



MDignum

DIGITAL TRANSFORMATION PLATFORM
FOR MEDICAL DEVICES

WHITE PAPER
V. 1.0

EXECUTIVE SUMMARY

MDignum is an ecosystem of solutions that enable healthcare organizations and providers to acquire novel/new-generation treatment and diagnostic devices at no up-front cost. This is achieved by using a Device-as-a-Service model, wherein device operators pay for use, rather than ownership. All devices in the ecosystem thus become income streams for vendors/manufacturers, while sales of new/upgraded devices become frictionless due to lack of risk for customers.

Risk-free introduction of novel devices will speed up adoption of new treatment and diagnostic methods, improving healthcare outcomes. Adding a standard digitalization module to devices will enable remote diagnostics and monitoring of device operation, allowing vendors to optimize service/maintenance schemes, including service schedules and spare part supply chains.

Introduction of platform for ecosystem development will take place in phases, with the first phase employing fintech solutions in order to improve medical device financing and spare part traceability.

MDignum Key Benefits

Bringing FinTech into Healthcare

We create and implement new business models based on blockchain and tokenomics principles. This will streamline and clarify finance relations among whole healthcare ecosystem.

Holistic engineering approach

Many years of medical hardware design and production plus experience in IoT and digital technologies is the key to success in making innovative devices.

Social responsibility

We believe our projects will improve quality of life for hundreds thousand people.

Strong software development skills

Our comprehensive portfolio includes apps for insurance, banking, retail, and other. This cross-industries experience will be in demand for ecosystem integration.

FDA/CE certification practice

We did it for previous models of our devices and understand how to minimize bureaucratic burden on the way to U.S. and European customers.

Focus on innovative products and solutions

It will help to reach great scalability and robust cash flow.

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INTRODUCTION

Healthcare is in crisis. None of the stakeholders – patients, doctors, medical device vendors, insurance providers, legislators – are satisfied with the status quo. Unfortunately, debates in the key of Obamacare vs. Trumpcare will not provide any substantive solutions. The roots of the problem go deeper.

To get a clear idea of what a solution might look like, we need to examine the healthcare industry the same way that a doctor examines a patient: gathers an anamnesis, sets a diagnosis, and offers a treatment plan.

Anamnesis Vitae

Despite the great progress made in life sciences in recent years, leading to the appearance of new diagnostic and treatment methods, the overall situation in healthcare seems to provide no cause for optimism: growing expenses outpace any improvement in outcomes or service quality.

Consider the following — in 1980, healthcare expenditures were \$256 billion, according to the Centers for Medicare & Medicaid Services. In 2010, U.S. taxpayers paid nearly \$2.6 trillion for healthcare services. Insurance does not guarantee favorable financial outcomes for patients — a high proportion of bankruptcies in the US are due to medical debt.

Healthcare is highly fragmented. More than half of U.S. physicians work in practices of three or fewer doctors; a quarter of the nation's 5,000 community hospitals and nearly half of its 17,000 nursing homes are independent; and the medical device and biotechnology sectors are made up of thousands of small firms.

The industry is highly regulated. While regulation was meant to reduce risks for patients, it has become a hurdle to innovation and led to the creation of a tremendous medical bureaucracy, which makes the system less effective while adding administrative expenses at every stage.

If we look at countries other than the US, we'll see that their healthcare systems are also far from ideal, while the situation in developing countries is further aggravated by low accessibility and the inability of large segments of the population to afford quality medical services.

Diagnosis

We can identify two main causes of the current crisis in healthcare:

First, lack of client orientation. This is a general problem, inherited from the 20th century, when vendors/manufacturers could impose their preferences on consumers. In the words of Henry Ford, "an automobile can be any color,

as long as it's black. Doctors have tended to conduct themselves the same way, showing minimal interest in the patient's preferences and feedback. Right now, we are in the Age of the Customer, with information technology having greatly increased both patient literacy and competition between providers. The old way of dealing with patients will never work again.

Second, healthcare is de-facto decentralized but most of the solutions have centralized architecture. Creating trust between participants using traditional means — documentation — leads to high transactions costs. It's no wonder that doctors complain that they have to spend more time writing than healing.

Compared to other spheres that have already undergone a significant digital transformation, such as telecom and banking, the healthcare seems to have stalled in terms of development and administrative efficiency.

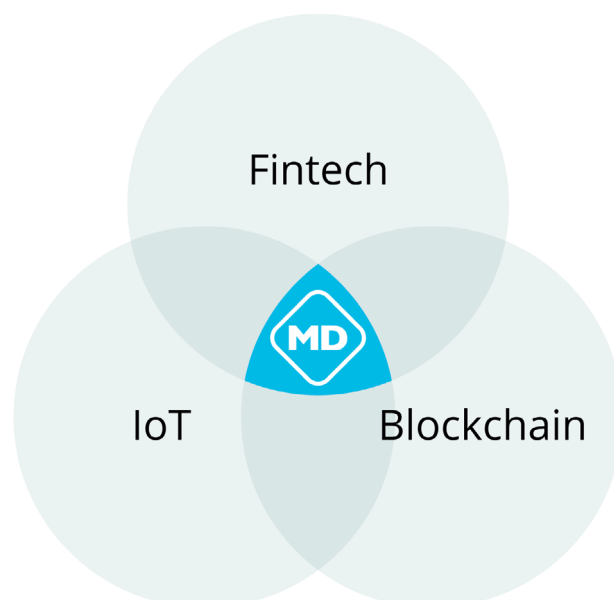
Treatment Plan

Vitamin 'Fintech'

