The COVID-19 pandemic breaking the European Union's healthcare policy path: In what way did the European Union need the COVID-19 pandemic to call for a pan-European model of processing health data?

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Title: The COVID-19 pandemic breaking the European Union's healthcare policy path**:** in what way did the European Union need the COVID-19 pandemic to call for a pan-European model of processing health data?

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Abstract:

The literature of historical institutionalism emphasizes the path dependent character of the policy making process in which critical junctures can alter prevailing policy monopolies and put new path dependent institutions in place, according to scholars in the field of Public Administration. However, ideational change and development of prevailing ideas in an institution could also be part of a non-punctuated institutional dynamic, because change in dominant ideas could happen overtime. In other words, institutions themselves also allow an endogenous dynamic of change. So, instead of focussing on the specific role of critical junctures on the decision-making process as scholars in the field of public administration tend to do, it is crucial to discuss the institutional environment that could be influenced by the critical juncture. This study will highlight the prevailing ideas in the EU's institutions on the usage of Big Data and Artificial Intelligence (AI) to protect public health in the EU before and during the COVID-19 pandemic, by establishing a Union-wide framework of collecting and analysing health data. The EU advocated for the need to use such technologies in the formulated EU4Healthplan that acted as a response to COVID-19. However, this programme could also elaborate on the results and ideas of such a Union-wide health and data framework relying on the EU's Health Programme 2014 – 2020. The latter would indicate a path of slow change in ideas within the policy cycle for EU policymakers. Therefore, this study will research the following question: 'How did the COVID-19 pandemic influence the adoption of Big Health Data infrastructure in the policy process of the EU?'. To answer this question, the study will discuss the development of a policy monopoly concerning digital health in the European Union via a process-tracing method of analysing documents and journals provided by the European Commission, European Parliament and the Council of the European Union and it will also take the public opinion into account. As a result, the method showed that prevailing ideas of using Big Data and AI to protect the public health were already high on the European policy agenda before the COVID-19 pandemic. However, COVID-19 was a crucial factor for the implementation of a pan-European model, in terms of using Big Data and AI to protect public health. It did not radically alter the ideas within Europe but accelerated the EU policy process. In this degree of agreement with the literature on critical junctures that it causes a shift in prevailing ideas, this study opts for a measured tone towards the role of a critical juncture opening up a window of opportunity by causing a shift in prevailing ideas – at the same time – will not underestimate it

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1) Introduction

Jean Monnet, a French diplomat who partly established the foundation of the European Project, is known for his famous citation: "Europe will be forged in crisis." This suggests that when things are at their worst, the EU will snatch victory from the jaws of defeat (Economist, 2021). If we project this argument on the most recent crisis, the COVID-19 pandemic, we can already see that Monnet's idea again rings true. In the middle of the COVID-19 pandemic, the German Council suggested that crises have always been an opportunity for Europe to call things that are considered a given into question and to be even better prepared to face the challenges of the future: ''The COVID-19 pandemic has shown more clearly than ever that Europe must achieve sovereignty in the digital domain in order to remain capable of action on its own also in the future'' (Auswärtiges Amt, 2020). Not long before the COVID-19 outbreak and before their Council of the European Union presidency of 2020, incumbent German Minister of Health Jens Spahn already pledged that Germany wants to use its Council presidency to shape a European digital health care system back in 2019 (Mischke & Karnitsching, 2019). Together with other European countries, Germany wanted to pave the way for a European, digital space for health data that also benefits research (Mischke & Karnitsching, 2019). ''We want to be at the forefront of the development of AI applications […], and if we want to defeat diseases such as cancer together in Europe and pool resources, we also need fast and secure data exchange across Europe'' (Mischke & Karnitsching, 2019). Germany's wish for such a system was supported by Dr Ozegowski (head of corporate development and digitization at the Techniker Krankenkasse), because in her opinion the COVID-19 outbreak helped in obtaining the idea that we need to work on healthcare at a European level (Mageit, 2021).

The situation outlined in the previous paragraph argues that the COVID-19 outbreak acted as a factor that accelerated the idea about fostering digital ability and knowledge to set-up an overarching health framework within Europe. As such, this development fits into the theoretical framework as presented by Punctuated Equilibrium Theory (PET), which claims that a shift in policy makers their ideas within a certain policy process can prevail via the interruption of *critical junctures* (e.g., wars and crises) (Timmermans & Scholten, 2006). This theory, often employed by scholars in the field of Public Administration, states that these critical junctures cause a *window of opportunity* and could lead to profound transformations of prevailing ideas in the policy process that, eventually, cause changes

in the formulation of policies (Demers, 2007). Therefore, this study has the objective to examine to what extent the assumptions of PET can be confirmed by the situation of COVID-19 as a critical juncture on the EU's health policy. By researching if the COVID-19 outbreak was a critical reason for a shift in policy makers' ideas towards upscaling digital initiatives in Europe, especially in the field of exchanging health data between Member States.

In order to be able to give clear insights on the possible influence of COVID-19 on the prevailing ideas within EU institutions related to its health policy, it is important to clarify some of the basic ideas underlying the EU's response to the COVID-19 outbreak. At first sight it seemed like that the European Union (henceforth EU) needed a crisis of this magnitude in order to establish itself as a sovereign actor in the digital domain and try to implement a digital health system among its Member States. And indeed, as a response to the COVID-19 pandemic the EU formulated the 'EU4Healthplan' which, as the largest health programme ever in EU monetary terms, aims to ensure a healthier EU in the future (Wilks, 2021). By looking to increase medical supplies for eventual pandemics and bolster existing healthcare systems (Wilks, 2021). Given the topic of this study, however, there are two main areas of action within the EU4Healthplan that are especially interesting to discuss further. Namely, increasing the surveillance of health threats and the digital transformation of the EU health system. So, by focussing on these topics it will probably generate clear insights on the prevailing ideas on the digitalization in the field of EU's health policy. First of all, the EU incorporated in the EU4Healthplan the objective to support and develop its capacity of surveillance and digital transformation with the help of a European Health Data Space (henceforth EHDS), by: ''improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange and surveillance'' (EP, 2021, L 107). Secondly, the EU4Healthplan has the objective to encourage the access to and use of health data for research, policymaking and regulation, with a trusted governance framework and sustain data-protection rules (COM, 2020, 7907993). Therefore, the Commission will support digital health services and clarify the safety and liability of new technologies, such as Artificial Intelligence (henceforth AI) and Big Data, in health (COM, 2020, 7907993).

However, the predominant view of sharing sensitive data (e.g., health data) between Member States is that mainly wealthier countries were not willing to strengthen health systems (Greer, S., L. et al., 2021). It has been a taboo topic for them due to the awareness of the scale of the EU and its territorial inequalities (Greer, S., L. et al., 2021). A second shared argument provided by the EU itself, is that it suffers from a legislative fragmentation between Member States for data protection, which makes it difficult to establish frameworks that could be used all over Europe (EASAC, 2021). On the other hand, it is interesting to mention that there are already initiatives of Member States using a cross border health data exchange system, such as the collaboration between Estonia and Finland. Estonia's *X-Road initiative* is a state-led online service, which also applies to Estonia's health care system (E-Estonia, 2021). The system compiles data for national statistics, so ministries can measure health trends, track epidemics, and make sure that its health resources are being spent wisely (E-Estonia, 2021).

In short, on the one hand there is the PET perspective on the role of COVID-19 causing a shift in the prevailing ideas within the EU, concerning its desire of fostering digital initiatives across Europe, especially on health data exchange across Member States. On the other hand, as outlined by the previous paragraph, there are also strong objections by Member States being hesitant to set-up such a framework and this is reinforced by the fragmented current state of EU's legislative framework for data protection. Also, there are already some local, alternative initiatives visible within Europe, such as the *X-Road initiative*.

With this knowledge it is valuable to research what the role of the pandemic was in the formulation of the EU4Healthplan, because it differs enormously from the previous EU Health Care Programs: for example, its budget is more than ten times as high as previous health programmes. The EU4Healthplan also incorporates actions like tackling cross-border health threats, making medicines available and financially supporting the strengthening and digitalizing of European health (Newsroom, 2021). Also, the programme calls for harmonization and coordinated action to avoid serious cross-border health threats in the future (Newsroom, 2021). However, according to scholars, there are still significant gaps visible concerning the implementation of the EU decision on serious cross-border threats to health. Possibly, such an EU framework could be constrained by

the obligation that it needs to respect the legislated framework of its Member States (Renda & Castro, 2020). Moreover, it could be argued that the EU was not able to create a process of generating consensus between its Member States on what needs to be fulfilled to address a recognized health crisis, next to the fact that there was a possible lack of coordination and deliberation. As emphasized by the existing literature on managing a crisis, these are the preconditions for generating consensus: an actor needs to provide a path of deliberation and internal coordination, and finally, it demands an overarching framework with those engaged in the crisis in order to manage processes of agreements and negotiation (Smith, 2021). It is arguable that the EU is lacking at some of these points concerning the way the EU managed a health crisis and will be discussed in the upcoming section.

A lack of generating consensus could possibly be explained by the institutional context in which the EU policymakers act and it can be argued that, according to scholars, the EU is strongly affected by its potential fragmentation. There are enduring problems among European institutions and its Member States in defining crisis situations, as the past showed during the financial crisis of 2008 (Smith, 2021). The EU also lacks the ability to reflect the limitations of institutional commitment and has to deal with information asymmetry across its Member States (Smith, 2021). In terms of a crisis, the EU's reaction to crises is constrained by different ways of mobilization due to treaty commitments by Member States or national dissimilarities, therefore the EU needs to manage its current situation of lacking an overarching way of acting (Renda & Castro, 2020). So, in accordance with the existing literature, we can assume that the implementation of a transnational health system could challenge the current institutional framework of the EU, because generating consensus is a precondition for managing a crisis in a proper way.

Yet, while the EU is facing a challenge to adopt a complex transnational system (e.g., digital health framework) across its Member States, due to its institutional difficulties, it is the question if COVID-19 outbreak has opened a *window of opportunity* for change in its digital health policy. A crisis of such a magnitude affecting crucial economic parts of the society, shrinking the global economy by 4.4% in 2020 (the worst since the Great Depression in 1930) (Lora et al., 2021). Also, the COVID-19 outbreak forced health systems to overstretch and at the same time the outbreak exposed critical gaps in the countries'

public health infrastructure (Lal et al., 2020). This situation could have altered the environment of the EU's policy framework, politics and problems regarding current health systems and, especially, trials by governments world-wide to embed eHealth – covering all health-related digital information systems – in regular care paths (Auener et al., 2020; Aanestad et al., 2017). The claim of such an ideational change touches upon the purpose of this study, because it will examine if the formulated policy objectives by the EU in the EU4Healthplan are the outcome of a possible shift in prevailing ideas, concerning the EU encouraging Member States to share health data accelerated by the COVID-19 outbreak.

1.1. Policy changes overtime and the research question

This study will discuss what kind of influence COVID-19, as a contemporary issue, has had on the EU policy making process. The case of the process of how the EU formulated its newest health care programme, one year after the COVID-19 outbreak, is a perfect example to research if PET is able to explain the influence of COVID-19 on healthcare related policymaking in the EU. In addition, this study will emphasize the challenging part of adopting a complex digital transnational transformation of a European health system. First of all, we need to investigate if the pandemic acted as an exogenous shock that heavily influenced the idea of policymakers, resulting in the formulation of the biggest health plan in EU's history. This development would imply that policymakers changed their behaviour in a positive way for implementing the policies of data exchange between EU Member States, to achieve its mandate of protecting the public health of all its citizens. However, according to scholars in the field of Public Administration, ideational change and development of prevailing ideas in an institution could *also* be part of a non-punctuated institutional dynamic, because change in dominant ideas could shift overtime (Leppo et al., 2013). In other words, institutions themselves also allow an endogenous dynamic of change. In the case of digitalizing health systems in the EU, policymakers could have gained more knowledge overtime on how to integrate a safe and well worked out digital network, to ensure the exchange of the health data of EU citizens and respecting the privacy sensitivity of it (Moschella, 2015). For example, the formulation of the EU4Healthplan also could elaborate on the results and ideas of implementing a Union-wide collecting and analysis of health data in the Health Programme 2014 – 2020. This

would indicate a path of slow change in ideas within the policy cycle for EU policymakers. Therefore, this study will research the following question: 'How did the COVID-19 pandemic influence the adoption of Big Health Data infrastructure in the policy process of the EU?'. So, this question relies on the underlying questions if the idea for implementing an infrastructure that facilitates a digitalized health system across Europe is taken up as a result of COVID-19 accelerating change in the EU's prevailing ideas, or has the idea been dormant in the EU institutions for some time? Or is it a result of the combination of these developments?

To answer this research question, we need to look at the previous health programs which served as a basis for further informed policymaking and thus generated knowledge and evidence on how to improve the public health in Europe. By comparing the EU4Healthplan with the EU's previous third health program between 2014 and 2020, to be able to research the main question of this study and investigate if PET is an adequate model to explain this shift of prevailing ideas towards the plan of health data exchange between Member States. So, this study will use a process-tracing model by covering as detailed as possible the EU's institutional context and reconstructing the chronology of events leading to the outcome in terms of the EU4Healthplan. A process-tracing method will describe the path towards the formulation of the EU4Healthplan. Also, the method will give insight into the sequence of events (e.g., adopted directives by the European Commission, European Parliament or the Council, and formulated EU Treaties), that could possibly have been influenced by the COVID-19 pandemic and altered the existing equilibrium of policymakers their ideas on formulating a digital transformation of a Europe wide transnational health framework.

1.2. Brief outline of contents

The study is organized as follows; the next section discusses more in detail the theoretical framework of PET, its concepts and its critiques in order to be able to answer the research question. Further, the study will elaborate on the European health policy framework in times of a crisis together with a discussion concerning the development of new relevant technologies such as Big Data in section 2. Besides a coherent theoretical framework for assessing the COVID-19 outbreak as a possible critical juncture in the EU's policy framework, the study needs a research approach to guide this in terms of a process-

tracing method and that will be discussed in section 3. Afterwards, in section 4, the empirical findings derived from working documents and legislatures by the European Commission, The European Parliament and the Council within the specific timeframe of 2014 till 2021 will be presented, in order to analyse if the pandemic acted as a critical juncture for the EU in the field of health policymaking. Also, this study emphasizes the importance of the public opinion that could also influence the prevailing ideas within the EU, so findings will be substantiate by data derived from the Eurobarometer – the public opinion survey of the EU. The collected empirical findings will be analysed via a Punctuated Equilibrium perspective, in section 5. This will facilitate the possibility for making concluding remarks on the critical role of COVID-19 during the EU's health policy process. At the end of this study, in Section 6, most important findings will be summarized, as also that it will provide critics on this study and discusses recommendations for future research. The study is also provided with several appendices that contains documents of the European Commission, the European Parliament, the Council of the European Union and the public opinion in terms of the Eurobarometer and these documents will be used as the sources for the data collection of this study.

