



Lessons from Covid-19 Vaccine R&D. Submitted to Public Consultation, EU HERA

Submitted by: Suerie Moon¹, Adrián Alonso Ruiz, Anna Bezruki, Surabhi Agarwal and Marcela Vieira

Global Health Centre, Graduate Institute of International and Development Studies
Chemin Eugène-Rigot 2 | Case Postale 1672
1211 Geneva 21 | Switzerland
Tel +41 22 908 4558
Email globalhealth@graduateinstitute.ch

Introduction

Understanding the role of the public sector in countermeasure R&D is essential to realize the opportunities presented by the proposal for the creation of HERA.

Here we present a descriptive analysis of how, when and which public actors invested in COVID-19 vaccine R&D, which sheds light on the current role of the European Union (EU) and its Member States (MS) in the countermeasure R&D global ecosystem, and its potential ensuring that future health challenges are tackled equitably and fairly within European borders and beyond.

COVID-19 vaccine development. The role of the US and EU.

The Global Health Centre has been analyzing publicly available information on investments directed to COVID-19 vaccine development. This submission is derived from the data and analysis published through the Centre's Knowledge Portal on Innovation and Access to medicines². Our submission is also informed by a review our team conducted of the literature on biosecurity R&D, which includes a historical overview, the different actors involved, scope and prioritization of activities, and the funding and incentive landscape³. Our review found that the US has developed by far the largest and most institutionalized national innovation system for countermeasure R&D, though France, the United Kingdom, China and Russia also have considerable arrangements in place. For this reason, this paper focuses on a comparison between the US and EU and its MS in Covid-19.

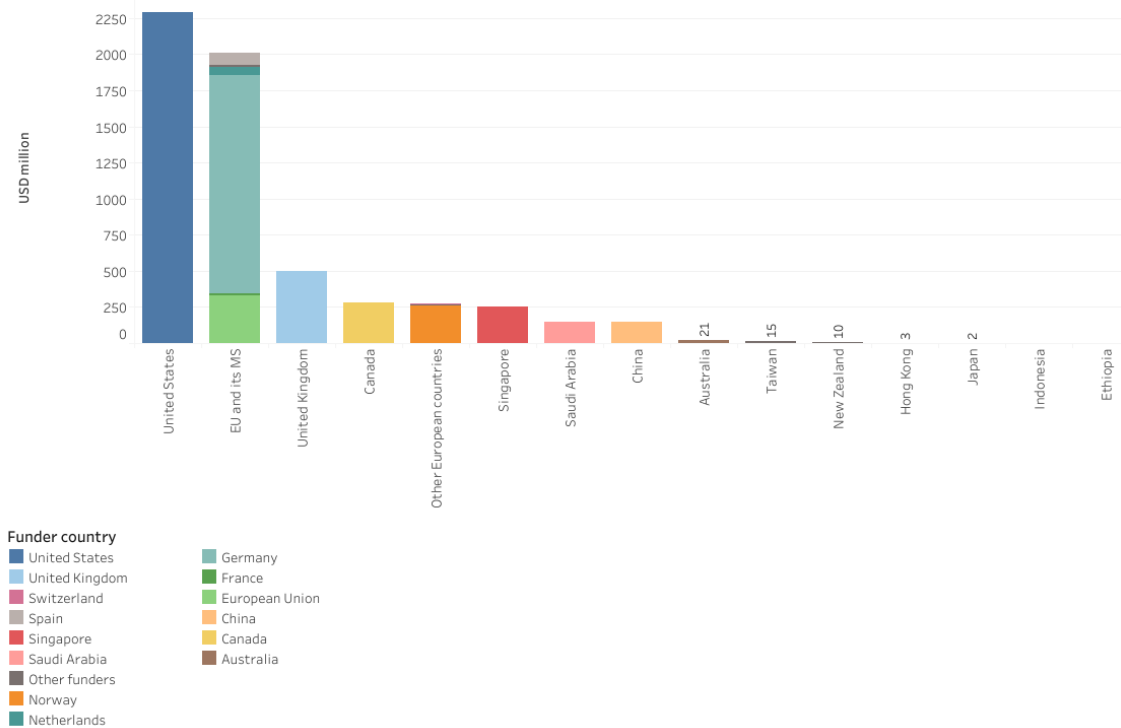
The urgent need to develop medical technologies to tackle the COVID-19 pandemic has yielded some differences with the traditional process of vaccine development, such as the unprecedented speed at which several candidates have been developed, and the level of public sector involvement at national and supranational levels, throughout the entire development process. Some of the key aspects assessed in this section are the size and timeline of the investments made by the public sector on COVID-19 vaccine development, and the actors involved in the R&D process.

