



SCIENTIFIC & STRATEGIC DEVELOPMENT

CMC
REGULATORY
& STRATEGY

NONCLINICAL
REGULATORY
& STRATEGY

CLINICAL
REGULATORY
& STRATEGY

CLINICAL
PHARMACOLOGY

MEDICAL DEVICES
& DIAGNOSTICS

COMBINATION
PRODUCTS

REGULATORY & COMPETITIVE INTELLIGENCE

CLINICAL REGULATORY & STRATEGY



EXPERTISE AND AGILITY TO ACCELERATE DEVELOPMENT

- Guidance on global or country-specific regulatory strategies and clinical development plans at all phases of therapeutic development
- Technical guidance and strategic development of regulatory submissions
- Evaluation of clinical trial design and selected endpoints for regulatory acceptability and approval
- Meeting with regulatory agencies and negotiations on complex issues
- Mechanisms of acceleration for regulatory pathways
- Strategic advice on product information, labeling, differentiation and positioning
- Benefit/risk assessment and risk mitigation strategies
- Due diligence support for in-licensing opportunities
- Integration of Health Technology Assessments into clinical trials
- Unparalleled experience with advanced therapy medicinal products (ATMPs) including gene therapy, somatic-cell therapy, and tissue engineered medicines

INTERESTED? EMAIL US AT INFO@MEDPACE.COM

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