A Social Network Analysis of the COVID-19 Vaccine Development and Procurement Stakeholder Ecosystem in the European Region.

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Abbreviations

BMGF - Bill and Melinda Gates Foundation

CEPI - Coalition for Epidemic Preparedness Innovations

CSO - Civil society organisation

DAC - Development Assistance Committee

EC - European Commission

EEA - European Economic Area

EMA - European Medicines Agency

EU - European Union

GAVI - Global Alliance for Vaccines and Immunisations

HERA - Health Emergency Preparedness and Response Authority

HPV - Human papillomavirus

IPR - Intellectual property rights

IPPPR – Independent Panel for Pandemic Preparedness and Response

JPA - Joint procurement agreement

MHRA - Medicines and Healthcare Products Regulatory Agency

NGO - Non-governmental organisation

OECD - Organisation for Economic Development and Cooperation

OECD DAC - Organisation for Economic Development and Cooperation's Development Assistance Committee

R&D - Research and development

SNA - Social network analysis

UK - United Kingdom

UK VTF - UK Vaccine Taskforce

WHO - World Health Organization

2 d.p. - 2 decimal points

Abstract

Introduction: The European COVID-19 vaccine development and procurement stakeholder ecosystem is composed of multiple stakeholders and partnerships. Considering the vitality of vaccines in pandemic preparedness, the strengths and weaknesses of the existing ecosystem ought to be analysed. This thesis does the above and provides recommendations for Disease X vaccine ecosystems.

Methods: A social network analysis was conducted using mixed-methods (i.e., quantitative and qualitative). A document analysis of databases, press releases and policies informed the social network graphs and calculations which quantified network characteristics and key stakeholders. Five key-informant interviews were conducted with CEPI staff and analysed according to the OECD DAC evaluation criteria.

Results: The overall network calculations (average degree (9.09) and path length (2.66)) indicated an interconnected ecosystem. Vaccine manufacturers were more prevalent within the network but vaccine developers were more influential. Key stakeholders were EC, EMA, CEPI, WHO, UK VTF and AstraZeneca. The ecosystem scored well in the OECD criteria of relevance, efficiency and impact. Coherence and effectiveness of the ecosystem could be improved. The sustainability criteria achieved the lowest score.

Conclusion: Strengths of the European COVID-19 vaccine ecosystem were agility in time, cost and resource use, increased collaboration between stakeholders and the positive impact of philanthropic organisations. Ecosystem weaknesses were stakeholder alignment, the manufacturing supply chain, and rigidity of EU procedures. Considering the influence of vaccine developers in the network, their democratic accountability must be given due consideration in future ecosystems.

Keywords: COVID-19 vaccine; stakeholder ecosystem; Europe; network analysis; vaccine development.

1. Introduction

1.1 Topic Relevance

COVID-19 is an infectious disease caused by the SARS-CoV-2 virus which first emerged in Wuhan City, China, in December 2019 (Baldwin & Mauro, 2020). It has since become a global pandemic. The SARS-CoV-2 virus pandemic has to date claimed countless lives and brought the world to a standstill (Baldwin & Mauro, 2020). In view of concerns around increasing cases throughout the past year, as well as effective but unsustainable and socioeconomically damaging mitigation efforts such as lockdowns and curfews, vaccination has become society's main hope to overcome the pandemic (Baldwin & Mauro, 2020). A vaccine is a substance that stimulates the production of antibodies and generates immunity against a disease (WHO, n.d.). The COVID-19 vaccine provides immunity against the disease caused by the SARS-CoV-2 virus. Stakeholders working to develop and procure (meaning purchase) COVID-19 vaccines have played a vital role in this pandemic.

The development and procurement of any vaccine requires partnerships between several stakeholders, like vaccine developers, manufacturers, academic institutions, philanthropic organisations (including civil society organisations (CSOs), non-governmental organisations (NGOs) and organisations funding research), regulators, national governments and supranational institutions (such as the European Union (EU) institutions) (Kamya et al. 2016). Some stakeholders are likely to hold more influence than others. The implications and accountability of such stakeholders are of interest. In the European region (herein defined as the European Union (EU), European Economic Area (EEA), Switzerland and the United Kingdom (UK)), there is a high degree of collaboration between all the above-mentioned stakeholders which forms a complex ecosystem (Kamya et al., 2016). Collaboration, in this context, is defined as the working together and formation of partnerships between stakeholders to tackle aspects of COVID-19 vaccine development and procurement. The exact purpose of stakeholder partnerships varies. All of the above-mentioned stakeholder partnerships together are referred to as an ecosystem or network (Kamya et al., 2016). Such an ecosystem also exists for COVID-19 vaccine development and procurement.

It is important to capture, illustrate and analyse such ecosystems to understand which stakeholders are involved in vaccine development and procurement and the consequent implications. This permits a characterisation of the strengths and weaknesses of partnerships formed between these stakeholders (Luke & Harris, 2007). Such an analysis can help draw lessons from existing ecosystems and identify areas that require further study in order to be better prepared for future pandemics. Pandemic preparedness (which includes efficient vaccine stakeholder ecosystems) helps ensure sufficient

preventative measures, including vaccines, are in place to minimise deaths and the overall negative impacts of pandemics (Simpson, Kaufmann, Glozman & Chakrabarti, 2020).

Recent initiatives to accelerate vaccine development emphasise the need to analyse and improve vaccine stakeholder ecosystems (Simpson et al., 2020). The World Health Organization (WHO)'s 'Research and development (R&D) Blueprint' for example, was established in 2016 for specific diseases that pose a public health threat due to their pandemic potential (WHO, 2020). It offers a global preparedness plan to fast-track the availability of diagnostics, vaccines and medicines during epidemics (WHO, 2020). It has listed 'Disease X' - a currently unknown, generic infectious agent that has suspected catastrophic, pandemic potential - as a priority area to accelerate research of yet unknown but encroaching infectious disease threats (Simpson, 2020; WHO, 2020). With these efforts to catalyse pandemic preparedness research comes the reactivation of the above-mentioned ecosystems to facilitate vaccine development and procurement for Disease X. To improve the efficiency of this future ecosystem, it is essential to capture the relevant stakeholder partnerships such ecosystems need to include. This can be done through analysing the stakeholders and partnerships engaged in existing vaccine stakeholder ecosystems. Lessons learned can be extracted from existing networks to improve the efficiency of future Disease X networks. The current COVID-19 vaccine development and procurement ecosystem presents the ideal opportunity for such analysis, to understand the strengths and weaknesses of existing vaccine stakeholder partnerships. This knowledge will allow stakeholders to establish more robust ecosystems and pandemic preparedness measures for Disease X.

It is especially interesting to study such a stakeholder network in Europe (meaning the European region) due to Member States sharing a higher degree of collaboration and interdependence (ECDC, 2020; EC, 2021). Importantly, within the European region, the EU is a supranational authority meaning EU law supersedes national law. This unique organisation results in a complex interplay between actors, as evident in COVID-19 where the Commission purchased vaccines centrally on behalf of all EU Member States (EC, 2021). The implications of this arrangement ought to be analysed.

1.2 Status Quo and Research Gap

One method of investigating stakeholder ecosystems is to conduct a social network analysis (SNA) (Luke & Harris, 2007; Scott, 2012). SNAs typically entail social network graphs and calculations which are at times paired with qualitative analysis methods (Kamya et al., 2016; Scott, 2012). Social network analyses have demonstrated utility in characterising past vaccine ecosystems (Scott, 2012).

SNAs conducted during the HIV/AIDS pandemic and the human papillomavirus (HPV) vaccine ecosystem allowed for the identification of key stakeholders and the types of partnerships which facilitated better vaccine procurement and delivery (Kamya et al., 2016; Soi et al., 2020). SNAs allow one to quantitatively analyse individual partnerships within networks of stakeholders or people.

Despite their utility, public health SNAs have, to date, been infrequently conducted across socioeconomically linked states such as those in the European region (Kamya et al., 2016; Soi et al., 2020). Indeed, in the case of COVID-19 vaccine development and purchase, an SNA of the relevant stakeholders within the European region is yet to be conducted. Consequently, it is difficult at present to have a clear view of this ecosystem – limiting our understanding of the functioning of stakeholder partnerships within the European region and how they facilitate vaccine development and procurement. This gap must be addressed to better assess the potential impacts of the existing collaborations upon pandemic preparedness. The knowledge acquired from this thesis can be used to issue recommendations and develop more efficient preparedness measures including efficient vaccine ecosystems for Disease X. An efficient Disease X vaccine stakeholder ecosystem will ensure efficacious vaccines are developed faster and thereby reduce the catastrophic societal, economic and health impacts of a potential Disease X pandemic (Simpson et al., 2020).

1.3 Research Aims and Questions

This thesis aims to foster a better understanding of the European COVID-19 vaccine ecosystems' strengths and weaknesses to help inform a more efficient European vaccine ecosystem – one fit to provide Disease X vaccine(s). A social network analysis of the existing COVID-19 vaccine development and procurement stakeholder ecosystem in Europe (also referred to as the COVID-19 vaccine ecosystem) was conducted to identify inefficiencies in the network. Research findings were used to make recommendations for vaccine development and preparedness for Disease X.

This thesis was guided by the following research questions:

- *To what extent do current European partnerships and key stakeholders facilitate COVID-19 vaccine development and procurement?*
- *What are the strengths and weaknesses of the COVID-19 vaccine development and procurement ecosystem in the European region?*
- *How can European networks be improved for future Disease X vaccine development and procurement ecosystems?*

2. Background Information and Relevant Notions

This chapter provides background information and introduces notions relevant to the research topic(s) which are discussed in subsequent chapters.

2.1 Social Network Analysis

This thesis conducts a social network analysis of the COVID-19 vaccine ecosystem. Network analysis has a long history and has evolved as an outcome of contributions from different disciplines (Luke & Harris, 2007). After the concept was initially discovered by a mathematician in the eighteenth century it has become the focus of research of many social scientists (Luke & Harris, 2007). Since the 1970s, SNAs have become increasingly popular in the field of public health (Hawe, Webster & Shiell, 2004). SNAs of public health organisations have been less common in the past, but are increasingly viewed as useful (Luke & Harris, 2007). Network analyses of public health organisations conducted during the HIV/AIDS pandemic and on the HPV vaccination were deemed invaluable (Luke & Harris, 2007; Soi et al., 2020). For example, network analyses of the HPV vaccine ecosystem revealed that the geographic location of technical assistance providers (such as WHO and the Global Alliance for Vaccines and Immunisations (GAVI)) impacted the success of vaccine delivery and that GAVI was a key facilitator of vaccine delivery (Soi et al., 2020).

A social network consists of actors that represent individuals or organisations (Hawe et al., 2004). An analysis of this network therefore involves the study of relational data (Hawe et al., 2004). SNAs are grounded in empirical data and provide graphical representations of the linkages between actors (Luke & Harris, 2007). A social network graph is the most commonly used method for an SNA. It allows one to visualise stakeholder ecosystems and the individual partnerships which compose them (Scott, 2012). This allows not only for an understanding of whom a certain stakeholder is paired with, but also for the identification of weaknesses within the network (Luke & Harris, 2007). Using software, network calculations can be conducted on this graph which provide a quantitative understanding of network features (such as connectivity between stakeholders) and key actors (Scott, 2012). Network graphs and calculations are frequently paired with qualitative analysis methods such as interviews with stakeholders involved in the ecosystem (Kamya et al., 2016). Interviews provide in-depth insights into the inner workings of the network – thus offering explanations behind the quantitative trends observed and further identifying strengths and weaknesses (Scott, 2012). Luke & Harris (2007) believe SNAs provide a base for future research and evidence-based recommendations. This thesis too aims to use the SNA to identify areas requiring further research and provide recommendations to improve Disease X ecosystems.

2.2 Process and Partnerships of Vaccine Development and Procurement and Changes During COVID-19

2.2.1 Processes and Partnerships of Vaccine Development and Procurement

Figure 1 describes the traditional processes of vaccine development and procurement. Stakeholder partnerships must be established to complete said processes (Smith, Lipsitch & Almond, 2011). Before investigating the strengths and weaknesses of the COVID-19 ecosystem, one must understand the processes and partnerships which typically constitute vaccine ecosystems.

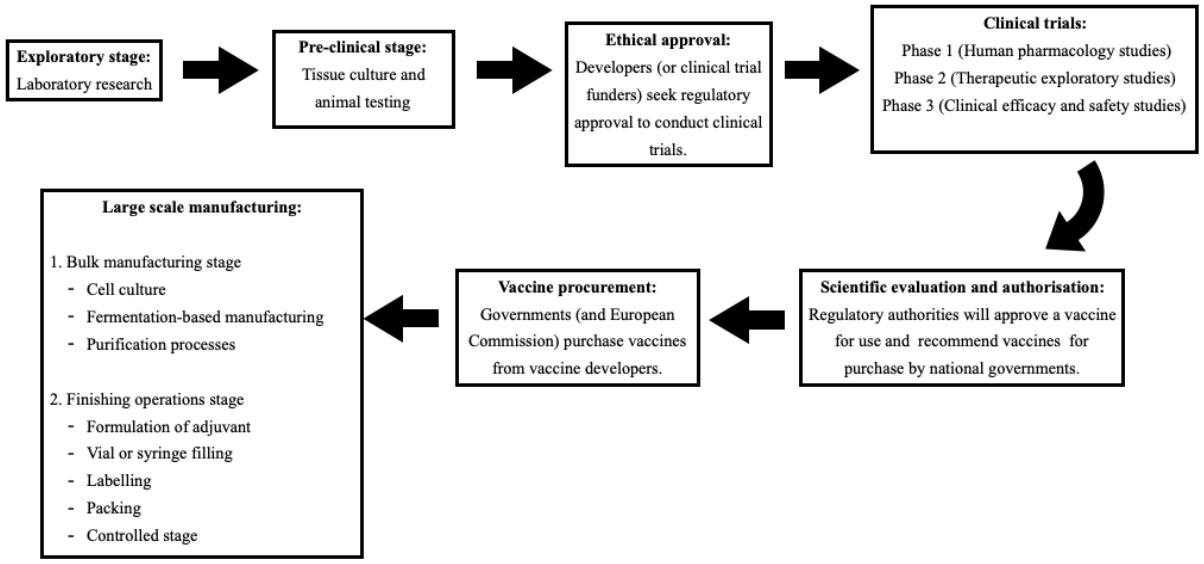

Figure 1: Stages of vaccine development and procurement
(Note: Diagram created by author) Information taken from: Douglas & Samant, 2018; Glanville, 2021; Gomez & Robinson, 2018; Sanofi, 2017.

Initially, basic research is undertaken to identify a specific pathogen that bears the potential to prevent disease (Glanville, 2021). Once a potential antigen has been developed it is tested in tissue or cell culture systems and animals (Glanville, 2021). Pharmaceutical companies usually rely on academia or small biotechnology companies to conduct research during the exploratory and pre-clinical stages (Rosenblatt, 2013). Nonetheless, pharmaceutical companies often provide grants and infrastructure support to assist with the costs of exploratory research (Rosenblatt, 2013).

If the vaccine is found to be safe during animal trials, it will be tested on humans in clinical trials (Glanville, 2021). Vaccine developers must seek ethical approval from national regulatory authorities to conduct clinical trials in those countries (Douglas & Samant, 2018). During clinical trials, the vaccine is administered to groups of people in three successive phases to observe human effects of the vaccine (Glanville, 2021). Based on the results of the previous phase, each phase increases the

number of participants involved and increasingly includes those with underlying health conditions (Glanville, 2021). Typically, only once clinical trials have started do larger pharmaceutical companies become involved. However, some multinational companies conduct vaccine research themselves (Rosenblatt, 2013). Pharmaceutical companies use partner university hospitals to recruit clinical trial participants (Rosenblatt, 2013). Late-stage vaccine development entails high financial risk and therefore vaccine developers are frequently funded by global organisations to develop vaccines against emerging infectious diseases for which there is no private market and hence no return on investment (Douglas & Samant, 2018; Excler, Privor-Dumm & Kim, 2021).

If a vaccine proves safe and efficacious in clinical trials, the developer then seeks scientific evaluation and approval from regulatory authorities (Glanville, 2021). Although national regulatory authorities can approve vaccines for use within their member state, developers can also seek regulatory approval from the European Medicines Agency (EMA) who is able to regulate a vaccine for use across all EU and EEA Member States (Glanville, 2021). This stage often involves an iterative dialogue between regulatory authorities and vaccine developers before the final regulatory approval is granted (Douglas & Samant, 2018). Once a regulatory authority has approved a vaccine, it will issue recommendations to national governments (Glanville, 2021). Based on these recommendations, government authorities enter agreements with vaccine developers to procure vaccines (So & Woo, 2020).

