Office of the Principal Scientific Adviser
to the Government of India

# NATIONAL TECHNOLOGY READINESS
## Assessment Framework

A Comprehensive Guide for
Assessing scientific and technical Project Proposals

***Developed by:*** *Confederation of Indian Industry (CII) at the behest of the Office of the Principal Scientific Adviser (PSA) to the Government of India.*

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## PREFACE

As India marches resolutely towards the vision of a *Viksit Bharat* by 2047, the role of science and technology has never been more pivotal. We are witnessing an unprecedented era of innovation where our laboratories, academic institutions, and startups are generating world-class intellectual property. However, the true measure of our scientific prowess lies not just in the brilliance of our discoveries, but in our ability to translate them into tangible, deployable, and commercially viable solutions that serve the nation and the world.

For too long, a significant number of promising Indian innovations have struggled to cross the proverbial "valley of death", the arduous journey from a laboratory proof-of-concept to a scalable, market-ready product. A primary contributor to this challenge has been the lack of a unified language to articulate technological maturity. When academia, industry, and funding bodies speak different dialects regarding "readiness", it leads to misaligned expectations, stalled transfers, and inefficient resource allocation.

To bridge this divide, it gives me great pleasure to unveil the National Technology Readiness Assessment Framework (NTRAF).

This document is more than just a set of definitions; it is a strategic compass for the Indian innovation ecosystem. While the foundation of this framework rests on the globally accepted Technology Readiness Levels (TRL) pioneered by NASA, we have significantly adapted and evolved it to suit the unique contours of the Indian R&D landscape. Developed by the Confederation of Indian Industry (CII) at the behest of my office, this framework integrates comprehensive programmatic indicators alongside technical milestones. It compels us to ask not only "Is the technology working"? but also "Is it robust enough for the operational environment"? and "Is it ready for deployment"?

This framework arrives at a critical juncture as we operationalize the Anusandhan National Research Foundation (ANRF) RDI Fund and other major RDI initiatives. It will serve as the definitive standard for objectively assessing projects seeking national funding, ensuring that public capital effectively de-risks innovations that are on a clear trajectory toward commercialization.

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I commend the CII and the multidisciplinary team of experts who have meticulously crafted this guide, including the sector-specific nuances for domains like Healthcare and Software. I urge all stakeholders - researchers, project investigators, industry leaders, and policymakers to adopt this framework as an integral part of their development lifecycle and give us feedback for further improvements.

Let this document serve as the bridge that connects our scientific ambition with industrial reality, ensuring that Indian innovation is not just inventive, but deployment-ready.

**(Ajay K Sood)**

**Date: 17th December 2025**

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## Foreword

Efficient allocation of resources and strategic prioritization are the cornerstones of effective public policy in science and technology. As India's innovation ecosystem expands in both scale and complexity, there is a growing imperative to standardize how we evaluate technical proposals, monitor their progress, and measure their readiness for deployment.

This publication, the National Technology Readiness Assessment Framework (NTRAF), serves as a pivotal guide to meeting this challenge. It provides a consistent, robust, and universally applicable methodology for funding organizations, research institutes, and industrial partners across the country. By establishing a common language for technology maturity, we aim to bridge the often-subjective gap between a researcher's claim of readiness and an investor's or evaluator's requirement for proof.

The strength of this framework lies in its move from qualitative estimation to a clear objective mechanism. It introduces a rigorous, evidence-based approach to assessment. The framework details a logical progression: starting from a pre-assessment to determine the Anticipated TRL, followed by a deep-dive into detailed readiness criteria where every critical question must be satisfied with tangible documentation. This structured scrutiny ensures that technology development is not just about scientific discovery, but also about engineering validation, manufacturing feasibility, and programmatic compliance.

Furthermore, the framework acknowledges that one size does not fit all. Different technology sectors have unique development trajectories and regulatory hurdles. The inclusion of sector-specific annexures, such as those for Healthcare & Pharmaceuticals and Software ensures that the tool remains versatile and relevant across the entire Research & Development spectrum, regardless of the domain.

This document is intended to serve as a definitive guide for the entire scientific community. For Project Investigators, it is a self-assessment tool to realistically gauge their standing and identify gaps in their development roadmap. For Review Committees and Funding Bodies, it serves as a standardized ruler to compare diverse proposals on an equal footing.

By integrating this progression framework into the lifecycle of any technical project, we ensure that our scientific endeavours have a clear, measurable trajectory toward impact and commercialization.

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## Foreword

In the dynamic landscape of global innovation, the ability to accurately assess the maturity of a technology is paramount for industrial adoption and economic growth. As India accelerates its journey toward becoming a global technology hub, the synergy between our research institutions and the industrial sector becomes the catalyst for this transformation. Industries operating in complex sectors such as space, aviation, defense, and energy have long recognized that a standardized metric for technology maturity is essential to mitigate risk and ensure successful deployment.

The **National Technology Readiness Assessment Framework** represents a monumental step forward in synchronizing the expectations of the research community with the rigorous demands of the industry. For too long, promising innovations have faced challenges in traversing the gap between a laboratory proof of concept and a commercially viable product. This divergence often stems from a lack of a common vocabulary regarding what constitutes a deployment ready technology. By adopting a robust process for assessment, we are creating a transparent mechanism where the status of a technology is universally understood by all stakeholders.

This framework is the result of concerted efforts by a dedicated multidisciplinary team of experts from industry, academia, and research laboratories who have leveraged their collective competence to craft a tool tailored for the Indian ecosystem. It integrates vital commercial indicators and does not look at technology in isolation. Instead, it incorporates elements of manufacturing maturity, quality assurance, and programmatic requirements into the assessment criteria.

Furthermore, the framework moves beyond subjective evaluation to a clear and objective mechanism. It mandates that every claim of advancement be backed by specific evidence, ensuring that a project classified at a high readiness level has indeed weathered the rigors of operational testing and validation. This rigorous approach will empower funding agencies to allocate resources with greater precision and enable private sector partners to invest with higher confidence.

The Confederation of Indian Industry is proud to have developed this framework at the behest of the Office of the Principal Scientific Adviser. We believe that its wide adoption will significantly reduce the friction in technology transfer. It will enable Indian industry to absorb and commercialize indigenous research with greater speed, ensuring that our nation remains at the forefront of the global technological frontier.

**Mr Chandrajit Banerjee**
**Director General**
**Confederation of Indian Industry (CII)**

## Executive Summary

In the domain of technology management, precision is paramount. A recurring challenge in the R&D lifecycle is optimism bias, where the perceived readiness of a technology often outpaces its actual engineering status. The **National Technology Readiness Assessment Framework (NTRAF)** is designed to address this asymmetry by deploying a rigorous, data-centric protocol for evaluation. Unlike traditional review mechanisms that may rely on qualitative narratives, this framework necessitates a granular audit of the innovation lifecycle. By calibrating globally accepted TRL methodologies to the specific operational realities of the Indian ecosystem, we have established a metric that scrutinizes not just the core scientific principle, but the integration and functionality of the entire system.

This document serves as a comprehensive operational toolkit for the scientific community. It introduces a structured, two-tier assessment logic: first establishing an "Anticipated TRL" and then subjecting it to a deep-dive verification against critical, non-negotiable criteria. This methodology effectively transforms the abstract concept of "maturity" into measurable milestones, ensuring that technical debt is identified and addressed early in the development curve. For the innovation ecosystem, this signals a pivotal shift from output-based reporting (such as publications) to outcome-based progression (such as validated systems), aligning the "supply" of academic research with the rigorous "demand" of industrial application.

As we scale up national efforts through the Anusandhan National Research Foundation (ANRF) and other deeptech vectors, the integrity of our assessment processes becomes the bedrock of success. This framework acts as the technical backbone for these initiatives, providing the requisite transparency to de-risk high-stakes investments. By adopting this standardized protocol, we are ensuring that Indian innovation is not only inventive but is also robust, reproducible, and engineered for global integration.

By,

Rohit Gupta
Chief Technology Officer,
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# 1. Introduction and Rationale

The successful transition of research breakthroughs into viable, deployable, and commercialized products is critical for India's technological self-reliance and economic growth. This document introduces the National Technology Readiness Assessment Framework (NTRAF), a robust, structured methodology designed to objectively measure the maturity and associated risks of technical project proposals. By providing a standardized metric for assessment, this framework enables consistent, transparent, and rigorous evaluation of innovations across diverse technology domains and development lifecycles, regardless of the funding source or sector.

### 1.1. Evolution of the Readiness Framework

Technology Readiness Level, or TRL, was developed by NASA in the mid 1970's and later formally defined in 1989 by Sadin et al. (Ref 1). This was aimed at assessing maturity of complex technology development and check flight readiness for a mission. The scale originally had 7 levels but was further modified in 1995 as a 9-level scale (Ref 2). In 1990s NASA adopted the TRL scale with 9 levels, which gained acceptance across organizations and industries around the world (Ref 3). Different organizations have tweaked the levels over the years to suit their specific needs, but the essence of the scale and the different levels have remained relatively same over the years. Additionally, different other "readiness level" measures were proposed too. For example, in the mid-2000s, United States Department of Defense (DOD) proposed Manufacturing Readiness Level (MRL) to measure the maturity of manufacturing process readiness of a technology, system or subsystem (Ref 4). The technology maturity of a particular technology was measured by TRL, but the interaction between multiple new technologies to form a system was not considered there. In 2006-2010 Gove and Sauser et al. developed the Integration Readiness Level (IRL) to measure integration maturity on a scale similar to TRL, and subsequently the defined Systems Readiness Level, or SRL, which combined multiple TRLs and IRLs to assess the maturity level of systems consisting of multiple technologies (Ref 5,6). It should be noted that there are several bodies of work by different authors and organizations around some of these concepts, with slightly different methodologies, all with the aim of being able to understand the progress of maturity more accurately in real world research and development, from conception of idea to production and commercialization.

