

Technology Readiness Level scale in Life Sciences & Health Technology

	EU general TRL description	Pharma / biotech	Health technology (incl software)
TRL 9	Technology in its final form and full commercial deployment	Post-marketing studies & surveillance	Post-marketing studies & surveillance
TRL 8	Technology in its final form	Phase III trial completed FDA approves New Drug Application; or Market Approval Authorization by EMA	FDA approves the PMA or 510(K) CE mark is granted;
TRL 7	Prototype near or at planned operational system. Represents a major step up from TRL 6.	Phase I & II trial completed Phase III clinical trial plan is approved by FDA or EMA Phase III is executed New Drug Application submitted to FDA; or Market Approval Authorization submitted to EMA	Final product design is validated and final prototypes are produced and tested
TRL 6	Representative model or prototype system, which is well beyond TRL 5. Represents major step in a technology's demonstrated readiness	IND application approved by FDA; or IMPD application and approved by EMA Phase I trial executed Phase II trial is executed	Prototype resembles final product, production resembles final manufacturing Class III device safety is demonstrated, 510(K) data demonstrates substantial equivalence to predicate device
TRL 5	Basic technological components are integrated with reasonable realistic supporting elements, so they can be tested in a controlled relevant environment	Pre-clinical studies; Preparation & submission for IND or IMPD	Pre-clinical studies; Prototype tested for components, or reasonably realistic integration
TRL 4	Basic technological components are integrated to establish that they will work together. This is relatively 'low fidelity' compared with eventual system.	PoC and safety of candidate drug formulation is demonstrated in a defined laboratory or animal model	PoC and safety of candidate device or system is demonstrated in a defined laboratory or animal model
TRL 3	Analytical studies to predict performance of separate elements of technology in appropriate context. Laboratory based studies to physically validate that analytical predictions are correct	Hypothesis testing and initial PoC in limited nr of in vitro & in vivo models	Hypothesis testing and initial PoC in limited nr of in vitro & in vivo models
TRL 2	Practical concepts or applications are formulated	Research ideas and protocols are developed	Research ideas and protocols are developed
TRL 1	Scientific research begins to be translated into applied research and development		