Simultaneously, vaccine developers establish contracts with vaccine manufacturers to begin large-scale manufacturing of the vaccine (Glanville, 2021). However, vaccine manufacturing itself is composed of two overarching categories each containing multiple steps. Bulk manufacturing includes cell culture and/or fermentation-based manufacturing followed by purification processes (Gomez & Robinson, 2018). The finishing operations stage includes formulation of the adjuvant if applicable, vial or syringe filling, labelling, packing and the controlled stage (Gomez & Robinson, 2018). Each manufacturer is usually responsible for only some stages (Gomez & Robinson, 2018; Sanofi, 2017). Therefore, in the manufacturing stage, vaccine developers must establish partnerships with multiple manufacturers (So & Woo, 2020). Each vaccine manufacturer in turn also conducts their designated stage for more than one vaccine developer (So & Woo, 2020). To multiply the complexity of this chain, manufacturers at each stage depend on the outputs of manufacturers who are contracted to conduct stages prior to theirs (Yadav & Weintraub, 2021). Lastly, the safety standards of all manufacturers must be assessed by national regulatory authorities. In recent years, to alleviate bottlenecks, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill and Melinda Gates Foundation (BMGF) have provided financial assistance at the manufacturing stage (Douglas & Samant, 2018; Excler et al., 2021).

Figure 2 illustrates the above discussed partnerships which form a vaccine development and procurement ecosystem. This thesis aims to identify the all partnerships and stakeholders shown below which contributed to COVID-19 vaccine development and procurement.

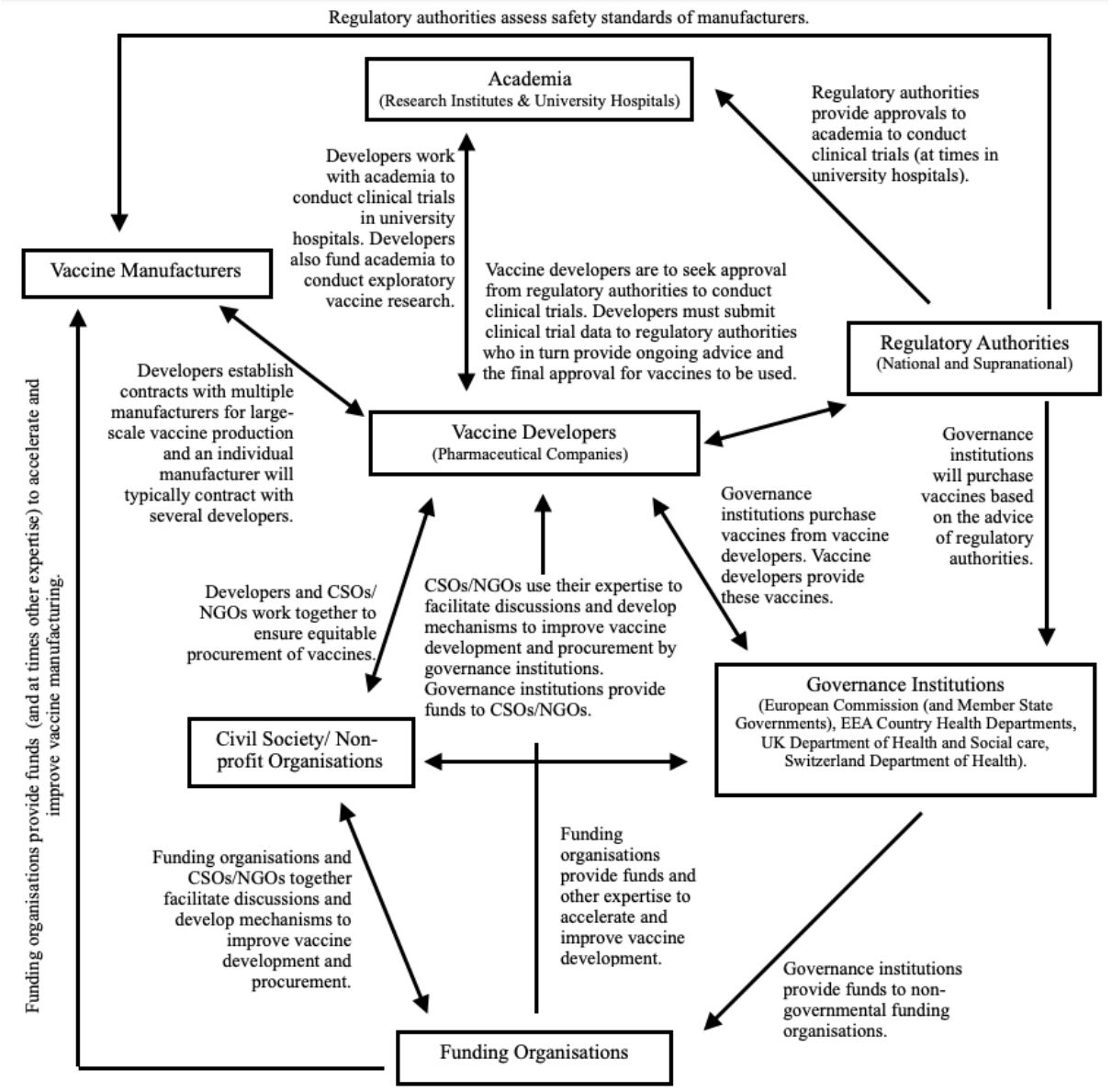

Figure 2: Vaccine ecosystem partnerships

(Note: Diagram created by author) Information taken from: Smith et al., 2011; Rosenblatt, 2013; So & Woo, 2020.

2.2.2 Unique Mechanisms/ Partnerships Employed in COVID-19

The processes and partnership structures related to vaccine development which were adapted during COVID-19 are described below.

Simultaneous Stages

Many of the stages described above were conducted in parallel to accelerate vaccine development and procurement (Glanville, 2021). For example, the clinical trial phases overlapped slightly (Glanville, 2021). Scientific evaluation was conducted on ongoing clinical trial data (Glanville, 2021). And prior to receiving scientific authorisation, large-scale manufacturing had begun and vaccine developers had negotiated deals for the procurement of vaccines with Member States (Glanville, 2021).

COVID-19 Taskforces

Certain organisations and governments have demonstrated agility through the establishment of COVID-19 taskforces (Hoen, Garrison, Boulet, Mara & Perehudoff, 2021). Agility here refers to the ability to adopt an interdisciplinary approach and act with flexibility to achieve better outcomes. The UK vaccine taskforce (UK VTF) membership for example convenes experts from the pharmaceutical industry, civil servants and scientists to establish a targeted, harmonised approach to secure access to vaccines for the UK population (Bingham, 2021; Hoen et al., 2021). Similarly, the EMA has established an expert taskforce combining EMA scientific committees to efficiently coordinate discussions around the evaluation and authorisation of medicinal products and vaccines (EMA, 2020). These taskforces were formed to improve the efficiency of processes (Bingham, 2021; EMA, 2020; Hoen et al., 2021).

European Union Action

During the COVID-19 pandemic, EU Member States decided that the EC - through the Joint Procurement Agreement (JPA) - will procure vaccines centrally on behalf of all EU countries (McEvoy & Ferri, 2020). However, the EU shares the competency of 'safety concerns in public health' with EU Member States and only has supporting competence in the 'protection and improvement of human health' (EC, 2012, Treaty 2012/C 326/01). This means the EC can only support or complement EU country activity suggesting the EU has limited legislative powers in the realm of healthcare (McEvoy & Ferri, 2020). The efficiency of central vaccine procurement, despite limited EU competencies, is interesting to study.

In 2021, the EU plans to establish a permanent Health Emergency Preparedness and Response Authority (HERA). HERA aims, amongst other things, to coordinate a European response to future pandemics, accelerate vaccine development and run joint procurements (EC, 2021). The recently

established HERA incubator, which focuses on new COVID-19 strains, is to serve as a blueprint for the permanent HERA (EC, 2021; Hoen et al., 2021). The anticipated significance of HERA for future ecosystems is of interest.

2.3 Democratic Accountability of the Pharmaceutical Industry

In this thesis, democratic accountability (also known as accountability) refers to the ability of the general public to (directly or indirectly) voice concerns and demand explanations on decisions undertaken by vaccine developers (Timmis, Black & Rappouli, 2017). This thesis simply aims to spark discussion about the relevance (and hypothetical risks of) democratic (un-)accountability in vaccine ecosystems with the main goal of encouraging future networks to give consideration to the topic. The vast majority of vaccine developers in this ecosystem are pharmaceutical companies and thus these terms are used interchangeably.

As indicated in figure 2, vaccine developers play a central role within this ecosystem (Hart, 2018). Since vaccine developers are private sector companies their decisions are not made democratically (Timmis et al., 2017). The democratic un-accountability of pharmaceutical companies means these stakeholders are free to act without public consent and the public is unable to hold them accountable (Dukes, 2002; Hart, 2018). Although un-accountability is common practice across all private sector companies, its implications are of particular relevance in the healthcare industry where public priorities are the driving force (Timmis et al., 2017). Un-accountability increases the risk that the agenda of pharmaceutical companies is not aligned with public priorities since public opinions have not been consulted (Dukes, 2002). Examples of outcomes include unaffordable pricing or the development of vaccines which do not address global health threats (Hart, 2018). On the other hand, too much accountability can delay vaccine developers from acting rapidly during emergencies and hinder their ability to innovate vaccines and drug technologies (Keohane, 2002). Thus, this thesis does *not* perceive democratic unaccountability as a critique but rather an aspect deserving consideration.

The difficulty lies in establishing mechanisms which increase accountability of pharmaceutical companies without hampering their freedom to innovate. One mechanism to tackle this conundrum entails closer collaborations between public sector (e.g., NGOs) and industry stakeholders through which the public sector stakeholders can ensure pharmaceutical company decisions are aligned with public priorities (Doh & Guay, 2006; Dukes, 2002). However, exactly which stakeholders are best positioned to do this within vaccin ecosystems remains unclear. Extensive research on the topic reveals public sector and non-profit stakeholders have a high degree of accountability. Therefore, their accountability is not discussed (Keohane, 2002; Wapner, 2002).

3. Methodology

Research nature, type and design

This thesis embarks on a cross-sectional, social network analysis using mixed methods to analyse the European COVID-19 vaccine development and procurement stakeholder ecosystem. This methodology is justified since it provides a quantitative and qualitative overview of the ecosystem. Past vaccine stakeholder ecosystems have also found utility in conducting SNAs (Kamya et al., 2016).

This SNA was conducted based on information collected using a document analysis identifying the relevant stakeholders and the partnerships in which they engage. The ecosystem was evaluated quantitatively through a visual inspection of the network graph and through network calculations. Simultaneously, a qualitative analysis was undertaken by conducting key-informant interviews to understand the inner workings of partnerships. Interviews revealed the implications of characteristics identified in the quantitative analysis. The content of the key-informant interviews was interpreted through the application of the Organisation for Economic Development and Cooperation's Development Assistance Committee's (OECD DAC) evaluation criteria. The specific methods are described in detail in this chapter. Figure 3 below provides a summary of the methodology.

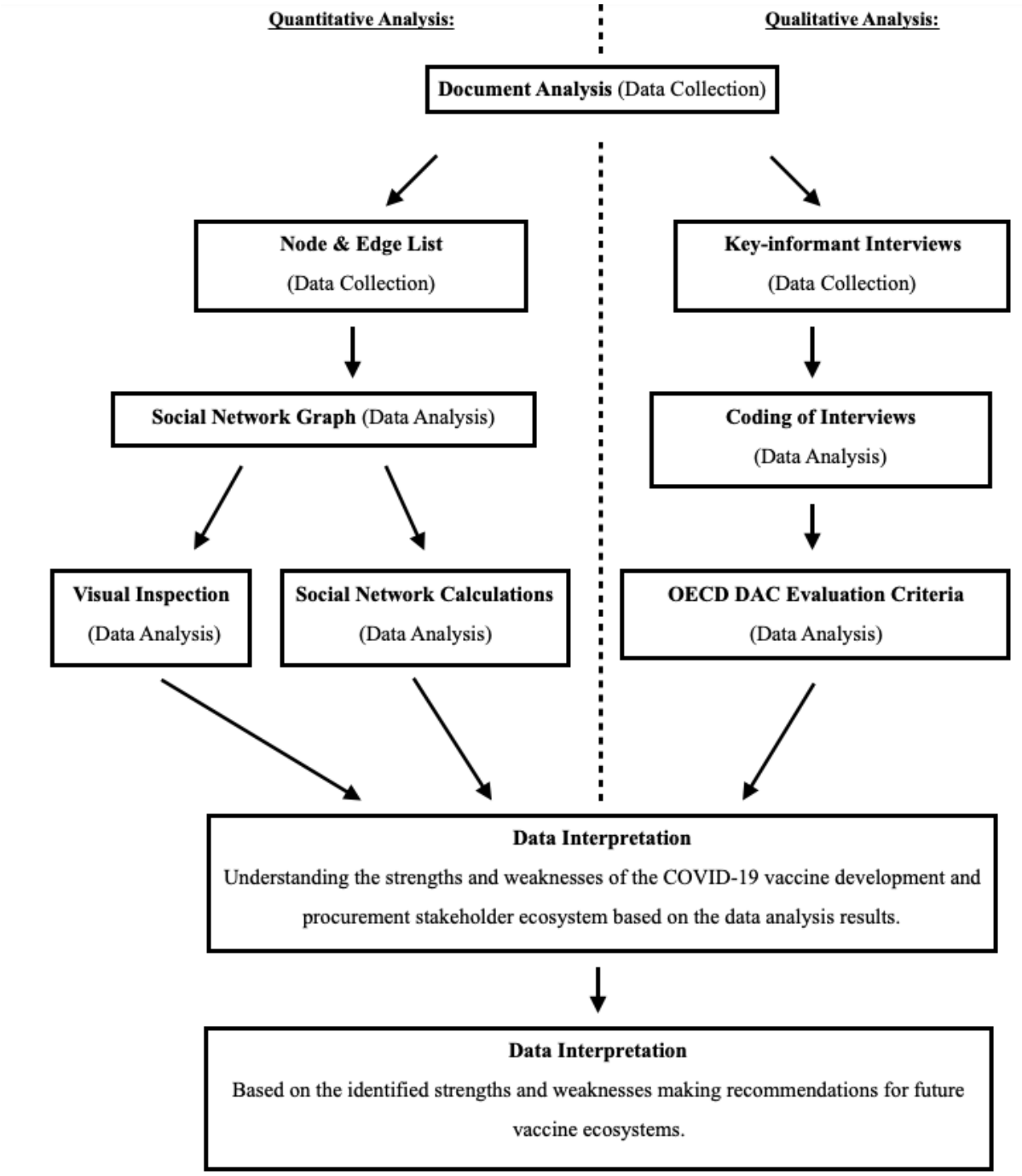

Figure 3: Methodology flowchart

(Note: Diagram created by author.)

3.1 Document Analysis (Data Collection)

To conduct an SNA of the European COVID-19 vaccine stakeholder ecosystem, the stakeholder partnerships outlined in figure 2 were searched in this document analysis. The WHO's 'Candidate COVID-19 Vaccine Draft Landscape Database and Tracker' (as updated on 1st February 2021) was utilised first to guide the search for vaccine developer partnerships for vaccines in the clinical trial stage (WHO, 2021). All vaccines which had at least one developer in Europe were retained. Following this, the UNICEF 'Vaccine Market Dashboard' and the Global Health Centre's database on 'COVID-19 Vaccine Purchasing and Manufacturing Agreements' were used to identify manufacturing and procurement partnerships across the European region (Global Health Centre, 2021; UNICEF, 2021). The Economist 'COVID-19 Health Funding Tracker', the 'EU Clinical Trials Register' and 'MHRA Register of Licensed Human Manufacturing Sites' were also used to identify funding, clinical trial and manufacturing stakeholder partnerships, respectively (Economist, 2021; EMA, 2021; MHRA, 2021). Only European stakeholders (defined as stakeholders within the EU, EEA, Switzerland and UK) were studied in all databases.

The European Commission, EEA countries', UK and Swiss government websites were then searched to find government policies or communications to the public detailing procurement partnerships. Lastly, the websites of each stakeholder identified through the above databases and government policies, were searched individually to locate relevant press releases detailing additional partnerships. The keywords and documents described in table 1 were used to search stakeholder websites. Each time a new stakeholder was identified in the search, the website of the newly identified stakeholder was also searched until the websites of all identified stakeholders in the network were searched. Table 1 describes which documents were expected to indicate certain partnerships, where these documents were searched, and the key words used when conducting the document search. The keywords below were chosen since they were considered sufficiently explicit to yield search results about COVID-19 vaccine partnerships.