Based on the existing processes in different organizations, global as well as Indian, an initial proposal of guidelines has been provided for a consistent and robust assessment of TRL by funding organizations and research institutes in India. The suggested next steps have been later summarized to take this forward to make consistent and robust TRL assessment a reality.

## 2. Core Definitions: Technology Readiness Levels (TRL)

TRL was developed by NASA as a metric to assess maturity of a specific technology as it progresses from a concept stage to implementation. Beyond the definitions, NASA has also provided descriptions for each level for hardware and software and exit criteria for each level (Ref 20). US DOD further added some descriptions to elaborate on the definitions. Subsequently, the European Union provided slight modifications to the definitions given by NASA.

The framework utilizes nine Technology Readiness Levels (TRL 1 to TRL 9). The following definitions and descriptions, adapted from the European Union, US DOE, and US DOD, are proposed for consistency:

| TRL | Technology Development Stage | Definition | Description |
|---|---|---|---|
| **1** | Basic Technology Research | Basic principles observed and reported | Lowest level of technology readiness. Scientific research begins to be translated into applied research and development |
| **2** | Research to Prove Feasibility | Technology concept formulated | Invention begins. Once basic principles are observed, practical applications can be invented. Applications are often speculative |
| **3** | Research to Prove Feasibility | Experimental proof of concept | Active Research and Development (R&D) is initiated. Work moves beyond the paper phase to experimental work and laboratory studies validate predictions |
| **4** | Technology Demonstration | Component and/or system validation in lab | Basic technological components are integrated to establish that they will work together. TRL 4-6 is the bridge from scientific research to engineering |
| **5** | Technology Demonstration | Laboratory scale, similar system validation in relevant environment | Basic components are integrated with reasonably realistic supporting elements and tested in a simulated environment |

| | | | |
|---|---|---|---|
| **6** | Technology Demonstration | Engineering/pilot-scale prototype demonstrated in relevant environment | Representative model or prototype system, which is well beyond TRL 5, is tested in a relevant environment. This is the step up from laboratory scale to engineering scale |
| **7** | System Commissioning | Full scale system prototype demonstration in operational environment | Prototype near, or at, planned operational system. Requires demonstration of an actual system prototype in an operational environment |
| **8** | System Commissioning | System complete and qualified through test and demonstration | Technology has been proven to work in its final form and under expected conditions. This represents the end of true system development |
| **9** | System Operations | Actual system proven in operational environment over full range of expected conditions | Actual application of the technology in its final form and under mission conditions (e.g., Operational Test and Evaluation) |

### 2.1 Adoption of TRL Assessment

Different organizations and industries have adopted TRL as a way to assess maturity and risk over the years for complex programs – these include industries in space, aviation, defense, oil and gas, and infrastructure (Ref: 7). There are two key aspects of utilization of TRL levels in organizations (1) Adoption and Integration of TRL levels along with the organization's own tollgate or review process, and (2) A Robust process for assessment of TRL levels. For example, the US DOD has mapped the TRL scale to their System Acquisition Process as shown in Figure 1 (Ref 7, Ref 8). Similarly, European Space Association (ESA) defined the TRL levels slightly differently based on their requirement and also integrated the TRL levels to their program decision making process (Ref 9). They recommended that the technology readiness assessment should be made by an independent review as part of the regular project reviews. They also mapped the TRL levels to their project phases -for example, Phase B1 – where the decision to move to industrial implementation is taken and implies significant financial investment – was recommended to include a TRL assessment and only programs at TRL 6 or higher should be able to move past this phase. However, they also mentioned that not all their phases are linked to TRLs, which indicates a partial integration of the TRL assessment in their program assessment mechanism. In another such example, the US Department of Energy (DOE) incorporate the TRL methodology in their critical decision-making process (Ref 10). From CD-0 to CD-5, the five Critical Decisions are major milestones that establish the mission need,

recommended alternative, acquisition strategy, and other essential elements to ensure project meets appropriate requirements. Guidance was put together to perform Technology Readiness Assessment (TRA) at 3 different stages, and recommended TRL completions were provided to map with the Critical Decision process.

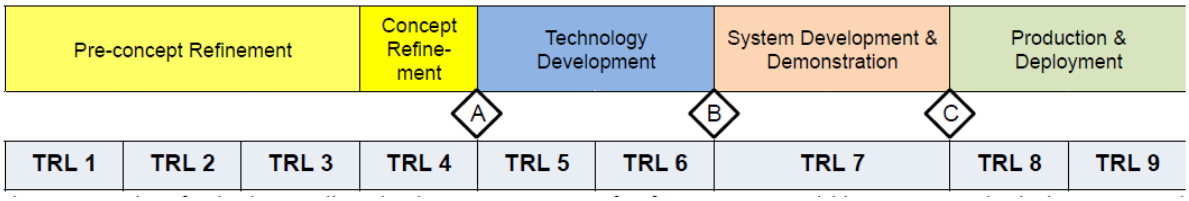



*Fig 1: DOD process integration for TRL (Ref 8)*

## 3. The Technology Readiness Assessment (TRA) Process

### 3.1 Definition

Several corporate research and development organizations have also adopted the TRL methodology as part of their processes and integrated the TRL assessment as part of their review system. For example, General Electric has adopted the TRL assessment methodology and uses the standard definitions as part of their review process and also to create a common understanding of progress and risk during handoffs between research, development and implementation teams. As an idea moves from Idea / Discovery phase, through Feasibility, Technology Transfer, and NPI (New Product Introduction) these are mapped with the appropriate TRL levels which form a common language between teams. Different business units have specific tollgate reviews or technology development milestones – which form part of the program management and review process in the company – mapped to different TRLs, essentially ensuring graduation from a specific TRL before crossing a particular review milestone.

Clearly, the TRL methodology has been adopted by a lot of institutions and one common thing which led to their successful adoption has been the integration of the readiness levels in their existing review mechanism. The other important ingredient for success is a defined (written) guideline in each of these institutes for the implementation of the TRL assessment – that is the Technology Readiness Assessment (TRA) process. Some of the key elements of that process, as seen in different institutes are summarized below.

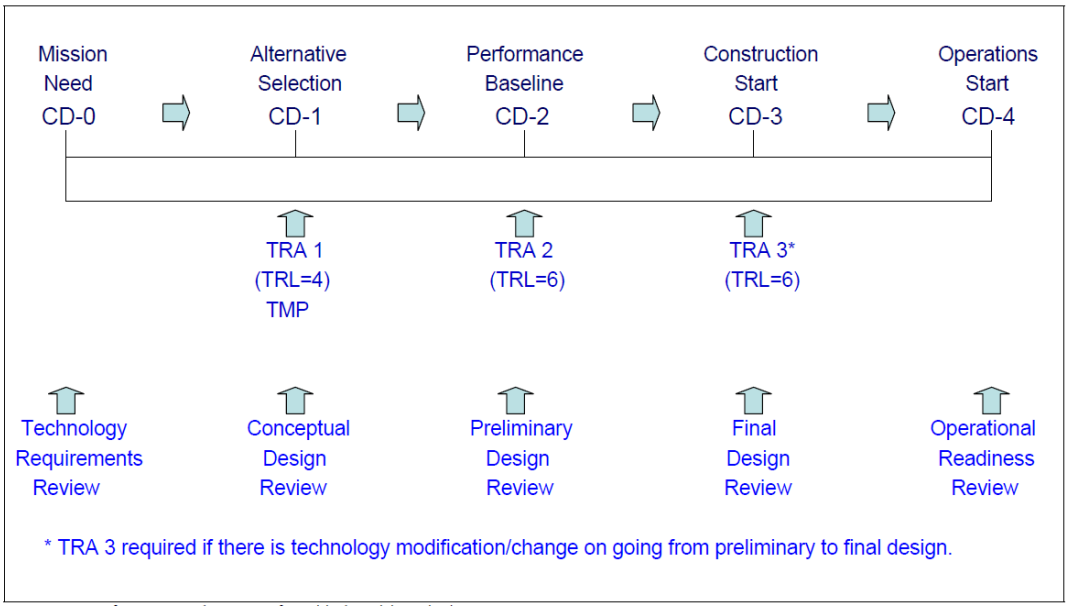



*Fig 2: DOE process for TRL integration with design review process (Ref 10)*

A few definitions that are important are given below – a further comprehensive list of definitions are available in the references:

**Breadboard**: Integrated components that provide a representation of a system/subsystem and that can be used to determine concept feasibility and to develop technical dat – may resemble final system in function only.

**Critical Technology Element (CTE)**: A technology element is "critical" if the technology element or its application is either new or novel and is critical to the success of the project. Typically, TRL assessments are done only for critical technology elements of the project.

**High Fidelity**: A representative of the component or system that addresses form, fit and function. A high-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specification within a laboratory setting.

**Low Fidelity**: A representative of the component or system that has limited ability to provide anything but first-order information about the end product. Low fidelity assessments are used to provide trend analysis.

**Operational Environment**: Environment that addresses all the operational requirements and specifications required of the final system to include platform/packaging.