¹ Co-Director, Global Health Centre. Professor of Practice, Interdisciplinary Programmes and International Relations and Political Science

² Global Health Centre. 2021. COVID-19 Vaccines R&D Investments. Graduate Institute of International and Development Studies. <https://www.knowledgeportal.org/covid19-r-d-funding>

³ Global Health Centre. 2020. Research Synthesis: Biosecurity Research and Development (R&D). <https://www.knowledgeportal.org/biosecurityrd>

Figure 1. Source of COVID-19 vaccine R&D investments, by source country



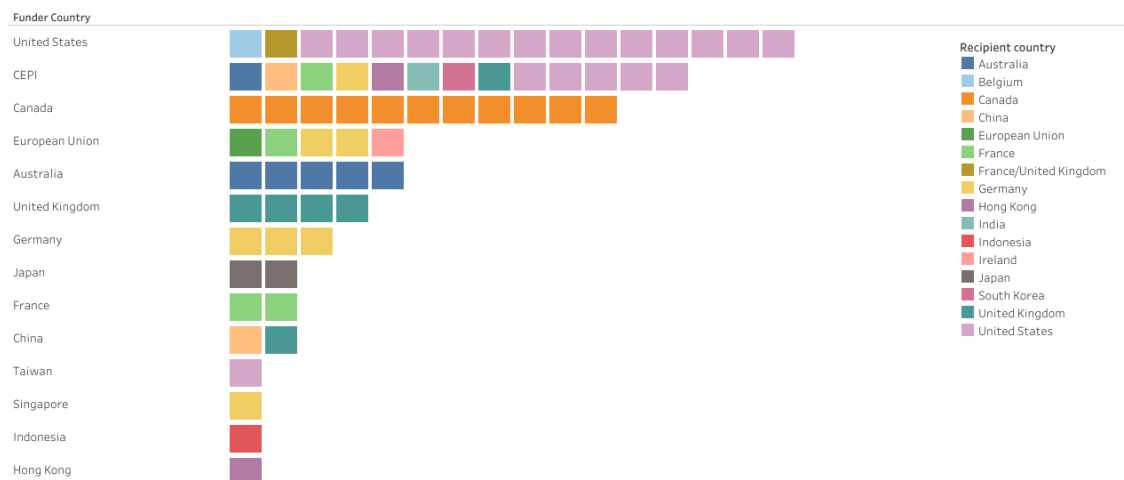
Note: Investments made by country/region. Only investments made by public institutions were included. Advanced purchase agreements are not included

Public institutions from the US and some EU's MS have led the investments dedicated to developing COVID-19 vaccines in 2020 and 2021 globally. However, the EU acted in an uncoordinated manner, with EU institutions investing less than some MS separately. Figure 1 shows the investments announced to support the development of COVID-19 vaccines. EU countries and institutions are grouped, showing the combined investments from Germany (the largest European investor and the second largest investor globally with USD 1.5bn invested), the EU (USD 327million), Spain (USD 87million), The Netherlands (USD 58 million) and France (USD 18 million). These investments include direct investments to R&D implementers and investments to intermediaries, mainly the Coalition for Epidemic Preparedness Innovations (CEPI).

When looking at direct investments to R&D implementers, both European and US public institutions invested primarily in pharmaceutical companies from their own region/country, suggesting a broader interest in investing in domestic R&D and industrial capacity as well as guarding against the risks of export bans.

In addition to direct investments to research institutions and pharmaceutical companies, the EU and its MS channeled 29% of its investments through CEPI, whereas the US did not, but rather invested directly. CEPI's mandate not only includes the development of vaccines against pathogens with epidemic potential, but also ensuring that these vaccines are made globally and equitably accessible. In addition, as shown in Figure 2, CEPI's R&D investments follow a more geographically diverse portfolio, than other national actors (including the EU).

Figure 2. Number and location of recipients per public funder location



Note: This figure shows the number of recipients and the country where each recipient is located, per public funder location. The figure only includes direct funding from public sources and the investments made by CEPI (Secondary funding from CEPI).

Considering the timing of investments is also relevant⁴, as earlier investments reduce risk for companies, and also enable them to begin the R&D process faster. In 2020, the US stands as the largest single investor, and also as one of the earliest investors, signing the first investment agreement in January 2020. The country's investments reach its maximum level in March 2020 with USD 903 million.

In comparison, the majority of EU MS' investments going directly to R&D implementers were made from Q2 2020 onwards with the highest investments made by Germany in Q3 2020, with more than USD 1bn invested between August and September. There is a lack of publicly available information on vaccine R&D investments from other EU MS; it is not clear if no investments were made or if the data is simply not accessible.

However, European investments channeled through CEPI started in Q1 2020 with contributions from Germany, that were followed in Q2 2020 by many other EU MS and non-EU European countries, with the highest investments made in Q2 2020. CEPI's investments (USD 0.9bn) started in January 2020 and reached its maximum level in May 2020 with USD 391 million invested, seemingly faster than EU MS and institutions' direct investments.