Table 1: Search strategy and keywords for data collection

Partnership type	Document type	Source	Keywords
Development partnerships	Press releases	Developer website, academic institution website	Coronavirus vaccine; vaccine partnership; COVID-19 vaccine; COVID-19; vaccine. Sometimes partner/ vaccine names identified from the WHO landscape map were directly searched.
Manufacturing partnerships	Press releases	Developer website, manufacturer website	COVID-19 vaccine; manufacturing; COVID-19 vaccine developer; vaccine; COVID-19; coronavirus; manufacture.
Procurement partnerships	Government policy, Commission policy, press releases	Government website, developer website	Coronavirus vaccine policy; COVID-19 vaccine; vaccines purchased; COVID-19; vaccines.
Philanthropy partnerships (incl. funding organisations and CSOs/NGOs)	Press releases, government policies	Developer website, government websites, philanthropic organisation website	COVID-19 vaccine; vaccine funding; vaccine; COVID-19; coronavirus; NGOs; CSOs; vaccine aid.
Regulatory partnerships	Government policies, regulatory authority documents	Regulator website, developer website, manufacturer website	COVID-19 vaccine; regulatory approval; vaccine; COVID-19; coronavirus; approved vaccines.

It should be noted that some stakeholder websites did not have a search bar on their webpage where keywords could be entered. In such cases, the press releases tab on the website was searched manually to identify relevant press releases.

Of the collected documents, firstly titles and abstracts or key points (where provided) were screened. Following this, the remaining documents were read and any documents which did not satisfy the eligibility criteria (described below) were excluded. A PRISMA flowchart (figure 4) detailing the documents shortlisted is included in the results chapter.

3.1.1 Eligibility Criteria

Eligibility Criteria Applied to Documents

Only documents published in English between December 2019 until (and including) March 2021 were included since SARS-CoV-2 was identified in December 2019 and the document search was concluded in March 2021 (Baldwin & Mauro, 2020). News articles about partnerships published by news agencies were excluded from the document analysis to ensure only official partnerships – recognised by stakeholders involved in the partnership - were included.

Eligibility Criteria Applied to Stakeholders and Partnerships

Firstly, only vaccines (and partnerships) which were in the clinical trial stage as of 01 February 2021 in the WHO landscape database were included. In terms of partnerships relating to vaccine developers - partnerships where either one vaccine developer was headquartered in the European region or partnerships between European governments and non-European vaccine developers were included due to the significance of vaccine developers in any vaccine ecosystem. For all other partnerships and stakeholder categories, only partnerships with both stakeholders headquartered in the European region were included as this thesis focuses on the COVID-19 vaccine ecosystem established within the European region specifically. The BMGF was the only exception of a stakeholder outside Europe included due to their significant influence within the European COVID-19 vaccine ecosystem. This influence was identified in the interviews.

Only institutions and organisations with a specific focus on health were included. Thus, commercial, non-pharmaceutical companies or individuals contributing to the ecosystem were excluded from this study. Moreover, documents which did not identify partnerships focusing specifically on COVID-19 vaccine development or procurement were also excluded. Thus, partnerships relating to general governance, logistics, storage or deployment strategies for COVID-19 vaccines, and partnerships focusing on medicines and diagnostics were excluded. Furthermore, where two stakeholders (who

were both included in the COVID-19 vaccine ecosystem) had established partnerships which focused on other health topics unrelated to COVID-19, these partnerships were excluded. Table 2 summaries the inclusion and exclusion criteria applied to the entire document and then to partnerships and stakeholders detailed in said documents.

Table 2: Summary of inclusion and exclusion criteria

	Inclusion criteria	**Exclusion criteria**
Documents	● Vaccines included in the WHO vaccine candidate landscape database on 01 February 2021. ● Documents published in English. ● Documents published between December 2019 to March 2021. ● Documents published officially by the stakeholders involved in the partnerships.	● Vaccines *not* included in the WHO vaccine candidate landscape database on 01 February 2021. ● Documents published in languages other than English. ● Documents published *before* December 2019 or *after* March 2021. ● News articles or newspapers.
	Inclusion criteria	**Exclusion criteria**
Partnerships and stakeholders	● Partnerships between stakeholders wherein *all* stakeholders engaging in said partnership were headquartered in the European region. The only exceptions were: ○ Partnerships between vaccine developers: partnerships with at least one developer located in the European region were included. ○ Partnerships between vaccine developers and governments:	● Partnerships between stakeholders who were not headquartered in the European region (barring specific inclusions detailed to the left). ● Partnerships involving commercial, non-pharmaceutical companies (i.e., companies which did *not* have a health focus). ● Partnerships where both stakeholders were present in the ecosystem and located in the European region but the partnership itself did not focus on COVID-19.

		procurement partnerships between non-European vaccine developers and European Member State governments were included.
Partnerships and stakeholders	● Organisations with a specific focus on health. ● Partnerships focusing solely on stakeholders working together for COVID-19 vaccine development and procurement.	

3.2 Social Network Graph (Quantitative Analysis)

Information collected in the above document analysis informed the network graph contents. In a network graph each stakeholder is depicted by a circle referred to as a node. A partnership between two nodes is shown by a line referred to as an edge or link.

Node and Edge List

The information gathered in the document analysis was recorded in an excel spreadsheet. This dataset was converted to a pdf and published on figshare to ensure accessibility of the data for future researchers (Kelkar, 2021). Identified stakeholders were recorded in a node list. Characteristics recorded in the node list include stakeholder name and the main role of the stakeholder. Appendix 1 includes a list of definitions created to categorise stakeholders into their main stakeholder type. Additionally, it was found that many stakeholders played multiple roles and thus all roles played by one stakeholder were also recorded as binary. The location of each stakeholder's headquarters was noted as well as the overarching region in which they were located - referred to as the 'region of primary activity' (e.g., EU or EEA or UK or Switzerland or US or Canada). Lastly, a unique ID was assigned to each stakeholder in order to create the edge list. Each partnership identified between two stakeholders was recorded as an edge in the edge list. Edges were undirected and all assigned a weight of one.

Analysis Process

The node and edge lists were imported into the software Gephi (version 0.9.2) (Bastian, Heymann & Jacomy, 2009). A network graph was generated and network calculations were conducted. The Fruchterman Reingold layout was used to visualise the network. This is a force-directed layout algorithm which allows for a structured network visualisation. Nodes were sized according to their eigenvector centrality (explained in section 3.2.2) to allow for better visualisation of the most influential nodes. Edges were coloured grey since they were undirected but nodes were colour coded as explained below.

3.2.1 Visual Inspection

A visual inspection was executed on the social network graph to understand ecosystem characteristics. Firstly, the overall network was inspected. Nodes were colour coded according to their main stakeholder type. This allowed for an understanding of the contribution of each stakeholder type to the ecosystem. Definitions were created for each stakeholder type to ensure a reliable method to categorise stakeholders into their main stakeholder type (appendix 1). Following this, the nodes were colour coded according to the (overarching) region of primary activity within which they were headquartered to visualise the most influential European areas in the ecosystem. All EU countries were coloured coded the same colour. Norway, Liechtenstein and Iceland were colour coded in another colour. Countries not in the EU or EEA were all colour coded individually. This colour coding arrangement allowed for a visualisation of the main regions of activity across Europe whilst preventing an overly complex and uninterpretable graph by limiting the number of colours. Lastly, key stakeholders in the ecosystem (identified by the network calculations) were individually inspected to understand the stakeholders with whom they have established partnerships.

3.2.2 Social Network Calculations

Network calculations were performed in Gephi (version 0.9.2) to quantitatively characterise the network and key stakeholders. The total number of nodes and edges were recorded to understand the complexity of the network (Hawe et al., 2004). The average degree and average path length quantified network interconnectedness (Hawe et al., 2004). Finally, the centrality measures of degree, betweenness and eigenvector centrality were used to identify key, influential stakeholders (Hawe et al., 2004). The top five stakeholders in each of the above centrality measures were recorded. These were deemed as the most influential ecosystem stakeholders. Table 3 provides definitions of each

calculation conducted. The node list spreadsheet containing these calculations was published on figshare (Kelkar, 2021).

Table 3: Network calculation definitions

Calculation name	Definition
Average degree	The average number of partnerships each stakeholder within the ecosystem is engaged in.
Average path length	The average number of stakeholders, stakeholder X will need to cross before they reach stakeholder Y, if the shortest path is taken.
Degree centrality	The number of partnerships each individual stakeholder within the ecosystem is engaged in.
Betweenness centrality	The number of times a particular stakeholder is located on the path between two other stakeholders.
Eigenvector centrality	The influence of a certain stakeholder within the ecosystem based on the number of influential connections that stakeholder is engaged in.

3.3 Interviews (Qualitative Analysis)

Interviews were conducted to better understand the inner workings of ecosystem partnerships and contextualise findings from the social network graph and calculations. They were interpreted through the application of the OECD DAC evaluation criteria. Five individual, in-depth, key-informant interviews lasting a maximum of one hour each were conducted. All interviewees worked at CEPI and were based in Europe. No further identifiers are provided to protect the identity of persons interviewed. Four interviewees were identified through convenience sampling and one interviewee was identified through snowball sampling. Five interviews were deemed sufficient due to the in-depth nature of the interviews and the time constraints of this thesis. Furthermore, to gain a true overview of ecosystem strengths and weaknesses it was necessary to interview high-level experts. Due to accessibility limitations of such experts all interviewees were recruited within one organisation. The interviews were conducted in a semi-structured manner. An interview protocol containing topics and questions was used to guide the interviews (see appendix 2). The interview guide and questions asked were developed partly through the information collected in the document analysis. Interviews were

conducted remotely by video call and recorded for transcription purposes. Interviews were transcribed manually and stored only on CEPI servers with restricted access.

3.3.1 Coding of Interviews

Interview transcripts were coded using the Braun and Clarke (2006) thematic analysis method. This method was selected since it has been widely used for qualitative analyses. The method ensures a rigorous and objective analysis which improves reliability.

A theoretical approach was applied whereby the analysis was driven by the predetermined research questions and the OECD DAC evaluation criteria (Braun & Clarke, 2006). During a second reading of the transcribed data, an initial set of codes were identified through systematically coding the complete interview transcripts. The codes were then reviewed and certain codes were combined into themes. The themes were reviewed to ensure they were representative of the coded extracts and the entire dataset. Lastly, a final set of overarching themes were retained. Themes were presented in thematic maps (see appendix 3).

3.3.2 OECD DAC Evaluation Criteria

The evaluation criteria developed by the OECD DAC were applied to the information acquired in the key-informant interviews in order to uncover ecosystem strengths and weaknesses. The DAC first laid out the 'Principles for Evaluation of Development Assistance' in 1991 (OECD, 1991). The updated version of 2019 was used in this paper (OECD, 2019). The purpose of the criteria is to evaluate the merits and significance of an international intervention (OECD, 2019). In this thesis the 'intervention' to which the criteria were applied, is the European COVID-19 vaccine development and procurement stakeholder ecosystem. The six criteria are: relevance, coherence, effectiveness, efficiency, impact, and sustainability. Appendix 4 defines each criterion in detail.

Two key principles for use outlined for the criteria emphasise the need to contextualise each criterion to the intervention being assessed and stakeholders involved (OECD, 2019). Consequently, certain criteria were slightly adapted to better evaluate the intervention at hand. The criterion of external coherence is typically used to assess the compatibility of an intervention with other ongoing interventions (OECD, 2019). However, since the COVID-19 ecosystem was developed on an ad-hoc basis to address a global emergency, the goal was not to ensure external coherence. Hence, this criterion was contextualised so it compares to what extent the COVID-19 network coheres with past

vaccine ecosystems. External non-coherence was not interpreted as a weakness. Appendix 4 provides the guiding questions used to assess the ecosystem against each criterion. These questions were developed prior to conducting the interviews specifically to assess the European COVID-19 vaccine network. Quotes from the interviews were used to answer the questions and thus validate the evaluation. Network gaps were interpreted as those criteria in which the ecosystem scored poorly. A traffic light system was invented to score the network against each criterion.

The DAC criteria were chosen since they have been specifically developed to determine the merits of international cooperation activities (OECD, 2019). The application of this criteria aimed to analyse the ecosystem in an objective manner and ensure findings were reliable. Additionally, each individual criterion was deemed relevant to assess the strengths and weaknesses of the COVID-19 vaccine ecosystem. The principles of use provided a sufficient level of flexibility. Despite this, a weakness of the DAC evaluation criteria is that they still allow for subjectivity wherein the interpretation of the quotes and their classification into the relevant criteria remains at the researchers' discretion.

3.4 Data Interpretation

The outcomes of both quantitative and qualitative data analysis methods described above were used to answer research questions. The social network graph collates the involved stakeholders and partnerships into a comprehensive model. The outcomes of the network calculations allow one to determine whether stakeholders have achieved the required degree of interconnectedness and identify the most influential stakeholders. The interviews and DAC evaluation criteria permit an in-depth understanding of partnership characteristics and help understand the reasoning behind the quantitative findings. Based on the identified strengths and weaknesses, recommendations for future Disease X ecosystems are provided.

3.5 Ethical Considerations

Prior to conducting the interviews, all interviewees were provided with an information sheet and required to sign an informed consent form (see appendix 5). Interview data was handled in accordance with the EU General Data Protection Regulation. Due to the high-level persons interviewed, any information pertaining to individual characteristics of the interviewees was not recorded or was anonymised to protect participant identity. Moreover, this study received ethics approval from the Maastricht University Faculty of Health, Medicine and Life Sciences.

4. Results

The document analysis, social network graph (and calculations) and interviews are analysed separately in this chapter. This was done to ensure a thorough application of the DAC evaluation criteria to the interviews and to ensure all findings were identified and discussed. Both qualitative and quantitative aspects of the study are interpreted together in the discussion chapter.

4.1 Document Analysis (Data Collection)

In total, 243 documents (of which six were databases) were eligible for inclusion in the document analysis. The PRISMA flowchart in figure 4 shows the filtering process applied to documents.

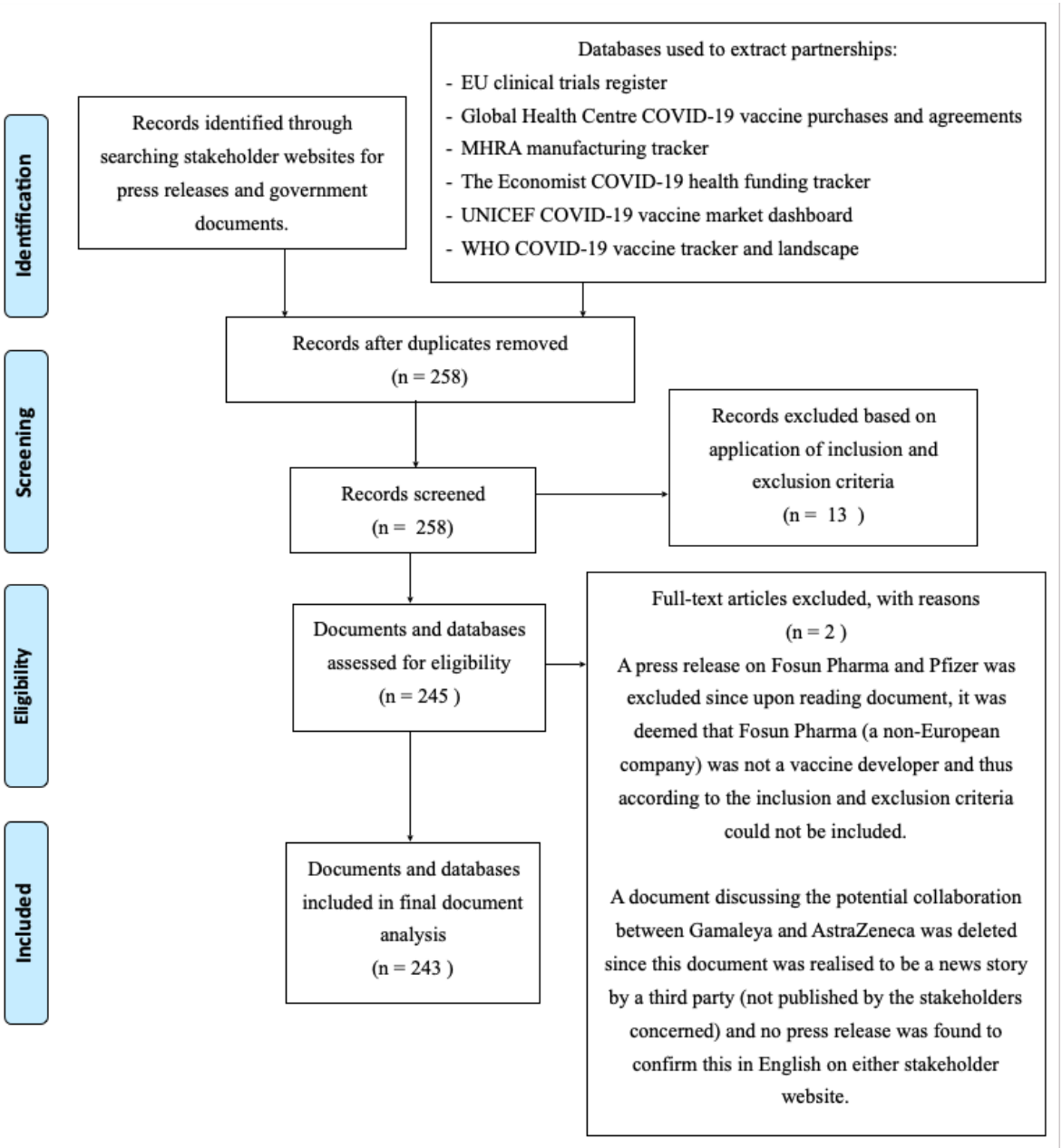

Figure 4: PRISMA flowchart

(Note: Diagram adapted by author) Moher, Liberati, Tetzlaff, Altman, and The PRISMA Group, 2009

Appendix 6 provides a reference list for documents shortlisted. Information retrieved from the document analysis was recorded in node and edge lists which were used to develop the network graphs.

