COVID-19 Vaccines: Target Product Characteristics (TPC) [1/5]

Vaccine Characteristic	CEPI Optimal	CEPI Minimal
Indication for use	For active immunization of persons considered potentially at-risk, based on specific risk factors, for • disease (in particular to prevent complicated / severe disease) to prevent COVID-19 morbidity / mortality, and • infection (in particular to prevent viral spread) to prevent COVID-19 transmission. Vaccine to be used in conjunction with other control measures to curtail or end an outbreak. Risk groups include:[1] • disease: elderly, underlying chronic diseases • infection: contact persons of patients with confirmed COVID-19, health care workers (HCWs).	For active immunization of persons considered potentially at-risk, based on specific risk factors, for • disease (in particular to prevent complicated / severe disease) to prevent COVID-19 morbidity / mortality. Vaccine to be used in conjunction with other control measures to curtail or end an outbreak. Risk groups include:[1] • disease: elderly, underlying chronic diseases • infection: contact persons of patients with confirmed COVID-19, health care workers (HCWs).
Product	A monovalent vaccine with or without adjuvant for protection against the COVID-19 emerging from Wuhan, Hubei Province, China, by generation of virus neutralizing antibodies or other immune response indicative of protection.	Same as 'Optimal'.
Target population	All age groups with a focus on populations at risk for complicated / severe disease as well as infection.[2] Acceptable benefit-risk profile for administration to pregnant women.[3]	Focus on healthy adults first, followed by elderly and paediatric populations, excluding pregnant and lactating women.

1) Human-to-human transmission to contact persons / HCW has been established. While severe disease / fatal outcome has been described in individuals with chronic medical conditions risk factors for severe COVID-19 disease are not yet fully established and evidence will be reviewed continuously; **2**) Infants defined as children <12 months of age; toddlers defined as children 12 to <24 months, young children defined as 24 months to <9 years, adolescents defined as 9 to <18 years. As of Jan 31st, COVID-19 transmission has mainly occurred in adults. As epidemiology evolves, all age groups (=contact persons) are potentially at risk; **3**) As of Jan 31st, no COVID-19 -infection has been confirmed to date in pregnant women – however, like in other systemic infectious diseases, COVID-19 infection may constitute a significant health risk for both, the pregnant women and the unborn.

CEPI

COVID-19 Vaccines: Target Product Characteristics (TPC) [2/5]

Vaccine Characteristic	CEPI Optimal	CEPI Minimal
Target countries	Countries at risk for COVID-19 transmission.	Same as 'Optimal'.
Safety / reactogenicity	Safety and reactogenicity sufficient to provide a highly favorable benefit/risk profile in the context of observed vaccine efficacy; ideally with only mild, transient adverse events related to vaccination and no related serious AEs. Additional pre-clinical data without evidence of harmful immune response in animal models (i.e., inducement of virus enhancing antibodies, eosinophilic lung infiltration).	Safety and reactogenicity whereby vaccine benefits clearly outweigh safety risks. Additional pre-clinical data without evidence of harmful immune response in animal models (i.e., inducement of virus enhancing antibodies, eosinophilic lung infiltration).
Protective efficacy	At least 90% protective efficacy against disease caused by COVID-19 in healthy adults. Preventing of virus shedding (e.g. evidence on reduction of viral load, duration of viraemia / virus shedding). If demonstration of clinical efficacy is not feasible, pre-clinical immunogenicity and efficacy in a standardized and relevant animal model together with clinical immunogenicity may be considered. In this case, clinical effectiveness data may have to be generated post licensure – to the extent possible. [4,5]	At least 70% protective efficacy against disease caused COVID-19 in healthy adults. A lower protective efficacy may be acceptable if other vaccine characteristics favour the vaccine in the context of this TPC as well as public health benefits considered relevant for the COVID-19 outbreak. If demonstration of clinical efficacy is not feasible, pre-clinical immunogenicity and efficacy in a standardized and relevant animal model together with clinical immunogenicity may be considered. In this case, clinical effectiveness data may have to be generated post licensure – to the extent possible. [4,5]
Indirect (herd) immunity / protection	N/A	N/A

4) These considerations should be discussed between vaccine developers and regulators early in the development process; 5) An attempt should be made to identify correlates of protection in an appropriate preclinical model

CEPI

COVID-19 Vaccines: Target Product Characteristics (TPC) [3/5]

