# The Contextual Health System

Whitepaper

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**Disclaimer**

In this document we mention both persons and patients. Each person is sometimes a patient (originally meaning ‘one who suffers’, in Europe the definition was later translated to user of health care services, whether healthy or sick[1]), but this is only at certain points in time of one’s life (i.e. when ill) under certain circumstances (i.e. when getting medical help). Being a patient does not define a person and therefore we have chosen to refer to persons as patients only when describing interactions between a medical professional and their clients, since it is nomenclature in that field.

Multiple examples provided are from the Netherlands, but can be seen in a similar manner in almost every country.

This is a work in progress and is subjective to change.

For any questions on this whitepaper, please contact me (rick@4medbox.eu).

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[1] https://www.who.int/genomics/public/eu_declaration1994.pdf

# Current state of Health

The worldwide healthcare system is under tremendous tension and needs to change to accommodate current needs and necessities with different governance. These tensions were visible even before the CoViD-19 pandemic hit[2] but were exacerbated by the pandemic. I would like to clarify these tensions by using examples. In the upcoming section there is a focus on the topic of mental healthcare (specifically stress), this is to indicate a bigger underlying problem I want to express.

The RIVM (Dutch institute for public health and the environment) reported in 2018 that 1 in 12 young people (12-25) in The Netherlands was psychologically unhealthy.[3] In young women (16-25) the numbers were even higher: 1 in 7,5. The publication shows an increase in mental health problems over the previous 10 years, not just in young people but across all ages. The report suggests perceived pressure does not lie in one isolated/specific domain, but in combined domains that can be different for each person. The report ends with the following phrase, which has been translated from Dutch:

> *"It is important to continue to listen to young people and to come to a joint approach that does justice to their perception and world of experience, without losing sight of the social context. After all, it is in this context that stress takes shape and becomes meaningful. It requires a broad approach with an eye for diversity, and co-creation with all stakeholders; starting from the living environment and together with young people, but not without making the connection with parents, policy makers and (care) professionals."*

While it specifies young people, one could argue that this goes for all age groups. The young person may just have a harder time identifying the root cause of their perceived stress.

The CoViD-19 pandemic aggravated the pressure on persons as also stated by a United Nations study. In May of 2020 the United Nations stated their concerns about the threat of CoViD-19 to mental health in Europe[4]. The study contains statistics from research in different Western-European countries. The most heavily impacted country is the United Kingdom with a 37% (25 million people) anxiety rate, with concerns mainly stemming from personal well-being (13%), job security (9,8%) and the impact on their finances (8,3%). Next to the generally high mental stress levels all over Europe currently exacerbated by the CoViD-19 pandemic, there is a constant shortage of medication, medical professionals, availability of treatment, and knowledge distribution.

This is mainly due to the way the healthcare system has been organized. The principle behind it is that health should not be a high financial burden and the responsibility of the person, healthcare insurers and/or the state should compensate for extreme costs but healthcare should always be performed in the most cost efficient way. While in theory this sounds reasonable, it incentivises cost reduction above healthcare and has its flaws. I would like to point out 3 examples of these flaws to clarify the reasoning for reorganization of the healthcare system.

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[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518343/

[3] https://www.rivm.nl/sites/default/files/2019-05/011281_120429_RIVM%20Brochure%20Mentale%20Gezondheid_V7_TG.pdf (Dutch)

[4] https://unric.org/en/concerns-are-raised-over-the-threat-of-covid-19-to-mental-health-in-europe/

Medical institutes have been partially placed in the private sector, which means that the free market gets to decide which treatment is "best". While this might have short term beneficial effects (cost reduction of medical treatments), it also has long term drawbacks. Since medical treatments should cost as little as possible and a business mindset has evolved, at some point the quality of medical treatments is reduced to accommodate more profit; and so are the humane aspects of care, for both professional and patient. Some of the examples of removing the humane aspect from the medical institutions is the withholding of healthcare when reimbursement is not ensured by health-insurance companies, or a so called "healthcare ceiling"[5] or "turnover ceiling" which is a financial ceiling for the hospital which, when reached, will not receive reimbursement for (non-emergency) care. While in theory one could switch to another hospital for better or other treatment, in practice this is difficult to impossible, due to socioeconomic reasons, travel distances, and the simple fact that in case of an emergency one cannot always choose.