4.2 Social Network Graph and Calculations (Quantitative Analysis)

4.2.1 Overall Network

The COVID-19 vaccine ecosystem is composed of 164 nodes (stakeholders) which are linked by 745 edges (partnerships) as shown in table 4. This suggests a large network. The network statistics indicate a highly interconnected network; The average degree is 9.09 meaning on average each stakeholder in the ecosystem has partnerships with 9.09 other entities (Hawe et al., 2004). For such a large ecosystem, an average degree of 9.09 indicates a highly collaborative and interconnected network. Furthermore, table 4 shows the average path length to be 2.66. This means, if the shortest path is taken, each stakeholder has to cross 2.66 other stakeholders on average before it reaches the desired stakeholder (Hawe et al., 2004). This is a relatively short path length, considering the large number of nodes, thereby indicating a well-connected network.

Table 4: Overall network statistics

Overall Network Measure	**Statistics (2 decimal point (d.p.))**
Nodes	164
Edges	745
Average Degree	9.09
Average Path Length	2.66

Findings from the network calculations were supported by a visual inspection of the network graph shown in figure 5, which also indicated a highly complex and interconnected network.

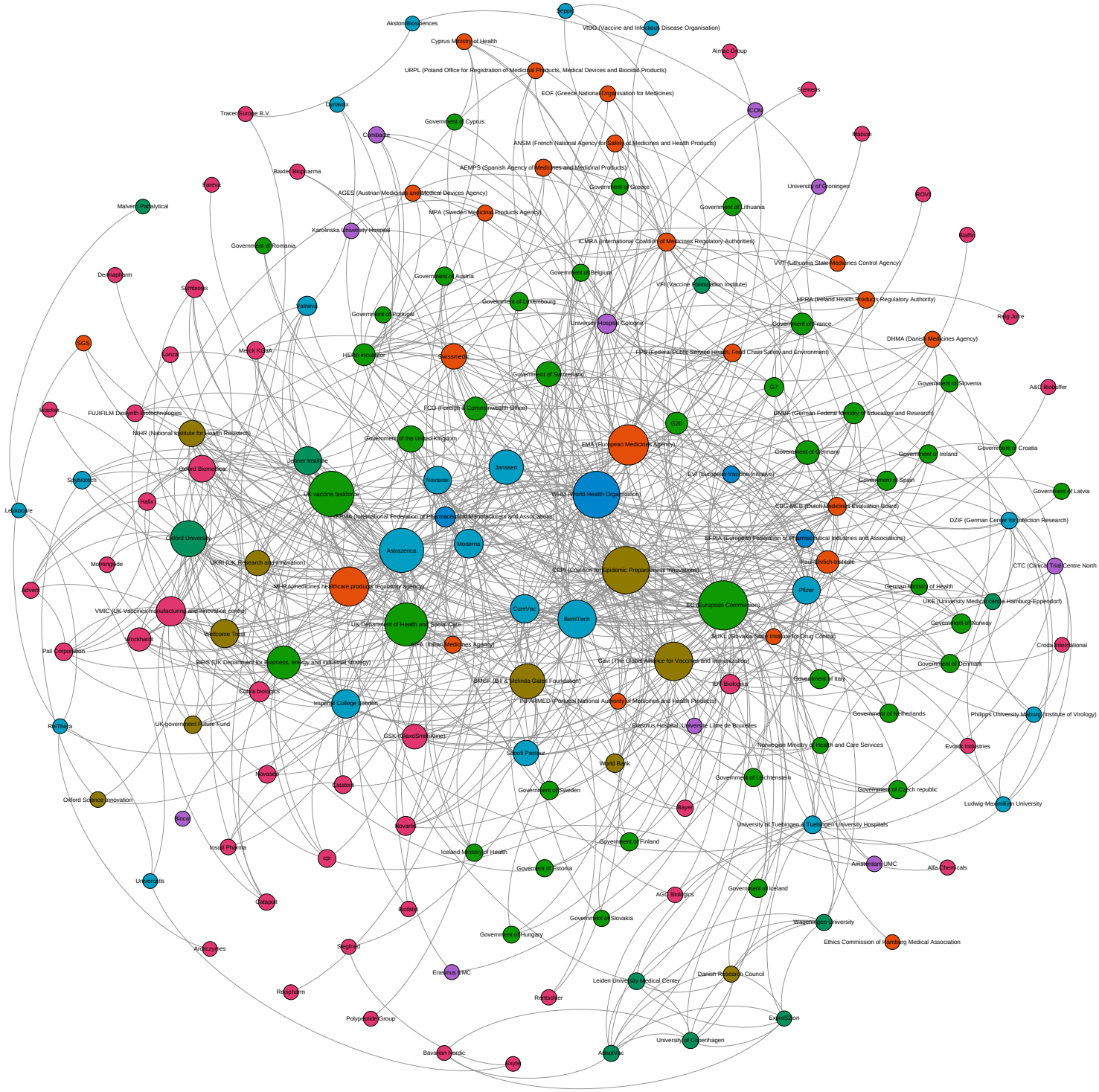

Figure 5: Network graph coloured by stakeholder type

4.2.2 Network by Stakeholder Groupings

Network by Stakeholder Type

Figure 5 has been colour coded based on the main stakeholder type of each stakeholder. Which stakeholder type each colour represents and the percentage of stakeholders belonging to a particular stakeholder type is explained in figure 6. Nodes have been sized by their eigenvector centrality.

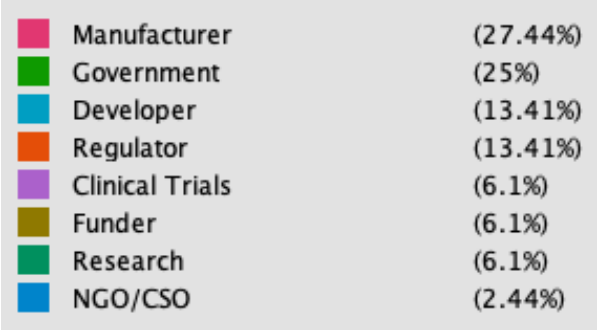

Figure 6: Colour codes of nodes coloured by stakeholder type

Figure 6 shows manufacturers are the most common stakeholder type composing 27.44% of the network. But a visual inspection of figure 5 indicated that most manufacturers are less connected within the network with most having only two or three links. A similar situation can be observed for the government stakeholder type which composes 25% of the network. Despite this, the visual inspection indicates that most governments appear to be small in size. Nevertheless, two or three government stakeholders - including the EC, UK Department of Health and Social Care and UK VTF - are amongst the largest sized nodes in the network. Larger node sizes represent a high eigenvector centrality.

The visual inspection also indicates that developers appear to be the stakeholder category with the overall highest population of larger-sized nodes. Undoubtedly vaccine developers must assume a key role in any vaccine ecosystem since all stakeholders rely on their outputs. Regardless, the notion of democratic accountability must be discussed considering the influence vaccine developers hold within the ecosystem.

Network by Region of Primary Activity

Figure 7 shows nodes colour coded according to their region of primary activity. Figure 8 explains which region each colour represents and the percentage of stakeholders headquartered in that region.

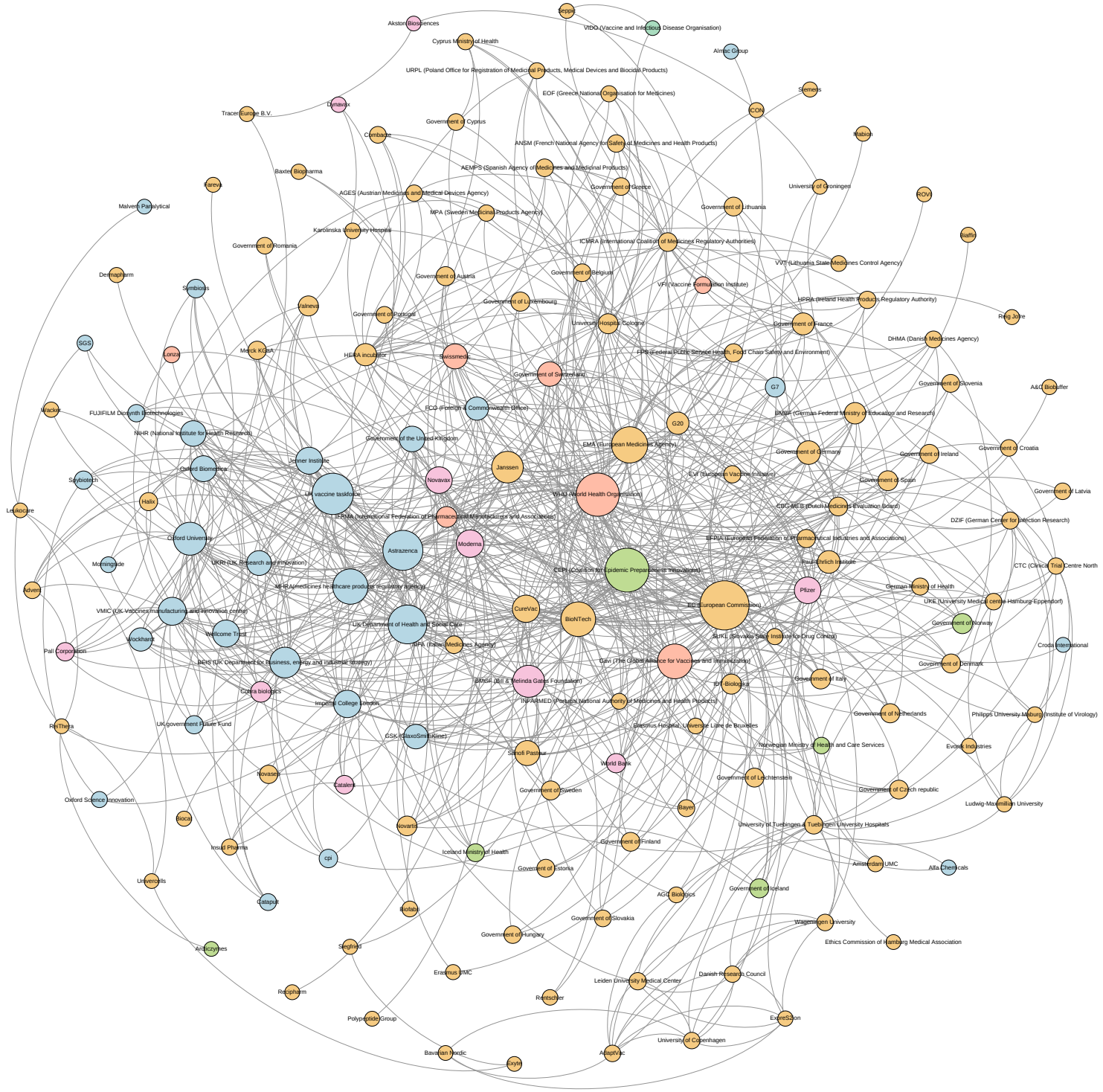

Figure 7: Network graph coloured by region of primary activity

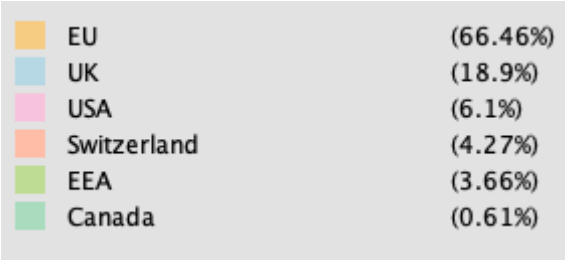

Figure 8: Colour codes of node coloured by region of primary activity

Figure 8 shows that most stakeholders in the COVID-19 vaccine ecosystem are headquartered within EU countries. However, compared to other non-EU countries, the UK hosts a much larger proportion of stakeholders (likely more than each individual EU country). This speaks to the significant influence the UK holds within the network. A visual inspection of figure 7 further showed that a large portion of the highly influential stakeholders (characterised by their larger node size) are headquartered in the UK. Contrary to the larger sized UK nodes, most nodes headquartered in the EU are smaller in size. This is likely to indicate small contributions made by multiple stakeholders (and states) across the EU.

4.2.3 Influential Stakeholders within the Network

The degree, betweenness and eigenvector centrality were calculated for each network stakeholder. The top five stakeholders for each measure and their statistical values are shown in table 5.

Table 5: Influential stakeholders

Stakeholder Name	Ranking (1-5)	Statistics (2 d.p.)
Degree Centrality		
EC (European Commission)	1	65.00
CEPI (Coalition for Epidemic Preparedness Innovations)	2	49.00
WHO (World Health Organization)	3	46.00
EMA (European Medicines Agency)	4	43.00
AstraZeneca	5	40.00
Betweenness Centrality		
EC (European Commission)	1	2858.14
BioNTech	2	2204.03
EMA (European Medicines Agency)	3	1796.46
AstraZeneca	4	1252.10
CEPI (Coalition for Epidemic Preparedness Innovations)	5	1153.01
Eigenvector Centrality		
EC (European Commission)	1	1.00
WHO (World Health Organisation)	2	0.86
CEPI (Coalition for Epidemic Preparedness Innovations)	3	0.85
UK vaccine taskforce	4	0.80
AstraZeneca	5	0.76

Table 5 shows that across all measures a very similar group of stakeholders score highly and thus are the most influential. The EC is consistently ranked the number one key stakeholder across the ecosystem. Furthermore, there is a considerable discrepancy wherein the Commission holds a significantly higher number of influential connections to other stakeholders (as indicated by the degree and eigenvector centrality). This depicts the EC to be a more influential stakeholder by comparison. The EMA also ought to be considered a key stakeholder scoring highly in degree and betweenness centrality. These statistics signify the importance of EU institutions across the European region network. Figures 9 and 10 show the individual partnerships which the EC and EMA, respectively, have established between themselves and other ecosystem stakeholders. A visual inspection of figures 9 and 10 depict both stakeholders to act as funnels through which all national EU governments and regulatory authorities channel their activities. This network configuration substantiates claims that EU Member States are unified in their approach to vaccine procurement (McEvoy & Ferri, 2020).

