PRECISION for medicine

Precision's Experience in Cellular Therapies

Cell therapy at Precision

With cellular immunotherapy products at the forefront of oncology research, we understand the unique challenges in managing these studies, especially allogeneic and autologous cellular matched, non-off the shelf cell-based therapeutics where maintaining chain of identity through the product life cycle is paramount. The logistic coordination of the product from collection, handling and shipping of each patient's cells, through the manufacturing process and then shipment of the finished product to the site for infusion requires a high level of coordination, organization and oversight to ensure chain of custody and traceability of the cells/finished investigational product is not disrupted through the product life cycle. We are adept at the logistical aspects required in sample traceability and have recently implemented the Cell Therapy Working Group within Precision Cellular Therapy Advisory Committee. The goal is to develop a library of forms, documents, best practices, and processes as well as cellular therapy training that can be easily adapted for cell-based therapy trials.

Precision is dedicated to remaining at the forefront of science in clinical trials. We have taken steps to advance our cellular therapy knowledge and experience by hiring teams who have specifically worked with these therapies in the past.

Considerations for site selection

Site selection is key to the successful conduct of cell therapy administration and research. The logistics of cell therapy treatment and research put pressure on site resources and systems. Precision has developed robust site-qualification materials and works closely with the sites to ensure that there are rigorous processes and site training. There is no room for error in cell therapy.

Facility

- Hospitalization and ICU capabilities
- Established process for working with leukapheresis department and cellular laboratories
- Coordination across departments and resource capacity

Staff

- Staff experienced in cell therapy logistics and patient management
- Trained staff at each step of the cell journey at site
- Site invested in cell therapy structure capacity

Leukapheresis Facility

- Proximity to treating department
- Site process for blood collection, data collection processing, and shipment

Cellular Laboratory

- Proximity to treating facility
- Cellular product transport requirements and standards
- Freeze and thaw protocols

Cell therapy-specific operational plans and forms

Studies with cell-based therapies require additional expertise to effectively manage the inherent challenges that present themselves through the product life cycle. To mitigate risks associated with these activities, it is important to develop appropriate planning documents, tracking systems and forms, as well as provide and document training on each facet of the life cycle.

Examples of the tools developed by Precision are:

- Apheresis cell collection and shipment plan
- Apheresis manual, infusion manual, cellular product traceability worksheets
- IP receipt and processing plan
- Cell laboratory manual
- SIV readiness checklist
- Toxicity management guidelines
- Risk management and mitigation plan
- Training materials

Precision adoptive cell therapy working group

Experienced individuals from different areas of the business who advise, train, and keep Precision informed of advances in the industry. Focusing on the regulatory environment, logistics management, site selection, startup materials and plans, staff training, data considerations, and patient safety management specific to the conduct of cell therapy studies.

Experience:	
Cell Therapy	24%
Leukapheresis	18%
GMO	16%
TCRs Therapy	13%
Personalized Vaccine Study	13%

Ongoing cellular therapy experience/studies

Product Type	Study Phase	Indication	Services	Dates
Allogeneic antigen specific T-cells	II	AML	Full service PM, clinical, regulatory, DM & safety protocol, consultancy and design	Ongoing
Allogenic CRISPR engineered T-cells (B cell malignancy)	I	Biomarker Assays (flow cytometry, multiplexed cytokine analysis, immunogenicity assays)	Labs & translational service	Ongoing
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	Ongoing
Neo-antigen T-cell matching patient specific vaccine	I/II	Multiple solid tumors	Full service, PM, clinical, regulatory, DM, safety and labs and translational services	Ongoing
Autologous NK cells	I	Patient selection – frequency of MDSCs under CLIA	Labs/translational services	Ongoing

Cellular therapy experience within the Precision team

Product Type	Study Phase	Indication	Services
Chimeric Antigen Receptor T-cell (CAR-T)	II	Solid tumors	Clinical/PM, biometrics oversight, site management, and data management
Chimeric Antigen Receptor T-cell (CAR-T)	I/II	Program of hematology indications	Clinical/PM, biometrics oversight, site management, and data management
Allogeneic stem cells	I & II	Patients with AML, ALL, MDS post induction or consolidation	Project management, medical monitoring, pharmacovigilance, data management, site startup, management, monitoring, and statistics
Tumor Infiltrating Lymphocytes (TIL)	II	Melanoma	Program development, project management, medical monitoring, pharmacovigilance, data management, medical writing, statistics, vendor management, and site startup, management, and monitoring
Gene modified donor T-cells	I/II	Hematological 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 startup, management, and monitoring
Tumor Infiltrating Lymphocytes (TIL)	II	Head and neck cancers	Project management, pharmacovigilance, data management, site startup, management, and monitoring
Chimeric Antigen Receptor T-cell (CAR-T)	I	Multiple myeloma	Protocol development, project management, pharmacovigilance, data management, vendor management, and site startup, management, and monitoring
Chimeric Antigen Receptor T-cell (CAR-T)	I	Multiple myeloma	Project management, pharmacovigilance, data management, site startup, 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
Pediatric: primitive neuroectodermal tumors (PNETs) (brain)	II	Neuroectodermal tumors (PNETs brain)	Stats programming, protocol review/development, and SAP review

Precision adoptive cell therapy working group (continued)

Gerry Messerschmidt, MD, FACS

Gerry is an oncology expert with over 30 years of experience in pharma, biotech, and CRO companies, with a focus on hematologic development programs. He has worked with studies involving small molecules, antibodies, antibody fragments, haptamers, therapeutic vaccines, oncolytic viruses, radiolabeled therapies, and cellular therapies.