2) Theoretical framework

As mentioned in the introduction, PET will be the overarching literature of this thesis and especially the dynamic of this theory within the EU and its policy process. Therefore, this study will elaborate on the ideational change within a policy process in general and in specific the policymaking process within the EU in times of health crises. In doing so, the study will focus on the exchange of Big Health Data, to generate clear theoretical predictions that can be used for empirical investigation.

2.1. The policy process within the EU

EU policy is influenced by international pressures, demands of non-EU states, major EU institutions (such as the Commission, Parliament and the Council of the European Union), regional policy interests' groups and cross-national policies pursuing shared interests in the policy making process (Greer S. L., 2014; McCormick, 2017). In other words, the EU is not acting on its own, but policies are decided by the EU together with its Member States and citizens (Greer S. L., 2014). Moreover, the policy cycle within the EU can be described

as follows: Member States have the duty to negotiate and approve the Treaties that represent the EU and legitimize its actions (McCormick, 2017). Next, Member States and the directly elected European Parliament (henceforth EP) can alter, decline or accept proposed EU legislation (Greer S. L., 2014). So, EU action is grounded on support of a qualified majority of Member States and a majority of the elected European parliamentarians. Within this policy cycle the Treaties that are declined or accepted by the majority are influenced by the dominant narrative within the EU and in what way groups within the EU can influence the manner how the agenda-setting is established (McCormick, 2017).

The agenda-setting of EU public policy can be remarked as a continuum process where at each stage interest groups originate from a broad range in the society, with each having their own ideas of goals and an agenda trying to influence broad policy process (Kauffmann & Bellver, 2005). During this process policymakers have the objective to identify alternatives, draw up the options and choose the most suitable and try to implement it (Kauffmann & Bellver, 2005). Also, scholars argue that policymakers can be captured to public scrutiny, because policymakers are aware of the fact that their success and decisions will be rewarded with public support; in other words, the input legitimacy of policymaking (Kauffmann & Bellver, 2005, p. 2; McCormick, 2017, p. 125). This implies that there are incentives for policymakers to ensure that they fulfil the needs of the majority of the population in the political agenda (Kauffmann & Bellver, 2005, p. 12).

Additionally, policymakers attach high importance to values of policies, because they have to deal with a 'logic of appropriateness' for the deliberation of the available policy options (Cox, 2004). The decisions made by policymakers are subject to an overarching, widely shared and prevalent interpretation of institutional ideas in a specific society (Cox, 2004). This means that some policy options are interpreted as more suitable at the expense of other possible reforms and this reflects on the decision of policymakers during their process of promoting reforms, because policymakers tend to follow the prevailing values in order to gain support for their policy proposals (Cox, 2004). This tendency of holding on to appropriate values in the policymaking process can be described as the 'path-dependency' of ideas (Skocpol & Pierson, 2002). This phenomenon in the policy process is a dynamic, self-reinforcing or positive feedback process in a specific political system

(Skocpol & Pierson, 2002). Once an actor (in terms of, for example, a Member State or policymaker) decides to move towards a particular path in the policymaking process it will be challenging to alter its direction, because this path established a basic prevailing political narrative and enhances self-reinforcing dynamics (Skocpol & Pierson, 2002). This situation led to the fact that alternatives that were once applicable become irrelevant or are even not addressed in the process by the involved actors (Skocpol & Pierson, 2002). Nevertheless, there are several ways on how new ideas and prevailing narratives occur during the policy process of an institution such as the EU, that shift the priorities of actors that normally try to preserve the status quo. The upcoming sections will elaborate on this literature via the *Punctuated Equilibrium Theory*.

In short, regarding EU policy and agenda-setting; there must be a political agreement on the existence of the problem before policies can be implemented in the EU and captured by a specific path-dependency (McCormick, 2017; Skocpol & Pierson, 2002). Also, it must be decided how to solve this problem while taking several preferences of the institutions, public opinions and elected officials, into account (McCormick, 2017). Moreover, there is a distinctive EU agenda that outlines broad policy goals, but they are torn between their national and European interests (McCormick, 2017, p.131). Yet, some scholars argue that the EU agenda is demanded by EU leaders rather than citizens, due to a lack of elected government officials, but this lack of legitimacy goes beyond the scope of this study (McCormick, 2017). Also, the EU policy process faces a complex overview of needs and priorities of Member States and formulating a consensus between Member States (McCormick, 2017). This situation makes it difficult to produce and identify pan-EU problems and discover the cause of such problems in order to build support for incorporated responses (McCormick, 2017).

2.2. Punctuated explanation

The previous sections outlined the process of EU policy making and it becomes clear that the process heavily depends on the dominant political narrative, the actors that are involved and the influence that alternative policy reforms will have on the society. This study also focuses on the aspect that is already briefly discussed, namely the influence of prevailing ideas on the policymaking process. In addition, prevailing ideas are maintained by the path dependent character of policymaking, but this study will highlight how a shift

in the policy process can occur via the interruption by *critical junctures* (Timmermans & Scholten, 2006). These junctures can be described as wars and crises that disrupting the existing economic or political balance in society (Acemoglu & Robinson, 2012). A theory that substantiates on what kind of factors account for such dynamics of change is the *Punctuated Equilibrium Theory* (PET). This punctuated explanation describes the dynamics that drive change in view of frictions in institutional and ideational terms. According to Cox (2004), the focus of the theory concerns organizational evolutions and especially shifts between patterns of policy stability and change. Moreover, '' […] this process defines periods of ideational stability are followed by periods of ideational change that, in turn, fall back on stability.'' (Cox, 2004, p.443).

If we move this discussion to the field of policymaking, it becomes clear that policy entrepreneurs can modify or reconstruct organizations their objectives, by using these triggering events (such as a crises) as an instrument to change values, strategies and structures (Timmermans & Scholten, 2006; Demers, 2007). Although, the reason why policy entrepreneurs have the chance to alter structures, as also the logic of appropriateness caused by the path dependency within an organization, is because of an exogenous shock that opens up a *window of opportunity* (Timmermans & Scholten, 2006). It is called a *window of opportunity* when these events lead to a shift in issue attention and therefore could lead to possible policy changes as Figure 1 shows on health care policymaking. In these situations, policymakers must make decisive choices without having sufficient contextual information and do not have general knowledge of the issue, which is problematic for predicting the outcome of different courses of action (Haas, 1992). Also, these triggering events have the ability to reshape the national interests and change the terms of debate, because scholars argue that such events drive major transformations of ideas and interests of states their (foreign) policy (see for instance Gilpin, 1981; Gourevitch, 1986; Ikenberry, 2001). These factors open up the way for introducing new ideas that create conditions to change the status quo of policies, within an institution, and could be consolidated in the stable subsystems of an organization (Acemoglu & Robinson, 2012). If we project this situation on establishing, for example, a long-term health policy, with the help of Figure 1, it shows that overtime policies can be influenced and guided by windows of opportunity during the policy making process that

eventually led to the outcome of a long-term health policy formulation (Widmaier, 2007; Moschella, 2015, see also Timmermans & Scholten in this issue).

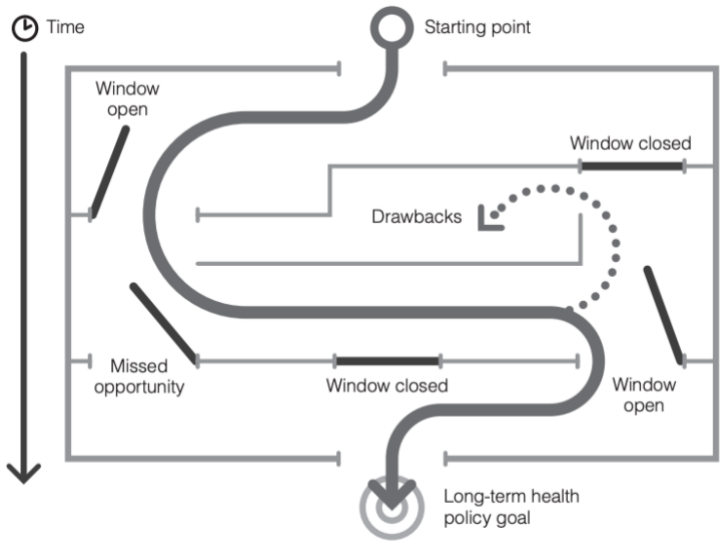

Figure 1. How a window of opportunity can shape the long-term policy making process (derived from Leppo et al., 2013)

Moreover, the role of experts in providing policymakers useful insights in understanding the complex issues and linkages during the decision-making process is important. Haas (1992, p. 14) acknowledges that: '' […] it often takes a crisis or shock to overcome institutional inertia and habit and spur them to seek help from an epistemic community''. Baumergartner and Jones (2010, p.32) describe this cooperation between policymakers and experts as an interaction within the *policy venues* sphere of influence, because these venues are institutional sites where the portrayal of problems and solutions takes place.

In addition, these policy venues have the ability to control and stabilize particular policy monopolies – a prevailing political understanding in the political system and an institutional arrangement that strengthen this understanding (Baumergartner & Jones, 2010). This institutional arrangement influences the policymaking process and therefore excludes specific actors from the process, because within these institutional arrangements there is a common idea which is associated to the institution (Timmermans & Scholten, 2006). These ideas are prevalent understandings and are so dominant that it evokes support or indifference by the people in the society, in other words: the institutional arrangement contains a powerful idea or image of the problem and the solutions (Timmermans & Scholten, 2006).

Furthermore, during the policymaking process powerful ideas in policies originate, obtain support and gain sustainability by being implemented as binding decisions in venues of formal political arenas, such as legislatures, Treaties and directives (Timmermans & Scholten, 2006). In order to get access to such a prevailing institutional arrangement, a policymaker or strategic actors thus try to seek venues where their ideas or images can get established and influence the dominant ideas and solutions, with the help of the momentum of these triggering events (Baumergartner & Jones, 2010). Hence, strategic actors can try to establish new institutions and ideas that substantiate their policies or alter prevailing existing institutional frameworks to gain advantage in the output of policies (Baumergartner & Jones, 2010, p. 13).

The previous paragraphs discussed what could cause ideational change within the PET, but as Cox (2004) already mentioned: after ideational change institutional stability will return. Once ideas consolidate in the stable subsystems of an organization a new equilibrium will be created (Moschella, 2015). This policy stability will in turn show path dependent characteristics, because of the prevailing ideas upon which the institution is created. The stability mainly maintains new arrangements of institutional cooperation between policymakers and experts, which will build a new policy monopoly (Timmermans & Scholten, 2006). This cooperation can be visible in, for example, the strategic timing in the release of advisory reports, the manner in which policy advice is formulated and the way topics are chosen (Timmermans & Scholten, 2006, p. 1115). In short, both institutional and ideational inertia creates stability (Hay, 2011, p. 68 – 69).

However, via the existing literature on the process of policymaking, we have to acknowledge that major changes often take a long time and calls for consecutive efforts by involved actors. It is not essential for the process of policymaking to have a particular window of opportunity, because policy changes often need incremental changes of time and can happen over decades (Leppo et al., 2013). The process of policymaking depends heavily on the political and public support, so the development of prevalent understandings is subjective and influenced by actors interacting with each other that could eventually lead to shared understandings (Moschella, 2015; Leppo et al., 2013). This institutional set-up not only constrains actors, but also enables actors to accelerate changes (see for instance Moschella, 2015). This ‘double nature’ of institutions can

provide ideational change also after triggering events (Leppo et al., 2013). Yet, the critical literature on PET admits that critical junctures play a role in creating uncertainties on ideas but undermines the idea that these junctures are the critical reason why institutional change is shaped. Due to the fact that all kinds of organizations have ideas that could cause changes at slow level, instead of depending on exogenous shock (Leppo et al., 2013). The long-term nature of policy development can be demonstrated by the case study of formulating global strategies for preventing Non-Communicable Diseases (NCDs) and will be briefly outlined in Box 1.

The process of NCDs prevention by countries uncovers a tight sequence of events that are linked together as if in a chain, because it shows an evolution of the public health approach on a global level. Combatting NCDs from a global approach raised awareness around the 1970s (Leppo et al., 2013). An increasing number of countries were concerned about the lifestyle of their citizens and wanted to encourage to change their behaviour in a healthier way. While a number of 'policy milestones' describes the path of a growing desire to address NCDs by global political and societal actors. In 2000, the World Health Assembly (WHA) endorsed the Global Strategy for the Prevention and Control of Noncommunicable Diseases (WHA, 2000, 53.17). Examples of specific treaties that WHA adopted, in order to combat NCDs, are the Framework Convention on Tobacco Control in 2003 and the Global Strategy on Diet, Physical Activity and Health in 2004 (WHA, 2004, 57.17). These policy milestones set by the WHA changed the policy discourse and encouraged countries to connect the essence of tackling NCDs with other concerns affecting global development such as poverty and the environment (Leppo et al., 2013). Furthermore, in 2008 the WHA formulated an action plan to enhance the implementation of the global NCDs strategy (WHA, 2008, 61.14). Together with a growing public concern on NCDs, these policies implemented by the WHA offered public authorities on local, national and international level the ability to develop action plans and effective interventions (Leppo et al., 2013). A growing public and political demand eventually led to the set-up of the First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control the WHO together with the Russian federation in 2011 (Leppo et al., 2013).

So, this case study fits seamlessly with the idea of a slow incremental policy change, because it described the development of a specific policy developed by actors with diverse interests and acting in different political environments but trying to reach an overall consensus due to a growing public and political demand that altered over time.

Box 1. Formulation of global strategies for preventing NCDs

2.3. The influence of the pandemic as a possible critical juncture in the policy process

Despite the challenges of PET, the theory provides useful insights on how critical junctures change policy monopolies. Scholars argue that policies are often made up on the fly in response to crises and emergencies, as discussed in the introduction of this study and the PET section (McCormick, 2017). Therefore, more information on the prevalent understanding on pandemic policy is needed so as to provide a clear theoretical prediction that will be used for further empirical investigation. This is the reason why this section focuses especially on the ideas, concepts, norms, and agendas that have shaped the structures and actors governing the field of pandemic preparedness. If we move to global governance, it can be argued that it faced epidemics, and pandemics quite often and scientists argued that these can occur on average once every 19.8 years (Eichel, 1922). Also, for decades cooperation at international level towards pandemics was driven by the concern of a possible new Spanish flu pandemic of 1918 (Kamradt-Scott, 2018, p. 535). This concern is not inappropriate and being well prepared to these health dangers is quite important and global interconnection can be pivotal in this situation, which is encouraged by key global institutions such as the World Health Organization (WHO), the World Bank, the United Nations (UN), and the International Monetary Fund (IMF) (Kamradt-Scott, 2018, p. 533).

