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Racing against COVID-19: a vaccines strategy for Europe

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Executive summary

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THE FAST DEVELOPMENT of vaccines is an essential part of the long-term solution to COVID-19, but vaccine development has high costs and carries the risk of high failure rates.

THERE ARE CURRENTLY too few promising projects in the clinical trial pipeline to guarantee at least one vaccine soon. More projects need to pass through the development pipeline in parallel. Vaccines should ultimately be widely available to all who need them at low cost.

PRIVATE LIFE-SCIENCES COMPANIES under-invest in vaccine development, especially when compulsory licensing and/or price regulations are imposed. Public funding is needed to reduce the risks of investing in vaccine development, and also to balance compulsory licensing and/or price regulations with incentives for private firms.

THE PUBLIC FUNDING being put into identifying COVID-19 vaccines is too limited to carry enough projects through so that at least one vaccine, and preferably more, become available at large scale and low cost. Public budgets for these efforts need to be multiplied up several times over. We propose a staged support scheme to tackle the COVID-19 vaccine challenge and a moon shot programme to meet the challenge of future pandemics. We calculate the public budget needed to ensure supply of COVID-19 vaccines. Although substantial, the budget represents a bargain compared to the avoided health, social and economic costs.

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1 The COVID-19 vaccine challenge

To stop the COVID-19 pandemic, reopen the economy and prevent the pandemic from restarting, the world needs vaccines. Given how difficult and costly it is to engineer natural immunity, vaccines are critical for helping to build herd immunity to manage the disease.

But so far, no vaccines (or therapies[1]) for COVID-19 have been approved by regulatory agencies. The genome of the virus was sequenced very quickly and put in the public domain, meaning that researchers were within a matter of weeks able to identify several promising vaccine candidates. Start-ups, legacy drug makers and research labs have stepped forward with plans to develop vaccines or treatments for COVID-19. National and international public authorities have pledged funding for treatments and vaccines. There is much hope that a COVID-19 vaccine will be available soon – most optimistically in the next six months, though the most frequent prediction is 18 months[2].

But many questions remain. Are there enough projects in the pipeline to ensure a vaccine soon? Once successfully developed, can a vaccine be manufactured quickly on a large scale? Will it be available at a fair price? Can open access and fair prices be ensured without discouraging private developers? Who should fund the development and production costs? We address these questions by examining success rates from previous vaccine-development projects and matching this, in terms of numbers of projects and funding, with what is currently in the pipeline for COVID-19. To ensure the successful development of COVID-19 vaccines in the European Union, we propose an EU publicly-funded support scheme.

2 The long road to vaccine development

Drug development (for both treatments and vaccines) typically follows a clear path (Figure 1). At each stage, the development of a drug might be stopped for technical, medical or economic reasons. The different stages are characterised by different probabilities of success, and strongly varying costs and durations.

Figure 1 shows that the average success rate for drug development is about 10 percent to 15 percent. The high risk rates imply that society needs many candidate substances at the outset of clinical trials to be sufficiently sure of getting a suitable product in the end.

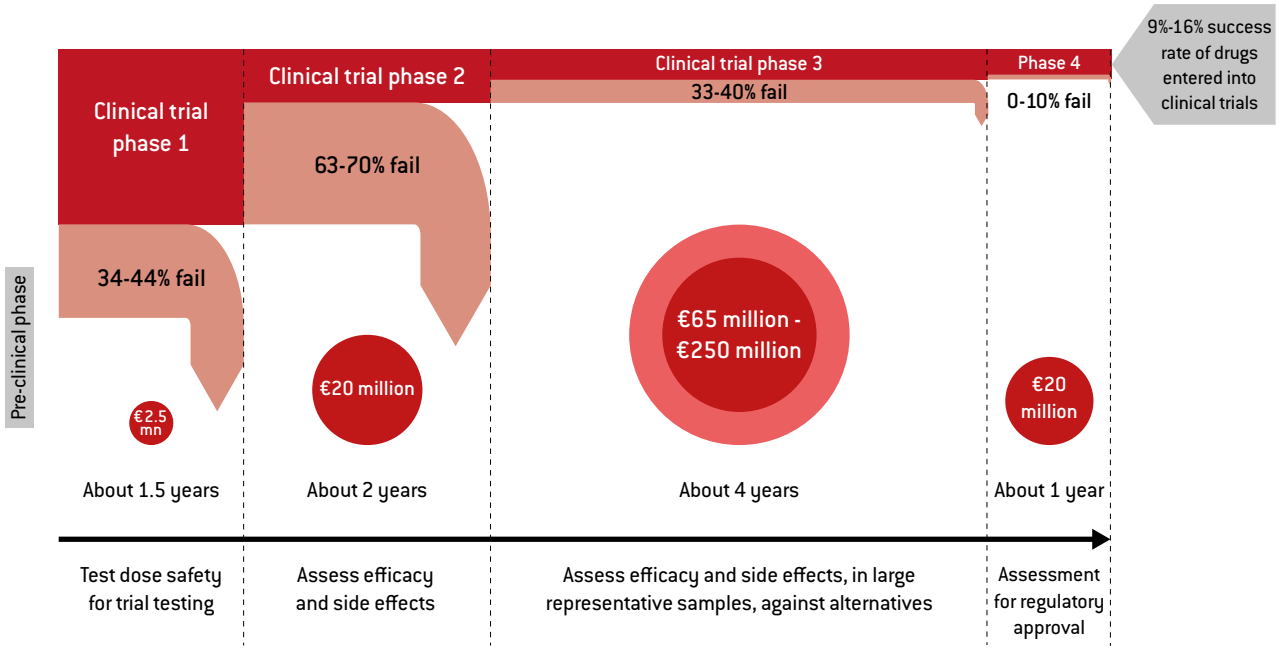
For vaccines, the success rates are higher than for medical drugs in general[3]. Success rates for vaccines that entered clinical trials can range from 20 percent to 40 percent (Figure 2). In particular, vaccines for new diseases, such as COVID-19, are more likely to pass the critical and expensive phase 3 because there are not yet benchmarks against which efficacy needs to be proved.

1 This contribution focuses on the economics of the development of vaccines, but many parts of the analysis would also apply to treatments for COVID-19. Vaccines and treatments are anyway complementary (see Eichenbaum *et al*, 2020).

2 *"Dr. Anthony Fauci, the head of the National Institute of Allergy and Infectious Diseases (NIAID), poured cold water on Trump's estimate, saying it would be more like a year to a year and a half."* See https://edition.cnn.com/2020/03/31/us/coronavirus-vaccine-timetable-concerns-experts-invs/index.html.

