Guiding notes to use the TRL self-assessment tool

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1 INTRODUCTION

This document defines the main elements of the TRL self-assessment tool developed under BRIDGE2HE and states how to use this tool properly. It gives some background information on the TRL scale and propose three driving questions to guide the users through the tool.

The tool together with this user's guide can be found under the Horizon Europe NCP Portal at:

https://horizoneuropencpportal.eu/store/trl-assessment

2 WHAT IS THE TECHNOLOGY READINESS LEVEL SCALE.

The Technology Readiness Level (TRL) scale was introduced into the EU funded projects arena back in 2014 as part of the Horizon 2020 framework program. The TRL scale was originally defined by NASA in the 1990's as a mean for measuring or indicating the maturity of a given technology, from a paper sketch to its entry into the market.

Typically, new technologies go through the various stages of the TRL scale in their life cycle. During the research and development phases, it is possible to have iterations among the different TRL levels. In this sense, the TRL scale also helps to evaluate the project progress.

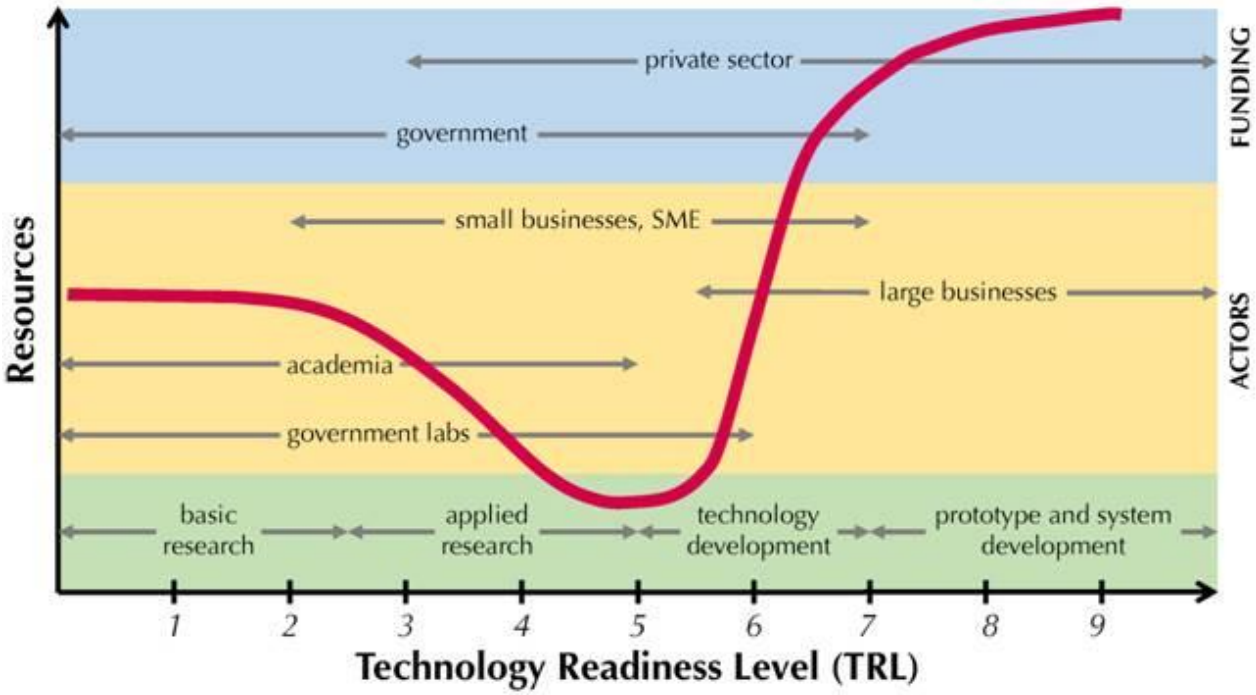

Figure 1 – Availability of resources for new product development at various TRLs. The gap in the middle is sometimes referred to as "The Valley of Death" (REHVA Journal 52, 58-62)

When a technology is at TRL 1, scientific research has just started, and the first results are used to be translated into future research and development. At TRL 2 basic principles have been studied and first experiments/tests are designed based on the initial findings. TRL 2 technology is still very speculative. When results from experiments/tests supports the initial idea, the technology is considered to be at TRL 3. Generally, both analytical and laboratory studies are required at this level to see if a technology is ready to go to the development phases. At TRL 3, a proof-of-concept model is constructed. Reaching to this point, one can conclude that the new technology is feasible from a scientific point of view.

