Helping you steer your

FILGRASTIM BIOSIMILAR DEVELOPMENT PROGRAM

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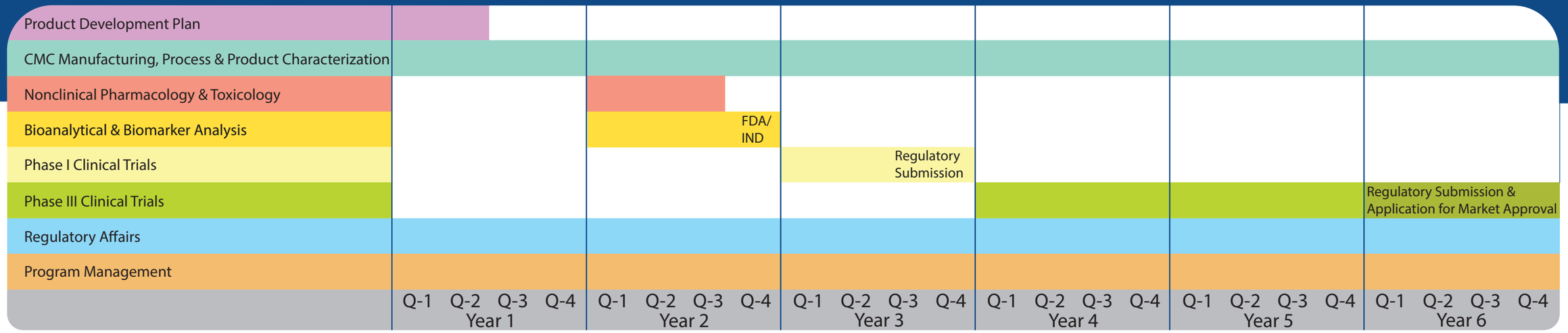
Filgrastim Biosimilar Program Overview



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	Repeat-dose toxicity - single dose and multiple dose 4-week toxicology in rats and rabbits: • Toxicokinetic (TK) analysis in rats, immunogenicity in rats and local tolerance in rabbits • In-life study protocol design, analysis and report • Full toxicological evaluation: clinical observations, clinical pathology and histopathology
Bioanalytical & Biomarker Analysis	Bioanalytical method development & validation: • PK and Anti-Drug Antibody (ADA) assays • Dose Solution Analysis - method development & validation • Biomarker analysis by flow cytometry for absolute neutrophil cell (ANC) and CD34+ counts • Bone biomarkers to assess bone changes after G-CSF treatment
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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