Another drawback of placing medical institutes in the private sector is that bankruptcy of a medical institution becomes a possibility. As a result it may have to sell all of its assets, including medical records of patients, to pay back their debts. In fact this already happened in the Netherlands with the "Slotervaart" and the "IJselmeer" hospitals, where curators – whose previous experience was not connected to healthcare – became managing directors of hospitals and had to ensure all debts were repaid. Fortunately these medical records were transferred to a different institute after about 18 months, but until now no fundamental rules and regulations have been created.

The CoViD-19 pandemic amplifies these flaws by putting an extra strain on the person and the people providing medical care even more. While there have been scripts for pandemics (which action should be taken when in case of a pandemic), these have been neglected since the main focus is placed on cost reduction and the general consensus was "*Infection diseases were over anyway*"[6].

This demonstrates that the current healthcare systems is failing and needs to be redesigned.

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[5] https://www.zorgwijzer.nl/zorgverzekering-2019/patient-niet-geholpen-in-ziekenhuis-door-omzetplafond (Dutch)

[6] https://www.ad.nl/binnenland/alarm-over-slagkracht-ggd-weggehoond-bewindsman-zei-infectieziekten-zijn-toch-voorbij~a594f3b2b (Dutch)

# Why 4MedBox?

The current healthcare systems (both technical and organizational) implemented in most parts of the world are not facilitating the health of the person, but are more focused on the financial reimbursement of time spent given care. The perspective of the current systems is not to provide health, but rather to make money. While reimbursement for time spent given care is important, it should not be the focus point for the entire healthcare system. The healthcare system should help translate symptoms to diseases, help provide information about diseases, help communicate with colleagues from the same or other fields, provide monitoring opportunities for the person and the medical professional, supports in self-determination, help in dietary advise, help in exercising advise, help in medical family history, etc. In short facilitate health for the person.

4MedBox is returning to the core of healthcare: health. We want to support the person in being as healthy as possible, by helping with both curative and preventive care, while also supporting a healthy lifestyle, well-being and privacy. One should be able to make decisions about one's health and choose who aids this process, while not giving away their personal information. By being the owner of your data you are in control over your health and can easily switch between healthcare professionals when necessary without losing medical information.

# What is the 4MedBox?

Our origins lies in the world of bioinformatics. The bioinformatics field is mostly an academic field where you help understand the fundamentals of biology and (modern) medicine by academic research. While this is an extremely interesting field, we searched for ways to make a social impact because we missed the added benefit for the person.

As bioinformaticians our specialty in analysing and understanding the nature of biology and medicine through data sciences. While discussing with medical professionals how bioinformatics could help identify diseases, we learned what information is currently available to medical professionals and how they obtain it, and how they decide on how to proceed with diagnosis and treatment.

In these discussions it became clear that the medical professional misses a lot of information to make an informed decision. For example: it is known that some medication doesn't work for people with certain genetic differences, but this information is not put to use because medical professionals do not have access to data of genetic characteristics of their patients. Even if the person could provide the data, medical professionals lack the right set of skills and tools to use the information. The information tools available to the medical professional are mostly closed systems, meaning it can only access data entered into/filed in the system by a user (a medical professional at an institute or practice) or an administrator. No outside information can be added or requested, and direct consultations with other medical professionals about a certain disease or a person cannot be performed. The systems mostly wants the medical professional to administer data so that reimbursement can be performed, it does not facilitate the medical professional in their decision making process. Due to the systems not being able to integrate with each other it does not facilitate the new ways of working where one needs as much information as possible to identify the right medical steps to take. By placing all medical information about a person at a personal level a medical professional can easily access necessary (historical) information and add or request new information. This does not only help with day-to-day practice but also with fundamental research, since contextual and medical information is stored one can search for unknown medical/pharmaceutical interactions.

