

2. Vaccines

Stage	Technology Readiness Level	Definition
Ideation	TRL-1	Need identified, Basic principles observed and reported (Scientific research begins to be translated into applied research and development)
Proof of Principle	TRL-2	Epidemiologic study, Research ideas developed, hypothesis formulated and protocols developed (Initial level <i>in vitro studies</i> , Development of working Cell Bank)
Proof of Concept demonstrated	TRL-3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of <i>in vitro</i> models and limited <i>in vivo</i> efficacy studies (Formulation development, complete in-house testing of the formulated vaccine by <i>in vitro</i> model studies and <i>In vivo</i> efficacy in limited number of animals)
Proof of concept established	TRL-4	Efficacy & safety of vaccine candidate is demonstrated in a defined animal model (Results of serological studies in different animals at preliminary level and efficacy in defined <i>in vivo</i> model, Manufacturing and QC release of vaccine for Studies, Scale up Development)
Early stage validation	TRL-5	Pre-clinical studies, including GLP efficacy, acute and chronic toxicity, all the studies mandatory for safe exposure to humans such as repeat dose toxicity (RDT) and safety in animal model producing sufficient data for DCGI application for clinical trials
	TRL-6	Material produced in GMP facility of clinical trials. Phase I Clinical trials done and results & safety of the vaccine candidate reviewed by DCGI for approving Phase II Clinical trials.
Late stage Validation	TRL-7	Phase II Clinical trials completed and data reviewed by DCGI and Phase III Clinical trial plan approved.
Pre-commercialization	TRL-8	Phase III Clinical trials completed successfully. DCGI approves the vaccine and provides commercial manufacturing license for market introduction.
Commercialization and post market studies	TRL-9	Commercial launch of the new vaccine, Post marketing studies and surveillance (Phase IV clinical trial)