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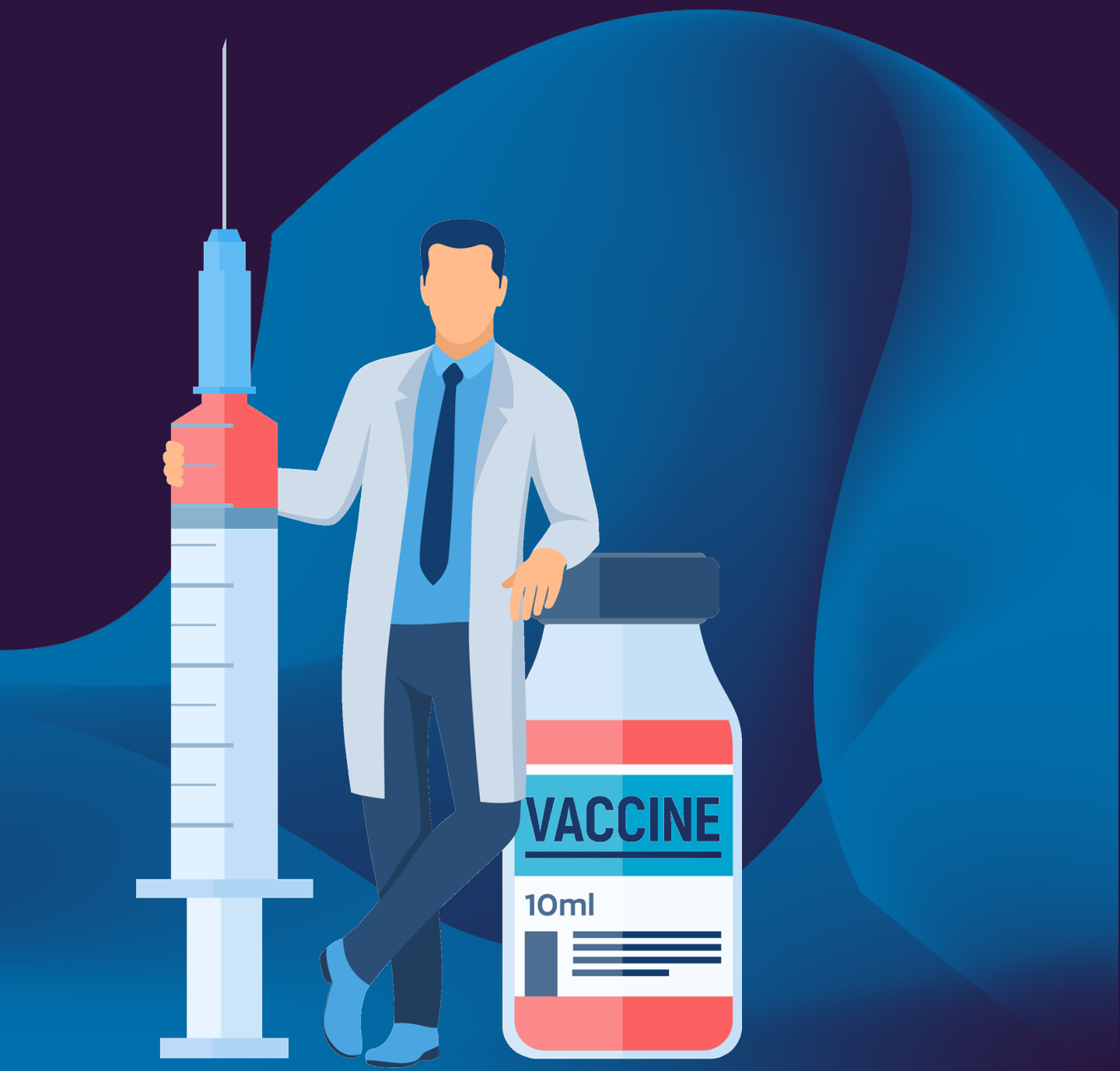
# COVID-19 VACCINES ARE COMING. ARE WE READY?

Etienne Grass –
November 2020



On November 9, companies BioNTech and Pfizer announced the eagerly awaited preliminary results of their phase 3 clinical trial for a COVID vaccine project. While it is unusual for this type of result to be published before the trial is finalized, the rolling review procedure sanctioned by regulatory bodies to speed up the assessment of new drugs has enabled this transparency.[1]

If the results have come as a positive surprise, it is mainly due to their high level of efficacy. The Food and Drug Administration (FDA) had indicated that it would be ready to authorize a vaccine with more than 50% effectiveness. The first figures available are much higher, at 90%.

