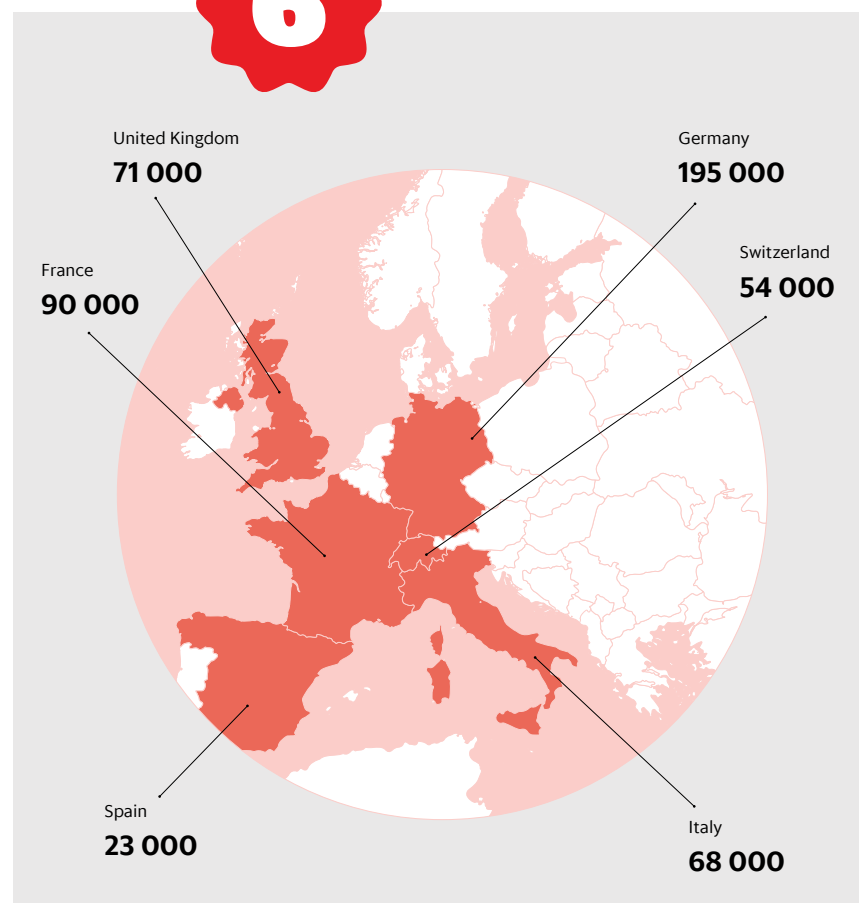
employees in Switzerland

With 54 000 employees, Switzerland has the highest number of medtech employees per capita in Europe.

TOP

6

European countries with the highest employment in the medical technology industry:



Medical Technology is the No.1 innovative industry in Europe.

12 200+

European patent applications

In 2016, the EPO received a total of 12,263 patent applications for medical technologies; 41% from Europe and 38% from the US.

European patent applications

The medtech industry is number one in terms of patents filed. A new European patent is filed every 50 minutes.

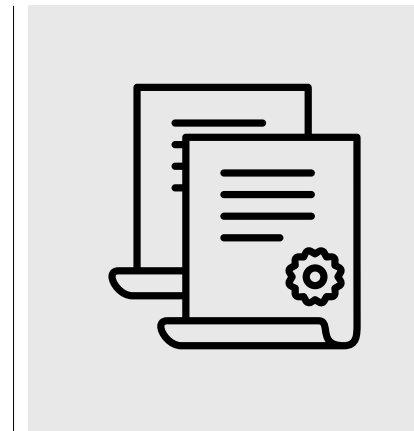


€14.1 billion

The value of Europe's medtech trade surplus in 2015

€5.6 billion

The value of annual Swiss medtech trade surplus in 2015



1 200

Patent applications in Switzerland

Each year, Swiss companies register patents for over 1,200 medical technology inventions.



US Startups rising

For the fourth consecutive year, investments in US healthcare venture fundraising in 2017 are certain to exceed \$6B and will probably exceed the 2015 record of \$7.5B. This could be the strongest year in the US healthcare history.

\$7.5 billion

An interesting trend is emerging that is worth watching: In the first half of 2017, \$3.5B was invested in 188 digital health companies – more than ever before in just half a year. Tech-focused venture capital investors are massively investing predominantly in companies that are developing artificial intelligence and in machine learning technologies designed for biopharma and diagnostic tools.

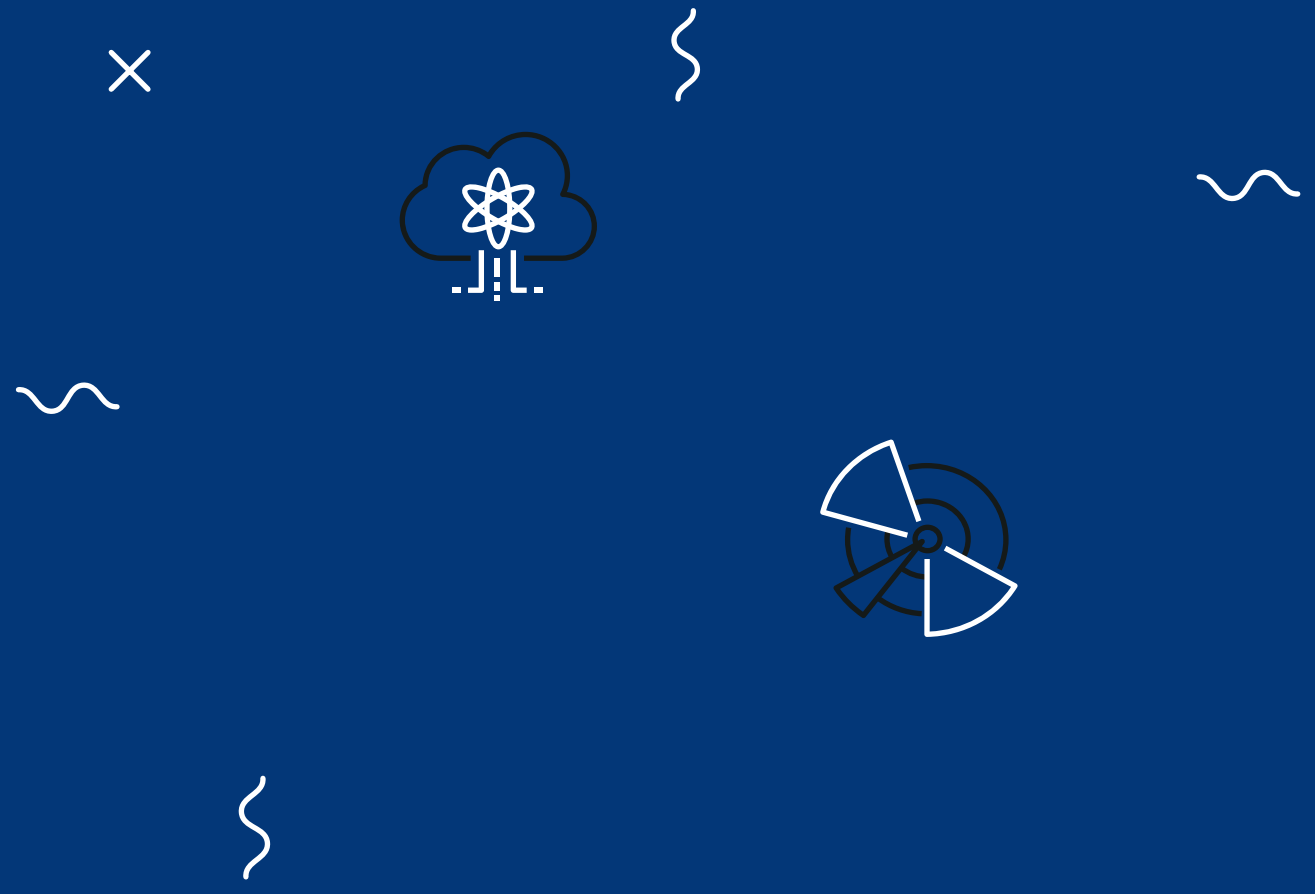
Sources

1. MedTech Europe (www.medtecheurope.org)
2. European Patent Office (www.epo.org)
3. SMTI Report 2016
4. SVB: Healthcare Investments and Exits Report
5. Rock Health Funding Database

New business opportunities, cost savings and informed decisions. Three main benefits that can be generated through data analysis and are of indisputable value for the medtech industry. We spoke about the challenges and disruptions generated by data science with Richard Bumann, senior business analyst at ERNI.

An interview with Richard Bumann, senior business analyst and service leader in machine learning and data science at ERNI.

HOW DATA IS TRANSFORMING MEDICAL TECHNOLOGY





Richard Bumann
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With a Master of Science in Biomedical Engineering, Richard Bumann leads our consulting activities in AI, machine learning and automation, specialising in medtech, telecom and public transportation. His skills vary from business analysis and requirements engineering to solution design and process improvement in large-scale IT- projects.

Medical companies, healthcare providers and patients are generating large amounts of data. How do you advise businesses on how to extract both reliable and useful information they can act upon?

The medical technology industry still has to get fully accustomed to working with data effectively. Many organisations keep generating it, but don't further use the collected data or in fact derive value from it. They might be aware of how important working with data is, but somehow struggle to embrace it. Only a few organisations have a clear vision of what can be extracted from data or how to implement data science and machine learning into everyday business decisions.

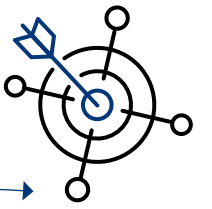
In most cases, companies simply collect data without setting clear goals on how to use it. That's why we usually start our consulting with a basic 'company-data vision' that brings more focus into the data collection process. This process is facilitated with a proper business analysis and ideation workshop. During this stage, we also identify all available sources. Our main goal is to help customers get closer to more targeted data collecting.