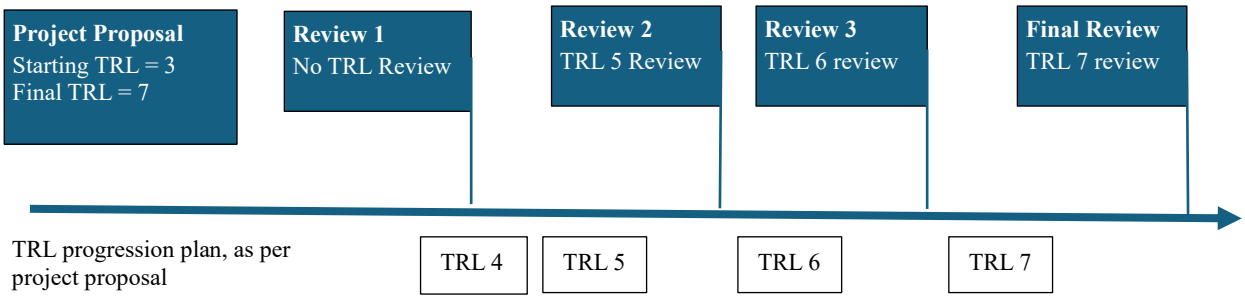
**Relevant Environment**: Testing environment that simulates the key aspects of the operational environment, such as physical and chemical properties

A key element of NTRAF is a defined and written guideline for the implementation of the TRL assessment. The assessment process is structured into a logical, two-step questionnaire flow:

### 3.2. TRA Process

The TRA process needs to be integrated with the process of funded research between the funding organization and research institute. In absence of comprehensive information of the existing processes, we are recommending some generic guidelines which can be tuned based on the specific processes for a specific organization.

Typically, when a project is funded, there is an initial TRL and the final desired TRL for the project which is documented along with the project proposal. Subsequently, the project goes through intermittent time based (e.g. quarterly, or half yearly) or toll gate based (T1, T2, etc.) reviews. Either way, the project plan is well documented in terms of requirements of progress within a specific period of time / specific tollgate. To be able to adhere to and accurately measure TRL progression, we propose that the TRL progression timeline should also be proposed at the time of project proposal and approved during fund approval along with project plan. There is no specific guideline on how long movement from TRLn to TRL(n+1) should take, as that depends on multiple factors like funding level, technology domain, project plan, etc. – however, the plan should be laid out and followed from then on. During the subsequent reviews, we propose that the TRL progression should be one of the review parameters, along with other technical and financial reviews. A sample TRL progression plan can be seen below:




In the above example, Reviews 2, 3 and the final Review should have appropriate TRL reviews built into the plan. In an alternate example, it could be decided before-hand specific critical TRL stages which will be reviewed in detail - e.g. TRL 4, TRL 6 and maybe the final TRL. Another aspect of the process is the process of TRL assessment itself. The next segment covers the methodology in detail – however it is important plan for TRA well in advance of the scheduled review timeline. Several documentations from US govt. funding agencies who use this rigorously shows that the process of assessment can take several weeks, so it is the responsibility of the TRA owner to start the process with enough time in hand so that it is completed in time for the review schedule.

Before the TRL review is started, preferably at the beginning of the program / or at least before the first TRL review, the Critical Technical Elements (CTEs) need to be identified. These are identified for each project based on the novelty of the technical elements, and their criticality to the success of the project. A typical project would have multiple CTEs, and TRL assessment needs to be performed on each determined CTE.

### 3.3 Process Flow

| | |
|---|---|
| 1 | Pre-Assessment: Start answering Level 0 questions. Based on the score, move to Level 1 questions |
| 2 | Start answering Level 1 questions from top. Once you hit a "yes", stop. That is the "Anticipated TRL". |
| 3 | Start answering Level 2 questions for Anticipated TRL (e.g. - if Anticipated TRL is 6, please answer TRL 6 questions in Level 2). |
| 4 | If all "CRITICAL" questions in Level 2 are answered Yes, then project is certified to be in that TRL |

| | |
|---|---|
| 5 | If any "CRITICAL" question in Level 2 is answered NO, or appropriate documentation is not provided, the program fails the particular TRL test. Please repeat step 2 for TRL (n-1) - i.e. TRL 5 in this example. |

| | |
|---|---|
| 6 | Submit TRL assessment for review. |

### 3.3. Step 1: Pre-assessment (Level 0 Questions)

| TRL No's | Indicator | Marks |
|---|---|---|
| **Proof of concept:** | | |
| 1 | Minimal evidence of a theoretical concept or basic principles | 5 |
| 2 | Some initial feasibility analysis conducted | 7 |
| 3 | Clear proof of concept demonstrated | 10 |
| **Prototype development**: | | |
| 4 | Early-stage development with some progress | 12 |
| 5 | Ongoing development with a functional prototype | 16 |
| 6 | Advanced prototype demonstrating key functionalities | 20 |
| **Manufacturing/Commercialization**: | | |
| 7 | Initial stages of planning for manufacturing | 23 |
| 8 | Manufacturing processes initiated but not yet at scale | 27 |
| 9 | Full scale manufacturing underway with established processes | 30 |
| | **Total** | |

Take an initiate TRL estimate based on the total scores:

1. Score is between 0-22: Most likely, the technology/ product will be in the Proof-of-Concept stage (TRL 1-3 band)

2. Score is between 23-70: Most likely, the technology/ product will be in the Prototype development stage (TRL 4-6 band)

3. If the Score is between 70-150: Most likely, the technology/ product will be in the Manufacturing/ Commercialization stage (TRL 7-9 band)

### 3.4. Step 2: Anticipated TRL (Level 1 Questions)

The Level 1 questionnaire involves asking top-level questions, typically starting from TRL 9 and moving down, or TRL 1 and moving up. The highest TRL for which the answer is YES (with supporting documentation) becomes the Anticipated TRL.

| TRL Stage | Top Level question (Step 1) | Basis & Supporting Documentation |
|---|---|---|
| 9 | Has the actual system successfully operated over full range of conditions in operational environment? | Operational Environment Testing Report - data and findings from testing the actual system in various operational conditions, demonstrating its successful operation |
| 8 | Has the actual system successfully operated in limited operational environment? | Limited Operational Environment Testing Report - data and findings from testing the actual system in specific operational conditions to validate its performance |
| 7 | Has the full scale system prototype successfully been demonstrated in relevant operational environment? | Full-Scale System Prototype Demonstration Report - Documents the successful demonstration of the full-scale system prototype in a relevant operational environment, including performance metrics and results |
| 6 | Has the engineering/pilot-scale prototype been demonstrated in relevant environment? | Engineering/Pilot-Scale Prototype Demonstration Report - details on the successful demonstration of the engineering or pilot-scale prototype in an applicable environment, highlighting key performance aspects |
| 5 | Has the laboratory scale prototype been validated in relevant environment? | Laboratory-Scale Prototype Validation Report - data and outcomes of validating the laboratory-scale prototype in an environment relevant to its intended application |
| 4 | Has the component / system been validated in lab? | Component/System Validation Report - data and findings related to the validation of individual components or the entire system in a controlled laboratory setting |

| | | |
|---|---|---|
| 3 | Has the proof of concept been demonstrated in a simulated environment? | Proof of Concept Simulation Report -details about the simulation methodology, data sources, results, analysis, conclusions, and recommendations for the demonstrated concept's feasibility |
| 2 | Has the technical solution for the system and/or process concept been formulated? | Technical Solution Formulation Document - outline the proposed technical solution, including architecture, design, and key components. Provide a clear description of how the solution addresses the identified problem with diagrams |
| 1 | Have the basic technology and principles been observed and reported? | Research Observation Report with supporting Literature Review and Research Findings |

### 3.5 Step 3: Detailed Readiness Criteria (Level 2 Questionnaire)

In Step 3, evaluation of the detailed questions is started one level below the anticipated TRL level for each CTE – e.g. if anticipated TRL is 6, in step 2, we start by answering questions corresponding to TRL 5. A final TRL is achieved when all the questions are answered yes. Note that these questions are not just technology focused in nature, but also incorporate elements of manufacturing, quality, program management, customer engagement and system thinking to some extent.

- **Pass Criteria:** All critical criteria for the target TRL (or lower) must be answered **YES**.
- **Failure Criteria:** If a critical criterion is answered **NO**, the project cannot be classified at that TRL and is pegged at the next lower TRL (TRL n-1).

This section provides the comprehensive criteria, categorized by **Technology (T)**, **Manufacturing (M)**, and **Programmatic/Quality (P)**, used to objectively score each TRL. All criteria marked with (Y) are **Critical** for achieving that readiness level.

| TRL Stage | Category | Critical (Y/N) | Answer (Y/N) | Criteria / Question | Basis & Supporting Documentation |
|---|---|---|---|---|---|
| **1** | **T** | **Y** | | **Paper studies confirm basic principles** | **Literature Review, Scientific Papers Confirming Principles** |
| 1 | T | | | Do rough calculations support the concept | Prelim calculations, data |
| 1 | T | | | Physical laws and assumptions used in new technologies defined | Assumption Documentation, Laws and Principles Applied |

| | | | | | |
|---|---|---|---|---|---|
| 1 | P | | | Initial scientific observations reported in journals/conference proceedings/technical reports | Published Observations and Technical Report |
| 1 | T | | | Basic scientific principles observed | Scientific Observations and Findings. |
| **1** | **P** | **Y** | | **Know who cares about technology, e.g., sponsor, money source** | **Stakeholder Identification and Communication Records** |
| **1** | **T** | **Y** | | **Research hypothesis formulated** | **Hypothesis Formulation Documentation** |
| 1 | T | | | Basic characterization data exists? | Characterization Data and Initial Observations |
| 1 | P | | | Know who will perform research and where it will be done | Research Team and research facility/lab Identification |
| 2 | P | | | Customer identified | Customer identification documentation |
| **2** | **T** | **Y** | | **Potential application(s) for system or component have been identified** | **Application identification and feasibility study conducted and record** |
| **2** | **T** | **Y** | | **Paper studies show that application(s) is(are) feasible** | **Feasibility Studies and Supporting Research.** |
| 2 | P | | | Know what system/program the technology will support | Identification of relevant system and its documentation |
| **2** | **T** | **Y** | | **An apparent theoretical or empirical design solution identified** | **Design identification and its documntation** |
| 2 | T | | | Desktop environment | Desktop Environment specifications documentation |
| **2** | **T** | **Y** | | **Based on shortlisted scieintific principles, expected performance predictions of each technological element to be documented"** | **Performance Predictions and Documentation.** |
| 2 | P | | | Customer expresses interest in application | Customer Interest and Communication Records |
| 2 | T | | | Initial analysis shows what major functions need to be done | Preliminary Function Analysis and Documentation |