For several weeks now, the head of the "*Operation Warp Speed*" program, Moncef Slaoui, who has been piloting American federal activities in support of vaccine production since May, had been telling *the New York Times* to be "*confident that there will probably be two vaccines available before the end of December*".

At Capgemini Invent, we have carried out work to develop an understanding of the implications of these results, which we acknowledge are still only interim. Our objective is to inform next steps in terms of how to embed the results in all the research currently in progress, to identify the challenges for the production and distribution of vaccines, and to set the priorities needed to build a sustainable and trustworthy vaccination strategy.

This work is based on scientific literature, the international press, and our knowledge of technological and *supply chain* issues. It is subject to change every day, depending on the progress of trials and operational preparation.

Vaccine authorization could potentially be granted before the end of the year. This is particularly likely for the two products developed within the framework of messenger RNA platforms. We have tried to shed light on the questions raised by the authorization procedures that have been initiated.

240 COVID vaccines are currently being developed globally, according to the regular census carried out by the World Health Organization. Of these, the WHO asserts 45 are in clinical trials[2], although only 35 according to *the New York Times*[3].

The WHO says that 10 products are already tested in phase 3 , a figure that rises to 11 according *to the New York Times*, which includes the recent progress of an Indian product in its assessment [4].

Within these phase 3 trials, four products are being tested in China[5] and one in Russia[6]. We do not have the same level of information on them as on vaccines developed in the United States and Europe.

## Technological platforms of current projects

Five products have in common that they are integrated into the American (*Operation Warp Speed-OWS*), British and European partnerships[7]. These products use various technological solutions, some of which weaken the virus and others sterilize it completely. The American authorities have defined four benchmark "technological platforms" to build their partnership and ensure a certain robustness and scalability in the industrialization phase. These platforms are:

### 1. The use of messenger RNAs (*the mRNA platform*)

This is the technology employed by the products developed by Pfizer / BioNTech and by Moderna / NIAID. It is new technology that has never been used to create a commercial vaccine. Nonetheless, it has given the two laboratories concerned a head-start in their research. By making it possible to launch phase 1 trials in March, the mRNA platforms sped up clinical trials. The two tests concerned started in July. For both products, the trials crossed the threshold of 30,000 subjects enrolled in the phase 3 trials at the end of October.

The Pfizer group recently announced that it wanted to enroll 44,000 people to finalize its trial[8]. At a press conference on October 26, the group's CEO, Albert Bourla, said he was considering seeking emergency clearance at the end of November, suggesting that first doses could be available before the end of the year. On November 9, he publicly confirmed this ambition by delivering interim results that concern 96 COVID events (the FDA's target is 150) and show a level of effectiveness that could reach 90%.

### 2. The use of live inactivation vectors (*replication-defective live- vector platform*)

This technology platform is being used in products developed by Johnson & Johnson / Janssen, and by AstraZeneca / Oxford University. The two products have initiated their phase 3 according to multi-country protocols; both have experienced interruptions in certain countries following reports of serious medical events. AstraZeneca's test resumed on October 1, 2020, while that of Janssen should resume soon.

### 3. The use of adjuvanted recombinant proteins (*recombinant- subunit - adjuvanted protein platform*)

This platform is being used by Novavax, which started its phase 3 trials in October, and for the vaccine developed by GSK and Sanofi (still in phase 2 trial).

### 4. The use of live vector mitigation of virus replication (*attenuated replicating live- vector platform*)

This is not currently being used by any project in the western world.

The two products using messenger RNA technology therefore currently seem to be in pole position for authorization in the United States before the end of the year. The tests are monitored in real time (*rolling review*) by the health authorities, in anticipation of an emergency authorization procedure (*Emergency Use Authorization*).

This technology is new. As the head of the UK Government's Vaccine Taskforce, Kate Bingan, wrote in a recent contribution to *The Lancet*, "*The most advanced vaccines… are based on novel formats for which we have little experience of their use as vaccines, although the initial immunogenicity and safety data are encouraging.*"[9]

## Operation Warp Speed (OWS)

The *Operation Warp Speed* (*OWS*) in the United States is not exempt from the usual rules of FDA approval. The same is true in Europe, where the *European Medicines Agency* has chosen not to communicate any guideline likely to impact its decision and is content to indicate that it will use its usual decision criteria.

