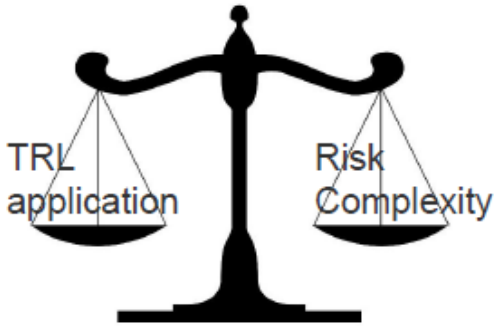
Technology Readiness Level (TRL)

- Technology readiness levels (TRLs) - Measurement of the maturity level of a particular technology
- TRLs are based on a scale from 1 to 9, with 9 being the most mature technology.
- Systematic addressing of TRLs is required, allowing a technology to evolve from conception through to research, development and deployment.
- Universities, along with government funding sources, focus on TRLs 1-4, while the private sector focuses on TRLs 7-9.
- The term 'Valley of Death' represents the often neglected addressing of TRLs 4 through to 7, where neither academia nor the private sector prioritize investment.

Purpose of TRL

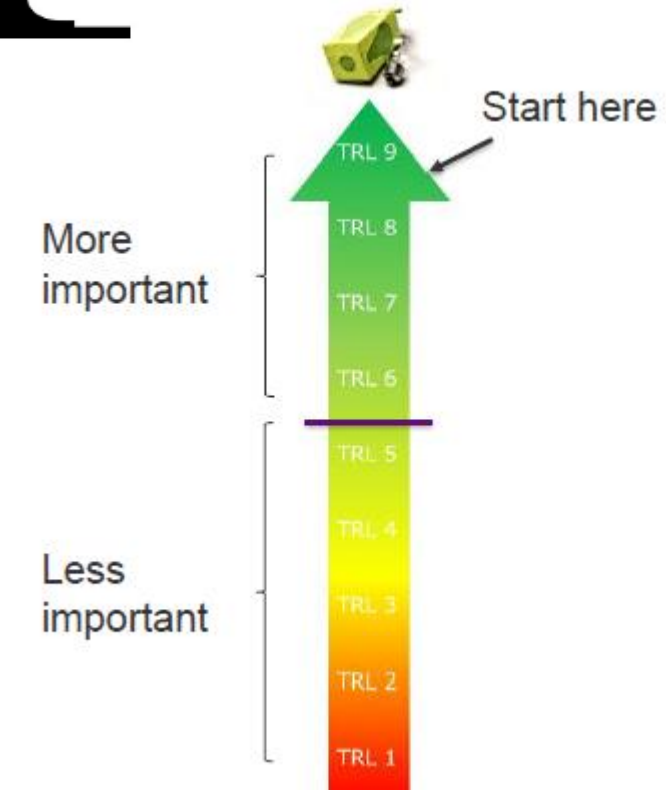


Communication tool

More objective assessment of the development level between stakeholders

Development roadmap

- Minimize risk in the development
- Develop products that are fit for purpose
- Encourage real-world testing and iteration
- Introduce "reality checks" in the development process



- Provides a common understanding of technology status
- Used to make decisions concerning technology funding
- Used to make decisions concerning transition of technology

European Union (EU) Technology Readiness Levels

- European Union (EU) normalized the NASA readiness-level definitions, allowing for easier translation to multiple industry sectors – not just space exploration.
- TRL started using in EU-funded research and innovation projects in 2014.
- In 2013, the TRL scale was further canonized by the ISO 16290:2013 standard.