Fintech acts like a blood thinner, getting capital moving through the industry instead of letting it accumulate with established, monopolistic players. Fintech services, such as instant payments, P2P lending, crowdfunding and others, have already helped turn the respectable-but-unwieldy finance business into one of the most dynamic and innovative sectors of the economy. Fintech can, without a doubt, do the same for healthcare.

Smart drug 'Blockchain'

In order to get rid of bureaucratic sclerosis and high administrative expenditures, we need to improve short-term memory and speed up the transmission of nervous impulses – i.e. create a seamless, automated end-to-end network of trust for all transactions within the healthcare ecosystem. This will drastically reduce administrative overhead, get rid of unnecessary middlemen, and reduce transaction costs.



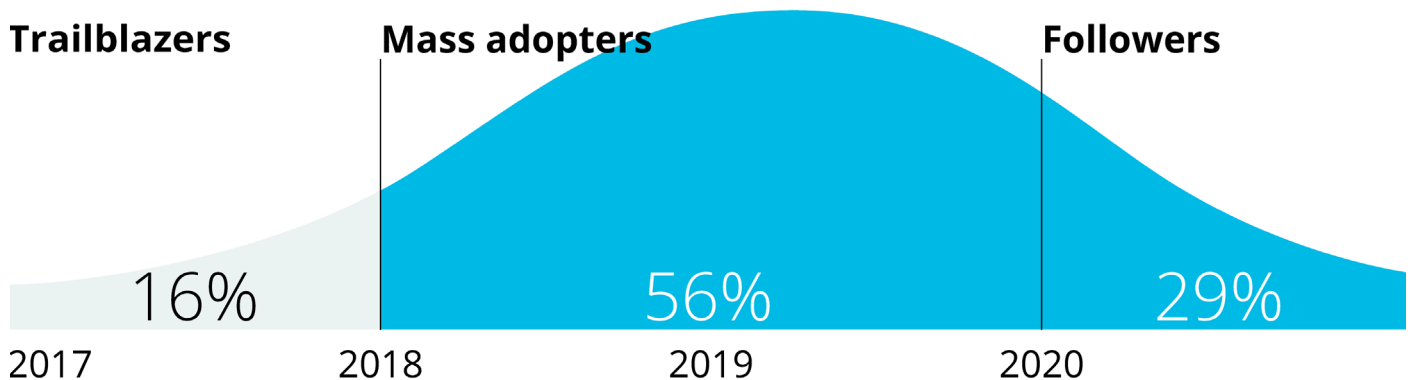
Injection 'IoT'

In order to speed up information delivery and make patients' medical information more portable, medical devices need to become a part of the ecosystem, able to seamlessly communicate with other participants. To be able to do this, medical devices must be equipped with various sensors and connectivity tools.

THREE WAVES OF BLOCKCHAINIZATION IN HEALTHCARE

Blockchain is everywhere and healthcare isn't exception. But for a while blockchain mindshare much more times exceeds its market share: everybody talks of this promising technology; however, few has implemented. Only 16% (in the U.S. – 8%) of healthcare respondents – the Trailblazers – expect to have a commercial blockchain solution at scale in 2017. (Source: IBM "Healthcare rallies for blockchains")

First to finish: Healthcare respondents' expectations of when they will have blockchains in production and at scale



You shouldn't be an analytic to guess that strict regulation is the main challenge on the way to healthcare digital transformation. As well, innovations don't penetrate all fields immediately. First, new technology hits on the weakest chain of the old universe to disrupt it. In healthcare such "weak chain" was Electronic Medical Records systems – weak in sense of readiness for blockchainization. Second wave is fintech diffusion bearing new business models into healthcare.

But third wave differs from them – it directly affects treatment and diagnostic processes, not information and money. That's why MDignum team focus efforts on the third wave.

First Wave – Electronic Health Records

The idea looks almost obvious – if you had a lot of tiny and huge repositories of medical records, sooner or later you'd like to blockchainize them. It is logical and predictable shift from a number of centralized ledgers to decentralized one – because people move from city to city, change doctors and clinics but need access to all their health data whatever they are. In fact, it is a shift to patient-centric model and similar transformations are happening in all industries.

According mentioned IBM research, 7 in 10 healthcare trailblazers expect the greatest blockchain benefits to be in clinical trial records, regulatory compliance and medical/health records. This reason is understandable – early investors

want to get fast and tangible output at the same time to avoid long-term burden with getting FDA or other regulatory approval.

So, you can see many startups offering blockchain based EMR/EHR systems. Currently their solutions are not widely adopted for a while but it is just a matter of time. Therefore, we in MDignum aim to make integrations with existing EMR/EHR but not develop our own – this isn't innovation any more (however not commodity yet).

