

Technology Development MTTF Stages of Development Category Definitions

There are two categories of stages of technology development one for Advanced Technologies and the other for bio companies requiring FDA or other regulatory approval. There can be additional steps in the commercialization process for bio companies and the time to commercialization is much different.

Rules for Category Selection

1. If a company has completed several stages of development, select the most advanced stage. For example, a company may be in beta testing and already have product sales. Therefore, the category for the company would be product sales.
2. Early biotech research may be difficult to determine if the experiments are in the proof of concept or reduction to practice stage.
3. The category selected should pertain to the technology developed for the TEDCO award. For instance, the project is in the alpha testing stage of developing a kit and the company is receiving revenues on another product. The correct category for our metrics is alpha testing.

ADVANCED TECHNOLOGIES (includes bio companies not seeking FDA approval)

1. Proof of Concept

This is the initial stage of commercialization. The development in this stage involves taking an idea and conducting enough research to prove that the idea is feasible and can work.

2. Reduction to Practice/Prototype

This stage of development takes the proof of concept and builds a working model (prototype). If the technology is a process or not a tangible product, the development involves moving the technology to the stage a working model or has real world function.

3. Pre-product testing

Pre-product testing involves a series of experiments and modifications to the prototype to evolve the technology to commercial application.

4. Alpha Testing

Alpha testing is the first step in the commercialization phase of product development. Alpha testing is the in-house testing phase of the commercial product.

5. Beta Testing

This is a critical stage in commercialization in that the company beta tests its product with end users.

6. Pre-commercial Product Sales

Company is selling beta or noncommercial grade products (beta) to customers for testing or for research and development purposes only.

7. Scale up/Production Design/Manufacturing

The company is ramping up for commercial production. It might involve the scale up of materials, planning the production design or actual manufacturing of the product.

8. Commercial Product Launch and Sales

A commercial grade product is introduced to the market for sale and revenues are generated

BIOTECH AND LIFE SCIENCES

Companies not seeking FDA approval or pursuing clinical trials should use the above advanced technology stages

1. Proof of Concept

This is the initial stage of commercialization. The development in this stage involves taking an idea and conducting enough research to prove that the idea is feasible and can work.

2. Reduction to Practice/Prototype (in vivo experiments)

This stage of development takes the proof of concept and builds a working model (prototype). If the technology is a process or not a tangible product, the development involves moving the technology to the stage a working model or has real world function.

3. Pre-product testing/Animal Testing

Pre-product testing and animal testing involve a series of experiments and modifications to the prototype to evolve the technology to commercial application.

4. Phase 1 Clinical Testing

Phase 1 clinical trials are the first step in the commercialization phase of product development. A Phase 1 clinical trial is the first human testing for dosing response.

5. Phase II Clinical Testing

Phase II clinical trials involve a larger number of subjects to study safety and efficacy.

6. Phase III Clinical Trials

This is the final clinical trial before FDA approval. This involves more subjects.

7. FDA Approval

The company has received FDA approval and is ramping up for commercial production.

8. Commercial Product Launch and Sales

Introducing the commercial grade product to the market for sale and revenues are generated.

**Technology Development
MTTF Stages of Development by Type of Company**

Software Network/ Wireless Engineering Nanotech	Bio Devices/ Diagnostics/ Tools (no FDA approval)	Drug Therapies/ vaccines other FDA/ regulatory approved products
Proof of Concept	Proof of Concept	Proof of Concept
Prototype/ reduction to practice	Prototype/ reduction to practice	Prototype/ reduction to practice
Pre-product testing	Pre-product testing	Animal Testing
Alpha testing	Animal Testing/ alpha testing	Phase 1 trials
Beta Testing	Beta Testing	Phase 2 trials
Pre- commercial Product sales	Pre- commercial Product sales	Phase 3 trials
Scale up/ production design/ Mfg	Scale up/ production design/ Mfg	FDA Approval
Commercial Product launch & sales	Commercial Product launch & sales	Commercial Product launch & sales