Life Sciences Technology Readiness Level (pharma, medical devices, digital health)

TRL 1	Basic principles and research data observed and reported. Scientific research findings reviewed and assessed and translation into applied research begun. Potential targets, mechanisms, concepts evaluation.
TRL 2	Technology concept and/or application formulated. Research ideas, hypothesis, experimental designs, potential targets, technologies, solutions (also digital), protocols identified and developed, peer reviewed and approved.
TRL 3	Active R&D, data collection and analysis initiated. First hypothesis testing, target identification, potential candidates characterization, data collection, technological components (also digital) evaluation, alternative concepts exploration carried out. Early proof of concept (PoC)/system application tested in laboratory environment, in a limited number of in vitro & in vivo models.
TRL 4	Preclinical R&D. PoC, safety of potential candidates, device or system demonstrated in a relevant laboratory or animal model (non-GxP). Formulation and manufacturing process development initiated (non-GMP). Identification of relevant parametric data required for technological assessment. 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 development.
TRL 5	Technology validated in relevant environment. Pre-clinical studies, including GLP animal safety & toxicity, ADME data collection sufficient to support submission of the selected candidate to phase 1. GMP manufacturing process and quality controls identified. Validation of system components/architectures and processes in relevant laboratory/operational environment. Classification of device/system by appropriate regulatory body established. Verification, validation and accreditation when appropriate initiated.
TRL 6	Technology demonstrated in relevant environment. Clinical development; phase 1 clinical trials evaluation proceeding to phase 2. Medical device/digital system prototype demonstrated in operational enviroment. Clinical testing and safety demonstrated and in line with predictions. Digital system components releases are “beta” versions and configuration controlled. Required accreditation in progress.
TRL 7	System prototype demonstration in operational environment. Phase 2 clinical trial completed. Phase 3 clinical trial plan defined and approved. Medical device/digital system final product design is validated and final prototypes intended for commercial use produced and tested. When appropriate, verification and validation for accreditation completed.
TRL 8	System complete and qualified. Manufacturing processes validated. Phase 3 clinical trial completed and licencing/authorisation given. Pre-market application submitted and approved for medical device. Digital system development completed and demonstrated in real life conditions, support structure in place to resolve technical issues.
TRL 9	Product launched/ready for launch. Post marketing studies and surveillance in place.