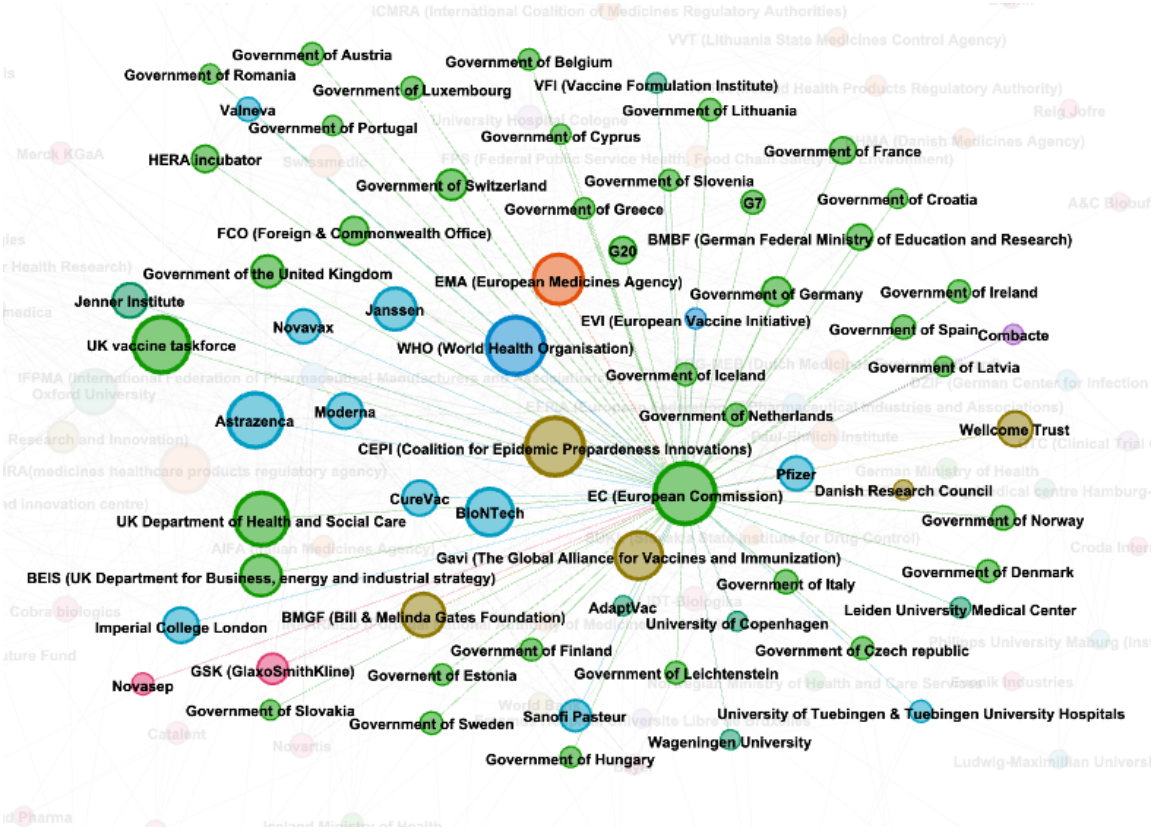

Figure 9: EC's stakeholder partnerships

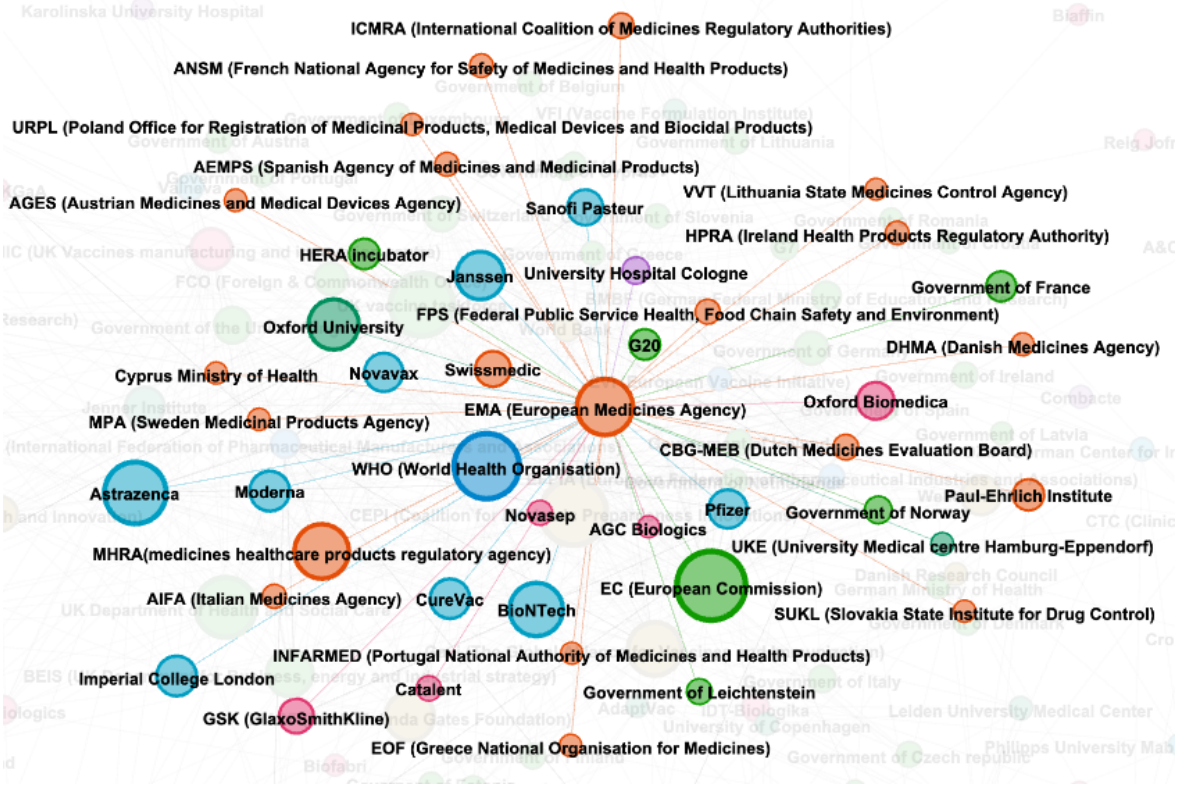

Figure 10: EMA's stakeholder partnerships

In addition, CEPI and WHO also scored highly in most centrality measures. Thereby indicating the influence and importance of philanthropic organisations within the ecosystem. Figures 11 and 12 showing their connections suggest that close collaborations with other NGOs/CSOs, Member States and industry is the probable cause of their centrality. The visual inspection indicates that these organisations are 'connecting' stakeholders through whom partnerships across sectors can be facilitated.

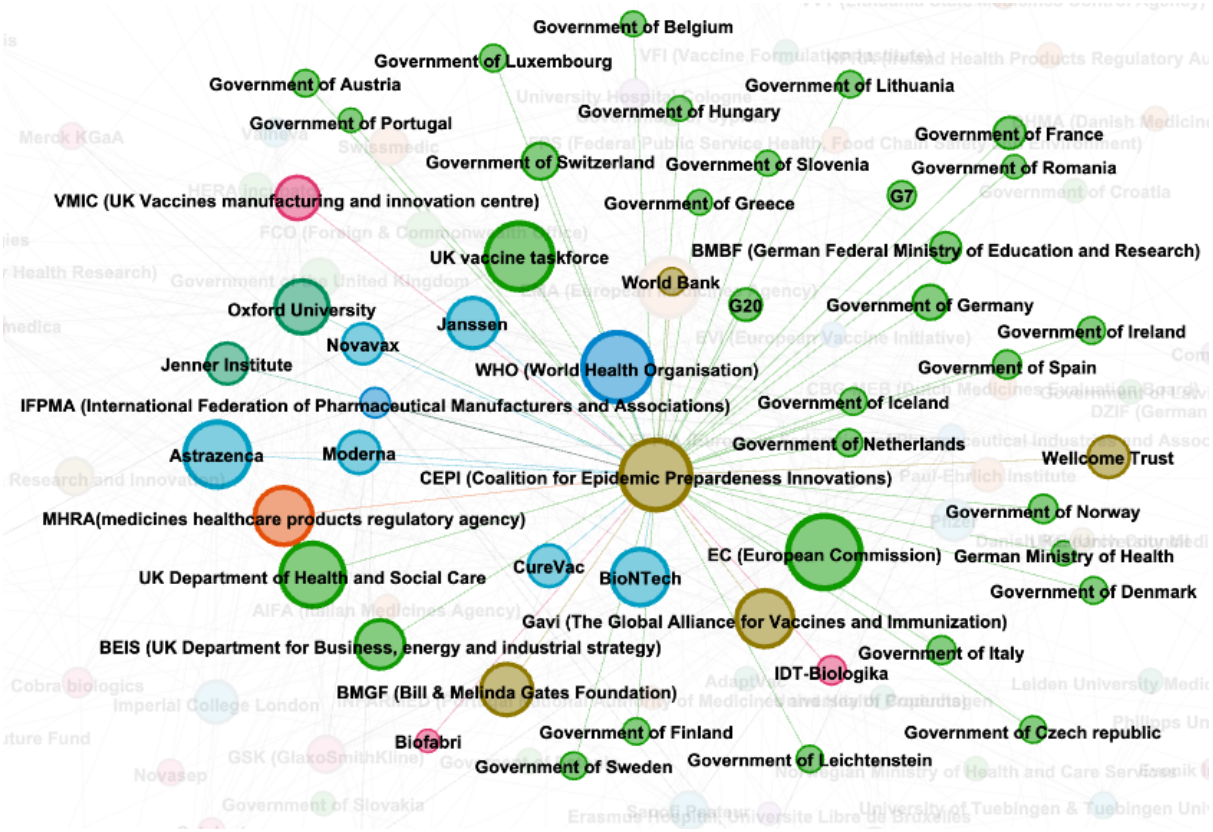

Figure 11: CEPI's stakeholder partnerships

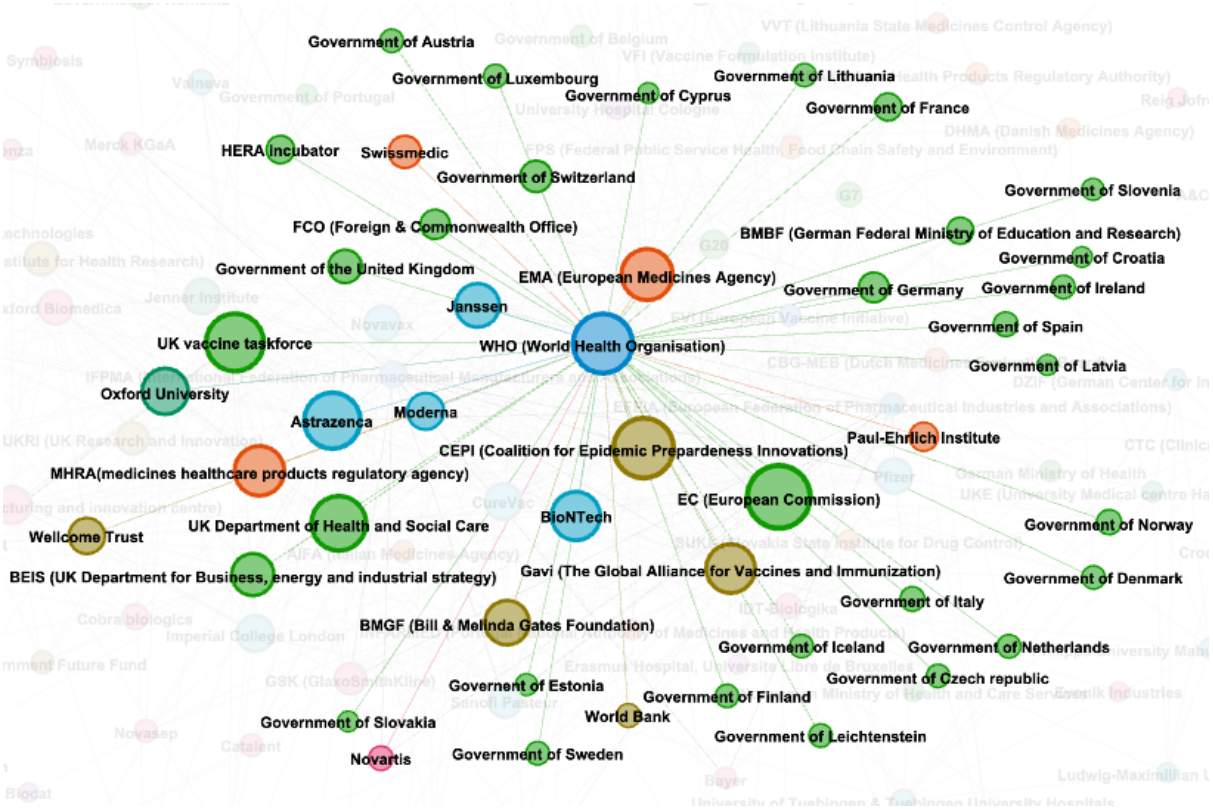

Figure 12: WHO's stakeholder partnerships

AstraZeneca is also consistently amongst the top five key stakeholders which differs compared to other vaccine developers who, although are an influential stakeholder type, do not hold the same level of influence. BioNTech is ranked second in betweenness centrality meaning it too holds a level of influence. The extent to which the positions of these stakeholders have broader implications (for topics such as democratic accountability) ought to be discussed. Lastly, the UK VTF is ranked fourth in eigenvector centrality indicating it is linked to many influential stakeholders. However, it does not rank in the top five for degree or betweenness centrality. This suggests that the taskforce has established fewer yet more effective and influential partnerships. The interviews conducted in this analysis aim to provide a better understanding of the roles these stakeholders play in the ecosystem.

4.3 Interviews (Qualitative Analysis)

As mentioned, five individual, key-informant interviews were conducted. All interviewees were based in Europe and employees of CEPI.

4.3.1 Coding of Interviews

The initial coding of all interviews yielded 35 codes. From this, 11 themes were generated and reviewed. The categorisation was illustrated in thematic maps. Following review, six final themes were shortlisted. The six DAC criteria served as the six final themes for which another thematic map was generated. All thematic maps can be found in appendix 3.

4.3.2 OECD DAC Evaluation Criteria

Table 6 scores the European COVID-19 vaccine development and procurement ecosystem against each criteria using a traffic light mechanism. The criteria in which the ecosystem had more strengths than weaknesses achieved a green score. Criteria where the ecosystem has a mixture of strengths and weaknesses were allocated an orange score. For criteria where the main goal was not achieved (despite some positives), the ecosystem was given a red score. The key points used to determine the score for each criterion are provided in the description column.

Table 6: OECD DAC evaluation criteria scores

Criteria	Score	Description
Relevance		+ Addressed public needs
Coherence		+ Coherence with past ecosystems +/- Alignment/coherence amongst ecosystem stakeholders
Effectiveness		+ Overall goal achieved - Roadblocks encountered (manufacturing and rigidity of EU systems)
Efficiency		+ Time efficiency + Economic efficiency + Agility (of resource utilisation)
Impact		+ Importance of philanthropic organisations
Sustainability		+ Lessons learned (stakeholder alignment and HERA) - Current sustainability

A detailed explanation of these considerations and the quotes used to justify the allocated score is provided below.

Relevance

A relevant ecosystem is deemed as one that addresses global needs. During the COVID-19 pandemic, the main need of the public was fast access to safe and effective COVID-19 vaccines. Interviewees explained that the network purposefully adapted previous practices to address global needs through quickly establishing more closely collaborative partnerships than previously done. This proves that European stakeholders and partnerships successfully facilitated development and procurement of the COVID-19 vaccine

"..that's really the difference, it's...the speed and intensity of the partnerships which actually fits the need to develop vaccines really quickly in this situation." (Interviewee 3, personal communication, March 26, 2021)

This adaptation to the usual way of working to better serve public needs, indicates a highly relevant ecosystem and thus a green score was allocated.

Coherence

External coherence measures whether and to what extent the ecosystem established for COVID-19 vaccine development and procurement in the European region differs from past ecosystems. Findings from the interviews implied that this ecosystem was not coherent with past ecosystems. However, this was interpreted as a good score for this criterion since the network diverged from past practices to better serve global needs. A key sub-theme which emerged was the increased collaboration amongst stakeholders through establishing unique partnerships to accelerate processes. Unique partnerships refer to the unusual pairing of contrasting industries or closer collaborations. In this network, philanthropic institutions and public and private stakeholders worked closely together on several aspects of COVID-19 vaccine development and procurement. Additionally, these partnerships were convened much faster which, although not coherent with past ecosystems, speaks to the interconnectedness of this network.

"Partnerships within and between academia or small biotech and large industry partners happened very quickly. COVAX which involves CEPI, GAVI, WHO [is] *an example of an end-to-end partnership at a global level which has never been attempted before...Overall, partnerships between the public sector and private sector... have increased." (Interviewee 3, personal communication, March 26, 2021)*

Internal coherence analyses the synergy between network stakeholders. Generally, stakeholders were aligned on the main goal of developing a COVID-19 vaccine for purchase. To reach this goal, stakeholders collaborated more intensely which bore a positive impact. Nonetheless, as stakeholders

began to form partnerships not coherent with the past and establish stronger collaborations, this resulted in a more interconnected ecosystem. Consequently, achieving alignment (which includes managing expectations) became increasingly complex yet necessary. Interviewees revealed that the COVID-19 vaccine ecosystem found this to be a source of inefficiency. This is to be expected in such a diverse ecosystem comprising multiple sectors since each stakeholder is likely to have different intermediate goals and means to achieve said goals. The challenges faced in achieving alignment caused delays to the overall outputs of the network.

"...managing expectations within the group because we all come from a very different angle [so to achieve alignment]*...takes a little bit of time."* (*Interviewee 3, personal communication, March 26, 2021)*

From the above, it can be concluded that the ecosystem achieved a good score in external coherence since it sufficiently adapted to better address global needs. But, internal alignment amongst stakeholders was an issue, thus an orange score was given.

Effectiveness

The effectiveness criterion assesses the extent to which the ecosystem has achieved set objectives. Some prominent issues which prevented or delayed the achievement of said goals were also analysed under this criterion. Overall, interviewees clearly indicated the effectiveness of this ecosystem in achieving the primary goal of developing a COVID-19 vaccine which has been purchased by European region authorities.

