Technology Readiness Level (TRL)

TRL	General description of TRL	Pharmaceuticals	Med Tech including diagnostics	e-Health (research based)	e-Health (concept based)
TRL1	Basic principles and research data observed and reported	Scientific research findings are reviewed and assessed, and translation into applied research begun. Potential targets and disease mechanisms evaluated. Focus is still on discovery.	Scientific research findings are reviewed and assessed, and translation into applied research and new technologies begun.	Scientific research begins to be translated into applied R&D activities. Concepts evaluated that can be implemented in development of e/m-technology (software, sensors, devices, infrastructure or process).	Observed need for either improved treatment procedure (process efficiency) or novel solution where e/m-technology (software, sensors, devices, infrastructure or process) can be advantageous.
TRL2	Technology concept and/or practical application formulated	Hypothesis, research ideas, protocols and experimental designs are developed. Potential therapeutic targets for intervention are identified.	Hypothesis, research ideas, protocols and experimental designs are developed. The potential ability of particular technologies, materials, and processes to address certain health problems identified.	Invention of potentially practical e/m-technology solutions addressing particular needs.	Invention of potentially practical e/m-technology or novel setup of existing technology solutions addressing particular needs.
TRL3	Analytical and experimental Proof of Concept of critical function and /or characteristics	Active R&D initiated. Hypothesis testing and target identification and potential candidates characterization, data collection, exploration of alternative approaches and early proof of concept in a limited number of in vitro & in vivo models.	Active R&D initiated. Hypothesis testing, data collection, identification and evaluation of critical technologies and components and early proof of concept in laboratory models including in vivo studies.	Active R&D initiated. Analytical studies to validate predictions of e/m-technology components of the technology that satisfy a need – forming the system application. System application tested in laboratory environment	Active development initiated. Studies to validate predictions of separate e/m-technology components of the concept that satisfy a need. System application tested in laboratory environment
TRL4	Validation of the technology in the laboratory	Preclinical R&D. Optimization of candidates and in vivo demonstration of activity and efficacy. Identification and integration of critical technologies (animal models, biomarkers, assays, etc.) in continued characterization of and development of potential candidates. Initiation of GMP process development and manufacturing of non-GMP	Preclinical R&D. Laboratory testing of critical components and processes. Proof of concept of device demonstrated in relevant laboratory and animal models.	System components integrated and tested regarding preliminary efficiency and reliability. Software architecture and other system components development to address reliability, scalability, operability, security etc. Other	System components integrated and tested for preliminary efficiency and reliability. Software architecture and other system components development to address reliability, scalability, operability, security etc.

		material and drug formulations. Evaluation of safety, pharmacodynamics and pharmacokinetic properties. Formulation of a Target Product Profile initiated.		system components development	
TRL5	Validation of technology in a relevant environment	Further characterization of candidate, i.e. absorption, distribution, metabolism and elimination. A manufacturing process established amenable to large scale GMP manufacturing and consistent with the intended use of the drug. Development of in process controls and relevant analytical assays. Continued development of animal models for efficacy and dose-ranging studies. Selection of candidate drug. GLP safety studies for IND submission and Phase 1	Further development of device candidates and system solutions. Validation of system components and processes in relevant laboratory environment. Classification of device by appropriate regulatory body and when appropriate an Investigational Device Exemption (IDE) prepared and submitted for review.	System component architecture established. System tested in relevant testing environment as expected in the operational environment. Verification, validation and accreditation when appropriate initiated.	System component architecture established. System tested in relevant testing environment as expected in the operational environment. Verification, validation and accreditation when appropriate initiated.
TRL6	Demonstration of technology in relevant environment	Clinical development. GMP production, IND submission and Phase I clinical evaluation performed proceeding to Phase II. Appropriate safety evaluations conducted to support further development	System/device prototype demonstrated in an operational environment. Clinical testing to demonstrate safety may be required. Depending on the classification of the device Premarket approval or Premarket notification (510(K)) apply.	Representative model or prototype system demonstrated in relevant live or simulated environment. System component releases are “beta” versions and configuration controlled. Support structure in development and verification and validation and when needed accreditation for safety reasons in progress.	Representative model or prototype system demonstrated in relevant live or simulated environment. System component releases are “beta” versions and configuration controlled. Support structure in development and verification and validation and when needed accreditation for safety reasons in progress.
TRL7	Technology prototype demonstrated in an operational environment	Phase II clinical study is completed. Manufacturing process scale-up and process validation initiated and stability testing ongoing. Continued safety studies to support further clinical testing. The TPP refined when necessary. Phase III clinical plans	Clinical safety and effectiveness trials conducted using a fully integrated prototype version of the medical device in an operational environment. Data evaluated to support further development The final product design validated and final prototype and/or device	System tested in an operational environment. Support structure in place and System component releases in distinct versions. Verification, validation and when appropriate	System tested in an operational environment. Support structure in place and System component releases in distinct versions. Verification, validation and when appropriate

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		defined and approved by regulatory authorities.	intended for commercial use produced and tested.	accreditation completed.	accreditation completed.
TRL8	Technology system completed and qualified through test and demonstration	Manufacturing processes validated. Pivotal clinical Phase III testing and safety studies completed. NDA or BLA prepared and submitted. Approved by appropriate regulatory authorities.	Premarket application or premarket notification submitted and approved	Development completed. System demonstrated to work under real life conditions. Testing of design specifications. System component releases are production versions. Support structure in place to resolve technical issues.	Development completed. System demonstrated to work under real life conditions. Testing of design specifications. System component releases are production versions. Support structure in place to resolve technical issues.
TRL9	Technology system in its final form ready for full (commercial) deployment in relevant operating environment	Product launched. Post-marketing studies (Phase IV) and surveillance	Product launched. Post-marketing studies and surveillance	Product launched.	Product launched.

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