If we move towards the policy making part of dealing with pandemics, we can define the main ideational objective within these policies and it is quite obvious, namely avoiding excessive human morbidity and mortality and to this extent protecting the public health (Kamradt-Scott, 2018, p. 540). Policies are focused on protecting the most vulnerable part of the population via vaccination programs. Therefore, biomedical knowledge, techniques, and technologies are central to pandemic-related policy (Kamradt-Scott, 2018). Yet, there is political contestation between scholars and policymakers on how to deal with preparing for possible pandemics the most appropriate way within the policy making process (Kamradt-Scott, 2018). It has been assumed that a virus would diminish to the extent that the case fatality ratio would not exceed that of the 1918 Spanish flu virus, because the chance that an influenza virus can achieve effective human-to-human transmission and in this way creates a potential for a pandemic is low (Morens et al., 2010). However, several pandemic policymakers assumed the 1918 Spanish flu pandemic

as the worst-case scenario that they needed to prepare for in the policy-making process (Moxnes & Christophersen, 2008).

Moreover, scholars argue that within pandemic influenza preparedness, planning evidence-based policy making plays an important role (Kamradt-Scott, 2018). Policymakers consistently framing their justifications for specific policy decisions on the 'evidence' (Kamradt-Scott, 2018). In addition, a series of econometric studies examining the potential impacts on national productivity, social cohesiveness, and economic functioning have increasingly been used to evaluate mitigation strategies (e.g., vaccination programs), justify policy decisions, and further emphasise the need for pandemic planning (Meltzer et al., 1999; Gust et al., 2001). Various government bodies increasingly combined evidence policy making, overtime, and economic analyses such as 'cost-benefit analysis' techniques in determining their planning and policy priorities for influenza (Nichol, 2001; Belsey, 2009). So, it can be argued that the current ideational objective within pandemic-related policy is that economic functioning plays an important factor in the policymaking process regarding the planning and policy priorities for influenza preparedness.

2.4. EU's Health policy

Regarding pandemic related policy in the EU, it has to be mentioned that the EU has the mandate to, according to the current version of the Treaty on the Functioning of the European Union (TFEU) Article 168 and 114, a '' […] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'' and underlines that ''Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.'' (see for instance Greer, 2014). Moreover, the Treaty concludes that: ''the Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.'' (Greer, 2014). However, the existence of a health article in the Treaties underlines that health is a clear objective within the policymaking of the EU with a high responsibility for its Member

States and it means that the EU has the obligation to balance objectives including health (Greer, 2014). Moreover, the politics of Public Health is embedded within the EU institutions which has been discussed at the beginning of the theoretical framework. It also indicates that Public Health policy is definitely a political exercise and every new idea or program regarding the improvement or alternation of Public Health is exposed to the same environment and constraints as every other EU policy reform (Elliot, 2013).

Moreover, regarding EU health policymaking, scholars argue that it is important to discover the politics behind the development of EU health information structure, such as the way the infrastructure is established and its capacity (Elliot, 2013). Remarkable is the fact that EU health policy is seen as a formal mandate when the EU was established in 1992, providing the first legal basis in the area of health in Article 129 such as epidemiological surveillance, and frameworks of institutions had to be built due to the rise of situations and crises (Elliot, 2013).

2.5. Information sharing between countries with the help of Big 'Health' Data

The previous paragraphs have shown that a lot of studies focusing on pandemic related policies emphasize the way data is generated through biomedical techniques between countries and the EU has the mandate to protect the Public Health of its Member States. However, this study will focus on the share of another type of information, namely Big 'Health' Data. To be able to analyse a European system of data exchange in this study we have to define the specific data that is used in today's data system of exchanging data, which is 'Big Data'. This concept can be defined as generating huge volumes of data that is too large for traditional processing systems, but which can be used to stimulate new processes, industries and products (Giest, 2017, p. 367 – 368; OECD, 2013, p. 4). A huge volume of data is shared and stored on servers through the use of the internet and implies an interaction between the actors producing the data and the storage system (EESC, 2016). On that account we can identify two concepts of Big Data: active Big Data in terms of a user directly sending data to a storage system (e.g., data collection by apps of mobile devices) and passive Big Data includes collected data of citizens by another person and puts it into an online storage system (e.g., personal details and results of analyses collected by hospital staff during health care) (EESC, 2016).

Nowadays the increased velocity and variety of data that is used across society and the economy, marks a switch towards a policy monopoly which contains a data-driven socioeconomic model (OECD, 2013). The value of such a Big Data chain includes the way data is generated, collected, stored and processed and at the end the analysis and distribution of the data that remains relevant (Laschkolnig et al., 2016, p. 11). Moreover, the model implies that data has become an important part of today's society which could drive innovation, development and accelerate sustainable growth (OECD, 2013). Yet, within this study the focus lies on Big Data in Health; '' […] it refers to large routinely or automatically collected datasets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and comprises the fusion and connection of existing databases for the purpose of improving health and health system performance. It does not refer to data collected for a specific study." (Laschkolnig et al., 2016, p. 11).

However, a shift towards such a data-driven socioeconomic model in policies requires new technologies and skills, since the data that can be used in policymaking is bigger, more varied and independent of the field of application (e.g., public health) (Giest, 2017, p. 367; Laschkolnig et al., 2016, p. 11). Therefore, scholars argue that acquiring a new set of skills by government workers is necessary, in order to understand how to work with big and varied data sets (Giest, 2017, p. 368). If policymakers have better understandings of identifying and evaluating the possible alternatives with the help of Big Data sets, it could possibly lead to a change in the nature of the adopted policies (Islam, 2003). Hence, policymakers have effortlessly available data within reach to make real time, so called 'nowcasts', ranging from flu epidemics to employment/unemployment trends, towards improving the quality of the policy-making process (Swallow & Labbé, 2010; Choi & Varian, 2009). These reasons substantiate the importance of timely and complete provision of information, so it can improve governance in its entirely (Islam, 2003, p. 5). To do so, governments have to train their personnel or could outsource the expertise of processing the higher variation of data in order to actually accelerate the development and sustainable growth (Islam, 2003).

Despite the fact that developed and sustainable data systems between Member States have significant benefits for the EU in its entirety, incorporating a system relying on the

usage of Big Data in the policy-making process faces difficulties and for public health data in specific. First of all, bigger and more varied data sets increases the risk of data breaches (OECD, 2013). Global companies, for example, are struggling with the thefts of electronic data surpassed losses of physical property, according to company surveys (Masters & Menn, 2010). Also, a higher volume of data means new data sources, new actors and processing more data raises the questions on how to deal with privacy protection frameworks and how they still be trustworthy (OECD, 2013, p. 6). A comprehensive usage of data exchange between Member States will stretch the limits of existing privacy frameworks in terms of the collection, storage of information and potential issues (OECD, 2013). Thus, Member States and companies need to define the limitations and specifications for the re-use of personal data to ensure the protection of consumers and its citizens. Lastly, actual data exchange between sectors can accelerate innovation and socioeconomic development is still lacking, because actors do not have clear economic incentives to do so (OECD, 2013).

However, we need to elaborate on the existing real-world example of a standardized data exchange framework between Estonia and Finland via the X-Road infrastructure, because it shows that an interoperable data system between states is possible. The main reasons why such an exhaustive data exchange could take place is because Finland and Estonia both faced an increased digitalization within their society with the help of a national data exchange layer that led to an institutional overlap on critical parts (Tuulas, 2020). According to the Deputy Director General at the Finnish Digital Agency (DVV) Timo Salovaara, the integrated cooperation can be established because of the fact that Finland and Estonia are using specific legacy systems already from the beginning of the century (Tuulas, 2020). Next to, both countries are constantly updating standardized security protocols and with the help of the X-Road middleware software it consolidates a standardized interoperable system that secures data exchange between the countries (Tuulas, 2020). The initiative erased the need for massive data storages and facilitated an effective and efficient governance by not having problems with duplicated data blocks that are stored all over the Estonian government and its departments (Priisalu & Ottis, 2017). On the contrary, the X-Road initiative secures the minimized demand for the storage or transmission of data and decreases the possible data breaches that it possibly could cause (Priisalu & Ottis, 2017).

As mentioned in the previous paragraphs by scholars, a triggering event could change the current state of the policy output in the EU by accelerating the urgency of implementing, in this situation, a comprehensive interoperable framework of data exchange between European Member States. A triggering event could increase economic incentives to review or redevelop the existing framework for data sharing between Member States by governments and other involved parties. This study will research if that was the case in the EU after the COVID-19 outbreak.

2.6. Hypotheses

The following paragraphs will outline two different hypotheses in order to investigate the central research question of this study: 'How did the COVID-19 pandemic influence the adoption of a Big Health Data infrastructure in the policy process of the EU?'. First of all, we already discussed the critical role crises can play in the EU policy making process, as the citation of Monet in The Economist (2021) described that ''Europe will be forged in crisis" and McCormick (2017) argued that policies are formulated on the fly because of responding to crises and emergencies. Therefore, it can be argued that the COVID-19 pandemic acted as such a crisis and altered the EU's prevalent policy paths, especially for health-related policies. The crisis has a significant impact on human health and touches upon the EU's mandate (TFEU 168 & TFEU 114) to protect its citizens from such a dangerous communicable disease.

We formulated two figures (Figure 2 and Figure 3) in order to provide a clarification of the effect COVID-19 has on the outcome of EU legislation. These figures describe the way COVID-19 altered the policy path before and during the outbreak. From this perspective, the COVID-19 acted as a window for opportunity for several policymakers within Member States and European institutions to make use of the altered public opinion that cared more about health concerning policies. Simultaneously, the pandemic acted as an incentive for policymakers and Member States to act decisively on taking care of such a crisis. By doing so, policymakers and Member States were looking for opportunities, such as AI and Big Data, that could help to reduce the impact of communicable disease. Therefore, the outbreak accelerated the possibility to implement new technologies. Hence, the European

Commission was urged to change its behaviour on current European health legislation and formulated the EU4Healthplan.

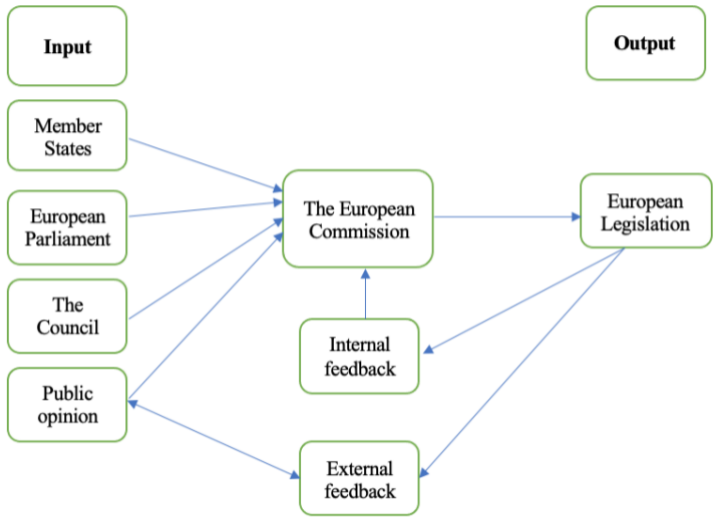

Figure 2. The EU policy making process before the COVID-19 outbreak

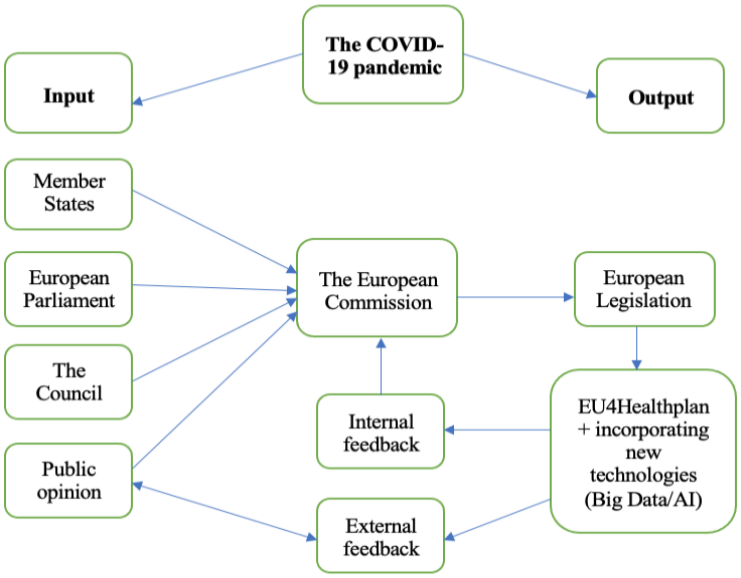

Figure 3. The EU policy making process during the COVID-19 outbreak

Because of the arguments provided by the previous paragraph, this study will investigate the possibility of the following hypothesis (H1): *The COVID-19 pandemic caused a window of opportunity in the existing policy process for policy entrepreneurs and generated an*

ideational change in the EU towards the implementation of Big Health Data exchange between Member States that contributed to the formulation of the EU4Healthplan.

However, if we move towards the critical literature on PET arguing that ideational institutional change does not have to be caused by exogenous shocks but can also be provided by slow institutional change, as described via the case of formulating NCDs global strategies in Box 1. The section that discusses the pandemic as a possible critical juncture also argued that the current ideational objective within pandemic-related policy is that economic functioning plays an important factor, in the policymaking process regarding the planning and policy priorities for influenza preparedness. A possible explanation could be that economic functioning became more dominant overtime, because of external factors (e.g., an aging population or a growing concern about specific non-communicable diseases within Europe). So, a second hypothesis needs to be formulated in order to investigate a possible slow institutional change within the EU towards the implementation of Big Health Data exchange.

Literature on EU health policy points out that Member States disapproved further integration of public health policies, due to a borderless competitive European market for health care providers, and further application of national legislations on their health systems (see for instance Greer, S., L. et al., 2021). Therefore, in this study we have to keep in mind, while analysing the EU Public Health policy related documents, that the process of EU policy is heavily influenced by its political, social and economic environment as so as EU policymakers. Member States still try to mobilize their self-interests and secure their values (Wolfram & Steffen, 2009). However, a further integration of health policies might not be a problem as long as its policy can rely on consensus among its addressees, in other words: *output legitimacy*. The case study of Box 1. also clearly described the policy path without a specific critical juncture that causes a window of opportunity. On the contrary, the implications of NCDs gained more public awareness overtime with the help of adopted treaties and organised conferences eventually led to the implementation of strategies to combat NCDs at a global level. This will also be the situation of the second hypothesis at a European level. By adopting several treaties and directives, the EU accelerated a slow process of further Public Health integration that finally led to the outcome of Member States acknowledging the need of a further integrated Public Health

policy, in order to serve the public good of their nation (Wolfram & Steffen, 2009). In terms of the formulation of the EU4Healthplan and creating a framework of data exchange with the help of advanced technologies.

First of all, it can be argued that renewing Europe's health plan is part of EU's common policy cycle, because it renews its health plan every seven years as part of the negotiations for allocating its budget, in other words the Multiannual Financial Framework (MFF) (COM, 2018, 98). Second, concerning the use of advanced technologies; an additional factor could be that institutions within the EU (ranging from tech companies to the European Parliament) gained knowledge through the years on how to decrease the risk of data breaches, data thefts by setting up a reliable data exchange network between Member States and accumulated knowledge of to properly use new technologies such as Big Data and AI. Finally, policymakers could have learned from real-world examples, such as the data exchange framework between Estonia and Finland and saw the possibility to implement a similar framework in EU policies. So, these previous developments led to the situation that Member States reached a consensus and had the confidence to advocate for a further integration of public health policies, such as a widely data exchange, in order to protect the Public Health in the future. The effect of specific external factors, among which COVID-19, is outlined by Figure 4, describing the policy cycle of the EU towards the legislation of its new EU4Healthplan and position towards advanced technologies such as Big Data and AI.

