

ANNEX 2 Technology Readiness Level (TRL)





TRL for General and Hard Engineering Types

LEVEL DEFINITION/STATUS

N/STATUS INDICATOR



Basic principles of the technology have been observed and reported.

- Basic assumption and law (e.g. physics/chemical) to be used in the (new) technology have been determined;
- Literature study (theoretical/ empirical – previous researches) on the basic principles of the technology to be developed; and
- 3. Formulation of the research hypothesis.



Concept formulation and/or formulation application.

- 1. The equipment and system to be used have been identified;
- Literature study (theoretical/ empirical) on the technology to be developed has feasible application;
- Theoretical and empirical design have been identified;
- Basic elements of the technology to be developed have been identified;
- Characterization of the components of the technology to be developed have been mastered and understood;





- Performance of each element composing the technology to be developed have been predicted;
- Initial analysis shows that the main functions needed perform well;
- 8. Model and simulation to verify the basic principles;
- 9. Analytical research to verify the basic principles;
- Components of the technology to be developed perform well separately;
- 11. The equipment to be used must be valid and reliable; and
- 12. Phases of the experiment to be performed are identified.

Analytical and experimental proof of concept of the essential functions and/or characteristics.

- Analytical study supports the predicted performance of the technology's elements;
- 2. Characteristics/nature and performance capacity of the basic system have been identified and predicted;
- Laboratory experiments have been performed to test the technology's application feasibility;
- Model and simulation have supported the predicted performance of the technology's elements;

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- The development of the technology by first using mathematical model is highly probable and can be simulated;
- Laboratory research to predict the performance of each element of the technology; Theoretically, empirically and experimentally, components of the technology system have been found to perform well;
- Laboratory research has been conducted by using dummy data; and
- 8. Scientific feasibility of the technology (analytical study, model/simulation, experiment).



Validation of component/ subsystem in laboratory environment. Laboratory testing of each separate component has been performed;

- The system requirements for application as expected by the user have been identified (adopter's expectations);
- Results of laboratory experiments on components have shown that these components are operational;
- Experiment on the technology's main functions in a relevant environment;





Validation of component/

subsystem in a relevant

environment

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INDICATOR

department.

8.

- 5. Laboratory-scale prototype of the technology has been made;
- 6. Research on component integration has begun;
- 'Key' processes for manufacturing have been identified and reviewed in the laboratory; and
- Laboratory-scale technology system integration and design & engineering have been completed (low fidelity).
- 1. Preparation for hardware production has been made;
- Market research (marketing research) and laboratory research to select fabrication process;
- 3. Prototype has been made;
- Equipment and supplementary machine have been tested in the laboratory;
- System integration has been completed with high accuracy (high fidelity), ready for testing in real/simulated environment;
- Prototype system's accuracy/ fidelity increased;
- Conditions of the laboratory have been modified to resemble the real environment; and



Demonstration of model or system/subsystem prototype in a relevant environment. The real operational environment conditions have been identified;

Production process has been

reviewed by manufacturing

- Investment requirements for equipment and fabrication processes have been identified;
- M&S for the technology's system performance in the operational environment;
- Manufacturing/fabrication department has approved and accepted the laboratory test results;
- Prototype has been tested with high laboratory accuracy/ fidelity in an operational environmental simulation (the real one outside the laboratory); and
- 6. Test results indicate engineering feasibility.



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TRL for Software



Basic principles of the technology have been observed and reported.

1. Constitute the lowest level

INDICATOR

- of technology readiness for software;
- Constitutes a new software domain which is being explored by basic research community; and
- 3. Also includes the development of basic level of use, basic characteristics of the software architecture, mathematical formulation, realizable device concept, basic principles review of a software, scientific principles, research hypothesis formulation, and general algorithm.

2

Concept Formulation and/or technology application.

- After the basic principles are observed, it proceeds to practical application creation;
- Application is speculative in nature, and there is a possibility that it might lack evidences or detailed analysis to support assumptions made/performed; and
- 3. Examples are restricted to analytical studies using

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- synthetic data (artificial).
 User/customer is identifiable, system or subsystem application has been identified
- 5. Software application feasibility study
- 6. Solution of empirical and theoretical designs have been identified
- 7. Technology's components are partially characterized
- 8. Performance prediction of each element has been made
- 9. User/customer impression/ interest on the software has been reviewed



Analytical and experimental proof of concept of the essential functions and/or characteristics.

