
Manufacture of Covid-19 Vaccine

Overview and Challenges

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SERUM INSTITUTE OF INDIA PVT. LTD.

Cyrus Poonawalla Group



SI IPL Introduction

- ❑ SI IPL was founded over 50 years ago in 1966
- ❑ World's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.6 billion doses)
- ❑ ***"It is our endeavor to make quality vaccines more affordable around the world because we firmly believe health should be the right of every child"***
- ❑ SI IPL has successfully scaled-up various path breaking technologies/ products over last five decades achieving huge economies of scale and resulting in optimisation of costs.
- ❑ SI IPL vaccines are used in **more than 170 countries**
- ❑ **65%** of the children receive at least one SI IPL manufactured vaccine

Serving Mankind
by ensuring good
health through
vaccines

"It is our endeavour to make quality vaccines more affordable around the world because we firmly believe that health should be the right of every child."

Dr. Cyrus Poonawalla, Chairman and Managing Director



INDIA Sites



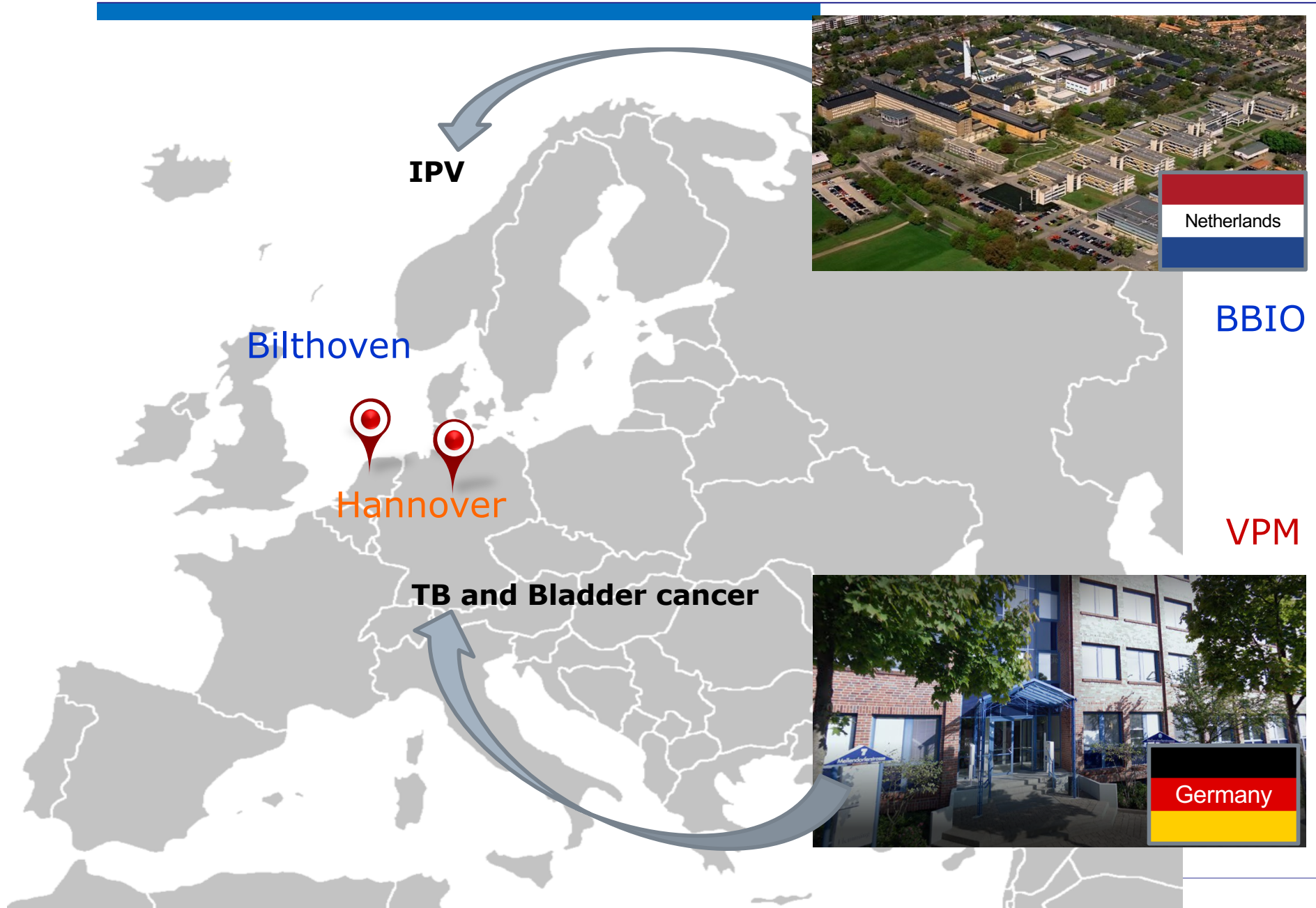
Hadapsar, Pune



Manjari, Pune



EU Sites



Covid-19 Vaccine Candidates with Collaborations

1	Codagenix (COVI VAC)
2	AstraZeneca-Oxford University - COVISHIELD
3	Novavax - COVOVAX (NVX-CoV2373)
4	SpyBiotech COVIVAXX (RBD HBsAg VLP)

Note: Due to confidentiality reasons it is not possible to disclose more information about these products at this stage



Covid-19 Vaccine Manufacturing

Vaccine manufacturing Technology	Challenges in method of manufacturing
messenger RNA (mRNA) vaccine	mRNA's extremely large size, charge, intrinsic instability, and high susceptibility to enzymatic degradation
Live attenuated viral vaccine	sensitivity towards adverse conditions such as extreme temperature
Inactivated viral vaccine	<ul style="list-style-type: none">- improper virus inactivation- possibility of destruction of viral-neutralizing epitopes at the time of inactivation process
Recombinant vaccine	<ul style="list-style-type: none">- selection of correct vector- efficacy of recombinent vector- stability of the insert



Covid-19 Vaccine Manufacturing and Scale up

- Single dose vials
- Multi dose vials - with preservative and without preservatives
- Prefilled syringes

Challenges:

- Selection of right cell line and vector
- Selection of precise methodology for purification
- Quick turn around for scale-up to achieve global demand
- Proper alignment of upstream and downstream processing units to handle large volumes
- Establishing analytical methods, specifications, method qualification and validation
- Hurdles in supply chain of essential raw materials and equipments
- Shortage of manpower
- Support from Regulatory Authorities



Covid-19 Vaccine - Supply Chain and Immunization

Challenges:

- Establishing large scale cold storage facilities for stock piling
- Labelling - each country has its own labelling requirements
- Set up supply chain network and contract with airlines within shorter time span
- Tracking of vaccine supply and post vaccination monitoring
- Mass Immunization - how to handle? single dose vaccine vs. multi-dose vaccine



Thank you