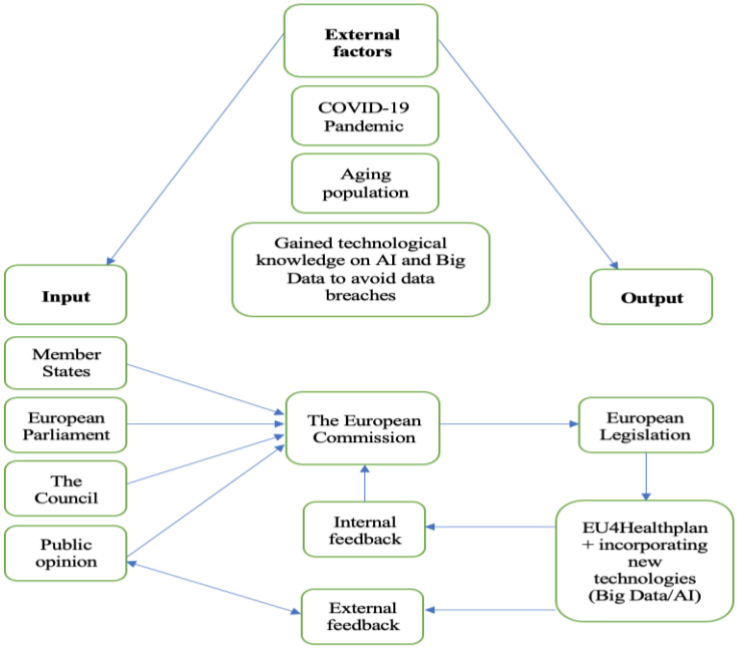

Figure 4. The Policy making process before and during the COVID-19 outbreak

Together with the arguments provided by the previous paragraphs, it is possible to formulate a second hypothesis that will be used to investigate the role of the COVID-19 pandemic on policy making process and will be discussed in section 5, (H2): *The implementation of Big Health Data exchange between Member States was already running, and it was just a matter of time to be implemented in the EU policy due to its behaviour of a slow ideational change. So, the COVID-19 pandemic played a small role in shaping policies but was not absolutely necessary for a change in adopting policies as H1 suggested.*

3) Research Design

3.1. Case selection

The case of this study concerns the policy path towards the formulation of the EU's ''EU4Healthplan 2021 – 2027'' and is a good example to test if the main narrative in the policy towards data exchange of Public Health records within the EU is altered due to the exogenous shock called "the COVID-19 pandemic''. This pandemic could be a possible *window of opportunity* for policymakers to change the dominant policy monopoly in the EU. On first sight it is plausible that the COVID-19 pandemic catalysed the willingness of Member States to exchange Public Data Health, in order to avoid or reduce the enormous consequences an identical pandemic could have in the future. However, the formulation of policies in the EU4Healthplan to digitalize Public Health across its Member States could also be a slow policy formulation as described by H2. Additionally, this case will give interesting insights on how the EU agenda-setting can be influenced and changed overtime. Also, it could describe a possible shift of Member States their attitude towards public health data exchange, between the formulation of the EU's ''Health Programme 2014 – 2020'' and ''EU4Health plan 2021 – 2027''. Thus, this timeline is suitable for analysing the impact of a crisis on the European policymaking process.

3.2. Operationalization of the variables

This section will operationalize the most important concepts from the theoretical framework, therefore we will discuss the following concepts: agenda-setting of EU public policy, critical junctures, window of opportunity, policy venues, policy monopoly and Big Data. These concepts are, despite the exhaustive theoretical framework, abstract and with

the help of this section it will be able to use these concepts to answer the research question and hypotheses of this study.

First of all, the agenda-setting of EU public policy is influenced by different political structures, policies, levels of wealth, because of this Member States approach EU integration and policy via different perspectives and at the same time policymakers are identifying policy alternatives (McCormick, 2017). Therefore, the concept of agenda-setting of EU public policy includes the following sources that are structured and unstructured. The first source is structured, namely: treaty obligations that outline the general goals and principles of EU integration, such as 'economic and social progress', and these obligations incorporate the task division within the EU and its institutions. Also, the agenda-setting of EU public policy is heavily influenced by a second, less structured, source: the public opinion. In the theoretical framework section, it was already discussed that policymakers cannot ignore the public opinion and are vulnerable to public scrutiny (Kauffmann & Bellver, 2005). In the EU especially, there is a growing demand by European citizens that their opinions should be taken into account and making sure that European citizens are satisfied with the decisions that are made in the EU and its institutions (Eurobarometer, 2016). On that account, we need to monitor the satisfaction of EU citizens related to the exchange of health data topics while collecting the data, by using the Eurobarometer. These surveys, conducted by the EU, cover a wide range of issues as also citizens expectations and perceptions towards EU health policies (EP, 2021). With the help of these surveys, we can investigate if the public opinion on health data exchange, from an EU perspective, altered and led to the situation that policymakers were feeling the need of changing policies.

The second concept is straightforward, concerning critical junctures that include emergencies and crises. From an EU perspective, it has dealt with these junctures from the very beginning and policies have often been redesigned in response to unexpected developments, an example is the British decision to leave the EU. This changed the status quo of the relationship between the EU and the United Kingdom, because the EU needed to identify alternatives to existing models of a pan-European collaboration for a post-Brexit area (Martill & Oliver, 2020) This brings us to the concept of *window of opportunity*, because a critical juncture opens up a window of opportunity according to the PET. In the

empirical findings' sections, we have to search for situations of policymakers trying to reshape the national interests and change the terms of debate on digitalizing public health in the EU. Therefore, policymakers could introduce new ideas in terms of health technology initiatives (e.g., track and trace applications) that create the conditions to change the status quo of health policies. In this way it is important to make clear distinctions between the prevalent narrative on cross border public health data exchange before the pandemic and during the pandemic to analyse if the COVID-19 pandemic changed the status quo of public health policies in the EU. Thereby, we acknowledge that policy is rarely static, and the goals of EU policy constantly will be redefined as argued by scholars (McCormick, 2017). Therefore, this study will analyse if there is a rise of new digitalized public health policy directives or regulations by the European Parliament and the Council, suggesting for legal changes in Commission proposals to conclude if the COVID-19 pandemic influenced health data policies within the EU in order to accept or reject the hypotheses of this study.

The next concepts that need to be operationalized are the concepts of policy venues and policy monopoly, which are also intertwined. First of all, the policy venues are the institutional constructions in which the formulation of the problem and solutions take place. In this study we will focus on venues in terms of formal political arenas: the legislative and executive branches. This implies that in this study we have to narrow down the focus to the prevalent policy monopolies in three main institutions within the EU: the Council of the European Union and the European Parliament both as part of the legislative branch within the EU and the European Commission as the executive branch (McCormick, 2017, p. 77 – 87).

Moreover, literature on policy venues also acknowledges the public narrative as an important policy venue, because it plays an important role in the process for policymakers in allocating attention and emphasizing a subsequent policy action (Baumergartner & Jones, 2010). Therefore, the public opinion on cross border health data has to be researched. In the past there are a lot of examples from triggering events that cause a shift of attention to alternative problem definitions and policy solutions. An example is the public attention of the oil spill from the Exxon Valdez that produced a window of opportunity for environmental and fishing policies, according to Birkland (1997).

Eventually this situation led to a change in laws concerning the pollution of oil and the way oil spills are cleaned up, because of increasing public attention via news coverage. Despite the fact that the COVID-19 pandemic is an event that affects not only EU public policy, but all policy on a regional, national and international level, while it can still be analysed if the public opinion altered its main narrative of the exchange of data between EU Member States in order to prevent a next pandemic. Therefore, this study will analyse proposed policies of the legislative branches towards the executive branch in the EU. This will have an added value to the discussion on the reliability of PET, to investigate if the treaties are based on common positions taken by Member States their representatives and if these common positions are affected by the public opinion that redefines the narrative of formal agendas on health data exchange between Member States in a desired direction.

The final concept that needs to be operationalized is 'Big Data'. The theoretical framework already provided information about the concept and it can be argued that it plays an important role in the current prevailing data-driven socioeconomic model. This study will focus in the analysis on a mixture of passive and active Big Data, because digital technologies (e.g., smartphones, wireless sensors etc.) have become more accessible and common to be implemented in remoting the public health (EESC, 2016). Yet, passive Big Data is still relevant because citizens can monitor each other in a health care setting (e.g., in case of a hospitalization it can be collected by hospital staff).

Moreover, the usage of Big Data will also lead to a shift in the skills of governmental workers to ensure a staunch and credible health data exchange system is accessible for citizens in every Member State. According to existing literature, in the analysis we need to focus on a possible shift in skills of governmental workers, because it raises costs for the EU to train their personnel on how to consume, utilize and create a better understanding of a more diverse set of information. In addition, this concept also will focus on the EU's need to create agencies and build up standard operating procedures in order to facilitate a credible health data system (Dunleavy et al., 2006).

3.3. Method of data collection

The study will use a qualitative research method, because it will research a unique event/exogenous shock that cannot be codified due to the need for interpretation of human cognition and action (Yang & Miller, 2008, p. 145). From an epistemological perspective, the study can be seen as transactional and subjective, because of the interactive link and mutual influence between the investigator and the investigated object (Guba & Lincoln, 1994). The overall approach of the research method is to understand and reconstruct a policy process and try to coalesce around consensus regarding the influence of the COVID-19 pandemic on the path of policy formulation of the EU between the establishment of the Health Programme 2014 – 2020 towards the effect COVID-19 pandemic has had on the formulation of the EU4Healthplan. Therefore, the data collection method will have an explanatory approach and is based on the grounded theory of historical institutionalism. The method defines questions about the process, path-dependence and a gridlocked situation, that can be applied to specific actions by EU policymakers during and before the COVID-19 pandemic. Hence, the study will research the possibility that this process has influenced policymakers their behaviour towards in the decision-making process of the policy path.

Moreover, the outcome of this study will have an added value on the accumulated knowledge concerning the impact of exogenous shocks on the policy process, as for example set out in the book 'The Palgrave Handbook of EU Crises'. The book acknowledges that recent studies provide rich, theoretically informed, empirical probes of how the EU has responded to crises across different policy fields, such as the migration crisis, the financial crisis and Brexit. Some scholars compared these specific crises, especially the migration crisis to the financial crisis as discussed by Schimmelfennig in his study in 2018 (Schimmelfennig, 2018, p. 982). However, the book 'the Palgrave Handbook of EU crises', attempts to take the 'birds-eye' perspective on the EU as a whole and in what way the COVID-19 crisis will affect EU integration. This study will put the role of the COVID-19 outbreak into question and discusses, next to the exogenous shock of COVID-19, a possible slow incremental change within the policy process of EU institutions. Hence, this situation led us to question whether current theories of punctuated equilibrium are adequate explanatory models.

3.4. Method of analysis

Via a historical institutional perspective, it can be researched if and in what way the pandemic played an important role in causing a *window of opportunity,* in the policymaking process regarding the implementation of the idea of 'standardized cross-border exchange of health data' within the EU institutions. Especially the Commission, the Parliament, and the Council of the European Union. Also, via this perspective we are able to analyse and explain how and if the pandemic alternates the old equilibrium in these institutions of having reservations on the exchange of health data across Member States, while there was already sufficient evidence for the added value of establishing a data exchange system across borders (see the X-Road initiative for example as discussed in section 2).

In addition, the aim of this study is making observations of different aspects of this case and are not quantifiable, while it does not fit a standard rectangular data matrix with rows for observations and columns for variables (Toshkov, 2016). Therefore, the research design will consist of process-tracing single case study. The underlying idea of process tracing is that it uncovers a tight sequence of events that are linked together as if in a chain (Toshkov, 2016, p. 300). Moreover, a typical direction for process-tracing research is recovering in as much detail as possible the institutional context and reconstructing the chronology of events leading to an outcome of interest. In order to gain more insight on this sequence of events towards the situation how the pandemic possibly have alternated the old equilibrium of policymakers, regarding the ideas of implementing health data exchange across borders, this study has to dive into reports provided by the Commission, Parliament and the Council of the European Union. Also, to reconstruct the chronology of events the study has to investigate the opinions of advisory committees, the overall public narrative and the interest of support groups. All this kind of material would provide but the raw information, which serve as evidence for or against the various hypotheses competing to explain the role of an exogenous shock (read the COVID-19 pandemic) on EU policy making regarding health data. So, according to Toshkov (2016, p. 300): '' […] process tracing incorporates individual events and general facts, mediates between structure and agency, and shifts between the abstract and the concrete when building

explanatory accounts.''. And will be the core of the research design of this study in order to be able to measure the main theoretical constructs in this case study.

3.5. The two hypothetical models

The data will be analysed via a model that shows how historical institutional processes would work for the EU4Health policy development under each of the two hypotheses. The model will analyse the possible change of an overarching, widely shared and prevalent interpretation of institutional ideas of the EU policy making processes and how it influences the decisions and interpretations of policy options as more suitable at the expense of other reforms.

The first model concerns H1 and approaches the policy process of the EU as heavily influenced by the COVID-19 pandemic. According to this model, the pandemic caused a situation of an opportunity to break with the dominant policy ideas in the EU regarding the usage of cross-border health data between Member States. If the policy-making process acts in line with the historical institutionalism, it would work as follows; before the pandemic there was an overall stability towards digitizing health systems across the EU and the possibility of cross-border health between Member States, was based on a voluntary contribution but together the Member States and the EU still have the mandate to combating serious cross-border threats to health (TFEU 168). The exogenous shock, called COVID-19, shifted the EU policy towards a pattern of change. Member States and EU policymakers saw the urgency and relevance to set up a system which is able to exchange and make use of data across borders, in other words an interoperability system - a system that derives on the ability of organisations to cooperate in order to mutually achieve their objectives, by sharing information and knowledge such as the exchange of data (COM, 2017, 134). From this perspective, both the EU and its Member States agreed upon the formulation of a more mandatory, in contrast to the treaties in the past as discussed in TFEU 168, cross-border health data network in terms of an overarching EU governance network. This resulted in the formulation of the EU4Health plan and treaties that altered the Treaties of TFEU 168 and 114 concerning cross-border health. Regarding the overall narrative in the society, this model claims that this narrative on data privacy is changed because of the COVID-19 pandemic. People are possibly more willing to share

their personal data with their government or gain trust in their government's ability to protect their data and are because of this situation more likely to embrace digital technologies. In order to investigate such development, this model will emphasize that a possible change of narrative and ideas, within the Commission, Parliament and the Council, plays a key role in the formulation of the EU4Healthplan and in what way these differ with the overall narratives that were the foundation of establishing the Health Programme 2014 – 2020.