At the beginning of every project, we work really hard to identify what data is worth looking at. We're able to shift from collecting big data to collecting smart data, and the result is process and cost efficiency. The major issue is diverse and unstandardised data sources that can significantly hinder targeted analysis. Part of the whole process is setting up clear expectations on cost structures.

What does the growing importance of data mean for large enterprises, and what does it bring to small companies?

For a big enterprise, data is crucial to keep its position on the market. For a smaller company, data can create an opportunity to grow. Small companies are generally more flexible and therefore can adapt and change processes or behaviour much faster. It's easier for such a company to identify a new niche on the market and adapt, whereas for a big one, it creates the need to transform the whole business.

The medical technology industry is built around hardware and chemical compounds or reagents, and those will always remain a core business and a major competency. But when it comes to data, a whole new expertise needs to be learnt. Finally, the patient should stay in the focus and data bears a huge potential.



Targeted data collecting

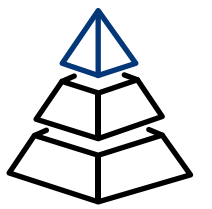
For a large enterprise, data is crucial to keep its position on the market.

Could the increasing importance of data cause a future loss of key advantages for a big enterprise?

In the medical field, hardware must not fail at any time. It must be extremely precise and innovative and there is a lot of expert know-how involved in ensuring this. This technological advantage will always be highly important for the success of medtech companies. Medical support will always require a high level of trust from the patient and that's why I think medtech can keep relying on its traditional products and the high product development standards the industry adheres to.

Nevertheless, the impact of data will be significant. Data can identify new market opportunities and create new products. From the perspective of existing processes, enterprises can use data-driven decisions to keep their key advantages. They can dramatically improve workflows and reduce maintenance costs, which results in greater profitability. Data-driven decisions are also a great sales booster, which is crucial when selling pharmaceuticals or reagents.

From the cross-industry perspective, data has the ability to connect two completely different industries. It's possible for medtech companies to gain more importance in other consumer areas. This can be true for many medtech companies, as new opportunities might emerge outside of their traditional field and as a result of new connections enabled by working with data. →



Opportunity to grow

How difficult is it for a company to start working with data? What does it involve?

First of all, the leaders must be truly convinced of its value. Change needs to be implemented top-down. Our consulting process helps a company or its division convince the leaders through shaping a clear vision, visualising the benefits and pursuing successful pilots.

Another challenge is to find trained people. The biggest issue is that most data scientists are either highly experienced or not experienced enough. Of course, a company would like to hire the most experienced person, but these experts are searching for the most interesting cases and infrastructure that a company without a lot of experience can't offer yet.

A consulting company like ERNI assists in executing pilots based on our experience, introduces data-driven decisions and accompanies customers while integrating the development of data products into their existing development processes. This gives a company that is new to data science a solid foundation. After the initial phase is finished, ERNI further accompanies and assists the company on its continuing data journey.

As a company leader or project manager, when can I expect the first results from a data science project?

Surprisingly, it's very fast in most cases. From defining the vision and goals to identifying data sources and relevant inputs, all the way to offline analysis and the feasibility study, it might take somewhere between a week and a month, depending on what the project is about. At ERNI, we are very efficient at delivering prototypes that demonstrate possible benefits. We can prepare a preliminary analysis and data quality assessment very quickly – it's the core of our approach.

Of course, these are only preliminary results and prototypes that will show which way the organisation can go. As the next step, a pilot or a small-scale solution can be set up, let's say in two months' time. A proper rollout and a full-scale implementation can take from six months to two years.

How dramatic is the change for the business once data science is implemented?

One of our strongest competencies is the ability to grasp and manage all the changes a company will face. We guide our customers through these changes to avoid any major drama and make all transitions go as smooth as possible. Take the simplest of situations. When you're using data to inform your internal processes, you don't want to implement any changes too dramatically. You aim for gradual improvements without affecting your core processes too much and too quickly.

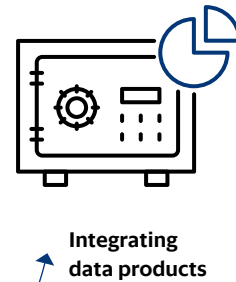
On the other hand, if you want to introduce a data product or implement major data-driven decisions, this might be different. Often, you need to define new processes from scratch, including a data-driven decision framework. An ideal process should specify the data product and not the other way round. Only a clear vision of the future process can serve as a solid base for such a data product.

Recent medtech research in Switzerland shows that company leaders are worried about the innovation capacity of their organisations. They said this is one of their top three concerns. Will data create more space for newcomers and possibly disrupt whole branches of the industry?

It definitely will. As an example from a different area, some solutions based on blockchain will have this potential very soon. This new technology enables a secure exchange of medical records and we know that, especially in the medical area, security is a big concern.

Blockchain will enable data exchange between companies and industries and between patients, labs and physicians. This is the space where even companies without traditional medtech know-how can cause a disruption without necessarily knowing too much about the traditional products. And this can happen elsewhere, too. It doesn't have to be a strictly medtech company that transforms the industry with an innovation.

This will put data regulations into a new context. Medtech is heavily regulated, and for good reason. The whole industry puts a lot of effort



into making sure that patient data is secure. As an example, you are not allowed to give away any data that may identify a patient. I can imagine that newcomers from other industries will take a more – let's put it mildly – experimental approach to personal data. That's why it's so important that legislation keeps up with the pace of recent development and creates appropriate frameworks for such innovative medtech companies.

If you were to name one thing that should be improved in the relationship between data and the medtech industry, what would it be?

Governments and organisations should put more emphasis on keeping people informed publicly and promoting how using data can be beneficial for patients and customers. We need to openly declare how data channels are secured to overcome the fear patients and healthcare workers have. People are afraid to give away their data because they don't know what exactly happens with it, who can access it and how the whole data system works.

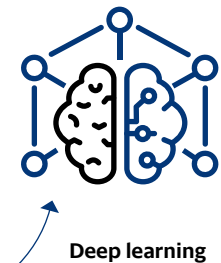
AI, cognitive agents, machine learning, deep learning. These are some of the buzzwords that are used frequently in the context of data science, yet their meaning and difference is often blurry. How can we tell them apart?

Artificial intelligence can be defined as the ability of a machine to sense, comprehend, reason, learn and act in order to fulfil a specific goal. Even though today's AI applications have made significant progress in past years, their field of application is still very limited. Recently, a 'narrow AI' that surpasses the performance of humans in specific areas was created, but we are still miles away from a 'general AI' that will be able to learn completely new applications on its own. To illustrate the difference, an AI application may perform better at specific tasks than a skilled human. But a general AI would be able to scan vacancies, prepare for an interview and acquire the necessary skills for a new job on its own. AI doesn't necessarily rely on how humans

approach a problem. If the algorithm behind the AI is inspired by humans, I would refer to it as a cognitive customer's algorithm.

Machine learning means that a machine is collecting massive amounts of data and it recognises patterns from which decisions can be deduced. It can apply these patterns to new input data. Machine learning doesn't have to be – but might be – an integral part of AI algorithms.

Deep learning uses neural networks to carry out the process of machine learning. It emulates the human brain in decision making and is capable of learning when given target values (supervised) or recognising new patterns (unsupervised learning).