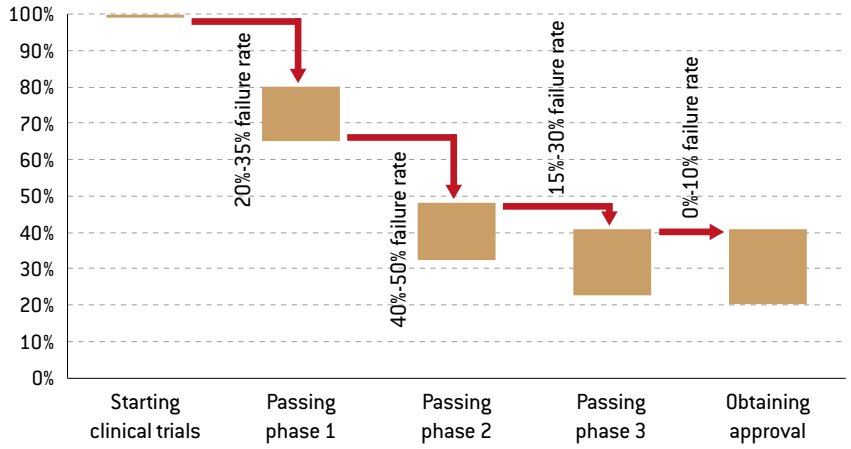
3 Fewer studies look at the success rates by type and phase, leading to less-robust estimates of success rates for vaccines at the different clinical trial stages. An extreme example is a study by Pronker *et al* (2013), quoted by Gouglas *et al* (2018), who reported: *"In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94% chance of failure."* The success rates we have used are based on a large set of studies, with the lowest and highest extremes eliminated.

Figure 1: A typical trajectory of drug development[4]



Source: Bruegel. Note: Reported success rates are averages from six review studies, with the minimum and maximum values eliminated. For a list of the review studies, see the References. See also https://en.wikipedia.org/wiki/COVID-19_drug_development.

Figure 2: Success rates for clinical trials of development for vaccines



Source: Bruegel based on review studies (see the References).

In addition, the time span for vaccine development can also be expected to be shorter than the average for drug development[5]. All regulatory authorities for medicines have fast-track procedures. Vaccines go through such fast tracking because they are typically developed in response to emergencies, often with no available benchmarks to prove efficiency against. Also, agencies can authorise **emergency use**, allowing vaccines that are still in the process of clinical trials to be made available to some patients. This is however only for restricted excep-

4 The research phase before the pre-clinical and clinical development phase is not considered here. This exploratory phase may take many years and involve many dead ends. Also not included are production and commercialisation. The costs of the production and commercialisation stages vary widely.

5 For instance, it took just ten months for the vaccine for Ebola to go from phase 1 to phase 3 trials (*The Economist*, 2020).

tional cases, such as for medical personnel, and never on a large scale.

Repurposed substances – substances already approved for other diseases –can reuse past results and typically go much faster through clinical trials, with lower costs and higher success rates[6].

Who develops vaccines?

Exploratory research and the pre-clinical and early stages of clinical trials can be done by researchers in research institutes or small firms. At later stages, however, particularly phase 3 and commercialisation, large life sciences firms typically take over. They have the financial resources for these more expensive stages, experience of managing large clinical trials and regulatory approval procedures, and they have the commercialisation capability (manufacturing, distribution and marketing)[7].

In the last few decades, the vaccine industry has been through a major consolidation, leaving only a handful of large life-sciences firms active on the market. The largest life sciences companies for vaccine production (in terms of vaccine revenues) are GSK, Merck, Sanofi and Pfizer (*Statista*, 2020). Johnson & Johnson, through its subsidiary Janssen Pharmaceutica, currently has the largest number of vaccine projects in preclinical trials (*Statista*, 2020).

How is vaccine development financed?

National and international public research money typically funds the initial exploratory **research** phase, often done by university labs or research organisations. Funders include the US National Institutes of Health, and the European Union through its multi-annual research programmes[8]. Philanthropists, such as the Bill & Melinda Gates Foundation, are prominent funders. Also big life sciences companies provide some funding for vaccine research.

The vaccine **development** phases, typically done by private companies, are funded either by large life-sciences firms themselves or through company partnerships. Their returns from investing in vaccine development depend on the exclusive ownership they can obtain of the right to use the ultimately approved substance or technology. As ownership of knowledge and claims can be identified clearly in drug development, patents are very effective in protecting the intellectual property and ensuring exclusive ownership during the patent lifetime. Patents are used heavily in this industry. Typically, platform technologies and mechanisms of action (how to treat a certain illness with a certain substance) are patented early on in the process. The owners of the patents for successful drugs/vaccines might be the original applicants, but developers can also acquire patent rights by buying or licensing from others during the development process.

External funding for development is available mostly through public-private partnerships. Particularly for the later more-expensive clinical trial stages, public funding if provided at all, is through co-funding with private developers. In the US, the public part of these partnerships is channelled through the Biomedical Advanced Research and Development Authority (BARDA, https://www.phe.gov/about/barda/Pages/default.aspx). At the EU level this is channelled through the Innovative Medicines Initiative (IMI, www.imi.europa.eu), a public-private partnership between the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Debt and equity funding for vaccines and other initiatives is also provided via the European Investment Bank's InnovFin Infectious Diseases Finance Facility (IDFF).

6 Hydroxychloroquine, used to treat malaria, is an example seen by many as a potential treatment for COVID-19. It has not been fully trialled as a COVID-19 treatment.

7 As an exception, a clinical trial for treatments for COVID-19, planned to involve 3,200 patients in eight European countries with severe COVID-19 infections, was started in March 2020 by the French national health research agency Inserm. This example shows that even phase 3 can be done without big pharmaceutical companies, and can be done with international coordination.

8 For a list of EU-funded research projects on vaccines, relevant for COVID-19, see https://erc.europa.eu/news-events/magazine/frontier-research-service-coronavirus-epidemic-response.

Another recent major funder of vaccine development is the global Coalition for Epidemic Preparedness Innovations (CEPI), set up in 2017 with a targeted $1 billion fund. Its financing partners include the Gates Foundation and a number of countries. The EU, through IMI, is also a partner (https://cepi.net).

3 Specific challenges for COVID-19 vaccine projects

On top of the high overall failure rate of clinical trials of vaccines, COVID-19 poses specific challenges (*The Economist*, 2020).

