

TRL Level	1	2	3	4	5	6	7	8	9
Basic Description	Review of Scientific Knowledge Base	Development of Product Hypotheses and Experimental Designs	Target/Candidate Identification and Characterization of Preliminary Candidate(s)	Optimization and Initial Demonstration of Safety and Efficacy	Advanced Characterization of Product and Initiation of Manufacturing	Regulated Production, Regulatory Submission and Clinical Data	Scale-up, Initiation of GMP Process Validation, and Phase 2 Clinical Trials	Completion of GMP Validation and Consistency Lot Manufacturing, Clinical Trials Ph3, and FDA Approval or Licensure	Post-Licensure and Post-Approval Activities
Key Activities	Scientific findings are reviewed and assessed as foundation for characterizing new technologies	Generate research ideas, hypotheses, and experimental designs for addressing related scientific issues. Use computer simulation or other virtual platforms to test hypothesis.	Research, data collection, and analysis to test hypothesis. Identify and evaluate critical technologies and components. Characterize candidate(s). Demonstrate in vitro efficacy. Identify lead series and file provisional patent.	Experiments to identify markers, assays, and endpoints for non-clinical and clinical studies. Assess endpoints for relevant impact in clinical practice. Conduct in vivo distribution and elimination studies. Non-GLP in vivo toxicity and efficacy of lead compound; pharmacokinetic studies.	Continue non-GLP in vivo studies, and animal model and assay development. Establish draft Target Product Profiles. Develop a scalable and reproducible manufacturing process amenable to GMP.	Manufacture GMP-compliant pilot lots. Prepare and submit Investigational New Drug (IND) package to FDA and conduct Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article.	Scale-up and initiate validation of GMP manufacturing process. Conduct animal efficacy studies as appropriate. Conduct Phase 2 clinical trial(s).	Finalize GMP manufacturing process. Complete pivotal animal efficacy studies or clinical trials (e.g. Phase 3), and/or expanded clinical safety trials as appropriate. Prepare and submit NDA/BLA.	Commence post-licensure/post-approval and Phase 4 studies (post-marketing commitments), such as safety surveillance, studies to support use in special populations, and clinical trials to confirm safety and efficacy as feasible and appropriate. Maintain manufacturing capability, as appropriate.