| | | | | | |
|---|---|---|---|---|---|
| 2 | P | | | System architecture defined in terms of major functions to be performed | System Architecture Documentation. |
| 2 | T | | | Rigorous analytical studies confirm basic principles | Analytical Studies Reports |
| 2 | P | | | Analytical studies reported in scientific journals/conference proceedings/technical reports | Analytical Studies Publications and Reports |
| 2 | T | | | Individual parts of the technology work (No real attempt at integration) | Individual Component Testing Records |
| 2 | P | | | Investment Strategy Sheet (cost, plan) | Sheet containing costing and planning |
| 2 | P | | | Know capabilities and limitations of researchers and research facilities | Researcher and Facility Assessment Documentation including resource availability, capacity, scaling etc as relevant |
| 2 | T | | | Know what experiments are required | Experiment details documentation |
| **2** | **P** | **Y** | | **Qualitative idea of risk areas (cost, schedule, performance)** | **Document related to quality assessment and performance measurement** |
| **2** | **P** | **Y** | | **Have rough idea of how to market technology (Who's interested, how will they find out about it?)** | **Rough Marketing Strategy and Audience Identification.** |
| 3 | P | | | Some key process and safety requirements for developing the technology are identified | Key Process and Safety Requirement Identification. |
| **3** | **T** | **Y** | | **Predictions of elements/components of technology validated by Analytical and/or experimental Studies** | **Predictions Validation Records** |
| 3 | T | | | Science known to extent that mathematical and/or computer models and simulations are possible | Mathematical/Computer Models and Simulation Plans |

| | | | | | |
|---|---|---|---|---|---|
| **3** | **P** | **Y** | | **Preliminary system performance characteristics and measures have been identified and estimated** | **Preliminary System Performance Characteristics Documentation** |
| 3 | M | | | No system components, just basic laboratory research equipment to verify physical principles | Equipment Verification Records. |
| **3** | **T** | **Y** | | **Laboratory experiments verify feasibility of application** | **Feasibility Verification Through Laboratory Experiments and reports** |
| **3** | **T** | **Y** | | **Predictions of elements of technology capability validated by Laboratory Experiments** | **Predictions Validation Through Laboratory Experiments and documented results and reports** |
| 3 | P | | | Customer representative identified to work with development team | Customer Representative Identification and Communication |
| 3 | P | | | Understand Voice of Customer | Document customer feedback or inputs |
| **3** | **T** | **Y** | | **Cross technology effects (if any) have begun to be identified** | **Cross technology effect identification, eports outline how different technologies or components may interact with each other.** |
| 3 | T | | | Paper studies indicate that system components ought to work together | research papers and articels etc |
| **3** | **T** | **Y** | | **Performance Metrics for the system established** | **Performance Metrics Documentation.** |
| **3** | **P** | **Y** | | **Scaling studies have been started** | **Documentation of scaling of technology** |
| 3 | M | | | Current manufacturability concepts assessed | Manufacturability Assessment Record and documentation |
| 3 | M | | | Sources of key components for laboratory testing of system identified | Identification of Key Component Sourcing documented |
| 3 | T | | | Scientific feasibility fully demonstrated | Demonstration result and reports |

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| 3 | T | | | Analysis of present state of the art shows that technology fills a need | Documentation of technology fir for purpose |
| 3 | P | | | Risk mitigation strategies identified | Risk management plan and strategy documented |
| 3 | P | | | Rudimentary best value analysis performed, not including cost factors | Best Value Analysis Records |
| **3** | **T** | **Y** | | **The individual components have been tested at a laboratory scale** | **Testing of components and their results** |
| **3** | **T** | **Y** | | **Overall system requirements for end user's application are known** | **System Requirements Documentation** |
| 4 | T | | | Cross technology issues (if any) have been fully identified | Cross-Technology Issue Identification Documentation |
| 4 | M | | | Laboratory components tested are surrogates for system components | Laboratory Component Testing Documentation and reports |
| **4** | **M** | **y** | | **Piece parts and components in a pre-production form exist** | **Pre-Production Component Documentation** |
| **4** | **T** | **Y** | | **Modelling and Simulation used to simulate some components and interfaces between components** | **Simulation reports, interface compatibility report** |
| **4** | **P** | **Y** | | **System performance metrics have been established & subsystem / component requirements derived from system metrics.** | **Performance Metric Documentation and list of components** |
| **4** | **M** | **Y** | | **Available components assembled into system breadboard** | **System Breadboard Assembly Documentation** |
| **4** | **T** | **Y** | | **Laboratory experiments with available components show that they work together** | **Lab experiment reports** |

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| 4 | T | | | Analysis completed to establish component compatibility | Component compatibility report - details on version compatibility, dependencies, and potential conflicts, |
| 4 | P | | | Science & Technology exit criteria established (understood, documented, and agreed upon by sponsor) | Relevant documents |
| **4** | **T** | **Y** | | **Technology demonstrates basic functionality in simplified/simulated environment** | **Basic Functionality Demonstration Reports** |
| 4 | M | | | Scalable technology prototypes have been produced | Scalable Prototype Documentation |
| 4 | P | | | Draft conceptual designs have been documented | Conceptual Design Documentation |
| 4 | M | | | Design techniques identified/defined to where small applications may be analyzed/simulated | Design Technique Documentation |
| 4 | P | | | Initial cost drivers identified | Costs documents and drivers of cost |
| 4 | M | | | Integration studies have been started | Report on study conducted on integration of components |
| **4** | **M** | **Y** | | **Key manufacturing processes identified and assessed in laboratory** | **Manufacturing process assessment report** |
| 4 | P | | | Scaling documents and diagrams of technology have been completed | Reports and documents related to scaling |
| **4** | **T** | **Y** | | **Low fidelity technology "system" integration and engineering completed in a lab environment** | **Simplified overview of the integration between different components or systems** |
| 4 | M | | | Mitigation strategies identified to address manufacturability / producibility shortfalls | Mitigation Strategy Documentation |
| 4 | P | | | Integrated Product Team (IPT) formally established with charter | IPT charter document |

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| **4** | **P** | **Y** | | **Preliminary Failure Mode and Effects Analysis (FMEA) or Risk Waterfall analysis performed** | **Risk analysis report** |
| 4 | P | | | Technology availability dates established | Relevant documents |
| 5 | T | | | Cross technology effects (if any) identified and established through analysis | Cross technology effect identified and established documented and reported |
| 5 | M | | | Pre-production hardware available | Pre-production Hardware Availability Documentation |
| 5 | M | | | Trade studies and lab experiments define key manufacturing processes | Trade Study and Experiment Documentation |
| **5** | **T** | **Y** | | **Interfaces between components/subsystems are realistic (Breadboard with realistic interfaces)** | **Interface Realism Documentation** |
| 5 | M | | | Tooling and machines demonstrated in lab | Tooling and Machine Demonstration Documentation |
| **5** | **T** | **Y** | | **High fidelity lab integration of system completed, and lab scale prototye created. Ready for test in realistic/simulated environments** | **High-Fidelity Lab Integration Documentation** |
| 5 | P | | | Form, fit, and function for application addressed in conjunction with end user development staff | Related document |
| 5 | T | | | Fidelity of system mock-up improves from breadboard to brassboard | Mock-Up Fidelity Improvement Documentation |
| 5 | M | | | Quality and reliability considered, but target levels not yet established | Quality and Reliability Assessment |
| **5** | **M** | **Y** | | **Initial assessment of assembly needs performed** | **Assembly need assessment** |

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| 5 | P | | | Draft Systems Engineering Master Plan (SEMP) addresses integration, test & evaluation, mechanical and electrical interfaces, and final performance | Master plan document |
| 5 | P | | | Draft Test & Evaluation Master Plan (TEMP) completed | Report of test conducted |
| **5** | **P** | **Y** | | **Value analysis includes life-cycle cost analysis** | **Value Analysis with Life-Cycle Cost Documentation** |
| **6** | **T** | **Y** | | **Cross technology issue measurement and performance characteristic validations completed** | **Cross Technology Issue Measurement and Validation Documentation** |
| 6 | M | | | Quality and reliability levels on manufacturing established | Standad quality documentation |
| **6** | **T** | **Y** | | **Operating environment for eventual system known** | **Operating and reliabiity document** |
| 6 | P | | | Collection of actual maintainability, reliability, and supportability data has been started | Data collecrtion for maintenance and reliability |
| 6 | M | | | Investment needs for process and tooling determined | Investment needs documentation |
| 6 | P | | | Final Test & Evaluation Master Plan (TEMP) | Final test and master evaluation master plan document |
| **6** | **T** | **Y** | | **Representative model / prototype tested in high-fidelity lab / simulated operational environment** | **Representative model document** |
| **6** | **T** | **Y** | | **Realistic environment outside the lab, but not the eventual operating environment** | **Realistic environment testing documentation** |
| 6 | P | | | Final Systems Engineering Master Plan (SEMP) | Related document |
| **6** | **M** | **Y** | | **Critical manufacturing processes prototyped** | **CMP documentation** |