"What [has] *been done to date has been good and has been phenomenally more successful to what's happened in the past" (Interviewee 2, personal communication, March 19, 2021)*

"I think we can be pretty impressed with ourselves. In terms of saying we'll have a vaccine in 12-18 months which was a pretty hard goal... But we delivered on that as a community." (Interviewee 4, personal communication, March 26, 2021)

However, the manufacturing supply chain was a major weakness of the ecosystem which hindered the achievement of the above goals, according to interviewees. Difficulties in import and export of raw materials resulted in manufacturing roadblocks. A potential cause of weaknesses is suspected to be vaccine nationalism but this aspect should be further investigated in future research.

"The whole manufacturing chain is something we need to look at more closely because it has presented some challenges for the...community." (Interviewee 2, personal communication, March 19, 2021)

"There is a political dimension to it in the form of vaccine nationalism with countries wanting to keep materials at home." (Interviewee 2, personal communication, March 19, 2021)

The above quotes also indicate that a lack of alignment amongst manufacturers within the ecosystem was perceived as another reason for manufacturing roadblocks. A lack of harmonisation makes it difficult for manufacturers to follow timelines, especially since manufacturers rely on one another for materials, as discussed in chapter two. A proposed solution is the establishment of a central monitoring system/infomediary (an infomediary is an internet company which gathers and links information on a particular topic) which can better provide an overview of capacities to all stakeholders and coordinate resources. The infomediary should provide data regarding supply of manufacturing capacity, finished products, delivery times, etc.

"...having some sort of control tower function...on manufacturing capacities is another gap." (Interviewee 4, personal communication, March 26, 2021)

Lastly, despite the network reacting rapidly and in an agile fashion overall, the rigid organisation and decision-making structures of EU institutions, were recognised as another weakness. Interviewees identified a possible reason to be the decision of all EU countries to procure vaccines centrally through the Commission. The shared competencies added a level of complexity as the Commission was required to consult all Member States before making decisions. Also, the EC and EMA, like other national governments and regulatory authorities, must also collaborate with industry. The engagement of such a large number of actors in decision making processes resulted in overly complex mechanisms which hindered the agile decision making required in emergencies. Consequently, the EU is thought to have made little contribution in funding R&D activities for the COVID-19 vaccine.

"The [EU] *system is so rigid because it's a member state driven organisation...so they have to go back to their Member States and get approvals for everything." (Interviewee 4, personal communication, March 26, 2021)*

"[EU]*...did not make very big investments in R&D. They also were several months behind in terms of procurement and they decided to do it at* [a] *European level which added a layer of complexity"* (*Interviewee 3, personal interview, March 26, 2021)*

Overall, despite experiencing roadblocks in the manufacturing supply chain and EU rigidity, the ecosystem achieved its main goal so a green score was given. However, roadblocks identified must be overcome to increase the effectiveness of future ecosystems.

Efficiency

This criterion investigates whether goals were achieved through the efficient use of time, cost and other resources. The strong time- and cost- efficiency of the COVID-19 vaccine ecosystem was recognised by all interviewees and attributed to agile use of time and cost resources. In particular, interviewees spoke about the unprecedented timescale at which vaccine development occurred compared to the past. The fact that vaccine development, which usually takes years, was completed in a matter of months was a key strength of this ecosystem. With regards to cost efficiency, interviewees expressed that investments in the ecosystem were more at risk since the chance of losing investments - if vaccine candidates were unsuccessful - was greater. This economic risk was deemed justified to provide the required funding to start vaccine R&D activities and capacity building for manufacturing immediately. Therefore, the ecosystem was considered cost efficient by interviewees.

"...usually it takes about 10 years...to develop a vaccine and vaccines now have been developed and scaled in 1/10th of that time. So, really quite extraordinary." (*Interviewee 3, personal communication, March 26, 2021)*

"...we have reached a clinical trial within 9 weeks after COVID-19 was identified and that has never been seen before, it was only due to...taking some economical risks." (Interviewee 1, personal communication, March 19, 2021)

Efficiency also investigates the efficient use of available resources. The vitality of convening resources in an agile fashion during global emergencies became evident. Organisations that were able to reorganise resources and act flexibly were comparatively more successful and influential. The UK VTF, for example, was praised, by interviewees, as an influential player within the ecosystem due to its agility and interdisciplinarity. Interviewees also predicted that CEPI's agile and rapid decision-making increased stakeholders' trust in the organisation and thus stakeholders were more willing to collaborate with CEPI. The opposite was seen for organisations that acted in a more rigid fashion, such as the EC, as discussed in the effectiveness criteria.

"...countries that were more successful had taskforces...to really look at how to get to a vaccine for COVID-19 and the UK is a prime example of that" (*Interviewee 3, personal communication, March 26, 2021)*

"...CEPI have a very fast decision-making structure and I think [it is] *important to be agile if communities are going to trust us to be any help" (Interviewee 1, personal communication, March 19, 2021)*

To summarise, the ecosystem achieves a green score in the efficiency criteria due to its efficient and agile use of time, costs and resources.

Impact

The impact criterion evaluates the ecosystem on any unintended and/or unexpected outcomes and findings of the ecosystem. One unexpected finding which emerged was a realisation of the importance of funders, NGOs and CSOs in utilising their agile processes to better address global needs. Due to freedom from the rigid processes which bind governmental institutions, in this pandemic, philanthropic organisations were able to demonstrate agility and thus fill gaps within the ecosystem such as improving manufacturing capacity. Furthermore, philanthropic stakeholders served as connectors between public and private organisations. They worked closely with both public and private sectors serving as an unbiased facilitator of partnerships to enhance vaccine development and procurement. In the below quotations, CEPI serves as a proxy for philanthropic institutions as an overall stakeholder category.

"...the investments in buying manufacturing capacity, reserving vials...those kinds of activities which...were new for CEPI. But there was a gap... so we filled those gaps." (Interviewee 4, personal communication, March 26, 2021)

"There is a unique role where CEPI is acting as an honest broker... a gate between industry and regulators" (Interviewee 5, personal communication, April 07, 2021)

To conclude, a positive, unintended impact of the ecosystem was the recognition of the importance of philanthropic organisations thus a green score was achieved for this criterion.

Sustainability

The criterion of sustainability focuses on the sustainability of the existing ecosystem and lessons learned for future pandemic preparedness. Interviewees expressed the unsustainability of the existing ecosystem. Key reasons for this included roadblocks discussed in the coherence criteria regarding stakeholder alignment. Additionally, participants explained that the current ecosystem has evolved in response to the COVID-19 outbreak, rather than as a preparedness measure. Thus, its main aim was to rapidly provide a vaccine which was done through adapting normal processes. Consequently, the established manufacturing supply chain lacks the robustness which was achieved in previous vaccine

networks through increased checks conducted over a longer time period. This lack of robustness hinders the sustainability of the ecosystem.

"...as it is now it is not sustainable, I dare say. It requires...a revisit of how these systems actually work so...the decision-making processes between organisations." (Interviewee 4, personal communication, March 26, 2021)

"...we will suffer over the next few years, because as you go fast you don't do things [as] *thoroughly as you would normally. So, the manufacturing processes will not be robust." (Interviewee 3, personal communication, March 26, 2021)*

Nonetheless, the unprecedented nature of this network - which was developed amidst a time of global emergency – has provided certain key learnings to be implemented in vaccine ecosystems for other pathogens to ensure better preparedness. For example, as a result of this ecosystem being more closely collaborative, the significance of focusing on stakeholder alignment within partnerships was recognised. Steps were already taken in this ecosystem to improve stakeholder alignment. Notwithstanding this, stakeholder alignment was a lesson learned in this ecosystem and serves an avenue for improvement in Disease X ecosystems.

"...bringing [stakeholders] *into alignment is a lesson that we learned through this process" (Interviewee 2, personal communication, March 19, 2021)*

The establishment of HERA is something that has emerged as a lesson learned from this pandemic. Interviewees anticipate that HERA will bear a positive impact on Disease X vaccine ecosystems by ensuring the EU is equipped with stronger, more well-established pandemic preparedness mechanisms. This will be achieved through a more agile approach undertaken across EU Member States through HERA.

"HERA which is a BARDA like organisation in [the EU] *includes things like the clinical trial capacity, manufacturing capacity, funding R&D projects, incentivising companies. That is something in formation and is a way for Europe to be better prepared for the next pandemic." (Interviewee 3, personal communication, March 26, 2021)*

Overall, the ecosystem received a red score in this criterion since it was not deemed currently sustainable. Despite this, there are several key learnings from the ecosystem which will be implemented for future vaccine ecosystems to improve sustainability.

5. Discussion

5.1 Analysis of Findings

This thesis firstly investigated the extent to which the current European stakeholders and partnerships facilitated COVID-19 vaccine development and procurement. Findings indicate these stakeholders to have successfully facilitated development and procurement of COVID-19 vaccines for countries across the European region. Consequently, the strengths and weaknesses of the European COVID-19 vaccine stakeholder ecosystem were studied by means of a social network analysis using mixed-methods. Based on this, recommendations to improve the efficiency of future ecosystems are put forward in this section. The EC, EMA, CEPI, WHO, UK VTF and AstraZeneca were identified as key stakeholders. The European COVID-19 vaccine ecosystem achieved the main goal of developing and procuring COVID-19 vaccines which is a key strength. However, certain weaknesses of the ecosystem were also identified. Lastly, considering the centrality of vaccine developers and rising concerns around the democratic unaccountability of the pharmaceutical industry, the broader implications of study findings on this notion, and mechanisms to reduce democratic un-accountability are discussed throughout this chapter.

This ecosystem achieved the above-mentioned goal (of developing and procuring COVID-19 vaccines) in a time-, cost- and resource- effective manner. This could be achieved due to the agility demonstrated by this network in which stakeholders undertook the necessary risks and a sufficiently interdisciplinary approach to develop a vaccine in record time. Stakeholders identified in the interviews to have undertaken an agile and interdisciplinary approach, appeared as highly influential in the network calculations, thereby supporting the claim that agility is a strength. Reports also praise the UK VTF for convening an interdisciplinary group of experts and decision-makers (Bingham, 2021). This agility in convening resources - partnerships included - explains how the UK VTF established fewer yet more powerful partnerships. In part, as a result of the UK VTF adopting such an agile and interdisciplinary approach, the UK as a nation was especially influential in this ecosystem. The necessity of agility to achieve network goals demonstrates the positives of organisations being unrestricted by bureaucratic measures such as accountability. Likewise, pharmaceutical companies leveraged their un-accountability to act with agility and rapidly innovate vaccines during the COVID-19 pandemic (Keohane, 2002). Therefore, while developing mechanisms to establish the accountability of industry, their ability to act in an agile fashion must be preserved to ensure efficiency and innovation. Additionally, considering the successes of the UK VTF, this thesis recommends the establishment of a Global Vaccine Taskforce which would become a key stakeholder in Disease X ecosystems. The Independent Panel for Pandemic Preparedness and Response (IPPPR)

has also put forward the establishment of a 'Global Vaccine Taskforce' as their chief recommendation (Hoen et al., 2021). This taskforce should aim to act with agility and convene an interdisciplinary set of actors to tackle issues of the ecosystem which are discussed later in this chapter (Hoen et al., 2021). The findings of this thesis (particularly the key stakeholders recognised) should be used as a foundation to determine which actors to engage in the taskforce. Although Lurie, Keutsch and Dzau (2021) discuss ad-hoc initiatives that were developed for similar purposes during COVID-19, the sustainability of such initiatives must be targeted. Especially considering the un-sustainability of the current ecosystem.

A second ecosystem strength was that philanthropic organisations (funders, CSOs and NGOs) proved to be crucial stakeholders in this network. This was deduced through the visual inspection and calculations which depicted CEPI and WHO as key 'connecting stakeholders' linking together public and private sectors. Interviewees too spoke of the successes of philanthropic organisations in bridging ecosystem gaps and uniting a wide array of stakeholders. The close partnerships of philanthropic organisations with industry revealed in this thesis, imply that philanthropic organisations can act as mediators which ensure that public needs are given due consideration by vaccine developers, thereby ensuring a component of democratic accountability in industry stakeholder decision-making (Doh & Guay, 2006). Such interventions have improved the state of affairs in the past (Doh & Guay, 2006). For example, during the HIV/AIDS epidemic, NGOs influenced pharmaceutical companies (to relax their intellectual property rights (IPR) for HIV/AIDS medications) to better align with public needs (Doh & Guay, 2006). Furthermore, due to the centrality of philanthropic organisations and their indispensable role in filling ecosystem gaps, the global vaccine taskforce mentioned above must engage these organisations (Hoen et al., 2021). Global philanthropic organisations work independently of governments and therefore are not bound by the rigid, bureaucratic procedures required of governments (Keohane, 2002). Consequently, their flexibility should be used to disseminate information rapidly and broker alignment between taskforce stakeholders during global emergencies.

A third strength of this network was the high level of stakeholder collaboration and therefore, ecosystem interconnectedness achieved. Through the network calculations, the short path length, high average degree and large number of edges quantitatively proved ecosystem stakeholders to be well-connected as visualised by the complex structure of the network graph. The OECD coherence criterion supported this claim by characterising the European COVID-19 vaccine ecosystem as different from past ecosystems, due in part to a stronger interconnectedness amongst stakeholders. The interconnectedness achieved is a key strength and lesson learned from this network. However, interviewees revealed that the increased collaboration and interconnectedness makes achieving alignment amongst stakeholders more complex and time consuming. This was identified as an avenue

for improvement in future networks. Unless this shortcoming is overcome, future ecosystems risk having inadequate alignment and hence slow decision-making amongst stakeholder collaborations. To overcome said weakness, an in-depth review of existing decision-making structures is recommended. The COVID-19 pandemic saw the increased establishment of public-private partnerships. Thus, the above-discussed review should also investigate how decisions in public-private partnerships were made. Through this, best practices for stakeholder alignment can be identified which ensure that, in such partnership structures, private stakeholders (i.e., pharmaceutical companies) are held democratically accountable while public sector stakeholders can learn to adopt more agile mechanisms used by their industry partners.

Continuing with ecosystem weaknesses, the manufacturing supply chain was found to be a major weakness in this ecosystem. The network graph depicted a large number of vaccine manufacturers to each play small roles within the ecosystem. Manufacturers also appeared to be less connected with other stakeholders. This explains why interviewees identified manufacturing as a cause of delay in the network. Vaccine nationalism and a lack of robust processes are suspected to play a role but this must be further investigated. Based on the interviews, the establishment of a centralised system or infomediary which monitors and stores data on manufacturing supply chains to prevent bottlenecks is recommended. Similar suggestions have been put forward by previous reports on the topic (Hatchett et al., 2021; Hoen et al., 2021; Yadav & Weintraub, 2021). Such a system ought to improve the robustness of current manufacturing processes through allowing manufacturers to identify and anticipate needs of fellow supply chain stakeholders (Hatchett et al., 2021; Yadav & Weintraub, 2021). Consequently, manufacturers can coordinate their activities with the timelines of other stakeholders and allow sufficient time for safety checks. Organisations identified in the network graph to hold central, connecting positions in the ecosystem can leverage their connections to bring together manufacturing stakeholders, monitor such infomediaries and ensure a harmonised supply chain (Yadav & Weintraub, 2021). This infomediary should be accommodated as one objective of the global vaccine taskforce since members of the global vaccine taskforce are likely best positioned to collate the necessary information (Hoen et al., 2021). Also because, in case bottlenecks are identified, global vaccine taskforce stakeholders ought to be among the first informed so global solutions can rapidly be devised.

A final weakness of this ecosystem was the rigidity of European Union institutions which hindered them from making significant contributions to COVID-19 vaccine R&D. Centrality calculations found the EC and EMA to be highly influential stakeholders who acted on behalf of and channelled the resources of individual Member States. Consequently, these governments played a minimal role in the ecosystem which was illustrated in the network graph. However, key-informant interviews revealed the inefficiencies of this approach which resulted in the EU making minimal contributions

within the network in terms of timely vaccine procurement and investments in R&D. Bearing in mind the health competencies of EU institutions, it is clear that the Commission struggled to maintain accountability (to its Member States) without being constrained by bureaucratic rigidity. These results are significant since they demonstrate the need to develop strategies which allow more impactful contributions to be made by EU institutions in future networks, whilst maintaining accountability. The interviews indicated the anticipated positive impact of HERA in this. This anticipation is shared by EU institutions themselves as indicated in the 'HERA Inception Impact Assessment' (EC & DG SANTE 2021). It is interesting to contrast the success of the UK VTF with the inadequacy of the EC since both work by convening high-level decision-makers. The key difference between both organisations appears to be that the UK VTF convened high-level decision makers from interdisciplinary backgrounds which is something that the EC perhaps lacked. This ought to be rectified in HERA and targeted in the global vaccine taskforce (Hoen et al., 2020). Bringing together experts and decision makers from various backgrounds allows rapid cross-disciplinary decision-making. Moreover, one must recognise that simply convening high-level experts and decision-makers does not lead to efficiency. Rather, active efforts must be taken and strategies devised to establish additional mechanisms which ensure agility whilst maintaining accountability. Such efforts must also be taken by the global vaccine taskforce (Hoen et al., 2021).