Actually, this first wave of blockchainization that changed patient-doctor relations. But isn't about changing healthcare itself – just around healthcare. It is all about information management, not about innovations in disease diagnostics and treatment.

Second Wave – Fintech Coming into Healthcare

As you know, blockchain revolution started in financial services from bitcoin appearing. By today's standards, fintech industry is quite mature and begins expansion into neighboring fields such as insurance, logistics, retail, etc.

Of course, fintech couldn't leave aside \$7,7 trillion worldwide healthcare market. From the other hand, healthcare feels thirst for speeding up payments and decreasing transactions cost. Then, after a short period of dating they got married.

Speaking seriously, fintech is able disruptively transform healthcare industry. Whole ecosystem must be rebuilt – we mean relations between all parties, including patients, doctors, insurance and leasing companies, pharmaceutical industry, medical devices manufacturers, and others.

What fintech solutions are demanded in healthcare? A lot of, i.e. asset tokenization, multi-brand loyalty platforms, any forms of crowdsourcing, KYC offerings, P2P lending and many others.

MDignum team has strong competence in fintech and established ties with many fintech leaders and we definitely intend to participate in the second wave of blockchainization of healthcare. (See use cases in our whitepaper.)

Third Wave – Digital Medical Devices

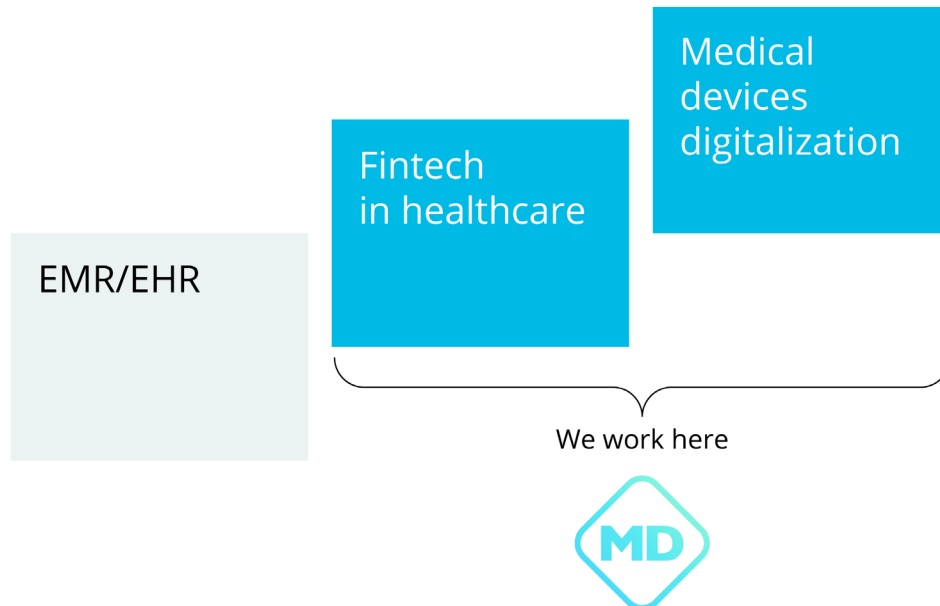
Real impact of blockchain on healthcare will be visible when new digitalized models of medical devices come into everyday practice. Thereby we achieve better integrity – data from any device will be delivered directly to EMR/HER system; and vice versa – prescribed by the doctor parameters for treatment procedure will be automatically set on device.

Here blockchain resolves its common task – eliminates “middleman” from the process and opens opportunity for remote device monitoring and servicing. Consider, 65% of respondents ensured that medical device integration brings some disruption.

Besides, blockchainization of medical devices unblocks new ways of financing prospective project and pushing them to the market.

