Syneos Health Cell and Gene Therapy Consortium

Syneos Health® recognizes that cell and gene therapies present new opportunities for important novel treatments and a unique set of challenges for our sponsor partners, investigators and patients. This is why we have invested in consolidating and expanding our capabilities via our Cell and Gene Therapy (CGT) Consortium. The CGT Consortium is the centerpiece of our knowledge and experience base, focused on bringing the right staff and specific solutions together to deliver your CGT Program.

Cell Therapy Trials

With deep experience spanning Phases I-IV in 24 trials located in over 500 sites and recruiting more than 2,500 patients within the last 8 years, Syneos Health has delivered cell therapy trials in:
- Oncology
- Cardiology
- Endocrinology
- Orthopedics
- Ophthalmology
- CNS

Gene Therapy Trials

In the last five years, Syneos Health has conducted over 28 gene therapy and recruited more than 1,000 patients
- in more than 18 countries
- at over 300 sites
- spanning Phases I-IV

Our therapeutic experience in gene therapy includes:
- Hematology and CAR-T
- Immunology
- CNS
- Oncology: Hematology and Solid Tumors
- Ophthalmology
- Pediatrics
- Rare Diseases

Therapeutic Expertise + Cell and Gene Therapy Experience

Successful cell and gene therapy trials depend on multiple factors:
- a delivery team guided by our cell/gene therapy experience
- a deep understanding of the therapeutic area
- strong scientific subject matter expertise and trial involvement

Syneos Health can work with you to ensure all of these aspects are well defined for your clinical trials.
What Is the Syneos Health Cell and Gene Therapy Consortium?

Cell and gene therapies (CGT) are often novel treatments, with complex study designs, focused on challenging patient populations with unique operational delivery requirements. The CGT Consortium brings together a team of internal experts leveraging their experience to deliver on the opportunities and challenges specific to CGTs. These experts and experienced staff members come from clinical operations, early phase, regulatory, real-world/late phase, consulting, commercial and our functional delivery teams. They ensure our collective knowledge is fully leveraged to deliver the solutions specific to the needs of each trial.

**Evolving Regulatory Landscape**

Rapid changes and new approval pathways present challenges and opportunities that our regulatory experts navigate and leverage to inform strategic decisions and study designs. These opportunities include nonclinical development planning for pre-preIND (INTERACT) FDA meetings and regulatory strategic support to determine the most efficient and applicable accelerated pathway to initiate the program and accelerate the program development.

**Operational Solutions**

Our experienced staff knows how to manage complex logistics for investigational product and patient care. When leveraging the Syneos Health Trusted Process® for delivery, our experts define CGT specific operational challenges and develop solutions while communicating the unique study needs to investigators, site staff and patients.

**Biopharmaceutical Acceleration Model™ (BAM)**

The Syneos Health Biopharmaceutical Acceleration Model (BAM) leverages our commercial expertise and reimbursement data to influence clinical development plans and study designs with the goal of developing products that bring needed treatments to patients and are well suited for commercial success.

---

**About Syneos Health**

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are shortening the distance from lab to life® at syneoshealth.com.

© 2019 Syneos Health® All rights reserved.