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| **6** | **P** | **Y** | | **Technology Transition Agreement has been coordinated and approved by end user** | **Architecture, functional and non-functional requirements, hardware and software specifications, security, testing, deployment, and maintenance guidelines** |
| **6** | **P** | **Y** | | **Technology ”system” specification complete** | **Related report** |
| **6** | **P** | **Y** | | **Final Technical Report** | **Final report** |
| **6** | **M** | **Y** | | **Production issues have been identified and major ones have been resolved** | **Production Issue Identification and Resolution Documentation** |
| 6 | M | | | Production demonstrations are complete | Production Demonstration Documentation |
| **6** | **T** | **Y** | | **Engineering feasibility fully demonstrated** | **assessment and testing of a project's engineering feasibility report** |
| **6** | **P** | **Y** | | **Final Transition Plan with Business Case** | **strategy and justification for transitioning a project or system to its final operational state.** |
| **7** | **M** | **Y** | | **Materials and manufacturing process and procedures initially demonstrated** | **procedures and outcomes of testing and validating materials and manufacturing processes for a product** |
| **7** | **T** | **Y** | | **Technology or system tested in relevant operational environment, but not the eventual platform, e.g., test-bed aircraft** | **procedures and results of testing a system or product in its intended operational environment** |
| **7** | **M** | **Y** | | **Materials, processes, methods, and design techniques are moderately developed and verified** | **Documentation on Moderately Developed Materials, Processes, Methods, and Design Techniques** |
| 7 | M | | | Pre-production hardware is available; quantities may be limited | confirms the availability of hardware components before the production phase begins |
| **7** | **T** | **Y** | | **Components are representative of production components** | **Report on how a selected component accurately represents the characteristics and** |

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| | | | | | **performance of the larger system it's a part of.** |
| 7 | M | | | Production planning is complete. | strategies, schedules, and processes for efficiently manufacturing products, including resource allocation, timelines, and quality control measures |
| 7 | T | | | Most functionality available for demonstration in simulated operational environment | report on the availability and performance of a system or component when tested in a simulated operational setting, often used for assessing reliability and readiness |
| 7 | M | | | Prototype improves to pre-production quality | Report on measures and strategies implemented to enhance the quality of a product or process before entering full-scale production. |
| **7** | **T** | **Y** | | **Fully integrated prototype demonstrated in actual or simulated operational environment** | **records the procedures, results, and evaluations of a fully integrated prototype to validate its functionality and performance in a real-world context** |
| 7 | T | | | System prototype successfully tested in a field environment. | records the procedures, observations, and outcomes of testing a system, product, or equipment in its intended field |
| 7 | M | | | Ready for Low Rate Initial Production (LRIP) | Outline the preparations, assessments, and criteria necessary to determine if a system or product is ready for the low-rate initial production phase, focusing on quality, reliability, and cost-effectiveness |

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| **7** | **P** | **Y** | | **Safety/Adverse effects issues have been identified and mitigated.** | **Compile information on potential hazards, safety measures, and adverse effects associated with a product, process, or technology, often for regulatory compliance and risk management purposes** |
| 8 | M | | | Cost estimates <125% cost goals (e.g., design to cost goals met for LRIP) | Calculations and explanations of the projected costs associated with a project, product, or service, including itemized expenses, labor, materials, and overhead costs |
| **8** | **T** | **Y** | | **Technology/system form, fit, and function has been demonstrated in operational environment** | **replacement or alternative component or system maintains the same form (physical characteristics), fit (compatibility with existing structures), and function (performance and capabilities) as the original component or system.** |
| 8 | P | | | Most training documentation completed and under configuration control | Documentation on management and oversight of training materials, records, and procedures to ensure that training is conducted consistently and effectively |
| 8 | P | | | Most maintenance documentation completed and under configuration control | Maintenance Documentation Control |
| **8** | **M** | **Y** | | **Manufacturing processes demonstrate acceptable yield and producibility levels** | **Manufacturing Process Documentation** |
| **8** | **T** | **Y** | | **All functionality demonstrated in simulated operational environmenet** | **Record the procedures, results, and findings of demonstrating the functionality and performance of a system, product, or component within a simulated operational setting** |

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| **8** | **M** | **Y** | | **All materials are in production and readily available** | **Availability of Materials Documentation** |
| **8** | **T** | **Y** | | **System qualified through test and evaluation on actual platform (DT&E completed). System meets specifications** | **System Qualification Documentation including test protocols, test results, inspection reports, validation procedures, and compliance records** |
| 8 | M | | | Ready for Full Rate Production | Document the outline of criteria, assessments, and preparations necessary to determine if a system or product is ready for full-scale production focusing on quality, reliability, cost-efficiency, and capacity to meet production demands |
| **9** | **T** | **Y** | | **System/technology functions as defined in Operational Concept document** | **Record of system, product, or project in alignment with and adhering to its operational concept, ensuring that it meets the intended operational requirements, goals, and specifications** |
| 9 | M | | | Cost estimates <110% cost goals or meet cost goals (e.g., design to cost goals met) | Cost Estimate Compliance Documentation including cost estimates, budget allocations, financial reports, and evidence of cost control measures, |
| 9 | M | | | Affordability issues built into initial production and evolutionary acquisition milestones | Affordability Integration Documentation including strategies, analyses, cost-benefit assessments, and cost-saving measures implemented to ensure that the project remains within budgetary constraints while maintaining quality and performance standards |

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| **9** | **M** | **Y** | | **Design stable, few or no design changes** | **Documentation of strategies that outline how cost-effectiveness and affordability considerations are integrated into the planning, development, and execution of a project, program, or product, with the aim of ensuring that budgetary constraints and financial goals are met while maintaining quality and functionality** |
| **9** | **T** | **Y** | | **System has been installed and deployed in intended operational environment** | **Instructions to guide the process of deploying a system, application, or technology into a production environment. Detailed steps, configurations, and considerations necessary to ensure a successful and smooth transition from development or testing to operational use** |
| **9** | **T** | **Y** | | **Actual system fully demonstrated** | **comprehensive record of the procedures, results, and findings of a complete and comprehensive demonstration of a system or product's functionality and performance under real-world or simulated condition** |
| 9 | P | | | Training Plan has been implemented. | Records and details related to the execution of a training plan within an organization including deliver training programs, workshops, or courses to employees or stakeholders, ensuring that they acquire the necessary skills and knowledge. |

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| **9** | **T** | **Y** | | **Operational Test and Evaluation (OT&E) completed** | **Includes test plans, test results, findings, recommendations, and any necessary corrective actions or follow-up steps based on the outcomes of the OT&E phase** |
| 9 | M | | | All manufacturing processes controlled to 6-sigma or appropriate quality level | Documentation for process workflows, quality control measures, standard operating procedures, equipment calibration and maintenance, material specifications, and process monitoring parameters. |
| 9 | M | | | Stable production | Data on production processes, quality control measures, performance metrics, and any adjustments or improvements made to ensure the ongoing stability and reliability of production operations. |
| **9** | **P** | **Y** | | **All documentation completed** | **Checklists, sign-off sheets, or formal reports indicating that all necessary documents have been prepared, reviewed, and are in compliance with established standards or regulations** |

## 5. Sector-Specific Annexures

To address the unique development pathways and regulatory requirements of distinct technology domains, the following criteria must be assessed **in addition** to the general TRL criteria. These have been illustrated in detail in Annexure A and Annexure B.

## 6. Governance and Documentation

### 6.1. The TRA Report

The purpose of the Technology Readiness Assessment (TRA) report is to document the processes and provide an explanation for the assessed TRL for each Critical Technology Element (CTE). The report should include:

- The assessed TRL and the rationale for the assessment.
- The planned TRL progression.
- Areas where TRL falls short of the criteria and plans to achieve the target levels.
- Assessment of the type and significance of risk to cost, schedule, and performance.

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## Annexure A: Healthcare & Pharmaceuticals

| TRL STAGE | Answer (Y/N) | Criteria / Question | Basis & Supporting Documentation |
|---|---|---|---|
| 1 | | Have you identified a specific need or healthcare challenge that warrants the development of a new technology or solution? | Problem statement documented |
| 1 | | Have the basic principles underlying this healthcare technology been observed and reported? | Scientific Publications and Literature Review |
| 1 | | Have you actively monitored the scientific knowledge base, and have scientific findings been reviewed and assessed as a foundation for characterizing new technologies? | Knowledge Base Assessment Report |
| 2 | | Has conceptual design of the healthcare or pharmaceutical technology been formulated | Conceptual Design Document outlining the design and approach |
| 2 | | Have preliminary in-vitro studies, such as biochemical experiments, been conducted to validate the initial concept? | Experimental Validation Reports detailing the biochemical experiments and their outcomes. |
| 2 | | Have potential challenges or limitations in implementing this concept into a practical solution identified? | Challenges and Limitations Analysis" report |
| 2 | | Have scientific "paper studies" been conducted to generate research ideas and hypotheses related to the healthcare or pharmaceutical technology? | Research Ideas and Hypotheses Report |
| 2 | | How have these "paper studies" informed the development of experimental designs for addressing the scientific issues associated with the technology? | Experimental Design Alignment Report |
| 2 | | Has computer simulation or other virtual platforms been utilized to test these hypotheses and validate the initial concept? | Simulation and Virtual Testing Records |
| 2 | | What are the practical applications or potential uses of the technology concept based on the basic principles observed during this stage? | Applications and Use Cases Document" based on observed basic principles |