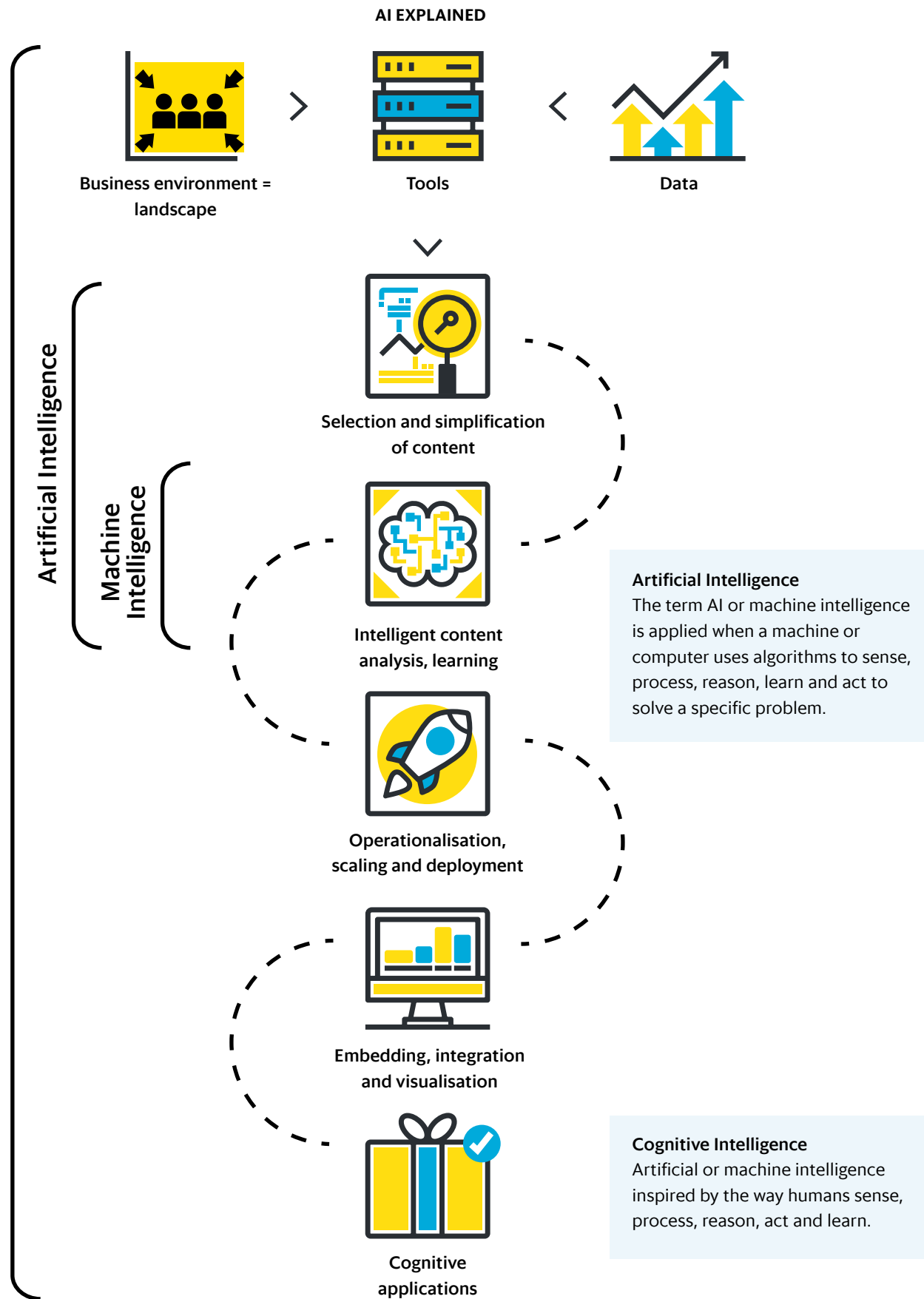


Let's expand on machine learning. How could companies use it to their advantage? What is the role of this area in medtech?

Machine learning is an integral part of working with your data. The goal for all medical diagnostic labs is to have as much throughput as possible to enable them to process as many samples as possible. They use dozens of machines. Some tests take only a few minutes, whereas others take hours. Samples are often delivered to a lab randomly, and this is where machine learning can optimise the order of sample processing and maximise the number of samples tested at a given time.

Another promising aspect of using machine learning is that it can significantly improve maintenance and operation processes; you can actually predict the time when a machine is going to fail and will be in need of servicing. In this case, we can optimise its maintenance, and even transfer workload to another instrument and use the redundancies in the lab. Machine learning may also help us by finding answers to questions such as "is it economical to have this machine serviced?", or by sending someone to repair it.

Finally, machine learning is a great tool for chemistry-based businesses. It may help discover new pharmaceuticals or analyse and improve sales channels for reagents – a billion dollars worth of in-vitro diagnostics. →



What about AI and cognitive services?

The area is relatively well developed for specific tasks. In our work, we routinely integrate cognitive services from major cloud platforms. Many ready-to-use solutions are available such as chat-bots, language processing or image analysis. They can be easily integrated into existing software and the customer experience can be boosted by smart assistance intelligently.

How important is it to not 'miss the data train'?

Generally speaking, in the case of a company that makes a product easily replaced by the use of data, it can have a negative effect very quickly. But for traditional medtech, data is not such a big threat because the industry will always need, precise and reliable physical instruments or chemical compounds. Therefore, data is creating new opportunities rather than posing imminent threats.

The potential of data is all about optimising the whole landscape in medtech. For example, France optimised the number of its laboratories last year by 25% – it consolidated labs, improved their cooperation, optimised processes and improved their input. I think that in the medtech field, it's much less about completely replacing a product than it is about improving processes and connecting products and services. ✕

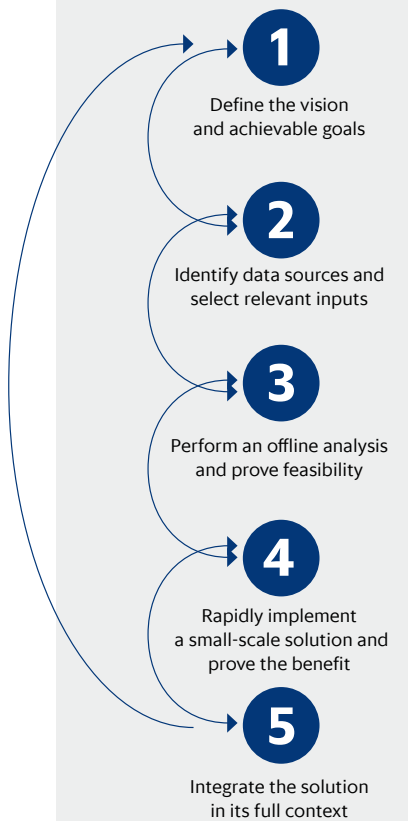


The ERNI approach to data projects

We support our customers in implementing data-driven solutions where it's necessary to decide what data is worth collecting and from what type of source. Not every data point is beneficial in achieving the goal of a project. By limiting the amount of collected data, our customers are able to reduce storage costs and keep high-quality data only. It's much easier to integrate additional sources when you have a good data structure.

In the next step, ERNI performs an offline analysis to prove the feasibility of the proposed concept. Does it work in real life? Does it fit into a customer's processes? After feasibility is proven, we promptly implement a small-scale solution. Our consultants collect feedback to see the first benefits of the approach and to prove them to the customer.

The final stage is to roll out the full-scale solution.



B

Briefing

Data security, regulations and medtech

ERNI CASE STUDY

Software development cost reduction – even under regulatory compliance

Medical device and diagnostic laboratory equipment manufacturers now face stricter regulatory compliance requirements. The increase in costs jeopardises market success. To achieve a more competitive cost structure, companies are relocating software development and/or software maintenance and using low-cost country sourcing.

In a recent case, our customer allocated software development locally and in a high-wage country in order to keep it close to the marketing and sales departments. Their teams were hard to scale as a result of a local war for talent and restrictive costs. Our goal was to lower the costs of software engineering and enable scalability while keeping the processes in full compliance with regulations.

We relocated all development and maintenance work to shoring countries using the ERNI infrastructure, processes and know-how, while managing to maintain a high-quality interface with the local customer through on-site ERNI staff.

Results:

Cost decrease of up to 30%

Team scaled up – up to 5 software engineers per month/per team

Quality of delivered software is stable/not affected



It is not just securing the transmission and storage of data against hacks that is important. Here are some easily missed security pitfalls:

Hoarding data

The amount of data produced and acquired is often greater than what is actually needed for the analysis. Therefore, it's important to decide which data is relevant to keep and how long to store it.

With an infinite hoard of data, it's much more difficult and less efficient to identify the useful part. Added security and regulatory measures for redundant data make efficient filtering even more crucial.

Data integrity

There is a need to collect and store accurate and consistent data: in other words, data integrity. A compelling amount of data can still be corrupt and useless for users, or dangerous for patients. This possibility cannot be neglected. For example, many users of fitness monitoring bracelets complain about inaccurate data output such as their heart rate measurement being off by tens of beats.



Stricter regulations on personal data even outside of health records GDPR

The upcoming EU General Data Protection Regulation (GDPR) is the most important change in data privacy regulation in 20 years, and it comes into force in May 2018. Relevant key points and brief explanations:

1. Expanded scope

With the GDPR coming into effect, the location of a company becomes irrelevant; all organisations processing EU residents' personal data have to comply.

2. High fines

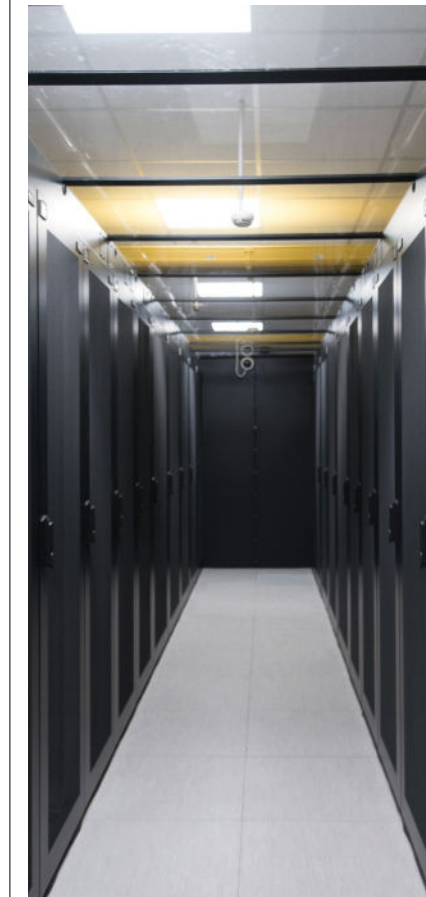
In case of a GDPR regulatory breach, organisations can face fines of up to 4% of their annual global turnover.

3. Breach notification duty

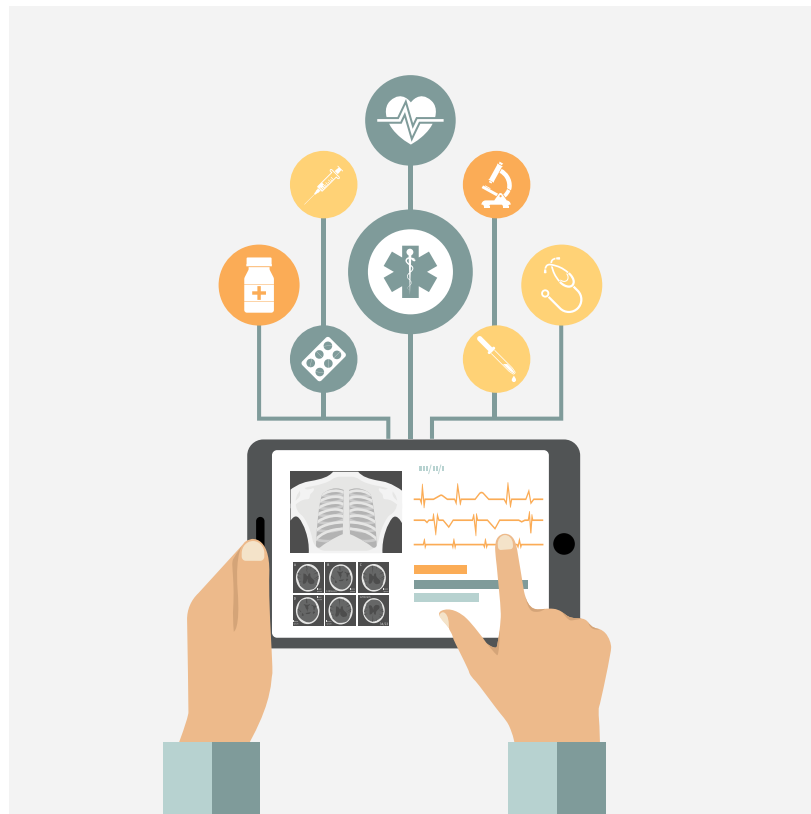
In case of a security breach, it's mandatory to send out notifications to healthcare organisations within the first 72 hours to make them aware of the breach.