The second model predicts the path of H2 and focuses on incremental policy changes within the EU with regard to the existing cross-border health data framework together with the development of prevalent understandings of this policy subject. According to this model, it is not merely the EU and its institutions that are able to influence the policy process. In fact, there are all kinds of organizations having ideas that could possibly cause changes at slow level instead of policy changes depending on exogenous shocks. A change could be caused by the way individuals are interacting with each other and creating shared understandings within the EU. Also, the EU has to deal with external factors such as an aging population and gaining technological knowledge overtime.

Therefore, this model will emphasise the influence of opinions and advisory committees over time that could eventually alter the EU's policies on cross-border data health in terms of using advanced technologies such as Big Data and AI to deal with external factors where the EU is exposed to. However, the H2 model will not deny that an exogenous shock could play a role in creating uncertainty on dominant policy ideas, so during the analysis of H2 we have to be aware of this. Also, the H2 model will focus on the development of trust within EU institutions in their capability to avoid possible data breaches and implementing a functioning and reliable overarching health data network between the EU and its Member States. Hence, it is important to research a possible change in the narrative of staff working documents and published initiatives by European institutions, within the timeline of European Health Programme 2014 – 2020 towards the formulation of The Programme in 2021. Following this model, technological knowledge has improved over the years in the EU. This is in line with the literature of a slow change in policies, and at this point in history the EU is able to fully implement a functioning (e.g., AI and Big

Data) framework that could protect the public health by reducing the inefficiency in healthcare systems across Europe and facilitate epidemiological surveillance.

3.6. Research design

In order to be able to reject or accept the hypotheses and research question this study needs a well-defined research design and this part of the study is divided in six sections. This design contains staff working documents of the Commission, EP and the Council of the European Union. Next to documents provided by the EU via their 'Official Journal of the EU' (OJ) for the period 2014 – 2021 in the field of 'The Programme', by inserting: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan' as the search terms. Published initiatives will also be analysed in terms of legislative proposals, regulations on the EHDS, digital health services, use of new technologies including AI and Big Data; concerning the collection, access, storage, use and re-use of data in healthcare on the framework of the existing cross-border healthcare.

The research design will be used as a framework in the discussion section that will include the topics by following order: Section 4.1 discusses documents of the Commission between 2014 – 2021. Section 4.2 discusses documents of European Parliament between 2014 – 2021. Section 4.3 discusses the documents of the Council of the European Union between 2014 – 2021. Section 4.4 discusses the public opinion in the EU, derived from the EU's own research platform called: 'Eurobarometer'. This will be of added value for substantiating this study, because a lot of staff working documents, EU directives and regulations are elaborating on the outcomes of the 'Eurobarometer'. The European Parliament launched the Eurobarometer in 2007 and has been part of the EU's policy process for a long time by providing detailed trends of the evaluation of public opinion on European issues (EP, n.d.). These are surveys covering a wide range of issues, specifically focused on the perception of its citizens' perceptions and expectations towards EU action, and the main challenges the EU is facing. This will be useful for this study, because the study tries to pinpoint the development of the narrative within Europe towards data exchange. With the help of this research design, it can be analysed if or at what point the overarching idea within the society about a data exchange framework shifted from a stage of reluctance towards the willingness to or the need for implementing it.

Table 1. Overview of how the data is operationalised

Data	Why collected	How collected	Operationalised
Staff Working Documents (SWD)	These documents include impact assessments, summaries of impact assessments and staff working papers that will give valuable insights on the current narrative within the Commission.	Consulted: Official Journal of the European Union (OJ) and inserted the key words: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan'.	Distinguish new and prevalent ideas in terms of digital health technology initiatives (e.g., track and trace applications) before and after the COVID-19 outbreak, focusing on proposed policies of the legislative branches (EP & Council) towards the executive branch (Commission) in the EU. Emphasize a possible shift in skills of governmental workers and establishing agencies and the set-up of standard operating procedures to facilitate a credible health data system.
Joint Staff Working Documents (JC)	Joint proposals of the Commission, the European Parliament or the Council with other European Institutions elaborating on communications, reports, white papers and green papers adopted by the Commission.	Consulted: OJ and inserted the key words: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan'.	Distinguish new and prevalent ideas in terms of digital health technology initiatives (e.g., track and trace applications) before and after the COVID-19 outbreak, focusing on proposed policies of the legislative branches (EP & Council) towards the executive branch (Commission) in the EU. Emphasize a possible shift in skills of governmental workers and establishing agencies and the set-up of standard operating procedures to facilitate a credible health data system.
EU Directives	These are legislative acts setting out goals that all EU countries must achieve, but it is up to the individual countries to devise their own laws on how to reach these goals.	Consulted: OJ and inserted the key words: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan'.	Distinguish new and prevalent ideas in terms of digital health technology initiatives (e.g., track and trace applications) before and after the COVID-19 outbreak, focusing on proposed policies of the legislative branches (EP & Council) towards the executive branch (Commission) in the EU. Emphasize a possible shift in skills of governmental workers and establishing agencies and the set-up of standard operating procedures to facilitate a credible health data system.
EU Regulations	These are binding legislative acts and must be applied in its entirety across the EU.	Consulted: OJ and inserted the key words: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan'.	Distinguish new and prevalent ideas in terms of digital health technology initiatives (e.g., track and trace applications) before and after the COVID-19 outbreak, focusing on proposed policies of the legislative branches (EP & Council) towards the executive branch (Commission) in the EU.

			Emphasize a possible shift in skills of governmental workers and establishing agencies and the set-up of standard operating procedures to facilitate a credible health data system.
Treaties of the European Union	These are binding agreements between Member States of the EU, setting out: EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its Member States.	Consulted: OJ and inserted the key words: 'cross border big health data exchange in the European Union', 'Health Programme 2014 – 2020' and 'EU4Healthplan'.	Agenda-setting within the EU, distinguish new and prevalent ideas in terms of digital health technology initiatives (e.g., track and trace applications) before and after the COVID-19 outbreak, focusing on proposed policies of the legislative branches (EP & Council) towards the executive branch (Commission) in the EU. Emphasize a possible shift in skills of governmental workers and establishing agencies and the set-up of standard operating procedures to facilitate a credible health data system.
Eurobarometer	Used by the EP to assess public opinion on specific topics, either focusing on specific socio-demographic groups such as the European youth or related to the activity of the institution (e.g., gender equality or the social and economic crisis).	Consulted: https://www.europarl.europa.eu/at-your-service/en/be-heard/eurobarometer, and focused on specific surveys by the following themes: 'digital society and technology', 'health and food strategy' and 'politics and the European Union' between 2014 and 2021.	Agenda-setting within the EU by analysing the overall narrative within the public opinion, with the help of the Eurobarometer.

4) Empirical findings

First of all, background information of the agenda-setting of controlling communicable diseases at a European level is necessary to be able to carry out an in-depth analysis via the theoretical scope of this study. The first framework for surveillance and control of communicable diseases between Member States was established by the Council in 1998 (EP, 1998, L268). Yet, in 2004 the Commission adopted the first coordinated eHealth EU Action plan between Member States, and it has been developing targeted policy initiatives aimed at fostering widespread adoption of digitalizing the interaction between patients and health service providers, the transmission of data from institution-to-institution or the communication between patients and/or health professionals; in other words: eHealth (COM, 2012, 736). The Commission strives to establish the semantic and technical

cross-border interoperability specifications and assets necessary for an eHealth interoperability framework (COM, 2012, 736). In this study we will focus on the institution-to-institution transmission of data. However, these opportunities also face challenges as the upcoming sections will define, because first of all: Member States their public administrations are too fragmented in 2014, resulting in increased costs and slow uptake by public authorities and citizens (SWD, 2015, 100). Second, Member States do not have clear mutually agreed goals, trust and rules, which is critical for providing cross-border service, such as health data exchange (Renda & Castro, 2020). Lastly, the Commission is witnessing digital skills mismatches and shortages across Europe of both citizens and employees (SWD, 2015, 100). As a consequence, it can be argued that Member States and their citizens did not benefit from innovation in the field of digitally enabled health care and services at that point in the past.

4.1. Prevailing ideas within the European Commission between 2014 – 2021

On the 11th of March 2014, the EU legislated its Third Health Programme in accordance with Article 168 of TFEU and it should be a means of promoting actions to support coordinated public health measures at a Union level to address different aspects of cross-border health threats. Surprisingly, the programme is ambiguous on how to coordinate an interoperable public health framework effectively. The Programme mentioned several times the need of fostering a knowledge system across Member States to contribute to an evidence-based decision-making process and a wide data exchange by further developing the standardized health information (EP, 2014, 282). However, there is a serious lack of an actual idea for incorporating an interoperable framework (EP, 2014, 282).

One year after the Third Programme was forced into power, former president of the European Commission, Jean-Claude Juncker, called for a paradigm shift. In 2015 he advocated for a more integrated interoperable framework by launching the Digital Single Market strategy (henceforth DSM): ‘’[…] enhancing the use of digital technologies and online services should become a horizontal policy, covering all sectors of the economy and of the public sector." (COM, 2015, 192). At the same time Member States were confronted by a merging public discussion of the incredible possibilities of using huge amounts of data stored in health databases and health records (COM, 2014, 2160915). The public and policymakers were questioning how to make effective use of this data and how public

authorities will protect the information of citizens (COM, 2014, 2160915). This development was one of the main reasons that, in 2015, the General Data Protection Regulation (henceforth GDPR) was adopted to promote data protection and data security in the field of health data (EP, 2018, C11/55). GDPR would also work as a useful tool to gain citizens' trust and at the same time protecting their privacy in an effective manner (EP, 2018, C11/55).

According to the staff working documents provided by the EU, the Commission is working towards an innovative public sector that improves digital transformation by striving to ensure an efficient and high-quality service for all citizens (COM, 2016, 180). In doing so, the Commission acknowledges that it needs to develop its knowledge of Big Data, the Internet of Things (henceforth IoT) and cloud technologies, because the Commission is convinced that these developments will cause a fourth industrial revolution (SWD, 2016, 195). Such a digital revolution was pointed out during the mid-term evaluation of the Third Health Programme, because the Commission highlighted that there is a growing demand to work more intensively in the coming years to help policymakers in better understanding this upcoming revolution (SWD, 2018, 289). The Commission also needed to specify the pros and cons of digitalization in health, to make sure that Europe can benefit from it (SWD, 2017, 331). In addition, the Commission and the Parliament argued the importance of Europe embracing innovative changes, because it could significantly gain its competitiveness and growth (SWD, 2018, 305). However, such Big Data analysis and available tools are largely unexploited by most Member states in 2017 (SWD, 2017, 331). Europe also deals with a lack of a broadband (e.g., 5G network) that's capable of providing large data sets, next to that it needs greater 'standardisation' of health care systems across the EU (SWD, 2017, 331). Therefore, in 2017 the Commission highlighted new digital issues that could have an enormous potential for health care, because of the growing role of data, AI and creating a European cloud to exchange data (SWD, 2017, 155).

However, the EU faces the problem of each Member State and their public administrations obtaining large amounts of data by using different data management methods, so the EU faces a lack of standardisation in this situation (COM, 2017, 134). These circumstances explain why in 2017 only 48% of the cases a reuse of existing information about citizens and businesses is visible (COM, 2017, 134). So, if no action is taken Member States will

further diverge in approaches of interoperability, resulting in an increase of digital fragmentation across the EU and failing to realize a Digital Single Market (COM, 2017, 134).

A fragmented method of collecting data would be problematic for the EU, because in several staff working documents it is mentioned that the EU has the mandate to ensure a robust data and computing capacity to identify infectious diseases (e.g., communicable diseases) before they become a threat to public health and thus limit the spread of epidemics (SWD, 2017, 155). Therefore, the Horizon 2020 programme of the EU Commission funded the COMPARE project for almost 21 million euros and has the objective to develop a globally linked data and information sharing platform, generating genomic data of infectious pathogens and integrate these data with other relevant (clinical, epidemiological, demographic, environmental etc.) data (SWD, 2017, 155).

Furthermore, the previous sections outlined that the Commission, by 2018, is trying to prevent a possible fragmented collection of data across the EU, but it was also far away from attaining a complete interoperable system. Once again, the Commission acknowledged that it needs a cross-border secure access to data sets and a shared computing and storage capacity to accomplish an appropriate large-scale health framework. This is also one of the main aspects of the mid-term evaluation of the Third Programme, because the evaluation advocates to put more emphasis on the digital transformation of health care encouraged by the Programme due to its high EU added value (SWD, 2018, 289). Ideally, Big Data mining (social media, physical activity trackers, electronic health records, insurance claim databases and patient registries) can improve the anticipation of epidemics and accelerate EU-wide identification of infectious threats (within days), thus allowing a swift response to infectious outbreaks (SWD, 2018, 126). In addition, the EU commission proposed another initiative to accelerate the connectivity and usage of high-performance computing by creating a truly European common data space (COM, 2018, 232). According to the Commission, such a data space uses the free flow of non-personal data to target the smart use of data and causes a transformative effect on all sectors of the economy and the public sector within the EU (COM, 2018, 232). These data-driven innovations can have a positive effect on public policy making, for example: sharing research data on the outbreak of epidemics can advance relevant

research much faster and contribute to a timelier response (COM, 2018, 232). However, the EU Commission faces three challenges in realising such an overarching Big Data digital framework: first of all, it is difficult that mining Big Data complies with GDPR requirements, second it lacks an overall novel IT infrastructure that is capable to process such high-performance computing and lastly it deals with a lack of actors and investments (SWD, 2018, 126; SWD, 2018, 305; COM, 2018, 233).

The latter, a lack of investments, is part of the discussion on budget allocation. In other words, the EU's financial framework towards smart growth in areas of data infrastructure, connectivity and cybersecurity. Therefore, EU policymakers acknowledge that an agreement on a new Multiannual Financial Framework (henceforth MFF) for the period 2021 to 2027 will be an important test of the EU's unity and capacity to act in a changing world (COM, 2018, 98). By investing more in these growing digital areas, it would help to secure a European leadership in the next generation internet, AI and Big Data, which would have a significant impact on filling the skills gap across its Member States. So, policymakers argue that leaders now have a *window of opportunity* to choose a more united and stronger EU together with a budget that delivers it (COM, 2018, 98).

If we move to the allocation of budgets in the MFF 2021 – 2027, it becomes clear that it has been revised in May 2020 due to the COVID-19 pandemic. The Commission proposed recovery measures in terms of 'Next Generation EU' with financial power of 750 billion euros but is exceptional and temporary, reflecting the size and challenge Europe is facing (SWD, 2020, 98). Also, the Commission proposed a new Health Programme to prepare for future health crises, because the COVID-19 crisis underlines the value of European cooperation and demonstrated that the EU must reinforce their capacity to respond to crises and future shocks (COM, 2020, 7907993). The MFF will support several initiatives to secure a digital transformation (COM, 2020, 7907993). A great example of such an initiative is the implementation of the European Health Data Space (EHDS), as mentioned in previous paragraphs. A legislative proposal for this initiative is envisaged for the fourth quarter of 2021 and has the objective to strengthen EU's health regulatory framework by supporting health data exchange and research while keeping the full responsibility of being compliant towards privacy concerns (SWD, 2020, 98).

