

# QUICK LINKS:

## Phases of Clinical and Translational Research

The T0 to T4 classification system is a way to describe where research sits on the translational science spectrum. Translation is broadly defined as:

*The process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public, from diagnostics and therapeutics to medical procedures and behavioral changes. – National Center for Advancing Translational Sciences*

Translational research involves moving knowledge gained from the basic sciences to its application in clinical and community settings. This concept is often summarized by the phrases “bench-to-bedside” and “bedside-to-community” research. In clinical and translational research, scientific discoveries are moved along a virtual path from the laboratory into real-world practice, leading to improved human health.

### **T0 Research:**

- basic biomedical research, including preclinical and animal studies, not including interventions with human subjects

### **T1 Research:**

- translation to humans, and focus on new methods of diagnosis, treatment, and prevention in highly-controlled settings
- tests findings from basic research for clinical effect and/or applicability
- yields knowledge about human physiology and the potential for intervention
- seeks to move basic discovery into a candidate health application

Types of studies:

- Preclinical and Animal Studies
- Human Physiology
- First in Humans (FIH) (healthy volunteers)
- Proof of Concept (POC)
- Phase I Clinical Trials: Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects)

### **T2 Research:**

- translation to patients, and controlled studies leading to clinical application and evidence-based guidelines
- tests new interventions in controlled environments to form the basis for clinical application and evidence-based guidelines



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### T2 Research (continued)

- yields knowledge about the efficacy of the interventions in optimal settings
- assesses the value of application for health practice leading to the development of evidence-based guidelines

#### Types of Studies:

- Phase II Clinical Trials: Studies the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety.
- Phase III Clinical Trials: A broad clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments.

### T3 Research:

- translation to practice, including comparative effectiveness research, post-marketing studies, clinical outcomes research, as well as health services, and dissemination & implementation research
- explores ways of applying recommendations or guidelines in general practice
- yields knowledge about how interventions work in real-world settings
- attempts to move evidence-based guidelines into health practice, through delivery, dissemination, and diffusion research

#### Types of Studies:

- Phase IV Clinical Trials: Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
- Health Services Research
- Clinical Outcomes Research

### T4 Research:

- translation to communities, including population level outcomes research, monitoring of morbidity, mortality, benefits, and risks, and impacts of policy and change
- interventions that influence the health of populations
- ultimately results in improved global health
- evaluates the “real world” health outcomes of population health practice

#### Types of Studies:

- Population-level Outcome Studies