MDignum Vision

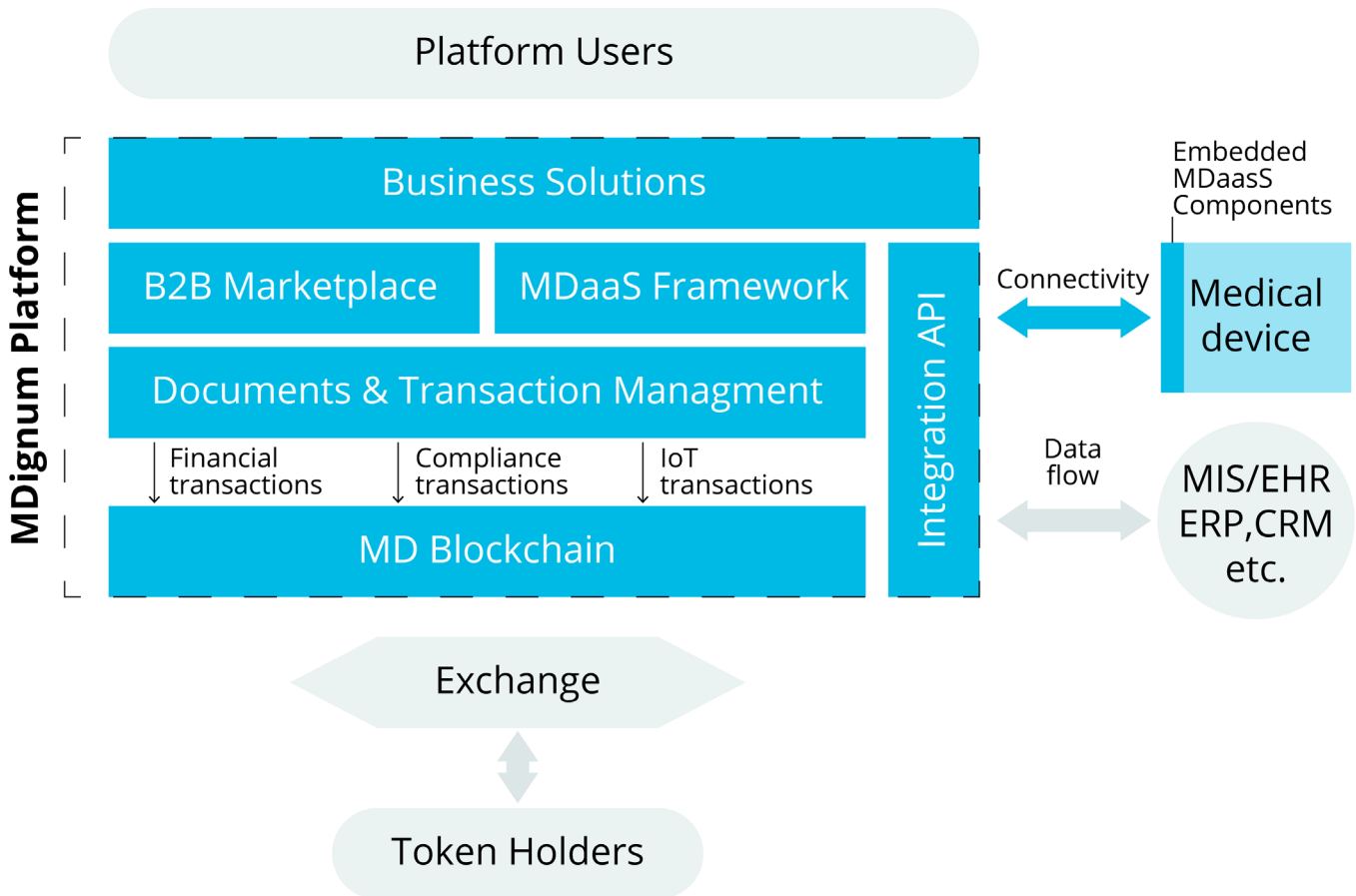
First wave – implementation of blockchain into EMR/EHR – is almost commodity. Sure, it provides solid basis for the next two waves. MDignum competitive advantage is the unique combination of deep fintech and engineering expertise, so we are to serf on the both waves, second and third.



What's further? Fourth, fifth waves. AI, robotics, bioprinting, genome technologies and so on. Everything we read about in science fiction books. Certainly, we want to participate in this game.

MDIGNUM – ALL-IN-ONE PLATFORM

MDignum is a universal platform that will enable the step-by-step creation and development of a wide-reaching ecosystem of solutions that will encompass all aspects of medical device use in the healthcare and wellness industries.



It will be created in three phases:

Phase 1

B2B Marketplace
for Medical
Devices

2020

Commercial platform for manufacturers/vendors and end-users of medical devices, based on next-gen fintech solutions.

- Optimization and acceleration of medical device vending and supply processes
- Attraction of new financing sources
- Multi-brand loyalty programs
- Traceability of device manufacture and spare parts supply

These platform functions do not require any alteration to existing medical devices, and thus do not require updates to device certification. This means that any medical device manufacturer/vendor can join the platform, forming the pipeline for the next phase.

Phase 2

MDaaS
Framework

2021

Medical Device as a Service — the transformation of conventional medical devices into connected digital devices will open up a wide range of new business opportunities:

- New models of licensing device use
- Monitoring and analytics for optimizing MRO
- Tokenization of medical devices

This phase will require the development and incorporation of specialized IoT modules based on a unified Digital Extension Framework, in order to enable remote monitoring of device operation. Incorporation of the modules will not affect the devices' fundamental treatment and diagnostic functions, so certification costs/times for new models will be kept to a minimum.

Phase 3

Digital Health
Solutions – go
B2C

2022

Entry to the consumer market — connection of in-home diagnostic and health maintenance devices to the platform.

- In-home use of medical devices for out-patient procedures and chronic disease treatment
- Health monitoring and healthy lifestyle maintenance through insurance-provided health quality schemes and loyalty programs

This phase will require scaling the platform for B2C and service marketing at the retail consumer level.