- There is active initiation of research and development process;
- 2. Scientific feasibility has been demonstrated through analytical and laboratory studies; and
- Also includes the development of a limited functional environment to validate a critical nature and analytical prediction by using:





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LEVEL DEFINITION/STATUS INDICATOR

A. Unintegrated components of software and B. Some representing data

- Predicted capability of each element of the technology has been validated through analytical study
- 6. Software algorithm outline is available
- Predicted capability of each element of the technology has been validated through modelling and simulation
- Laboratory experiment has been able to ensure software feasibility
- 9. User representatives may now be included in the development of the software
- 10. Scientific feasibility is fully demonstrated here
- 11. Risk mitigation has been identified



Validation of subsystem module in laboratory environment.

- Integrated basic software components perform well together;
- Relatively primitive in regard to efficiency and reliability (robustness) compared to the final system/product;
- 3. Architectural development has begun by covering issues

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related to interoperability, reliability, ease of maintenance, capability for improvement, scalability, and security;

- There are efforts to adjust to the latest elements (technology); and
- 5. Current prototype is developed to demonstrate various aspects of the final system/product.
- "Cross-technology" issues (if any) have been fully identified
- Formal architectural development of the software system has begun
- 8. Documents of user requirements
- 9. Algorithm has been converted into pseudocode
- 10. Format data requirements analysis is complete
- Software demonstration has been performed in a simple environment
- 12. Software size estimation
- 13. Integration review has begun
- 14. Conceptual design draft has been documented







5

Validation of module and/ or subsystem in a relevant environment.

- Constitutes a level where the software technology to be developed is ready for integration into the existing system;
- Implementation of prototype which corresponds with the environment/interface;
- 3. Experiments are developed by real problems.
- 4. Simulation on the interface of existing systems;
- 5. System's software architecture has been completed; and
- 6. Algorithm runs on (multi) processor in an operational environment with characteristics as expected
- "Cross-technology" influence (if any) has been identified and determined through analysis
- 8. System interface requirements have been identified
- 9. System's software architecture has been determined
- 10. Analysis of internal interface requirements is complete
- 11. Function/module coding is complete
- 12. Prototype has been created
- 13. Quality and reliability are taken into consideration
- 14. Laboratory environment has been modified to resemble the operational environment

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- 15. Risk management has been documented
- 16. Function has been integrated into modules
- 17. Draft test and evaluation master plan



Validation of module and/ or subsystem in a relevant "end-to-end" environment.

- Constitutes a level where engineering feasibility of the software technology is demonstrated; and
- 2. Also includes implementation of laboratory prototype with full-scale realistic problems, where software technology is partially integrated into the hard/software of existing systems.
- Characteristic validation of "cross-technology" measurement and performance is complete
- 4. Level of quality and reliability has been determined
- 5. Operational environment has been identified
- M&S is performed to simulate system performance in operational environment
- 7. Test and evaluation master plan is final
- 8. Analysis of database and interface structures is complete



- 9. Documentation of restrictive software is available
- 10. "Alfa" version of the software is released.

TRL for Agriculture /Fisheries/Livestock

formulated.

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DEFINITION/STATUS LEVEL **INDICATOR** Basic principles of the 1. Formulation of research technology have been questions or research observed. hypotheses are available; 2. Literature study on basic principles related to the research has been conducted; and 3. Means/method/process/ product to be observed and developed are available and have a potential of success. Concept of technology Means and infrastructures to 1. 2 and application has been be used have been identified;

- 2. Literature study results have been validated; and
- 3. Theoretical and empirical research designs have been identified.





DEFINITION/STATUS LEVEL **INDICATOR**

Essential concept and characteristics of the technology have been proven analytically and experimentally.