Find key changes online

<http://www.eugdpr.org/key-changes.html>



Innovation in Medical Technology



The majority of challenges that businesses in the medtech industry have to face are related to innovation and market access, says a study carried out by the Swiss Medical Technology Institute. Let's have a look at the innovation process that ERNI uses to facilitate innovation in the medtech industry.

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How do you manage innovation? Swiss medtech companies rely mostly on three types of solutions: building internal development centres, collaborating with universities and startups (open innovation), and innovating through partnerships with other companies and consultancies. About one-fifth of the companies purchase third-party ideas and prototypes using market screening and incubation programmes in the process of merger and acquisition. These solutions often occur side by side.

According to the Swiss Medical Technology Institute, preserving innovative capacity concerns 79% of companies and was listed as the main challenge by medtech business leaders in the study. About 60% of companies are worried about accelerating innovation cycles in the market and also see the increasing demand for solutions instead of products as a challenge.

Top challenges for medtech companies

(In % of all 319 responses. Source: Swiss Medical Technology Institute Study 2016. Respondents: Manufacturers, suppliers, specialised service providers and commercial enterprises)

79% Preserving innovative capacity

74% Quality and documentation requirements

65% Finding suitable specialists

61% Accelerating innovation cycles in the market

59% Increasing demand for solutions instead of products

This article showcases the customer-centric innovation process model as used at ERNI. We focus on two approaches to facilitate our customers.

1. As a customer, you can partner with us and together we can cover the full path from ideation (generating ideas) to scaling up and implementing the innovation sustainably.
2. We can collaborate with your internal development centre in selected innovation stages only, providing you with tools and methods that are most appropriate for your challenge.

By breaking the innovation process down, we identified six steps that will take you all the way

from the beginning to the ready-to-be-implemented innovative product or solution: Searching fields, Ideation, Customer journey, Prototyping, Market validation and Full approach.

First two phases of innovation in detail

Let us illustrate the two initial phases (searching fields and ideation) with one of our recent cases. The customer operates in the area of in vitro diagnostic tools and is a well-established company with a diverse portfolio of middleware products for IVD laboratories.

A few of its products are at the end of their product lifecycle and the company already plans to introduce a new and innovative product in the coming five years that will replace some of the existing solutions. ERNI was approached by the company to help with the initial stages of the innovation process and to enable the development of the new product.

The focus was set on customer insights, market segmentation, future markets, technology trends and the ideation process. The overall goal was to craft a product vision for the customer's future portfolio and to collect innovative ideas to be used as a backlog for the necessary innovation.

At the beginning, we conducted several workshops with our customer's customer-facing teams to identify customer segments and describe specific needs for each segment.

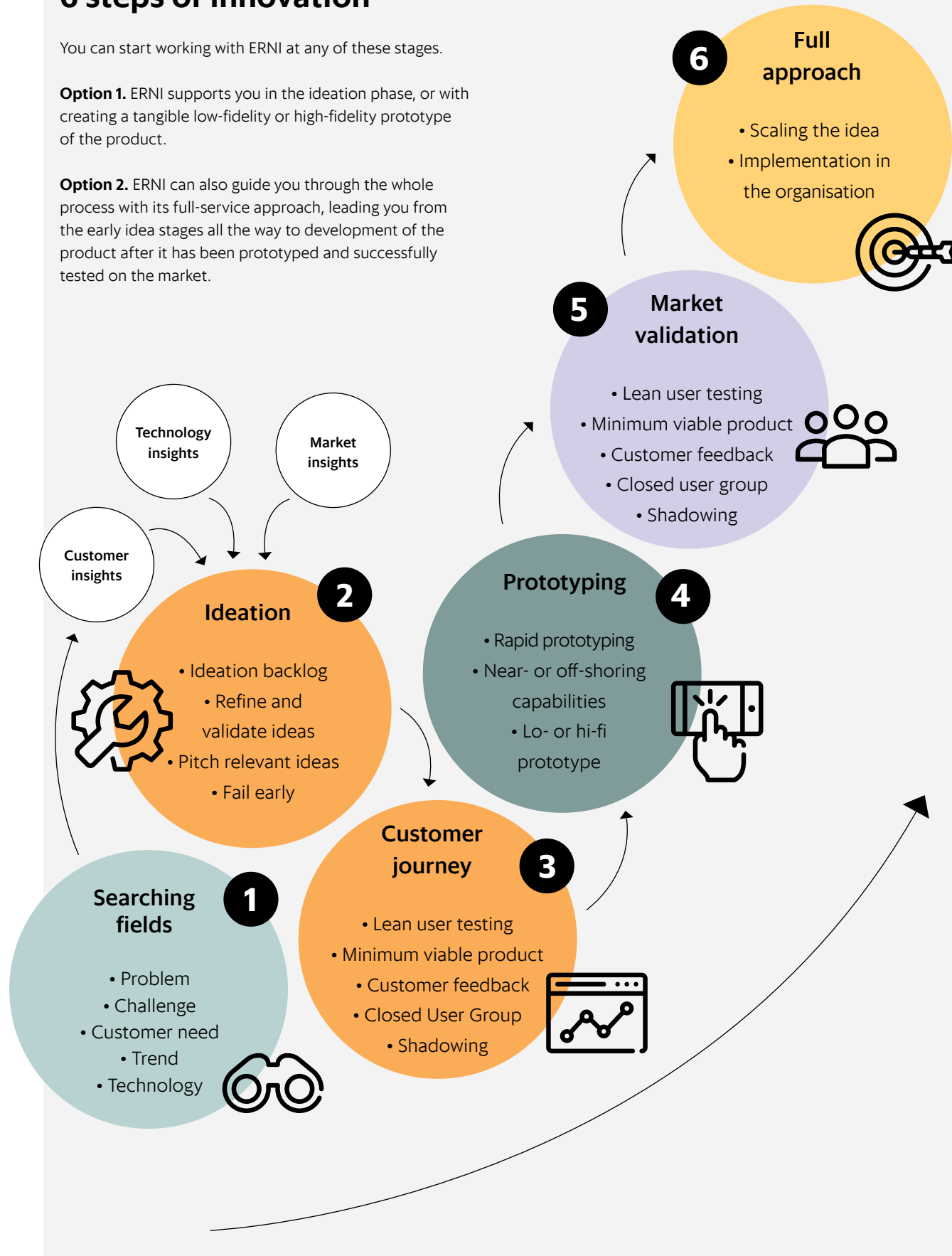
Throughout several additional workshops, we analysed the needs and proposed a list of product features that are likely to fulfil a specific need of a large segment. Working in close collaboration with the customer's area representatives and using their knowledge of different geographical and vertical markets, we prepared a simulation of how these markets will develop and what each one's needs will likely be. We also researched technology reports, summarised trends and identified which of the technology areas are relevant for the client's goals. →

6 steps of innovation

You can start working with ERNI at any of these stages.

Option 1. ERNI supports you in the ideation phase, or with creating a tangible low-fidelity or high-fidelity prototype of the product.

Option 2. ERNI can also guide you through the whole process with its full-service approach, leading you from the early idea stages all the way to development of the product after it has been prototyped and successfully tested on the market.



Strengths and weaknesses of current products

Innovation does not always have to be disruptive. It's all about finding the right balance – keeping what works and adding new features and approaches if needed.

That's the reason why we also performed a strengths and weaknesses analysis of the current products. We used structured questionnaires to ask stakeholders from the departments of research and development, sales, product management and field service to identify strengths and weaknesses of the products. The initial feature list was further amended after the inquiry.

As our customer already had the competitive analysis prepared before we started our collaboration, we included the analysis and combined it with the rest of the data collected. The final list of ideal features for a new product was identified from these various sources.

Crafting a product vision

To craft a product vision, we recommend the KANO model, which helps to focus beyond basic product functions, and introduce and better understand the role of the 'delighters' – product features that resonate with customers.