On the other hand the person has no idea what type of medical information there is about them and cannot easily transition from one medical professional to the other in the same area, country or other countries. This is mostly due to the different types of data that is stored in different systems and the unwillingness of the software providers to have open data standards or/and open up their systems for machine-to-machine communication. This also prohibits the contribution of data by the person through for example medical/fitness IoT (Internet of Things) devices, which – while properly validated – could add vital information about the health, well-being and possible origin of diseases of the person.

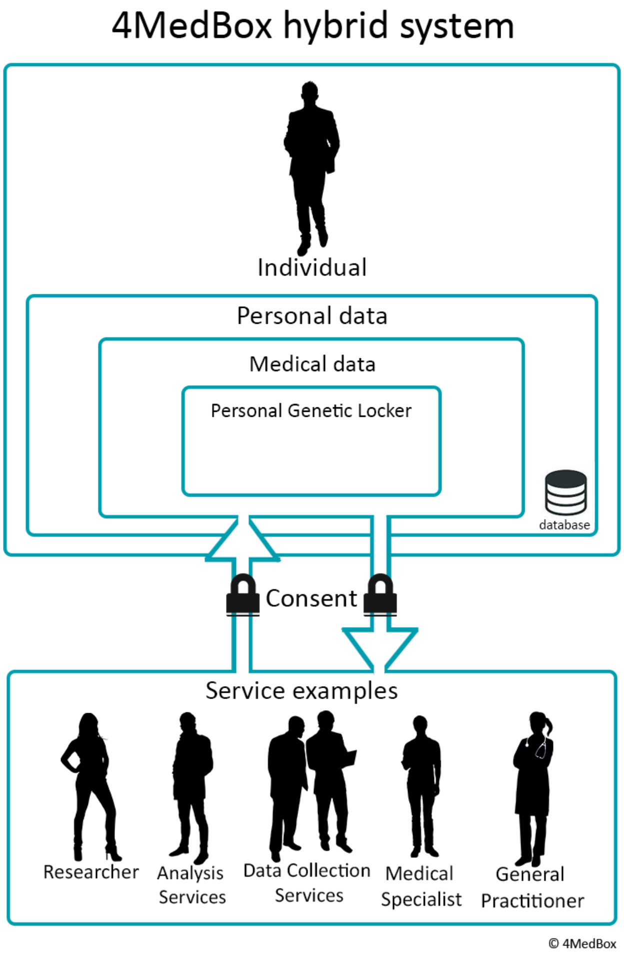
The idea behind the 4MedBox is to facilitate the well-being and health of the person by providing a system wherein all types of medical professionals can work together with the person, while the person is in control over their own data. In this manner the person can add data, or give consent to add or analyse data by others.

The person is facilitated in choosing where the data is stored, which further facilitates the freedom of choice for the person. By facilitating this free movement of data, from one place to the other, the person is also better facilitated in their own free movement, since the person can take all their information (medical and/or otherwise) with them wherever they go.

For example: the general practitioner of a person can look at their healthcare information and make a prognosis (analysis), without the person having to make an appointment and physically come to the general practitioner. If the general practitioner needs extra information, they can ask another medical professional such as a colleague general practitioner or a secondary care provider through the system and – after the person has given consent – the other medical professional can help interpret the data (and only the data that is needed at that point). If the patient moves to another country, temporarily or permanently, they can take their information with them and provide this to a medical professional at this new location.

This is useful during pandemics – such as the CoViD-19 pandemic – but also while working abroad, during vacations, or in places where there is a lack of medical professionals.

In the below image we have visualized the control over the data by the person by giving (or not giving) consent. For a better understanding of the "Personal Genetic Locker" please visit the page about which projects we are involved in.