First, there is no current close substitute vaccine available from other corona- or other viruses, which could be repurposed quickly for COVID-19. The 2003 outbreak of SARS (severe acute respiratory syndrome), also caused by a coronavirus, was controlled after four months, impeding the development of a vaccine. In hindsight, this was unfortunate, as a SARS vaccine could have helped to accelerate the development of a COVID-19 vaccine.

Another challenge is the scale at which the vaccine, when available, needs to be produced and made available throughout the world to provide herd immunity. A vaccine made for the world has never been done before. The Gates Foundation is already trying to address these large-scale manufacturing challenges by funding new factories for potential coronavirus vaccines[9].

Nevertheless, existing technologies to develop and manufacture vaccines can be used as a platform for a COVID-19 vaccine. Some COVID-19 vaccine projects are based on proven approaches to vaccines, which use modified forms of the virus. The advantage of this approach is that it is well tested, with a stock of expertise, including for manufacturing. However, as it involves cultivating live cells, manufacturing cannot be quickly scaled up. Other projects use newer approaches focusing on genetically engineered synthetic vaccines that activate the body's immune response. The active ingredient in these vaccines can be the virus's DNA or RNA (the genetic instructions for building proteins), or the proteins/spikes that let the virus enter into human cells. These vaccines can be quickly developed, as scientists only need the virus's genetic code, which was made available very quickly for COVID-19. Such synthetic vaccines should in principle be faster and cheaper to manufacture at large scale. However, they face a higher risk of failure in clinical trials. There are no human DNA or RNA medicines on the market yet[10].

Because each approach carries specific risks, a variety of approaches will be needed to get a successful vaccine for COVID-19 through development. Vaccines developed through different approaches might also be better suited to specific population subtypes.

9 This is being done though the money could be wasted if vaccines are not developed. See Brianna Moné, 'Bill Gates is funding new factories for 7 potential coronavirus vaccines, even though it will waste billions of dollars,' *Business Insider*, 3 April 2020, available at https://www.businessinsider.nl/bill-gates-factories-7-different-vaccines-to-fight-coronavirus-2020-4/.

10 For a more detailed description of the various approaches, see, for example, Cohen (2020), Thanh Le *et al* (2020) and *The Economist* (2020).

4 The pipeline of COVID-19 vaccine projects

The World Health Organisation by March 2020 had identified more than 40 promising COVID-19 vaccine projects[11]. CEPI by the end of March had identified 78 active projects (Thanh Le *et al*, 2020). The list grows by the week, helped by the genetic code of the virus being made available very early on. See the Appendix for more information on current vaccine development projects.

The list of COVID-19 vaccine projects grows by the week, helped by the genetic code of the virus being made available very early on

Almost all of the projects are, at time of writing, still exploratory or at the preclinical stage. The only projects to have started clinical trials (as recorded on the ClinicalTrials.gov website) are *Moderna* and *Inovio* in the US and *CanSino Biologics* in Hong Kong. Two mainland Chinese projects have also started clinical trials[12]. All of these started clinical trials in March 2020 and have thus not yet produced results from tests on actual patients, which is when the major drop outs occur (Figures 1 and 2). Europe has several projects at the exploratory research or preclinical stages, but no projects in clinical trials at time of writing.

The projects cover various technological trajectories. Projects using the newer but riskier genetic engineering technologies are for the moment in the lead: *Moderna* and *CureVac* are using mRNA (Messenger RNA) technology and *Inovio* DNA technology in clinical trials. These approaches have a clear advantage in speed of development, but come at a greater risk of not getting a vaccine successfully through clinical trials, as DNA and mRNA synthetic engineering technologies have never been trialled successfully on humans.

Among the large life-sciences companies, only Johnson & Johnson, Sanofi and Pfizer are actively involved in developing a COVID-19 vaccine, in partnership with small biotech or research organisations. GlaxoSmithKline (GSK) and Merck, each with substantial experience in vaccine development, are not yet directly involved, although GSK is providing its adjuvant 'booster' technology to other developers, including Pfizer.

Nevertheless, engagement in vaccine development by large life-science companies cannot be taken for granted. While research institutes stay mostly confined to the early research stages, small biotech firms are the typical lead developers for COVID-19. The few trials at the time of writing are being carried out by companies that are small and/or inexperienced in phase 3 clinical trials and that lack large-scale vaccine manufacturing capability. In addition, as small biotech companies do not have deep pockets, external funding for the more expensive later development stages still needs to be secured.

Of the COVID-19 clinical trial projects underway, external funding for phase 1 has been secured by *Moderna* (from the US National Institutes of Health and CEPI) and *Inovio* (from CEPI and the Gates Foundation). However, neither has yet secured funding for the most expensive later stages, nor secured large-scale manufacturing capacity. For the preclinical and exploratory research projects funding has been secured only for the early stages, if at all. All would have to seek partnerships with large life-sciences companies, or with public and philanthropic funders. The German *CureVac* project is a notable exception. It had the good fortune to secure a substantial amount of European public funding from the European Investment Fund to cover its total development costs. Johnson & Johnson has also secured enough funding for the whole pipeline, with the US Biomedical Advanced Research and Development

11 See https://www.who.int/blueprint/priority-diseases/key-action/Novel_Coronavirus_Landscape_nCoV_Mar26.PDF?ua=1. The WHO is not directly funding projects, but is involved as coordinating international exchange of information, developing and sharing common blueprints, and international cooperation to accelerate diagnostics, therapies and vaccines.

12 The two Chinese projects are from Shenzhen Geno-Immune Medical Institute, a very recently established institute, funded by the Shenzhen government. There is no information available on their COVID-19 vaccine projects on the WHO site, nor on the Institute's English website. In addition, Xinhua reported on 14 April 2020, the start of two more COVID-19 vaccine clinical trials in China, but neither is reported on ClinicalTrials.gov. One of these trials is from Sinovac (see the Appendix), and the other is from the Wuhan Institute of Biological Products, a subsidiary of state owned SinoPharm.

Authority providing half of their funding. Box 1 provides an overview of what the EU is currently funding for COVID-19 vaccines.

Box 1: EU COVID-19 vaccine funding

Prior to the COVID-19 pandemic, the EU already provided €500 million for vaccine and vaccination research through the Horizon 2020 research programme (2014-2020). It has also co-funded the development of vaccines through IMI (see section 2) and the European Investment Bank.

To respond to COVID-19, the EU has provided emergency funds to support research and development of diagnostics, therapeutics and vaccines. A rapid reaction has been made possible by the standing budget line for emergency health research that the Commission maintains as part of the Horizon 2020 annual work programmes.

