

# U.S. Cell & Gene Therapy Contract Research Organizations Market Size, Share & Trends Analysis Report By Type (Drug Discovery, Preclinical, Clinical), By Service, By Indication, By Modality, And Segment Forecasts, 2025 - 2033

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## Abstracts

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### Market Size & Trends

The U.S. cell & gene therapy contract research organizations market size was estimated at USD 2.09 billion in 2024 and is projected to reach USD 4.86 billion by 2033, growing at a CAGR of 9.91% from 2025 to 2033. The growth of the market is due to growing complexity of cell- and gene-based therapeutics, rising clinical trial volume in CGT, increased outsourcing by biotech firms, regulatory complexity, among others.

The market is being driven by growing collaboration among scientific innovation, regulatory changes, and evolving sponsor needs. A growing number of advanced therapies-including autologous cell therapies, gene editing interventions, and in vivo viral vector-based treatments-are reaching investigational and clinical stages, often requiring highly tailored preclinical and clinical development programs. Most small-to-midsize biotech firms lack the internal infrastructure to navigate the complex clinical, regulatory, and bioanalytical demands of such therapies, especially those targeting rare or ultra-rare conditions. This gap fuels demand for CROs with niche expertise in translational biology, GMP-compliant sample management, and immunogenicity testing.

Furthermore, an increase in strategic outsourcing models, where sponsors form integrated partnerships with CROs to reduce fixed operational costs and increase

scalability, is also one of the factors driving the market growth. The high logistical and patient-specific complexity of therapies such as CAR-T or AAV-based interventions necessitates deep coordination between trial sponsors, clinical sites, and regulatory bodies, prompting sponsors to engage CROs that bring both scientific depth and operational agility. The expansion of academic-industry partnerships, government initiatives supporting rare disease trials, and growing venture capital inflows into cell and gene therapy startups further amplify CRO demand.

## U.S. Cell & Gene Therapy Contract Research Organizations Market Report Segmentation

This report forecasts revenue growth at country level and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. cell & gene therapy contract research organizations market report based on type, phase, service, indication, and modality:

### Type Outlook (Revenue, USD Million, 2021 - 2033)

#### Drug Discovery

Target Validation

Lead Identification

Lead Optimization

#### Preclinical

#### Clinical

Phase I

Phase II

Phase III

Phase IV

### Service Outlook (Revenue, USD Million, 2021 - 2033)

Project & Clinical Trial Management

Regulatory Strategy

Data Management & Medical Writing

Clinical Monitoring

Quality Management / GMP Compliance

Biostatistics & Safety Monitoring

Patient & Site Recruitment

Technology Transfer

Others

Indication Outlook (Revenue, USD Million, 2021 - 2033)

Oncology

CNS Disorders

Infectious Diseases

Immunological Disorders

Cardiovascular Diseases

Respiratory Diseases

Diabetes

Ophthalmology

Pain Management

Others

Modality Outlook (Revenue, USD Million, 2021 - 2033)

Cell-Based Therapies

Gene Therapies

Gene-Modified Cell Therapies

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