- Research design has 1. been prepared (selected methodology, phases, and data required for research);
- Theoretically, empirically and 2. experimentally, components of the technology system have been found to perform well; and
- 3. The technology is scientifically feasible (analytical study, model/simulation, experiment).
- Laboratory testing of each 1. separate component has been performed;
- Performance of each 2. component of the technology (means/method/process/ product) to be developed has demonstrated a good result;
- 3. Experiment on the technology's main functions in a relevant environment has been performed;
- 4. Laboratory-scale prototype of the technology has been made;
- 5. Research on component integration has begun;
- 6. Initial analysis shows that the main functions needed perform well; and

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7. Laboratory-scale technology's components integration and design & engineering have been tested (low fidelity).

Technology components have been validated in a relevant environment.

- Prototype of the technology is 1. ready for testing in a laboratory condition modified to resemble the real environment:
- 2. Accuracy/fidelity increased;
- Technology's components 3. integration have been tested with high accuracy (high fidelity).



Model or Prototype has been tested in a relevant environment.

- Requirements of the 1. technology have been identified (optimum condition);
- Technology has been tested 2. with high accuracy in operational environment simulation with complete data (corresponds with the research design);
- Test results indicate 3. engineering feasibility; and
- Draft economic analysis 4. (initial estimation of economic feasibility) is available.





Technology components have been validated in the laboratory environment.



TRL for Health-Vaccine /Biological Products

LEVEL	DEFINITION/STATUS	IN	IDICATOR
1	Basic principles of the technology have been observed and reported.	1. 2. 3.	Scientific literature study on the basic principles of the technology to be developed is available; Initial market survey has begun and has been assessed; Potential scientific application for problem-solving has been described.
2	Concept formulation and/ or formulation application. (Intellectually intensive which focuses on problems, resulting in literature studies reviewing and generating research ideas, hypotheses, and experimental designs related to scientific issues.	1. 2. 3. 4.	Hypotheses have been established; Research design has been developed; Research protocol for verifying the principles is available; and Protocol has been reviewed by expert groups and has been approved.
3	Analytical and experimental proof of concept of the essential functions and/ or characteristics. Initiation	1.	Analytical studies supporting the predicted performance of the technology's elements are available;



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of Proof of Concept for vaccine product development is described through limited researches whether *in vitro or in vivo* on model animals.

- 2. Characteristics/nature and performance capacity of the basic system have been identified and predicted;
- 3. *In vitro* laboratory experiments have been conducted; and
- *4. In vivo* laboratory experiments on model animals have been conducted.



Validation of component/ subsystem in laboratory environment.

Basic components of the technology are integrated, showing that the technology will work together. Currently low fidelity (errors are still possible) compared to the original technology. Example of addition of *ad hoc* equipment in the Laboratory.

Non-GLP laboratory research is conducted to define the hypotheses and identify the relevant data necessary for technology assessment in accurate experimental designs.

Explorative and critical studies of the technology

- Laboratory-scale prototype has been created;
- Laboratory-scale prototype of Good Laboratory Practice (GLP) has been created for Preclinical test material;
- 'Key' processes for production have been identified and reviewed in the laboratory;
- Laboratory-scale technology's components integration and design & engineering have been completed (low fidelity);
- 5. Target Product Profile (TPP) has been determined, comprising substance administration, substance content, indication, dosage, dose ranging, method of administration, benefits, possible side effects, type of substance; and
- 6. Initial pre-clinical test in the form of safety and efficacy





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for effective integration into biological/vaccine candidates (pH, adjuvant, stabilizer, preservative, buffer, method of administration, proposed purification method, chemical and physical characterization, metabolite production and its excretion/elimination, dose ranging, challenge test (for protection). Vaccine/ biological candidate has been tested on model animals to observe potentials, biological effects, safety, side effects and toxicity. A marker to determine the end point of pre-clinical and clinical tests have been identified.



test of a biological/vaccine candidate has been described and defined on model animals.



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potential test, proposed production will comply with GMP convention on a pilotscale, identification and proof of concept on the test animals may predict tests on human, through appropriate markers. Perform GLP toxicity test on the test animal. determine the markers for clinical test prediction on human, and proof of immunogenicity and potential, as well as PK and PD and initiation of study on substance stability.

GLP substance have been performed:

- 5. Design for clinical test on human has been prepared and registered with the National Agency of Drug and Food Control (Badan POM) based on the pre-clinical test;
- Design for stability test and 6. restrictive stability test have been completed.

