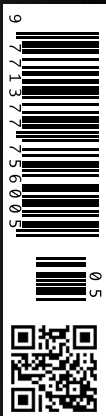




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# The EU Health Data Centre: A New Total Virtual Organisation

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The COVID-19 pandemic revealed that the EU has no clear health data architecture regarding health data, its availability and comparability. There is a lack of harmonisation and an absence of an EU-level centre for health data analysis and use to support a better response to public health crises. Through extensive desk review, interviews with key actors and enquiry into experiences from outside the EU/EEA area, a recent study for the Panel for the Future of Science and Technology (STOA) highlights that the EU must have the capacity to use data more effectively and make data-supported public health policy proposals and inform political decisions.



## Key Points

- The COVID-19 pandemic has made it clear all data may be needed to prevent, perceive, detect, alert, respond and recover.
- Centralised governance structure in a crisis must have the capacity to use data more effectively.
- The pandemic has shown that the EU needs a new weapon - a European Health Data Agency – to better prepare, prevent and respond to similar or worst crises and to welcome the possibility of a new breed of EU Agencies, born out of virtuality and “materialised” in a totally virtual format as a Total Virtual Organisation.
- Four types of public health data were considered: Data on Communicable Diseases (DCD); Data on Non-Communicable Diseases (DNCD); Data about the Health System (DHS); and Data with a public health relevance (DPHR).

## The Issue at Hand

The COVID-19 pandemic brought about such significant societal impacts in the European Union (EU) that only time and distance will allow us to grasp their full extent (European Commission Communication 2020). The STOA study “EU health data centre and a common data strategy for public health” (Martins 2021) is a “humble attempt to take a picture of an incredibly fast-moving object, the size of the Union, and impacting each and every one of its millions of inhabitants in unique, unforeseen, radical and life-changing (for some, unfortunately, life-taking) ways”. This paper aims to present a summary of this study, advance a personal opinion about the options presented and suggest an innovative way forward for the establishment of a new type of EU Agency, akin to the new

times and future needs in health data exploration. This is ever more pressing when “early lessons learnt with COVID-19 have shown that the current system has not ensured an optimal response at EU level to the COVID-19 pandemic” (European Commission Proposal 2020).

Alemanno (2020) advances a set of provisional explanations for what he calls “the global suboptimal response to an essentially foreseeable outbreak such as a pandemic”. He suggests one explanation is “the inability to mobilise the unprecedented wealth of data collected today to counter the virus due to the absence of a data governance and data-sharing culture as well as public-private infrastructure”. This refers to data relevance in public health. In its official position, the European Parliament, in its resolution of 10 July 2020 on the EU’s public

health strategy post-COVID-19 (Parliament 2020), called for a strong push on a European Health Union, where data is central to this construct.

Despite the EU Member States (MS) sharing of a set of health system common values, reiterated by the 2006 European Council conclusions, the best word that characterises the EU response since the first day is: **Heterogeneity**. Regarding data, its availability and comparability, the COVID-19 pandemic revealed that **the EU has no clear health data architecture** and that even simple statistics on elements like intensive care beds, the number of active cases under surveillance or availability of professionals were limited by national and even regional idiosyncratic differing interpretations. The lack

achieve. A centralised governance structure in a crisis must have the capacity to use data very effectively and make data-supported public health policy proposals and inform political decisions.

Four types of public health data were considered: 1. Data on Communicable Diseases (DCD); 2. Data on Non-Communicable Diseases (DNCD); 3. Data about the Health System (DHS); 4. Data with a public health relevance (DPHR), which means non-health data with the potential to be relevant for public health functions.

There is no well-defined or ill-defined common European strategy on how to collect data. Simply **there is NO strategy which could be considered “common” on data collection.**

## The COVID-19 pandemic revealed that the EU has no clear health data architecture

of harmonisation in these practices is also a result of the lack of national comparable data and the absence of multilateral collaboration on data analytics. The problems with differing criteria for recording, documenting and using populational health data have long been identified by a series of projects funded by the European Commission (EC) and collaboration networks.