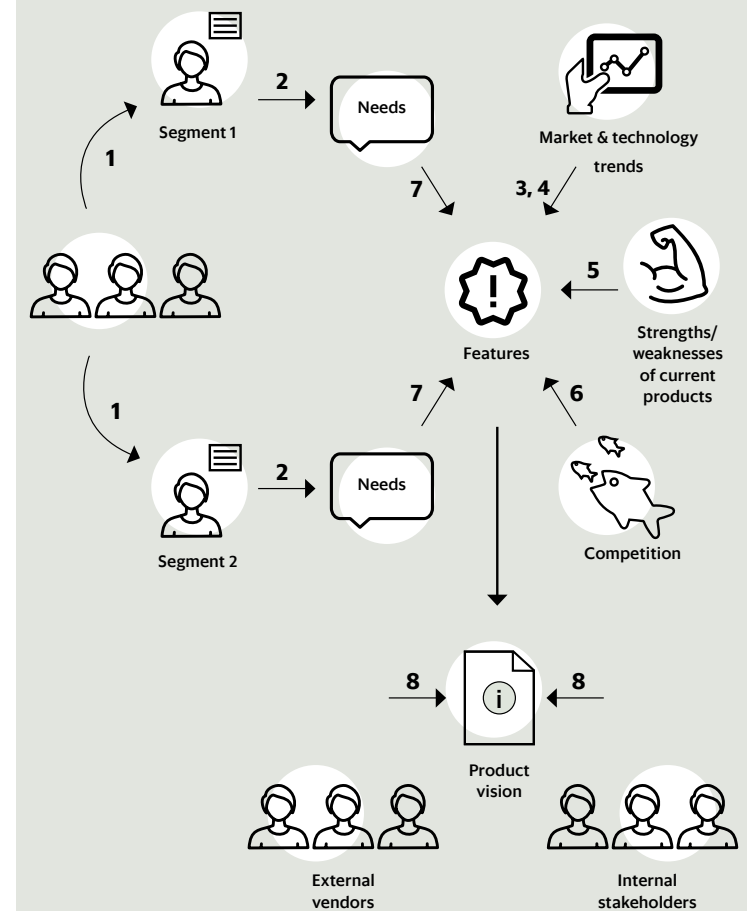
According to the KANO model, we distinguish between the basic features, the performance features and the excitement features of a product. The basic and performance features are very easy to identify if you already have a product portfolio and experienced product managers. Where it gets really interesting is the excitement features. These are the features that most people would refer to as innovation.

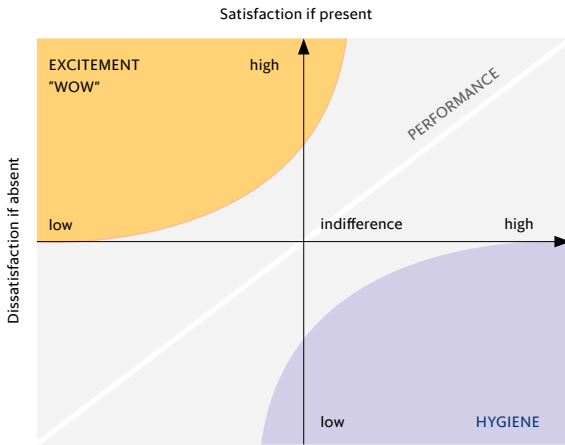
In this particular case, we identified cognitive technologies as the trending topic and prepared a workshop with the customer to identify how cognitive technologies can be implemented in the field of in vitro middleware. We looked into the role of a technician working in the IVD laboratory of the future, and implemented chosen cognitive features that would simplify their everyday tasks – from manipulating substances to assisted computer interaction. →

In the picture: Two initial phases (searching fields, ideation) broken down into specific steps

Workshops with customer-facing teams identify needs and product features. The innovation process starts with specifying customer segments (1). Once the segments are defined, a list of needs (2) is isolated. Together with the examination of technology trends (3) and cross-checking the results with the customer's field of work, it gives realistic ideas of what to focus on in the new project development.

To improve the product experience and future product portfolio, as the next step, strengths and weaknesses (4) of the current products are isolated through a series of interviews. Competition offering similar products is examined and compared to our customer's products (5). All of this helps determine and refine realistic product features (6) to better answer and fulfil the list of customer needs. Using these features, a product vision is then developed (7) and internal stakeholders and external vendors are consulted.





Case 2: Customer journey and prototyping

Another customer of ERNI was running a hardware-related business. This type of business can lose margins on its product sales in medtech when the hardware becomes a commodity and activities of their competitors push prices down. That was the starting point for our recent collaboration – and our goal was to find solutions to secure or even increase its margin.

We guided the company through the initial stages of becoming a software and service-oriented company. Our collaboration consisted of ideation, customer journey and low-fidelity prototyping.

As a result of the series of workshops, the customer then had five integrated business models to choose from, all with concrete product ideas for services and for software solutions that would complement its existing hardware business effectively and open up opportunities for future business models to be implemented.

Iterative process

After generating tens of ideas for the backlog during the ideation phase, we applied the customer journey mapping to assess and compare these ideas with real customer needs. This meant that we took a selected customer persona – a typical user of the future product – through his possible journeys interacting with the new business model/service idea/product.

The goal of this phase was to understand the pains and gains of the customer and where they occur; this further led to the process of visualising the final result in a value proposition canvas.

Ideally, you want to move between ideation and customer journey in several iterations. Run a customer journey mapping workshop, learn about the pain points and then adapt the business model or ideas. In the case of our hardware company, we ran four such cycles.

Validation

To make the idea tangible and get the stakeholder’s approval, we recommend two to three iterative prototyping sessions. They will allow you to take the first steps towards market validation.

With prototypes available, your team can go outside, meet customers and other stakeholders and test the idea in a broader business context. In our case, the first test happened in front of the management stakeholders, where we received not only some valuable feedback but also confirmation that the ideas had the potential to work from the perspective of the business as a whole.

After getting management buy-in, you can further continue with the market validation by going out and meeting real customers, performing prototyping workshops with them, delivering additional rapid prototypes and deploying prototype solutions to the market to gain more feedback.

Again, these two phases (prototyping and market validation) are iteratively connected, and you can move back and forth several times before adapting the idea to a final prototype.

Full approach

This generic pattern can be applied to any problem statement with the need to create a new product idea or business model, or even used for company-focused innovation initiatives such as when you wish to innovate your internal processes.

After that, you can do the full approach and realise the innovation, either through a pilot project or a full implementation. Doing this, you also have to consider the impact on the cultural setting and be prepared to transform your organisation towards the innovation mindset as a whole. ✕

The Entry Points

What are the questions and situations that start the innovation process in medtech companies?

Digitalisation, the Internet of Things, smart data and cognitive services are changing the medtech industry. Let’s have a look at some of the situations, opportunities and questions that can start your next innovation initiative with ERNI.

Your hardware has become a commodity

Hardware is losing its importance in the medtech environment. It often slowly turns into a commodity and customers cannot distinguish market participants just by looking at hardware. On the other hand, software, cognitive services and data used along with the hardware are becoming the important players. They can enhance your hardware solution and help distinguish your business from the competition.

Downtime of instruments and their predictive maintenance

Another problem that our medtech customers face is instrument downtimes. There are multitudes of complex instruments on the market and each of them needs a lot of maintenance. As of now, predictive maintenance is getting more important in the area of medtech and in the industry in general. What you can do is to analyse the health status of an instrument (for example, by creating a digital twin), predict its potential future failures and fix situations even before they happen.

Error reduction

A decrease in human error can be achieved by automation of devices and therapy records. This is relevant especially for hospitals and subacute care facilities.

You are unsure what data to collect and analyse

In medtech, there are three types of data worth collecting: medical data (substances that your device measures in blood and urine), user data (either how people use your device, or in the case of personal health care, what they do in their everyday lives that influences their medical results) and technical data (the status of the device itself). Based on our predictions, major innovations will happen in the intersection of these three areas.

Regulations as an innovation starter

One challenge that many of our customers face is the need to make huge efforts to submit a new drug – from the regulatory point of view. An innovative approach they can take is to substitute some of the studies they have to carry out with data analytics. Besides running their own studies, medtech companies can use data available on the market or in academia to prove that a certain drug or medicine is effective for a particular disease.

A new business model has entered the field – and the expectations of customers or patients have changed with it

High customer value can be created through data – if the competitor manages to introduce a new business model based on data science, other companies will need to follow. From the end-user or patient perspective, connectivity and data management will play a big role. The more data sources I can combine in my medical profile as a patient, the more interesting it gets. Combining different data sources and creating new information will give patients broader perspectives, open new treatment options and spur innovation.

Reimbursement and personalised healthcare

Another example that leads to innovation in medtech is the pressure of reimbursement. Medtech companies don't get reimbursed for medicine and drugs that don't have any effects on individual patients. This creates a new trend and strategy for many companies to offer personalised healthcare. Through this, they can make sure that if a patient takes their medicine, it really fits their personal genomic type.

Monitoring patients remotely

Remote patient monitoring (RPM) is already helping to monitor vital statistics and increase prevention in senior living healthcare, where it has proven to be highly effective. RPM is about collecting and transmitting patients' real-time data to their caregivers, or doctors or nurses who are monitoring these patients from a different location.

Shaving costs through the Internet of Things

Real-time data transmission will allow patients to be discharged from hospitals and be transferred to less expensive long-term facility care more efficiently and faster. Shifting the healthcare industry from reactive to preventive will provide substantial cuts to medical fees as well.

Wearables

By 2021, the yearly revenue of the health-related wearables market will be worth \$17.8 billion (Source: Tractica report, 'Wearable Devices for Healthcare Markets'). Manufacturers are planning to include the next generation of specialised wearables such as hearing aids, skin patches, smart contact lenses or implantable wearables in the existing markets of heart monitors, sleep or step trackers and smart glucometers.

Personal data

From the end-user or patient perspective, connectivity and data management will play a big role too. The more data sources I can combine in my medical profile as a patient, the more interesting it gets. Combining different data sources and creating new information will give patients broader perspectives, open new treatment options and spur innovation.

Objective reports

Access to precise, recorded reports on nervous system levels means that healthcare providers don't have to rely on subjective patient reports. Instead, they can objectively evaluate device data and prescribe a patient's therapy more efficiently.