- IMI in March 2020 started a fast-track call for projects on development of coronavirus therapeutics and diagnostics. Preventive vaccines were explicitly excluded from this call. The EU provided €45 million for this call, with the same amount expected to be provided by the private partners in IMI.
- Initially €10 million, subsequently increased to €47.5 million, was provided for research projects to respond to the COVID-19 pandemic. Of the 18 research projects short-listed for funding in March 2020, two were for a potential vaccine:
  - €3M for Sweden's Karolinska Institutet. Its project will start animal testing soon, with first trials on humans expected to begin in 2021 (https://news.ki.se/vaccine-development-against-coronavirus-enters-next-phase).
  - €2.7M for a consortium led by Denmark's AdaptVac, for the development and clinical testing of a novel vaccine. The company said it aims for the vaccine to complete initial human clinical testing within 12 months (https://www.adaptvac.com/news).
- The March 2020 round of the European Innovation Council Accelerator call, with a budget of €164 million, includes a fast-track for coronavirus relevant proposals; see https://ec.europa.eu/info/news/startups-and-smes-innovative-solutions-welcome-2020-mar-13_en.
- The European Institute of Technology Health opened in April 2020 a call to EIT partners to send proposals for COVID-19 projects with rapid implementation. EIT Health will fund each project with up to €600,000. Vaccine and drug development are not supported under this call. See https://eit.europa.eu/our-activities/opportunities/apply-now-eit-health-covid-19-support.

CEPI funding and the EU contribution to CEPI

In January 2020, CEPI (Coalition for Epidemic Preparedness Innovations) announced the start of programmes to develop COVID-19 vaccines. On 6 March, CEPI called for $2 billion in additional funding these programmes[13]. CEPI's total investment in COVID-19 vaccine R&D, at time of writing, is $29.2 million. The EU has contributed to CEPI via Horizon 2020.

5 Are there enough projects and funding in

13 See https://cepi.net/news_cepi/2-billion-required-to-develop-a-vaccine-against-the-covid-19-virus-2/.

the pipeline for a COVID-19 vaccine soon?

Based on failure rates of past vaccine development projects (Figure 2), we can predict how many projects[14] are needed at the start of the COVID-19 clinical trial pipeline, in order to have **close to certain chance (say 99 percent) of at least one successful vaccine**.

If there is a probability of between 20 percent (pessimistic scenario) and 40 percent (optimistic scenario) that COVID-19 vaccine projects that start clinical trials will reach the final stage (Figure 1), between nine projects (optimistic scenario) and 21 projects (pessimistic scenario) are needed. With only two COVID-19 vaccine projects having started clinical trials in the US so far – five when including the Chinese projects – it is not yet sure there will be at least one vaccine at the end, even in an optimistic scenario[15].

If the cost of the various clinical stages are similar to the costs for drugs in general[16], then the costs covering the full development of a vaccine associated with a 99 percent probability of success will be from €500 million euro in the optimistic scenario of needing only nine projects starting clinical trials to around €2 billion in the pessimistic scenario in which 21 projects are needed. These amounts would cover only clinical development and regulatory approval, and not the early research and preclinical trial phases. Costs of production and supply of the vaccine are also excluded.

However, it is not a winner-takes-all race in a search for one successful vaccine. Different vaccines might be needed. Multiple pathways to a vaccine are important, as this will help to reduce the risks. Multiple vaccines might also address the large-scale production challenge and will prevent monopoly bargaining positions at the end of the pipeline, which would impede large-scale availability at low prices. Multiple vaccines would also be better address differences in effectiveness in view of differences in immunity or tolerance for different groups of the population.

If enough substances are brought forward to enable success with a probability of 99 percent, statistically there will be on average four successful projects. To be **99 percent sure of getting at least three different success cases**[17], about 20 projects should start clinical trials in an optimistic scenario (taking the upper bound of success probabilities), and 40 projects should start clinical trials in a pessimistic scenario (taken the lower bound of success probabilities). This would increase the cost range to around €725 million (optimistic) to €3 billion (pessimistic).

6 The need for public support

14 This section is focusing on the likelihood of securing vaccines. In terms of how long it will take for vaccines to be available, we are aligning on the most frequent prediction of about 18 months.

15 The number of projects needed increases non-linearly with required success rates. In other words, getting in the optimistic scenario to an 80 percent success probability would require only three projects compared to the nine projects required for a 99 percent success rate. Five projects would already give a 93 percent success rate. We believe that in the case of COVID-19, society cannot afford a probability that is not as close as possible to certainty.

16 As we don't have reliable estimates of the costs of vaccine-development projects, we use the numbers from general drug development reported in Figure 1: €2.5 million for phase 1; €20 million for phase 2, €65-250 million for phase 3 and €10 million for approval.

17 CEPI's ideal scenario is to have funding for three successful projects at the end of the pipeline: https://cepi.net/news_cepi/2-billion-required-to-develop-a-vaccine-against-the-covid-19-virus-2/.

The social value of a universally accessible COVID-19 vaccine is huge. The health, human and economic cost of COVID-19, which would be avoided if there was a vaccine, is difficult to appreciate. Even if only early estimates are considered of a global loss of GDP of 6 percent in 2020 (IMF, 2020) from COVID-19, the cost would be about $5 trillion.

Compared to what is socially desirable, private companies are likely to underinvest or invest too slowly in the development of a COVID-19 vaccine. Private companies and their investors, when deciding to engage in COVID-19 projects, will balance the development costs and risks against the returns they expect, making comparisons to alternative possible projects. Companies can decide to shift developers from other, commercially more promising, work to COVID-19 or *vice versa*. If private life-sciences companies do not believe governments will allow them to charge high enough prices for a vaccine, in order to recover the costs and risk of development, they will only work with limited resources or not at all on the development of a vaccine for COVID-19, preferring to focus on other more profitable development projects. Fully focusing their expertise and attention on COVID-19 requires a proper balancing between government intervention and incentives for private firms. Yet, the private business case for vaccine development is not straightforward, explaining why the share of private R&D expenditure on vaccines compared to other drugs is small[18].

