Helping you steer your

RITUXIMAB BIOSIMILAR DEVELOPMENT PROGRAM

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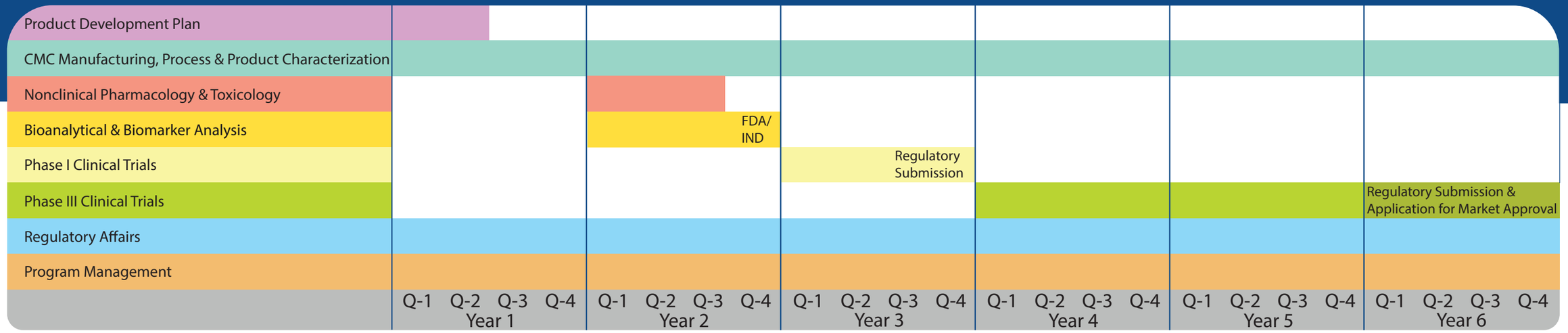
Rituximab Biosimilar Program Overview



Helping you steer your biosimilar along the right path

Product Development Plan (PDP)	Customized product development plan
CMC Manufacturing & Process	Product characterization: • CMC manufacturing and process review • Product characterization and data review • Regulatory liaison for CMC regulatory submission
Nonclinical Pharmacology & Toxicology Studies	4-week single dose and multiple dose toxicokinetic & tolerability studies in rats and cynomolgus monkeys with a 13-week recovery phase: • In-life study protocol design, study conduct, analysis and report • Toxicokinetic (TK) analysis, Immunogenicity (ADA) and peripheral blood immunophenotyping in rats and monkeys • Toxicokinetic evaluation: clinical observations, clinical pathology (coagulation, hematology, clinical chemistry and urinalysis), gross pathology and histopathology
Bioanalytical & Biomarker Analysis	Bioanalytical method development, validation & sample analysis: • PK, Anti-Drug Antibody (ADA) and Neutralizing Antibody (Nab) assay method development, validation, and sample analysis • Dose Solution Analysis - method development, validation and sample analysis • Peripheral Blood Immunophenotyping: method validation and analysis by flow cytometry
Phase 1 Clinical Trials	Clinical pharmacology evaluations: • Phase 1 planning: single dose cross-over & multiple dose protocol development • Clinical study conduct (IRB, recruitment, screening and clinical trial management) • PK & ADA sample analysis, statistical services and clinical study report • Comparability of PK & PD between biosimilar and innovator reference product
Phase 3 Clinical Trials	Efficacy & safety assessments: • Phase 3 planning: protocol development in target disease populations • PK, ADA, Nab bioanalysis in human serum • Biomarker analysis by flow cytometry for ANC and CD34+ counts • Pharmacovigilance: medical monitoring, adverse events and risk management plan • Clinical data analysis and all supporting clinical research services
Regulatory Affairs	• CMC regulatory submission • Pre-IND, IND, clinical and regulatory meeting activities • eIND Submission • Regulatory Affairs for clinical and product market authorization
Program Management	• Dedicated program managers for nonclinical & clinical development • Nonclinical development & IND submission • Early phase & Late phase clinical development

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