Technology Readiness Levels

GENERAL TRLS-Technology Readiness Levels (TRL)* are a method of estimating technology maturity of critical technology elements of a program during the acquisition process. TRLs are based on a scale from 1 to 9 with 9 being the most mature technology. The TRLs enables consistent, uniform discussions of technical maturity across different types of technologies. Decision authorities will consider the recommended TRLs when assessing a program risk.

*as defined by the Department of Defense

1. BASIC PRINCIPLES OBSERVED AND REPORTED
   Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.
2. TECHNOLOGY CONCEPT AND/OR APPLICATION FORMULATED
   Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.
3. ANALYTICAL AND EXPERIMENTAL CRITICAL FUNCTION AND/OR CHARACTERISTIC PROOF OF CONCEPT
   Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.
4. COMPONENT AND/OR BREADBOARD VALIDATION IN LABORATORY ENVIRONMENT
   Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" software in the laboratory.
5. COMPONENT AND/OR BREADBOARD VALIDATION IN RELEVANT ENVIRONMENT
   Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment.
6. SYSTEM/SUBSYSTEM MODEL OR PROTOTYPE DEMONSTRATION IN A RELEVANT ENVIRONMENT
   Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness.
7. SYSTEM PROTOTYPE DEMONSTRATION IN AN OPERATIONAL ENVIRONMENT
   Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle or space.
8. ACTUAL SYSTEM COMPLETED AND QUALIFIED THROUGH TEST AND DEMONSTRATION
   Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test

and evaluation of the system in its intended weapon system to determine it meets design specifications.

9. ACTUAL SYSTEM PROVEN THROUGH SUCCESSFUL MISSION OPERATIONS
   Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.

LIFE SCIENCE TRLS-Technology Readiness Levels (TRL)* provide a metric that may help to describe the progression of a technology in its development. Several groups have adopted the TRL system for use regarding life science technologies, including the Department of Health and Human Services. TRLs are based on a scale from 1 to 9 with 9 being the most mature technology. The TRLs enables consistent, uniform discussions of technical maturity across different types of technologies. The TRL format was originally developed by NASA and the Department of Defense.

*adapted from the National Institutes of Health (NIH)

1. REVIEW OF SCIENTIFIC KNOWLEDGE BASE
   Active review and analysis of scientific literature. Identify rationale for a potential new product.
2. DEVELOPMENT OF HYPOTHESES AND EXPERIMENTAL DESIGNS
   Screen potential compounds; initial experimental designs for technology solution; Initial intellectual property search for patentability.
3. IDENTIFICATION AND CHARACTERIZATION OF PRELIMINARY PRODUCT; PROOF-OF-PRINCIPLE
   Select compounds to advance to lead, begin non-GLP testing program; Explore prototypes, critical design features and components; demonstrate in vitro efficacy; file IP.
4. OPTIMIZATION AND DEMONSTRATION OF ACTIVITY AND EFFICACY
   Identify markers, assays, and endpoints for nonclinical and clinical studies, define formulation and product profile, select final pre-clinical lead compound; Initiate Design Control activities, establish Design and Development Plan, develop regulatory strategy.
5. ADVANCED CHARACTERIZATION OF PRODUCT AND INITIATION OF MANUFACTURING
   Explore potential manufacturing options as well as manufacturability and sustainability of product design, including third-party partners and seek regulatory guidance, if appropriate. Begin studies supporting regulatory requirements.
6. REGULATED PRODUCTION, REGULATORY SUBMISSION, AND CLINICAL DATA
   Prepare and submit regulatory filings, if appropriate. Begin P1 safety for NCE/NBE or P2 on repurposed compound; Manufacture product compliant with quality protocols or GMP depending on device classification.
7. SCALE-UP, INITIATION OF GMP PROCESS VALIDATION, AND PHASE 2 CLINICAL TRIAL(S)
   Scale-up manufacturing, process validation; P2 efficacy program; post-P2 FDA meeting; device scale-up, device and diagnostic outcomes validated, regulatory submissions for marketing clearance; supply chains finalized.
8. COMPLETION OF GMP VALIDATION AND CONSISTENCY LOT MANUFACTURING, CLINICAL TRIALS PH3, AND FDA APPROVAL OR LICENSURE
   Relevant regulatory submissions to request marketing.
9. MARKET LAUNCH AND POST-MARKET SURVEILLANCE
   Supply chain contracts active, sales and distribution forces active, post-marketing studies active (as required).