# Impact

We have matched our goals with the goals defined by the United Nations Sustainable Development Goals, to visualize the impact that the 4MedBox makes. They align with the following goals:

Since the person owns their data they can choose to sell or donate their data for research, or other, purposes to institutes and companies which can then analyse that data.

| SDG ID | Description |
|---|---|
| 1.4 | By 2030, ensure that all men and women, in particular the poor and the vulnerable, have equal rights to economic resources, as well as access to basic services, ownership and control over land and other forms of property, inheritance, natural resources, appropriate new technology and financial services, including microfinance |
| 1.5 | By 2030, build the resilience of the poor and those in vulnerable situations and reduce their exposure and vulnerability to climate-related extreme events and other economic, social and environmental shocks and disasters |
| 1.a | Ensure significant mobilization of resources from a variety of sources, including through enhanced development cooperation, in order to provide adequate and predictable means for developing countries, in particular least developed countries, to implement programmes and policies to end poverty in all its dimensions |
| 1.b | Create sound policy frameworks at the national, regional and international levels, based on pro-poor and gender-sensitive development strategies, to support accelerated investment in poverty eradication actions |

With our holistic approach and a bioinformatics point of view we help to better understand the data and help in current and future decisions.

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| 3.1 | By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births |
| 3.2 | By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births |
| 3.4 | By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being |
| 3.7 | By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes |

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| 3.8 | Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all |
| 3.9 | By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination |
| 3.b | Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all |
| 3.d | Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks |

There is no bias build into the system, only data that is needed for a specific task - after consent - will be visibile for the service provider. Gender is most of the time not one and will thus not create a bias.

| | |
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| 5.4 | Recognize and value unpaid care and domestic work through the provision of public services, infrastructure and social protection policies and the promotion of shared responsibility within the household and the family as nationally appropriate |
| 5.6 | Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences |
| 5.b | Enhance the use of enabling technology, in particular information and communications technology, to promote the empowerment of women |

New technologies and algorithms can be, after validation, connected to the system and used for the entire EU market. Thus helping new innovations thrive.

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| 9.5 | Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending |

By re-use of data less traffic, solutions and throw-away items have to be used. This will lessen the environmental and climate impact.

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| 11.5 | By 2030, significantly reduce the number of deaths and the number of people affected and substantially decrease the direct economic losses relative to global gross domestic product caused by disasters, including water-related disasters, with a focus on protecting the poor and people in vulnerable situations |

Healthcare professionals can access data in case of emergencies, and the system profides decision making support. This saves precious time.

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| 13.1 | Strengthen resilience and adaptive capacity to climate-related hazards and natural disasters in all countries |

The basis of the system is build to facilitate transparency on all levels. Every step taken, decision made, communication send, or otherwise is recorded and can be made available after a court order.

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| 16.5 | Substantially reduce corruption and bribery in all their forms |
| 16.6 | Develop effective, accountable and transparent institutions at all levels |
| 16.10 | Ensure public access to information and protect fundamental freedoms, in accordance with national legislation and international agreements |

17 PARTNERSHIPS FOR THE GOALS

The infrastructure has been designed as an EU infrastructure, so that each technology that is connected to the system can easily be re-used in other countries.

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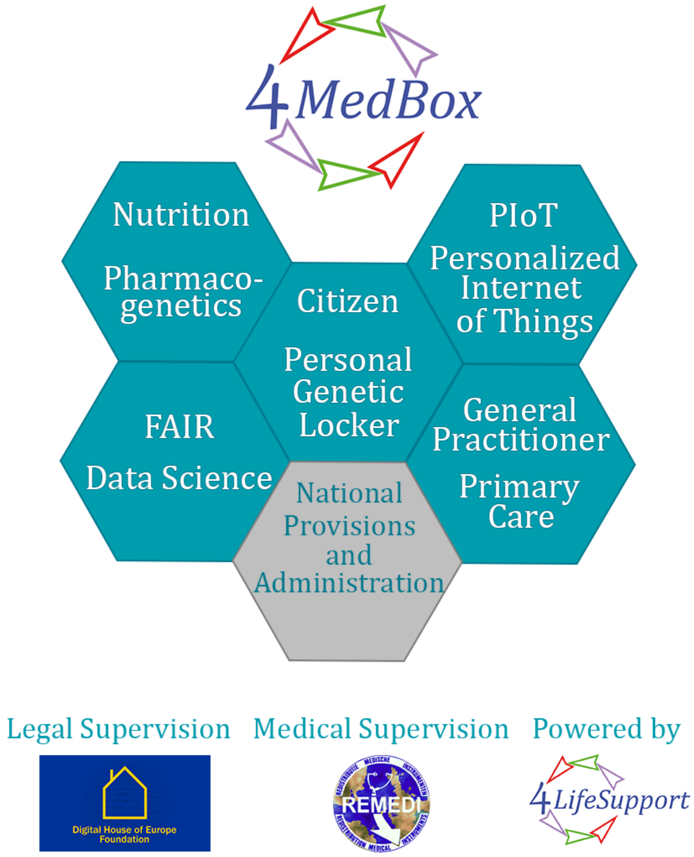
| 17.6 | Enhance North-South, South-South and triangular regional and international cooperation on and access to science, technology and innovation and enhance knowledge sharing on mutually agreed terms, including through improved coordination among existing mechanisms, in particular at the United Nations level, and through a global technology facilitation mechanism |

