



CTC Technology Readiness Levels

Readiness: Software Development

(Adapted from CECOM's Software Technology Readiness Levels)

Level 1: Basic principles observed and reported.

Lowest level of software readiness. Basic research begins to be translated into applied research and development. Examples may include a concept that can be implemented in software or analytic studies of an algorithm's basic properties

Level 2: Technology concept and/or application formulated.

Invention begins. Once basic principles are observed, practical applications can be postulated. The application is speculative and there is no proof or detailed analysis to support the assumptions. Examples are still limited to analytical studies.

Level 3: Analytical and experimental critical function and/or characteristic proof of concept.

Active research and development is initiated. This included analytical studies to produce code that validates analytical predictions of separate software elements of the technology. Examples include software components that are not yet integrated or representative but satisfy an operational need. Algorithms run on a surrogate processor in a laboratory environment.

Level 4: Technology component and/or basic technology sub-system validation in laboratory environment.

Basic software components are integrated to establish that they will work together. They are relatively primitive with regard to efficiency and reliability compared to the eventual system. System software architecture development initiated to include interoperability, reliability, maintainability, extensibility, scalability, and security issues. Software integrated with simulated current/legacy elements as appropriate.

Level 5: Technology component and/or basic sub-system validation in relevant environment.

Reliability of software ensemble increases significantly. The basic software components are integrated with reasonably realistic supporting elements so that it can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of software components.

System software architecture established. Algorithms run on a processor(s) with characteristics expected in the operational environment. Software releases are "Alpha versions and configuration control is initiated. Verification, Validation, and Accreditation initiated.

Level 6: Technology system/subsystem model or prototype demonstration in a relevant environment.

Representative model or prototype system, which is well beyond that of level 5, is tested in a relevant environment. Represents a major step up in software demonstrated readiness. Examples include testing a prototype in a live/virtual experiment or in a simulated operational environment. Algorithms run on processor of the operational environment are integrated with actual external entities. Software releases are “Beta” versions and configuration controlled. Software support structure is in development. Verification, Validation and Accreditation is in progress.

Level 7: System prototype demonstration in an operational environment. Represents a major step up from Level 6, requiring the demonstration of an actual system prototype in an operational environment. Algorithms run on processor of the operational environment are integrated with actual external entities. Software support structure is in place. Software releases are in distinct versions. Frequency and severity of software deficiency reports do not significantly degrade functionality or performance. Verification, Validation and Accreditation completed.

Level 8: Actual system completed and qualified through test and demonstration. Software has been proven to work in its final form and under expected conditions. In most cases, this level represents the end of true system development. Examples include test and evaluation of the software in its intended system to determine it meets design specifications. Software releases are production versions and configuration controlled, in a secured environment. Software deficiencies are rapidly resolved through support infrastructure.

Level 9: Technology System proven through successful operations.

Application of the software in its final form and under usage conditions, such as those encountered in operational test, evaluation and reliability trials. In almost all case, this is the end of the last “bug fixing” aspects of the system development. Examples include using the system under operational conditions. Software releases are production versions and configuration controlled. Frequency and severity of software deficiencies are at a minimum.

Readiness: Hardware/Software Development (Adapted from NASA’s Technology Readiness Levels)

Level 1: Basic principles observed and reported.

Lowest level of technology readiness. Research begins to be translated into applied research and development. Examples might include paper studies of a technology’s basic properties.

Level 2: Technology concept and/or application formulated.

Invention begins. Once basic principles are observed, practical applications can be postulated. The application is speculative and there is no proof or detailed analysis to support the assumptions. Examples are still limited to analytical studies.

Level 3: Analytical and experimental critical function and/or characteristic proof of concept.

Active research and development is initiated. This included 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.

Level 4: Component and/or basic technology sub-system validation in laboratory environment.

Basic technology 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 hardware in the laboratory

Level 5: Component and/or basic sub-system validation in relevant environment. Fidelity of sub-system representation increases significantly. The basic technological components are integrated with realistic supporting elements so that the technology can be tested in a simulated environment. Examples include “high fidelity” laboratory integration of components.

Level 6: System/subsystem model or prototype demonstration in a relevant environment. Representative model or prototype system, which is well beyond the representation tested for level 5, is tested in a relevant environment. Represents a major step up in a technology’s demonstrated readiness. Examples include testing a prototype in a high fidelity laboratory environment or in simulated operational environment.

