# Technology Readiness Level

| TRL | Stage | Description (Generic) | Domain-Specific Examples | Regulatory / Translational Checkpoints |
|---|---|---|---|---|
| 1 | Basic Research | Basic scientific principles observed and reported | New molecule identified, novel concept proposed, theoretical model framed | None yet |
| 2 | Concept Formed | Hypothesis or technology concept formulated | Target identified, early literature support, draft design, in-silico model | No ethics or regulatory steps yet |
| 3 | Proof of Concept | Experimental proof-of-concept shown in controlled lab settings | In vitro studies, simulations, early animal studies, prototype feasibility demonstrated | Basic lab validation, animal ethics clearance (if applicable) |
| 4 | Component Validation | Subsystem or component tested in lab environment | GLP animal studies, pilot formulation, prototype V1, algorithm tested with test datasets | Preclinical or pre-verification study plan formed |
| 5 | Integrated Validation | Components integrated and tested in relevant environment | GLP/ISO preclinical completed, formulation scaled up, beta prototype tested, early user studies | IND or IDE filing prepared (for pharma/medical devices) |
| 6 | Prototype Demonstration | System or prototype demonstrated in | Phase I clinical trials, usability studies, human factors validation, functional | Ethics and regulatory approval obtained for trial |

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| | | simulated real-world conditions | prototype in hospital or field | |
| 7 | System Readiness | Prototype tested in actual operational environment | Phase II/III trials, pivotal studies, device verification and validation complete | NDA/BLA/CE Mark submission underway |
| 8 | Final Product Ready | Final product proven in actual setting and ready for launch | Marketing authorization obtained, launch materials created, technology integrated into workflows | Regulatory approval received (e.g., FDA, DCGI, EMA, CDSCO, ISO, CE) |
| 9 | Real-world Operation | Technology in widespread use, monitored, improved based on real-world feedback | Post-marketing surveillance, real-world data collection, PMS, PV, user training, Version 2.0 based on feedback | Ongoing compliance and improvement (e.g., PSUR, PVPI, MDR reporting) |