Funding Friday Series - Episode 2

UNDERSTANDING TRL 6 ACROSS LIFE SCIENCES SECTORS

WHAT TECHNOLOGY VALIDATION REALLY MEANS FOR EIC ACCELERATOR SUCCESS

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The Technology Readiness Level (TRL) framework provides the common language evaluators use to assess innovation maturity.

While the 2026 EIC Accelerator Work Programme requires achieved TRL 5, successful applications demonstrate clear pathways from TRL 6 (technology validated in relevant environment) to TRL 8 (technology is system complete and qualified). This distinction determines whether your evidence package convinces expert reviewers or triggers immediate rejection.

Understanding what TRL 6 actually means across different life sciences sectors is the critical gap separating funded companies from rejected applications. The difference isn't philosophical—it's evidential.

SECTOR-SPECIFIC TRL 6 REQUIREMENTS

TRL 5 — technology validated in relevant environment—creates a common threshold across all life sciences sectors. The path to achieving this milestone and demonstrating clear progression toward **TRL 6** — the current **threshold** for the EIC Accelerator (2026) — reveals fundamental differences in validation complexity, timelines, and capital requirements. The universal requirement is evidence that technology functions reliably outside controlled laboratory conditions, in environments approximating real-world deployment. However, sector-specific divergence emerges in execution.

Med Tech companies achieve TRL 5 through prototype testing with clinical samples, cadaver studies, or simulated use conditions — typically requiring 12-18 months and €0.5-€1M in capital.

Biotech Therapeutics face substantially higher bars: efficacy and safety demonstrated in disease-relevant animal models with comprehensive preclinical packages (pharmacokinetics, toxicology, dose-response) sufficient for regulatory discussions — demanding 24-36 months and €1-2M+ investment before clinical trial authorisation.

Digital Health applications must prove clinical utility beyond algorithmic accuracy — requiring prospective validation across diverse patient populations, equipment types, and clinical workflows, not just retrospective dataset performance.

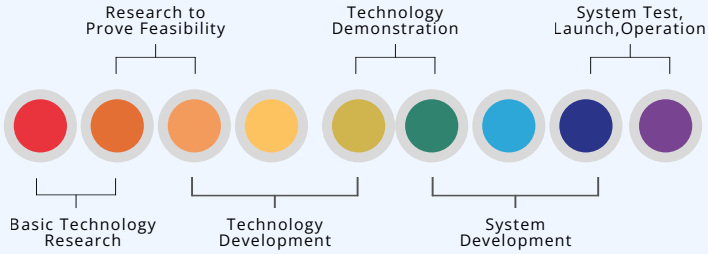
Deep Tech medical solutions navigate dual validation requirements: both the underlying technology platform AND its medical application must function reliably together in relevant biological or clinical environments.

Sustainable Livestock innovations possibly face the most complex validation landscape, with field trials in commercial farm settings or accounting for environmental variables, herd-level effects, species-specific safety, residue studies for food-producing animals, and integration with existing agricultural practices, all while addressing veterinary regulatory requirements fundamentally distinct from human healthcare pathways.

These distinctions have **strategic implication** for companies across Life Sciences as they must align validation planning and funding strategy with their specific requirements. For sectors that typically require 3-4 years fo reaching TRL 6, intermediate funding instruments (e.g. Eureka Eurostars or national grants) can unlock access to the more competitive EIC Accelerator programme.

Technology Readiness Levels (TRLs)

TRL 1 to 9 measure technology maturity from basic principles (TRL 1) to proven operational deployment (TRL 9).



https://zenith.finos.org/docs/roadmap/roadmap-trl/

Sector-Specific Innovations

Med Tech *- Medtech innovations are new technologies, services, or business models that fundamentally change the medical technology landscape by making healthcare more accessible, affordable, and efficient;* ***Biotech Therapeutics*** *- Biotech therapeutics are new solutions that dramatically improve patient outcomes, lower healthcare costs, enhance patient's quality of life, and potentially cure or prevent diseases;* ***Digital Health*** *- Digital health innovations are characterised by new technologies, business models, or solutions that may initially seem simple but end up replacing traditional systems by offering more accessible, efficient, and personalised solutions;* ***Deep Tech*** *- Deep tech medical innovations include the use of data and analytics to drive decision-making, the use of artificial intelligence and machine learning to improve patient care, and the use of digital technologies to improve the delivery of care;* ***Sustainable Livestock*** *- Innovations in sustainable livestock farming raise the balance between environmental protection, animal welfare, and economic viability. It minimises the negative impacts of livestock farming by using resources wisely, reducing pollution, and improving animal health, while also ensuring the long-term profitability for farmers and supporting social equity.*

