

# Cell and Gene Therapy Institute

End-to-end leader in delivering cell and gene therapy (CGT) solutions for tomorrow's patients today through faster delivery and operational efficiencies in clinical research.

Regardless of where your asset is along the drug development journey, our PPD® clinical research solutions help enable you to bring your drug to the clinic quickly and safely. Leveraging nearly 40 years serving as a CRO leader in advanced therapies, we continually focus on driving operational excellence, deploying state-of-the-art technologies, and keeping pace with evolving regulatory landscape to deliver on our clients' commitment.

#### What makes our solutions different?

As the only CRO that can seamlessly integrate manufacturing capabilities, laboratory services, ultra-cold chain logistical support and clinical trial management from early development to post-market authorization, PPD, Thermo Fisher Scientifics's clinical research business, is poised to better serve clients needing a streamlined process to simplify complexity and reduce vendor management risks and burden.

Through accumulated experience in the development and manufacturing of cell and gene therapies, several key practices have been identified to help address challenges, ensure high quality standards, and contribute to enhancing the overall patient experience.



#### Support for patients and caregivers

Participation in cell or gene therapy clinical trials can place significant burdens on patients and their families. To best support patients and strengthen our understanding of their needs, we engage with patient advocacy groups and other stakeholders to bring patient voices into the trial development process as early as possible. Because of the high level of patient commitment and compliance required in these studies, we provide ongoing education and support to patients and caregivers to ensure that patients start and stay with the trial to the very end. Our robust education and awareness campaigns connect patients with cell and gene trial opportunities while our patient concierge service walks

each patient through the trial process to anticipate and address their needs. A variety of travel services can also be coordinated to reduce patient/caregiver stress and burden.

Alternatively, to lessen patient's burden and bringing trials closer to home, our comprehensive Digital and Decentralized Services provide options to provide patients with electronic consent, home healthcare and nursing, as well as telemedicine services. These are some examples of tools we can help deploy to support patient retention in advanced therapies, especially for studies requiring long term follow up.

### Why should you trust us with your study?

CGT development often comprises the most intricate clinical value chain in modern medicine, demanding a CRO partner that appreciates both the technical and regulatory nuances of the field. As a newer therapeutic modality, CGT trials and approvals require diligence in collecting safety and efficacy data, and present unique logistical and scientific challenges.

Our Cell and Gene Therapy Institute (CGTI) enables our clients to develop and execute successful trial strategies through a cross functional team of experts who provide diverse experience in study design, technologies, clinical operations and regulatory.

## BENEFITS TO YOU A robust evidence generation plan from pre-clinical to post-authorization Access to operational, functional, Better anticipation and technical, regulatory and therapeutic mitigation of risks associated with these specialized trials CGT expertise across all phases Agile and flexible solutions to Greater confidence and capabilities to quickly advance your CGT asset ensure your CGT clinical trials and through each stage in the process long-term follow-up meets enrollment goals and retains patients to ensure quality data collection to support your study outcomes