Specifically within cellular therapies, Gerry has been involved with the following:

- Head of the experimental hematology medicine branch at NCI for several years.
- Head of the "Experimental Hematology Section" Medicine Branch, NCI, NIH where he was a key member of the team involved with the first cell therapies.
- Part of Steve Rosenberg's team that identified several T-cell growth factors and eventually resulted in the whole field of Tumor Infiltrating Lymphocytes (TILs).
- Fred Hutchinson Cancer center cellular infusion researcher; subsequently started 2 academic bone marrow hematopoietic stem cell transplantation (HSCT) programs (Texas and Michigan).
- Primary developer and oversight in many cellular research programs. These have ranged from lymphocyte, other WBC cell types, and specialized cellular [infusion] therapies.

Most recently, Gerry has been involved in adoptive cell infusion programs and has assisted many biotechs with scientific discussions and protocol designs.

Deborah Phippard, PhD

Deborah is a translational sciences expert with over 25 years of experience in pharma and CRO companies with a focus on understanding MoA, biomarker discovery & implementation and patient stratification. She has worked with many biologics, including bispecific antibodies, ADCs and BiTES, as well as therapeutic vaccines, oncolytic viruses, and cellular therapies.

Specifically within cellular therapies, Deborah has designed multiple translational programs:

- Stratification of patients based on circulating levels of MDSCs – design and implementation of CLIA flow-based assays
- Full translational programs to determine and track immune response to autologous engineered T-cell therapies, both solid tumors and hematological malignancies
- Personalized tumor vaccines in combination with checkpoint inhibitors

Most recently, Deborah has been involved in autologous cell therapy programs and assisted many biotechs with scientific discussions and design of translational programs.

Megan Liles, MS

Megan brings over 21 years of industry experience in clinical research, with a focus on trial operations at both CROs and pharmaceutical companies. She served as global head of clinical operations department, including project management, monitoring, and regulatory/startup, for a UK-based CRO where she worked to establish a functional service model for sourcing of CRAs across Europe and US for a program of CAR T studies. Megan's experience in various cellular therapy programs includes CAR T cells (2 multiple myeloma trials), personalized vaccines derived from patient tumor tissue (solid tumor), Tumor Infiltrating Lymphocytes (cervical; head and neck) and umbilical cord stem cells (inherited metabolic disorder). She presented a webinar "Operational Excellence in Immuno-Oncology Clinical Trials" and has worked with project directors to develop an internal Cellular Immunotherapy Working Group.

Precision adoptive cell therapy working group (continued)

Tina Bees

Tina has over 20 years of clinical research experience and more than 13 years in oncology project management. She has experience in phase 1 through 4 studies in various therapeutic indications, supportive therapies, and devices across hematologic and solid tumors. Tina leads the Precision for Medicine Cell Therapy Working Group. She has extensive experience in various cellular therapies to include CAR T cells, Tumor Infiltrating Lymphocytes (TILs), and stem cells.

Specifically, Tina has been involved in the following studies:

- Stem cells in patients with AML, ALL, and MDS
- Tumor Infiltrating Lymphocytes (TIL) in melanoma
- Tumor Infiltrating Lymphocytes (TIL) in cervical cancer
- Tumor Infiltrating Lymphocytes (TIL) head and neck cancers
- Chimeric Antigen Receptor T-Cell (CAR T) in multiple myeloma
- Personalized vaccine in multiple solid tumors
- Allogeneic Antigen Targeted T Cell Receptor in AML

Clare Fourrier

Clare has 20 years of experience in global clinical operations, with in-depth experience in phase 1 through 3 oncology clinical research in both solid and hematological oncology indications, with a specific focus on early phase and adaptive design studies. Clare has maintained a specific interest in research at the forefront of developing new therapies, and her position as leader in CRO clinical research delivery has given her exposure to the evolution of the immuno-oncology therapeutic approaches and the requirements for their successful operationalization. Clare gained experience on the first global CAR T registration programs and has built on this to support cellular-driven therapy studies with a number of different biotech companies.

Specifically, Clare has experience in:

- Phase I/II autologous CAR T global study in NHL
- Phase II autologous CAR T study in mantle cell lymphoma
- Phase I/II autologous CAR T global study in ALL
- Phase I/II autologous CAR T study in multiple myeloma
- Phase I/II T cell-derived neoantigen matching personalized vaccine in multiple solid tumor indications

Gary Acton, MD, FRCP

Gary has over 27 years of experience in pharma, biotech, and CRO companies, with a focus on oncology development programs.

Specifically within cellular therapies, Gary has been involved in the following studies over last 18 months:

- Autologous T-cell receptor-modified therapy AML and MDS: Phase II
- Autologous CAR T pediatric neuroblastoma: Phase I
- Autologous CAR T multiple myeloma: Phase I
- Allogeneic dendritic cell vaccine NSCLC: Phase II
- Allogeneic CAR T solid tumor (ovarian, pancreatic, renal): Phase I
- Autologous CAR T plus checkpoint inhibitor: Adult T-cell leukemia/lymphoma: Phase I

To learn how Precision for Medicine
can accelerate your trial, please contact us
at info@precisionformedicine.com
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