Technology Readiness Levels

Level	TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9
Science & Engineering	Basic Idea	Concept Developed	Experimental Proof of Concept	Lab Demonstration	Lab scale validation (early prototype)	Prototype demonstration	Capability validated on economic runs	Capability validated over range of parts	Capability validated on full range of parts over long periods
							Pilot system demonstrated	System incorporated in commercial design	Proven system ready for full deployment
				Component and/or system validation in laboratory environment	Laboratory scale, similar system validation in relevant environment	Engineering/pilot-scale, similar (prototypical) system validation in relevant environment	Full-scale, similar (prototypical) system demonstrated in relevant environment	Actual system completed and qualified through test and demonstration	Actual system operated over the full range of expected mission conditions
Software			Software to test and evaluate basic concepts on simple model problems representative of final need.	Escalate model to more realistic representation of industrial system. Confirm basic formulation.	Model contains all major elements of need. Solve industrial strength problems by code developers OR achieve functionality by expert users. Document performance. GUI.	No specialist intervention required from programmers/developers. This includes basic GUI interface. If required, programming to be according to ISO standards.	Install, run and evaluate software in actual goal environment (e.g. prospective client's computers). Demonstrate use by clients	Evaluation done by target representative clients on representative hardware platforms. Complete GUIs, users manuals, training, software support etc. Typical user driven "bug hunting"	Product proven ready through successful operations in operating environment.
Medical Science	Basic Research		Preclinical Research		Late Preclinical Research	Phase I Trials	Phase II Trials	Phase III Trials	Phase IV Trials
Phase	Research			Translation/Development				Commercialisation	

Image Source: Univ. of Cape Town R-2-M

Complexity of System

- ***TRL 8-9 - System :*** **All technical elements** that comprise the project **operating as a single system** to **deliver a defined capacity**.
- **TRL 6-7 – Model :** A **physical or virtual model** used to evaluate the **technical or manufacturing feasibility or utility** of a particular **technology or process, concept, end item, or system**.
  - A **functional form of a system**, **generally reduced in scale, near or at operational specification**. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
- **TRL 4-5 - Breadboard** : **Integrated components** that provide a **representation of a system/subsystem** and that can be used to determine concept feasibility and to develop technical data.
  - Typically **configured for laboratory use** to **demonstrate** the **technical principles** of immediate interest. May **resemble final system/subsystem in function only**.
- **TRL 3-4 - Component :** A **single element of technology**. The lowest sub-system that provides sufficient granularity to identify technical risks and opportunities.

Environmental Description

- **TRL 8-9 – Actual operations :** Implementation of the final system by the **end-user** as they seem fit **in their day-to-day operations**
- **TRL 7 – Operational environment :** Environment that **addresses all** the **operational requirements** and specifications required of the final system
- **TRL 6 – Simulated operational environment :** Either (1) a real environment that can simulate all the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype
- **TRL 5-6 – Relevant environment :** Testing environment in a **lab or other controlled environment** that **simulates** both the most **important** and most **stressing** aspects of the **operational** environment.
- **TRL 3-4 – Laboratory :** The normal environment where the technology or product is developed, usually **not related** to the **environment where it will be used**
- **TRL 1-2 – Desk/Lab**

Technology Readiness Level – Development Stages

TRL	Description	Example
1	*Basic principles observed*	• *Scientific observations* made and reported. Examples could include paper-based studies of a technology's basic properties.
2	*Technology concept formulated*	• Envisioned applications are *speculative* at this stage. Examples are often limited to analytical studies.
3	*Experimental proof of concept*	• Effective research and development initiated. Examples include studies and laboratory measurements to validate *analytical predictions.*
4	*Technology validated in lab*	• Technology *validated through designed investigation*. Examples might include analysis of the technology parameter operating range. The results provide evidence that envisioned application performance requirements might be attainable.

Technology Readiness Level Examples

TRL	Description	Example
5	*Technology validated in relevant environment*	• Reliability of technology significantly increases. Examples could involve validation of a *semi-integrated system/model* of technological and supporting elements in a simulated environment.
6	*Technology demonstrated in relevant environment*	• *Prototype system verified*. Examples might include a prototype system/model being produced and demonstrated in a simulated environment.
7	*System model or prototype demonstration in operational environment*	• A major step increase in technological maturity. Examples could include a prototype model/system being verified in an operational environment.