As mentioned by policymakers of the Commission, one of the main drivers was that the COVID-19 pandemic highlighted the importance of having timely access to health data for research and policy-making purposes (COM, 2020, 7907993). Therefore, the Commission advocates together with the Council for increasing data access by companies and research organizations, in order to advance representative scientific developments in the EU as a whole and can help improve EU's coordinated actions if necessary, such as in a situation of a pandemic (COM, 2020, 767). Yet, the planned legislative framework has to tackle some problems, because there is fragmentation of digital standards and limited digital interoperability between healthcare systems. Also, Member States have different approaches for access to and sharing of health data and the re-use of health data held in cross-border databases is difficult due to the different applications of the GDPR in the areas of health and research in the Member States. And the EU has to deal with a serious lack of digital knowledge of European Citizens. As of 2019, there were 7.8 million ICT specialists with a prior annual growth rate of 4.2% (COM, 2021, 118). This situation is problematic, because the EU will be far below the projected need of 20 million experts (e.g., for key areas, such as cybersecurity or data analysis), if this trend continues (COM, 2021, 118). This problem is intensified by a lack of capacity in terms of specialised education in areas such as AI, Big Data and cybersecurity, which are preconditions for establishing a digital transformation (COM, 2021, 118). These difficulties and different approaches across the EU limit the cooperation, governance and IT infrastructure at EU level and hinders health data access for researchers, public institutions and regulatory bodies (COM, 2020, 7907993).

Shortly before the release of the fourth European health programme (EU4HealthPlan) in March 2021, the Commission published its ambitious '2030 Digital Compass' in which it advocates for pursuing digital policies that empower people and business to seize a human centred, sustainable and successful digital future by the end of the decade (COM, 2021, 118). The Commission acknowledged that the COVID-19 pandemic radically changed the role and perception of the usefulness and chances of digitalization in the society, and it exposed the current vulnerabilities of the EU digital space (e.g., dependence on non-European technologies) (COM, 2021, 118). Also, according to members of the Commission, one of the key lessons of the pandemic is that digitalization has the opportunity to enable a society where geographical distance matters less, because people

can work, learn, interact with public administrations, make use of health care systems, be entertained or meet and discuss with people anywhere in the EU, including in rural and remote areas (COM, 2021, 118). Thus, in order to make use of the opportunities provided by digitalization, the Commission find it crucial that the EU increases the involvement and commitment of the public and all stakeholders to achieve a higher connectivity, increasing digital knowledge and creating a more productive society.

4.2. The prevailing ideas in the European Parliament between 2014 – 2021

The previous section described the Commission' standpoint on encouraging data exchange across borders to improve the public health facilities, so with this knowledge we need to describe the prevailing ideas on exchanging health data from 2014 onwards in the second important institution in the EU: the EP. Via information, derived from the EP documents, it becomes clear that members of the EP were concerned about challenges posed by a digital revolution (EP, 2014, CE 35/1). Within the EP there is a prevailing idea that Europe needs to engage in dialogue with the rest of the world, in particular on the protection of personal data in order to avoid possible data breaches (EP, 2014, CE 35/1). Also, the EP invited the Commission to facilitate cooperation among Member States by implementing a framework of cross-border interoperability solutions in order to deliver better public services with fewer resources (e.g., benefit fully from interoperable health data infrastructure). Therefore, public administrations of Member States must be modernized and standardized to increase the interoperability and could contribute to a completion of data exchange through the back offices of these administrations and supports the 'free flow of data' across EU borders in order to consolidate such data exchange (EP, 2015, L318/1; EP, 2017, C316/254; EP, 2018, C11/55).

From EP's perspective, health data is a crucial part of the data-drive economy that will be a key of Europe's economic growth in the future and emphasizes the opportunities that 'new' ICT technologies such as Big Data, cloud computing and AI can bring to the economy and society, when integrated with other sectors such as education and health (EP, 2015, L318/1; EP, 2017, C316/254; EP, 2018, C11/55). However, the EP brings up several challenges that the Commission faces before these technologies can be implemented in a proper way. First of all, a condition for further exploiting the opportunities of this kind of

data usage in society, is building trust of citizens and consumers in a data driven economic sector (EP, 2018, C11/55). In order to build in trust within the society, the EU can use GDPR, as mentioned before, as a useful tool to secure this trust (EP, 2018, C11/55). Second, health data is acknowledged as extremely sensitive information and therefore the EP encouraged the Commission to further develop policies and enforcement instruments in order to keep track of that data, while it should not be turned over to, for example, commercial companies and their free software as it is unclear how they might will use the knowledge that is gathered (EP, 2019, C433/42). Lastly, Big Data and AI have the ability to fuel research initiatives such as analysing data streams to detect health threats and disease outbreaks and can improve the performance of Member States public health systems, but policies must be implemented in order to guide this development while making sure that initiatives will not lower the prevailing ethical standards (EP, 2020, C449/37).

Moreover, the EP argued that there is a chance of a possible fragmentation in the implementation of GDPR across Member States that undermines the efforts to establish cooperation between researchers enabled by, for example, cloud computing (EP, 2018, C252/285). In addition, the EP argued in 2017 that the EU's digital infrastructure was insufficient at that moment. This was partly caused by the fact that there was a lack of clear structures of incentives for sharing data, also it lacked an interoperability of scientific data systems and EU public administrations its researchers and innovators were almost pushed moving to places outside the EU that have higher cloud capacity available (EP, 2018, C252/285). So, in 2017, the EP concluded that the EU was lagging behind on several data related aspects that could facilitate a policymaking process of Member States based on cross-border data exchange (EP, 2018, C252/285).

However, the EP called for including a robust next-generation programme and a cross-sectoral cooperation, despite the enormous challenges the EU is facing (EP, 2019, C162/51). This programme should have the ability to address issues on a cross border basis such as European Reference Networks (henceforth ERNs). This network will concentrate knowledge on complex diseases via data exchange across Europe and therefore facilitates the implementation of digital health in Europe that must be incorporated in the MFF of 2021 – 2027 (EP, 2019, C162/51). One of the main reasons

why the EP advocates improvements in health-related fields is the following: ‘‘[…] good health is a prerequisite for achieving other goals set by the EU and the policy fields of agriculture, environment, employment, social issues or inclusion also have an impact on the health of Europeans’’ (EP, 2019, C162/51).

So, it is a key strategic challenge for the EU to design, develop and implement suitable, trustable technologies for health and care, therefore the EP adopted health data related amendments at the end of 2018, taking into account the aging European society (EP, 2020, C388/459). A main priority for the EU is the creation of accessible health systems and unleash the potential of a data-driven economy and digital innovation for better health and person-centred care building on open European data infrastructures. That relies on secure storages such as a 5G network across Europe and conditions for high performance computing centres for the effective, ethical and integer collection and use of health data (EP, 2020, C388/459). In addition, the EP constantly insisted on the need to come to terms between strengthen security and safeguarding fundamental rights including data protection and privacy (e.g., GDPR) (EP, 2019, 608.870).

Previous sections outlined the situation of the EP supporting further integration and technological improvements concerning the usage of health data across EU Member States, before the COVID-19 outbreak. After the outbreak the EP, the Commission and the Council acknowledged in a joint conclusion that the COVID-19 crisis had an enormous impact on new technologies that shape the way we live and transform how we learn, work, socialize and consume. On the other hand, the epidemic exposed the capacity issues Europe is facing and an insufficient broadband infrastructure in particular (EP, 2021, CI 18/5). In the opinion of the EP: EU has the mandate to defend the value of European citizens and therefore it needs to focus on the protection of data and upgrade the infrastructure immediately, by using this current momentum and setting up Europe’s ambitious plan towards digitalization (EP, 2021, CI 18/5).

Additionally, according to the EP, the pandemic accelerated the swiftness of change picked up in all Member States for the usage of digital technology in the health sector, because the pandemic redefined how and in what way care is delivered. The year 2020 can be remarked as accelerating a rise in digital tools that provide effective support for

institutions during a pandemic that allows the deployment of novel digital healthcare at different stakeholders' levels, including the government (EPRS, 2021, 690.548). Also, the pandemic accelerated the usage of electronic devices and applications for active and healthy ageing in particular gained popularity (EPRS, 2021, 690.548). To be more specific, there is a rapid proliferation of mobile health solutions (e.g., mobile apps, mobile sensors, mobile data collection forms) as an increasing number of European citizens own a smartphone. Also, as mentioned by the Commission, there are more than 3000 mobile health (m-health) apps available on the EU market and this number has doubled in comparison with 2015 (EPRS, 2021, 690.548). These circumstances result in an increase of Big Data sets across the EU and the EP argues that the usage of such datasets is contributing positively to the resilience of the health service delivery system (EPRS, 2021, 690.548). The outbreak also showed that actors were more willing to cut through the international red tape that normally restricts data sharing between countries (EPRS, 2021, 690.548). So, scientists, for example, were able to exchange data across borders concerning the information about genetic sequences from COVID-19 to investigate how it has spread and, in this manner, they could try to track the virus (EPRS, 2021, 690.548). Also, the EP acknowledged that funding dedicated to digital health is increased massively in EU's projects such as Horizon2020, the Digital Europe programme and its EU4Healthplan (EPRS, 2021, 690.548). Therefore, together with the Council and the Commission, the EP wants to work on a truly functioning single market for digital services that are in line with the ethical boundaries and push forward digitalization notably with regard to education and health (EP, 2021, CI 18/01).

4.3. The prevailing ideas in the Council of the EU between 2014 – 2021

The final institution of the EU policy making process that will be discussed in this study is the Council of the European Union. This institution is already discussed in previous paragraphs and the theoretical framework. The following paragraphs will elaborate on these prevailing ideas and provide a more in-depth discussion of the Council's behaviour, towards the formulation of a cross border exchange of health data framework across Member States. Back in 2011 the Council adopted specific directives concerning articles that the Commission have to support Member States in the development of the earlier mentioned ERNs. From the Council's perspective, ERNs have the objective to reinforce

research and can facilitate epidemiological surveillance that must be based on voluntary participation by its Members (Council, 2011, L 88/45). The Council pronounced that, with the help of the adoption of these directives, it supports the fact that the Union needs to strive for supporting and facilitating cooperation and exchange of information among Member States on a voluntary basis (Council, 2011, L 88/45). At the same time the Council calls for the urgency that national authorities responsible for digital health frameworks (eHealth) designated by the Member States need to set up an interconnected framework (Council, 2011, L 88/45).

Following the Council's standpoint of an interconnected framework; in 2015 the Council invited the Commission to develop common principles on the collection of data (such as health) and a legal framework to make a well-functioning institutional framework available at a European level (Council, 2015, C421/2). This will gain interoperability across the EU and will allow analysis of health data on a larger scale while taking compliance of data protection legislation into account (Council, 2015, C421/2). The Council's positive narrative towards the exchange of data continued, because of the urgency that the EU needed to adopt global trends in digitalization of modern societies becoming more information driven and citizens changing their attitudes and expectations towards the way healthcare is delivered (Council, 2015, C421/2). Therefore, the Council emphasized that European health systems need to consider innovative approaches and models of health care moving away from hospital centred systems towards more integrated care (Council, 2017, C440/3). An integrated care could be facilitated with the help of new opportunities arising from Big Data and improved data analytics capabilities (Council, 2017, C440/3).

However, the Council noted that these changes will bring up several challenges, because information systems that are currently used in health systems are not capable of facilitating the exchange of data within national systems, let alone that it could facilitate it across its borders (Council, 2017, C440/3). The current data infrastructure is lacking interoperability as also a funding and financial incentives for business and governments to share health data. Thus, the progress of implementing data-driven digital solutions in health sectors is limited, due to these circumstances (Council, 2017, C440/3).

On the other hand, the Council emphasizes that cross border exchange of health data is fundamental to combat cross-border health threats of biological, chemical and environmental origin (Council, 2017, C440/3). Sharing data via a well-worked out infrastructure has enormous potential to assist this prevention, early detection, and control of infectious disease outbreaks. Yet, to facilitate this infrastructure, the Council argues that the Commission needs to maintain public trust in digital health services and raise awareness by developing communication strategies for policy makers concerning the pros and cons of digital health for the quality of healthcare (Council, 2017, C440/3). An example advocated by the Council, is to build upon the existing infrastructure of European Clouds, but Member States and the Commission need to work together with the aim of improving the access to large European datasets and ensuring European digital leadership (EP, 2021, CI 18/5). In addition, the Council notes that existing national and administrative frameworks need to be reviewed in order to remove obstacles of data exchange and to enable the use of health data for research and innovation while considering the full compliance with data protection legislations (Council, 2017, C 440/3).

Shortly after the COVID-19 outbreak the Council recognized that this COVID-19 crisis demonstrated the importance of digital transformation of health and care. The outbreak also underlined the importance of an overarching and accessible digital framework that has the potential to guide the development of effective prevention. Therefore, the Council wanted the Commission to present specific proposals on data governance, while encouraging the development of digital frameworks in terms of a European Health Data Space (as mentioned before, a framework called 'EHDS') (Council, 2020, CI 202/1). In addition, the Council insisted on the consolidation of a joint effort between the public and the private sector in order to provide a data space that incorporates high quality data involving all parties (Council, 2020, CI 202/1). Yet, such a data space must have the purpose of being quality driven, so a common understanding of the usage of health data being compliant with the GDPR, international, European and national law is essential (Council, 2020, CI 202/1).

So as to achieve an EHDS, the Council advocates for the necessity of enabling considerable efforts towards the exchange of health data in the legislative and technological field. The

latter implies that the Council recognizes the importance of accelerating the knowledge of priority areas of AI, Big Data and cybersecurity to enable technological European sovereignty, a successful digital transformation and ensuring Europe's competitiveness at a global level (Council, 2021, C124/01). Therefore, the EU must support the integration and use of trans-European digital infrastructures, sustained by agreed European digital standards in areas of public interest, such as healthcare, to facilitate the implementation of cost-efficient health systems and interoperability (Council, 2021, C124/01).

4.4. The prevailing public opinions till 2021

As mentioned in the research design and empirical findings, the EU adds a high value on the public opinion and monitors in general the public opinion on EU membership and political priorities and values. During plenary sessions members of European institutions are provided with the results of relevant Eurobarometer results to empower and assist members in their political and communication activities (EP, n.d.). Moreover, policymakers are influenced by the public opinion of the European citizens. These citizens have the demand that their opinions are taken into account, therefore policymakers are urged to make sure that European citizens are satisfied, in general terms, with the decisions that are being made in order to consolidate the trust in European institutions, as mentioned earlier (Eurobarometer, 2015, 84). So, within this section several Eurobarometer reports conducted by the Parliament, concerning citizens perception of what the EU should prioritize, overall trust in institutions and personal data exchange across borders in the period of 2015 till 2020, will be discussed in order to provide an in-depth analysis about the possibility that policymakers are part of a public scrutiny.