On 11 November 2020, the EC presented a pack of proposals under the ‘European Health Union’ umbrella to help address the EU response to public health crises. Some steps towards a new “sort of agency”, called Health Emergency and Response Agency (HERA), have materialised slowly. Now, November 2021, one year later, and on the verge of another wave of pandemic uprise it is time to ask the question. European Health (data) Union: Quo vadis?

**There is no comprehensive health data governance at the EU level, and very few MS could be said to have one at the national level as well.** This impacts severely any holistic thinking of data usage and information systems, but this is an opportunity for ground-breaking policy. In today’s world, with learnings from the COVID-19 pandemic and foresight into larger, possibly hybrid, cross-border threats, **all data may be needed to prevent, perceive, detect, alert, respond and recover.** Even with such a holistic and encompassing view of data usage, MS freedom and responsibility for organising their health systems may not be disturbed as much as needed for public health safety, a responsibility which they also have, and that, increasingly, can only be met in multilateral work, even in inter-critical periods.

A “truly centralised” governance structure for dealing with these types of crises is needed. Not just on a structure for “governance of data and how it helps emergency coordination and response” but the “governance of the overall EU-level response”. Without the latter, the former is more difficult to

As the EU discusses the recently proposed ‘Data Governance Act’ (European Commission Proposal on European Data Governance 2020) and has a scheduled legal discussion on the European Health Data Space, it is worth mentioning that both can be legal umbrellas for a ‘Health (Public Health) Data Governance Act’ only if there is a wider understanding of its complexities and necessities as subsequent legislation. An alternative policy option is to have a stand-alone, albeit articulated, legal and organisational stream dedicated only to “health data” understood in a broad sense and not in a narrow classical public health perspective. A set of policy solutions to the present absence of a common European strategy on data collection was offered **as four preliminary options were formulated in advance.**

### Establishing a European Health Data Agency – A Stand-Alone Agency

After a careful appreciation of the EU regulatory framework in the fields of data collection/exchange, testing/reporting methodologies and public health and the law of “cross-border” health threats and the analysis of the adequacy of current EU institutional structures **four preliminary options** were suggested for the institutional “home” of an **EU Health Data Centre**. The centre can only fulfil its mandate if it **has the power and competency to influence MS public-health-relevant data ecosystems and institutionally link with their national actors.** Such a response structure needs to be a continuous activity, capable of driving the EU health data strategy and agenda, and capable of liaison with MS internal public health data structures and authorities to **establish functional public-health-relevant data pipelines** by building technical connectivity and upskilling the workforce in digital health and data science. The **institutional structure can be located inside an agency or as a stand-alone agency,**



bearing a mix of regulatory agency and technical competence centre attributes.

A permanent central structure dealing with health data at EU level, particularly if it covers public health data understood in the broad sense **will fill a severe actual governance gap**. However, to really have an impact on public health preparedness and betterment of populational health in the EU, such a structure should support multiple EU-level actors/agencies, and needs access and the capacity to process four large sets of data/health information from MS. To show how the structure would undertake its role and serve its mission during a

European and societal debate about health data and health-care outcomes in the Union. Finally, such a setting could create conditions for a future European Public Health Authority (EPHA), with full-fledged powers to be activated under certain conditions and in strict articulation with existing EU powers. In this case, a new agency – European Health Data Agency (EHDA) - is created. EHDA is created as a stand-alone agency, not just to use public-health-relevant data during a public health crisis, but to fundamentally collect, use and analyse the four main types of health data in crisis and inter-critical periods.

## There is no comprehensive health data governance at the EU level, and very few member states could be said to have one at the national level

crisis and in between crises, an illustrative set of main operational activities/services it would entertain were outlined.

The study also outlines the main tenets for an **“European strategy on how to collect data for preventing, detecting and curing diseases”**. The legal mandate of the EU Health Data Centre should contain the provisions for “emergency-only” digital services, such as some advanced analytic solutions, definitely persons surveillance via digital and Artificial Intelligence (AI) powered tools, and the opening of digital therapeutics and digital interaction services direct to EU citizens. Explaining these services to each citizen should be guaranteed during and after emergency, and when they utilise AI.

Combining options studied regarding an EU Health Data Centre and a common European strategy to collect health data to help coordination and emergency response to a serious cross-border threat resulted in four main options (“do nothing” is not discussed) of which three are outlined and correspond to three organisational arrangements and two levels of strategy formalisation.