Private developers and private funders will want to be compensated by the expected returns on vaccine sales in case of success, but vaccines, compared to other drugs, might carry greater commercial risks. Vaccines for highly communicable diseases with serious negative health effects, such as COVID-19, need to be made widely available to all in need. This makes the potential market for these vaccines huge, and would generate the reputational gain from giving the world a COVID-19 vaccine it so desperately needs, but these returns on a COVID-19 vaccine might not be sufficiently interesting for private drug companies, compared to the high cost and risk, and compared to alternative projects. There are several reasons why the private profits to be made from developing a COVID-19 vaccine will be drastically below the vaccine's social value:

- Patients will be much more willing to pay for drugs that help them directly, than for vaccines that help them in case of an outbreak, and which have positive immunity effects against others.
- These externalities imply that vaccines for highly communicable diseases such as COVID-19 cannot simply be sold to the highest bidders. These vaccines should be available on the basis of social needs, not individual willingness and capacity to pay. Generating herd immunity to eradicate the pandemic requires access to vaccines for all social classes in rich and poor countries and this would require fairly low prices. For these reasons, COVID-19 vaccines are more likely to be purchased by government agencies and at low prices. Commercial developers must worry that they cannot negotiate prices freely with governments, increasing the commercial risks.
- Finally, the existence of front-runners in COVID-19 vaccine development represents a commercial risk to other developers. It implies a significant uncertainty over the size of the market.

With private returns drastically below the COVID-19 vaccine's social value, public intervention is needed to ensure that a socially-sufficient number of vaccine projects are under development at a socially-sufficient speed. Public intervention is also needed to have vaccines being manufactured and distributed to all that need them and soon (Blanchard, 2020). This public intervention can take the form of public funding of development, funding or provision of manufacturing facilities, conditions on access to the proprietary technology of the successful vaccines through compulsory licensing, and/or controls on the prices of

18 Established pharma companies only devote about 5 percent of their total R&D expenditures on vaccines. See CCVI (1993).

the vaccines. Some countries have already said they will look into compulsory licences for COVID-19 vaccines[19]. The problem with these interventions is that they need to be balanced against the incentives for private developers. For this reason, public de-risking of vaccine development and fair access should go hand-in-hand.

An additional concern with public intervention is that individual countries might have an incentive to underinvest in public support for a COVID-19 vaccine compared to what is globally socially optimal. Individual countries might bet on acquiring foreign solutions when they become available, instead of spending their own financial, medical and research resources. The countries that are able to provide finance should collaborate, with a commitment to supply the successful vaccines to all countries in need.

7 Our proposal

Although the pipeline of COVID-19 vaccine projects at the exploratory and preclinical stages is substantial, and there are public funding initiatives, more projects are needed and more public money than currently should be put into getting them through clinical trials.

Based on past clinical trial success rates, we calculated that at least nine projects starting clinical trials are needed (to have a 99 percent probability of at least one vaccine, using the upper bound of success rates). Ideally, more projects are needed to ensure multiple vaccines.

The current public funding we have been able to identify is too limited to enable a sufficient number of competing projects, in order to be sufficiently sure that vaccines can be available quickly. Missing in particular is a commitment to public funding of projects through their later, more-expensive stages of development. With a few exceptions (including CureVac, Johnson & Johnson and Sanofi-GSK), and disregarding for now the Chinese projects, typically backed by the Chinese state, none of the preclinical projects have secured funding for the later stages of development, should they succeed in their early phases.

Although Europe has projects in the pipeline, it has no projects yet in clinical trials. Most European projects are not assured yet of public funding for the later, more-expensive stages of development. As it stands currently, European citizens cannot be sure they will be likely to have affordable access to a vaccine soon, particularly if vaccines successfully developed in the US or China face export restrictions, even though the EU and its members are willing to increase funding for the development of COVID-19 vaccines[20]. To address the possible shortfall, an EU funding scheme should be put in place to increase the number and speed of projects to get a COVID-19 vaccine through clinical trials. The scheme would involve a series of awards or grants, organised as an open continuous call until the critical number of projects is reached. The aim would be to identify at least three suitable vaccines at the end of the pipeline, with more than 99 percent probability. Public funding would cover the costs of each phase and would be conditional on projects starting the phase. Table 1 sets out the scheme of awards.

Table 1: COVID-19 vaccines public funding scheme

Numbers and amounts of awards needed for each stage to ensure that at least three vaccines

19 Germany, Canada, Australia and Chile have all taken steps or are weighing up moves to issue compulsory licences more easily. AbbVie gave up its global intellectual property rights for Kaletra, an HIV drug being assessed as a COVID-19 treatment, after Israel issued a compulsory licence that enables the country to use it against coronavirus without the patent holder's consent. See Donato Paolo Mancini and Hannah Kuchler, 'AbbVie drops patent rights for Kaletra antiviral treatment', *Financial Times*, 23 March 2020, available at https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b.

20 European Commission president Ursula von der Leyen said on 15 April she would host an *"online pledging conference"* on 4 May 2020. See https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_20_664.

complete all clinical phases, under optimistic and pessimistic assumptions

	Optimistic scenario (high success probabilites, low cost estimates)			
	Assumed success rate	Size of the award	No. awards at this stage	Total cost of awards
Phase 1	40%	€2.5 million	18	€45 million
Phase 2	51%	€20 million	13	€260 million
Phase 3	85%	€65 million	6	€390 million
Approval phase	100%	€10 million	3	€30 million
	Pessimistic scenario (low success probabilites, high cost estimates)			
Phase 1	20%	€2.5 million	40	€100 million
Phase 2	32%	€20 million	25	€500 million
Phase 3	63%	€250 million	10	€2500 million
Approval phase	90%	€10 million	5	€50 million

Source: Bruegel (see Figure 2)

Project proposers at each stage would have to agree when receiving an award that on final success, the patented technology will be made freely available for manufacturing. This compulsory licensing would be balanced by the full public funding of the development costs, thus not jeopardising the incentives for private applicants to engage in development of a COVID-19 vaccine.

The total budget required for the scheme would range from €725 million in an optimistic scenario to about €3 billion in a pessimistic scenario. The total is driven up by the projects in phase 3, representing 80 percent of the total budget in the pessimistic scenario, or somewhat more than half in the optimistic scenario.

Even though the staging of the scheme would help reduce the risks, the required budgets are nevertheless substantial and above what could typically be done within the EU budget. One way to raise the amount of money to finance the scheme would be to build on the idea of corona or recovery bonds, which could use the EU budget as a financial vehicle to borrow funds on the market and leverage them for large-scale investments. The EU would not have to be the sole funder. With a pledging event, it could collect a pool of money from public and philanthropic donors. But the EU should use its capacity to take the lead in setting up the financing, by pledging a substantial share of the total amount required.

It would be a valuable signal if the EU would already today commit to providing funds, even if the detailed rules are only spelled out tomorrow. To save time, the organisation of the scheme should be done by an agency with a track record in organising funding schemes for vaccine development. IMI comes to mind, particularly if it can collaborate closely with the European Investment Fund and particularly with CEPI, in which it is already a partner.