The United States has instigated further support for manufacturers. OWS ensures enhanced and closer coordination of the public and private initiatives underway in the United States. It was initiated on May 15, 2020 and its name literally means "*Lightning Speed*" – a nod assumed to Star Trek fans.

OWS optimizes the sharing of information as much as possible to simplify the different phases of testing, anticipate logistical challenges and, above all, start production as soon as possible. The operation brings together the *Department of Health and Human Services* (*HHS*), the *Department of Defense* (*DOD*)[10] and the six listed companies under a common management. The scope of the operation covers all the areas of research, development, manufacturing, distribution of vaccines, drugs and diagnostic tests related to COVID[11]. Considerable resources ($ 10.8 billion) have been allocated[12].

Federal agencies have set up "*technical assistance*" to support laboratories in carrying out their tests, assistance which goes well beyond *rolling reviews*.

As of the end of June, the *Food and Drugs Administration* (*FDA*) published "guidelines" (*guidance*). Under strong pressure from the political authorities, it completed its guidelines in October[13] and has not stopped communicating since. The highlights of these guidelines are as follows:

- The agency considers that an efficacy of 50% will be sufficient to grant a temporary authorization, with a minimum threshold of the 30% confidence interval;
- The FDA also asked for a median follow-up of two months to assess all the effects of the vaccine (a decision that excluded an announcement before the US presidential election).

## Pending questions for authorization

Under the EUA (Emergency Use Authorization) procedure, the laboratory can request authorization of the product as soon as it is able to establish that the vaccine "*may be effective*" and that its benefit / risk ratio is favorable. The authorization will then be issued subject to continuing the tests over time and monitoring the results within the framework of a "*data and safety monitoring board*" (DSMB).

The scope of this requirement is currently being debated given its ethical consequences. The FDA's guidelines explicitly state that the trial be continued on the basis of its protocol authorization despite the issuance of the authorization[14]. This raises the question of the loss of opportunity for the patients included in the control arm. In an exchange of letters with the FDA, Pfizer group officials indicated in particular that they did not want to comply with the recommendations of the FDA[15]. *The Vaccines and Related Biological Products Advisory Committee* (*VRBPAC*) held a public meeting dedicated to this issue on October 22,[16] as well as numerous hearings. No clear solution emerges.

More generally, a trade-off seems necessary between the need to promote rapid access to vaccines by immediately issuing authorizations and the risk of greatly destroying research by authorizing too early a product that could benefit from a "*winner takes all*" effect for the distribution.

This issue is even more important since the question of efficacy evaluations is also under debate. The efficacy of the vaccine depends not only on the number of patients included in the trials and on the effectiveness of the products, but also on the existence of a sufficient number of useful terminals (*endpoints*) in the control arms of the trials. The main challenge of the ongoing phase 3 trials is therefore that of the geographic evolution of the virus. The more COVID circulates in the experimental areas, the faster the results will consolidate. Conversely, if COVID is short lived, only vaccines with highly significant effects will be able to reveal their efficacy.

Pfizer thus announced that it had finalized its first independent safety review on its vaccine project[17]. The group then indicated that 96 patients included in its trial had been affected by COVID. Its protocol provides for a threshold of 150 infected patients to deliver results leading to authorization.

These protocols nevertheless have three limitations:

1. They do not consider the level of severity of the infection;
2. They do not consider the patient's level of vulnerability and in particular any chronic illnesses;
3. They do not stratify patients according to age, which is a key parameter of the immune response and its level of protection[18]

Conversely, some trials pay particular attention to these dimensions: the British taskforce, for example, indicates that trials should be "*focused on vaccines which have the capacity to obtain immune responses in the population over 65, which represents three quarters of deaths linked to COVID infection*"[19].

Another issue is how long the vaccine will last. Vaccination strategies, implementing two types of vaccines, can be considered:

