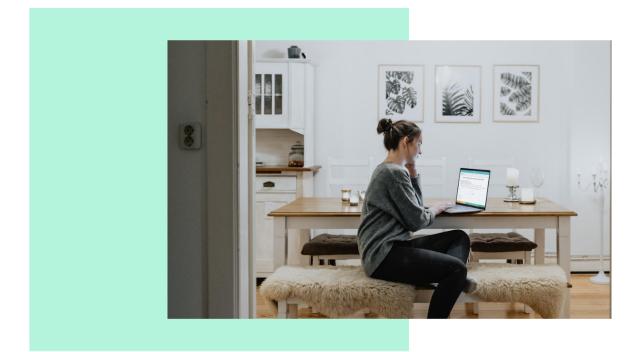


The digital Citizen Portal and SORMAS@DEMIS



Climedo

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Starting Point and Project Emergence

In light of the unexpected COVID-19 pandemic and given the lack of a nationwide unified digital solution for case and contact person management, the German Federal Ministry of Health (German: "Bundesministerium für Gesundheit" –"BMG" for short) aimed to roll out a unified solution. This involved support needs for the **registration and tracking of people who tested positive for Covid-19 as well as their contacts**. At the time, each health office was using its **own self-developed standalone solutions** given the absence of a uniform federal solution. Among other things, people were queried via telephone by the health offices, managed in Excel spreadsheets and citizens were sometimes contacted manually by email.

These processes not only led to **poor data quality** and time-consuming manual processes; in the long term, they were **not manageable** with the available resources and in view of the **high incidence rates**.

The BMG's goal was therefore to ensure that the processes were automated and **digitalized across the board**. Thus, the BMG launched the initiative to digitalize the health offices and introduced the "**SORMAS**" solution for contact person management. For querying the daily health status of contact persons, Climedo provided the "**Digital Symptoms eDiary**". A combination of these two solutions replaced the manual query via telephone calls or email and significantly relieved health office staff.

Project Description

Climedo's digital Symptoms eDiary enables the fast and secure capture of patient data on any device (**smartphone, tablet, computer**). All transmitted data appears in **real time** in a **unified, secure system** which health office staff can access from any standard browser. **No software installation** or app is required.

The digital Symptoms eDiary was developed in coordination with the BMG and with the involvement of Robert Koch Institute (**RKI**), the German Federal Office for Information Security (German: "Bundesamtes für Sicherheit in der Informationstechnik" – **BSI**), the German Federal Commissioner for Data Protection and Freedom of Information (German: "Bundesbeauftragten für den Datenschutz und die Informationsfreiheit" **BfDI**) and the Academy for Public Health. Partner companies include Netzlink, the ITZ Bund, SurvNet, SORMAS and Vitasystems.

Process flow for Covid cases

Health office employees enter affected citizens into the Climedo system and start the



automated symptoms query via email or SMS. Using a simple link sent by email or SMS, Climedo queries the health status of Covid-19 cases and contact persons on a daily basis during the quarantine period. Citizens then enter their symptoms and body temperature into the questionnaire – without an app and on any device with an internet connection. The health office can quickly and easily filter and **prioritize critical cases accordingly**. Symptom-free courses do not need to be proactively processed further.

If symptoms persist at the end of the quarantine, the health office reaches out to the person affected and the quarantine can be extended if necessary. This enables **full automation of the quarantine monitoring process** and query.



Overview of the Development Phases

Figure 1: Development phases from digital Symptoms eDiary to citizen portal

Phase I – Piloting and standalone

By June 2020, six offices were already using the standalone variant of Climedo; this means that they worked exclusively in the Climedo system without the SORMAS interface. By the end of 2020, **32 German health offices** were already using the standalone version of Climedo.

Phase II – Interface development and roll-out

As part of the SORMAS@DEMIS project, the **interface between Climedo and SORMAS** was finalized in November 2020. This enabled a solution without media breaks, meaning that contact persons and index cases could be added directly to Climedo **via a simple click** in the SORMAS platform. Between January and March 2021, about 130 more offices were added via the interface, bringing the total number to 158.

Phase III – Enhancements to the digital Symptoms eDiary

In December 2021, several health offices and German states requested extensions. This was not only about the daily digital query of the symptomatology, but also about:

• The digital reporting of contacts by Covid-19 cases,



- the reporting of **master and medical data** to the health office by Covid-19 cases and contacts,
- as well as automated, digital dispatch of quarantine notices.

By the end of 2021, these enhancements had been developed by Climedo and went live in January 2022. By March 2022, they had been rolled out to an additional 30 health offices.

Today, **160 health offices** are connected to Climedo's digital Symptoms eDiary – about 130 of them via the SORMAS interface and 30 as standalone versions.

Results and Benefits

By now, more than **1.6 million citizens** have been enrolled in Climedo and more than **50 million queries** about their daily health status have been sent out. Although the use of the digital Symptoms eDiary is voluntary for citizens, the **response rate is on average 90%**, thanks to the high user-friendliness.