Validation of component/ subsystem in a relevant environment.

Intensive period of nonclinical and pre-clinical studies is performed by involving parametric data and analysis is performed of a validated system, and pilot-scale production of biological/ vaccine candidate. Research result shows appropriate

- 1. Preparation for production and facilities of GMP;
- 2. Pilot-scale biological/vaccine production has been designed and conducted;
- 3. Biological/vaccine substance master formula has been reviewed by the Quality Assurance and has complied with GMP convention:
- 4. Pre-clinical tests on the safety, biological immunology/ activities and efficacy of the

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Demonstration of model or system/subsystem prototype in a relevant environment. Pre-IND discussion with Badan POM has begun and documents have been prepared and submitted, Phase 1 CT has been performed on a small number of participants and the subjects are intensively controlled and evaluated for any clinical symptoms.

Data about immunogenicity and or pharmacokinetics and pharmacodynamics are available for prediction of phase 2 CT on human.

- Phase 1 clinical test on a 1. limited number of humans has been performed and has met the safety requirements and demonstrated the expected result of immunogenicity and pharmacokinetics (PK) and pharmacodynamics (PD); and 2. Data about phase 1 clinical
- test result which supports the preparation of protocol for clinical test phase.



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TRL for Health-**Medical Device Product**

LEVEL	DEFINITION/STATUS	INDICATOR	
	Technology's Basic	1.	Lowest level
	Principles Report.		readiness;
		2.	Theoretical e technology's
		3.	Initial survey the technolo
		4.	Basic concep scientific the the related m technology;
		5.	Formulation and theoretic
		6.	Scientific lite relation to th basic princip
2	Technology Concept Formulation.	1.	Formulation preparing hy planning of e design to find problems on
		2	technology c

- evel of technology s;
- cal explanation on gy's basic principles;
- rvey on the benefits of nology;
- ncept review of theories underlying ed medical device gy;
- tion of basic concept pretical substantiation;
- literature review in to the technology's nciples.
- tion of research topics, g hypotheses, and of experimental find the solution to s on the basis of the gy concerned;
- 2. Preparation of scientific hypotheses. Research and protocol planning have been reviewed and approved; and



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3. Through literature review and scientific discussions, a research and study plan is prepared to identify the potential and opportunity for therapeutic targets. Documented in the form of protocol or research plan to be reviewed and approved.



Research to substantiate the technology concept (Research of Technology Concept).

- Basic research, experimental 1. data collection and analysis, to test the prepared hypotheses. Checking for alternative concepts, and identify and evaluate the technology's components;
- 2. Initial testing on the design concept and evaluation of various alternatives;
- 3. Design verification, component specification determination;
- Initial proof of concept of 4. limited medical device's technology and laboratory models; and
- 5. Documentation of results of laboratory-scale experiments providing initial proof of concept of the medical device's technology.





Laboratory-Scale

Prototype.



Laboratory-scale validation of components and/or sets of system (validation component in laboratory).

- Laboratory-scale experiment and testing to evaluate and review the level of safety, side effects, and efficacy;
- Preparation of procedures and methods to be used in a nonclinical and clinical studies;
- Proof of concept of the technology and safety level; and
- Publication (peer-reviewed) of data about proof of concept of the technology and safety level.
- Designation of classification (class 1, 2, or 3) of the medical device prototype based on its equivalence with existing medical devices;
- Lab-scale testing of prototype's safety level against the applicable standard (for example: iec60601);
- Lab-scale validation testing on prototype's efficacy and side effects, and its disruption to/ by other devices. (for medical device classes 1-2); and
- Lab-scale substantiation of prototype's safety level and efficacy.



LEVEL DEFINITION/STATUS



Industrial Scale Prototype.



- Industrial-scale limited validation testing of the prototype on its efficacy and side effects, and its disruption to/by other devices. (for medical device classes 1-2);
- 2. Industrial-scale limited phase 1 clinical testing of the prototype to find out its safety level and efficacy (for medical device class 3); and
- Industrial-scale limited substantiation of the prototype's safety level and efficacy.





