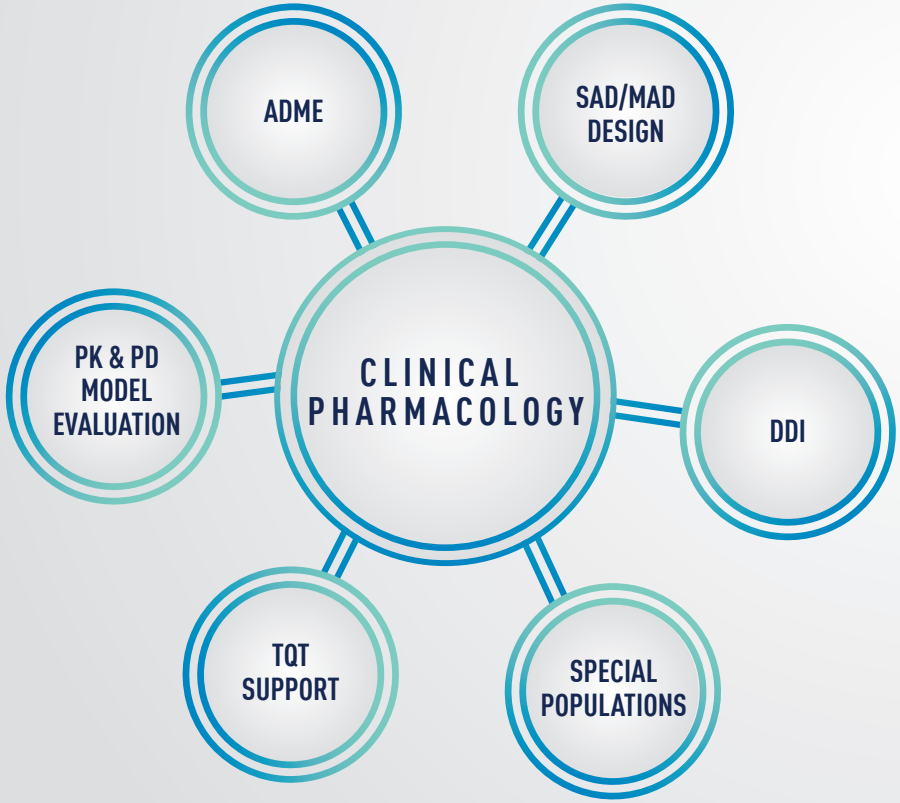
SCIENTIFIC & STRATEGIC DEVELOPMENT

CMC REGULATORY & STRATEGY | NONCLINICAL REGULATORY & STRATEGY | CLINICAL REGULATORY & STRATEGY | **CLINICAL PHARMACOLOGY** | MEDICAL DEVICES & DIAGNOSTICS | COMBINATION PRODUCTS

REGULATORY & COMPETITIVE INTELLIGENCE

CLINICAL PHARMACOLOGY

SEAMLESS INTEGRATION OF CLINICAL PHARMACOLOGY SOLUTIONS TO MAXIMIZE DEVELOPMENT EFFICIENCIES



EXPERTISE AND AGILITY TO ACCELERATE DEVELOPMENT

- Optimal integration of nonclinical data into clinical trial design (including human dose determination, elucidation of mechanism-of-action, & acceleration to proof-of-concept)
- Development of SAD and MAD study designs, including effective sampling strategies
- Critical evaluation of available information to inform on use in special populations (geriatric, pediatric, renal/hepatic impairment, ethnic groups) and potential for drug-drug interactions
- Leveraging regulatory and competitive intelligence to optimize the clinical pharmacology program to avoid unnecessary clinical assessments
- Strategically positioning clinical pharmacology to maximize the value of your clinical program
- Industry-leading guidance and support for scientific advice meetings with Health Authorities
- Development and critical evaluation of the clinical pharmacology program in-line with regulatory expectations

INTERESTED? EMAIL US AT INFO@MEDPACE.COM

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