TECHNOLOGY ADVANCEMENT
Program

Technology Readiness Levels

Understanding Technology Readiness Levels (TRL)

Technology Readiness Levels (TRLs) are a standardized framework used to assess how far a technology has advanced, helping to inform next steps as it moves from early-stage research toward real-world application. The scale is based on NIH standards and it ranges from TRL 1 (basic scientific research) to TRL 9 (clinically or commercially available solutions).

To be eligible for the SickKids Technology Advancement Program (TAP), projects must demonstrate clear potential for real-world impact, along with early evidence supporting further development.

Eligible projects should have fulfilled the requirements for the following TRL:

- Therapeutics/Vaccines: TRL 3
- In-Vitro Diagnostics: TRL 3
- Clinical Software: TRL 3
- Medical Devices: TRL 3

If you are uncertain about your project's TRL or it falls outside the suggested range but has strong justification, please contact the Industry Partnerships & Commercialization (IP&C) office before applying.

1 Basic Research
- Fundamentals are observed and reported

2 Technology Conceptualization
- Technology concept and application formulated

3 Proof of Principle
- Experimental/analytical proof of principle

4 Development & Feasibility Testing
- Technology characterized and validated in lab

5 Validation & Optimization
- Technology validated in relevant environment

6 Prototype Demonstration
- Technology demonstrated in relevant environment

7 Product & System Development
- Technology demonstrated in operational environment

8 System Integration & Approval
- Technology fully validated & qualified

9 Clinical/Commercial Use
- Technology deployed in real environment

Resources

TRL Descriptions for Therapeutics/Vaccines

TRL Descriptions for Diagnostics

TRL Descriptions for Medical Devices

TRL Descriptions for Clinical Software

Acronym Glossary

TRLs adapted from: https://www.medicalcountermeasures.gov/trl/integrated-trls, https://www.medicalcountermeasures.gov/trl/trls-for-medical-devices, https://ncai.nhlbi.nih.gov/ncai/resources/techreadylevels, https://ised-isde.canada.ca/site/innovation-canada/en/technology-readiness-levels, *https://www.research.va.gov/programs/tech_transfer/Biomedical-TRL-Guideline-Sheets.pdf*

SickKids | Industry Partnerships & Commercialization

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TRL Descriptions for Therapeutics/Vaccines

Required TRL Completed for SK TAP Competition = 3 with some aspects of 4

TRL	Stage Description	Activities Completed
1	**Basic Research** Continuously review and knowledge base to inform technology development and ensure innovations are grounded in current knowledge.	☐ Initial observations of potential targets/compounds
2	**Technology Conceptualization** Generate research ideas and practical hypotheses through literature analysis and virtual modeling; design experiments based on observed principles and potential applications.	☐ Screened potential targets/compounds ☐ Performed initial IP search ☐ Characterized disease epidemiology ☐ Assessed clinical care patterns and unmet needs
3	**Proof of Principle** Collect data and begin testing hypotheses; explore alternative approaches, identify and evaluate key technologies, and characterize early-stage candidates.	☐ Identified target/candidate ☐ Synthesized novel compound series ☐ Demonstrated in vitro activity of candidate ☐ Generated preliminary in vivo efficacy data (non-GLP) ☐ Filed intellectual property protections
4	**Development & Feasibility Testing** Integrate assay components and validate for the intended use case. Outline early regulatory and reimbursement strategies.	☐ Developed animal models, assays, and reagents for target indication ☐ Produced lab-scale (non-GMP) bulk and formulated product ☐ Demonstrated non-GLP in vivo activity aligned with intended use ☐ Conducted initial non-GLP toxicity, PD/PK, and immune response studies ☐ Initiated identification of assays, markers, endpoints for further evaluation
5	**Validation & Optimization** Advance preclinical studies while refining animal models, assays, and target profiles; begin developing a scalable, GMP-ready manufacturing process.	☐ Refined animal models for efficacy and dosing ☐ Initiated analytical assays for product release ☐ Began small-scale GMP-ready manufacturing ☐ Drafted Target Product Profile, including storage and packaging ☐ Demonstrated ADME/immune responses in non-GLP studies ☐ Identified efficacy markers and minimum effective dose
6	**Prototype Demonstration** Produce GMP-compliant pilot batches, prepare regulatory submissions (e.g., IND), and conduct Phase 1 clinical trials to assess safety and pharmacokinetics.	☐ Continued animal model development ☐ Qualified QC and immunogenicity assays ☐ Manufactured and tested GMP product for IND submission ☐ Completed GLP non-clinical studies ☐ Submitted IND package to FDA ☐ Completed Phase 1 trial assessing safety, PK, and immunogenicity
7	**Product & System Development** Scale and validate GMP manufacturing; conduct animal efficacy studies and Phase 2 clinical trials to further evaluate product safety and performance.	☐ Refined animal models for GLP efficacy studies ☐ Validated QC and immunogenicity assays ☐ Scaled and validated GMP manufacturing ☐ Completed GLP animal efficacy studies ☐ Conducted expanded Phase 2 clinical safety trials
8	**System Integration & Approval** Finalize GMP processes, complete pivotal studies, and submit applications for regulatory approval or licensure.	☐ Completed validation and consistency lot manufacturing at FDA-scale ☐ Finalized stability studies to support expiry dating ☐ Finalized Target Product Profile for FDA submission ☐ Completed GLP processes, Phase 3 trials and/or expanded safety studies ☐ Submitted NDA or BLA to FDA ☐ Obtained FDA approval or licensure
9	**Clinical/Commercial Use** Widespread deployment, carry out post-marketing commitments and maintenance.	☐ Conducted special population trials ☐ Maintained manufacturing capability ☐ Continued safety surveillance