Connectivity

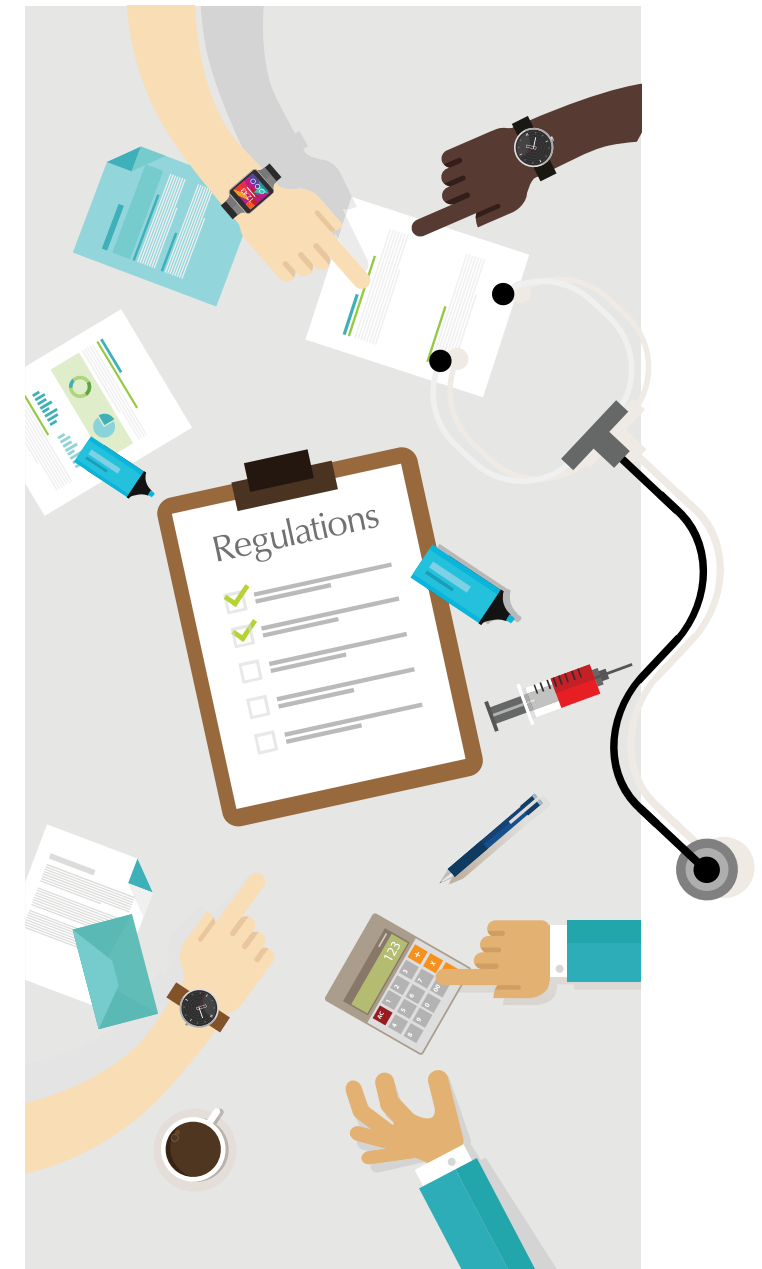
The trend of connectivity will bring more and more devices and data sources together, and create pressure to innovate. In the past, all medical devices were stand-alone – as opposed to most of the future medical devices that will be interconnected.

Endnote: When innovation meets regulations

In the medtech industry, regulations play a big role – but if you are too concerned with regulations in the early stages, it can also significantly hinder your efforts. Every product idea should start out of the box, without taking external factors outside of customer needs too much into consideration, as these factors can easily bury any innovation effort too early.

We recommend this approach for the early stages so that you still leave space for iterative working and testing of the product towards the customer needs on the market. But in the later stages of the innovation process, after successful market testing, you should start considering external medtech specifics – and the regulation needs especially. There are many successful companies in the market that are living proof of this advice: that you need to test and adapt first and, only later on, take care of how this will be submitted successfully to the authorities. You'll find many unsuccessful companies that did just the opposite.

However, in medtech, the regulations and sensitive patient data must be considered relatively early compared to other industries. After ideation and prototyping, other industries would typically follow with a minimum viable product and just test the idea on the market. That is usually not possible in the medtech area, because the patient data is very sensitive and you can rarely just introduce the product on the market and see how it works. For this very reason, to avoid investing money in the wrong innovative idea, we use customer panels and simulations to generate valid market feedback data. ✕



How DIY Medical Testing Could Save Your Life

During a TEDx talk in Calgary, Alberta last summer, MIT doctoral student Steven Keating explained how curiosity about his brain led him to volunteer to have it scanned for a study. The result was the diagnosis and eventual removal of a cancerous brain tumour. Keating was a convert. He has since amassed nearly 70GB of personal medical data, curated from hospital and doctor records, research labs and direct-to-consumer medical testing, and insists that everyone could benefit from creating their own ‘medical selfies’.

Thanks to a spate of new startups entering the healthcare realm, it’s never been easier to generate a snapshot of your personal health. Dozens of companies offer direct-to-consumer tests on saliva, urine, blood or cheek swabs that can indicate either the presence of or the genetic susceptibility to disorders ranging from diabetes to cancer. With the strike of a computer key, you can order a DNA testing kit to determine if you have increased vulnerability to any number of chronic diseases, to predict how you will respond to frequently prescribed medications, or to obtain diet, exercise and skincare regimens geared to your unique genetic makeup. You can even learn about the bacteria that have taken up residence inside your gut, and how they influence your health. Are these medical testing companies the new Ubers of healthcare, poised to disrupt the industry and usher in an age of patient-driven, on-demand medicine?

In his 2015 book *The Patient Will See You Now*, cardiologist Eric Topol predicts just such a medical revolution, in which newly empowered patients with smartphones will take charge of their own health-care.

It’s no mystery why direct-to-consumer testing is so appealing: as the price of healthcare rises, consumers can’t help but think twice before running to the doctor for tests. On the other hand, the information you can request in the privacy of your home is unprecedented. Color Genomics will analyse a saliva sample for mutations on 19 genes known to affect risk for breast and ovarian cancer, including BRCA1 and BRCA2. Couples planning to have children could send their saliva to companies such as 23andMe and Counsyl to learn if they are carriers for rare inherited diseases such as Tay-Sachs, cystic fibrosis, sickle-cell or Bloom syndrome. DNA4Life predicts how you will respond, based on your genetic makeup, to more than 120 commonly prescribed medications. Dozens of companies offer genetic testing directly to consumers to provide information about nearly 400 diseases and traits.

Several home testing products currently under development promise even more. Cue’s elegantly designed ‘deep health tracker’ will use saliva, nasal swabs and blood to track levels of testosterone, inflammation, vitamin D and fertility – and to detect influenza infection – and send the results to your smartphone. Scanadu’s Scout, a scanning device modelled on the one used by Star Trek’s Dr Bones, will relay heart rate, blood pressure, body temperature, blood oxygenation and respiratory rate to a smartphone app. QuickCheck Health, a self-described ‘clinic in a box’, is developing home tests for common ailments such as urinary tract infection and strep throat.

Meanwhile, consumers are able to send raw data from testing companies like 23andMe to interpretation websites such as LiveWello and Promethease. These companies will analyse information on thousands of different mutations, generating even more extensive health information related to health risks and other traits. The rise in DIY medical testing has sparked

concern among doctors and public health officials who fear that consumers might not understand the implications of the test results, or could be unduly alarmed – or falsely reassured – by the findings. But such concerns are not a reason to block consumers’ access to information about their own bodies: the benefits of individuals gaining deeper insight into factors that may influence their health outweigh the negatives, as long as they defer to the expertise of their doctors before acting on any test results. Doctors and genetic counsellors can contextualise genetic test information, for example, and advise consumers on how to proceed in terms of screenings or treatment.

Geneticist Greg Lennon, a co-founder of SNPedia, which operates the Promethease system, concedes that disease risk based on genetic data alone is far from definitive. Environment and lifestyle play big roles as well, as does interplay between different genes.

But definitive or not, I would certainly want to know about anything that affected my future disease risk. Perhaps it would motivate me to be more conscientious about my screenings, or drive me to commit more fully to a healthier lifestyle. We all recognise that regular exercise, low-fat/high-fibre diets and sufficient sleep are good for us – but knowing we harbour an increased vulnerability to disease might be the push we need to adhere to healthy regimens. “DNA is not destiny,” says Lennon, “but what you learn from your DNA may provoke you to change your actions – and that changes your destiny.” ✕

Lori Miller Kase is a freelance writer focusing on health and nutrition. Her work has been published in *The Atlantic*, *Vogue* and *Scientific American*. Edited by Pam Weintraub.

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The Internet of Medical Things

Why it matters
What to do about it

Richard Bumann is ERNI consultant on machine learning and data science. We spoke to him about the Internet of Medical Things.



**8 billion
IoMT
devices**

Predictions say that there will be 8 billion IoMT devices worldwide by the end of this year and up to 21 billion by 2020.

The Internet of Things is gaining momentum in MedTech. What kind of new challenges would this area pose for established hardware companies?

Medtech companies traditionally manufacture highly technological, autonomous devices. The IoT enables those instruments to be connected together, and connected to instruments from other companies or even different industries.

Integration will be one of the most challenging aspects. Proper and easy integration of the vast numbers of devices is a market demand and necessary to keep key advantages.

Also, companies often struggle to align practices in hardware development with more agile processes necessary for digitized industries, so a more flexible approach will be in high demand. Our consultants promote best agile practices and standardised processes in developing IoT systems and digital transformation.

How can the industry profit from the IoT and connecting medtech devices to other industries?

First of all, the IoT means better, fact-based diagnosis. Data science allows us to analyse numerous sources regarding a patient's condition of illness or disease and recommend treatments or preventive action to a doctor. Thus, the doctor does not need to rely solely on his experience, but can assess and complement the outcome from a sophisticated computer-assisted analysis.