Starting from 2015 onwards, Europeans had significantly higher trust in public and financial institutions to protect their personal data, according to Eurobarometer 431 concerning Data Protection of 2015. About 74% trust health and medical institutions in protecting their personal information. It differs immensely in comparison with the trust in European institutions protecting personal information, because 51% of the participants indicate that they trust a European institution and 13% do not trust them at all (Eurobarometer, 2015, 413). The willingness to share personal health data with health institutions remained high in comparison with the willingness to share it with public

institutions, according to Eurobarometer 460 conducted in 2017. The questionnaire derived from Eurobarometer 460 clearly shows a radical difference between the trust in health care institutions and public authorities, 65% and 21% respectively, regarding to Figure 5 (Eurobarometer, 2017, 460). Moreover, 23% of the 27901 respondents are not willing to give access to their personal health data under any circumstances.

However, over the past three years the attitude of European citizens changed in a positive way concerning the willingness of Europeans to share their data. The most recent Eurobarometer about health data showed that EU citizens are more comfortable and willing to share their data to improve medical research and care (42%), but also to improve the response to crisis situations such as epidemics (31%), regarding to Figure 6 (Eurobarometer, 2019, 503). With the support of this data, it can be argued that there is a broad support within the EU for sharing their personal data to help other citizens and ultimately benefiting society. The reason behind this shift is behind the scope of this study and it needs to be mentioned that this survey was conducted before the COVID-19 pandemic hits the European Member States. However, despite the willingness, the transfer of personal health data is fuelling a debate over the right of institutions and companies towards the fact who owns and controls that personal data: the patient, the healthcare provider, the state or the companies that collecting all kinds of data it (EPRS, 2021, 690.548). As mentioned before, health data is sensitive and raises questions about the individuals its right to privacy (EPRS, 2021, 690.548).

QD: Would you be ready to give access to your personal health and wellbeing data (medical and care data, lifestyle, physical activity, nutrition, etc.)? (MULTIPLE ANSWERS POSSIBLE) - **(%EU)**

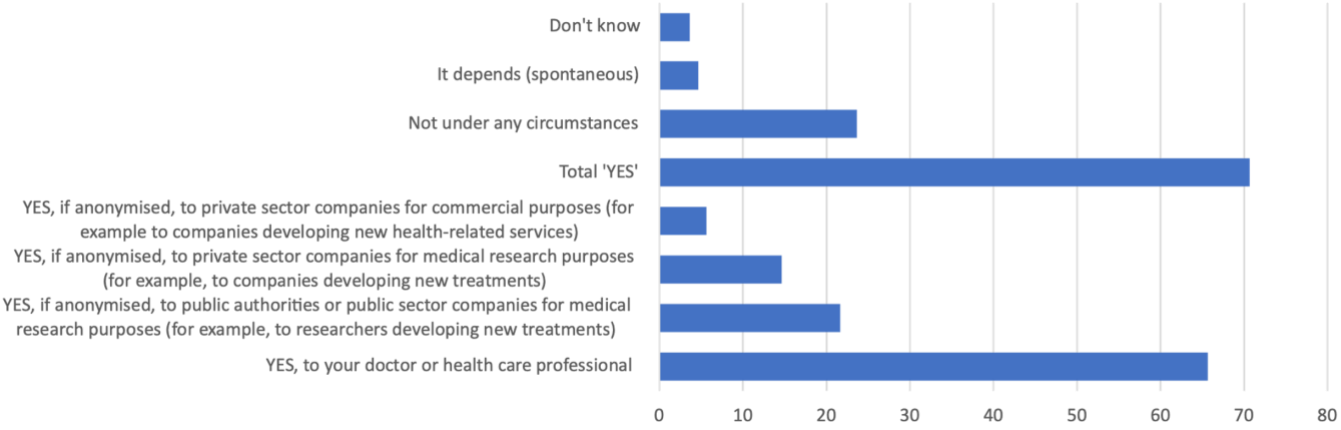

Figure 5. Public opinion on willingness to give access to your personal health, derived from Eurobarometer 460, 2017

QC: Public services could be improved if people shared some of their personal information. For what purposes would you be willing to share some of your personal information securely? (MULTIPLE ANSWERS POSSIBLE) - **(%)**

	To improve medical research and care	To improve public transport and reduce air pollution	To improve energy efficiency	To improve the response to crisis situations (e.g., natural disasters, epidemics, terrorist attacks, etc.)	For other purposes	You are not willing to share any of your personal information for any purposes	Don't know	Total 'Willing to share'
EU28	43	27	24	31	8	34	6	60
EU27	42	26	24	31	8	34	6	59

Figure 6. Public opinion on sharing personal data, derived from Eurobarometer 503, 2019

The second important topic covers the public opinion of prioritizing EU policies and these topics changed significantly between 2010 and 2021, regarding to Figure 7. This figure is derived from the European Parliament Research Service (henceforth EPRS). The figure clearly outlines the fact that improving consumer and public health protection has not been a significant priority for the European citizens, on the contrary, it decreases from 2010 till 2016 with 8%. As a result, it ranked fifth as the most important policy area for the EU (ERPS, 2016, 596.847). However, this changed in the most recent Eurobarometer on the public opinion in the EU by 2021 (Eurobarometer, 2021). The outbreak of COVID-19 accelerated a change in priorities of the public opinion (Eurobarometer, 2021). According to the most recent Eurobarometer: public health protection should be the spending priority of the EU followed by economic recovery and new opportunities for businesses and climate change and environmental protection ranked third (Eurobarometer, 2021).

QC: The European Parliament promotes the development of certain policies at EU level. In your opinion which of the following policies should be given priority? Firstly? And then? (MAX. 4 RESPONSES) – **(% EU)**

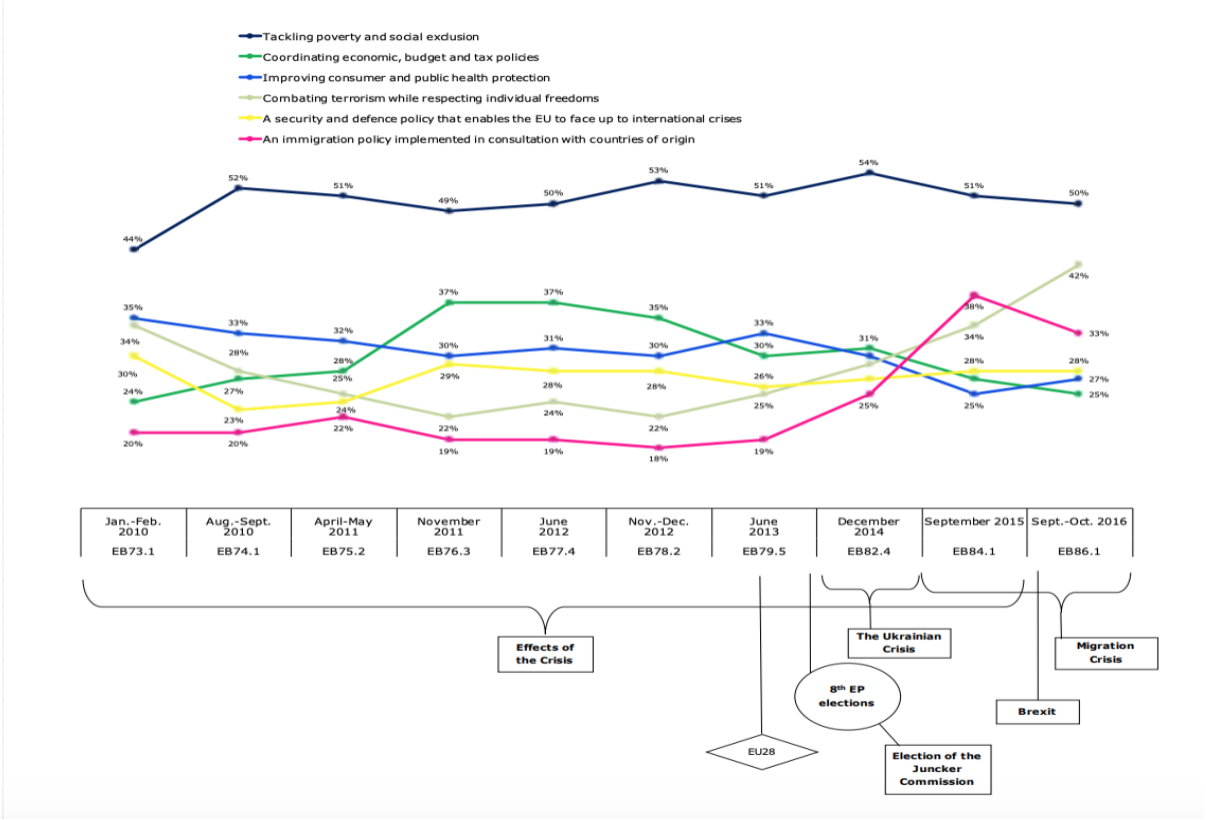

Figure 7. Major changes in European Public opinion regarding the European Union (2016 edition; Published by EPRS; PE 596.847 – November)

5) Discussion

5.1. Prevailing policy venues of public digital health and Big Data within the three institutions and public opinion, before the COVID-19 outbreak

According to the literature there are several Treaties describing the dominant policy venue within the EU, in particular Treaty 168 and 114. These latter two Treaties cover the EU's public health mandate, stating that a: ''[…] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'' Also, they underline that the ''Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.'' (Greer, S., L. et al., 2021). By 2014, the Third Health programme was implemented by the

EU Commission, in line with the mandate of the EU. It encouraged, with the help of the programme, to incorporate a wide data exchange between Member States by further developing the standardized health information in order to facilitate an evidence based decision-making framework (EP, 2014, 282). However, the EP argued shortly after the launch of the Third Health Programme, that the EU is facing an enormous challenge called 'the digital revolution' (EP, 2015, C421/03). Europe is forced to adjust its attitude and legislatures to global trends of digitalization (EP, 2015, C421/03). In addition, the Council claims that citizens' expectations towards healthcare changed overtime, due to the ability of making use of more innovative health care approaches and people making more use of digital tools in their personal and professional lives in general (Council, 2015, C421/2). This changing expectation of society led the Council to also advocate for making use of digital opportunities that could improve data analytic capabilities, such as Big Data and AI, and ensure a more efficient cooperation.

The described developments within the Council and EP showed a slow shift from a certain level of reluctance towards a more positive attitude towards the implementation and usage of technological initiatives. Moreover, European institutions needed to fulfil the demands of European citizens and utilize the possibilities of digitalization to secure Europe's economic and political benefits. An example that substantiates the latter argument is found in the way in which the EU implemented the DSM strategy in 2015, to create a horizontal policy framework of digital technologies across its Member States (COM, 2015, 192). The implementation of the DSM strategy could be marked as a path dependent decision, because it was a milestone within the policymaking process towards digitalization. It exemplified the EU's desire to undertake action and make use of the opportunity of digitalization, in order to stay competitive at a global level, from both political and economic strategic perspective (SWD, 2016, 195).

Previous sections clearly described the shift within the EU towards a policy monopoly of developing knowledge on new digital technologies such as Big Data and AI. In the formulation of the Third Health Programme, there was hardly any attention for a data driven socioeconomic model. Yet as the empirical findings clearly showed, in 2016 the Commission, the EP and the Council advocated for developing more knowledge concerning Big Data, cloud computing and AI, because these technologies causing a fourth

industrial revolution (SWD, 2016, 195). Here it is argued that these technologies could help the EU to improve its public sector, for example, its Member States' health systems. This shows that the EU's policy process can be described as a continuum process between Member States, citizens and ideas within institutions and can alter overtime.

Yet, while in 2016 all three institutions advocated for a comprehensive approach towards expanding its knowledge of Big Data, AI and cloud computing, in 2017 all three institutions noted that the EU is lagging behind from a policy perspective as well as with regard to technological standards. The Commission argued that Big Data is largely unexploited between its Member States and argued that there is a serious lack of a standardized broadband, as well as a lack of a joint approach to achieve harmonization across the EU. Also, the EP and the Council noted that the EU is seriously lagging behind technological initiatives and failing in the objective to achieve an interoperable framework of data change between Member States. On a positive note, towards the usage of data in the policy process, all three institutions mentioned the implementation of GDPR as a proper tool to ensure the trust of citizens and their view towards protecting their privacy (EP, 2018, C11/55). Also, GDPR created guidelines to strengthen the overall data security and safeguard fundamental rights towards data protection (EP, 2019, 608.870). In the same time scale, a second positive trend regarding the data exchange across Europe is visible, namely the EP advocating for the implementation of ERNs across Europe that will increase the EU's ability to reduce the danger of complex diseases by exchanging expertise and knowledge (EP, 2019, C162/51).

So, there is a serious support within the three EU institutions to invest in its digital knowledge, however it needs to be discussed why the EU lacks to achieve its objectives. Here, the argument is twofold. First of all, Member States deliberately formulate their policies based on evidence but also on economic analyses such as 'cost-benefit analysis', as described by Nichol (2001) and Belsey (2009), concerning their planning and policy priorities for health threats such as influenza. In this case it can be stated that data exchange across borders in order to improve Member States' public health systems does not have the highest priority. Moreover, no Member State feels the urge to take the lead, because in doing so it would probably bear the highest burden by setting up such a costly data infrastructure. As such, the Member States have strong political objections to

implementing a health data framework because of a low public willingness to share their health data with public institutions in 2017 (Eurobarometer, 2017, 460). Besides this political threshold, we can identify an economic problem limiting the willingness to implement a health data framework. Around 2017 there is no clear economic incentive for Member States to set up an EU-wide IT infrastructure that is able to process high-performance computing and exploit the possible benefits of Big Data technologies, despite the fact that these developments are causing a fourth industrial revolution.

5.1.1. Logic of appropriateness towards data sharing across borders

As became evident in the previous section, Member States did not make sufficient efforts to establish an overarching infrastructure across Europe. Therefore, the EU needed to step into this vacuum of guiding an increased amount of data in the European society (OECD, 2013). Furthermore, the EU also have the mandate to ensure the public health of its citizens and therefore needs to take care of initiatives that could increase, for example, the overall computing capacity within Europe in order to identify infectious diseases before they become a threat to public health (Greer S. L., 2014; COM, 2017, 155). Hence, we can argue that the EU proposed the EHDS to improve its public policymaking and achieve its mandate to protect the public health (COM, 2018, 232). It was strengthened by the milestone/success of DSM strategy, that previously paved the way towards digitalization.

However, before the proposal of creating an overarching common data space throughout the EU was made, it was already mentioned by EU policymakers that leaders could take the initiative to secure a European leadership in the digital revolution. To do so, a larger budget to AI and Big Data had to be allocated in the agreement of a new MFF in 2021 till 2027. From the perspective of public scrutiny, we can argue that leaders and policymakers in general were unsympathetic to allocate a large amount of money to something as uncertain as a 'common data space', because investing in such a health data space would not be the most appropriate available policy option. The need to improve the protection of public health was not widely shared as the most suitable policy option according to the Eurobarometer in 2016 (ERPS, 2016). On the contrary, the public wanted to allocate a budget to tackle poverty and social exclusion (ERPS, 2016). That is one of the main reasons why there was less priority for policymakers to establish a common data

space, but they were willing to invest in technological initiatives such as AI and Big Data in order to make use of the technological opportunities and to stay competitive at a global level (SWD, 2016, 195). So, it can be argued that investing in a common data space to improve the existing public health framework was given less priority by EU-policymakers and political leaders before the COVID-19 outbreak. A summary of the most important findings concerning EU's health policy path before the COVID-19 outbreak is summarised below in Table 2.