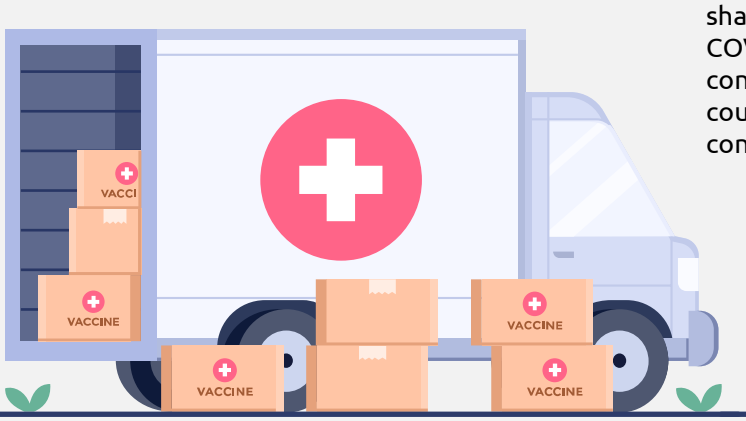
- the vaccines that "sterilize" are used to interrupt transmission of the virus and thus increase the immunity of the population group
- other vaccines, which protect against the disease, do not prevent the transmission of infection and this reinforces the need to focus on the protection of specific populations

As it stands, the protocols will not give any results concerning this or that subpopulation and beyond a follow-up of two months. They will not make it possible to assess any additional risks either. They must therefore be supplemented either by prolonged studies (for example over six months) or by real-life data and reinforced pharmacovigilance systems. These questions will be at the heart of the decisions that will be taken at the time of authorizations.

## The question of global production capacities

To allow manufacturers to anticipate the production effort, the United States and the European Union have negotiated advance purchase contracts. They have committed considerable budgets to this: 2.3 billion euros in the European Union and 10.8 billion dollars in the United States. No public information is available today on the priority clauses contained in these contracts, nor on the sale prices.

The European Union says it has pre-ordered 1.4 billion doses of vaccines[20]. The United States has pre-ordered 700 million doses of vaccine[21]. Britain negotiated 250 million doses[22]. Japan has pre-ordered 490 million doses, including 250 million from Novavax.




Canada and Switzerland have pre-order agreements with Moderna. Canada has also pre-ordered 76 million doses of Novavax . Switzerland has pre-ordered 5.3 million doses from AstraZeneca. *The Coalition for Epidemic Preparedness Innovations* preordered 300 million of doses from AstraZeneca on behalf of poor countries and underdeveloped economies.

The people in charge of *Warp Speed* have set themselves the task of covering the entire American population, i.e. 300 million doses and up to 600 million doses for products requiring two injections. Moncef Slaoui, who heads OWS, said the laboratories they work with will provide 15 million doses in November, 30 million in December, then 80 to 90 million doses per month. Vaccines based on mRNA platforms have in fact already started their production at scale, on the basis of pre-financing contracts.

The entire American population could thus be vaccinated by next April before the injection of a second dose, as provided for in most of the protocols tested (except for Johnson and Johnson). This was the initial objective given to OWS when it was created.

## Allocation: a global issue

Vaccinating the entire American population is clearly not the best vaccine strategy globally. The COVAX initiative, co-led by *the World Health Organization* (*WHO*), the *Gavi Alliance* and *the Coalition for Epidemic Preparedness Innovations* (*CEPI*), brings together 180 countries, which agree to pool their resources to maximize as broad as possible access to vaccines. WHO has estimated that 15 billion doses should be made available to meet the needs of the world's population.

COVAX provides rules to prevent the hoarding of vaccines, in particular the obligation to distribute the doses when at least 20% of the population is vaccinated. But neither the United States nor Russia have taken part. The European Union only participates as a funder, without submitting to the sharing rules. France, although the initiator of COVAX, has still not announced its financial contribution to the program. China, like many other countries, has joined COVAX but has not yet contributed financially.

The COVAX project is therefore far from resolving the issues of international cooperation today. As the UK Vaccine Workforce states: "*We urgently need international cooperation to pool risks and costs, remove barriers to access and increase manufacturing capacity to produce doses sufficient for protecting all persons exposed to the risk of infection by SARS-CoV-2 in the world*"[23].

More generally, it is impossible to determine today what priority will be given by laboratories in a context of limited resources. We note that neither Pfizer nor Moderna currently appear on the list of contracts signed by the European Commission, but are in pole position in the race for contracts across the Atlantic. It should also be noted that the prices per dose announced by the laboratories vary according to a ratio of 1 to 8, which raises the question of the proper allocation of public funds.

## The logistical chain

In the United States, the logistics system put in place by OWS is still being clarified. It will be greatly constrained by the challenges of ensuring a cold chain for messenger RNA vaccines, which involves storage at minus 83 degrees.

The objective of OWS is to ensure that, from the first day of the vaccine authorization, distribution will be possible, from transport by ship, to local distribution.

At the federal level, large contracts have been signed with private companies to:

1. Address the federal logistics chain.
2. Create and operate an information system to follow this chain until the administration of the product.
3. Support the administration of vaccines in certain distribution chains and in particular pharmacy groups.

