

# PRECISION'S UNIQUE EXPERIENCE

## CELL THERAPY STUDY EXPERIENCE

Product Type	Study Phase	Indication	Services
Allogenic CRISPR Engineered T Cells (B Cell malignancy)	I	Biomarker Assays (flow cytometry, multiplexed cytokine anal, immunogenicity assays)	Labs and Translational Service
CD19-directed genetically modified autologous T Cell immunotherapy	N/A	Pediatric and young adult patients with relapsed/ refractory B-cell acute lymphoblastic leukemia	Training Materials, Presentations, Patient Materials, Scientific Papers, Fact Sheets, Physician Guides, Manuals, Site Training
Biopsy neo-antigen T Cell matching patient specific vaccine	I/II	Melanoma, NSCLC, Head and Neck, Urothelial Carcinoma (TCC), Renal Cell (RCC)	Start up, Medical Monitoring, Data Management, Monitoring and Site Management, Biostatistics, Project Management, Safety
Allogeneic Multi-Antigen Targeted T Cell Therapy	II	AML or MDS	Project Management, Clinical, Medical Monitoring, Safety, Data Management, Statistics, Medical Writing (CSR), Consultancy and Design
Allogeneic T Cell Therapy	I	Relapsed/Refractory Multiple Myeloma	Program Development, Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
Autologous T Cell Therapy	I-IIa	Advanced Solid or Hematological Cancer	Program Development, Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
Autologous T Cell Therapy	I	Solid Tumours	Program Development, Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
Cell therapy- human embryonic stem cell-derived retinal pigment epithelial cells	I/IIa	Dry AMD	PM, Clinical, DM, Biostatistics, MW, Safety, QA
Allogeneic Mesenchymal bone marrow cells cell therapy	I/II	cutaneous photoaging	PM, Clinical, DM, Biostatistics, MW, Safety
Allogeneic Mesenchymal bone marrow cells- cell therapy	IIa	heart failure	PM, Clinical, DM, Biostatistics, MW, Safety
Autologous T Cell Therapy	I	Solid Tumours	Program Development, Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
CAR-T Therapy	II/III	B Cell acute lymphoblastic leukemia and diffuse large B-cell lymphoma	KOL Identification And Engagement, Advisory Board Meetings, Disease State Slide Decks, Branded Speaker Slide Decks, Patient Case Development, Speaker Training, Symposia, Congress Support, Reprint Carriers And Annotated Reprints, Technical Operations Training Materials, Sales Training, Patient Services Materials And Call Center Training
Cell therapy- human embryonic stem cell-derived retinal pigment epithelial cells	I/IIa	Dry AMD	PM, Clinical, DM, Biostatistics, MW, Safety, QA

# PRECISION'S UNIQUE EXPERIENCE

## GENE THERAPY STUDY EXPERIENCE

Product Type	Study Phase	Indication	Services
Gene Therapy	II	AADC deficiency	Prelaunch Activities, Medical Writing, Congress Activities, Disease State Awareness Campaigns, Advisory Board Meetings, Speaker Training Meetings, Internal Training Materials
Gene Therapy	Approved in 2017	Leber's congenital amaurosis	Postlaunch Content Development Branded And Disease State Awareness Content, Slide Deck Development, Advisory Board Meetings, Internal Training Materials
Gene Therapy	I	Glioblastoma at first recurrence	Biostatistics
Gene Therapy	I	Recurrent Malignant Glioma	Biostatistics
Gene Therapy	Ib	Recurrent Glioblastoma or Gliosarcoma	Biostatistics
Gene Therapy	II	Rucurrent Glioblastoma or Gliosarcoma	Biostatistics, Data Management, Safety
Gene Therapy	II/III	Recurrent Glioblastoma / Anaplastic Astrocytoma	Biostatistics
Gene Therapy	Ib	Solid Tumors or Lymphoma	Biostatistics, Data Management, Medical Writing
Gene Therapy	I	Multiple	Biostatistics, Clin Ops, Project Management
Gene Therapy	IND, I, II	Multiple	PK, ADA/Tab, NAb, ELISpot
Gene Therapy	I,II,III	XLMTM	PK, ADA/Tab, NAb, ELISpot
Gene Therapy	IND, I, II, III	Multiple	Tab, NAb, ELISpot, Biostatistics
Gene Therapy	Preclinical	Multiple	Custom ELISpot (AAV)
Gene Therapy	I/II	Wet AMD	NAb Assay, Biodistribution (ddPCR)
Gene Therapy	I/II	Fanconi Anemia	Tab Assay, Biodistribution (ddPCR)
Gene Therapy	I/II	DMD	AAV Tab assay (human), NAb assay, MSD, Nanostring
Gene Therapy	III, Commercial	OTC Deficiency	NAb Assay, Biostatistics, CDx Development, Filing & Commercial Testing
Gene Therapy	III, Commercial	Hemophilia B	NAb Assay, Biostatistics, CDx Development, Filing & Commercial Testing