Lastly, although discussed throughout this chapter, the broader implications of thesis findings on the notion of democratic accountability are summarised. AstraZeneca and BioNTech were identified as key stakeholders. These two developers, in particular, may be influential due to being the European frontrunners in COVID-19 vaccine development. The exact reasoning requires further research. Regardless, the network graph indicated vaccine developers overall to be arguably the most influential stakeholder category. The influence and power held by vaccine developers is interesting considering the absence of democratic accountability of pharmaceutical companies. Yet, the agility to make rapid decisions without requiring multiple stakeholder consultations explains the success of pharmaceutical companies in developing COVID-19 vaccines on an exceptionally short timescale (Keohane, 2002). However, unaccountability risks a communication gap wherein industry is unable to understand and sufficiently address public needs (Timmis et al., 2017). Going forward, thesis findings recommend developing mechanisms which allow philanthropic organisations to act as mediators who are able to inform industry of public needs (Doh & Guay, 2006). In developing such mechanisms a balance between bureaucratic rigidity and agility is key to ensure accountability measures do not prevent the ability of pharmaceutical companies to innovate (Doh & Guay, 2006; Keohane, 2002). Concerns surrounding accountability are applicable to all ecosystems which include the pharmaceutical industry such as ecosystems tackling neglected or non-communicable diseases (Dukes, 2002). Thus, considering the wide-spread impact of democratic unaccountability this topic ought to be discussed presently.

5.2 Strengths and Limitations

In conducting this research, several measures were undertaken to ensure a high level of research quality, reliability and validity. Despite this, limitations of this paper must be recognised and considered when interpreting research findings.

Firstly, all organisations identified in the ecosystem were searched with the same level of rigour. Despite this, due to human error, especially considering the large number of stakeholders and documents researched, it may be possible that certain partnership documents were missed and thus their impact within the ecosystem was not considered. However, it is highly unlikely that such missed partnerships would alter the key stakeholders identified in the network calculations. This thesis also made significant use of grey literature such as government documents and press releases to identify partnerships. Since grey literature is not peer-reviewed, it is possible that certain documents were backed by the organisation's political agendas or did not reveal accurate information. Still, the impact of grey literature on this thesis was considered negligible since the literature was not used to directly address research questions but only to quantitatively identify partnerships. In terms of the quantitative analysis, as there is no scale which can be applied to contextualise the network calculations, it is difficult to gauge the interconnectedness of this ecosystem in comparison to other (vaccine) networks. However, since no similar analysis has been conducted before and all calculations in this paper were interpreted by the same researcher, the interpretations of the calculations in this thesis are considered valid and not influenced by subjectivity. Interpretations were based on calculation analyses of past public health SNAs.

Regarding the key-informant interviews, due to their semi-structured nature, questions asked differed slightly per interviewee which may have influenced their answers. However, this was deemed necessary to ensure the expertise of each interviewee were leveraged and unique perspectives derived. Furthermore, only five interviewees were included in the study. This was deemed a sufficient number considering the time restrictions of this thesis. Especially since interviewees all appeared to agree on key themes, it was not thought necessary to conduct further interviews. Additionally, there is a risk of information bias since all interviewees worked at the same organisation. This was due to difficulties in acquiring access to high-level experts from various organisations. However, all interviewees had a wide array of experiences through their past professional histories which they were asked to draw upon. Therefore, they were deemed to have a sufficiently broad perspective to minimise bias. Nonetheless, it is recommended that future research includes a larger sample of interviewees working in various organisations to gain more insight into different perspectives. Also, deriving key interview themes and the application of the DAC criteria entailed an element of subjectivity. To minimise the impact of this, the methodological approach of Braun and Clarke (2006) thematic analysis was

employed which permits replicability of findings. Prior to conducting the interviews, questions were also developed to assess the ecosystem against each DAC evaluation criteria (appendix 4) which ensured specificity while applying the criteria. A final limitation of this study is that, in view of the ad-hoc nature of the COVID-19 ecosystem, the generalisability of findings to long-established vaccine ecosystems should be considered carefully.

Despite the above limitations, the reliability of results was ensured by thoroughly describing the search strategy of the document analysis which allows replicability of methods. The strict application of inclusion and exclusion criteria further strengthened reliability. The use of quantitative methods ensured the validity and objectivity of the results. Also, since node and edge lists have been made publicly available, the replicability and accessibility of findings is improved. Overall, the limitations are thought to have a minimal impact on study outcomes and this thesis is considered to have maintained an adequately high research quality.

5.3 Recommendations

5.3.1 Policy Recommendations

With regards to policy recommendations for Disease X ecosystems, this thesis supports the IPPPR recommendation for the establishment of a sustainable, global vaccine taskforce to ensure agility in future ecosystems (Hoen et al. 2021). It is imperative that this taskforce includes decision makers and experts from diverse, interdisciplinary backgrounds to enhance rapid and effective policy making. The purpose of such a taskforce would be to ensure a more rapid and effective global response to future pandemics from an angle that individual nations are unable to achieve (Hoen et al., 2021). In view of the importance of philanthropic organisations as connecting stakeholders, the global vaccine taskforce must engage these organisations (Hoen et al., 2021). To tackle the issue of manufacturing supply chain bottlenecks, Yadav and Weintraub (2021) recommend the establishment of a centralised monitoring system or infomediary which is able to maintain an overview of manufacturing supply chains. Thesis findings support the establishment of such systems and recommend they be integrated into the role of the global vaccine taskforce. The taskforce would serve as a key stakeholder in Disease X vaccine ecosystems.

Other than the global vaccine taskforce, future vaccine ecosystems must strive to achieve better and faster stakeholder alignment. To achieve this, it is first necessary to conduct a review of existing alignment strategies and decision-making structures between sectors. Moreover, the decision-making structures of EU institutions must be revised and new organisations such as HERA should be

leveraged to achieve an agile and interdisciplinary approach and thus allow the EU to make a greater impact in future networks.

5.3.1 Research Recommendations

Henceforth, future research should focus on a thorough understanding of the impacts of vaccine nationalism on manufacturing supply chains. Furthermore, the network calculations identified AstraZeneca and BioNTech as key network stakeholders. The factors which result in certain companies exerting greater influence than others in similar contexts should be investigated. Lastly, the democratic un-accountability of pharmaceutical companies affects all sectors in which the pharmaceutical industry is involved including neglected and non-communicable diseases (Dukes, 2002). The notion has been a growing cause of concern (Dukes, 2002). The findings of this research suggest that philanthropic organisations may be able to allow for some accountability of pharmaceutical companies. Consequently, it is vital to research how collaboration between industry stakeholders and philanthropic organisations can be increased (Doh & Guay, 2006). How to develop mechanisms which balance the need for accountability with granting industry sufficient freedom to innovate and respond rapidly in times of emergency requires further investigation (Keohane, 2002). If such balanced mechanisms are developed successfully, they will benefit all involved stakeholders since the public will have a certain (albeit indirect) influence in pharmaceutical decision making. Simultaneously, the pharmaceutical industry will be able to easily understand and address public needs.

5.4 Conclusion

Overall, the COVID-19 vaccine stakeholder ecosystem facilitated COVID-19 vaccine development and procurement in the European region. In doing so, several strengths and weaknesses were uncovered. The main objective of developing and procuring COVID-19 vaccines through agile use of time, costs and resources was achieved. The role of philanthropic organisations and the increased collaboration amongst stakeholders were also strengths. Ecosystem weaknesses included stakeholder alignment, the manufacturing supply chain and rigidity of the executive functioning of the EU. The EC, EMA, CEPI, WHO, UK VTF and AstraZeneca were identified as key stakeholders. Vaccine developers were a particularly influential stakeholder category. Thus, closer collaborations between industry and philanthropic organisations are recommended to resolve concerns of democratic un-accountability. Another main recommendation is the establishment of a global vaccine taskforce. To conclude, being one of the first studies to undertake the novel approach of an SNA, spanning

across several countries, this thesis revealed ground-breaking, evidence-based insights about the strengths and weaknesses of the COVID-19 vaccine development and procurement stakeholder ecosystem in the European region. From this, much needed recommendations for the establishment of more effective Disease X ecosystems were issued. These recommendations will ensure better pandemic preparedness and mitigate the catastrophic consequences of future pandemics.

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Declaration of Plagiarism

I, Mihika Kelkar, confirm that this thesis is my own work. I have acknowledged and fully cited all materials and sources used in the preparation of this thesis. I have not plagiarised the work of others.

Mihika Kelkar.
(29/06/2021)

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Appendices

Appendix 1

Main Stakeholder Type Definitions

Research: Stakeholders involved in the initial research required prior to vaccine development. These stakeholders conduct the exploratory and pre-clinical stages. Within the COVID-19 vaccine ecosystems this stakeholder category includes research institutes, mostly within universities.

Developer: Organisations which engage in the process of vaccine development. Vaccine development involves the process of taking a new antigen or immunogen identified in research and developing this substance into a final vaccine that can be evaluated through clinical studies. Typically, pharmaceutical companies are vaccine developers. At times, where a stakeholder was a vaccine developer and manufacturer/researcher/clinical trial stakeholder the main stakeholder type of the stakeholder was determined to be vaccine developer.

Manufacturer: Organisations that produce the developed vaccine at a large scale. For this study, stakeholders manufacturing raw materials, vaccine assembly, formulation, labelling and fill and finish are included. Stakeholders manufacturing glass vials and non-chemical substances required for the vaccine manufacturing were not included.

Regulator: Stakeholders who grant permission to execute clinical trials and/or stakeholders that conduct the scientific evaluation and authorisation of the vaccine for use. Regulatory stakeholders include national authorities but also international and supranational regulatory organisations. Regulatory stakeholders here also include agencies that assist stakeholders through the regulatory processes.

Clinical Trials: Stakeholders that fund or support clinical trials of COVID-19 vaccines within Europe. These stakeholders were identified using the EMA's EU clinical trial register (EMA, 2021). Note, that regulatory authorities were not considered clinical trials stakeholders.

Government: The organisations which govern decisions and form policy surrounding the COVID-19 vaccine development and procurement within a defined geographical area. The EC and HERA incubator were considered government stakeholders. Where stakeholders were governments and funders, the main stakeholder type of the stakeholder was determined to be government.

Funder: Organisations which fund stakeholders involved in the COVID-19 vaccine development process within the European region. In this study, only organisations whose main expertise is within health were included. Therefore, non-pharmaceutical, commercial companies or individual donors were not included.

NGO/CSO: Organisations not related to governments which work predominantly on a non-profit basis. These organisations aim to act in the interests of the public.

Appendix 2

Interview Protocol

General Introductions (10 minutes)

Hi, it's nice to meet you. Firstly, thank you for agreeing to this interview.

This interview is being recorded so it can later be transcribed. The study is conducted in accordance with the GDPR.

Topic Introduction

Just to provide you with an overview of the research being undertaken here, this is an internal project for CEPI (and a part of my bachelors' thesis). We are conducting a retrospective analysis into the COVID-19 vaccine development and procurement ecosystem. The main aim of this research is to understand how this particular ecosystem came into being and the strengths and weaknesses of this ecosystem.

In this case by ecosystem, I am referring to the European stakeholders and partnerships which played a role in the development and procurement of COVID-19 vaccines. In order to analyse this ecosystem, we have categorised actors/stakeholders into 8 'stakeholder categories' (including developers, manufacturers, regulators, research institutes/ organisations, governments purchasing the vaccines and funders such as CEPI).

Compared to the several other mapping exercises of COVID-19 stakeholders and partnerships being undertaken, we are attempting to map the stakeholder categories and partnerships against a commonly used OECD/DAC evaluation framework to provide a unique assessment of strengths and weaknesses.

[pause for questions]

The interview is structured as follows, firstly, I am going to ask about your understanding of the ecosystem. I will then ask more about specific partnerships before moving on to the strengths and weaknesses of the ecosystem as a whole.

Topic 1: Defining the ecosystem generally (10 minutes)

- Do you think this conceptualisation of the COVID-19 vaccine development and procurement stakeholder ecosystem makes sense?
- In a normal (non COVID-19) scenario, could you describe briefly how a European vaccine developer works with [manufacturers/ other stakeholders] to achieve their objectives? (For example, where a European vaccine developer identifies manufacturing

needs it cannot meet itself, what is their typical approach to engaging partners to meet those needs) ?

- Do you think there were any key roadblocks in initial collaborations between stakeholders?

Topic 2: Characterising ecosystem stakeholders in the COVID-19 context (15 minutes)

- Thinking now about the COVID-19 partnership ecosystem, what if anything changed from previous vaccine development ecosystems in terms of European vaccine developers' & purchasers' partnership approaches?
  - To what extent do you think the outcomes of this stakeholder's partnership approach address public need?
    - How could the public's needs be better addressed?
  - Do you think there were any key roadblocks in the initial collaboration with their partners?
- In your recollection, as the COVID-19 vaccine ecosystem began to come together, did any specific trends or interesting partnership approaches come to mind?

Topic 3: Network strengths and weaknesses (25 minutes)

Thank you, I will now move on to understanding the overall European COVID-19 vaccine development and purchase network.

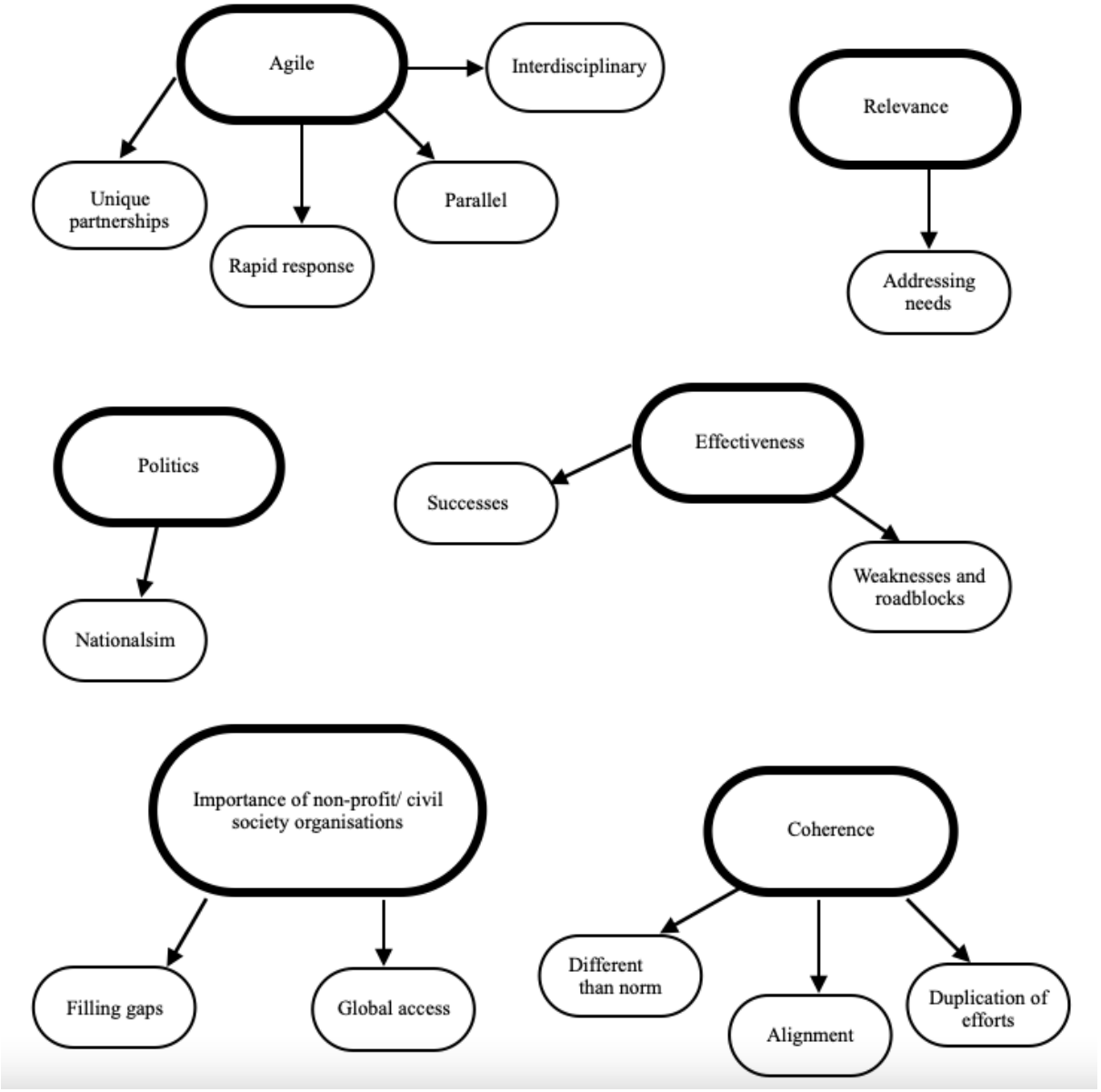
To fairly and objectively assess the strengths and weaknesses of this ecosystem, we will be using the OECD DAC'S evaluation criteria which is used to assess the successes and impacts of international programmes, interventions and/or policies. I am providing you with this information so you can better understand the rationale behind the questions I am about to ask.

