CELL & GENE THERAPY
Clinical Development Solutions

With specialized expertise, coordinated capabilities and focused investments across preclinical, clinical and post-approval phases, we’ll help you to reduce the time and risk in your product’s development.

Supported the development of BOTH FDA approved CAR-T therapies and helped advance the first 2 FDA-approved GENE REPLACEMENT THERAPIES

Clinical Studies
► Unique datasets
- Ideal site selection
- Optimal patient recruitment
- More accurate forecasting
► Expertise in oncology, immuno-oncology, rare diseases and pediatrics
► Protocol modeling
► Project management and oversight
► Medical monitoring and specialized training for AEs
► First in Human/dose range-finding
► Proof of Mechanism/Proof of Concept (PoM/PoC)
► Long-term follow-up and testing strategy

Conducted for cell and gene products across the U.S., Europe and Asia

Conducted (autologous and allogeneic) with 1,100+ patients across 263 sites in the US, Europe and Asia

40+ Clinical Studies
19 CAR-T Clinical Studies
20 Therapeutic Indications

Bioanalysis
► Biodistribution, persistence and shedding of product or transgene
► QPCR, flow cytometry and ELISA
► Immunogenicity assessment– NAb assays

Biomarkers
► Strategy
► Assay development
► RUO & regulated testing
► Genomics and proteomics
► Specialty services
► Companion diagnostics

Central Labs
► Kits
► Logistics
► Safety testing
► Genomics and flow cytometry
► Nimble handling of time-sensitive samples globally

Of clinical study experience with gene and cell therapies
Regulatory & Strategic Product Development Consulting
- Clinical development plan
- Target product profile
- Regulatory agency interactions
- Integrated development strategies focused on value inflection points
- Differentiation strategy
- Study design/protocol development
- Global labeling
- Regulatory review and registration path
- Dossier assembly, publishing and submission

CMC Analytical Testing
- Analytical control strategy development
- Phase-appropriate method development and validation
- Safety, identity, strength, quality and purity testing
- Comparability of preclinical and clinical lots
- Lot release and stability

Commercialization
- Market access and strategy
- Value communication
- Evidence generation

Post-Approval Planning
- Real-world evidence
- Post-marketing commitments
- Long-term follow-up
- Patient and field support
- Patient safety and pharmacovigilance

Precision Medicine Solutions Designed Around Your Needs
Visit us at www.covance.com/CGT

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