At TRL 4, the validation of the technology has been performed at the laboratory level, testing each component so at this point a laboratory prototype is available. TRL 5 is a continuation of TRL 4, but the testing environment become as closer as possible to a realistic one, although still the environment is under a control mode. Reaching to this point, one can conclude that the new technology is feasible from a technological point of view.

In TRL 6, the prototype has to be demonstrated in a real environment, so to confirm the engineering is feasible. At TRL 7 the technology requires that the working model or the prototype developed to be demonstrated in an operational environment, typically under industrial conditions and timings. Reaching to this point, one can conclude that the new technology is reliable from the technological point of view.

In TRL 8 technology is ready for implementation into an already existing technology or technology system. Once the technology system has been proven during operations, it can be called TRL 9 and considered a commercial technology.

Horizon Europe uses the TRL scale as an indicator to position proposals and projects in the program. The TRL scale for Horizon Europe is defined in the general annexes and set that:

"Where the specific call conditions require a Technology Readiness Level (TRL), the following definitions apply, unless otherwise specified:

- *TRL 1 — Basic principles observed*
- *TRL 2 — Technology concept formulated*
- *TRL 3 — Experimental proof of concept*
- *TRL 4 — Technology validated in a lab*
- *TRL 5 — Technology validated in a relevant environment (industrially relevant environment in the case of key enabling technologies)*
- *TRL 6 — Technology demonstrated in a relevant environment (industrially relevant environment in the case of key enabling technologies)*
- *TRL 7 — System prototype demonstration in an operational environment*
- *TRL 8 — System complete and qualified*
- *TRL 9 — Actual system proven in an operational environment (competitive manufacturing in the case of key enabling technologies, or in space)*

In that sense, the TRL enables applicants and reviewers to align with the expectations of the EC in the context of a Call for Proposals and the different HE instruments, which can be positioned across the whole scale. The most relevant ones are the following:

- **Horizon Europe Research and Innovation actions (RIA & IAs)**

The Research and Innovation Actions cover typically projects starting at TRL 2-3 and reaching TRL 5-6 while the Innovation Actions are covering projects that start at TRL4-5 and end at TRL6-8.

- **European Research Council actions (ERC)**

The European Research Council actions are typically targeting blue sky research so, in this context, it is not relevant the entry point (TRL 1 or 2) but only the expected output if able to test ideas that may lay the foundations for a future technology to be developed. If this is the case one of its main instruments, the ERC Proof-of-Concept allows project to reach a proof of concept of the technology at a TRL 3 or 4 level.

- **European Innovation Council instruments (EIC)**

Due to the nature of the EIC, the use of the TRL scale is very relevant to its main three instruments:

  - The EIC Pathfinder program aims to fund project from TRL 1-2 to reach TRL 3-4.
  - The EIC Transition program aims to fund projects from TRL 3-4 to reach TRL 5-6.
  - The EIC Accelerator program aims to fund companies to move from TRL 5 to TRL9.

3 HOW TO USE THIS TRL SELF-ASSESSMENT TOOL.

Since the TRL of the project is **self-declared**, it is important for you to know how the TRL definition and scale is applied within your sector, especially because the transition between TRL levels can be a bit elusive if just applying the general Annex definition. As the process of assigning TRL to a project is not an easy task, especially because it is not consistent across different disciplines, BRIDGE2HE has developed an expanded TRL matrix to offer applicant a support to correctly define the TRL according to basically three questions.

1. **What is the type of solutions to be developed by the project?** This is a very close question with 5 possible types of outputs from a project. The response to this question will determine the row of the matrix you have to enter. If you have more than one project output, you may need to conduct your TRL assessment to each of it.

    - A product that is manufactured
    - An industrial process
    - A software
    - A medical device
    - A drug

2. **What is missing from your innovation to be in its final form?** This question assesses the robustness and completeness of the innovation status. Use this question to navigate in the row selected in Question 1. If the project is in a scenario with the main features of the innovation in place, then this is still a prototype (TRL 4 or 5). Conversely if they already have the innovation in its final form but still not certified or ready to be manufactured in mass, the TRL can increase up to TRL 6 or 7 can only be TRL8-9 when it can already be commercial.