## International system

4MedBox is fundamentally an international system, and national modules can be attached to it. 'Health' is an international definition, but with national, regional and personal differences. This means that a system which facilitates the health of people needs to be able to connect with different modules based upon the location and preferences of the person.

For example: Reimbursement is generally provided at a national level by healthcare insurers or the state, so the 4MedBox needs to connect with them to make reimbursement possible. It would then only give access to needed data. This ensures no data will make it into systems that the person does not have control of and that if the person moves they take their entire medical record with them.

The below image visualizes the modular system that is the 4MedBox and shows the organisations that are involved in building up the system.



By making a system that is modular and able to be easily connected to national provisions it is perfect for international deployment and scaling will be easy, since little to no adjustments have to be made.

## Reciprocity

One of the missing ingredients in healthcare research is reciprocity. It could be argued that helping someone getting better is enough reciprocity, but the data created during the healthcare process is very intimate and a lot of knowledge can be created from it (both about the person as fundamentally). This is why we propose that the person receives the data that is collected. This could then be disclosed only under set conditions (for example only during medical examination by a medical professional or for a specific research). With this data long term health implications can be better correlated and other participants of the study can be informed about these implications when necessary.

## Autonomy Support

Last few years there has been a tendency towards patient and person-centred care, and this has caused a shift in the patient – health professional relationship. There's an increased focus on participation and empowerment, and boosting health literacy. Both patient-centred care and health literacy are associated with better health outcomes.

Health Literacy Europe[7] defines the concept as follows: "Health literacy is linked to literacy and encompasses people's knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."

Existing structures and digital systems are created around the health professional, instead of the person. This creates a barrier to acquiring knowledge about lifestyle and treatment because it lessens accessibility to (personal) health information. In other words: these systems don't support health literacy and create dependency.

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[7] https://www.healthliteracyeurope.net/

# What added benefit for who?

## Person

- Always have your medical information with you, wherever you go.
- Health, well-being, and lifestyle can be combined
- Evidence driven health
- Easily get second opinions about medical subjects.
- Family health history can be taken into account and donated to next generations
- Take external factors into account, like weather and pollution (asthma) stressors (job loss etc as mentioned above), seasonal changes (seasonal depression, vitamin D status, hayfever)
- Integrate new fields of medicine, not just DNA but for example microbiome
- Know what effect a certain medication will have on your body by looking at your complete context
- Can help in medical and pharmaceutical research by giving access to certain parts of the data you collect.
- Choose to keep to yourself, sell or donate your data.
- Have a medical professional, which you trust, help you with your data collection and use.
- Have direct interactions with medical professionals without having to make an appointment.
- Be able to read back/replay appointments to better understand the situation.

## Medical Professional

There are different types of medical professionals, some benefits are for all, while some benefits are for a subset of these types. The shared benefits are:

- Can access the medical data of the patient at any time at any place, when patient gives consent or during emergencies.
- Be facilitated in the automatic handling of the administrative tasks that are standard and cost too much time.
- Decision Support System
    - Use pharmacogenomics in the prescription of medication.
    - Use pharmacokinetics in the prescription of medication.
- Can interact with patients without having an appointment.
- Can directly interact with other medical professionals.
- Easily get to all the data about the patient I need to perform my job.

