

# Cell Therapy Research & Clinical Development Services

Precision's experience developing a broad range of cell therapies, including CAR-T cells, stem cells, autologous and allogeneic products, and tumor-infiltrating lymphocytes, gives us insight into the challenges of cell therapy as a whole, as well as how development of each of these cell types differs. We understand the needs of each program and our integrated, multidisciplinary team can create a bespoke solution appropriate for your unique project.

## Precision's integrated, end-to-end cell therapy solutions



Biospecimen  
Solutions



Central Lab  
Services



Specialty Labs  
& Biomarker  
Assays



Clinical Trial  
Design &  
Conduct



CDx  
Development &  
Commercialization



Biospecimen Solutions

- PBMCs (healthy and disease state)
- Leukopaks & mobilized leukopaks



Central Lab Services

- Clinical sample collection kit development: specialized processes to accommodate complex or rare disease studies
- PBMC processing at 11 labs across 5 continents
- Global sample logistics, shipping, and biostorage
- Real-time sample data analytics and virtual sample inventory management



Specialty Labs & Biomarker Assays

### Immune Monitoring

- Flow cytometry up to 31 colors - example: T cell phenotyping
- ELISpot/Fluorospot - example: T cell functional phenotyping
- Cell phenotyping via epigenetics (Epiontis ID)
- Monitoring of specific cell types and activation states - example: Tregs

### Bioanalysis

- ADA assays - example: analysis of CAR antigens to CAR-T
- Cytokine analysis via Mesoscale, Luminex, Quanterix, ELISA

### Genomics

- NGS - examples: TCR sequencing, RNAseq to monitor gene expression change after treatment
- ddPCR/qPCR: PK, CAR-T biodistribution
- Nanostring - example: CAR-T characterization panel

### IHC/mIF and Pathology

- IHC, including CLIA assays
- Multiplex immunofluorescence: assess tumor microenvironment and spatial biology (up to 8 concurrent markers)

### Liquid Biopsy

- CTC capture and enrichment with proprietary ApoStream technology
- CTC phenotyping
- cfDNA/ctDNA analysis
- Pharmacodynamic assessments



Clinical Trial Design & Conduct

- Full service global clinical trial design and conduct
- Patient recruitment and enrollment: specialization in rare disease trials
- Dedicated cell therapy working group to ensure alignment with current regulatory environment and best practices for study conduct



CDx Development & Commercialization

- Biomarker discovery and assay development
- Preclinical planning and strategy
- Assay development into single-site PMA CDx with full regulatory and market access support

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To learn more about Precision for Medicine, please contact us at [info@precisionformedicine.com](mailto:info@precisionformedicine.com), or visit [precisionformedicine.com](http://precisionformedicine.com).

