	1	2	3	4	5	6	7	8
Basic Description	Review of Scientific Knowledge Base	Development of Product Hypothesis	Identification and Characterization of Product Candidate	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 Trial(s)	Completion of GMP Validation and Consistency Lot Manufacturing, Clinical Trials Ph3, and FDA Approval or Licensure
DRUG OR BIOLOGICAL								
Core activities	Scientific findings are reviewed and assessed as a foundation for characterizing new technologies	Test activities of candidate compounds in vitro Initial product ideation Identify and validate disease target Screen potential compounds to develop preliminary hits	Preliminary product concept(s) identified Critical function and/or proof-of-concept In vitro efficacy and toxcity Identify, characterize preliminary product Decision on which compounds to advance in development. Synthesize novel series of compounds; test efficacy and toxicities in vitro	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 Initiate experiments to identify markers, assays, and endpoints for further non-clinical and clinical studies	Develop a scalable and reproducible manufacturing process amenable to GMP Develop assays/analytical methods for product characterization and release (potency, purity, ID, sterility, etc) Perform IND-enabling toxicology studies Begin stability testing on drug substance Initial clinical trial design	Prepare and submit IND Initiate Phase I study	Post Phase 2 meeting with FDA Determine dosing and treatment population for Phase 3 study	N/A
De-risking milestones	Define disease mechanism	Identify compound series	Demonstrate in vitro efficacy. Preliminary efficacy demonstrated in small animal model. Identify lead series.	Finalize formulation. Identified preclinical candidate compound and animal models for GLP tox studies. Draft Product Profile. Determine Regulatory strategy. Characterize current reimbursement mechanisms, economic burden of illness and treatment costs	Identify candidate. Demonstrate acceptable ADME characteristics and/or immune responses in GLP animal studies as necessary for regulatory filing. Identify manufacturing partners. Pre-IND meeting with FDA. First draft of a target product profile/package insert	Manufacture GMP-compliant pilot lots Prepare and submit regulatory package to FDA and conduct Phase 0 and/or 1 clinical trial(s)	Scale-up and validate GMP manufacturing process Complete stability studies of the GMP drug product in a formulation, dosage form, and container consistent with Target Product Profile Complete Phase 2 clinical trials	Finalize GMP manufacturing process Complete clinical efficacy trials Prepare and submit New Drug Application or Biologics Licensing Application NDA/BLA
THERAPEUTIC DEVICE								
Core activities	Scientific findings are reviewed and assessed as a foundation for characterizing new technologies	Development of product hypothesis Use of computer simulation or other virtual platforms to test hypotheses where possible Perform exploratory in vitro studies Scientific "paper studies" to generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues.	Test prototypes Identify and characterize the product candidate Animal models proposed End points defined Explore prototypes, identify and evaluate critical technologies, critical design features needed, and components.	Iteration and elimination of prototype designs based user feedback, bench testing, ex vivo and non-GLP in vivo testing Integration of critical technologies Initiation of animal model development (if necessary) Identify endpoints for further non-clinical and clinical studies	Develop test methods for device characterization, performance testing, and product release if relevant. Develop a scalable and reproducible manufacturing process amenable to GMP. Explore potential manufacturing options as well as manufacturability and sustainability of device design, including third-party partners.	Complete testing, bench, in vitro and in vivo GLP study to validate product design Initiate Shelf Life/Product Stability studies. Finalize packaging of the device and sterilization validation Initiate manufacturing using scalable and reproducible process. Integrate Quality. Complete testing, bench, in vitro and in vivo GLP study if necessary	Validate manufacturing processes at production . Implement CAPA and other Quality requirements. Support activities needed to complete clinical trials (for de novo or PMA pathway , if needed).	N/A
De-risking milestones	Basic identification of opportunity	Concept formulation	Initial proof-of-concept is demonstrated in a simple animal model Identification of reimbursement and regulatory classification (pathway identification).	Initiate Design Control activities Establish Design and Development Plan, capture Design Inputs. Non-GLP in vivo efficacy demonstration in accordance with the product's intended use. Determine regulatory & clinical strategy. Characterize current reimbursement mechanisms, economic burden of illness and treatment costs. Preliminary FDA meeting.	Design inputs to support regulatory filing (Design freeze) First draft of a target product profile/product label Demonstrate intended device design addresses reimbursement strategy. Preliminary FDA meeting (depending on device type and classification).	Manufacture GMP-compliant devices Complete Design Verification and Validation testing Prepare and submit regulatory package to FDA	Validate GMP manufacturing process Complete clinical trials Regulatory submission of results. Design Transfer activities such as scale-up	Finalized GMP manufacturing process. Prepare and submit for market approval: Premarket Approval (PMA), Premarket Notification (510(k)), HUD or Humanitarian Device Exemption (HDE). Prepare postmarket clinical strategy/surveillance plan
DIAGNOSTIC (ASSAY/TEST)								
Core activities	Active monitoring of scientific knowledge base. Identify links between disease in humans and animals	Development of product hypothesis Scientific "paper studies" to generate research ideas, hypotheses, and experimental designs for addressing the related scientific issues.	Explore assay components via prototypes and screening Begin characterization of lead design. Identify and evaluate critical technologies and components Initiate user feedback	Integration of critical technologies and components (including hardware and software) Select appropriate candidate reference and QC (quality control) reagents	Develop a scalable and reproducible manufacturing process aligned with regulatory guidelines (as needed) Finalize QC criteria Design freeze	N/A	N/A	N/A
De-risking milestones	Basic identification of opportunity	Concept formulation	Demonstrate preliminary assay with simplified sample/artificial matrices. Demonstrate sensitivity and specificity with spike/recovery studies in the appropriate matrices.	Assay/ test method validation in accordance with the product's intended use (Sample type, volume, assay components). Establish Draft Product Profile. Characterize current reimbursement mechanisms, economic burden of illness and treatment costs. Formulate initial regulatory and reimbursement strategies	Identify supply chain and/or manufacturing partners. Demonstrate acceptable performance as necessary for regulatory filing and for impact on clinical care. Preliminary FDA meeting.	Manufacture product compliant with quality protocols. Based on regulatory classification (e.g. CLIA vs IVD route), submit regulatory package	Product quality assays validated. Assays used to assess critical outcomes in clinical trials and in animal efficacy studies are validated.	N/A

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