Why would such a scheme be needed, compared to what the EU is already doing?

- Compared to the normal pipeline of projects funded by the European Commission, a focus on development rather than research is needed, and not only on the initial stages, but through to the end of the pipeline. This requires bigger than normal public funding.
- The division into different phases would mean the bigger amounts only need to be activated for those projects that reach the more expensive later phases. Staging would avoid the need to commit large funds upfront.
- Under our proposal, contenders would be sure from the start that there is a scheme available for funding all stages in case of success, including the more expensive later stages. Some projects might have been able to secure full funding from private sources, but only those with a high enough probability of being first. Full funding from private sources cannot be assured for all the projects that are needed by society at the start, in order to generate multiple successful vaccines.

- The scheme would be run as an open, continuous call, not with fixed call deadlines, and with awards given out in parallel rather than serially. Offering the awards in parallel would reduce the overall timeline. The same applicants can also apply simultaneously to the various calls with multiple projects at different phases.
- Our proposal does not back one winner initially, nor does it bet on one winner at the end. It is calibrated to ensure multiple successful projects at the end. Supporting multiple projects at the start would reduce the high risk of clinical trial failures and ensure at least three vaccines.
- The compulsory licensing condition will mean vaccines become available for production and distribution at competitive market rates. This compulsory licensing is a clear condition *ex ante* in return for the full public funding of the development costs. It should therefore not reduce the incentives for applicants to engage in a COVID-19 vaccine project. It also lessens the commercial uncertainty surrounding the use *ex post* of compulsory licensing for COVID-19 by at least some countries, which might deter private companies from engaging in the development of a COVID-19 vaccine.

For COVID-19, it is critical that vaccines should be available at large scale and low cost. Our scheme does not include public support for the manufacturing and distribution of the successful vaccines. However, it does contribute to addressing this critical challenge.

- Ensuring multiple vaccines at the end, combined with compulsory licensing, will lead to a competitive supply of vaccines at no/low licensing cost, avoiding supply restrictions and marked-up prices from firms with market power. The scheme thus avoids the need for public funding *ex post* to provide subsidies so vaccines can be bought by all who need it. It also avoids having to deal with the complexity of designing a socially-optimal subsidy scheme, to match willingness to pay with needs, and to deal with problems of segmenting markets and parallel imports. It should also remove the incentives for private big pharmaceuticals firms to go it alone, in the hope of being the first to win the market in search of monopoly rents.
- In addition, the organising agency can set up a taskforce dedicated to finding the capacity and funding for manufacturing at large scale for the successful candidates. It can do this from the start of the scheme to save time, even when it is not yet clear which projects will be successful[21].
- The agency could also plan the optimal distribution of the vaccines to where they are needed most within the EU.

Although the scheme would be an EU initiative activating EU funds to ensure that EU citizens have quick access to COVID-19 vaccines, the initiative should not become a 'fortress Europe.'

- The agency running the scheme should seek out international collaboration with other similar initiatives. Having a significant European instrument might provide leverage in *ex-ante* negotiations of international cross-licensing agreements (with the US or China). An agreement to cross-license final vaccine technologies would reduce the number of projects needed under each programme, reducing the financial burden. Such negotiations are easier to do *ex ante* than after one of the partners has already found a vaccine.
- This agency could also coordinate with the appropriate organisations, such as the World Health Organisation, to allocate the vaccines worldwide to where they are needed most.
- The EU would have with this scheme a tool to provide the compulsory licensing terms for the successful vaccines it generates, not only within the EU but also to all those around the world who need it. The initiative would thus show the EU as a beacon in dark times when leadership

21 As the Gates Foundation is doing; see footnote 9.

is critically needed to organise global coordination and deal with the COVID-19 pandemic.

In addition to this series of awards to address COVID-19, we call for a moon shot programme in order to be better prepared for the next pandemic. This would support research into new and faster approaches to vaccine development, universal vaccines and broad platforms for vaccine development. This programme can involve a normal grant competition. It could be done within the regular EU framework programme, but would be best done with international coordination, for example with CEPI or the Gates Foundation, which in summer 2018 (together with Larry Page) launched a $12 million fund for universal vaccine projects. One could easily imagine a budget of double that for an EU moon shot at 'vaccines for the future'.

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Appendix: COVID-19 vaccine projects (up to 15 April 2020)

Although the pipeline of COVID-19 vaccine projects at the exploratory and preclinical stages is substantial, and there are public funding initiatives, more projects are needed and more public money than currently should be put into getting them through clinical trials.

Based on past clinical trial success rates, we calculated that at least nine projects starting clinical trials are needed (to have a 99 percent probability of at least one vaccine, using the upper bound of success rates). Ideally, more projects are needed to ensure multiple vaccines.

The current public funding we have been able to identify is too limited to enable a sufficient number of competing projects, in order to be sufficiently sure that vaccines can be available quickly. Miss

1 COVID-19 vaccine projects in clinical trials (source: ClinicalTrials.gov website)

Moderna, US

The frontrunner in vaccine development for COVID-19 is Moderna, a biotech firm based in Cambridge, Massachusetts. Moderna's approach is an mRNA vaccine, a vaccine technology which is expected to have a faster development (its mechanism of action is mRNA-1273). The first human trial for a vaccine began on 17 March 2020. It has received funding from the US National Institutes of Health/NIAID. For its phase 1, it has research funds from CEPI. Moderna, in case of success, does not have the manufacturing capacity to supply the vaccine on its own. It will have to find this capacity elsewhere.

CanSino Biologics, Hong Kong

CanSino Biologics Inc., a company founded in 2009, and quoted on the Hong Kong stock exchange, develops and manufactures biological vaccines using its adenovirus-based viral vector vaccine platform, which also delivered a vaccine for Ebola. Past experience with adenovirus type 5 (Ad5) raises concerns about safety (dangerous side effects) and immunity of subpopulations to Ad5. CanSino phase 1 clinical trials for a COVID-19 vaccine on 23 March, in Wuhan, China, in alliance with the China's Academy of Military Medical Sciences.

Inovio Pharmaceuticals, US

Inovio Pharmaceuticals, a small biotech firm founded in 1979, has had grants from the Gates Foundation and CEPI to accelerate testing of a COVID-19 vaccine which uses the DNA sequence for the spike protein by which the virus attaches to and enters human cells, to deliver viral antigens. The firm started phase 1 trials in the first week of April 2020. Inovio was able start early on COVID-19 in part because it was already testing a vaccine for MERS, another coronavirus.