As candidates approached late-stage clinical trials and approvals, governments concluded various advanced purchase agreements (APAs) with producers. The APA timeline seems to follow a similar pattern, as the US started to sign these agreements in Q2 2020, and the EU followed later in Q3 2020. Additionally, the ACT-Accelerator (and its vaccine pillar COVAX) that have received substantial support from European countries and institutions, signed its first APA in Q2 2020 (the agreement was signed initially by CEPI but was then included under COVAX's umbrella). In total, the US has invested USD 16.4 billion in APAs (defined as purchase agreements finalized before the earliest vaccine candidate approval by a Stringent Regulatory Agency and including

⁴ Annex 1 contains a figure with the investment timeline

contract extensions as part of the total investments)⁵. The European Commission, invested USD 22.5 billion in APA, becoming the highest investor according to our estimates.

APAs can be understood as incentives for R&D as they provide a secure demand stimulus for manufacturers to invest in production and clinical trials. In addition, some agreements (e.g., US Operation Warp Speed) likely included funding for both R&D and the advance purchase of final products, but due to the lack of transparency, the amounts dedicated to each activity are not clear.

Conclusion

HERA is intended to address fragmentation of countermeasure R&D efforts in the EU⁶. Indeed, data on direct public investments directed to COVID-19 vaccine development shows a fragmented and slower response from the EU and its MS compared to other actors, such as the US or CEPI. However, by contributing to CEPI the EU and EU MS attained a faster deployment of economic resources to run R&D activities.

By collaborating with global health initiatives such as CEPI, the EU displayed an initial commitment to achieve global access to COVID-19 vaccines. This is also an important objective for HERA⁷. HERA could achieve broader global impact for the EU by requiring that recipients of its investments contribute to achieving global access to countermeasures, for example, through allocation of a proportion of initial supply to developing countries, technology transfer and sharing of intellectual property. It could also reach a more geographically diverse R&D portfolio by continuing to participate in global health initiatives like CEPI.

The level of public investment in developing, purchasing and deploying COVID-19 vaccines is unprecedented in size and speed. Although EU involvement in both funding R&D activities and signing APAs seems to have taken place after the US, the EU and its MS are collectively the largest global investor when combining direct R&D investments and APAs, and the second largest investor when considering R&D investments (either direct investments or through CEPI) which likely allowed for the faster development and production of COVID-19 vaccines.

The creation of an operational and infrastructure Authority as HERA could reinforce increased coordination and speed across EU MS and institutions to address global health threats, strengthening the role of the EU as a global actor by ensuring equitable and global access to medical countermeasures developed by HERA and the creation of an end-to-end approach to develop health technologies in a space where public sector engagement is essential.

⁵ We acknowledge that this could overestimate the “pull” effect for extensions agreed after SRA approval. However, extensions were included in the initial contract, and could be understood as a demand signal for manufacturers, reducing uncertainty.

⁶ [https://eur-lex.europa.eu/legal-content/ES/ALL/?uri=PI_COM:Ares\(2021\)674649](https://eur-lex.europa.eu/legal-content/ES/ALL/?uri=PI_COM:Ares(2021)674649)

⁷ Ibid. “HERA would also support the EU as a global actor and help to ensure improved availability and access of crisis-relevant countermeasures, which are also needed in countries outside of the EU. To this end, HERA would coordinate and collaborate with international partners, stakeholders and organisations at an international level.”

Methodology and Limitations

This analysis relies on public disclosure of R&D investments for COVID-19 vaccines in 2020 and 2021⁸. Information on R&D investments is collected from news, reports, academic articles, and data repositories⁹. Funding directed to basic research, supply of vaccines or technology transfers was not included.

Advance purchase agreements (APAs) are those reported on a date prior to vaccine approval (emergency approval included) by a Stringent Regulatory Agency (SRA). Agreements with data on the amount invested were included, and contract extensions were considered part of the initial agreement¹⁰. When more than one SRAs had approved the vaccine candidate the earliest date was taken.

Given the changing nature of the COVID-19 vaccine R&D landscape, the different definitions applied in the funding agreements and the sensitive nature of pharmaceutical R&D investments, the data may contain inaccuracies or be out of date. Pharmaceutical industry investments are not included in the database, given the lack of publicly available data. Similarly, investment data coming from some countries may be underreported.

The data collected show R&D investments and/or commitments to invest, but do not show current disbursements of the funding agreed. Additionally, it does not differentiate between grants, loans or other types of funding agreements.

⁸ Last Update was done on May 11th, 2021

⁹ Policy Cures Research COVID-19 R&D tracker, ACT-Accelerator Tracker. Data for APAs comes from our COVID-19 Vaccine Arrangements tracker (Global Health Centre. (2021). COVID-19 Vaccine Purchases and Manufacturing Agreements. Graduate Institute of International and Development Studies. <https://www.knowledgeportalia.org/covid19-vaccine-arrangements>)

¹⁰ Ibid., 5

Annex 1. Figure 3. Investment timeline by country and type of funding

Figure 3. Investment timeline by country and type of funding