Table 2. Overview of the most important findings before the COVID-19 outbreak

Concept	**Most important findings**
Agenda-setting of EU public policy	● EU institutions mentioning a 'digital revolution'. ● DSM strategy implementation. ● GDPR implementation. ● The EU needs to transform its attitude towards adapting technological AI and Big Data knowledge in order to stay competitive at a global political and economic level. ● Public expectations towards healthcare changed overtime and health care providers making more use of the available technological tools.
Critical junctures	● Not specific.
Window of opportunity	● The path of formulation of the MFF could be a window of opportunity to adjust more budget for improving technological knowledge.
Policy venues & policy monopoly	● Lack of economic incentive for Member States to create an overarching common data space throughout the EU. ● Investing in such a health data space would not be the most appropriate available policy option. ● The EU's mandate to ensure the public health of its citizens and therefore needs to take care of initiatives that could increase overall computing capacity within Europe in order to identify infectious diseases before they become a threat to public health. ● The EU proposed the EHDS to improve its public policymaking and achieve its mandate to protect public health.

Big Data	● A larger budget to AI and Big Data must be allocated in the agreement of a new MFF in 2021 till 2027. ● No specific knowledge on the level of government workers technological skills. ● Mentioned the situation of seriously lagging behind technological initiatives and failing in the objective to achieve an interoperable framework of data change between Member States.

5.2. Prevailing policy venues of public digital health within the three institutions and public opinion, after the COVID-19 outbreak

This section will discuss the impact of COVID-19 on the political narrative and the way in which it accelerated possible changes within society and policies from the perspective of PET. First of all, we can conclude that the COVID-19 outbreak affected the society negatively, because it is an enormous threat to public health globally, let alone that it has an immense impact on the current state of the global economy (Jones et al., 2021; Lal et al., 2021). Therefore, COVID-19 can be described as a critical juncture. It reshaped interests, changed the terms of debate and challenged the status quo of digitalization of health within European institutions and the society. Moreover, COVID-19 forced people to enhance digital opportunities and showed that geographical distance matters less, because people still can work remotely or still can make use of health care systems (COM, 2021, 118). COVID-19 thus accelerated different social and policy changes within the society, since it highlighted the importance of timely access to health data for policy and research purposes (COM, 2020, 7907993)

More specifically, COVID-19 can be discussed as a *critical juncture* for triggering the EU, together with its Member States, to implement advanced technologies, such as Big Data in health care. European policymakers were urged to formulate a quick and adequate response to the COVID-19 outbreak and therefore were forced to revise the MFF in May 2020. As such, COVID-19 acted as a *window of opportunity* to secure a digital transformation in the public sector. Substantiated by the EP, the momentum created by the pandemic could be used to set up the EU's ambitious plan towards digitalizing and upgrading its digital infrastructure and protection of data immediately (EP, 2021, C 18 I/02). One of the initiatives that the revised MFF supports is the legislation of EHDS that will be discussed at the fourth quarter of 2021, in order to reinforce the EU's capacity to

respond to future crises. According to the literature, a time of crisis is often followed by a period of stability (Cox, 2004). For example, the EHDS will probably be implemented as a binding decision in the policy venue of the EU and this situation correspondents with Timmermans and Scholten' idea of stability that will maintain new arrangements affecting the institutional cooperation between policymakers and experts and could eventually build a new policy monopoly (Timmermans & Scholten, 2006). The question now is whether the EU is capable of putting these theories into practice, as it is attempting by presenting its plan for 'NextGenerationEU'. Although the EU substantiates this plan that this is EU's moment and we are in the unique position of investing in a collective recovery and a better future for next generations (SWD, 2020, 98). The question remains to what extent this idea will be realized.

Moreover, moving to the data exchange between countries. More Member States and policymakers were willing to cut through the prevailing status quo of restrictions of data sharing between countries to push forward digitalization, especially on education and health concerns, and therefore were willing to allocate more budget to digital health in EU projects such as the EU4Healthplan (EP, 2021; EP, 2021, C 18 I/02). This change of behaviour is in line with the change of prevailing ideas within the public opinion. Despite the fact that in general the EU citizen was already feeling comfortable to share their data to improve medical research and care or to help other citizens and ultimately benefiting society (Eurobarometer, 2019), the public priority within the European society shifted towards the urgency to also allocate more budget to public health (Eurobarometer, 2021). An additional factor is also that the pandemic accelerated the usage of electronic health devices that increased the amount of Big Data bases (EP, 2020, 690.548). So, European institutions are forced to guide this amount of data properly in order to make use of its opportunities and protect the data of European citizens. Therefore, the Council insisted in 2020 to consolidate a joint effort between the public and private sector in order to establish a coherent data space, involving all important parties (Council, 2020, C 202 I/01). Despite the objective to facilitate a joint effort this study argues that the EU is too fragmented on several points that results in a strained collaboration across Member States, due to different approaches in governing and an incoherent data infrastructure constraints research, public institutions as also regulatory bodies to access health data (COM, 2020, 7907993).

All in all, the previous sections showed a clear outline of the ideas that are constantly developing in the European society and its institutions. This is a standard procedure and acknowledged by the theory of this study (see for instance the continuum process by McCormick, 2017). If we project this state of affairs on the current situation in the EU, we can argue that an overarching EU health network, in terms of an EHDS, is not ready for processing large amounts of data. This is to current ambiguous privacy concerns, a too fragmented Europe from an administrative perspective, absence of digital knowledge across Member States and a lack of a sufficient standardized data infrastructure across EU countries. However, COVID-19 created a certain degree of importance and willingness of policymakers and actors to exchange data in order to increase Europe's ability to respond to crises in the future and not miss out on the opportunities of the digital revolution to be competitive at a global level. The table below (Table 3) summarised the most important findings during the COVID-19 outbreak.

Table 3. Overview of the most important findings during the COVID-19 outbreak

Concept	**Most important findings**
Agenda-setting of EU public policy	● Possible implementation of the EHDS legislation in the 4th quarter of 2021. ● NextGenerationEU
Critical junctures	● COVID-19 pandemic
Window of opportunity	● MFF 2021 - 2027 to secure digital transformation. ● EU4HealthPlan to implement legislation to accelerate the digitalization of health care facilitates and data exchange between Member States.
Policy venues & policy monopoly	● Support integration and use of trans-European digital infrastructures. ● Fragmentation of digital standards and limited digital interoperability between member states and their healthcare systems.

	• Importance of having timely access to health data for research and policy-making purposes. • The EU must reinforce their digital capacity to ensure its global competitiveness. • Cut through the international red tape that normally restricts data sharing between countries. • The society is forced to work remotely and must enhance digital opportunities and get more well-known with the possibilities of digital technologies.
Big Data	• Accelerating the knowledge of priority areas of AI, Big Data and cybersecurity to enable several things such as: technological EU sovereignty, a successful digital transformation and ensuring Europe's competitiveness at a global level. • Lack of digital knowledge by European citizens causing a problematic situation of needed ICT experts in the EU. • The pandemic accelerated the usage of electronic health devices by citizens that increased the amount of Big Data bases.

5.3. Summary of findings

The objective of this study was to research if the COVID-19 pandemic caused a *window of opportunity* for policymakers to implement new technological opportunities (e.g., Big Data) in the current European health framework. In H1 we stated that this happened in the formulation of the EU4Healthplan and there is evidence suggesting that the pandemic caused an ideational change towards the usage of Big Data in the EU. This is due to two reasons. On the one hand you have the situation that people are pushed to work remotely, thus getting more comfortable with a 'digital' situation. This constitutes the positive side of the pandemic. It developed a prevailing idea that more things, such as making use of health care systems, should be within easy reach and therefore must be digitalized (COM, 2021, 118). On the other hand, Member States and policymakers are being forced to cut

through the so-called 'red tape' of data sharing at a European level in order to tackle the pandemic and future crises in a proper way. From this perspective it can be argued that the COVID-19 pandemic accelerated the usage of technologies such as Big Data and became a more common part of society. Member States were being forced to become more familiar with the challenges and opportunities of incorporating these technologies in their economic, social and political systems as also their health systems. Thus, the COVID-19 outbreak pushed both citizens, Member States and policymakers to adopt a positive attitude towards digitalization and sharing information in terms of big datasets.

The pandemic thereby challenged and altered the prevailing understanding of data usage in the society, while also making visible its vulnerabilities. However, it is crucial to discuss the possible adoption or rejection of H2 to formulate a proper answer on the possible slow ideational change within EU institutions concerning the implementation of Big Data in health systems across borders. This study widely discussed the situation and prevailing ideas of using Big Data for health purposes, within The Commission, The European Parliament, the Council and public opinion before the outbreak of COVID-19. A policy path can also be part of a slow change of ideas overtime (see for instance Moschella 2015; Leppo et al., 2013). In 2015, with the establishment of DSM by former President of the European Commission Jean Claude Juncker, the EU enhanced a digital Europe, encompassing all aspects of the EU including the usage of digital technologies in the public health sector. At the same time, the EU implemented the GDPR across the EU, to guide large amounts of data and to strengthen confidence in society for using data in the policymaking process (EP, 2018, C11/55). Subsequently, in 2017 all three institutions encouraged policymakers and companies across Europe to implement more Big Data, AI and cloud computing initiatives (SWD, 2018, 305). However, the three institutions faced a serious lack of coherency between Member States: although striving for the same objective, namely an interoperable infrastructure, the problem was a serious level of fragmented digital standards from an administrative perspective. Therefore, the EU institutions tried to establish a 'common data space' across its Member States in 2018, but the latter were reluctant to do so because of a high level of public scrutiny (COM, 2018, 232). Also, with regard to public health specifically, the EP and the Council advocated to implement ERNs across Europe to reduce the possible danger of complex disease by

sharing data in terms of knowledge and expertise and was already legislated before the COVID-19 outbreak (Council, 2011, L 88/45; EP, 2019, C162/51).

From this perspective it is of course hard to say what the future without COVID-19 had led us to, but what we can say is that the prevailing idea of using Big Data and other digital technologies was already present within European institutions and is in line with H2. However, its implementation was held back due to reluctancy among Member States. It can be argued, however, that COVID-19 was the milestone necessary to convince Member States and policymakers to formulate a legislation for a novel digital infrastructure and enhance the possibilities of digital technologies such as Big Data in order to reinforce its capacity to respond to future crises and is in line with H1. As such, for a long time it was not expected that an interoperable European public health framework, that encouraged the access to and use of health data for research, policymaking and regulation, could be facilitated because of EU's policy cycle implications and its institutional environment but due to the COVID-19 outbreak it will most probably be legislated in the immediate future.

6) Conclusion

To conclude, this study has shown that from a PET perspective it can be argued that COVID-19 generated a *window of opportunity* in EU institutions and for policymakers to move towards the implementation of a framework of advanced digital technologies such as Big Data across Europe. Due to a growing public demand and clear political and economic incentives, that were accelerated by the COVID-19 outbreak, Member States were more willing to implement a novel (Big) data infrastructure across its Member States by the formulation of an EHDS that will most probably be legislated at the fourth quarter of 2021. The study also confirmed the argument that Europe is built on crises, as described by McCormick and Jean Claude Monet in the beginning. The COVID-19 outbreak gained momentum of the EU's administrative apparatus and accelerated digital health related policy initiatives such as the formulation of the EHDS.

Moreover, the main objective of this study was to compare the prevailing ideas in the EU institutions on using Big Data to protect the EU public health before and during the COVID-19 pandemic, via a process-tracing method. This method showed that prevailing ideas of

making use of Big Data were already high on the European policy agenda. To substantiate this, the study described the path of the EU policy making process towards the idea of establishing a data exchange framework across Europe. It outlined that EU institutions were implementing several policies; first of all, the EU legislated the GDPR in 2015 in order to gain trust in the European society to make use of data in the policy making process as also to guide large data sets. Secondly, EU policymakers formulated policies to facilitate ERNs across Europe. Lastly, policymakers are slowly moving to the situation of prioritizing a 'common data space' to secure the EU's resilience at a geopolitical level that could be a tool to protect the public health. So, this study showed that if a policy process is affected by a critical juncture, it does not mean that it will cause a clear shift of prevailing ideas, as being argued by scholars in the field of Public Administration such as Demers (2007) but a critical juncture could accelerate certain dormant ideas in institutions.

In short, the previous paragraph argued that ideas that were dormant in the EU institutions could, with the help of a critical juncture, be formalized in a specific legislation as we have seen in the form of the EHDS and the altered MFF affecting the EU4Healthplan in a positive way regarding the allocation of budget to formulate policies that will foster the data exchange across Europe. Due to the fact that Member States had clear economic (economy shrunk by 4.4%) and political (a changing public opinion on health) incentives to implement a Europe wide infrastructure. Thus, it is problematic to conclude that we face a new policy monopoly within EU institutions, but we can argue that COVID-19 accelerated the formulation of dormant ideas on Big Data in EU legislation in order to fulfil the EU's mandate of protecting public health.

Yet, this study outlined some mismatches, because it became clear that the EU is lagging behind on technological knowledge that causes a problematic situation of needed ICT experts. So, at this moment there is a mismatch between the EU's willingness to compete at a global digital level and enhancing large datasets to improve its policymaking process, while government workers have not largely adopted new sets of skills in order to understand how to work with big and varied data sets. Also, this study outlined that the EU is too fragmented at a legislative and administrative level in order to facilitate a standardized data infrastructure across Europe at this moment, but there is an opportunity that this will decrease after the implementation of the EHDS across Europe.

6.1. Recommendations for future research

The design can be criticized due to the possibly biased way of conducting information that is subjected to the need of interpretation of human cognition and action (Yang & Miller, 2008, p. 145). Therefore, this study could possibly have some degree of subjectiveness, due to the interactive link between the investigator and the documents of the EU that were acting as the investigated object. Thus, this study recommends casting an eye once again over the documents of the European Commission, European Parliament, the Council and the Eurobarometer from a PET perspective in order to eliminate a possible degree of subjectiveness in this study. In addition, the study could be extended by public opinion surveys that comply seamlessly with the objective of this study to measure the effect of the public opinion on the prevailing policy ideas within the EU. Because in this study the Eurobarometers being used did not always comply with the purpose of this study.

Also, future research is recommended in a way of analysing the implementation of the EU4Healthplan and the EHDS after the COVID-19 outbreak, during a period that can be characterized by a certain degree of stability. This will be of added value, because it will provide clear insights on the EU's policy cycle in a period just after a critical juncture. As well as it can be explored if the policy monopoly of digital transformation in the field of health care remains and it can elaborate on the exposed mismatches provided by this study concerning the implementation of a standardized data infrastructure across Europe.

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