CELL & GENE THERAPY
Preclinical, Clinical & Post-Approval 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.

Reduce scientific, regulatory and commercial risks and accelerate development wherever you are in the process with expertise in each phase and across the continuum

- Preclinical, clinical, laboratory, post-approval solutions
- Gene therapies, gene-modified cell therapies, etc.
- Rare diseases, pediatrics, oncology and immuno-oncology
- Adoptive T-cell therapies

Reduce development timeline whitespace, complexity and risks with coordinated capabilities from one partner

- Science
- Program consultation and management
- Regulatory
- Commercialization
- Biomarkers and companion diagnostics

Supported development of BOTH FDA approved CAR-T therapies

Helped advance the first 2 FDA-approved GENE REPLACEMENT THERAPIES

Delivering development solutions for cell and gene therapy products

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Delivering development solutions for cell and gene therapy products

Access impactful innovation to advance your precision and regenerative medicines through our focused investments in and commitment to cell and gene therapy development

- Corporate strategic area of focus and resource alignment
- Ongoing investments in people, process and technologies
- Partnerships and acquisitions – MI Bioressearch, OmniSeq®, MissionBio™, Envigo and more
## Preclinical Solutions:
- In vitro and in vivo pharmacology and toxicology
- Bioanalysis: distribution, persistence and shedding
- Biomarkers
- Regulatory and strategic product development consulting
- CMC analytical testing
- Clinical development preparation
- Commercialization strategy

### Conducted
- Conducted for cell and gene products in the last 4 years (pharmacology and toxicology; mostly in vivo studies)

### Published
- Published in peer-reviewed journals for cell and gene products

## Clinical Phase Solutions:
- Clinical studies, with focused expertise in oncology, rare diseases and pediatrics
- Regulatory and strategic product development consulting
- Biomarkers, including companion diagnostics
- Central Labs
- Bioanalysis: distribution, persistence and shedding
- CMC analytical testing
- Commercialization strategy

## Post-Approval Solutions:
- Long-term follow-up monitoring and studies
- Real-world evidence
- Pharmacovigilance
- Post-marketing commitments
- Regulatory consulting
- Specialized clinical testing
- Commercialization
- CMC analytical testing

### Conducted
- Conducted in the last 4 years for cell and gene products across the U.S., Europe and Asia Pacific

### Submissions
- Submissions in the last 5 years, and 67 in prior positions for strategists and PMs (all product types & therapeutic areas)

### In the U.S., Europe and Asia Pacific
- In the U.S., Europe and Asia Pacific supporting RWE studies and post-marketing commitments (all product types & therapeutic areas)

### Experience
- Experience in post-approval studies, globally (all product types & therapeutic areas)

## Precision Medicine Solutions Designed Around You®
Visit us at www.covance.com/CGT