Level 7: System prototype demonstration in an operational environment. Prototype near or at planned operational system. Represents a major step up from level 6, requiring the demonstration of an actual system prototype in an operational environment.

Level 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 most cases, this level represents the end of true system development. Examples include test and evaluation of the system in its intended final environment to determine if it meets design specifications.

Level 9: Technology System proven through successful operations. Application of the technology in its final form and under usage conditions, such as those encountered in operational test and evaluation and reliability trials.

Readiness: Biomedical Developments

(Developed with the USC Regulatory Science Program, School of Pharmacy)

Device Development

Level 1. Basic conceptual development. Basic concept of what the device will do and theoretical principle of how it will work are defined. Design inputs have been identified.

Level 2. Proof of concept Research that validates basic idea and supports feasibility has been done. The design inputs have been defined. Device specifications are defined. A plan for the development of a prototype has been completed. The design process has not yet been initiated.

Level 3. Prototype development. A basic prototype has been designed and built. Development process has been documented.

Level 4. Pre-clinical research and benchmark testing. Validation tests of device. The device has proven to work under expected conditions in the laboratory. Toxicology and pharmacology studies have been done. Device design has been updated if deemed necessary. Manufacturability and production requirements have been defined.

Level 5. Animal Testing. An animal model has been chosen and animal testing has been done to corroborate the safety of the device and to validate design inputs.

Level 6. Clinical Trials

A detailed plan for human trials has been developed and executed. The safety and efficacy of the product has been tested. The device design has been validated.

Level 7. Commercialization

The device design has been completed and tested for safety and efficacy. The product is ready for manufacturing and launching.

Device Development- Regulatory Readiness**Level 1. Device conception.**

The development has been identified as a medical device.

Level 2. Regulatory Pathway Identification.

Applicable regulations have been identified.

A preliminary regulatory pathway for the device has been identified, along with the resources required to meet product specific regulations.

Level 3. Regulatory Pathway definition

A completed regulatory pathway for the device has been identified.

The appropriated notified body (NB) has been chosen.

The industry standards that the product will conform to have been identified.

Design and quality control systems are in place.

Level 4. Animal Testing

Appropriated Institutional Animal Care & Uses Committee approval has been obtained.

An application for exempt status (Investigation Device Exemption (IDE)) has been submitted.

Animal testing has been completed.

Level 5. Preparation for Clinical Trials

An Investigation Device Exemption (IDE) has been obtained.

Clinical studies protocols have been developed.

Procedures for inspections by regulatory authority on NB have been established.

Level 6. Clinical Trials

Clinical trials have been done after the approval by the Institutional Review Board (IRB).

Information required in preparation of FDA application /notification to market product has been collected.

Level 7. Filing

Pre-market notification 510K or Premarket Approval (PMA) has been filed.

Level 8. Post approval

Clearance for marketing of the device has been obtained.

Device has been marketed according to FDA and FTC advertising and labeling rules.

Post marketing device tracking has been performed (class III devices).

Device Development: Business Readiness:**Level 1. Discovery and invention disclosure.**

Possible applications of the device have been identified.

A technology disclosure form has been filled and submitted to the USC Office of Technology Licensing (OTL).

Level 2. Preliminary market research and patent protection.

Preliminary technology and market assessment has been performed.
Patent application has been reviewed and approved by the researcher and OTL.
The Office of Technology Licensing has filed a provisional patent.

Level 3. Development of business model

A market for the device, and possible competitors have been identified.
A risk assessment has been performed and a strategic position has been defined.
A complete technology feasibility analysis has been done.
Financial need has been quantified and initial funding sources identified.
A marketing plan and a sales strategy have been developed.

Level 4 Initial financing.

Technical assistance for prototype development and capital for initial product development have been secured.
Research of potential funding sources has been done.

Level 5 Access to money sources.

Disclosure agreements have been signed and presentations have been given to the possible money sources.
Capital has been secured and negotiations with investors have been completed.
Comprehensive business plan has been developed.

Level 6 Commercialization

The device is ready for manufacturing and launching.
Marketing plan has been executed.

Readiness: Biotech Developments

(Developed with the USC Regulatory Science Program, School of Pharmacy)

Drug Development**Level 1. Molecule identification.**

A molecule with the potential for therapeutic effect has been identified.