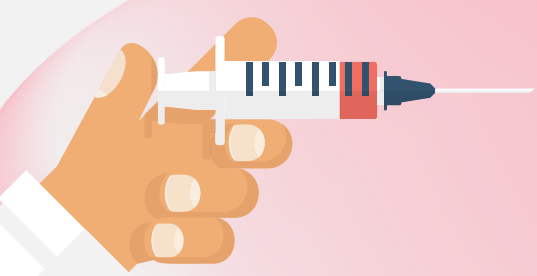
OWS officials have asked states to provide them with plans for vaccine distribution by October 16. These plans must be ready to be activated before November 1[24]. The dividing line between federal responsibilities and state responsibilities is, however, not currently clarified and gives rise to questions from many states.

In the United Kingdom, the government communicated widely on its mobilization during the last week of October. It announced the mobilization of the army and the *National Health Service* to structure a *hub and spoke* organizational model: seven "*Nightingale*" centers will be opened, which will be both distribution platforms and mass vaccination sites. Mobile sites and traveling teams will be deployed. The military and veterinarians could be allowed to vaccinate.

As the UK Vaccine Taskforce states, "*No one has ever done mass vaccination of adults anywhere in the world before and the two-dose regimen, plus cold chain restrictions for some vaccines, adds to the complexity of this deployment operation. NHS England has flexible deployment plans to start the vaccination of prioritized cohorts as soon as the vaccines are approved by the regulatory authorities, currently not to be co-administered with the influenza vaccination. Deployment plans have been developed for a range of settings from mass vaccination sites to large and small mobile (e.g. popup) sites, general practitioner surgeries and pharmacies, and even roving teams to visit people in care homes and people who are housebound or shielding*". [25]

In France, an inter-ministerial taskforce on vaccines has been set up, positioned with the Ministry of Finance.

The High Authority for Health announced in July the potential need to provide for changes in the texts relating to prescription and performance in the Vaccination Act "*with the objective of safety, relevance and quality of care and monitoring*". It also stated that "*traceability must be there.*



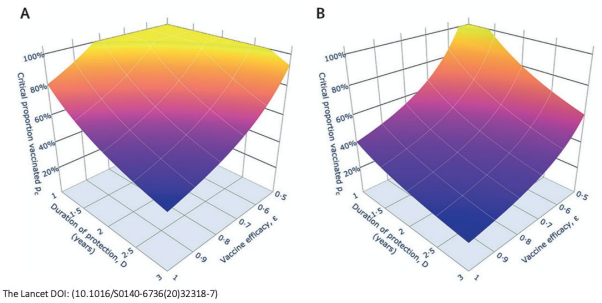
*The opportunity to disseminate / generalize the establishment of an electronic vaccination record should be considered. Particular attention should be paid to monitoring the cold chain and the storage of vaccines in suitable refrigerators in front-line caregivers.* " [26]

## Priorities of vaccine strategies

A fair and effective vaccination strategy involves achieving a level of collective immunity (herd immunity) sufficient to protect the most vulnerable and reduce the virus. It depends, of course, on the effectiveness of the vaccine itself, as well as on the speed of distribution, the audiences prioritized for vaccination campaigns, and the level of commitment of the populations concerned.

In a context of scarce resources, the success of vaccine strategies will mainly be a matter of speed and prioritization. They will necessarily be adaptive, given the initial uncertainties concerning how long the vaccine will be effective and its effects by age. The models developed[27] show a very high sensitivity to these parameters and the need to immediately constitute a large-scale cohort of vaccinated people.

*Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination*




The Lancet DOI: (10.1016/S0140-6736(20)32318-7)

The goal should be to intensify the effort within a set period of time to achieve as much as possible 70 to 80% collective immunity.

These questions imply the need for focused work combing a logic of vulnerability and a logic of effectiveness in preventing transmission.

This work was carried out respectively by the American Academies of Science, Engineering and Medicine[28] (in September) and by the *Royal Society*[29] in the United Kingdom (in October) in conjunction with the *Joint Committee of Vaccination and Immunizations*, which established the first guidelines[30].

In France, an opinion from the "vaccine" committee, dated July 9, also addressed the subject.

All these institutions have proposed a strategic framework aimed at ensuring an equitable and efficient allocation of vaccines throughout their deployment and which identifies two priority audiences:

- Health professionals (priority 1) and more generally professionals in contact with the population;
- Vulnerable people either because of their age or because of one or more chronic diseases.

