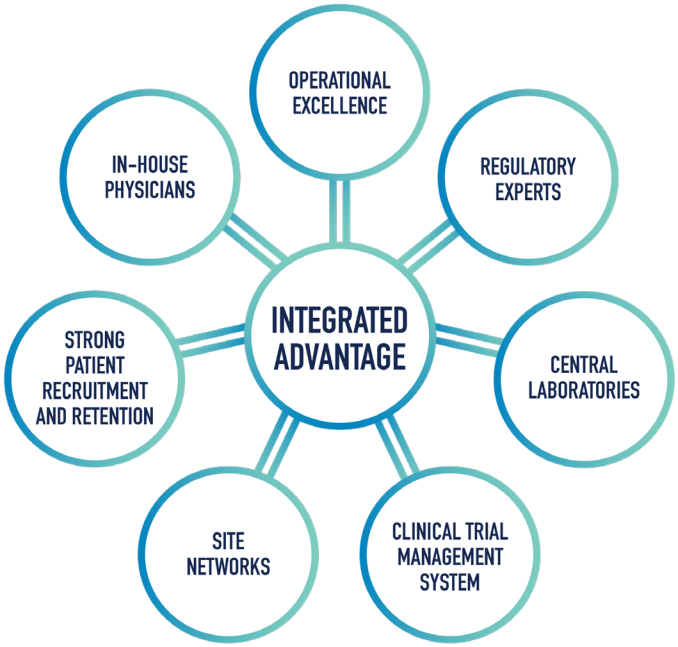
MEDPACE®

THYROID EYE DISEASE CLINICAL DEVELOPMENT

Beyond its clinical manifestations, Thyroid eye disease (TED) imposes a substantial burden on patients through pain, visual disturbance, and disfigurement, often leading to decreased productivity and reduced quality of life. While advances have been made, many patients continue to experience unmet needs due to disease heterogeneity, treatment limitations, and variable response. Ongoing innovation and the development of novel therapeutic approaches are essential to improving disease control, preserving vision, and addressing the full spectrum of patient impact.

Medpace's expertise in ophthalmology, rare disease, and autoimmune studies and consistent track record of success as a full-service CRO ensures the flexibility to adapt to the unique needs of each thyroid eye disease trial. Our cross-functional experience is key for managing complex ophthalmology trials, including thyroid eye disease.

Our expertise and multi-disciplinary teams are experienced in many different areas to provide guidance on the complexities often involved in this research. The specialized knowledge coupled with global regulatory authorities, early planning, and collaboration with Sponsors accelerates the path to approval. Medpace facilitates clinical development by fully embedding medical leadership and a wide array of relevant therapeutic expertise, integrated across all functional areas throughout the lifecycle of the clinical trial.



EXPERTS

- In-house medical leadership, (board certified ophthalmologists, endocrinologists, and immunologists) actively involved throughout the project lifecycle
- Experienced trial and data managers drive efficiency and quality
- Highly-trained clinical operations team, including clinical trial managers and project coordinators
- Cohesive study team with expertise in monitoring ophthalmic disease progression across large populations

EXPERIENCE

- Experienced in thyroid eye disease clinical development across a wide range of scope and complexity
- Able to address key clinical and operational considerations

EXECUTION

- Long-term relationships with successful, experienced sites, networks, and key opinion leaders
- Proactive patient recruitment and retention planning tailored to global rare disease studies
- CAP accredited central lab services for safety testing, PK/PD, biomarkers, and genomic testing
- ClinTrak® - A proprietary, feature-rich, and fully customizable Clinical Trial Management System to inform decision making, drive efficiencies, and keep your study on track

SPECIALIZED TEAMS

Our in-house medical leadership, including board certified ophthalmologists, endocrinologists, and immunologists, are embedded within the project team and are fully-involved throughout the lifecycle of the project providing leadership, consulting with Sponsors, and training project teams and investigative sites to ensure our operational strategy is firmly aligned with the Sponsor's scientific and medical objectives.

With demonstrated expertise leading Thyroid Eye Disease trials, Medpace prioritizes investigator and site training on examination technique, endpoint definitions, and sources of inter-rater variability to ensure data consistency, especially in a global trial. Small changes in proptosis or diplopia can determine trial success; therefore, standardized examination techniques are critical to ensure reproducible, high quality measurements. TED trials rely on a relatively small, specialized network of oculoplastic and orbital disease experts, as well as endocrinologists. These investigators are engaged and supported by our team through familiarity with the nuances of TED and its clinical management. Through integrated, cross-disciplinary medical oversight, Medpace ensures both patient safety and reliability of trial endpoints.

Additionally, our operational teams, including clinical trial managers and project coordinators, are therapeutically aligned to facilitate specialized training to sites. From study start, we work closely with the sites to understand the flow of patients to determine the operational and logistical strategy unique to each site dependent on the site being ophthalmology or endocrinology focused. Operationally, Medpace has a proven track record of rapid study start-up, successful recruitment and retention, high quality site monitoring and oversight, and proactive risk mitigation. With turnover rates that are lower than the industry standard, teams are often consistent from project initiation to completion, adding continuity and efficiency to the study.

PROACTIVE PATIENT RECRUITMENT & RETENTION

Due to the unique challenges associated with rare disease studies, partnering with a CRO with experience recruiting and enrolling patients and relationships with key investigative sites is crucial. Our multi-dimensional recruitment model enables us to implement innovative, comprehensive, and customized recruitment and retention strategies to effectively target members of specific patient populations.

CENTRAL LAB

Medpace's wholly-owned central laboratories with state-of-the-art infrastructure are fully integrated with Medpace CRO services. Medpace central labs are experienced in clinical research from discovery and proof of concept through large, long-term global trials. Medpace has CAP-accredited central laboratory services for safety testing, PK/PD, biomarkers, and genomic testing, and utilizes a single laboratory information system to ensure perfect harmonization of global data.

PURPOSE-BUILT CLINICAL TRIAL MANAGEMENT SYSTEM

As part of the full-service, single-vendor outsourcing strategy, Medpace offers a proprietary Clinical Trial Management System, ClinTrak®, that ties all study data together in a single platform. This leading edge technology informs decision making, drives efficiencies and productivity throughout the clinical trial process, and keep studies on track.

MAKING THE COMPLEX SEAMLESS®