Technology Readiness Level Examples

TRL	Description	Example
8	*System complete and qualified*	*System/model produced and qualified*. An example might include the knowledge generated from TRL 7 being used to manufacture an actual system/model, which is subsequently qualified in an *operational environment*. In most cases, this TRL represents the end of development.
9	*Actual system proven in operational environment*	System/model proven and ready for full *commercial deployment*. An example includes the actual system/model being successfully deployed for multiple missions by end users.

Technology Readiness Level (TRL) Process

NASA's quest to make jet engines quieter led to the development of chevrons, which moved relatively quickly through the TRL process to be deployed into the commercial marketplace.

TRL 8-9 (2005-now)

- Certification by the Federal Aviation Administration
- Deployed into market

TRL 7 (2001-2005)

- Validation of concept in flight
- Flight tests, final design

TRL 6 (1998-2000)

- Full scale tests for acoustics and aerodynamics
- Static engine tests

TRL 4-5 (1995-1997)

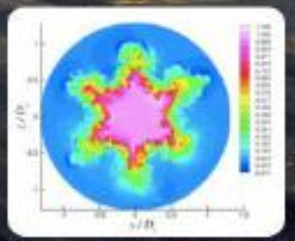
- Model tests for acoustics and aerodynamics
- Sub-scale model tests

TRL 3 (Early 1990s)

- Applications to small nozzles and airfoils
- Lab tests, concept on paper

TRL 1-2 (1980s)

- Fundamental investigations of air-mixing devices (tabs, chevrons, etc.)
- No specific application, basic research in fluid physics



Generic TRL → Specific TRL

The TRL is generic → the stages and definitions have to be adapted to the specific project

"Technology validated in relevant environment"

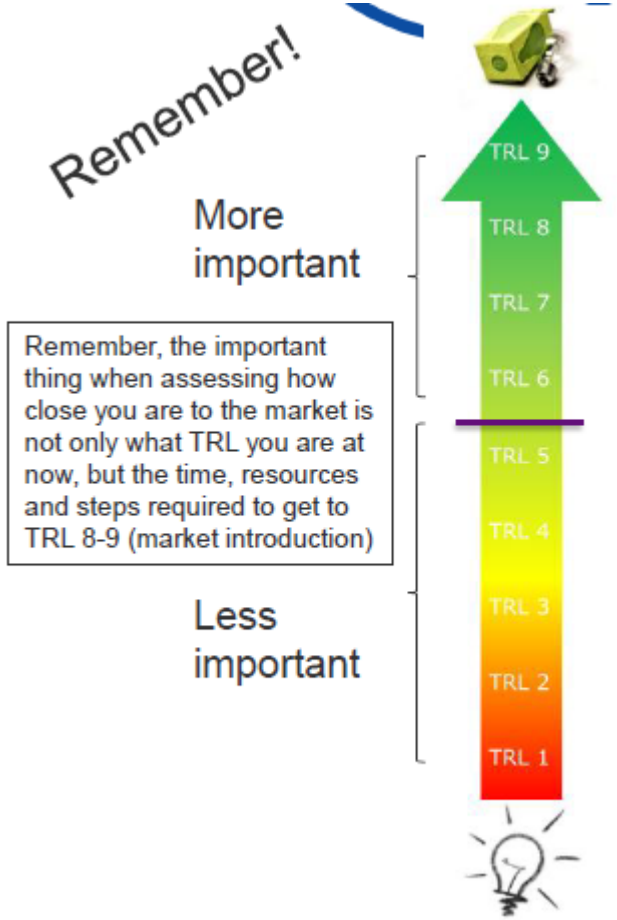
Technology development stage

Proof-of-Concept?
Validation?
Demonstration?
System?
Technology?
Component?