Kate Bingham, head of the UK government's vaccine taskforce said that only 30 million people, or half of the UK population, will have access to the vaccine, which will lead to the priority targeting of people over 65, healthcare professionals, and vulnerable people.

The American Academies have proposed four phases of scaling up, gradually expanding the target population according to vaccine availability. This strategy leads to the establishment of a vaccination obligation for health professionals.

In the United States, Moncef Slaoui (*Warp Speed*) states: "*We are working with bio-ethicists and experts from the NIH, the CDC, BARDA, and the Centers for Medicare and Medicaid Services to address these critical issues. We will receive recommendations from the CDC Advisory Committee on Immunization Practices, and we are working to ensure that the most vulnerable and at-risk persons will receive vaccine doses once they are ready. Prioritization will also depend on the relative performance of each vaccine and its suitability for particular populations.*

*Because some technologies have limited previous data on safety in humans, the long-term safety of these vaccines will be carefully assessed using pharmacovigilance surveillance strategies.*"[31]

### Trust: the only ally of a successful strategy

Here comes the most decisive question, that of trust. It is the backbone of any vaccine strategy.

It is essential to recognize that this trust takes extremely different paths in different societies due to history and cultures. When it passes from the individual to the collective, the link between confidence and health becomes fragile. The contemporary suspicion of vaccines is a dramatic illustration of this. It is particularly strong in France, where one in three French people no longer trust vaccines. This was only one in ten 30 years ago. What is troubling is that this lack of trust is stronger among those with the highest level of education. Even more disturbing, it has now won over a significant number of health professionals.

A communication campaign on vaccines is necessary but it will not solve everything. Several studies also show links between the level of exposure of citizens to a subject such as vaccines and their level of mistrust. The relationship between information and trust is therefore more complex than is often believed. More exactly, this relationship takes the form of a valley: for people who are not experts, any additional information first of all generates stress and then loss of confidence. It is only after having crossed a level of expertise that positive information again conveys confidence. Becoming aware of the valley of mistrust makes us see health democracy in a different light.

The valley of mistrust also raises awareness of the self-censorship reflex that strikes scientists whenever it comes to making their work known to the public. This makes the information unevenly distributed. A small number are exposed to wide publicity, sometimes in defiance of the demands of evidence-based medicine. But the most expert are often in hiding. And their behavior is rational.

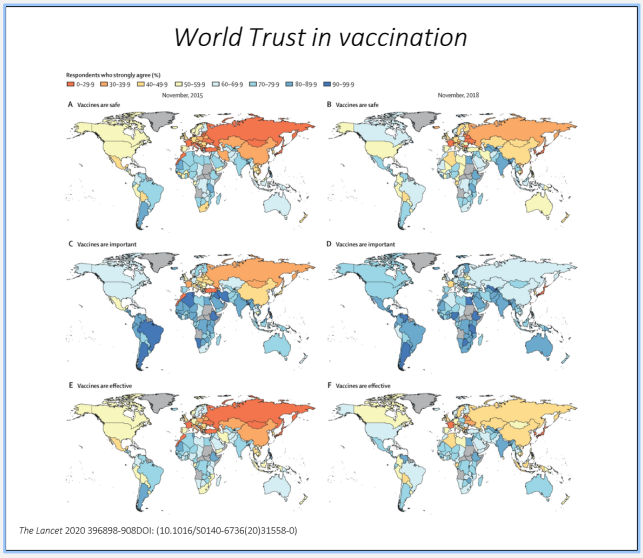
Whoever wishes to organize an honest debate on an emerging and complex health problem, knows that he will first create a period of turmoil around it.

The first effect of providing information is to create doubt. It will be a long way through the valley. It is a double challenge for political leaders in the distribution of vaccines: ensuring end-to-end transparency and knowing how to monitor trust over the long term.

We must become aware of the valley, particularly in countries, such as France, in which mistrust has established itself for a long time. The roots of the French “society of mistrust”[32] are well documented, as well as the effect of hysteresis, which permanently undermines public policies. These roots lie in the very hierarchical organization of French society, inherited from history and its educational model. Mistrust is a remnant of the past that we find hard to get rid of – what economists call "hysteresis". It is also the consequence of the fragmentation of society.