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| 3 | | Have research activities and data collection efforts been initiated to test the hypotheses related to the healthcare or pharmaceutical technology? | Research Progress Report" detailing initiated efforts to test hypotheses. |
| 3 | | In exploring alternative concepts, have critical technologies and components been identified and evaluated for the development of the technology? | Concept Exploration and Technology Evaluation Document |
| 3 | | Have candidate(s) been characterized, and what key attributes or properties have been assessed at this stage? | Candidate Characterization Report |
| 3 | | Have you identified the target and/or candidate for the technology's development? | Target/Candidate Identification Document |
| 3 | | Have in vitro studies or experiments been conducted to demonstrate the activity of candidate(s) in counteracting the effects of the threat agent ? | In Vitro Activity Assessment Report |
| 3 | | Have you generated preliminary in vivo proof-of-concept efficacy data at this stage, and if so, what are the key findings and outcomes? | Proof-of-Concept Efficacy Study Report summarizing key findings and outcomes. |
| 4 | | Have you progressed to the prototype development stage, and have critical technologies been integrated into the candidate development? | Prototype Development and Integration Report. |
| 4 | | Have defined animal models been developed or initiated to demonstrate the efficacy and safety of the candidate drug formulation? | Animal Model Development and Safety Assessment Report. Covers the development of animal models, safety assessments, and alignment with the intended use of the product. |
| 4 | | Have formulation studies, pharmacokinetic studies, ADME studies, PD studies, and safety assessments been conducted to demonstrate the efficacy and safety of the candidate formulation at this stage? | Formulation and Safety Study Report. Details studies including formulation, pharmacokinetics, ADME (Absorption, Distribution, Metabolism, and Elimination), PD (Pharmacodynamics), and safety assessments. |

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| 4 | | Have laboratory-scale quantities of the bulk product and proposed formulated product been manufactured (non-GMP)? | Laboratory-Scale Manufacturing Report (non-GMP). Summarizes the manufacturing of laboratory-scale quantities of bulk and formulated products (non-GMP). |
| 4 | | Have experiments been initiated to identify markers, correlates of protection, assays, and endpoints for further non-clinical and clinical studies? | Experimental Design and Assessment Report. Highlights experiments related to markers, correlates, assays, and endpoints for non-clinical and clinical studies. |
| 4 | | Specifically, have animal models been developed or initiated for the desired indications aligning with the product's intended use? | Animal Model Alignment Report. Describes the alignment of animal models with the product's intended use. |
| 4 | | Have assays and associated reagents been developed for the desired indications? | Assay and Reagent Development Report. Details the development of assays and associated reagents for desired indications. |
| 4 | | Have non-GLP toxicity studies been conducted to determine pharmacodynamics, pharmacokinetics, or immune response in appropriate animal models? | Non-GLP Toxicity Study Report detailing pharmacodynamics, pharmacokinetics, and immune response in animal models. Covers non-GLP toxicity studies, including pharmacodynamics, pharmacokinetics, and immune response in animal models |
| 4 | | Have experiments been initiated to determine assays, parameters, surrogate markers, correlates of protection, and endpoints for further non-clinical and clinical studies to evaluate and characterize the candidate(s)? | Assay and Endpoint Identification Report. ummarizes experiments related to assays, parameters, surrogate markers, correlates of protection, and endpoints for further studies. |
| 5 | | Have pre-clinical studies, including GLP efficacy studies and acute/chronic toxicity studies in animal models, produced sufficient data for DCGI (Drug Controller General of India) application for clinical trials? | Pre-Clinical Data Report" summarizing GLP efficacy and toxicity studies in animal models, demonstrating the readiness for DCGI application |
| 5 | | Have you obtained DCGI approval for a Phase 1 clinical trial? | DCGI Phase 1 Approval Document" indicating formal approval granted by the Drug Controller General of India for conducting a Phase 1 clinical trial. |

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| 5 | | Are non-GLP in vivo studies, animal model development, and assay development continuing as part of the technology's advancement? | Non-GLP Study Progress Report" documenting the ongoing nature of non-GLP in vivo studies, animal model development, and assay development as essential components of technology advancement |
| 5 | | What progress has been made in establishing draft Target Product Profiles (TPPs) for the healthcare or pharmaceutical technology? | Draft TPP Document" outlining evolving product attributes and performance expectations to guide further development efforts |
| 5 | | Have you drafted a preliminary Target Product Profile (TPP), and have questions of shelf life, storage conditions, and packaging been considered to ensure alignment with anticipated product use for FDA approval? | Preliminary TPP Document" addressing factors such as shelf life, storage conditions, and packaging, ensuring alignment with anticipated product use for potential FDA approval. |
| 5 | | Have you demonstrated acceptable Absorption, Distribution, Metabolism, and Elimination (ADME) characteristics and/or immune responses in non-GLP animal studies as necessary for IND (Investigational New Drug) filing ? | An "ADME and Immune Response Study Report" summarizing results demonstrating acceptable Absorption, Distribution, Metabolism, and Elimination (ADME) characteristics and immune responses in non-GLP animal studies, supporting the IND filing process |
| 5 | | Are efforts ongoing to establish correlates of protection, endpoints, and/or surrogate markers for efficacy for use in future GLP studies in animal models? | Relevant document establishing corelations |
| 5 | | Have you identified the minimally effective dose to facilitate determination of a "humanized" dose once clinical data are obtained? | Relevant document for the minimalistic dose |
| 6 | | Has the material been produced in a GLP (Good Laboratory Practice) facility specifically for use in clinical trials? | GLP Material Production Report" detailing the production of materials in a Good Laboratory Practice (GLP) facility for use in clinical trials. |

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| 6 | | Have Phase 1 clinical trials been conducted, and have the results been submitted to the regulatory authority, such as DCGI (Drug Controller General of India)? | Phase 1 Clinical Trial Results Submission" is a document summarizing the results of Phase 1 clinical trials and their submission to the regulatory authority, such as the Drug Controller General of India (DCGI). |
| 6 | | Has the Investigational New Drug (IND) application been reviewed by DCGI for approval of Phase 2 clinical trials? | DCGI IND Application Review Document" indicating that the Investigational New Drug (IND) application has been reviewed by the DCGI for approval of Phase 2 clinical trials. |
| 6 | | Are GMP (Good Manufacturing Practice)-compliant pilot lots being manufactured, and has the IND package been prepared and submitted to the FDA for Phase 1 clinical trial(s)? | GMP Pilot Lot Production and IND Package Submission Document" explaining the manufacture of Good Manufacturing Practice (GMP)-compliant pilot lots and the preparation and submission of the IND package to the FDA for Phase 1 clinical trials. |
| 6 | | Have Phase 1 clinical trial(s) been conducted to determine the safety and pharmacokinetics of the clinical test article, and what are the key outcomes? | Phase 1 Clinical Trial Outcomes Report" summarizes the outcomes of Phase 1 clinical trials, specifically focusing on safety and pharmacokinetics |
| 6 | | Have GLP non-clinical studies been conducted for toxicology, pharmacology, and immunogenicity as appropriate ? | GLP Non-Clinical Study Report" detailing the conduct of Good Laboratory Practice (GLP) non-clinical studies, including toxicology, pharmacology, and immunogenicity assessments, as appropriate |
| 6 | | Has the full IND package been prepared and submitted to the FDA to support initial clinical trial(s) ? | FDA IND Package Submission Document" signifies the preparation and submission of the full IND package to the U.S. Food and Drug Administration (FDA) to support initial clinical trial |
| 6 | | Have Phase 1 clinical trial(s) been completed, providing an initial assessment of safety, pharmacokinetics, and immunogenicity, as appropriate ? | Phase 1 Clinical Trial Completion Report" summarizing the successful completion of Phase 1 clinical trials and providing an initial assessment of safety, pharmacokinetics, and immunogenicity |

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| 7 | | Have Phase-II clinical trials been completed, and has the data been reviewed by the regulatory authority, such as DCGI (Drug Controller General of India)? | Phase-II Clinical Trial Completion Report" summarizing the completion of Phase-II clinical trials and a "Data Review by Regulatory Authority Document" indicating that the data has been reviewed by the regulatory authority, such as the Drug Controller General of India (DCGI). |
| 7 | | Has the Phase-III clinical trial plan been approved? | Phase-III Clinical Trial Plan Approval Document" signifies the regulatory approval of the Phase-III clinical trial plan |
| 7 | | Is there a scale-up and validation of the GMP manufacturing process underway? | "GMP Manufacturing Scale-Up and Validation Report" detailing the scale-up and validation of the Good Manufacturing Practice (GMP) manufacturing process. |
| 7 | | Are Phase 2 clinical trial(s) being conducted at this stage? | Phase 2 Clinical Trial Progress Report" outlines the progress of Phase 2 clinical trial(s) at this stage |
| 7 | | Is there an ongoing refinement of animal model development in preparation for pivotal GLP (Good Laboratory Practice) animal efficacy studies? | Animal Model Refinement Document" explaining the ongoing refinement of animal model development, particularly in preparation for pivotal Good Laboratory Practice (GLP) animal efficacy studies |
| 7 | | Are you scaling up and validating the GMP manufacturing process at a scale compatible with USG (United States Government) requirements? | GMP Manufacturing Scale-Up for USG Compatibility Document" describes the efforts to scale up and validate the GMP manufacturing process to meet United States Government (USG) requirements |
| 8 | | Have Phase-III clinical trials been completed successfully? | Phase-III Clinical Trial Completion Report" summarizing the successful completion of Phase-III clinical trials. |
| 8 | | Has DCGI approved the New Drug Application (NDA) and provided a commercial manufacturing license for market introduction? | DCGI Approval and NDA/Commercial License Document" indicating DCGI approval of the New Drug Application (NDA) and the provision of a commercial |

