Hwb Gwyddorau Bywyd Cymru
Life Sciences Hub Wales

Understanding Sector-Based Technology Readiness Levels

Technology Readiness Levels (TRLs) describe how developed an innovation is. In the health and care sector, they track progress from bench to bedside. However, as different types of innovation follow different development paths, TRLs are not a one-size-fits-all approach. The table below provides a flexible guide to how TRLs can be applied across sectors. It is not exhaustive and should be interpreted in the context of your specific innovation. For a simplified overview, see *Understanding Technology Readiness Levels*.

TRL	Pharmaceuticals	Medical Devices	Digital and Pathways
1. Basic principles	Early-stage research is reviewed to inform the development of new technologies.	Scientific research identifies the basic principles behind innovation.	A health or care problem is identified. No working technology or pathway exists yet.
2. Concept formulated	Problem definition, hypothesis generation, and preliminary research to explore key parameters and identify candidate agents.	Conceptual designs, initial ideas and paper studies are developed. Feasibility is assessed through simulations or virtual platforms.	Defining the problem, proposing solutions, and exploring their potential impact.
3. Proof of concept	*in vitro* and *in vivo* studies designed to test the hypothesis and gather supporting data.	Early prototypes are created and tested in a lab to validate predictions and assumptions.	Initial development and testing of feasibility of basic innovation in a controlled setting.
4. Innovation validated in lab	Pre-clinical animal studies are used to evaluate pharmacokinetics/dynamics, safety, toxicity, and side effects.	Updated version of prototype tested in controlled lab environment, to observe functionality, safety and collect feedback.	Innovation is validated through pilot testing in a lab or simulation. Collect user feedback, usability and impact.
5. Validated in relevant environment	Pilot drug batches on lead compounds are made for safety, toxicity studies in animals and to support Phase 1 clinical trial planning.	The prototype is tested in pre-clinical environment, such as animal models or benchtop systems, for performance, toxicity, characterisation and reproducibility.	Validation of a working version is carried out by key stakeholders in relevant setting. Early integration with clinical systems for constant monitoring and feedback.
6. Demonstrated in relevant environment	Phase 1 clinical trials: to evaluate the pharmacokinetics and safety in a small group of healthy human participants.	A near-final prototype is tested in small cohort of healthy volunteers for performance, toxicity, characterisation and reproducibility.	A small-scale pilot runs in a real setting with users. Impact and usability are evaluated. An early business case is developed.
7. Demonstrated in operational environment	Phase 2 clinical trials are carried out to gather preliminary data such as efficacy, stability, and pharmacodynamics in users with the targeted condition.	The device prototype is tested in larger cohort of human participants. Usability and safety are closely monitored.	Innovation tested at scale in a clinical setting for consistent performance. Outcomes and cost-effectiveness are evaluated. Initiation of training and support plans.
8. System complete and qualified	Phase 3 clinical trials are conducted in large cohort of users, confirming safety and efficacy of the drug candidate compared to standard treatments.	Final device design is validated through regulatory approvals and large cohort of participants to ensure it meets all quality, safety, and performance standards.	Final version approved and evaluated at scale in multiple settings. Regulatory compliance is achieved. A full business case and support model are in place for adoption.
9. Adoption into operational environment	The new compound is approved for distribution and marketing. Phase 4 studies, including ongoing safety surveillance and clinical trials in special populations, continue to support its use.	The device is fully approved, manufactured at scale, and used routinely in clinical practice. Ongoing post-market surveillance and monitoring for improvement.	Innovation is adopted into health or social care pathways for routine use. Ongoing monitoring and improvement continues. It is scalable across regions or populations.