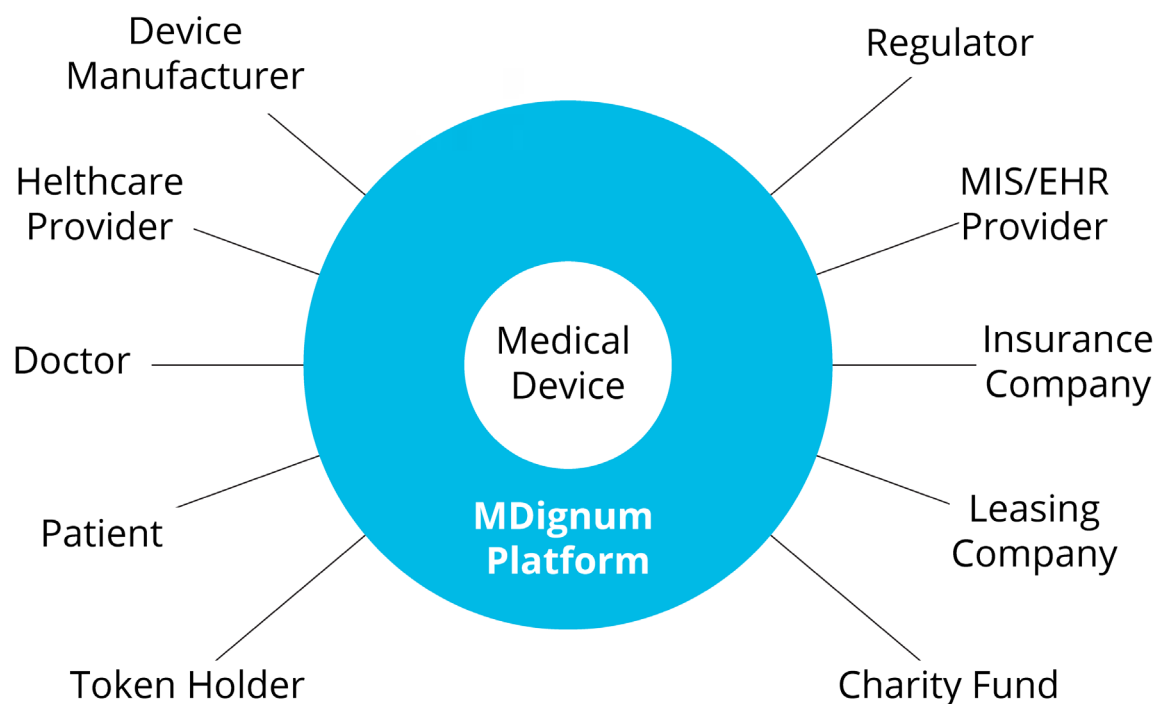
Personal Medical Data

The platform does not process personal medical data. The platform exclusively monitors the total volume of services rendered through connected devices in order to enable their monetization. The platform operates in the B2B segment, wherein the parties are the manufacturers of medical devices and their operators. Integration with MIS/EMR is at the discretion of each individual device vendor.

B2B MARKETPLACE FOR MEDICAL DEVICES

MDignum is a B2B marketplace for manufacturers and buyers of medical devices. Marketplace participants will be able to simplify and reduce the cost of supplying and servicing of medical equipment. MDignum enables this by implementing next-generation digital transaction management and tracking of contractual rights and obligations.

If you look at the issue more broadly, we will see that the matter is not limited to the purchase contracts. The supply and use of medical equipment are a complex set of relations between various parties:



And, of course, doctors and patients – as end users of medical devices. Token holders, as well, are considered as a part of the platform ecosystem.

Let's try to consider the above business process using blockchain. Thus, each record or transaction will be entered into a distributed registry and is stored in a common database for all. In this case, a copy of the registry will be created for each participant (manufacturer, leasing company, regulatory authority, etc.). Thus, all entries will automatically be checked by all interested parties. Therefore, to forge documents or hack the database will be almost impossible.

MDignum B2B isn't just e-commerce web site. It provides secured infrastructure for whole medical device life cycle – from manufacturing till utilization.

MEDICAL DEVICE AS A SERVICE

Device-as-a Service (DaaS) applies the principles of outsourcing to capital-intensive equipment. The customer does not pay to own a device, but only for the value brought by the device to their business.

A similar approach was introduced more than 50 years ago in aviation. “Power-by-the-Hour,” a Rolls-Royce trademark, was invented in 1962 to support the Viper engine on the de Havilland/Hawker Siddeley 125 business jet. A complete engine and accessory replacement service was offered on a fixed cost-per-flight-hour basis. This aligned the interests of the manufacturer with those of the operator, who only paid for engine uptime.

Hewlett-Packard was one of the first companies to introduce this approach to IT, offering its customers printing service instead of equipment and supplies for purchase. This allowed HP to not only remain in the highly competitive printer market during a time of falling margins, but to increase its market share by including even competitors’ devices in its service contracts. After all, the client is not interested in a printer’s brand or its price – only in the print quality, cost per page, and uninterrupted service.

Medical facilities are in a situation that also demands a new approach. Equipment is becoming more complex and expensive, new models are emerging more and more quickly. Transitioning to the DaaS model is becoming an increasingly viable alternative to device ownership.

MDignum aims to introduce the DaaS business model, successfully used by Rolls-Royce and HP in their respective fields, to the medical device market.

‘Smartization’ of Medical Devices

Although DaaS is, at its core, just a particular business process, with a differently structured contractual relationship between the device user and the device vendor, conventional medical devices do not fit well into this model.