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| | | | manufacturing license for market introduction |
| 8 | | Is the GMP (Good Manufacturing Practice) validation and consistency lot manufacturing completed? | GMP Validation and Consistency Lot Manufacturing Report" outlines the completion of Good Manufacturing Practice (GMP) validation and consistency lot manufacturing. |
| 8 | | Have pivotal animal efficacy studies or clinical trials (e.g., Phase 3) been completed or are they ongoing? | Completion of Pivotal Efficacy Studies Report" indicating the successful completion of pivotal animal efficacy studies or clinical trials, such as Phase 3. |
| 8 | | Is there a preparation for the submission of the NDA or Biologics Licensing Application (BLA) to the FDA? | DA or BLA Preparation and Submission Plan" details the preparation phase for the submission of the New Drug Application (NDA) or Biologics Licensing Application (BLA) to the U.S. Food and Drug Administration (FDA). |
| 8 | | Has the GMP manufacturing process been finalized and validated at a scale compatible with USG (United States Government) requirements? | "Finalization and Validation of GMP Manufacturing Process Report" highlighting the finalization and validation of the Good Manufacturing Practice (GMP) manufacturing process at a scale compatible with United States Government (USG) requirements |
| 8 | | Have stability studies been completed in support of label expiry dating? | Stability Studies Completion Report" summarizes the successful completion of stability studies conducted in support of label expiry dating. |
| 8 | | Is the Target Product Profile finalized in preparation for FDA approval? | Finalized Target Product Profile Document" signifying the finalization of the Target Product Profile (TPP) in preparation for FDA approval. |

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| 8 | | Are pivotal GLP (Good Laboratory Practice) animal efficacy studies or pivotal clinical trials (e.g., Phase 3) being completed ? | Completion of Pivotal GLP Efficacy Studies Report" confirms the successful completion of pivotal Good Laboratory Practice (GLP) animal efficacy studies or pivotal clinical trials, such as Phase 3 |
| 8 | | Is the preparation and submission of the NDA or BLA to the FDA in progress ? | NDA or BLA Submission and FDA Approval Document" indicates the progress in the preparation and submission of the NDA or BLA to the FDA and the final achievement of FDA approval or licensur |
| 8 | | Has FDA approval or licensure been obtained ? | Licence |
| 9 | | Has the new drug been successfully launched into the commercial market? | Commercial Launch Success Report" summarizing the successful launch of the new drug into the commercial market |
| 9 | | Have post-licensure/post-approval and Phase 4 studies, including safety surveillance and studies to support use in special populations, commenced as required? | Commencement of Post-Licensure/Approval and Phase 4 Studies Report" outlines the initiation of post-licensure/post-approval studies, including safety surveillance and studies to support use in special populations, |
| 9 | | Are clinical trials being conducted to confirm safety and efficacy as feasible and appropriate during the post-approval phase? | Progress in Post-Approval Clinical Trials Report" detailing the ongoing clinical trials conducted to confirm safety and efficacy during the post-approval phase, as feasible and appropriate. |
| 9 | | Is manufacturing capability being maintained as appropriate to meet market demands and quality standards? | Manufacturing Capability Maintenance Plan" describes the measures in place to maintain manufacturing capability as needed to meet market demands and quality standards. |

## Annexure B: Software

| TRL STAGE | Answer (Y/N) | Criteria / Question | Basis & Supporting Documentation |
|---|---|---|---|
| 1 | | Has a specific need or challenge been identified that warrants the development of new software technology at this stage | Problem Statement or Needs Assessment Report with Supporting Documents like Market Research Reports, and Literature on the Identified Need |
| 1 | | Have the fundamental principles and basic properties underlying this software technology been developed and reported | Research Paper or Technical Report with Supporting Documents including Data, Reports, and Publications |
| 1 | | Is there progress in the development of basic software architecture, mathematical formulations, and general algorithms as a foundation for this technology | Software Design Document with Supporting Documents such as Algorithm Documentation, Mathematical Models, and Code Repositories |
| 2 | | Have research ideas been developed to advance the software technology concept ? | Research Proposal or Research Idea Document with Supporting Documents like Literature Review, Research Plans, and Grant Proposals |
| 2 | | Has the technology concept or application been formally formulated at this stage ? | Technology Concept Document or Application Proposal with Supporting Documents including Conceptual Diagrams, Use Case Scenarios, and System Architecture |
| 2 | | Is there active progress in analytics studies, and has coding begun for the technology? | Progress Report on Analytics Studies and Coding with Supporting Documents such as Code Repositories, Data Analysis Reports, and Coding Guidelines |
| 2 | | Are comparative studies being conducted to assess competing technologies related to this concept | Comparative Technology Assessment Report with Supporting Documents like Comparative Analysis Data, Technology Evaluation Criteria, and Competitive Analysis Reports |

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| 3 | | Have initial runs been conducted to validate the concept or script's functionality ? | Validation Test Results or Experiment Reports with Supporting Documents such as Test Plans and Observation |
| 3 | | Is there ongoing refinement of the working draft based on early testing and user feedback ? | Working Draft with Supporting Documents including User Feedback Reports, Test Iteration Logs, and Bug Tracking Records |
| 3 | | Have key features or components of the technology been identified and integrated into the working draft | Working Draft with Integration Documentation and Supporting Documents like Feature Lists and Component Integration Plans |
| 4 | | Is the development of limited functionality environments underway to validate critical properties and analytical predictions, using non-integrated software components and partially representative data | Validation Plan with Supporting Documents including Test Data, Validation Reports, and Environment Configuration Details |
| 4 | | Have results been obtained and documented, demonstrating the validation of critical functionalities at this stage | Experimentation Records with Supporting Documents like Reports, Data Analysis, and Tests |
| 4 | | Have experiments been conducted to assess the functionality of the technology in a controlled environment | Software Development Plan with Supporting Documents such as Integration Plans, Interface Specifications, and Implementation Documentation. |
| 4 | | Are there ongoing efforts to refine and improve the limited functionality environments based on validation results | Validation Improvement Plan with supporting documents such as Validation Reports, Test, and Records |
| 4 | | Has there been an evaluation of the software components and data used for critical property validation to ensure representativeness | Component and Data Evaluation Report with supporting documents like Validation Protocols, Component Documentation, and Data Validation Records. |
| 5 | | Have software technologies been developed to integrate seamlessly with different aspects of the existing system | Integration Plan with supporting documents such as Integration Test Reports, System Architecture Diagrams, and Interface Specifications. |

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| 5 | | Do the implementations of these software technologies conform to the target environment and interfaces | Conformance Assessment Report with supporting documents like Interface Documentation, Test Results, and Conformance Checklist |
| 5 | | Have experiments been conducted using realistic problems to validate the software's performance and functionality | Performance Validation Plan with supporting documents such as Test Scenarios, Test Data, and Validation Results |
| 5 | | Is there rigorous alpha testing ongoing to identify and address any issues or bugs in the software | Alpha Testing Plan with supporting documents like Test Cases, Bug Reports, and Alpha Test Logs |
| 5 | | Are there plans in place to assess the scalability and robustness of the software technologies | Scalability and Robustness Assessment Plan with supporting documents such as Scalability Test Results, Robustness Test Cases, and Assessment Reports |
| 6 | | Has the feasibility of the software technology been successfully demonstrated on full-scale realistic problems | Feasibility Study Report with supporting documents like Feasibility Analysis, Test Results on Full-scale Problems, and Feasibility Assessment |
| 6 | | Is there ongoing technology validation in a relevant end-to-end environment | Technology Validation Plan with supporting documents such as Validation Test Scenarios, Validation Environment Specifications, and Validation Reports |
| 6 | | Are rigorous beta testing activities being conducted to identify and address any issues or shortcomings in the software | Beta Testing Plan with supporting documents like Beta Test Cases, Beta Test Logs, and Bug Reports |
| 6 | | Have the scalability and performance of the software technology been evaluated in a real-world context | Scalability and Performance Evaluation Plan with supporting documents such as Scalability Test Results, Performance Test Scenarios, and Evaluation Reports |
| 6 | | Is there evidence of successful integration with existing systems and technologies in the target environment | Integration Success Report with supporting documents like Integration Test Results, System Integration Documentation, and Integration Logs. |

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| 6 | | Are there plans in place to gather user feedback and make necessary improvements based on beta testing results | User Feedback and Improvement Plan with supporting documents such as User Feedback Reports, Improvement Proposals, and Action Plans |
| 7 | | Has the software technology undergone rigorous testing and validation by third parties to ensure its reliability and performance | Third-Party Testing and Validation Report with supporting documents like Testing Contracts, Test Plans, Test Results, and Validation Certificates |
| 7 | | Is there independent verification and validation of the software's functionality and effectiveness | Independent Verification and Validation Report with supporting documents such as Verification Test Cases, Validation Test Cases, Validation Reports, and Audit Logs |
| 7 | | Have comprehensive security assessments and audits been conducted by third-party experts to identify vulnerabilities | Third-Party Security Assessment and Audit Reports with supporting documents like Security Assessment Plans, Audit Findings, and Security Audit Logs. |
| 7 | | Is there evidence of successful interoperability with other systems and technologies in the broader ecosystem | Interoperability Evidence Report with supporting documents such as Interoperability Test Results, Interoperability Compatibility Documentation, and Interoperability Log |
| 7 | | Have any potential user requirements been met through third-party evaluations | Compliance Evaluation Report with supporting documents like Compliance Checklists, Evaluation Findings, and Compliance Certificates. |
| 8 | | Has the software quality been assessed and validated according to ISO/IEC 9126 or equivalent international standards | Software Quality Assessment and Validation Report with supporting documents like Quality Assessment Plans, Validation Test Results, and Quality Certificates |