There are also other uses such as personalisation or remote healthcare. For example, the data from your smartwatch can improve diagnostics and help you receive more personalised treatment. Also, various sensors, cameras and devices can help with monitoring patients who are treated at home, allowing them to function more independently. There is a lot of space for new ideas and innovation.

Another IoT potential lies in much simpler visualization of the health conditions of individuals, which can lead to greater motivation to live a healthy lifestyle and to better prevention of illnesses.

Agile management
This topic is introduced in our briefing on pages 20-22.

30%

Time-effectiveness during treatment. Healthcare plans of the future place a key responsibility on clinical IoT devices. Those wearables' data will speed up a clinician's assessment significantly by 2019. We're talking a time savings of up to 30%. Hospitals will start to rely on robots for the delivery of medication and supplies and as IoT-enabled biosensors.

(Source: IDC Future Scape: Worldwide Healthcare IT 2017 Predictions)

\$169.3 billion

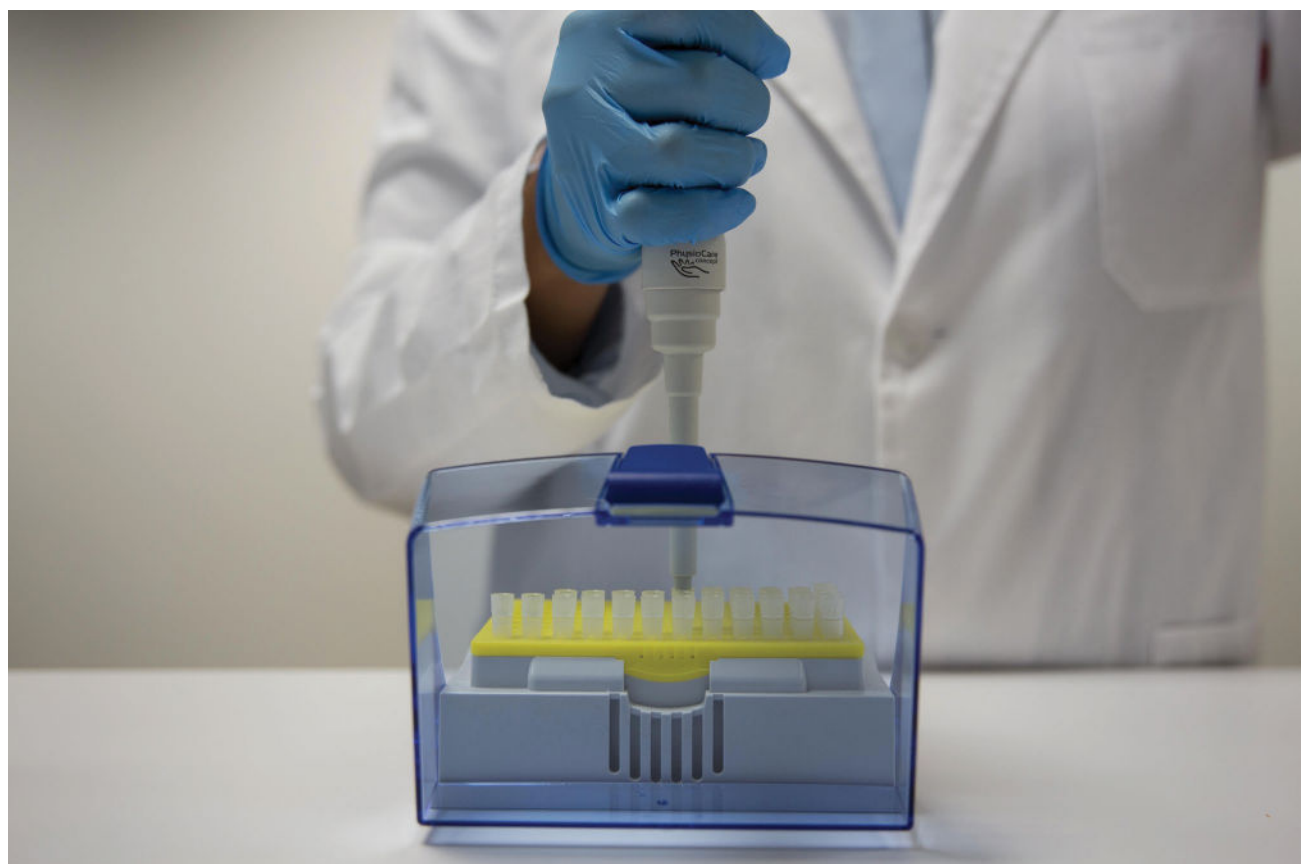
Remote Healthcare
A revenue of \$169.3 billion is expected in the global smart healthcare market by 2020. Remote monitoring will play a prominent role in the future.

(Source: Technavio)

**3.2 billion
downloads**

Health apps are in high demand now, as the download numbers show.

(Source: mHealth App Economics 2017 report)



Inside ERNI Lab

Testing the latest medical technologies

The former industrial area of Poblenou belongs to the district of Sant Martí, located on Barcelona's eastern coast on the Mediterranean sea. It has been part of the urban renewal over the past 17 years. The district, also called 22@, is considered one of Europe's hotbeds of ingenuity, where the most innovative companies research, training and tech transfer centres co-exist. Last summer, it also became the new address of ERNI Laboratory facilities, where modern medtech hardware and software is being tested and developed.

„We took up the challenge from one of our customers when we needed a real laboratory environment to carry out two projects, but had nothing in place,“ says Bart Vermeire, the Project Lead of the lab. „This was at the end of August 2016. Fast forward to the beginning of September and we already had a physical office space and had started building two new labs that we combined with an office space.“

„The first time I arrived here, no carpets were on the floors and there was metal scaffolding everywhere,“ says Nuria Lluch, who works in the ERNI Lab as lab and test manager. „The lights were hanging on cables from the ceilings. It was really amazing to watch how quickly it grew. Everything was built in a little over two months. It was so fast!“

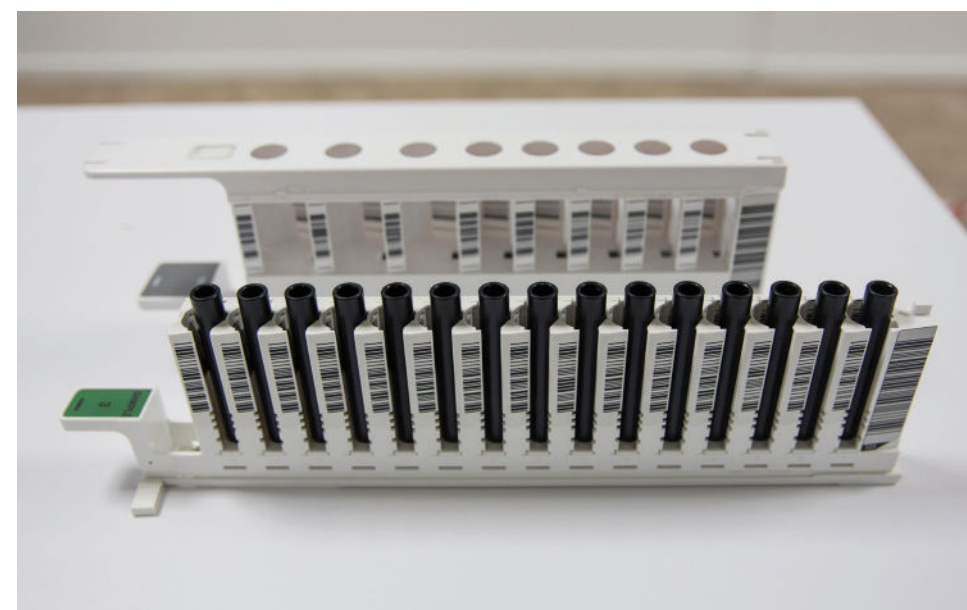
The biggest challenge came after the lab was finished. The team of people who used to work in the office at Barcelona's Plaça de Catalunya had to deal with all the paperwork and establish the new lab according to numerous regulations and quality standards. „Everything had to be finalised before February because that was when we were about to start the first project,“ adds Lluch. „This was a huge challenge. We were used to providing support to medical software, but we had never built a laboratory from scratch. This was a completely new experience.“

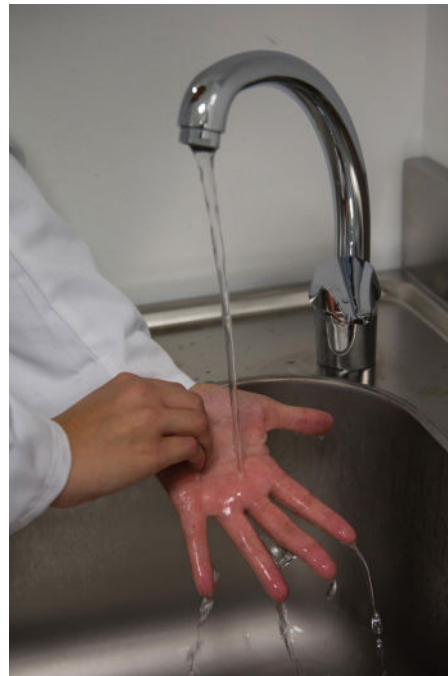
The establishment of the lab has gone really well. „By mid-November, we had the first instrument delivered and installed and we already had people working in the lab; and this is two and a half months before the project officially needed the laboratory,“ explains Bart Vermeire.

Today, more than one year into the lab's existence, everything runs smoothly. The teams are currently working on several projects and towards meeting customers' requirements. „We get customer visits quite often and we can say that they are extremely satisfied with the running of the lab,“ says Lluch, who was one of our guides when we visited the lab.

