10.Veterinary

Stages	Technology Readiness Level	Definition
Ideation	TRL 1	• Need identified, Basic principles observed and /or reported (Scientific research begins to be translated into applied research and development)
Proof of Principle	TRL 2	• Research ideas developed, hypothesis formulated and protocols developed (Idea to be proven at preliminary research level through *in vitro* studies*)*
Proof of concept demonstrated	TRL 3	**Drugs/Vaccines** Initial characterization of the target molecule for biological activity by in vitro studies.
		Devices Analytical and laboratory studies to physically validate the analytical predictions of separate elements of the technology.
		Diagnostics Expression and Purification of the diagnostic agent, its characterization and initial validation at lab level using standard immune assays.
Proof of concept established	TRL 4	**Drugs/Vaccines** Optimizing Production of the target molecule in Lab Scale fermenter (1 to 2 L). Purification and biological Validation of the molecule under laboratory conditions. (using standard immuno assay/s and compared with gold standard assays)
		Devices Basic physical components are integrated to establish that they will work together. (first Laboratory test)
		Diagnostics Physical and biological Characterization of candidate antigen/s produced in different batches (around 5 batches)
Early stage validation	TRL 5	**Drugs/vaccines** Demonstration of proof of concept (PoC) in limited number of animals (by serological studies). Working on feasible formulation development and conducting safety and efficacy studies)
		Devices "high-fidelity" laboratory integration of components. The basic technological components are integrated with reasonably realistic supporting elements so they can be tested in a simulated environment.
		Diagnostics Establish all the diagnostic kits to have desired specificity & sensitivity based on the data generated.
Early stage validation		**Drugs** Establishment of Shelf life of the drug. Conducting the toxicity studies in the laboratory animal model.

	TRL 6	**Devices** Representative model or prototype system tested in a relevant environment (a high-fidelity laboratory environment or in a simulated operational environment).
		Vaccines Evaluation of duration of the immune response, Shelf life and toxicity in experimental animals/ target species. Conduct animal challenge studies wherever possible.
		Diagnostics Conduct extensive field evaluation.
Late stage Validation	TRL 7	**Drugs/Vaccines** Scale up under cGMP conditions and Conduct extensive field trials. Further confirm by Challenge studies where ever possible., Third Party Validation preferably government agencies
		Devices Prototype near i.e. demonstration of an actual system prototype in an operational environment. Final prototype produced and demonstrated.
		Diagnostics Third Party Validation, preferably government agencies
Pre-commercialization	TRL 8	• Regulatory approval for the New Application and provides commercial manufacturing license for market introduction
Commercialization and post market studies	TRL 9	• Commercial launch, Post marketing studies and surveillance