

DELAWARE RURAL HEALTH INNOVATION



HEALTHCARE TECHNOLOGY READINESS LEVEL FRAMEWORK

A pathway-aware framework for applicant self-assessment and reviewer verification

Proposed reference framework for the Rural Tech Catalyst Fund

Issued by Delaware Prosperity Partnership (DPP)

in partnership with Delaware Health and Social Services (DHSS)

CORE ELIGIBILITY THRESHOLD

H-TRL 4 or higher

The company has built an integrated version of the core technology and has objective evidence from controlled testing that it performs its essential intended technical function.

Framework purpose

This framework provides a consistent way to interpret healthcare Technology Readiness Levels (TRLs) across materially different development pathways. It is designed to assess the maturity of the technology itself—not company maturity, market traction, team quality, or rural-health fit.

The framework uses one universal 1–9 readiness backbone with pathway-specific interpretations for Digital Health / Software / AI, Medical Devices, Diagnostics, and Therapeutics / Biologics / Treatment Innovations.

1. Framework Design & Use

1.1 Design Principles

- One common H-TRL scale preserves a consistent meaning of technical maturity across the portfolio.
- Pathway-specific examples recognize that software, devices, diagnostics, and therapeutics mature through different technical evidence.
- Regulatory readiness and technology readiness are related but distinct. FDA milestones may support a rating but do not automatically define it.
- H-TRL evaluates the technology—not the overall startup. Team, market, financing, commercialization, and rural-health relevance should be assessed separately.
- Applicants self-classify; reviewers verify the highest level supported by demonstrated evidence.

1.2 First Identify the Technology Being Rated

What specific technology are you assessing?

Rate the maturity of the innovation proposed to the Rural Tech Catalyst Fund—not the maturity of the company, the underlying industry, or mature third-party technologies incorporated into the solution.

COMPANY SCENARIO	TECHNOLOGY TO RATE
New long-acting insulin formulation	The formulation / therapeutic technology
Novel wearable device for automated insulin delivery	The insulin-delivery device
Remote glucose-monitoring and clinical decision-support software used with established diabetes treatments	The software / monitoring technology
Diabetes clinic using commercially available glucose monitors, insulin products, and established treatment protocols	A distinct novel technology may not exist; service-model maturity should not be represented as a technology TRL.

1.3 Applicant and Reviewer Roles

APPLICANT	DPP / REVIEWER
Select the pathway that best fits the primary technology.	Confirm that the correct technology and pathway are being assessed.
Select the highest H-TRL the company believes it has achieved.	Verify the highest level for which all essential criteria are supported.
Describe and provide evidence supporting the claimed level.	Evaluate whether evidence demonstrates actual performance—not planned work.
Explain any combination-product or cross-pathway considerations.	Use professional judgment and document the rationale for borderline cases.

2. Universal Healthcare Technology Readiness Scale

The universal backbone defines what each readiness level means regardless of technology pathway. Pathway tables in Sections 3–6 translate these milestones into technology-specific examples.

LEVEL	UNIVERSAL MILESTONE	DEFINITION	PLAIN-ENGLISH INTERPRETATION
H-TRL 1	Scientific basis identified	Basic scientific, technical, or computational principles relevant to the proposed technology have been observed.	We see a potentially useful phenomenon or capability.
H-TRL 2	Technology concept formulated	A specific healthcare application and technical approach have been defined, but there is little or no experimental demonstration.	We know what we want to build and why it should work.
H-TRL 3	Proof of concept demonstrated	Critical technical functions or hypotheses have been demonstrated independently through experiments, models, simulations, or early code.	We have evidence the idea can work.
H-TRL 4	Integrated prototype demonstrated	Core technology components have been integrated into a functioning prototype and tested under controlled conditions, generating evidence that the intended technical function works.	We built it, and we have evidence that it works at prototype level.
H-TRL 5	Validated in a relevant environment	The prototype has been tested under conditions meaningfully representative of intended healthcare use.	It works under conditions that begin to resemble the real world.
H-TRL 6	System demonstrated in a relevant healthcare environment	A substantially integrated system has been demonstrated with representative users, specimens, workflows, data, or patients, as appropriate.	The technology works in a healthcare-relevant setting.
H-TRL 7	Operational / clinical prototype demonstrated	A near-final system has been used and evaluated in its intended or closely representative operational or clinical environment.	The near-final product works where it is ultimately intended to be used.
H-TRL 8	System complete and qualified	Development is substantially complete; verification, validation, and other evidence needed for intended use have been completed or substantially completed.	The product is ready for routine deployment, subject to any remaining approvals.
H-TRL 9	Proven in routine use	The completed technology has demonstrated successful, sustained performance in real-world healthcare use.	It is deployed and proven.