I favour option four - **Establishing a European Health Data Agency (EHDA)**. If one year ago that was dubious and debatable, now, in November 2021 that is “crystal clear”. Such an agency’s core mission would be to aggregate all existing capacities and digital health EC competencies, as well as public health indicator activities, include additional ones needed and serve the EC and its Agencies. Finally, act as the main governance agency on the European Data Space on behalf of the “health sector” more broadly, a key discussion as the EDS governance has not yet been finalised.

The actions of the EHDA on health data at the EU would be subject to the development of sustainable strategy under the mandate of **a health (public health) data governance act**. Such would have the virtue of stimulating a much needed

### The Concept of Total Virtual Organisations (TVOs)

The idea that an EU agency must occupy a physical building often in one of the MS capitals, is disputed by many due to the fact that it constitutes a source of city income and reputation while providing sustainable attraction for highly differentiated professionals and fixation of EU-financial streams can also be disputed. The move of EMA was an example of such paradigm, but for a European Health Data Agency, to be launched as early as possible but always in 2023 or beyond, there are other possibilities.

There are organisations that bear no physical existence. Often private or non-for-profit organisations, in the humanitarian domain, the standardisation world, in the arts, scientific societies, or other international examples. Many multinational companies have experimented successfully with “digital academies”, “data analytic centres of excellence” operated from staff residing in their homes under strict tele-leadership command and control scenarios.

These experiments constitute totally virtual organisational arrangements, parts of organisations, or indeed complete organisations. A virtual organisation is therefore an organisation that does not have, or will have, any physical headquarters, nor have “facilities” of its own, it does not have a “home” in the physical world. To be true to the spirit of total dematerialisation, a virtual organisation where there is never a moment where its members meet in the physical world could be considered a Total Virtual Organisation (TVO).

TVOs make sense when data is the core substance of work. Data is an intangible asset. EU law covers extensively how outsourced physical data centres – hosting mega computers, servers and all the necessary information technology (IT) – can be used lawfully and under strict cybersecurity EU rules.

## How to Move and Start a New Type of EU Agency

The second more important resource for the success of a European Health Data Agency (EHDA) is human capital. The widest access to the best professionals, not just informatic professionals, but health informaticians, public health and other clinical specialist knowledge and many other societal health multidisciplinary knowledge workers. They are in abundance in the EU. Often, they are not willing to move into one “corner” of the EU space, often with complex family and work networks fundamental for their intellectual pedigree. These are not “common” officials we need, but highly skilled and advanced individuals who, by nature of their longstanding education and essential knowledge networks cannot be easily displaced or are willing to temporarily move. Bringing them together online, is possible, effective and is a lesson from the COVID pandemic.

How to start? Large consensus on the need of the EHDA is necessary and requires political initiative from the Council, but also from the European Parliament. A set of Member States can initiate the debate and explore the idea of a first-ever totally virtual EU Agency. Discussions in the European Parliament can be stimulated by the STOA study, led by interested MEPs, and amplified by the future legal debates on the European Commission proposals for new Regulations under the European Health Union pack and future coming European Health Data Space legislation. Discussions by clusters

of member states in Council initiatives or as part of bilateral and multilateral policy initiatives could also be a way to start. Whatever is the way, we need to start sooner rather than later.

## Conclusion

The future is a mystery, but worse and more likely hybrid threats (bio and cyber viruses or other) loom on the horizon. However, the EU can prepare for these by using health data much better. While doing that, it can add public health value in areas of public health smouldering crises that never come to be called emergencies (such as cancer or mental health). Policy in EU health digital integration may take large world-astonishing leaps, through courageous legislation and institutional reshaping to achieve real effective public health safety for its inhabitants

If the COVID-19 pandemic has shown us that we need a new EU weapon – a European Health Data Agency – to better prepare, prevent and respond to similar or worst crisis that isolated us and made us work virtually, it also inaugurates the possibility that such EHDA can be a new breed of EU Agencies, born out of virtuality and “materialised” in a totally virtual format as a Total Virtual Organisation.

## Conflict of Interest

None. ■

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