3. **How controlled are the conditions in which you are operating**? This question measures the completeness of your testing environment. Use this question to navigate in the row selected in Question 1. The more real conditions you are (meaning elements out of your control may happen), the closer you are to TRL9. If you are tested your innovation, independently of its form under controlled scenarios, you are not beyond TRL6. Only when you have your product tested real live in relevant timeframes, you can say that you are in TRL8. Obviously in those markets which undergone regulations (health), the TRL is closely link to the phases you are concluding.

With the row obtained from Question 1 and the lower TRL value obtained from your responses from Question 2 and 3, you calculate the TRL of the project. Use the examples of the tool to double check that your project and the one in the example are in similar situations that justify your TRL assessment.

4 THE TRL SELF-ASSESSMENT TOOL: MAIN ELEMENTS.

The TRL self-assessment tool is composed of 5 TRL scales, one per each of the type of solution to be developed by the project, according to the Question 1. The description of the different TRL levels is performed for each of the 5 cases according to their framing conditions, taking into accounts the elements assessed in the Question 2 and 3. The completeness of the solution with respect its final form and the completeness of the testing environment with respect the final real environments of application. A row of examples to be inspired is included per row taken from the Horizon Europe Results platform.

In the following table, the TRL matrix can be found.

What is your solution?	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9
A Product that is manufactured	Analytical studies on separate elements of the technology. Laboratory based trials that show the feasibility of the predictions.	Basic technological components integrated together to show that they work together. At this point, durability is not yet important.	Basic technological components integrated within realistic context under a fully controlled environment in or outside the lab.	A functional version of the product working on a realistic environment able to draw conclusions on the technical and operational capabilities of the product.	A manufacturable version of the product working on an environment which addresses all the operational requirements for the product.	Product in its final form working in full mode under expected conditions and periods.	Product in its final form under full commercial deployment.
Examples to be inspired	link	link	link	link	link	link	
An industrial process	Laboratory experiments are designed to verify that the conceptual process works as expected.	Process components are validated individually and could be integrated in an ad hoc manner at lab scale.	Integrated validation of the process to produce small outputs or short batches of the end product.	Development of a pilot-scale testing plant or unit (1/100th of commercial scale) including engineering-scale equivalents of all the operations that will be required at scale.	Successful demonstration of the continuous operation of the pilot plant/unit during a relevant timeframe.	Demonstration plant is constructed (1/10th of commercial scale) and operated in continuous mode, including working outside normal parameters.	Commercial plant/unit set up and running for full range of operating conditions.
Examples to be inspired	link	link	link	link	link	link	
A software	Initial script & functions to solve the desired problem.	Alpha version of the software tested internally (both functionalities and process) by the development team.	Alpha version of the software functionalities tested by outsiders of the development team.	Beta version of the software functionalities tested by selected end-user under a control mode.	Beta version of the software functionalities widely open to end-users.	Stable version of the software available for the market.	Stable version of the software available for the market in full business plan conditions.
Examples to be inspired	link	link	link	link	link	link	link

What is your solution?	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9
A medical device	Initial proof of concept demonstrated with a limited number of in vitro & in vivo trials including the expected device characteristics.	Proof of concept and safety of the device is demonstrated in vitro, ex vivo or in vivo conditions (non-GMP, Good Manufacturing Practice). System components integrated and tested regarding preliminary efficiency and reliability.	Pre-clinical studies including GLP (good laboratory practice) animal safety & toxicity. GMP manufacturing process and quality controls identified. Classification of the device by appropriated regulatory body established. Accreditation when appropriate initiated.	Medical device prototype demonstrated in operational environment. Clinical testing and safety demonstrated. Required accreditation in progress.	Medical device final product design is validated. Final prototypes intended for commercialization use produced and tested. When applicable, accreditation completed.	Manufacturing process validated. Pre-market application submitted and approved for medical device. Device demonstrated in real life conditions, support structure in place for technical problems.	Medical device ready to be acquired by the clients and end users.
Examples to be inspired	link	link	link	link	link	link	
A drug	Initial proof of concept demonstrated with a limited number of in vitro & in vivo models.	Proof of concept and safety of the candidate is demonstrated in a laboratory or animal model.	Pre-clinical studies including GLP animal safety & toxicity to support the Investigational New Drug (IND) application or similar EU process.	Phase 1 clinical trials completed to proceed with Phase 2 clinical trials. If it is the case, Investigational New Drug application submitted and reviewed.	Phase 2 clinical trial completed & Phase 3 plan is approved.	Phase 3 clinical trial completed. Regulatory body approves IND application.	Drug available for the market.
Examples to be inspired	link	link	link	link	link	link	