TRL Descriptions for In-Vitro Diagnostics

Required TRL Completed for SK TAP Competition = 3 with some aspects of 4

TRL	Stage Description	Activities Completed
1	**Basic Research** Early-stage research to understand disease mechanisms and identify potential diagnostic markers.	☐ Identified relevant biomarkers and disease pathways ☐ Characterized links between animal and human disease
2	**Technology Conceptualization** Develop conceptual foundation for diagnostic technology. Hypotheses, study designs, and potential diagnostic strategies are proposed.	☐ Developed research hypotheses and experimental plans ☐ Conducted initial IP search for patentability ☐ Characterized disease epidemiology and market landscape ☐ Assessed clinical care patterns and unmet needs
3	**Proof of Principle** Develop a functional prototype and test with simplified or artificial matrices. Assess technical feasibility and preliminary performance.	☐ Developed prototype assay components and reagents ☐ Demonstrated sensitivity and specificity in spiked matrices ☐ Identified critical components and gathered early user feedback ☐ Filed IP protections
4	**Development & Feasibility Testing** Integrate critical technologies and begin demonstrating safety and efficacy through non-GLP animal studies; initiate model development and identify markers and endpoints for future studies.	☐ Validated assay using relevant sample types and volumes ☐ Established draft Target Product Profile (TPP) ☐ Selected reference and QC reagents ☐ Outlined preliminary regulatory and reimbursement strategies
5	**Validation & Optimization** Finalize product design and develop scalable manufacturing processes. Identify key supply chain partners and confirm performance in near-real conditions.	☐ Finalized product design and quality control criteria. ☐ Demonstrated performance consistent with intended use. ☐ Identified manufacturing and supply chain partners. ☐ Held preliminary meeting with FDA
6	**Prototype Demonstration** Pilot manufacturing was conducted under quality-compliant protocols. Regulatory submissions were prepared and filed.	☐ Manufactured product under quality-compliant conditions ☐ Submitted regulatory package based on classification (e.g., CLIA, IVD) ☐ Initiated clinical or pivotal studies
7	**Product & System Development** Analytical verification and continuation of clinical/pivotal studies	☐ Evaluated assay and integrated diagnostic system performance ☐ Continued clinical evaluations ☐ Began preparation for full-scale production of instruments and assays
8	**System Integration & Approval** Finalize GMP processes, complete pivotal studies, and submit applications for regulatory approval or licensure.	☐ Completed validation and consistency lot manufacturing at FDA-scale ☐ Finalized stability studies to support expiry dating ☐ Finalized TPP for FDA submission ☐ Finalized and submitted regulatory filing (e.g., 510(k), PMA, BLA) ☐ Received FDA approval or licensure
9	**Clinical/Commercial Use** Widespread deployment, carry out post-marketing commitments and maintenance.	☐ Deployed product in clinical or commercial settings ☐ Implemented post-market surveillance and quality systems ☐ Secured reimbursement and market access