The laboratory is divided into two separate rooms where the instruments are placed. The main difference between these two labs is in the levels of safety. The lab where biological material is handled has a biosafety laboratory level 1 (BSL-1), which requires employees to wear lab coats, safety goggles and gloves while manipulating the samples and instruments. The second one is the 'BSL' lab where only lab coats are mandatory.

Lluch explains that the lab has to pass numerous regulations in accordance with legislation. „We have to keep an inventory of all products stored in the lab. Before and after work that is performed in the lab, we need to follow exact procedures: how to clean our hands, how to manage the temperature in the fridge or write an accident report if something goes wrong. It's necessary to know precisely how to dispose of any biological waste, which is handled by a specialised company.“





NURIA LLUCH

nuria.lluch@erni-espana.es

Lab Manager and Test Manager

- Identifies training needs and evaluates all testing personnel
- Keeps lab instruments operational, and ensures the proper handling, storage and disposal of hazardous materials
- Carries out risk assessments for the laboratory
- Maintains and ensures compliance with applicable regulations
- Reviews test results, worksheets, QC records and proficiency testing results
- Defines and supervises lab procedures
- Keeps track of the new/changed requirements of projects
- Develops the test plan for tasks, dependencies and participants
- Arranges hardware and software requirements for test setups
- Assigns and monitors tasks carried out by testing team members
- Ensures content and structure of testing documents
- Attends regular customer calls and discusses weekly reports with the customer
- Ensures timely delivery of different testing milestones
- Prepares dashboard metrics of testing activities

Nuria Lluch has been working for ERNI for three years and has been Lab Manager since its opening. Lluch has participated in numerous large projects and one project extension. "We've had projects that needed testing and development done using real instruments. It's something you cannot do with simulators only; you need the actual hardware," she says.

When running tests, our instruments require the use of authentic biological material. Samples are provided by

the customer and it all happens under strict quality control. "We use the samples to test whether the system calculates properly. The calculations run inside the appliance and in case we change the software, we need to ensure that it works under regular circumstances too. After we analyse a serum, the results should be within previously defined values. If this is confirmed during the testing, we know we did it correctly," says Lluch.



OSCAR LLORENS

oscar.llorens@erni-espana.es

Development Lead, Scrum Master

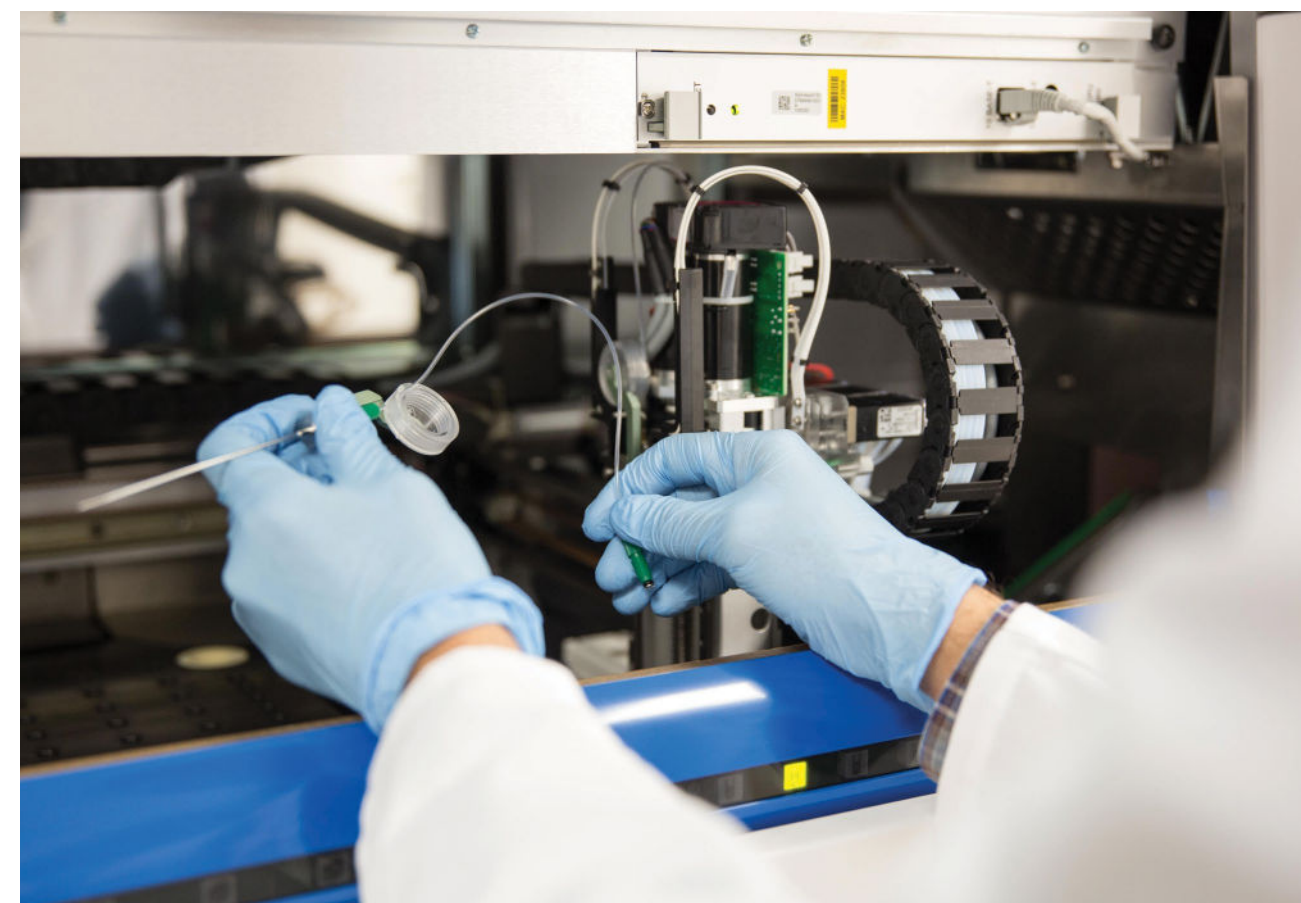
- Team Lead
- Scrum Master
- C++ Code migration
- Implementation of new functionalities
- Solves known issues
- Creates database schemas import and software deploys
- Manages translations
- Provides unit testing (including automated testing)
- Documentation
- Effort estimations

Most of the daily responsibilities of Team Lead and Scrum Master Oscar Llorens are connected to projects dealing with data migration from old software or with new features of the hardware.

“We are working on System Software that controls an instrument that analyses human samples (such as blood or urine),” says Llorens. “Our team had to migrate to the latest version of all technologies used. We have developed a new functionality associated with an interlock feature that prevents the user from putting their hand inside the instrument. We also added test and reagent traceability, implemented new functions that enable control of the instrument remotely from a server and fixed many existing defects in its older versions. It’s worth mentioning that we had to lead all software and hardware testing and verification. Currently, we are

developing an IoT solution that will register all instructions executed by the hardware and upload them to the cloud to be further analysed. The solution will also be able to predict failures before they happen.”

Llorens’ team deals with both hardware and software issues. It’s extremely important to the whole team that the lab owns real working devices. During our visit, Llorens was working on a solution to a problem that occurred inside the instrument. It was a perfect example of how software and hardware work together. “We discovered a software issue caused by an incorrect distance between the needles: they were too far apart,” he says. “We started to manipulate them to reproduce the issue and then fix it. Now the software must unlock the cover to be able to access the needles.”





ALEX POLBACH (left)
alex.polbach@erni-espana.es

Development Lead
for Application Software

- Third-level support for questions, complaints or investigations regarding the project's application software
- Finds the root cause and provides workarounds to complaints and investigations from the customer
- Provides feasibility and risk analysis on software fixes or new requirements
- Develops software fixes and releases on reported issues and new requirements
- Liaises with ERNI software project leader

BART VERMEIRE (right)
bart.vermeire@erni-espana.es

Service Unit Leader, Project Lead for Lab
Building and ISO Certifications On-site

- Works with either agile or waterfall projects, focusing on correct delivery while maintaining high quality in each project (following ERNI and ISO 13485/ISO 27001 standards)
- Works on setting up a BSL-1 laboratory
- Migrations of software in medtech
- Implements new packages for a data-driven application
- Implements various MVPs using Cloud services and cutting-edge technologies
- Migrations of a live web page and database to a Cloud-based and updated solution

Alex Polbach and Bart Vermeire work together on maintenance projects. They use two different medical instrument lines with two different layouts to reproduce errors reported by customers in the same environment. "Actually, what we do here is very much like an air crash investigation," says Polbach. "When there is an incident in a lab somewhere in Europe or elsewhere around the world, the affected lab asks our customer for the reason behind this unexpected behaviour. Sometimes they can answer, sometimes they cannot. When the issue is too complex, the investigation ends up here. We need to provide them with a meaningful answer, and suggest suitable workarounds and how to fix the issues."

The instruments used in this particular project have been developed for analysing blood samples to detect different types of viruses such as HIV. The whole process uses two different instruments. The first instrument

extracts the DNA from the blood and transfers the DNA to the second instrument, which then performs the PCR (Polymerase Chain Reaction) process to amplify the amount of DNA material used for accurate detection of the viral load. The ERNI team doesn't necessarily need to use reagents and samples during this process, because all they need is to detect possible errors within the instrument or the application software. Vermeire adds that the ERNI Lab helps accomplish a mission: "We accepted the challenge to help our customers through showing them our support. If our customers want broader maintenance of the instrument or software changes for the instrument, we are able to provide them with an all-care package with close access to the instruments located within ERNI facilities." ✕





Bridging the shortage of resources

ERNI supports companies that are looking for a gradually extensible development team or specialists with specific expertise in requirements engineering, project management, testing or implementation of complex solutions.

Our customers determine which specific skills are needed for the success of a particular project and specify the time frame for which the additional capacity is needed.

better ask ERNI