ELIGIBILITY BOUNDARY

The H-TRL 3 → 4 distinction

H-TRL 3 demonstrates that the underlying idea can work. H-TRL 4 demonstrates that an integrated version of the technology has been built and that objective controlled testing shows its essential intended technical function works.

3. Digital Health / Software / AI

Use this pathway for clinical software, artificial intelligence and machine learning tools, telehealth technologies, remote monitoring platforms, workflow technologies, patient applications, and other software-enabled health products. Regulatory status does not determine the H-TRL.

H-TRL	DIGITAL / SOFTWARE / AI INTERPRETATION
1	Algorithmic, behavioral, clinical, or computational principle identified.
2	Intended user, use case, inputs/outputs, and software concept defined.
3	Individual algorithm or function demonstrated using preliminary, historical, synthetic, or test data; proof-of-concept code may exist.
4	Functional MVP/prototype integrates the critical features and successfully performs its core intended function using controlled or test data.
5	Prototype evaluated using representative real-world data, simulated workflows, representative users, or realistic use conditions.
6	Integrated product demonstrated prospectively or within a representative healthcare workflow or environment.
7	Near-final product deployed in a pilot healthcare environment with intended users and evaluated under actual workflows.
8	Production-ready system technically validated, including required reliability, security, interoperability, usability and, where relevant, clinical validation.
9	Product routinely deployed and demonstrating sustained performance in intended healthcare settings.

Minimum evidence expected for H-TRL 4

- Functioning software rather than wireframes alone.
- Core functionality demonstrated end-to-end.
- Documented test results.
- Algorithm/model performance on an appropriate dataset where AI is central to the technology.
- Demonstration of the integrated MVP or equivalent prototype.

GENERALLY BELOW H-TRL 4

What is usually not enough

A clickable mock-up, product wireframe, prompt, algorithm description, isolated model experiment, or planned integration without evidence of an integrated functional prototype would generally remain H-TRL 2–3.

4. Medical Devices

Use this pathway for physical medical devices and device systems, including products that may ultimately follow 510(k), De Novo, Premarket Approval (PMA), or other regulatory pathways. Regulatory pathway and H-TRL should be assessed separately.

H-TRL	MEDICAL-DEVICE INTERPRETATION
1	Scientific or engineering principle underlying the device identified.
2	Device concept, intended function, and preliminary architecture defined.
3	Critical components or functions demonstrated independently through breadboards, models, simulations, or comparable methods.
4	Critical components integrated into a functional benchtop prototype and key technical performance characteristics demonstrated under controlled conditions.
5	Prototype tested using relevant anatomical models, simulated-use environments, representative materials or specimens, or comparable conditions.
6	Integrated prototype demonstrated in a representative clinical or use environment; may include appropriate preclinical or early clinical testing.
7	Near-final design demonstrated with intended users and/or patients in an operational or clinical environment, as appropriate.
8	Design substantially finalized; required verification and validation complete or substantially complete and technology qualified for intended use.
9	Commercial or final device demonstrates sustained successful use in actual healthcare practice.

Minimum evidence expected for H-TRL 4

- Integrated prototype photographs, video, or demonstration.
- Engineering or benchtop test data.
- Measured performance against defined technical specifications.
- Repeatability or comparable evidence appropriate to the device.

REGULATORY DISTINCTION

FDA pathway ≠ H-TRL

A 510(k), De Novo, PMA, or other regulatory milestone may provide supporting evidence, but it should not automatically be mapped to a particular H-TRL. Technical maturity is determined by what has been built, tested, and demonstrated.