However, there are solutions. A recent study published by the medical journal *The Lancet* showed that confidence in vaccines is very unevenly distributed around the planet. Depending on the country, it is more or less dependent on the level of education, age, religion and social networks. But what is most reassuring in this study is that some countries, such as France, managed to significantly improve the level of confidence expressed by the population in vaccines between 2015 and 2019[33] .

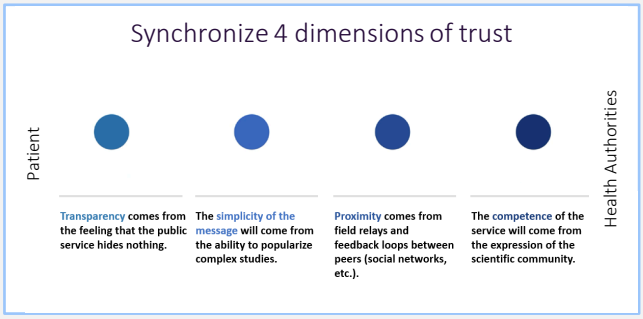
 




This improvement is linked to the reaffirmation of vaccine obligations and to a continuous discourse on the need for vaccination.

The humanities and social sciences have fully investigated this question for 20 years and particularly the teams of Nicholas Bloom at Harvard. They have shown that focused and sustainable policies can be successful in building confidence. Four ingredients should be combined:

- Transparency in the dissemination of information;
- Simplicity of the message;
- The presence of local relays and in particular the validation by peers of public health messages;
- The ability to include this information in a collective narrative and to ensure its credibility.




This path is demanding, but it is also very powerful. It is becoming increasingly necessary for successful vaccination strategies.

Confidence in vaccines will be like a symphony. Renowned musical conductor Sir Colin Davis said in this regard that the real role of a conductor is to hold music as one holds a bird in one's hand: if you hold too tightly, you suffocate it. If we open too much, it escapes. Between these two extremes, after a year of confinement, there is room for collective hope.

**Etienne GRASS,**
**Global head of Public Sector,**
**Capgemini Invent**

**I am part of Invent for Society initiative** which aims to value how social impact is part of the fabric of what we do every day with our clients. As a globally renowned technology and digital leader, we have the responsibility, the ambition and the means to contribute to solving major societal questions that are shaping our future world – and at Capgemini Invent we are contributing to realizing this ambition.
Within Capgemini Invent we leverage digital technologies and our team members are engaged in projects that shape the future in areas that include waste reduction, energy transition, education, digital inclusion, predictive healthcare, employment, poverty prevention and housing. And the list continues to grow.

# REFERENCE


[1.] On the notion of vaccine efficacy, read Marc Lipsitch's paper : Understanding COVID-19 vaccine efficacy , By Marc Lipsitch , Natalie E. Dean, Published Online21 Oct 2020

DOI: 10.1126/science.abe5938

https://science.sciencemag.org/content/early/2020/10/21/science.abe5938

[2.] WHO regularly maintains a list of vaccines being tested: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

The last follow-up dates back to October 29, 2020

[3.] https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

[4.] The difference is the recent inclusion (10/29/2020) of the product from India's Bharat Biotech

[5.] *Sinovac, Sinopharm/ Wuhan Institute of Biological Products, Beijing Institute of Biological Products/Sinopharm, CanSino Biological Inc./Beijing Institute of Biotechnology*

[6.] The so-called " Sputnik 5 " vaccine developed by the Gamaleya Research Institute

[7.] Operation Warp Speed also referenced a sixth product, prepared by GSK and Sanofi, but which is currently only in phase 2 testing.

[8.] https://www.wsj.com/articles/pandemic-dents-third-quarter-sales-for-pfizer-11603799937

[9.] Vaccine Taskforce, Department for Business Energy and Industrial Strategy, UK Government, Kate Bingan, « The UK Government's Vaccine Taskforce: strategy for protecting the UK and the world », *The Lancet,* 27/10/2020

DOI: https://doi.org/10.1016/S0140-6736(20)32175-9; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32175-9/fulltext

[10.] The creation of Warp Speed should make it possible to drain the expertise of the NIH, the ASPR, the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority (BARDA) and the DOD towards common objectives. , including the Joint Program Executive Office for Chemical, Biological , Radiological , Nuclear Defense , and the Defense Advanced Research Projects Agency

[11.] Recently Mohammed Slaoui agreed to deliver a mid-term review of the operation as part of an interview with *the New England Journal of Medicine*: https://www.nejm.org/doi/full/10.1056/NEJMp2027405