To get the most out of the transition to DaaS, devices need to become «smarter». They need to be able to report their maintenance status, amount of work performed, and, if applicable, supplies used. This will allow for automated management, reducing the cost of implementation down to a reasonable minimum.

This requires smart devices to be equipped with sensors for remote monitoring and connectivity tools that will transmit device data to the vendor.

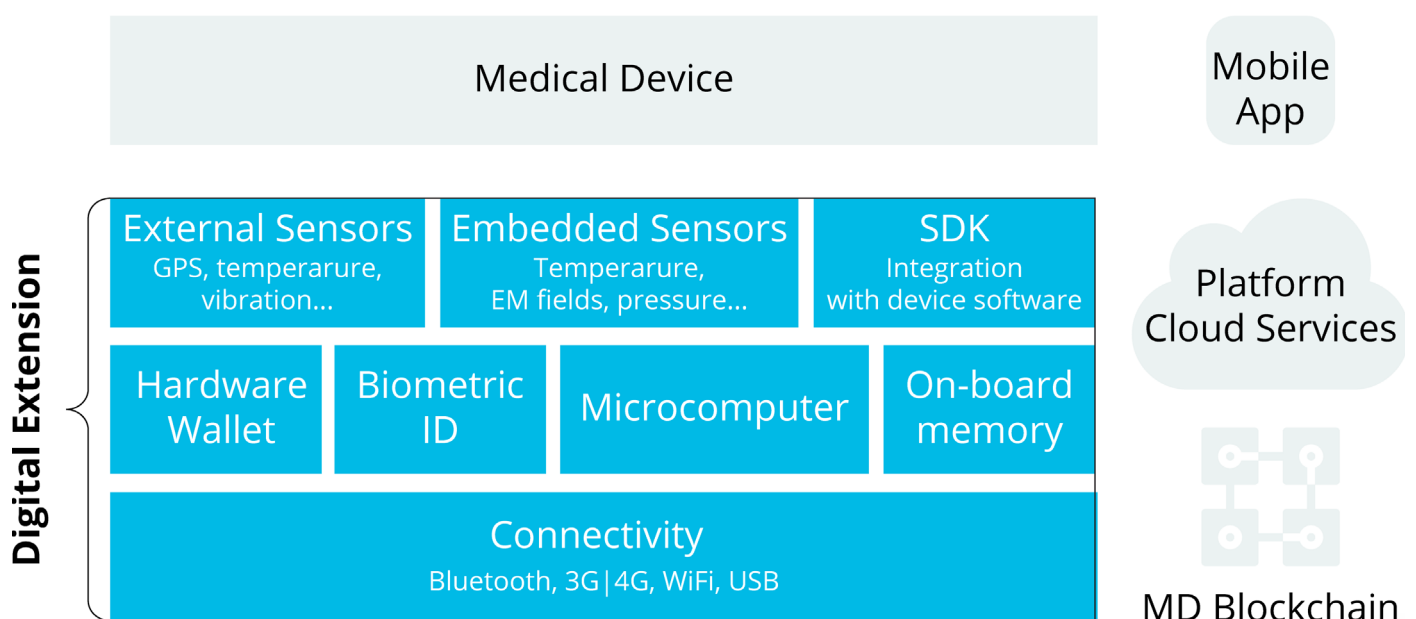
In addition, since there is a wide variety of medical devices, a unified system of use management is needed. This system needs to be built on a foundation of common standards and meet high cybersecurity requirements.

MDignum is this very system. To facilitate the connection of smart medical devices to this platform, we are developing a Digital Extension framework. The framework includes a standard set of sensors to monitor device parameters, track time in use — accounting for different operating modes, number of sessions, etc.

On the basis of these data, the platform calculates delivery schedules for spare parts and supplies, and bills the operator. As historical data on device operation are accumulated, predictive analysis models can be developed to improve the accuracy of service planning and preventive maintenance. This will reduce the device downtime and increase operational efficiency.

Another Digital Extension component is the connectivity module, which provides secure data transfer via Bluetooth, 3G/4G, Wi-Fi, or USB, depending on the size and features of the connected device.

The SDK included with the platform will allow developers to create mobile and web applications to visualize device information and interact with the platform's core services.