Definition of the environment in which the technology has been tested

Improvements of Existing Products

- New Product Development
  - TRL is most clear cut when dealing with genuine New Product Development with high inherent risk and insecurity (that's what it was designed for)
  - Requires more thought when applied to product or process improvements
- Improvement of Existing Product
  - Substantial improvement of a TRL 8-9 system = starting again at TRL 2
  - The road from a low TRL to a high TRL may be very short and fast.



TRL - Software Development

TRL 9	v1.x, v2.x, etc. – continuous development and improvement
TRL 8	v1.0 - Final stable release to the end-users
TRL 7	Open beta testing - open for anyone who signs up ("Black-box")
TRL 6	Beta testing for invited end-users ("Black-box")
TRL 5	"Black-box" alpha testing for selected external end-users or in-hose users/testeers not associated with the development
TRL 4	Alpha testing of the software by one or a few in-house developers or testers ("White-box")
TRL 1- 3	Concept/pre-alpha: script is more of an abstract idea than an actual working program. Through this stage the coding starts and changes to functions are being made until a working draft is created

Alpha: working script, probably lots of bugs, might not have all features, but the core of the program is running and can be tested extensively

Beta: program near completion, all features working, may be some bugs that may not have shown up in alpha testing

White-box: tests internal structures or workings of a program, as opposed to the functionality exposed to the end-userby

Black-box: examining functionality without any knowledge of internal implementation. The tester is only aware of what the software is supposed to do, not how it does it.

TRL - Pharmaceutical Development

TRL 9	Post marketing studies and surveillance
TRL 8	Phase 3 clinical trial is completed. FDA (CDER) approves New Drug Application (NDA)
TRL 7	Phase 2 clinical trial is completed. Phase 3 clinical trial plan is approved by FDA (CDER)
TRL 6	Phase 1 clinical trials support proceeding to phase 2 clinical trials. Investigational New Drug (IND) application submitted to and reviewed by FDA (CDER)
TRL 5	Pre-clinical studies, including GLP animal safety & toxicity, sufficient to support IND application
TRL 4	PoC and safety of candidate drug formulation is demonstrated in a defined laboratory or animal model
TRL 3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of *in vitro & in vitro* models
TRL 2	Research ideas and protocols are developed

Source: US Army Medical Department

Medical device development

TRL 9	Post marketing studies and surveillance
TRL 8	FDA (CDRH) approves the Premarket Approval (PMA) for medical device or applicable 510(K) for devices
TRL 7	Final product design is validated and final prototypes are produced and tested.
TRL 6	Class III device safety is demonstrated. 510(K) data demonstrates substantial equivalency to predicate device.
TRL 5	MD-CDRH review of Investigational Device Exemption (IDE) results is sufficient to begin investigation
TRL 4	PoC and safety of candidate device or system is demonstrated in a defined laboratory or animal model
TRL 3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of *in vitro & in vitro* models
TRL 2	Research ideas and protocols are developed

TRL - BIRAC, DBT, GoI

- Keeping NASA TRLs as a reference, BIRAC has come up with detailed definitions of levels in the TRL scale for each of these thematic areas.
- These TRL definitions intend to guide the innovators, evaluators and investors in identifying the stage of technology under development more objectively.
- The definitions also include some of the regulatory approvals and quality certifications which may be relevant for progression of TRLs and commercialization of the technology/products in India.

https://www.birac.nic.in/desc_new.php?id=443

1.) *Drugs (including Drug Delivery)*

2.) *Vaccines*

3.) *Biosimilars*

4.) *Regenerative Medicine*

5.) *Medical Devices and Diagnosis*

6.) *Artificial intelligence, Big Data Analysis, IoT's, software development & Bioinformatics*

7.) Industrial Biotechnology (including secondary agriculture) 8.) *Agriculture*

9.) *Aqua Culture and Fisheries*

10.) Veterinary