- From your perspective, in the early stages of the pandemic response, what were the overarching objectives of the vaccine development community that may have driven the approaches to building partnerships we discussed earlier?
  - Could you talk a little more about whether you think the initial objectives set were realistic or helpful?
  - Were there any key early challenges for vaccine development stakeholders in achieving these objectives?
- Looking more generally at the characteristics of the COVID-19 vaccine development and procurement ecosystem, what do you think are the key strengths/ weaknesses?
  - How could the weaknesses you mentioned/ partnerships be improved for future vaccine development and procurement?

    - How do the strengths and weaknesses of this ecosystem compare to the ecosystems established for other CEPI priority pathogens?
- How do the cost and time investments made in building the COVID-19 vaccine development and procurement ecosystem compare to previous efforts? Can you identify any specific efficiencies that were realized?
- What are your thoughts on the sustainability of the existing partnerships and network as a whole (do you think these partnerships will continue post- COVID-19)?
    - How do you think the sustainability of the ecosystem as a whole can be enhanced in the future?
- Do you have any other comments or insights you would like to share?

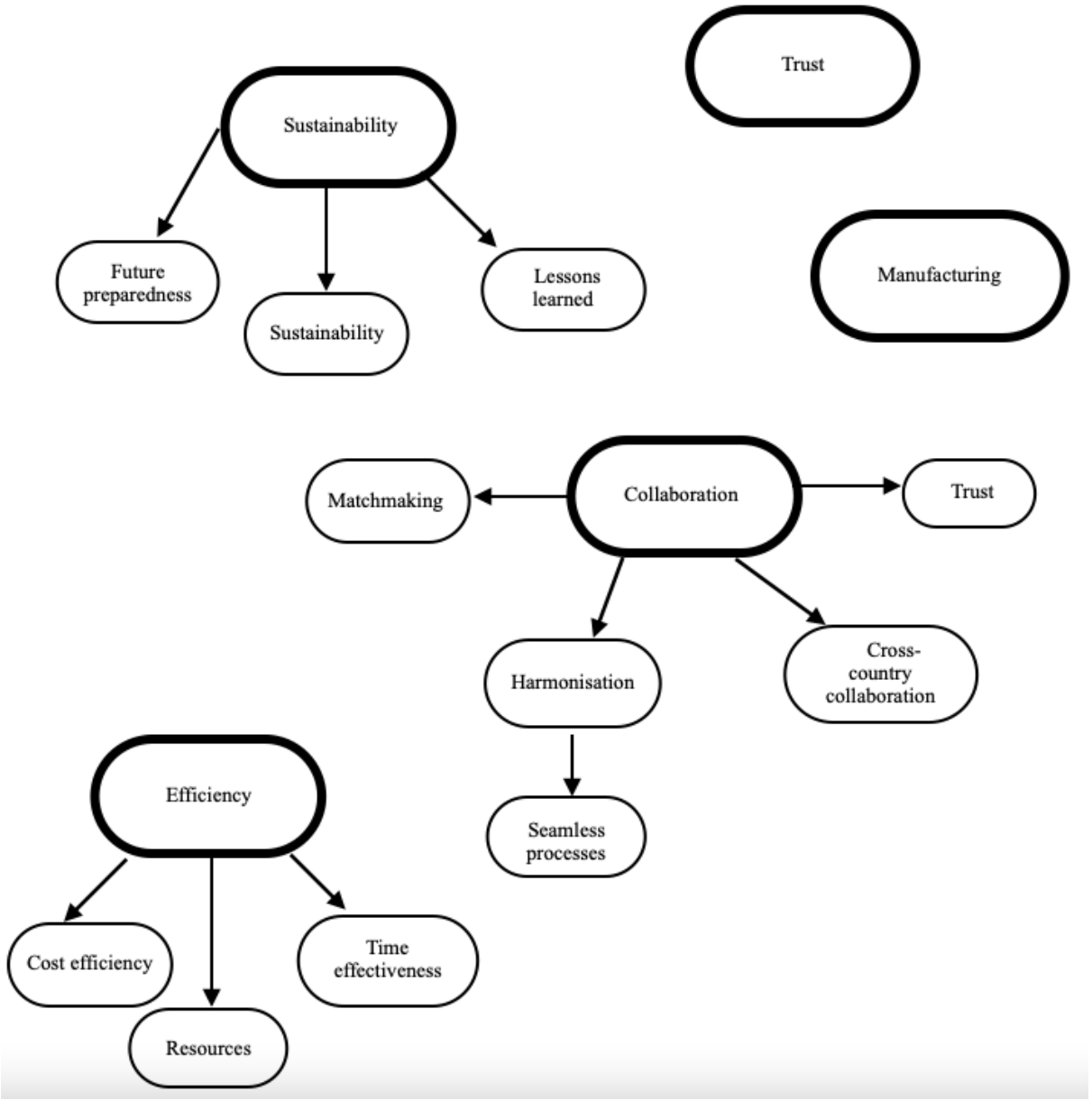
Appendix 3

Thematic Maps from Interview Coding



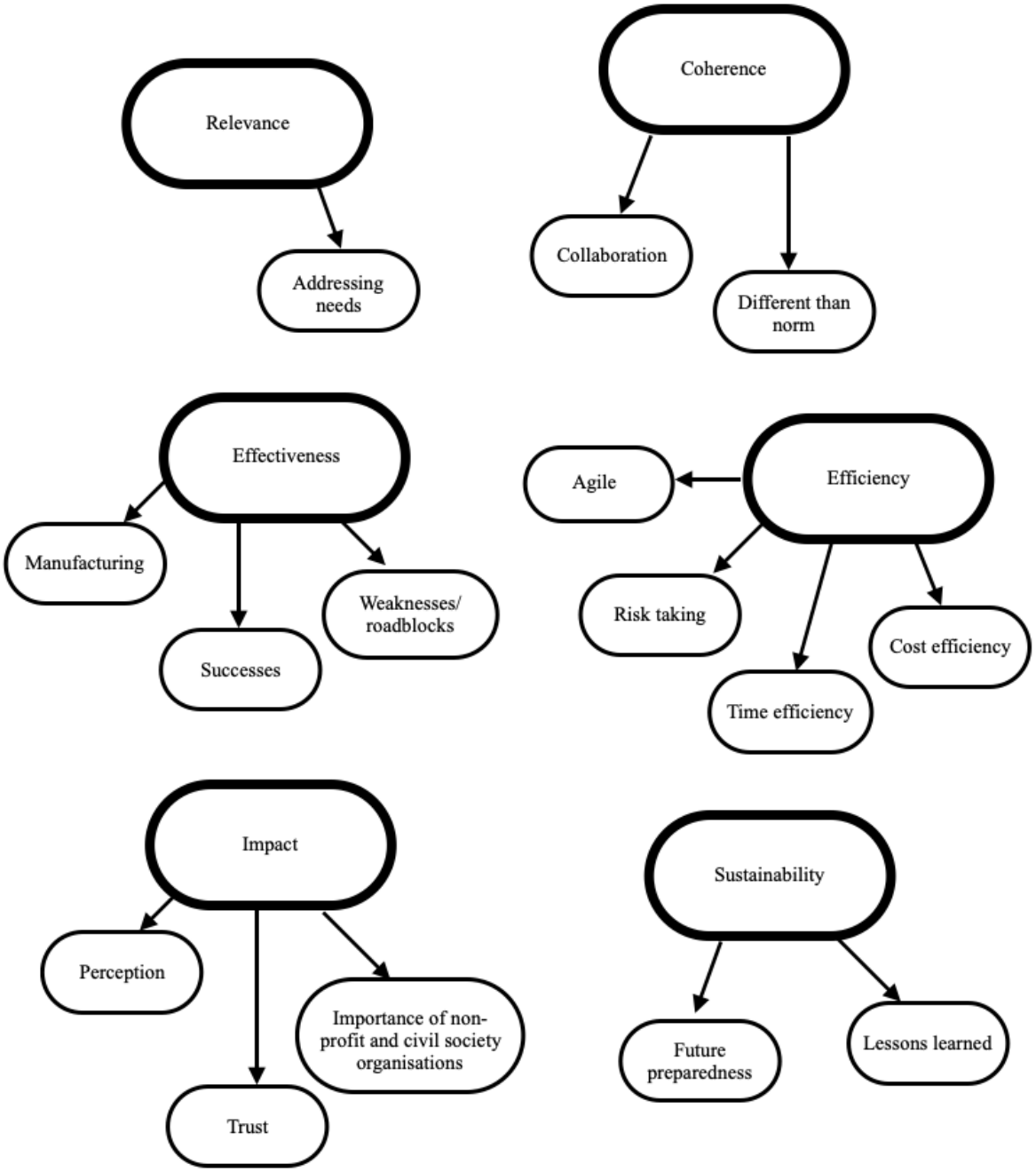
Appendix figure A1: Initial thematic map codes 1-6

Note: Diagram created by author.



Appendix figure A2: Initial thematic map codes 7-11

Note: Diagram created by author.



Appendix figure A3: Final thematic map with 6 key themes

Note: Diagram created by author.

Appendix 4

OECD DAC Evaluation Criteria Definitions and Questions

Table A1: OECD DAC Evaluation Criteria definition and questions

Criteria	Definition	Questions
Relevance	The extent to which the ecosystems's objectives respond to global needs and priorities.	Are the public's needs being addressed through (the outcomes of) this ecosystem?
Coherence	**External Coherence:** The differences of this ecosystem in comparison to ecosystems established for vaccines in the past.	External Coherence: What, if anything, was different in the partnerships and stakeholders involved in the COVID-19 vaccine development and procurement ecosystem compared to past vaccine development and procurement ecosystems?
	Internal Coherence: The synergy between stakeholders within the current ecosystem.	Internal Coherence: To what extent are the various stakeholders involved in the ecosystem aligned regarding the purpose and objectives of this ecosystem? To what extent does this ecosystem ensure a harmonised and seamless process of COVID-19 vaccine development and procurement across Europe?

Effectiveness	The extent to which the ecosystem is expected to achieve its objectives.	Has the ecosystem succeeded in the development and procurement of a COVID-19 vaccine in Europe? What, if any, were the key roadblocks which are/were preventing or delaying the ecosystem from achieving its objectives?
Efficiency	The extent to which this ecosystem is able to deliver the results in a timely and economic manner (economic refers to funds, expertise, resources, etc.).	Was the ecosystem able to achieve its objectives in a time- and cost-effective manner? How does the cost and time taken to develop and purchase the COVID-19 vaccine compare with the costs and time required to develop and purchase past vaccines? And were the differences considered to be justified? Were the expertise and resources available mobilised and, where relevant, adapted to ensure ecosystem efficiency?
Impact	The extent to which this ecosystem (and the stakeholders involved) has generated or is expected to generate significant positive or negative, intended or unintended effects.	Which stakeholder categories played an especially impactful role in this ecosystem and why? What, if any, were the unexpected results emerging from the COVID-19 ecosystem? Were these positive or negative?

Sustainability	The extent to which the ecosystem can be maintained for future outbreaks.	Can this ecosystem (as it stands) be maintained to tackle future pandemics and develop vaccines? Why? What are the lessons learned from this ecosystem to establish future Disease X ecosystems which better ensure pandemic preparedness? What, if any, efforts were taken by the existing ecosystem stakeholders to improve ecosystem sustainability for the future?

Appendix 5

Information Sheet and Informed Consent Form

Informed Consent Form

Informed Consent Form for key-informants who work for stakeholders involved in the European COVID-19 vaccine stakeholder ecosystem.

Name of Principal Researcher: Mihika Kelkar
Name of Organisation: Coalition for Epidemic Preparedness Innovations (CEPI)/ Maastricht University.
Name of Project: Analysis and evaluation of the European COVID-19 vaccine stakeholder ecosystem.

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (for signatures if you choose to participate)

You will be given a copy of the full and signed Informed Consent Form

Part I: Information Sheet

Purpose of the research

COVID-19 has highlighted the importance of vaccines in combating and overcoming pandemics. However, the development and purchase of the COVID-19 or any vaccine involves several stakeholders and partnerships. The more effective such vaccine development ecosystems are, the more effective and faster vaccines can be produced. However, to improve the effectiveness of vaccine development stakeholder ecosystems, we need to evaluate existing ecosystems.

The aim of this research project is to conduct a social network analysis which analyses the roles of stakeholders within the COVID-19 vaccine development and purchase ecosystem and the nature of the partnerships which compose this ecosystem. Further, we would like to identify the strengths, weaknesses and consequent implications within the existing COVID-19 vaccine development ecosystem. From the findings, we will develop policy recommendations for future coronavirus and Disease X vaccine development.

Type of Research Intervention

This research will involve your participation in a virtual (recorded) teams or zoom interview lasting one hour maximum. The interview will be undertaken by the principal researcher under the supervision of her supervisor at CEPI .

Participant Selection

You are being invited to take part in this research because we feel that your experience working within CEPI can contribute much to our understanding and knowledge of the European COVID-19 vaccine stakeholder ecosystem.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your current activities. You may change your mind later and stop participating during the interview or ask that your records be discarded (up to 4 June 2021). After 4 June 2021, the research will be completed and potentially published and therefore it will not be possible to withdraw your consent beyond this date. Nevertheless, your data will remain confidential and anonymised.

Procedures

A. A brief introduction to the format of the research study.

This research is being undertaken to write a bachelors' thesis. The research/thesis will conduct a social network analysis of the COVID-19 vaccine stakeholder ecosystem. To gather information for the social network analysis key-informant interviews and a document analysis will be undertaken.

B. Interview process and your rights

The interview will take place remotely via a teams or zoom call (link will be sent to your email). In the interview only you, the CEPI supervisor and the principal researcher will be present. The interview will be recorded so your answers can be transcribed later. Any information recorded is confidential, and no one else except the principal researcher, her supervisor and the Head of Epidemiology at CEPI will have access to the information documented during your interview.

Should we wish to include specific quotes in the paper, which were obtained during your interview, we will contact you again to request specific permission for the use of certain quotes.

C. Type of questions asked

During this interview you will be asked general questions pertaining to the COVID-19 vaccine development and procurement ecosystem e.g. how/ why these partnerships are formed and how they

function in general. The interview will focus on questions such as: do you believe the partnerships within the COVID-19 ecosystem are effective and sustainable? What do you think are particular strengths and weaknesses of the COVID-19 vaccine development ecosystem? What do you think can be improved for future vaccine development?

Duration

You will be required to participate in the interview only once for a maximum duration of one hour. The research itself however takes place over five months (February 2021 - July 2021).

Risks

Since this research and the interview questions pertain to institutions and policy processes as opposed to you individually or any human behavior, all risks are minimal. Regardless, the European General Data Protection Regulation (GDPR) will be observed in this research and any personal data will remain confidential.

Benefits

There will be no direct benefit to you, but your participation is likely to help form recommendations, and thus develop more effective vaccine stakeholder ecosystems in the future which ensure more effective and faster vaccine development and purchase.

Confidentiality

During the interview no personal information about you (e.g., name, position within the organisation, etc.) will be asked or recorded where possible. Should any personal information arise naturally during the interview, it will be anonymised (assigned a number instead of the word) and excluded from the final thesis/ research document. Furthermore, the interview recording and transcripts will only be accessible to the three people granted access (the principal researcher, the supervisor at CEPI and the Head of Epidemiology at CEPI) and will *not* be shared externally. Overall, this research complies with the European GDPR to ensure your data privacy.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may refrain from answering certain questions during the interview or choose to stop the interview at any time. You also reserve the right to withdraw your data up to 4 June 2021.

You may also demand a copy of your interview recording/ transcript at any point.

Who to Contact

If you have any questions, you may contact the principal researcher (Mihika Kelkar) on any of the following:

Phone: +44 7817034845

Email: mihika.kelkar@cepi.net

Part II: Certificate of Consent

I have read the above information sheet. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant:

Signature of Participant:

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately provided all relevant information in the interview information sheet above, and to the best of my ability ensured that the participant understands that the following will be done:

1. They will be interviewed about the role of the stakeholder (for whom they work) within the COVID-19 vaccine ecosystem and the partnerships this stakeholder engages in.
2. The interview will be conducted for one hour remotely via teams or zoom. The interview will be recorded.
3. All personal information collected about the participant in this interview will remain confidential and be anonymised.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent: Mihika Kelkar

Signature of Researcher: _____

Date: _____

Day/month/year

Appendix 6

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