Stage	Definition	Phase	Description
T1	Your project is in translational stage T1 (Pre-Clinical) if you are… • Applying fundamental discoveries made in the lab to further understand the basis of human disease • Testing hypotheses using cell or animal models; samples of human or animal tissues; computer simulations; or devices; ideally, using experimental parameters (conditions) that mimic stage T2 as closely as possible	Target to Hit	The development of a molecule (protein, etc.) to successfully bind to the biological site of choice or development of device to measure assigned outcome
		Hit to Lead	Evaluating all molecules that bind to the target and determining the optimal one
		Proof of Concept / Target Validation	Demonstrating that the selected molecules bind to the site in question and induce the expected biological or behavioral result in a non-human population
		Model Development (computational)	Using algorithms and/or large datasets for modeling of disease/health state
		Model Development & Implementation (in vitro)	Creating a disease/health state model outside of living body (e.g. cell culture); utilizing samples of human or animal samples or tissues using parameters that aim to mimic stage T2 optimally/Development of device efficacy or biocompatibility
		Model Development & Implementation (in vivo)	Creating a disease/health state model using a living organism using parameters that aim to mimic stage T2 optimally/Development of device efficacy or biocompatibility
		GLP	Validating one's model using Good Laboratory Practices (Done to prepare for FDA or preclinical studies)
T2	Your project is in translational stage T2 (Clinical) if you are… • Testing the efficacy and effectiveness of treatments and interventions (including devices) in humans • Testing safety and effectiveness using behavioral, observational, or clinical trial methodologies	Proof of Concept / Target Validation	Demonstrating that the selected molecules bind to the site in question and induce the expected biological or behavioral result in the human population; Demonstrating that the intervention induces the expected biological and behavioral result; development of device efficacy or biocompatibility
		Model Development (in situ)	Developing a care model for a specific disease/health in a patient or professional population
		Phase 0 Clinical Trial	Exploratory studies that often use only a few small doses of a new drug (subtherapeutic) in a few patients to verify mechanism of action or device to evaluate safety and performance- There is no expectation that the patients will benefit from taking the drug.
		Phase 1 Clinical Trial	Dose finding and safety levels of drug in healthy volunteers - no placebo control
		Phase 2 Clinical Trial	Testing of drug or therapeutic intervention on patients or device to assess efficacy and side effects - determine therapeutic dose
		Phase 3 Clinical Trial	Testing of drug, therapeutic intervention or device on patients to assess efficacy, effectiveness and safety - usually multicenter trials
		Phase 4 Clinical Trial	Safety surveillance (pharmacovigilance) and ongoing technical support of a drug after it receives permission to be sold.
T3	Your project is in translational stage T3 (Clinical Implementation) if you are… • Involving the adoption of interventions into routine clinical care for the general population • Conducting implementation research to evaluate clinical trial results	Model Development	Show proof of principle and demonstrate clinical use of drug/device/intervention
		Dissemination & Implementation	Develop SOPs and assist professionals with rolling out the intervention/treatment/device
T4	Your project is in translational stage T4 (Public Health) if you are… • Studying population level outcomes to determine the effects of diseases and efforts to prevent, diagnose, and treat them	Health metrics	Refinement and analysis of concepts of interest and clinical outcome measures for intervention/treatment
		Health Outcomes	Analysis of outcome measures and development of new directions/evaluate long-term safety and efficacy for device

NOTE: Not necessarily linear - can jump steps or steps may be NA depending on project and starting point

Stage	Definition	Phase	Description
Commercialization	Your project is in the process of commercialization if you are… • Taking a product or idea to market	Pre-Disclosure	Consult with IURTC
		Invention Disclosure	IURTC Case Manager assigned
		Assessment/provisional patent filing	Patentability and marketability of disclosure assessed by IURTC and provisional patent filed if applicable
		Provisional Patent converted to US or PCT patent	Full patent filing
		Start Up	Funding, staffing and business development strategies discussed with Innovation and Commercialization specialists
		Licensing	Rights to technology conditionally released by University