Target Product Profiles

Roadmap strategic goal: Develop and make available of vaccines **for use in outbreak settings (outbreak) and/or** with **long-term protection for administration to those at high ongoing risk of COVID-19 (LT).**

Vaccine characteristic	**Preferred**	**Critical or Minimal**
Indication for use	Outbreak: For active immunization of persons in the area of an on-going outbreak for the prevention of COVID-19 to curtail or end an outbreak.	Outbreak: For active immunization of persons in the area of an on-going outbreak for the prevention of COVID-19; to be used in conjunction with other control measures to curtail or end an outbreak
	LT: For active immunization of at-risk persons to prevent COVID-19	LT: For active immunization of at-risk persons to prevent COVID-19
Contraindication	None	Some contraindications (e.g., immunocompromised) may be acceptable, depending on the platform used.
Target population	All ages[2]. Suitable for administration to pregnant and lactating women.	Adults, including elderly, patients with co-morbid conditions or increased risk of complicated course of disease
Safety/Reactogenicity	Safety and reactogenicity sufficient to provide a highly favourable benefit/risk profile in the context of observed vaccine efficacy; with only mild, transient adverse events related to	Outbreak: Safety and reactogenicity whereby vaccine benefits outweigh safety risks[3]. LT: Safety and reactogenicity sufficient to provide a highly

[2] Recognize that herd immunity (and transmission blocking) will depend on broad immunization, likely including children.

[3] Benefit/risk may depend on age, other factors. Benefit/risk assessment should take potential for enhanced disease into account

Vaccine characteristic	**Preferred** vaccination and no serious AEs.	**Critical or Minimal** favourable benefit/risk profile in the context of observed vaccine efficacy; with no severe adverse events related to vaccination. Insight into possible mechanisms for risk minimization
Measures of Efficacy	At least 70% efficacy (on population basis, with consistent results in the elderly and special at risk populations)[4]. Endpoint may be assessed vs. infection, disease, severe disease, and/or shedding/transmission. Outbreak: Rapid onset of protection (less than 2 weeks). LT: rapid onset of protection is less important	Clear demonstration of efficacy (on population basis) ideally with ~50% point lower estimate[4]. Endpoint[5] may be assessed vs. infection, disease, severe disease, and/or shedding/transmission[6].
Dose regimen	Outbreak: Single-dose primary series[7]. LT: Lower frequency (yearly or less) of booster doses is preferred	Outbreak: No more than two dose regimen with minimal (e.g. 2-4 weeks) interval. [8] LT: Booster doses[9] permitted

[4] The lower confidence limit of the efficacy estimate could be lower. These levels of efficacy are chosen based on their ability to confer important individual, public health, and indirect effects, recognizing that achievement of herd immunity might also require non-vaccine interventions. It should be understood that other factors held constant, higher levels of efficacy are more desirable than lower levels of efficacy.

[5] If regulatory authorization is provided with incomplete clinical efficacy data, effectiveness data are to be generated during use

[6] Efficacy in reducing the proportion of individuals who shed viruses may be an acceptable marker predicting efficacy against transmission

[7] Note strong preference for single-dose, but do not desire to discourage development of 2-dose vaccines if that is what is feasible

[8] note cholera is 2 dose, and many 2 dose vaccines confer partial protection after a single dose. For two-dose vaccines, protection after single dose should be assessed

[9] Booster doses are defined in the context of protection from the primary regimen

Vaccine characteristic	**Preferred**	**Critical or Minimal**
Durability of protection	Confers protection for at least 1 year.	Confers protection for at least 6 months[10].
Route of Administration	Outbreak: Any route of administration is acceptable, if vaccine is safe and effective LT: any route of administration is acceptable, if vaccine is safe and effective	Any route of administration is acceptable, if vaccine is safe and effective.
Product Stability and Storage	Higher storage temperatures and higher thermostability will greatly enhance vaccine distribution and availability, and are thus strongly preferred.	Outbreak: Shelf life of at least 6-12 months as low as -60—70°C[11], and demonstration of at least 2-week stability at 2-8°C. LT: Storage at -20°C or higher;
Co-administration with other vaccines	Outbreak: stand-alone product LT: potential for coadministration[12] with other vaccines that are typically administered in campaigns (e.g. influenza) preferred	Stand-alone product

[10] This might not be demonstrated in initial clinical studies, but could be supported by follow-on studies, animal data, etc.
[11] For drug product, storage at temperatures below -20C would require additional infrastructure and may impede distribution of vaccine, and would thus need to be addressed. This concern may be overcome by providing data supporting some storage at -20 and higher degrees.
[12] Defined as separate administration but on the same day

Presentation	Outbreak: Availability of multi-dose presentation is generally preferred for use in campaigns. Maximum parenteral dose volume: 0.5 mL	Multi- or mono- dose presentations are acceptable.
	LT: mono-dose or multi-dose presentations are acceptable Maximum parenteral dose volume: 0.5 mL	Maximum parenteral dose volume: 1 mL
Level of evidence	**Preferred**	**Critical or Minimal**
Efficacy	Outbreak: (short term) clinical efficacy data from phase III trial(s) providing sufficient evidence of VE for the intended schedule. LT: clinical efficacy data from phase III trial(s) providing sufficient evidence of VE for the intended schedule and preliminary insight into persistence and (possible) need for booster vaccination.	Outbreak: (short term) immunogenicity data (and interim efficacy data) from phase II- III trial(s) and providing evidence of VE a one dose schedule. LT: immunogenicity data and interim efficacy data from phase II- III trial(s) and providing evidence of VE the intended dose schedule
Safety	Sufficient experience (numbers and follow up) to ascertain safe use of the vaccine up to risks below 1:10.000 (very rare events) . Risks adequately described in RMP.	Outbreak: sufficient experience in numbers to ascertain short term safe use of the vaccine up to risks below 1:1000 (rare events) LT: sufficient experience in numbers to ascertain safe use of the vaccine up to risks below 1:1000 (rare events) following the primary vaccination series

[13] If feasible, vaccines consistent with an "open vial" policy may have additional advantage