Shenzhen Geno-Immune Medical Institute, CN,

Shenzhen Geno-Immune Medical Institute, founded by the Shenzhen Government in 2016, focuses on advanced lentiviral vector technology to develop various therapeutic solutions for cancers and other genetic diseases. Based on this technology, it registered to start in March 2020, two clinical trials for testing synthetically engineered COVID-19 minigenes based on multiple viral genes.

2 Selected COVID-19 pre-clinical projects

The listed projects are from the WHO's list of vaccine projects (https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf), checked against company websites. COVID-19 projects are only listed where sufficient information could be found on company websites. The list includes the six other projects (beyond Moderna and Inovio) supported by CEPI.

CEPI-supported projects:

CureVac, Germany

CureVac a German biotech firm started in 2000, is developing an mRNA vaccine for COVID-19. It is currently still at pre-clinical stage, but expects to start clinical trials by June 2020. It is funded by CEPI with an $8 million grant. The company was also offered an €80 million loan guarantee by the European Investment Bank to fund development of a manufacturing facility, after an alleged attempt by President Donald Trump to acquire the company or its technology. The company's largest shareholder is the co-founder of software company SAP. Another major investor in CureVac is the Gates Foundation.

Novarax, US

Novavax is creating COVID-19 vaccine candidates using its proprietary recombinant protein nanoparticle technology platform to generate antigens derived from the coronavirus spike (S) protein. Novarax expects to use its proprietary Matrix-M™ adjuvant with its COVID-19 vaccine candidate to enhance immune responses. CEPI will provide initial funding to Novavax to enable preparations for phase 1 trials.

Institut Pasteur (France), joint with Themis and the University of Pittsburgh.

CEPI will invest an initial $4.9 million in a partnering agreement with the Institut Pasteur-led consortium, which will include Themis, an Austrian biotech firm started in 2009, and the University of Pittsburgh, to develop a vaccine candidate against COVID-19 based on an S-protein measles-vector technology. In a first step, CEPI funding will support the preclinical testing, initial manufacture of vaccine materials, and preparatory work for phase 1 studies.

University of Hong Kong

Researchers at the University of Hong Kong have created a vaccine candidate using a weakened version of the flu virus and have adapted it to express the surface protein of the COVID-19 virus. This approach has previously been used to develop pre-clinical vaccine candidates against MERS. CEPI is providing initial funding to HKU (US$620,000) to undertake pre-clinical testing of their vaccine candidate, and will consider additional funding for further clinical testing pending results of these pre-clinical studies.

University of Queensland, Australia

The University of Queensland is developing a 'molecular clamp' vaccine platform, a transformative technology that enables targeted and rapid vaccine production against multiple viral pathogens. This is still in pre-clinical. It received funding from CEPI for up to $10.6 million for the development of a COVID-19 vaccine.

University of Oxford, UK

CEPI is also funding the University of Oxford pre-clinical project, based on their adenovirus vaccine vector and for the manufacture of vaccine materials required for pre-clinical and phase 1 testing.

Selected other projects at pre-clinical stage:

BioNTech, Germany

BioNTech, a small German immunotherapy company started in 2008, will be co-developing with Pfizer a vaccine using the German biotech's mRNA-based drug-development platform. It expects to start testing its potential coronavirus vaccine in humans by the end of April 2020.

Takis/Evvivax, Italy

Takis, an Italian biotech company with experience in oncology vaccine through Phase 1 and 2 prototypes, is working on a prototype for COVID-19, planning to start testing on animals soon. Takis/Evvivax is looking for a big life-sciences partner for funding and production.

AdaptVac, Denmark

AdaptVac is leading a consortium for the development and clinical testing of a novel virus like particle (VLP) vaccine. The company announced that its goal is to have the vaccine complete initial human clinical testing within 12 months. Being one of the 18 research projects which were short-listed for EU funding in March 2020, it acquired €2.7 million euro in funding from the European Commission.

eTheRNA, Belgium

eTheRNA a clinical stage biotech company, founded in 2013 as a spinoff of VUB, announced on 24 March 2020 that it had formed a consortium with other biotech companies to start developing an mRNA vaccine for COVID-19.

Ziphuis Therapeutics, Belgium

Ziphius is a small pre-clinical gene technology company focusing on mRNA vaccines. It announced on 20 March 2020, it would start on its mRNA platform the development of a vaccine against COVID-19: ZIP-1642, working with the University of Gent.

DIOSynVax, UK

DIOSynVax, a spin-out company set up in 2017 at Cambridge University, has received funding from the Bill & Melinda Gates Foundation and the UK innovation agency Innovate UK, to develop new vaccines for diseases ranging from influenza to Ebola, and has now refocused all of its work on COVID-19. The vaccine is being tested in mice to establish if it generates an immune response. DIOSynVax is seeking funding to pursue its work further, and a pharmaceutical company with which to partner on clinical trials.

Vaxil Bio, Israel

Vaxil Bio is an Israeli biotech company, based at the Weizmann Institute, focused on immuno-oncology. In March 2020, they announced that they had identified a coronavirus (COVID-19) vaccine candidate, based on the proprietary VaxHit bioinformatics platform, and had started a pre-clinical programme to test its efficacy as a COVID-19 vaccine candidate.

Heat Biologics, US

Heat Biologics Inc. is a US biotechnology company, founded in 2008, and focused on cancer immunotherapy. It announced in mid-March 2020 a strategic collaboration with the University of Miami Miller School of Medicine to support the development of a vaccine leveraging its proprietary gp96 platform designed to target the coronavirus that causes COVID-19.

Vaxart, US

Vaxart, a clinical-stage biotechnology company developing oral recombinant vaccines administered by tablet rather than by injection, announced mid-March 2020 that it has entered into an agreement with Emergent BioSolutions, with Emergent deploying its molecule-to-market

contract development and manufacturing services to help develop and manufacture Vaxart's experimental oral vaccine candidate for coronavirus disease (COVID-19). Vaxart's oral recombinant vaccine candidate is based on its proprietary VAAST platform.

GeoVax, US and BravoVax, China

GeoVax, a biotechnology company based in Atlanta US, together with BravoVax, a vaccine developer in Wuhan, China, announced in January 2020, their intention to jointly develop a vaccine against the new coronavirus. GeoVax will use its MVA-VLP vaccine platform and expertise to design and construct the vaccine candidate. BravoVax will provide further development, including testing and manufacturing support, as well as direct interactions with Chinese public health and regulatory authorities.