Level 2 Synthesis or extraction of new molecules formulated.

Study for the development of new therapeutic agents has begun.
Models for pharmacology and toxicology have been designed.
Models of manufacturing have been developed.
New molecules have been produced.
GLP (Good Laboratory Practice) laboratories have been identified.

Level 3 Preclinical pharmacological/pharmacokinetic testing of compounds

Animals, cell cultures and tissues, as well as computer models, have been used to explore the pharmacological activity and therapeutic potential of compounds.
The potential beneficial activity of compounds has been determined.
Drug metabolism has been assessed.

Level 4. Preclinical dosage formulation and stability testing of compounds

The active compounds have the form and strength suitable for human use.
Dosage forms and strength have been determined.
Design of optimum drug delivery system have been initiated.

Level 5. Preclinical toxicology and safety testing of formulated compounds.

The potential risk for the compounds to man and the environment has been tested. Information about dose-response pattern and toxic effect of the compounds has been obtained.

Level 6. Phase I Clinical Trial

The new compound has been tested in Healthy human subjects at small-scale basis. The tolerance level at different doses has been established. The pharmacological effects of the compound at anticipated therapeutic levels and the patterns of absorption, distribution, metabolism and excretion in humans have been determined.

Level 7. Phase II Clinical Trial

Controlled clinical testing of new compound has been conducted in a relatively small number of patients. New compound's preliminary efficacy and short-term side effects or risks for particular indication or indications in patients with the disease have been evaluated.

Level 8. Phase III Clinical Trial

Controlled and uncontrolled clinical testing of the new product has been conducted in large patient populations. Additional information about effectiveness and safety to evaluate benefit-risk relationship of the new drug has been obtained.

Level 9. Commercialization

Clinical trials have been completed. The new drug has been approved and is available for physicians to prescribe.

Drug Development-Regulatory Readiness:**Level 1. Drug conception.**

A new potential drug has been identified.

Level 2. Regulatory pathway identified.

Applicable regulations have been identified.

A preliminary regulatory pathway for the drug has been identified, along with the resources required to meet the drug specific regulations.

Level 3. Regulatory pathway definition.

A completed regulatory pathway for the drug has been identified. Design and quality control systems are in place.

Level 4. Preparation for IND application

Toxicology and pharmacological data has been gathered and a General Investigation Plan has been defined, in preparation for the Investigational New Drug Application.

Level 5. Regulatory Review I

An Investigational New Drug (IND) application has been filed, and has been approved by the U.S. FDA.

Level 6. Preparation for NDA application.

Scientific information about the drug, gathered during the drug discovery and development process, has been documented in preparation for a New Drug Application.

Level 7. Regulatory Review II.

A New Drug Application (NDA) has been filed, and has been approved by the U.S. FDA.

Level 8. Monitoring

Periodic reports to FDA have been submitted, including any cases of adverse reactions and appropriated quality-control records.

Drug Development-Business Readiness:**Level 1. . Discovery and invention disclosure.**

A new potential drug has been identified.

A technology disclosure form has been filled and submitted to the USC Office of Technology Licensing (OTL).

Level 2. Preliminary market research and patent protection.

Preliminary technology and market assessment has been performed.

Patent application has been reviewed and approved by the researcher and OTL.

The Office of Technology Licensing has filed a provisional patent.

Level 3. Development of business model

A market for the drug and possible competitors has been identified.

A risk assessment has been performed and a strategic position has been defined.

A complete technology feasibility analysis has been done.

Financial need has been quantified and initial funding sources have been identified.

A marketing plan and a sales strategy have been developed.

Level 4 Initial financing.

Capital for pre-clinical testing has been secured.

Research of potential funding sources has been done.

Level 5 Access to money sources.

Disclosure agreements have been signed and presentations have been made to the possible money sources.

Capital has been secured and negotiations with investors have been completed.

Comprehensive business plan is developed.

Level 6. Clinical Trials and manufacturing planning

Capital has been invested in clinical trials.

Manufacturing processes have been designed.

Promotional material has been submitted to FDA for approval.

Level 7. Commercialization

The device is ready for full scale manufacturing and launching.

Licensing agreements have been sought.

Marketing plan has been executed.