

How Technology Readiness levels in Life Science Development can help you define your R&D activities to obtain R&D Salary tax reductions and grants.

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Many life science organisations directly or indirectly engaged in the development of medical solutions struggle to clearly define and track their R&D activities, which significantly reduces the financial benefit they could gain from making use of Belgian R&D withholding tax exemptions rules or from obtaining government grants.



Technology Readiness levels (TLRs) could help these companies to firstly identify their R&D activities and help to evaluate the qualification of related expenses for governmental support.

TLR is a methodology originally developed at NASA in the 1970's, for evaluating the maturity of technology during the Research and Development phase. The use of TRLs enables consistent and uniform comparison of the technical maturity across different types of technology.

VLAIO – The Flemish Innovation and Entrepreneurship agency makes use of TRL's to evaluate the status of submitted projects at the specific level in their innovation trajectory. For several continuous or ad-hoc grant calls, VLAIO has defined the required TRL range. At the same time, since these TRLs clearly define the various levels of Research and Development, the activities of employees engaged in specific levels could qualify for partial R&D Salary withholding tax exemption.



The Research and Development range in the TRLs start at level 1 which includes any activities related to scientific research gathering, idea development and feasibility studies, go over TRL 3 which includes experimental Proof of Concept delivery till TRL 8 which includes the late stage clinical validation of any life science product in the hospital or other relevant medical environment.

Whereas for organisations in TRL phase 3 to 5, it is clear which tasks are considered R&D, this might be less defined for organisations engaged during early (1 to 2) or late (6 to 8) TRL phases.

Typical examples of activities which are related to R&D and which thus qualify for partial R&D Salary withholding exemption are:

Consultants to the life science industry, often outsourced profiles including mechanical and data engineers, clinical research professionals, statisticians.



Hospital / Medical organisations whom, from time to time, perform clinical investigations or trials, either under an agreement the pharma/medtech industry or by their own scientific interest.

Whether these organisations insource project or outsource employees, does not matter in context of the qualification of the R&D Salary tax exemption.

Flemish government (VLAIO) grants are typically awarded to organisations or clusters having a clearly defined project plan which covers several TRL's. It remains however important to understand the specific range of TRL. For example, a typical project considered for a VLAIO Research grant has activities ranging from TRL1 till 3 while Early Development grant projects have activities ranges from TRL 4 till 5. Project in the range of TRL 6-7 can be awarded VLAIO grants and are considered Pilot or Demo projects. Activities in TRL 8 till 9 which are considered 'Implementation' are not considered as R&D.



The following provides an overview of the TRL classification as supported by the European Directorate-General for Research and Innovation 2017, European Commission. (<https://op.europa.eu/en/publication-detail/-/publication/d5d8e9c8-e6d3-11e7-9749-01aa75ed71a1/language-en/format-PDF/source-61073523>)

Overview of the TRL classification

By European Directorate-General for Research and Innovation 2017, European Commission.

TRL 1: Basic principles observed

Identification of the new concept
Identification of the integration of the concept
Identification of expected barriers
Identification of applications
Identification of materials and technologies based on theoretical fundamentals/literature data
Preliminary evaluation of potential benefits of the concept over the existing ones

TRL 2: Technology concept formulated

Enhanced knowledge of technologies, materials and interfaces is acquired
New concept is investigated and refined
First evaluation about the feasibility is performed
Initial numerical knowledge
Qualitative description of interactions between technologies
Definition of the prototyping approach and preliminary technical specifications for laboratory test TRL

3: Experimental proof of concept

First laboratory scale prototype (proof-of-concept) or numerical model realized
Testing at laboratory level of the innovative technological element (being material, sub-component, software tool, ...) but not the whole integrated system
Key parameters characterizing the technology (or the fuel) are identified
Verification of experimental application through simulation tools and cross-validation with literature data (if applicable).

TRL 4: Technology validated in lab

(Reduced scale) prototype developed and integrated with complementing sub-systems at laboratory level
Validation of the new technology through enhanced numerical analysis (if applicable).
Key Performance Indicators are measurable
The prototype shows repeatable/stable performance (either TRL/4 or TRL/5, depending on the technology)

TRL 5: Technology validated in relevant environment

Integration of components elements and auxiliaries in the (large scale) prototype
Robustness is proven in the (simulated) relevant working environment
The prototype shows repeatable/stable performance (either TRL4 or TRL5, depending on the technology)
The process is reliable and the performances match the expectations (either TRL5 or TRL6, depending on the technology)
Other relevant parameters concerning scale-up, environmental, regulatory and socio-economic issues are defined and qualitatively assessed

TRL 6: Technology pilot demonstrated in relevant environment

Demonstration in relevant environment of the technology fine-tuned to a variety of operating conditions
The process is reliable and the performances match the expectations (either TRL5 or TRL6, depending on the technology)
Interoperability with other connected technologies is demonstrated
Manufacturing approach is defined (either TRL6 of TRL7, depending on the technology)
Environmental, regulatory and socio-economics issues are addressed

TRL 7: System prototype demonstration in operational environment

(Full scale) pre-commercial system is demonstrated in operational environment
Compliance with relevant environment conditions, authorization issues, local/national standards is guaranteed, at least for the demo site
The integration of upstream and downstream technologies has been verified and validated
Manufacturing approach is defined (either TRL6 of TRL7, depending on the technology)

TRL 8: System complete and qualified

Technology experimented in deployment conditions (i.e. real world) and has proven its functioning in its final form
Manufacturing process is stable enough for entering a low-rate production.
Training and maintenance documentation are completed
Integration at system level is completed and mature
Full compliance with obligations, certifications and standards of the addressed markets

TRL 9: Actual system proven in operational environment

Technology proven fully operational and ready for commercialization
Full production chain is in place and all materials are available
System optimized for full rate production

<https://op.europa.eu/en/publication-detail/-/publication/d5d8e9c8-e6d3-11e7-9749-01aa75ed71a1/language-en/format-PDF/source-61073523>