TRL for Pharmacy

LEVEL DEFINITION/STATUS

1

Basic principles of the technology have been observed and reported.

 Review and assessment of scientific findings as a foundation for characterizing new technologies;

INDICATOR

- 2. Initial survey on the market and assessment has been conducted; and
- Available explanation on potential scientific application for the defined problems.

2

Concept formulation and/or formulation application.

Intellectual focus on the problem, resulting in review of scientific publications discussing and generating research ideas, hypotheses and experimental design in regard to related scientific discourses.

- 1. Hypotheses have been generated.
- Research plan and or research protocol have been developed, reviewed and approved.

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LEVEL DEFINITION/STATUS

Drug candidate initial synthesis has been performed, identification of sites and mechanisms of action along with candidate drug initial characterization in a preclinical study. vivo research models; and

INDICATOR

2. Commencement of basic research, data collection and analysis to test the hypotheses, exploration of alternative concepts and identification and evaluation of the technology supporting the drug development.



Validation of component /subsystem in a relevant environment.

- Decision point at which it is determined that sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an Investigational New Drug (IND) application;
- 2. Non-clinical and clinical researches have been strictly performed comprising parametric data collection and analysis in a method wellformulated with the candidate drug pilot lots (validated prototype);
- Result of the research using pilot lots has provided a foundation for a production process which complies with cGMP (current Good Manufacturing Practice) – compliant pilot lot production;



Analytical and experimental proof of concept of the essential functions and/or characteristics.

Initial proof of concept has been performed and substantiated as candidate drug on limited *in vitro* and *in*

1.



DEFINITION/STATUS LEVEL **INDICATOR**

Demonstration of model or

in a relevant environment.

system/subsystem prototype

- 4. GLP safety and toxicity studies have been conducted by using model animal;
- 5. Clinical efficacy endpoints or its surrogate have been identified;
- Review has been conducted to 6. evaluate the pharmacokinetics and pharmacodynamics of the candidate drug; and
- 7. Research on stability has begun.
- 1. Phase 1 clinical tests have been conducted to demonstrate the safety of the candidate drug in a small number of humans and under careful supervision with clinical conditions being monitored;
- 2. IND application is prepared and submitted;
- 3. Production technologies are demonstrated through cGMP plant qualification; and
- 4. Result from Phase 1 test is available and has met the clinical safety requirements and justify proceeding with Phase 2 clinical test.

TRL for Social, Humanity and Education

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LEVEL **DEFINITION/STATUS INDICATOR** Basic principles of the 1. research have been observed and reported.

- Background and objectives of R&D have been defined
- 2. Available R&D guestions (question research) to be answered.
- 3. Facts and basic arguments which are relevant and support the need of R&D
- 4. R&D are required to support government policy, discover phenomenon or solutions to a problem, etc.



Support of Initial Data, Hypotheses, Design & Procedures for R&D have been explored.

- 1. R&D hypotheses have been prepared
- Support of initial data to the 2. R&D questions to be answered
- R&D design (research design) 3. to be conducted has been explored (determination of data topic, preparation of questionnaire, FGD themes, etc.)
- Alternative methodology, 4. procedure and phases to be followed have been traced.

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3

Research Design and Methodology have been completely prepared.

- Methodology design to be used for answering the research questions has been prepared
- 2. Design of determination of the sample, and/or the collection of the required data as well as data collection technique have been prepared
- 3. Data adequacy and completeness have been determined
- Technical evaluation and result prediction have been completed
- 5. Scenario and alternatives for data completeness have been prepared
- 6. R&D design is complete.

4

Data Collection, Validation in Simulated Environment or Examples/Activities of R&D.

- Collection of the primary data has been conducted (questionnaire/FGD/or other forms)
- 2. The data obtained have been validated to ensure relevancy
- Support of secondary data may supplement the initial data previously obtained
- 4. Existing data have been tested for validity and reliability.
- 5. Data and system reliability is still (relatively) low compared to the expected system



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Data Completeness and Analysis in Simulated Environment/Activities of R&D.

- INDICATOR
- 1. Data reliability significantly increased.
- 2. Data is adequate and has met the requirements for further analysis.
- 3. Initial analysis of the complete data has been performed
- 4. Data is integrated for conclusion analysis
- 5. Progress Report (preliminary analysis has been performed) and draft output have been prepared.