Vaccine Characteristic	CEPI Optimal	CEPI Minimal
Onset of immune response	At least 70% of vaccinees with immune response considered to be protective at max. 1 week after completing primary immunization and at least 90% after max. 4 weeks.	At least 50% of vaccines with immune response considered to be protective at max. 1 week after completing primary immunization and at least 70% after max. 4 weeks.
Duration of protection	Confers protection for at least 1 year without booster vaccination. Duration of protection may be inferred from immune kinetics, as well as documentation of breakthrough cases.	Confers protection for at least 6 months without booster vaccination. Duration of protection may be inferred from immune kinetics, as well as documentation of breakthrough cases.
Contraindication	No contraindication for use in individuals with compromised immune function.[6] No absolute contraindication in pregnant women.	Contraindication in some special populations (e.g. individuals with compromised immune function, pregnant women) acceptable if other vaccine characteristics favor the vaccine in the context of this TPC.
Co-administration	N/A (the vaccine will most likely be given as a stand-alone product in an emergency situation not co-administered with other vaccines). Evidence on safety and immunogenicity when co-administered with influenza vaccines should be considered.	N/A (the vaccine will most likely be given as a stand-alone product in an emergency situation not co-administered with other vaccines). Evidence on safety and immunogenicity when co-administered with influenza vaccines should be considered.

6) Severe 2019-nCoV disease has been described in elderly with underlying chronic medical conditions including impaired immune function.

COVID-19 Vaccines: Target Product Characteristics (TPC) [4/5]

Vaccine Characteristic	CEPI Optimal	CEPI Minimal
Dosing schedule	Single-dose primary immunization.	Two-dose primary immunization regimen with preference for short interval between doses (max. 0-28 days) and with some protection / immune response considered to be protective after first dose.
Dosing regimen compliance risk	Completion of primary immunization.	Same as 'Optimal'.
Route of administration	Injectable (I.M.) using standard volumes for injection. Easy to administer to all preferred age groups. Vaccination device disposable. Needle-free delivery, oral or other non-parenteral route desirable.	Injectable (I.M., S.C. or I.D.) using standard volumes for injection. Other routes of administration (including those involving electroporation) acceptable if other vaccine characteristics favor the vaccine in the context of this TPC.
Coverage	Protective against COVID-19 strains infecting humans.	Same as 'Preferred'.
Presentation (for parenteral vaccines)	Vaccine provided as a liquid or lyophilized product in mono-dose or multi-dose presentations with a maximal dose volume of 0.5 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's multi-dose vial policy (MVDP) (briefly: opened vial can be used for up to 28 days after opening if it meets criteria set forth by MDVP).[7] Lyophilized vaccine will need to be paired with a separate vial of the appropriate diluent.	Vaccine provided as a liquid or lyophilized product in mono-dose or multi-dose presentations with a maximal dose volume of 1.0 mL. Multi-dose presentations should be formulated, managed and discarded in compliance with WHO's MVDP (briefly: opened vial can be used for up to 28 days after opening if it meets criteria set forth by MDVP).[7] Lyophilized vaccine will need to be paired with a separate vial of the appropriate diluent.

7) WHO 2014. https://apps.who.int/iris/bitstream/handle/10665/135972/WHO_IVB_14.07_eng.pdf.

CEPI

COVID-19 Vaccines: Target Product Characteristics (TPC) [5/5]

Vaccine Characteristic	CEPI Optimal	CEPI Minimal
Stability / shelf life	Shelf life of 5 years at 2-8°C. Additional data on thermostability at higher temperatures. The need for a preservative is determined and any issues are addressed. Vaccine vial monitor (VVM): Proof of feasibility and intent to apply a VVM to the primary container for multi-dose vials.	Shelf life of at least 12 months at up to -70°C. Stability of at least 1 month at 2-8°C should be demonstrated. The need for a preservative is determined and any issues are addressed. VVM: Proof of feasibility and intent to apply a VVM to the primary container.
Product registration path	EMA / FDA, China, WHO PQ, additional national regulatory agencies in affected countries.	Same as 'Optimal'. Consider the *Emergency Use Assessment and Listing* (EUAL, in future: EUL) procedure for candidate vaccines for use while COVID-19 is declared a *Public Health Emergency of International Concern* (PHEIC).[8]
Vaccine access	Should comply with CEPI's equitable access to vaccines policy.	Same as 'Optimal'.
Scalability / manufacturing capacity	High productivity, scalable manufacturing platform capable of supporting at least 10M doses per month during an outbreak.	Scalable to produce at least 1M doses per month of drug substance.

8) WHO 2015. http://apps.who.int/medicinedocs/documents/s21987en/s21987en.pdf