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| 8 | | Is data privacy and protection compliant with international standards, such as HIPAA norms, and have privacy audits been conducted | Data Privacy and Protection Compliance Report with supporting documents such as Privacy Compliance Checklists, Audit Reports, and Privacy Compliance Certificate |
| 8 | | Has the software been successfully launched in the intended market or user environment | Software Launch Report with supporting documents like Launch Plans, User Feedback Reports, and Market Release Notes |
| 8 | | Are there measures in place to monitor ongoing software quality and compliance with international standards post-launch | Post-Launch Monitoring and Compliance Plan with supporting documents such as Quality Monitoring Logs, Compliance Reports, and Post-Launch Improvement Plan |
| 8 | | Have any necessary post-launch updates or improvements been identified and planned | Post-Launch Updates and Improvement Plan with supporting documents like Update Proposals, Improvement Roadmaps, and Post-Launch Enhancement Agreements |
| 9 | | Is there a process in place for continuous improvement, including the development of new versions based on user demand and feedback | Continuous Improvement Process Document with supporting documents like Improvement Roadmaps, User Feedback Analysis Reports, and Version Development Plans. |
| 9 | | Are new features being continuously incorporated into the software as per user demand and feedback | Feature Incorporation Plan with supporting documents such as Feature Requests, User Feedback Summaries, and Feature Development Proposals. |
| 9 | | Is there a mechanism for collecting and evaluating user feedback to drive ongoing enhancements | User Feedback Collection and Evaluation Framework with supporting documents like User Feedback Forms, Feedback Analysis Reports, and Enhancement Prioritization Guidelines. |

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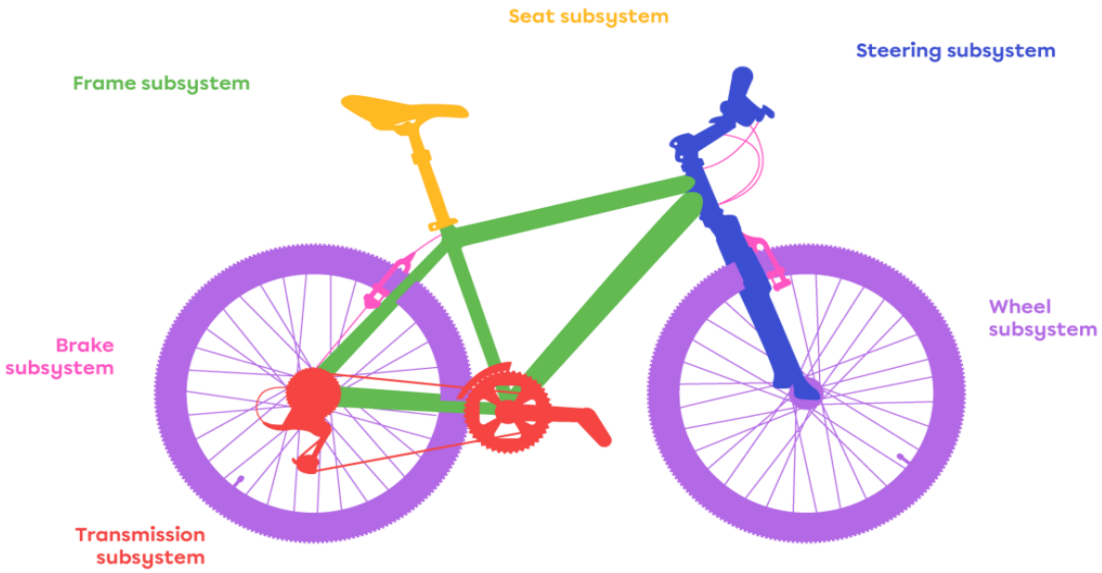
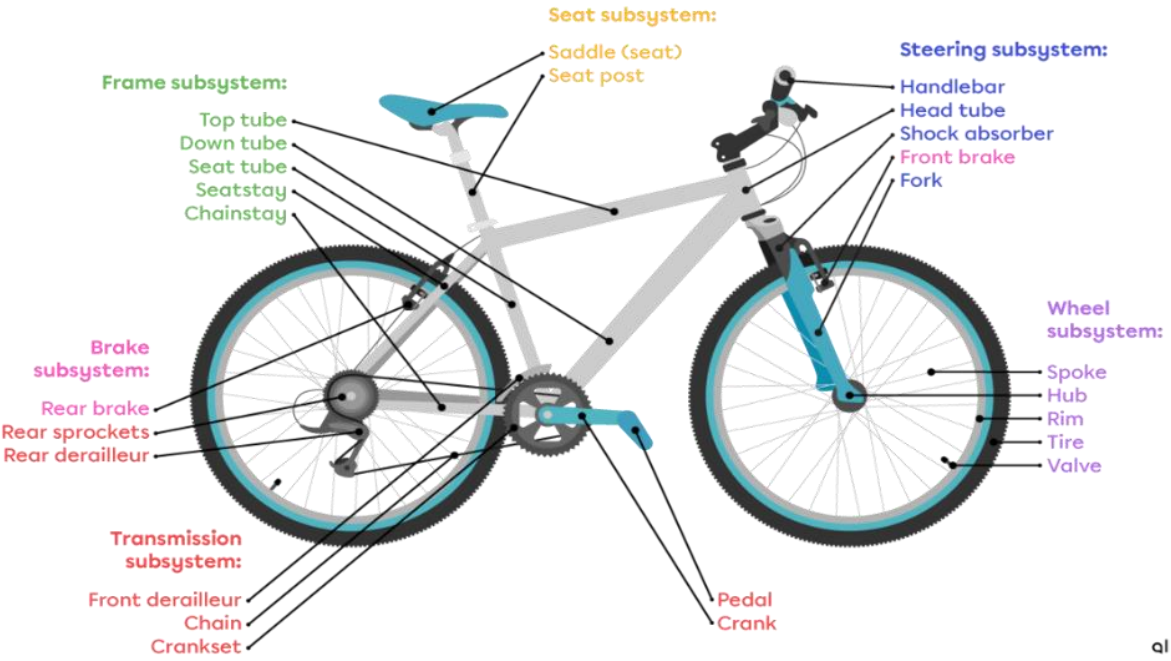
| 9 | | Have any regulatory or compliance changes been promptly addressed and implemented as part of continuous improvement efforts | Regulatory and Compliance Change Management Plan with supporting documents such as Change Impact Assessments, Regulatory Updates, and Compliance Change Logs |
| 9 | | Are there plans for long-term maintenance and support to ensure the software's sustained effectiveness | Long-Term Maintenance and Support Strategy with supporting documents like Maintenance Plans, Support Agreements, and Sustained Effectiveness Reports. |

## Annexure – C: Definitions

Reference: System Bicycle



| Terms | Definition |
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| System | A system is an organized set of interconnected subsystems with all the technical elements that influence one another to accomplish an overall function/outcome. *(See example of system as bicycle)* |
| Subsystems | A subsystem is a set of components that performs a specific function within a technological system. If one of the subsystems fails, the system cannot function. *(See example of subsystems in the system of bicycle)* |
| Component /Element of Technology | A component is a piece, part or device within the subsystem that has a primary function and optionally more than one auxilary function. A single element of technology, the lowest sub-system that provides sufficient granularity to identify technical risks and opportunities. *(See example of components making up a subsystem, in the system as bicycle).* |
| Desktop Environment | Conducting paper studies for the relevant technology under development |
| Breadboard | breadboard, or protoboard is a construction base used to build semi-permanent prototypes. It can be defined as an Integration of components that provide a representation of a system/subsystem and that can be used to determine concept feasibility and to develop technical data. Typically it is configured for laboratory use to demonstrate the technical principles of immediate interest. It may resemble the final system/subsystem in function only. |
| Brassboard | Usually a second improvised prototype after the breadboard to demonstrate improvements in technical feasibility |
| Cross Technology Effects | Each element of technology/component is designed for delivering a required functional performance. When the whole system is integrated, the expected system level functional output can be sub-optimal based on how one element of technology influences the functional performance of the other, defined as cross technology effect. |
| Integrated Product Team (IPT) | Usually the product owning/managing team which oversees the development of the system/sub-system/component by one or more than one technology development teams. They conituously monitor the Technology readiness assessment report for each TRL level to either create a plan to increase technology readiness/maturity sufficiently to support technology transition to a product or to demonstrate to customers that the technology is in fact ready for transition to a product in an expo/Field demo. A representitive from potential customers is recommended to be part of the IPT |
| Interfaces between components/subsystems | In order to enable the subsystem maintain its required performance, the physical and functional integrity should be maintaned by its components and their interface (mechanical, thermal, data, electrical, magnetic) with the subsystem |
| Simulated environment | An environment that can simulate all the operational requirements and specifications required of the final system, to determine whether a developmental system meets the operational requirements and specifications of the final system. |

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| Relevant testing environment | Testing environment in a lab or other controlled environment that simulates both the most important and most stressing aspects of the operational requirements, Testing environment that simulates the key aspects of the operational environment; such as physical and chemical properties. |
| Operating Environment | Environment that addresses all the operational requirements and specifications required of the final system to include platform/packaging. |
| High/Low Fidelity | Fidelity explains the level of detail and functionality that a design or prootype has. Fidelity can vary in content, visuals, and interactivity. A Low fidelity model or experiment would represent a basic illustration of the products intended layout and user journeys. A high fidelity model or experiment will look as close to the finished product as possible. Typically, as the experimentation and testing moves from desktop to breadboard to brassboard, the fidelity of the models / experiments increase from low to high. |
| DT&E | Developmental Testing & Evaluation (DT&E) is a test used to compare a system / subsystem / components to verify that requirements have been met. It includes the T&E of components, subsystems, hardware/software integration, and production qualification testing. It encompasses the use of models, simulations, testbeds, and prototypes or full-scale engineering development models of the system. |


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