5. Diagnostics

Use this pathway for in vitro diagnostics, assays, biomarker-based tests, diagnostic platforms, and related technologies. Although many diagnostics are legally medical devices, a separate interpretation makes analytical and specimen-based evidence easier for applicants and reviewers to assess.

H-TRL	DIAGNOSTIC INTERPRETATION
1	Biomarker, analyte, or detection principle identified.
2	Diagnostic concept and proposed assay or detection approach established.
3	Detection principle demonstrated; individual assay components or biomarker relationship shows proof of concept.
4	Prototype assay or system integrates critical components and demonstrates reproducible detection or measurement under controlled conditions.
5	Analytical performance demonstrated with increasingly representative specimens, matrices, concentrations, interfering substances, or comparable conditions.
6	Integrated diagnostic demonstrated using clinically representative specimens and workflow.
7	Near-final diagnostic evaluated prospectively or in its intended clinical or use environment.
8	Analytical and required clinical validation substantially complete; final system qualified for intended use.
9	Diagnostic routinely used and demonstrating sustained real-world performance.

Minimum evidence expected for H-TRL 4

- Integrated prototype assay or detection system.
- Reproducible controlled testing.
- Preliminary performance metrics appropriate to the technology, which may include accuracy, precision, sensitivity, specificity, limit of detection, or comparable measures.
- Evidence beyond identification of a promising biomarker or detection principle alone.

6. Therapeutics / Biologics / Treatment Innovations

Use this pathway for new therapeutic candidates, biologics, formulations, delivery technologies, combination approaches, and other treatment innovations. The technology being rated must be identified explicitly when the company's innovation builds on an established or already-approved therapeutic.

H-TRL	THERAPEUTIC / TREATMENT-INNOVATION INTERPRETATION
1	Biological mechanism or therapeutic principle identified.
2	Therapeutic concept, candidate approach, or treatment technology formulated.
3	Proof of concept demonstrated through appropriate in vitro, ex vivo, computational, formulation, or initial biological evidence.
4	Integrated therapeutic candidate, formulation, or delivery technology demonstrates reproducible intended activity or technical function in a controlled experimental setting.
5	Candidate or technology validated in increasingly representative preclinical models or use conditions.
6	Sufficiently mature candidate or system demonstrated through relevant preclinical and/or appropriate early human investigation.
7	Near-final therapeutic approach demonstrated through meaningful clinical evaluation in the intended population or use context.
8	Development and required validation substantially complete for intended use; applicable regulatory requirements substantially satisfied.
9	Therapeutic or technology routinely used with demonstrated real-world performance.

Special consideration: established therapeutics

A company should not claim a high H-TRL merely because an underlying drug or therapeutic is already mature. Reviewers should identify and rate the actual innovation—for example, a new formulation, delivery device, monitoring technology, combination approach, or other technical element. A conventional service model using established therapies may not have a distinct technology to which a TRL can meaningfully be assigned.

REGULATORY DISTINCTION

Clinical phase or IND status ≠ automatic H-TRL

Investigational New Drug (IND) status, clinical phase, or other regulatory milestones may support the evidence record, but the H-TRL should reflect demonstrated technical maturity of the specific innovation.

7. Applicant Self-Assessment & Evidence

Recommended application questions

#	APPLICANT PROMPT
1	Which pathway most closely describes your primary technology? Digital Health / Software / AI; Medical Device; Diagnostic; Therapeutic / Biologic / Treatment Technology; Combination / Other.
2	What specific technology are you rating? Briefly describe the product or technical innovation whose readiness is being assessed.
3	What is the highest H-TRL your technology has achieved? Select one level from 1–9.
4	Describe the evidence demonstrating that the technology has achieved this level. Focus on work completed and results obtained, not planned activities.
5	Provide or identify supporting evidence, if available—for example, test reports, validation data, prototype demonstrations, technical documentation, study results, or applicable regulatory documentation.