TRL Descriptions for Medical Devices

Required TRL Completed for SickKids TAP Competition = 3 with some aspects of 4

TRL	Stage Description	Activities Completed
1	**Basic Research** Assess foundational science to understand clinical problems and identify relevant biological, engineering, or technological principles.	☐ Identified unmet clinical or patient care needs ☐ Explored basic biological or technical mechanisms
2	**Technology Conceptualization** Generate research hypotheses, early device ideas, virtual models/simulations. Define potential configurations based on feasibility and need.	☐ Developed hypotheses and early design ideas ☐ Conducted initial IP search for patentability. ☐ Characterized disease epidemiology and market landscape ☐ Explored design variants via simulation or modeling
3	**Proof of Principle** Build and test preliminary prototypes to demonstrate basic functionality and potential effectiveness. Collect initial user feedback and conduct early benchtop or animal testing to assess safety and efficacy.	☐ Created and tested early prototypes ☐ Demonstrated preliminary efficacy ☐ Gathered user feedback on design and usability ☐ Filed provisional patent ☐ Identified likely regulatory and reimbursement pathways
4	**Development & Feasibility Testing** Refine prototypes through iterative design informed by user input and preclinical results. Establish design inputs, initiate Design Control documentation, and define intended use and regulatory strategies.	☐ Collected and applied user feedback ☐ Conducted non-GLP in vivo studies ☐ Initiated animal model development (if needed) ☐ Defined design inputs and Design & Development Plan ☐ Held preliminary FDA meeting
5	**Validation & Optimization** Finalize device design (design freeze) and develop scalable manufacturing processes with quality controls. Validate component performance and draft a target product profile and regulatory strategy.	☐ Finalized design configuration ☐ Developed test methods and performance criteria ☐ Explored and assessed manufacturing options ☐ Identified supply chain partners ☐ Drafted target product label and reimbursement plan
6	**Prototype Demonstration** Conduct design testing under quality protocols. Manufacture GMP-compliant units, finalize packaging and sterilization, and submit regulatory documentation.	☐ Completed Design Verification and Validation (V&V) testing ☐ Manufactured devices under GMP conditions ☐ Finalized packaging and sterilization validation ☐ Submitted regulatory package (e.g., 510(k), IDE)
7	**Product & System Development** Support clinical trials and scale manufacturing while meeting regulatory and quality system requirements. Validate large-scale production processes and prepare for market readiness.	☐ Completed clinical trials (e.g., EFS or IDE, if applicable) ☐ Scaled and validated GMP manufacturing processes ☐ Implemented quality systems and CAPA (Corrective and Preventive Actions)
8	**System Integration & Approval** Obtain FDA approval or clearance and finalize all premarket documentation. Prepare for launch with complete labeling, marketing, and post-market surveillance plans.	☐ Received FDA approval/clearance (510(k), PMA, HDE) ☐ Finalized product labeling and packaging ☐ Prepared post-market monitoring plan
9	**Clinical/Commercial Use** Widespread deployment, carry out post-marketing commitments and maintenance. Use post-market data to inform improvements and support adoption.	☐ Deployed product in clinical or commercial settings. ☐ Implemented post-market surveillance and reporting ☐ Collected real-world data on safety and effectiveness

TRL Descriptions for Clinical Software

Required TRL Completed for SickKids TAP Competition = 3 with some aspects of 4

TRL	Stage Description	Activities Completed
1	**Basic Research** Early-stage exploration to understand the clinical problem, data modalities, and computational methods. Generate research hypotheses. Foundational work establishes feasibility and informs potential algorithmic approaches.	☐ Identified unmet clinical need or workflow challenge ☐ Developed hypotheses around proposed clinical indication and/or intended use ☐ Explored literature on disease mechanisms, algorithmic approaches, or decision-making gaps ☐ Assessed foundational data availability and quality ☐ Determine if third-party software elements may be required
2	**Technology Conceptualization** Establish intended clinical use, data requirements, and initial algorithmic strategy. Early modeling and design concepts support feasibility assessment.	☐ Conducted initial IP search and market landscape review ☐ Fully characterized user groups and disease epidemiology (if relevant) ☐ Developed initial algorithm or model and review third-party licenses to ensure commercial path forward ☐ Collected initial datasets for exploratory analyses ☐ Assessed clinical care patterns and unmet needs
3	**Proof of Principle** Refine preliminary algorithms or prototype modules and demonstrate technical feasibility using retrospective, synthetic, or limited real-world datasets. Early performance characteristics are established.	☐ Developed prototype algorithm or model ☐ Demonstrated feasibility using retrospective, simulated, or real-world data ☐ Established baseline performance metrics ☐ Filed initial IP protections (if relevant) ☐ Review likely regulatory classification and reimbursement pathways (if applicable)
4	**Development & Feasibility Testing** Refine and integrate core software components and conduct retrospective validation against clinically relevant datasets. Outline regulatory classification, data governance needs, and potential clinical evaluation strategies.	☐ Expanded model training and internal validation ☐ Conducted retrospective validation against gold standards ☐ **Required Milestone:** Identified category of clinical-grade digital health innovations (SaMD, CDS, DTx, AI-driven diagnostics, and predictive analytics) ☐ Identified clinical partners for data access and testing
5	**Validation & Optimization** Finalize software design for a validation-ready build. Validate software performance using external or prospective datasets and optimize model behavior for clinical relevance. Further define intended use, risk management considerations, and begin regulatory planning process for entering SaMD or CDS pathways.	☐ Finalize algorithm design and performance criteria ☐ Conducted prospective or external validation studies ☐ Early meetings with regulatory bodies (if applicable) ☐ Developed scalable data pipelines and QC processes ☐ Drafted reimbursement plan (if applicable)
6	**Prototype Demonstration** Produce a clinically deployable prototype and initiate early clinical usability or pilot testing under appropriate approvals (e.g., IRB/REB). Prepare documentation supporting regulatory submissions and quality-controlled development practices.	☐ Prepared and submitted regulatory package (if applicable) ☐ Initiated clinical usability or pilot studies ☐ Produced quality-controlled software builds ☐ Implemented cybersecurity and safety controls
7	**Product & System Development** Conduct larger scale validation and verification in relevant clinical settings and mature software engineering, cybersecurity, and monitoring systems. Finalize regulatory submission materials and prepare for quality compliant deployment.	☐ Conducted pivotal clinical validation ☐ Scaled engineering infrastructure and monitoring systems ☐ Finalized regulatory submission documentation (if applicable) ☐ Established post-market data collection plans

