# BIA Vaccine Manufacturing Taskforce FAQs

UK BioIndustry Association

**FAQs**

*1. What money has the taskforce received so far from Government to support this effort? What is the money going towards?*

**BIA**

Government funding will help will support both Oxford Universities and Imperial College London's clinical trials and manufacturing capability. The money will help accelerate the manufacturing capacity and capability of the UK and support vaccine candidates, and other COVID-19 therapies, which are needed in this global health crisis.

*2. COVID-19 has shown that the UK has limited or no vaccine manufacturing capability, are there plans to address that?*

**Cobra Biologics**

The UK has the capability certainly in the near term. 1 million doses should potentially be generated per 200L run. Across the Oxford consortium there is the potential for six such runs per month from mid-2020; total of 6 million doses per month. If there is a target of 24 million doses then this would be achievable in 4 months. There is the potential to expand this within existing Oxford consortium too. Cobra Biologics is currently expanding with additional manufacturing capabilities available by Q3 2020,

**Oxford Biomedica**

Yes, there are existing facilities suitable for the manufacture of vaccines, including some specifically set up for the manufacture of viral vectors, the technology used for the Oxford University vaccine candidate. For example, one of the Oxford Vaccine Consortium members, Oxford Biomedica is commissioning a new 78,000 sq ft facility with 4 new viral vector manufacturing suites providing capacity for large scale production of the Oxford vaccine candidate . The Consortium members and Oxford Biomedica are working to add this large new UK-based capacity to the combined capacity including Cobra and VMIC as soon as possible. This additional capacity will come on line in early summer 2020, significantly adding to the UK's capacity for rapid manufacturing of such viral vector-based vaccine candidates.

*3. There are numerous issues with global supply in regard to PPE, ventilators and testing, have you identified pinch points in the supply chains for these vaccines?*

**Cobra Biologics**

All the partners in the Oxford consortium alongside the MHRA are working closely together to build on the production process that has already been developed by Dr Douglas' group from the Jenner Institute at the University of Oxford to establish a robust process at the planned production scale. The aim is to parallel track as many activities as possible including equipment procurement and to share and pool the knowledge and experience of the consortium to limit both the required development activities and to identify and mitigate the potential risks that can be encountered in the development and manufacturing scale up.

*4. Which companies will be manufacturing the vaccine for a. Oxford and b. Imperial?*

**BIA**

a. A team at Oxford led by Professor Sandy Douglas, with Professor Sarah Gilbert and the CBF, successfully put in a bid to UKRI in partnership with BIA members Pall, Fujifilm, Cobra, Oxford Biomedica, Cell and Gene Therapy Catapult and VMIC to develop rapid scale up of such a vaccine to a 1M dose scale by this summer.

b. The taskforce is also supporting the work of Imperial College London, led by Professor Robert Shattock, where the team is focusing on an mRNA vaccine, supported by CPI Biologics and Fujifilm.

**BIA**

The taskforce is also supporting the work of Imperial College London, led by Professor Robert Shattock, where the team is focusing on an mRNA vaccine and where human clinical trials are expected to begin in the summer of 2020

*5. What are the key challenges in developing a Covid-19 vaccine? E.g. Time/money/resource/rapidly growing number of people infected so impact on finding healthy volunteers who have not been infected?*

**KTN**

The key challenges in developing a COVID-19 vaccine are essentially the same as developing any vaccine with the added challenge that COVID-19 is an ongoing public health emergency. Time is obviously of the essence, but certain key activities still need to be done to ensure that the vaccine is safe and effective. Increasing the manufacturing scale is a technical challenge to maintain the safety profile and efficacy of the vaccine. The identification of healthy volunteers can be done using a relatively simple antibody screening test. In any pandemic, not everyone will become infected due to the genetic diversity of the population.

**Professor Sarah Gilbert, Oxford**

"The lockdown in the UK could make it more difficult to test the vaccine, as human contact is low, so researchers will have to conduct trials somewhere with a higher rate of transmission, to get a quicker result"

*6. Have we learned anything from research so far that suggests a vaccine is either closer or further away than we thought?*

**KTN**

There are many vaccine candidates being developed worldwide. The diversity of approaches and the on-going public health emergency should ensure that a safe and effective vaccine will be available quicker than under normal circumstances.