Recommended reviewer verification rubric

REVIEWER QUESTION	ASSESSMENT
Is the specific technology being assessed clearly identified?	Yes / No
Does the evidence demonstrate all essential characteristics of the claimed H-TRL?	Yes / No
Are the critical technology components integrated to the degree required at this level?	Yes / No
Was the technology actually tested, rather than merely designed or planned?	Yes / No
Is the testing environment appropriate for the claimed level?	Yes / No
Are results documented and reasonably reproducible?	Yes / No
Does any cited regulatory milestone support technical maturity rather than merely regulatory planning?	Yes / No / N/A

REVIEWER RULE

Assign the highest demonstrated level

Final H-TRL = the highest level for which all essential criteria are supported by evidence. A company's planned next milestone, anticipated regulatory submission, or expected future validation should not increase its current rating.

8. H-TRL 4 Eligibility Decision

DPP SCREENING TEST

The H-TRL 4 Test

A startup is H-TRL 4+ when reviewers can reasonably state: “The company has built an integrated version of the core technology and has objective evidence from controlled testing that it performs its essential intended technical function.”

Evidence that generally supports H-TRL 4

- An integrated functional prototype, MVP, assay, device, formulation, or other pathway-appropriate technical embodiment.
- Controlled testing of the integrated technology.
- Objective results showing that the essential intended technical function works.
- Documentation sufficient for a reviewer to understand what was tested, under what conditions, and with what result.

Evidence that generally does not establish H-TRL 4 by itself

- Ideas, research findings, or product concepts without an integrated prototype.
- Slideware, mock-ups, wireframes, CAD drawings, or product designs without functional demonstration.
- Isolated components that have not been integrated sufficiently to demonstrate the core technology.
- Preliminary algorithms or models without an integrated product-level demonstration.
- Regulatory plans, future studies, planned prototypes, or milestones that have not yet been completed.
- Use of mature third-party technologies where the company has not identified and demonstrated a distinct technical innovation.

Borderline cases

Reviewers may record a working notation such as “H-TRL 3/4 — insufficient evidence to verify H-TRL 4” when an applicant appears close to the threshold. For eligibility purposes, however, the verified rating should remain H-TRL 3 until sufficient evidence is provided to demonstrate H-TRL 4.

9. What H-TRL Does—and Does Not—Measure

H-TRL MEASURES	ASSESS SEPARATELY
Technical maturity of the specific healthcare technology	Rural-health relevance and challenge alignment
Degree of integration and demonstrated technical function	Market demand and customer validation
Appropriateness of testing environment for the claimed maturity level	Team capability and organizational readiness
Evidence that technical milestones have actually been achieved	Commercialization strategy and business model
Progression from concept through real-world technical use	Funding readiness, economic-development potential, and program fit

IMPORTANT PROGRAM-DESIGN PRINCIPLE

Do not use H-TRL to judge rural-health fit

A highly mature technology may be poorly suited to rural deployment, while an H-TRL 4 technology may strongly address a priority rural-health challenge. Apply the H-TRL ≥4 eligibility screen first, then assess rural-health applicability and implementation potential as separate dimensions.

10. Reference Basis

This proposed framework adapts the logic of established Technology Readiness Level systems to healthcare development pathways. It is intended as a DPP screening and communication tool rather than a substitute for regulatory, clinical, engineering, quality, or scientific review.

- NASA Technology Readiness Levels: progression from basic principles through proof of concept, validation in relevant environments, system demonstration, qualification, and successful operation.
- U.S. Food and Drug Administration (FDA) digital health and Software as a Medical Device guidance and resources.
- FDA medical-device regulatory pathways, including 510(k), De Novo, and Premarket Approval.
- FDA in vitro diagnostic regulatory resources.
- FDA drug development and Investigational New Drug resources.

Working framework note

Before publication or incorporation into program materials, DPP/DHSS should confirm that the framework and H-TRL 4 interpretation are consistent with the applicable Centers for Medicare & Medicaid Services (CMS) Rural Health Transformation requirements and any controlling award terms or guidance.

Selected primary-source references

NASA Technology Readiness Levels; FDA resources for Software as a Medical Device, medical-device regulation, in vitro diagnostics, drug development, and Investigational New Drug development.