## ONCOLYTIC VIRUS AND VACCINE STUDY EXPERIENCE

Product Type	Study Phase	Indication	Services
Oncolytic Virus	I/II	Solid Tumour/ Melanoma	Data Management, Biostatistics
Oncolytic Virus	II	Advanced Solid Tumor (ST)	Start Up, Project Management, Medical Monitoring, Monitoring Site Management, Safety, Data Management, Biostatistics, Medical Writing
Oncolytic Virus	I	Solid Tumour/ Melanoma	Start Up, Clinical Monitoring, Data Management, Study Management
Oncolytic Virus	I	Solid Tumour/ Melanoma	Data Management And Clinical Programming, Site Monitoring And Management
Oncolytic Virus	II	Ovarian Solid Tumours	Study Start Up, Project Management, Site Management, Site Monitoring, Data Management, Biostatistics, Medical Writing, Pharmacovigilance, Medical Monitoring
Oncolytic adenovirus	I/II	Malignant melanoma	Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
Cancer Vaccine	III	Prostate Cancer	Real-time Flow Cytometry, PBMC isolation, ELISpot
Cancer Vaccine	IV	Prostate Cancer	Cell-based Assay for Efficacy Response
Oncolytic Virus	III	Advanced Solid Tumor (ST)	Start up, Project Management, Medical Monitoring, monitoring site management, safety, Data Management, Biostatistics, Medical Writing
AVV	Preclinical	X-Linked Myotubular Myopathy	Statistical consulting

# PRECISION'S UNIQUE EXPERIENCE

## RADIO-LABELLED STUDY EXPERIENCE

Product Type	Study Phase	Indication	Services
Radio Labelled	I/II	Advanced Solid Tumor (ST), Head and Neck, NSCLC	Clinical, Site Management And Monitoring, Safety, Data Management, Biostatistics, Project Management, Medical Monitoring, Clinical Study Report
Radio Labelled	II	Prostate/Solid tumour	Start Up, Project Management, Site Management, Site Monitoring, Data Management, Pharmacovigilance, Medical Writing, Biostatistics
Radio Labelled	III	Prostate/Solid tumour	Feasibility/ Recruitment, Start Up, Project Management, Monitoring And Site Management, Safety, Data Management, Biostatistics, Medical Writing
Radio-labelled Diagnostic Imaging	I	Metastatic Cancer Expressing NTSR-1	Project Management, Medical Monitoring, Pharmacovigilance, Vendor Management, And Site Start Up, Management, And Monitoring

## PRECISION EXPERIENCE IN RNA THERAPIES

Product Type	Study Phase	Indication	Services
RNA-I therapy	I	Alport Syndrome	Clinical, Project Management, Data Management
RNA-I therapy	II/III	Alpha 1-Antitrypsin Deficiency	Clinical, Project Management, Data Management
RNA-I therapy	I	Alpha 1-Antitrypsin Deficiency	Clinical, Project Management, Data Management
RNA-I therapy	II	Hepatitis B, Hepatitis D	Clinical, Project Management, Data Management
mRNA	Preclinical	Urea Cycle Disorder	Clinical, Project Management, Data Management

## CELLULAR THERAPY EXPERIENCE WITHIN THE PRECISION TEAM

Product Type	Study Phase	Indication	Services
Chimeric Antigen Receptor T-cell (CAR-T)	I/II	Solid Tumours	Clinical/PM and Biometrics Oversight
Chimeric Antigen Receptor T-cell (CAR-T)	I/II	Program of Haematology indications	Clinical/PM and Biometrics Oversight
Allogenic stem cells	I & II	Patients with AML, ALL, MDS post induction or consolidation	Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Site Start Up, Management, and Monitoring, Statistics
Tumor Infiltrating Lymphocytes (TIL)	II	Melanoma	Program Development, Project Management, Medical Monitoring, Pharmacovigilance, Data Management, Medical Writing, Statistics, Vendor Management, and Site Start Up, Management, and Monitoring
Gene Modified Donor T-cells	I/II	Haematological Malignancies	Clinical Monitoring
Autologous CAR-T plus checkpoint inhibitor	I	Adult T cell leukemia/lymphoma	Medical Monitoring
Allogeneic CAR-T	I	Solid tumor (ovarian, pancreatic, renal)	Medical Monitoring
Tumor Infiltrating lymphocytes (TIL)	II	Cervical Cancer	Project Management, Pharmacovigilance, Data Management, Site Start Up, Management, and Monitoring
Tumor Infiltrating Lymphocytes (TIL)	II	Head and neck cancers	Project Management, Pharmacovigilance, Data Management, Site Start Up, Management, and Monitoring
Chimeric Antigen Receptor T-cell (CAR-T)	I	Multiple Myeloma	Protocol Development, Project Management, Pharmacovigilance, Data Management, Vendor Management, and Site Start Up, Management, and Monitoring
Chimeric Antigen Receptor T-cell (CAR-T)	I	Multiple Myeloma	Project Management, Pharmacovigilance, Data Management, Site Start Up, Management, and Monitoring
Autologous T-cell receptor modified therapy	II	AML and MDS	Medical Monitoring
Autologous Chimeric Antigen Receptor T-Cell (CAR-T)	I	Pediatric neuroblastoma	Medical Monitoring
Autologous Chimeric Antigen Receptor T-Cell (CAR-T)	I	Multiple myeloma	Medical Monitoring
Allogeneic dendritic cell vaccine	II	NSCLC	Medical Monitoring
Paediatric: primitive neuroectodermal tumors (PNETs) (Brain)	II	Neuroectodermal tumours (PNETs Brain)	Stats Programming, Protocol Review/Development, and SAP review.