BUILDING THE EVIDENCE PACKAGE

Understanding these sector-specific TRL 6 requirements enables strategic validation planning. **First**, identify the minimum **evidence package** evaluators expect for the technology category — medical devices need clinical samples or cadaver studies, therapeutics require animal models with human disease relevance, diagnostics demand multi-site clinical validation, and Sustainable Livestock innovations require field trials. **Second**, document everything with **regulatory-grade rigour**: detailed protocols, statistical analysis plans, data quality assurance procedures, and independent oversight where possible. Third, show that the technology performs consistently across relevant variables (patient populations, disease stages, equipment types, environmental conditions). The companies succeeding in EIC Accelerator applications treat validation evidence as regulatory submission preparation. They invest in **Good Laboratory Practice (GLP**) studies, engage **Contract Research Organisations (CROs)** for independent verification, obtain **Ethics Committee** approvals for clinical work, and secure **regulatory authority feedback** through pre-submission meetings or scientific advice procedures. The strategic implication for companies is thus to first confirm that their innovation is genuinely disruptive rather than incrementally superior, then align validation planning, funding strategy, and grant application timing with their sector's specific evidence requirements. This approach simultaneously strengthens applications while advancing regulatorypathway progression, creating compound value from validation investments.

Sector-Specific Success Stories

Med Tech *- Intelligent Implants (Sweden-Ireland) - EIC Award (2021). intelligentimplants.com*
TRL 6 Validation Evidence for SmartFuse:
- *Large-animal ovine lumbar fusion studies showing accelerated bone formation*
- *Wireless power transfer + control systems operating reliably in vivo*
- *Impedance-based real-time bone growth monitoring validated*
- *Integrated successfully into standard and minimally invasive surgical workflows*
- *FDA Breakthrough Device Designation confirming strong regulatory validation*

Biotech Therapeutics *- Celtic Biotech (Ireland) - EIC Award (2023). celticbiotech.com*
TRL 6 Validation Evidence for lead drug CB-24:
- *Preclinical efficacy: 83% tumour inhibition (Lewis lung), 69% (MX-1)*
- *Mechanism of action fully characterised (crotoxin heterodimer)*
- *Phase I clinical trial in France completed with exceptional safety profile*
- *Tumour responses observed in 14 treated patients*
- *Demonstrated selective targeting of cancer cells over healthy tissue*

Digital Health *- Powerful Medical (Slovakia) - EIC Award (2024). powerfulmedical.com*
TRL 6 Validation Evidence PMcardio:
- *15+ independent prospective clinical validation studies (EU + US)*
- *Real-world validation: 24,513 consecutive chest-pain patients across 5 Swedish EDs*
- *Clinical-scale deployment: 100,000+ clinicians, 400,000+ patients screened*
- *CE Class IIb certification; FDA Breakthrough + TPLC programme*
- *Robust multi-site, multi-equipment performance; published in EHJ–Digital Health*

Deep Tech *- QDI Systems (Netherlands) - EIC Award (October 2024). qdisystems.com*
TRL 6 Validation Evidence for Quantum dots-based imaging:
- *First quantum-dot CMOS X-ray imaging chip demonstrated (with CSEM)*
- *Validation by Tier-1 industrial partner Teledyne DALSA*
- *Commercial R&D sales to Teledyne DALSA and Varex Imaging*
- *10× sensitivity vs amorphous selenium; 2× SNR above industrial requirements*
- *Operational production lab (July 2023) with reproducible QD manufacturing*
- *90% product readiness towards commercialisation*

Sustainable Livestock *- CattleEye (UK - Northern Ireland) - EIC Award (March 2022). cattleeye.com*
TRL 6 Validation Evidence for AI-powered livestock monitoring:
- *Peer-reviewed validation: 6,040 mobility scores (Frontiers in Vet Sci, 2023)*
- *RCT: 4× reduction in severe lameness; zero score-3 cows vs 6.7% in control*
- *Scaled deployment: 200,000+ cows monitored across UK, Wales, Arizona*
- *Performance comparable/superior to vets (sensitivity 0.52 vs 0.29)*
- *Demonstrated economic impact (£175–350/cow) and retailer validation (Tesco, Sainsbury's)*
- *Early detection up to 23 days before clinical signs*
- *Acquisition by GEA confirming market-ready maturity*

REFERENCE: EIC official announcements & press releases (2021-2025); Company websites; Public disclosures; European Commission CORDIS database

CONCLUSION: TRL 6 EVIDENCE THRESHOLD

The **TRL threshold** is the **primary point** of **failure** for most EU grant applications. Success hinges on the **quality of evidence** provided, demanding that innovators understand sector-specific requirements and build comprehensive, **regulatory-grade evidence packages**. For European healthcare companies, achieving TRL 6 is crucial, but it serves a greater purpose: demonstrating that a technology works reliably in the **real-world environments** where it will deliver clinical **impact** and **commercial value**. However, ultimately, European innovation programmes seek **breakthrough technologies** that create new markets or fundamentally transform existing ones. Incremental improvements, **irrespective** of their **technical merit** or **TRL achievement**, will not secure competitive funding.

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