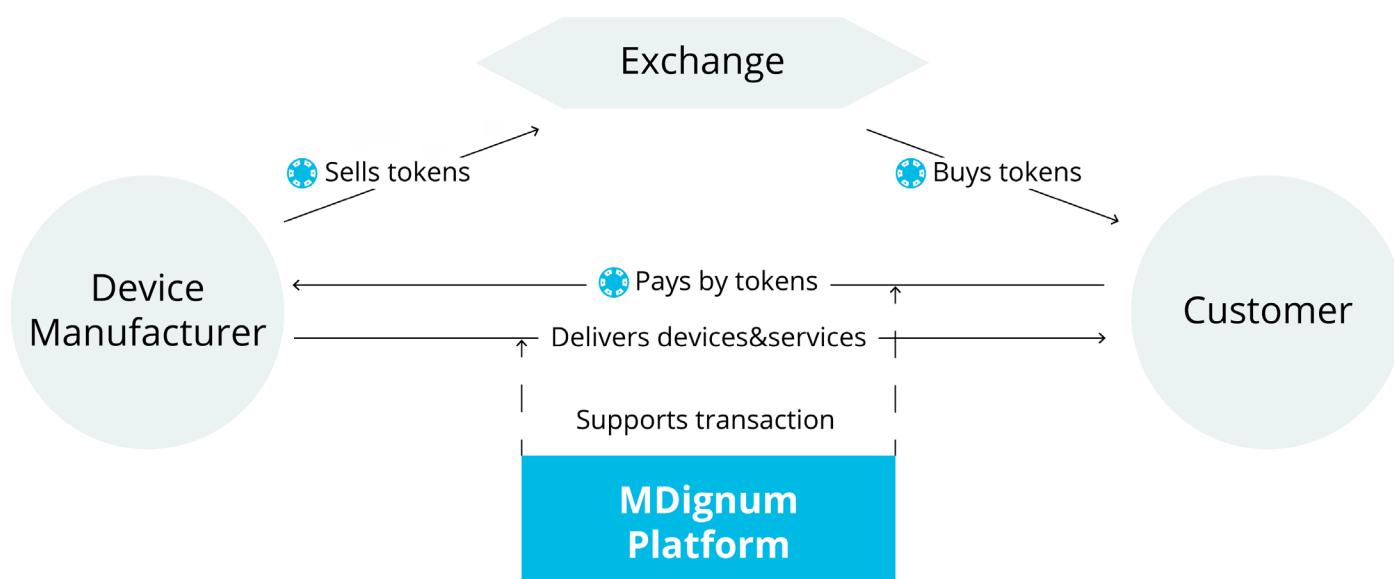


MEDG TOKEN

MEDG will be implemented on the public Ethereum blockchain as an ERC20 token, which serves as a tool for securing transactions in MDignum.

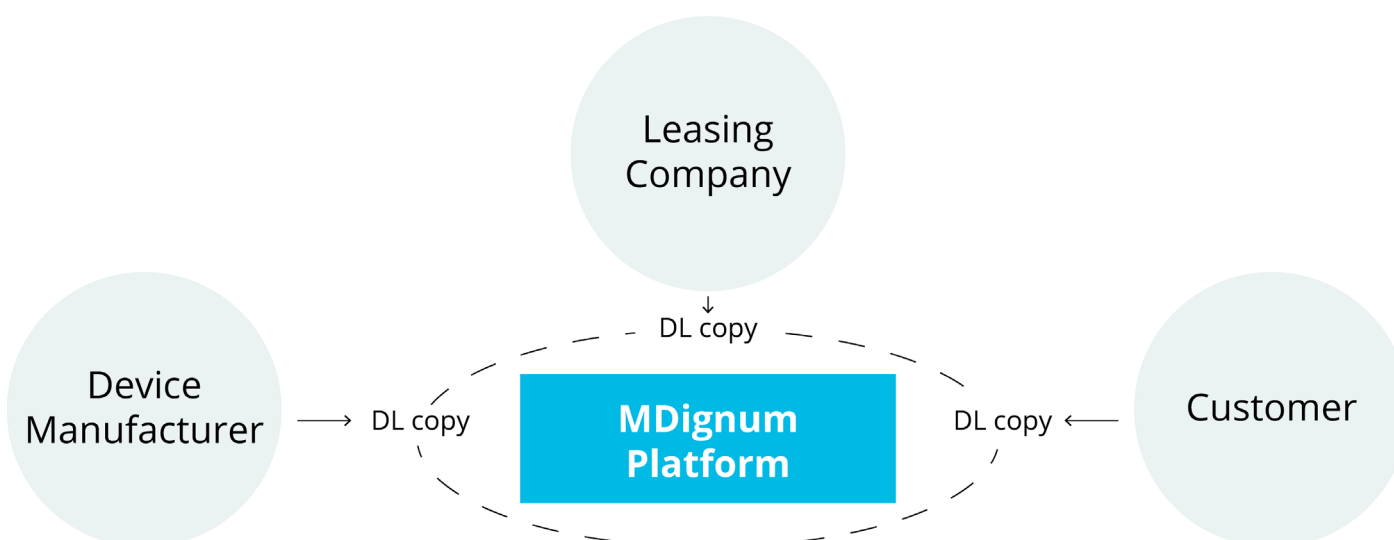
In the MDignum ecosystem, tokens will be used to pay for medical devices, spare parts, and consumables, as well as related services, including maintenance and training. MEDG tokens can be purchased on an exchange.

In order to protect consumers from token price volatility, all goods and services in the marketplace will be also be denominated in dollars, euros, or in the local currency. At the same time, ecosystem participants will be able to make purchases at a special low price, which will not be available to customers paying in fiat currency.