[12.] To allow appropriate comparisons between candidate vaccines and optimize vaccine use after FDA approval, the Phase 3 trial endpoints and test readings have been aligned through a collaborative effort. involving *the National Institute of Allergy and Infectious Diseases* (*NIAID*), *the Coronavirus Prevention Network*, *OWS* and corporate sponsors

[13.] FDA final guidance on "*Emergency Use Authorization for Vaccines to Prevent COVID-19*" (October 2020)

[14.] "*The FDA expects that, following the submission of an EUA application and the issuance of an EUA, a sponsor will continue to collect placebo-controlled data in all ongoing trials as well, as long as possible and is also working on submitting a Biologics License Application (BLA) as soon as possible.*"(Section III, page 4)"*The FDA does not view the availability of a COVID-19 vaccine under the EUA, per se, as a reason to stop blind tracking in an ongoing clinical trial* ." (Section VI, page 11 of the guidelines)

[15.] "*We believe that while ensuring the blindness of the study for as long as possible, Pfizer and BioNTech would nevertheless have an ethical responsibility to inform all study participants of the availability of a vaccine. emergency authorized, if authorized, and the eligibility conditions for such a vaccine. If Pfizer's vaccine obtains emergency use clearance, we will propose to modify our current study to allow crossbreeding of eligible placebos to the active vaccine arm if they wish at any time. Statistical considerations and details regarding appropriate protocol language, informed consent, and the logistics of this process should be carefully developed in collaboration with the regulator. We encourage CBER to open up to other scientifically and statistically sound methods to assess the long-term efficacy and safety monitoring of recipients of our vaccine candidate (e.g. comparison of cohorts and permanent safety registers )*."

https://www.regulations.gov/document?D=FDA-2020-N-1898-0018

[16.] This entire meeting is available online:

https://www.youtube.com/watch?v=1XTiL9rUpkg&feature=youtu.be&ab_channel=U.S.FoodandDrugAdministration

[17.] The protocol adopted by Pfizer provides that half of the trial participants receive 2 doses of the vaccine three weeks apart, the other half receiving a placebo. One week after the second administration of the vaccine, symptoms are monitored. The FDA requests a minimum of two months of observational follow-up data for each participant.

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[18] As the opinion of CARE - COVID-19 Scientific Committee - COVID-19 Vaccine Committee in France notes : " *in all cases the question of immunization of subjects over 75 years of age in whom it is probable that a weak vaccine response will be obtained and that it will be necessary to cover by protective measures barriers. "CARE - COVID-19 Scientific Committee - COVID-19 Vaccine Committee," Vaccines, against SARS-Cov19, a vaccination strategy, July 9, 2020*"

https://solidarites-sante.gouv.fr/IMG/pdf/avis_vaccins_9_juillet_2020_-_care_-_conseil_scientifique_-_comite_vaccin.pdf

[19] Vaccine Taskforce, Department for Business Energy and Industrial Strategy, UK Government, op cit

[20] Sanofi-GSK: 300 million doses, July 31, 2020; Johnson & Johnson: 200 million doses, and an option for 200 million more, on August 13, 2020; AstraZeneca: 300 million doses, and an option for 100 million, August 14, 2020; CureVac: 225 million doses, August 18, 2020; Moderna: 80 million doses, and an option for 80 million, on August 24, 2020; BioNtech-Pfizer: 200 million doses with an option of 100 million, September 9, 2020.

[21] AstraZeneca: 300 million doses, May 21, 2020; Pfizer et BioNTech: 100 million doses, and an option for 500 million, on July 22, 2020; Moderna: 100 million doses, and an option for 400 million, on August 11, 2020; Novavax: 100 million doses; Johnson & Johnson: 100 million doses.

[22] These orders were placed with 4 suppliers: AstraZeneca, Valneva, BioNTech/Pfizer and Sanofi (60 million doses). The British government then placed a pre-order with Novavax as well.

[23] Vaccine Taskforce, Department for Business Energy and Industrial Strategy, UK Government, op cit

[24] Information disclosed by the Wall Street Journal:

https://www.wsj.com/articles/state-health-authorities-worry-about-slow-planning-for-covid-19-vaccine-distribution-11600377802

[25] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32175-9/fulltext#section-3d6acba1-acea-4be2-8dc9-b7e14e5b6583

[26] https://solidarites-sante.gouv.fr/IMG/pdf/avis_vaccins_9_juillet_2020_-_care_-_conseil_scientifique_-_comite_vaccin.pdf

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