8	**System Integration & Approval** Achieve regulatory clearance or approval and complete system-level testing in clinical environments. Finalize regulatory labeling (instructions for use, user manuals, on-screen instructions, indications, contraindications, warnings) risk management, integration requirements, and post-market monitoring plans for clinical implementation.	☐ Received regulatory approval (e.g., FDA, HC) ☐ Finalized risk management and labeling ☐ Completed system-level verification and validation ☐ Prepared for deployment in clinical settings
9	**Clinical/Commercial Use** Deploy the software in live clinical or commercial settings and conduct ongoing post-market surveillance. Monitor real-world performance and update algorithms or models as needed to ensure continued safety and effectiveness.	☐ Successfully deployed software in clinical or commercial settings ☐ Implemented post-market surveillance ☐ Monitored real-world performance and safety ☐ Updated models/algorithms as needed for sustained accuracy and performance

Acronym Glossary

Acronym	Full Term	Definition
CAPA	Corrective and Preventive Action	A quality system process for identifying, addressing, and preventing the recurrence of issues in product development or manufacturing.
CDS	Clinical Decision Support Tool	A software tool that provides clinicians with patient-specific information and clinical knowledge, intelligently filtered and delivered at the right time to guide decision-making and improve patient care.
CLIA	Clinical Laboratory Improvement Amendments	U.S. federal standards regulating laboratory testing performed on human specimens for diagnosis, prevention, or treatment.
cGMP	Current Good Manufacturing Practice	Regulations enforced by the FDA to ensure proper design, monitoring, and control of manufacturing processes and facilities.
DTx	Digital Therapeutic	A software that delivers a clinically validated therapeutic intervention to prevent, manage, or treat a health condition.
EFS	Early Feasibility Study	A small-scale clinical study used to evaluate a novel medical device early in its development, typically before pivotal trials.
FDA	Food and Drug Administration	The U.S. regulatory agency responsible for protecting public health by overseeing drug, device, and diagnostic safety and efficacy.
GLP	Good Laboratory Practice	A set of principles intended to ensure the quality, integrity, and reliability of non-clinical laboratory studies.
GMP	Good Manufacturing Practice	Practices required to conform to guidelines that control the production and testing of pharmaceuticals, diagnostics, and devices.
HC	Health Canada	The Canadian regulatory agency responsible for protecting public health by overseeing drug, device, and diagnostic safety and efficacy.
HDE	Humanitarian Device Exemption	An FDA regulatory pathway allowing limited use of medical devices intended to treat or diagnose rare conditions.
HUD	Humanitarian Use Device	A medical device intended to benefit patients with rare diseases or conditions affecting fewer than 8,000 individuals per year in the U.S.

Acronym	Full Term	Definition
IDE	Investigational Device Exemption	FDA permission to use an investigational device in a clinical study to collect safety and effectiveness data.
IFU	Instructions for Use	Detailed information provided by manufacturers outlining how to properly and safely use a medical product or device.
IP	Intellectual Property	Legal rights that protect creations of the mind, such as inventions, designs, and patents.
IVD	In Vitro Diagnostic	Tests performed outside the human body, typically on blood or tissue samples, to diagnose conditions or diseases.
PMA	Premarket Approval	The FDA's most stringent regulatory pathway for class III medical devices, requiring scientific evidence of safety and effectiveness.
QC	Quality Control	A set of processes used to ensure products meet specified quality criteria and regulatory requirements.
R&D	Research and Development	Activities related to the innovation, introduction, and improvement of products and technologies.
SaMD	Software as a Medical Device	Software that performs a medical function on its own without being part of a physical medical device.
TRL	Technology Readiness Level	A system used to assess the maturity of a particular technology throughout its development lifecycle.
V&V	Verification and Validation	Verification ensures a product meets its design requirements; validation confirms it meets user needs and intended use.