Leasing

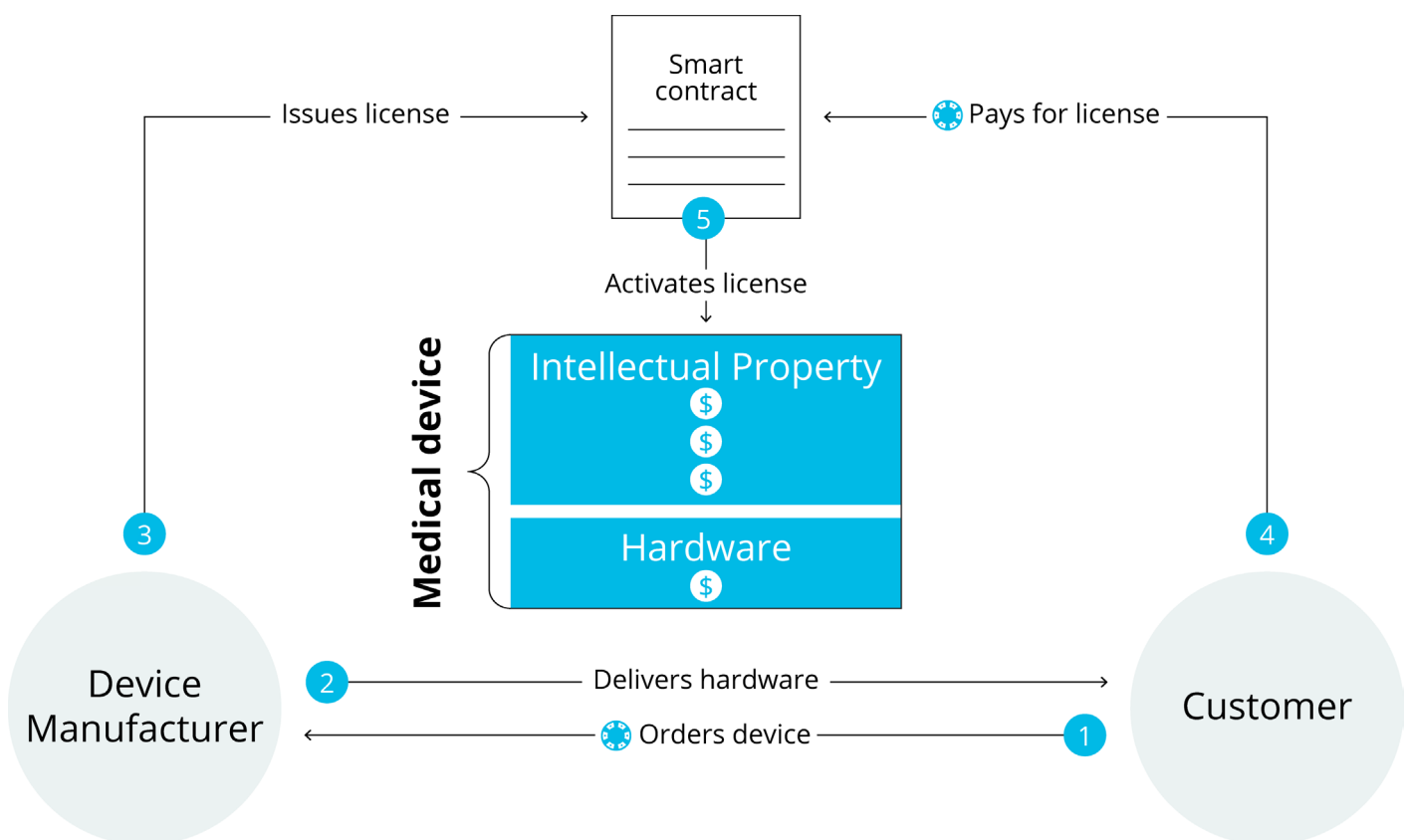
Medical equipment leasing is widespread, as it allows clinics to reduce their initial investment and save on taxes. However, leasing adds legal complexity to transactions and mutual settlement agreements.



Transforming Medical Device Supply

Intellectual property is a significant part of the cost of high-tech equipment. For example, according to a recent study by TechInsights, the total cost of all components in the iPhone XS Max, together with testing and assembly costs, is \$443. The XS Max retails for \$1,249 in the US. For medical equipment, the picture will be similar.

In this regard, there is one problem: the more expensive the delivered goods, the more overhead costs arise in the process of delivery to the end user – customs duties, shipping insurance, agent commissions, etc. On the other hand, software delivery is devoid of these added costs – the user simply pays the vendor the cost of the license and downloads the product online.



Process description

1. Customer orders a device from the vendor.
2. Vendor delivers hardware.
3. Vendor issues the user license for the device and encodes it in a smart contract.
4. Customer sends tokens to smart contract as a payment for the license.
5. Smart contract activates the license, allowing the customer to use the device.

Transferring the supply chain to MDignum enables us to transform the traditional business process and separate the intellectual property contained in the device from the hardware, provided that the device is equipped with a Digital Extension module.

This approach has considerable flexibility and allows manufacturers and vendors to implement a variety of business models for the provision of medical device services:

- Different service plans, with monthly or annual payments
- Payment for use, i.e. pay-as-you-go
- Limited use under specific service plans
- Added options -- analytics, specialized operating modes, etc.

This way, device providers will be able to generate more diverse offerings for different types of consumers and offer their latest equipment without high up-front costs.