*7. The timescale for development is often given as 12-18 months. Can you help us explain why the process is inherently lengthy? What are the stages that cannot be sped up? UPDATE WITH CURRENT DATES, reiterate what they said?*

**VMIC**

The 12 to 18-month estimate has been quoted as an expected timescale by experts for developing a new vaccine. This timescale includes the time taken for process development and manufacture as well as to test in animal and human subjects during a clinical trial.

Scientists will need to assess the safety and effectiveness of the vaccine over several weeks and months. Then regulatory approval is needed. There is not really a stage that can be sped up, but regulatory approval of promising candidates could be prioritised in an emergency situation, and large scale manufacturing could be done concurrently while the clinical trial is ongoing, which would shorten the overall timescale for vaccine development.

Using a platform technology approach, i.e. a vaccine delivery system that has been used before and can be adapted for a new pathogen can also shorten initial development time. Oxford University are using all these strategies in order to try to make our vaccine available as rapidly as possible once it is proven safe and effective.

**Cobra Biologics**

The challenge to make 1 million doses of any vaccine is dependent to a large degree on the dose size required and the productivity of the production system. A key point about the adenoviral vaccine developed by the Jenner institute, is that it has been shown to be both potent and productive and is very well suited to the production of large quantities of vaccine. The dose sizes for this type of vaccine developed by the Jenner Institute for other coronavirus based infections such as MERS and SARS are in the region of $5x10^{10}$ viral particles. It is possible to make such quantities of viral particles in 0.2ml of culture, or 5 doses /ml of cell culture. Therefore, it should be possible to make

1,000,000 from 200L of cell culture, which is not uncommon. The ambition is a realistic one and should be achievable, and the consortium is looking at establishing production of these scales at multiple sites.

In terms of the specific process, the challenge will be to ensure the robustness of all stages of the process from the cell culture through to the final formulation of the product. A key thing about viral vectors is that they are very large and complex, making them difficult to characterise and analyse from a manufacturing perspective; we are therefore dependent upon controlling the manufacturing processes to ensure that product quality, safety and efficacy are achieved. The key parameter will be to develop sufficient knowledge of the manufacturing process to enable further scale up and process transfers to manufacturing sites whilst retaining the essential quality attributes of the vaccine.

*8. Some people involved in coronavirus vaccine projects have talked about an "accelerated pathway" for a new vaccine. What does this mean?*

**VMIC**
"Accelerated pathways" have been used for other vaccines and refer to the type of clinical evidence the regulator requires to licence the vaccine. For example, this may include using certain biological indicators to predict the effectiveness of the vaccine.
See: https://www.fda.gov/media/82306/download

*9. Have any regional or physical differences emerged in the vaccine efforts/studies in different countries?*

**KTN**

The development of vaccine candidates is a Worldwide effort. The approach should be essentially the same to ensure that a safe and effective vaccine is available in the shortest possible time.

*10. In simple terms, what is the difference between DNA and RNA vaccines? is one more likely to be helpful in protecting against Covid-19?*

**KTN**

All vaccines look to elicit an effective immune response in an individual so that, when the individual encounters the real infectious agent, they're protected against the disease. Both DNA and RNA vaccines look to use bits of nucleic acid to encode proteins from the virus after vaccination. These proteins will then elicit the required immune responses. DNA and RNA are just different types of nucleic acid and there will be differences in the development requirements of each type as there would be with protein vaccines, live attenuated vaccines, peptide vaccines etc.

*11. What are the risks in accelerating vaccine development from 15-20 years to 12-18months?*

**KTN**

Many development risks exist within the vaccine development pathway, but these will be minimised as far as possible in order to end up with a safe and effective vaccine, the end goal of all vaccine development efforts Worldwide.

*12. More than 40 separate teams globally developing a vaccine - what are the downsides and upsides to such a huge number? Could working together produce working vaccine more quickly? Danger of not sharing data?*

**KTN**

Given the on-going public health emergency, collaboration is more likely. Certainly, pre-competitive and regulatory collaboration is happening across the Globe:

https://www.ema.europa.eu/en/news/first-regulatory-workshop-covid-19-facilitates-global-collaboration-vaccine-development

**Cobra Biologics**

On the contrary, there are multiple platforms that can be used to develop a vaccine and the number of teams involved reflects the multiple options available and means a successful vaccine should be found. The key collaborative aspect is more likely to occur when it comes to the manufacturing, approval, and distribution of the vaccine.

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