R&D Result is essential and significant to support decisions and policies.

- 1. Report (analysis has been concluded) has been prepared.
- 2. Social, Humanity, and Education R&D results/ output (preparation of recommendation / policy brief and other matters) have been generated.
- Draft recommendations (alternative government regulation, policy, or intervention) have been generated.
- 4. List of parties related to the recommended regulation/ policy/intervention has been identified.



- 5. Initial communication with the related parties (internal/ external) has begun.
- Cover Letter for R&D Results / Output submission has been prepared.

TRL for the Arts

LEVEL DEFINITION/STATUS

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Basic principles of the arts have been observed and reported.

1. Background and problem

INDICATOR

- statement have been identified;
- Answered R&D questions (research/creative question) to obtain findings;
- R&D purposes have been defined by observing the R&D problem statement;
- Problem has been identified to obtain foundation of thoughts as the approach;
- Research/design/creation/ broadcast approach has been determined;
- Empirical facts and basic arguments which are relevant and support the need of R&D;
- Previously available literature study, research theory/empirics to serve as the basis of the R&D;
- 8. Means/method/process to be observed/created/applied and developed are available and have a potential of success.



2

Concept and/or application of forms of the arts has been formulated and explored;

- Basic principles of the R&D have been explored;
- Available basic principles of R&D which are qualitative, unique, particularism (facts, details), meanings interpretation, and descriptivenarrative;
- R&D design (research design) has been communicated to a focus group discussion (FGD) (for art creation and certain research topics only) which refers to the creative, productive, and distributive flowchart;
- Basic elements of the arts, namely appearance, content, and performance have been determined;
- Characteristics of the aesthetic elements have been mastered and understood;
- Alternative methodology, procedure and phases to be followed have been traced;
- Available model and simulation of creative process for art creation which can determine the result;
- Analysis to verify the basic principles of the creation has been performed;

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INDICATOR



Methodology of Research/ Design/Creation/Broadcasting has been completely prepared.



- 2. Argumentation has been prepared for the research questions and the creative questions on the design/ creation/broadcasting which are designed according to the source of art creation and/or gathering of needs and data collection techniques;
- Identification of the problem of the research/design/ creation/broadcasting has been established to determine the theoretical foundation or foundation of thoughts;
- Research/design/creation/ broadcasting approach has been mastered and understood;
- Characterization of aesthetic components and cultural elements to be developed have been mastered and understood;







DEFINITION/STATUS LEVEL **INDICATOR**

- 6. Adequate and complete data;
- 7. Technical evaluation of the creative process of the research/design/creation/ broadcasting;
- 8. Research/design/creation/ broadcasting design have been theoretically and empirically identified.

Creative process implementation of studio works or laboratory environment in the development of the art work prototype.

- Integrated basic components 1. of the creation method and process perform well and are sustainable;
- 2. Originality and uniqueness of the art product enriches national personality and identity;
- 3. The resulting prototype is of studio-scale;
- Testing has been performed 4. to obtain evaluation or critics from the circle of competent observers.

Validation of studio-scale prototype/product/art work.

- The category of the art work 1. prototype has been determined based on its equivalence with similar type of art work;
- 2. Studio-scale prototype has been developed as part of

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INDICATOR

innovation and actualization of the art style.

- 3. Studio-scale testing of the prototype's representational level against the national and international standards applicable.
- Studio-scale validation testing 4. of the prototype has been performed by using currently applicable aesthetics.



Demonstration of model or system/subsystem prototype in a relevant environment.

- Studio-scale validation testing 1. of the prototype constitutes a strategic part of the dissemination of the relevant cultural art product with competitiveness.
- 2. Studio-scale testing of the prototype to find out the level of public trust or satisfaction regarding the product's quality.
- Substantiation of the level of 3. public trust or satisfaction and the prototype's effectiveness on a commercial scale in a limited number.
- Prototype has been tested 4. with high studio/laboratory accuracy/fidelity in a public simulation as its social basis.
- 5. Studio test has been conducted to analyze technical and financial feasibility in creative business.







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