- Extension possible when scientific research is translated into new medical fields. This is occurring now with DNA, in the future possibly with microbiome or other.
- Be facilitated by personalized prediction models for my patients.[8]

## General Practitioner

- Moves from managing diseases for the patient to helping the person have a healthy balanced life (pro-active).
- Use bio-metric data in preventive care.

## Researcher

- Perform analysis on medical data and pharmaceutical data directly from the person which has been collected in a validated way.
- Perform research on the day-to-day performance of medical processes and pharmaceutical agents.

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[8] https://pubmed.ncbi.nlm.nih.gov/29598923/

# What projects is 4MedBox involved in?

4MedBox is involved in multiple projects, while honoring the aforementioned motivations. All are with partners from academic and/or industry.

## Personal Genetic Locker

The Personal Genetic Locker (PGL) project is lead by the Leiden University Medical Center, and provides an approach to enable the use of personal genomic data in primary care. The first publication has been written: "*Using Personal Genomic Data within Primary Care: A Bioinformatics Approach to Pharmacogenomics*"[9].

## SENSE

The Societal impact of gENetical SciencE (SENSE) project is a project set up by all University Medical Centers in the Netherlands, which promotes the genetical diagnostics in the medical practice. The project proposes to bridge the gap between the medical practice and genetical diagnostics by uniting the different expertise and deliver tools, guidelines, and a new conceptual (ethical) framework.

"*SENSE will: 1) Validate genetic tools for specific frontrunner applications (pharmacogenetics, oncology, cardiovascular and eye disease) in diverse Dutch healthcare settings; 2) Integrate the required social, ethical, legal and communicative guidelines, health-economics models, and frameworks for responsible clinical and societal implementation of such tools. 3) Provide a direct positive societal impact through implementation of the frontrunners. 4) Provide a manual on implementation of genetic applications for the complete health care.*"

## Family History

An inexpensive way of detecting hereditary diseases is to look for common diseases in the family history. Many tools have been created to create a family history and to detect diseases. Several studies have been conducted to measure their effectiveness in the US.

In this family history project, we have talked to parties to integrate a tool into our back-end so that the person can own the data and pass it on to their children. The tool should also be able to assist the medical professional in detecting and quickly identifying if a particular hereditary disease is present.

## Community Pharmaceuticals

The CoViD-19 vaccine research and production demonstrated that the general speed in which the creation of medication can be performed can be improved. With the help of the 4MedBox system this improvement can be facilitated, while still complying to privacy and ethical standards. By facilitating the person in becoming the owner of gathered data, and being able to request that data by interested parties such as pharmaceutical companies, a much bigger context can be created around each person and therefor better and faster research can be performed. While some data could not yet be gathered the 4MedBox can help in the full automation of the gathering of data in both medical as home environments in a validated way.

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[9] https://www.mdpi.com/2073-4425/11/12/1443

The 4MedBox also facilitates the research and production of pharmaceuticals by communities that are interested in medication that is less interesting for bigger pharmaceutical companies. We can help crowd-source/crowd-fund these communities and get community driven pharmaceuticals.

## What Communities are aligned with the 4MedBox?

We facilitate communities of people with research that they are interested in, by providing tools to collect and analyse data in a manner that would otherwise not be possible for them.

### “Healthy vitamin B12” / “B12”

The Healthy vitamin B12 community performs a citizen science research project. When someone has a B12 deficiency they have “vague symptoms”, such as fatigue, which can easily be mistaken for having other causes. The community would like to identify if a questionnaire for diagnosis of B12 deficiency could be enough or if blood analysis should be performed, and if there are other corresponding factors in the body that can directly impact the levels of B12.

### “4Relevi” / “De verademing”

The 4Relevi community ('De Verademing') aims to improve the health of people with respiratory ilnesses by measuring and improving the air quality. The 4MedBox is to be implemented as a tool to improve personal health by combining personal health measurements with sensor data of local particulate matter levels.