Greffex, US

Greffex, a US genetic engineering company, said in March 2020 it was ready to move to animal testing of a COVID-19 vaccine. Greffex is using an adenovirus-based vector vaccine, which are genetically engineered. Part of its research is funded by NIH.

Medicago, Canada

Medicago is a clinical-stage biopharmaceutical company using a novel plant-based manufacturing and virus-like particle (VLP) technologies to rapidly develop innovative vaccines. It announced in mid-March 2020 the successful production a VLP of the coronavirus, ready for pre-clinical testing. Medicago expects to start human trials by July/August 2020. This research is being partially funded by the Governments of Canada and Quebec.

Sinovac Biotech, China

Sinovac Biotech is making a COVID-19 vaccine by chemically inactivating whole virus particles and adding an immune booster called alum. Sinovac used the same strategy in the past for a SARS vaccine it developed and tested in a phase I clinical trial. On 14 April 2020, Xinhua reported that Sinovac had started its clinical trials. It has however not yet been reported on the ClinicalTrials.Gov website (as of 15 April 2020).

Clover Biopharma, China

Clover, a Chinese (Chengdu) biotech company, founded in 2007, is using its proprietary Timer-Tag© technology that has been shown to be recognised by antibodies produced by multiple previously-infected coronavirus patients, to develop its S-Trimer as a vaccine candidate. This is still at pre-clinical stage, with no announcement yet of when clinical trials could start.

3 Selected COVID-19 vaccine projects at research institutes (source: Bruegel based on WHO and/or research lab's websites)

Karolinska Institutet, Sweden

At Karolinska Institutet, virus researchers Ali Mirazimi and Matti Sällberg are working to develop a prototype vaccine against the new coronavirus. Several vaccine candidates are currently available, which target those parts of the virus that are genetically stable and that therefore can protect against other types of coronaviruses as well. The first animal studies were expected to begin at the end of March, with the first trials in humans expected to begin in 2021. It is one of the projects selected by the EU in its March 2020 call, receiving €3 million. For later phases, it "will need more money or a collaboration with a pharmaceutical company". See https://news.ki.se/vaccine-development-against-coronavirus-enters-next-phase

University of Copenhagen, Aarhus University and the Serum Institute, Denmark

Have received DKK25 million (€3.3 million) from the Carlsberg Foundation to develop a vaccine against COVID-19 in a short time, based on a promising but previously untested vaccine concept.

Imperial College London, UK

Robin Shattock, head of mucosal infection and immunity within the department of infectious disease at Imperial College London, is leading an effort to create an mRNA vaccine against coronavirus.

Oxford University, UK

Researchers led by Sarah Gilbert, head of the Jenner Institute's influenza vaccine and emerging pathogens programme, are planning a trial on humans of what is touted to be the UK's frontrunner vaccine. The product uses a virus that is genetically modified so it is unable to replicate in human cells.

Migal Galilee Research Institute, Israel

Researchers at this Israeli lab are working to adapt a vaccine initially developed to prevent respiratory disease in poultry for the prevention of COVID-19. The government-funded institute hailed a scientific breakthrough in February when it isolated COVID-19, with human trials for its candidate expected to start by end-April.

VIDO-InterVac, Canada

The University of Saskatchewan's Vaccine and Infectious Disease Organisation-International Vaccine Centre (VIDO-InterVac) has received C$23 million from the Canadian government to expedite work on COVID-19. A test vaccine is being trialled on animals. The lab, which has previously worked on vaccines for SARS and the Zika virus, is also exploring alternatives, like antiviral medication, that could fill the gap for patients until a vaccine is available.

Fudan University, China

A joint research team from Fudan University, Shanghai JiaoTong University, and RNACure Biopharma is currently working on a vaccine for COVID-19.

Tongji University, China

An mRNA vaccine targeting the novel coronavirus is being co-developed by the CDC, Shanghai-based Tongji University School of Medicine and Stermirna Therapeutics Co., Ltd. Animal tests started in February 2020.

4 Life-sciences firms working on COVID-19 vaccines (source: Bruegel based on company websites)

Johnson & Johnson's

Johnson & Johnson's vaccine unit, Janssen Vaccines, based in Flanders, is applying knowledge gained in the development of vaccines for Ebola, Zika and HIV (in partnership with Flemish biotech research centres including VIB and REGA) to come up with a new vaccine against COVID-19. Like CanSino, its approach uses an adenovirus, Ad26. Phase 1 clinical trials are planned to start in September 2020. The budget amounts to $1 billion, with BARDA (US) bringing in almost half of the amount. The company claims it can make 600 million vaccine doses by the end of 2020 in case of success (of which 300 million will be manufactured in the US). It also claims it is engaged in this project on a non-profit basis.

Sanofi

Sanofi, through its global vaccines business unit, Sanofi Pasteur, is not active yet in clinical trials for a COVID-19 vaccine. It is however leveraging previous development work for a SARS vaccine. It is collaborating with BARDA to establish state-of-the-art facilities in the United States for the sustainable production of an adjuvant recombinant vaccine that can be used for the COVID-19 programme. In addition, Sanofi Pasteur is collaborating with Translate Bio, an mRNA therapeutics company, founded in 2011, in Massachusetts (US), to develop a novel mRNA vaccine for COVID-19. But this is still very early stage. A spokesperson said Sanofi aims to put a vaccine into a phase 1 clinical trial between March 2021 and August 2021.

GSK

GSK, which worked on the swine flu, has plenty of manufacturing knowledge, but is not working on a vaccine for coronavirus. Instead, it's offering its drug adjuvant to other developers, essentially a booster that can make immunisation more potent. The CEPI-funded University of Queensland will have access to the British drugmaker's vaccine adjuvant platform technology. GSK said that Clover Biopharmaceuticals Inc., a Chinese biotechnology company, is also using its adjuvant technology in combination with its vaccine candidate, COVID-19 S-Trimer, in preclinical studies. GSK and Sanofi said on 14 April that they would join forces: Sanofi with its S-protein COVID19 antigen, based on recombinant DNA technology, co-funded by BARDA, and GSK with its adjuvant technology. The companies plan to start phase 1 clinical trials in the second half of 2020. They also announced their commitment to making any vaccine that is developed through the collaboration affordable to the public and through mechanisms that offer fair access for people in all countries.

Pfizer

Pfizer: is jointly working with BioNTEch. See Appendix section 2.

Merck

Merck: A major vaccine company which had a vaccine for Ebola approved in 2019, is not working on a coronavirus vaccine.