

Technology Readiness Levels (TRLs) in Healthcare

A therapeutic example

How close is an innovation to helping patients?

TRL 1-3

DISCOVERY

Could it work?

TRL 1



Observation of a scientific principle

Researchers discover the role of a protein in cartilage damage in osteoarthritis.

TRL 2



Potential solution proposed

Scientists design a drug to target that protein and screen candidates with lead optimization.

TRL 3



Early proof of concept

Drug candidates reduce cartilage damage in cellular studies.

OUTPUTS

Scientific discoveries | Research papers | Patents | New therapeutic concepts



TRL 4-6

DEVELOPMENT

Does it work?

TRL 4



Drug testing in lab and in vivo

Lead drug candidate(s) tested for safety and toxicity in the lab and animals.

TRL 5



Drug validated in a relevant environment

Lead drug candidates are tested for effectiveness in appropriate animal models.

TRL 6



Drug demonstrated in a relevant environment

Initial regulatory authorization (e.g., FDA IND) submitted and clinical testing occurs in patients in a Phase I study.

OUTPUTS

Preclinical testing | Feasibility studies | Pilot data and Phase I trials | Clinical validation data



TRL 7-9

ADOPTION

Can healthcare use it?

TRL 7



Phase II and III studies and use in a real clinical environment

Clinicians use the drug treatment, collecting clinical effectiveness and safety data for regulatory approval.

TRL 8



Regulatory approval and development readiness

The drug has received approval (e.g., FDA NDA approval) and is ready for widespread adoption.

TRL 9



Routine clinical practice

The new drug is used across multiple hospitals and patient populations and improves clinical outcomes.

OUTPUTS

Clinical research | Approved products | Commercialization | Population-level impact