Thanks to the automation and digitalization of important processes, health offices enjoy **significant time and cost savings**. On average, daily **phone calls have been reduced by 80%**. Thanks to Climedo, Covid-19 cases can be handled with maximum efficiency – allowing health office employees to monitor up to 500 people at once. In addition, **data quality has been significantly improved** and the **error rate has been significantly reduced**.

Since all tracking and monitoring takes place in SORMAS, there is no media break.

Using the Climedo software can be learned within **30 minutes** and **without programming knowledge**.

> **150** Health offices **1.6 Million** Citizens > 50 Millionen
Outgoing links

90% Response rate

Figure 2: Current figures for the Climedo Symptoms eDiary

Quotes

"The digital Symptoms eDiary makes it possible to record several health status feedbacks per day. The software tells you where you need to follow up again in case of doubt. At the moment, very few people actually manage to call once or twice a day. This is where this diary can help. Thanks to this relief, the health office can take care of other



important things again. [...] It meets all data protection and data security requirements. I can only encourage health offices to use it."

Jens Spahn, former Minister of Health, at Dialog ÖGD digital (2021)

"Climedo makes our work much easier. So far, we have entered and managed 2.000 patients. Around 50 colleagues work with the program at the same time. It is fast and uncomplicated. The introduction was also quick. We were trained and could start right away because we didn't have to install anything. Thanks to the citizens filling out the digital diary themselves, we only have to call 10-20 people a day."

- Rebekka Clamer, Health Office Pinneberg (2021)

"Climedo is very easy to use and provides a great workload reduction for our health office. The dashboards can be customized, which gives us a good overview of all activities. What I like most is that you can see which person developed symptoms today with just a single click. The program is also very good for statistics."

- Anika Staack, Sachbearbeiterin, German Health Office (2021)

"For us, the eiary is a very important component in our daily work. Thanks to its ease of use, employees can be quickly trained. Without Climedo, daily tracking of Covid-19 infected contacts would no longer be possible. At the same time, the response rates from citizens are very high, and the tool is very well accepted by both health office staff and citizens."

- Health office Garmisch-Partenkirchen (2021)

Data Protection and Security

The Climedo system is audited according to relevant standards and guidelines such as **ICH GCP, FDA 21 CFR Part 11 and EU GMP Annex 11**. Climedo has been audited several times both by the German Federal Office for Information Security (**BSI**), as well as by **private IT security service providers**. We comply with the German Data Protection Regulation (**DSGVO**) and all data is hosted exclusively on **German servers**.



Conclusion and Outlook

At the end of 2021, further modules were requested, which together form the Climedo **citizen portal**. This is now to be extended to other infectious diseases in order to digitalize every contact point between citizens and the health office and every associated process per infectious disease. If a citizen reports themselves as having tested positive as well as people they have had contact with, contact persons can also report their symptoms and all receive the quarantine notice.

Based on feedback from over 50 health offices, the prospects of the Climedo citizen portal go **well beyond Covid-19**. For example, Climedo could be used to manage the digitalization of the **entire infection control system** with all notifiable diseases (**tuberculosis, monkeypox** etc.). In this context, Climedo could be used to collect data on various infectious diseases and transfer them directly to the IfSG (German: "Infektionsschutzgesetz" – **IfSG**) specialist application of the health authorities via appropriate interfaces.

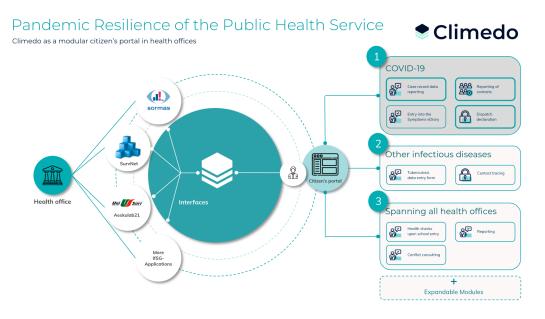


Figure 3: Climedo as a modular citizen portal in the health office

Beyond infection control, the citizen portal will strive for the digitalization of cross-health office processes in communication with citizens, such as the **youth medical service** (school entry examination), conflict counseling or **expert opinions**.

Beyond SORMAS, Climedo therefore strives to connect to other IfSG specialist applications, such as SurvNet, Aeskulab21, Octoware etc.

Further information on the digital Symptoms eDiary is available here.



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About Climedo

Climedo offers a digital health platform for hybrid clinical trials and observational studies. Its easy-to-use, modular and secure solutions for data management include electronic data capture (EDC), ePRO, eCOA, and Telemedicine. This enables pharma and medtech companies to validate their medical innovations more efficiently in the post-market phase and to capture data in decentralized, real-world settings. As a result, they accelerate studies, save costs, and improve data flow and quality, while fostering innovative trial designs. By connecting all stakeholders (industry partners, study sites, physicians and patients) in one cloud-based system, Climedo is revolutionizing clinical research and making trials more accessible and patient centric. Learn more at <u>www.climedo.com</u>.

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