MEDICAL DEVICE AND DIAGNOSTICS
DEVELOPMENT CASE STUDY

Progressive myopia treatment evaluation in a multifocal contact lens trial.

Unlike regular myopia (shortsightedness), progressive myopia worsens over time and leads to increasingly severe visual impairment. It often begins during childhood or adolescence and can continue into adulthood if left untreated. Asian ethnic children are disproportionately affected by progressive myopia. Studies show a higher prevalence in this population compared to the general population.

Running trials that target this affected population requires not only detailed knowledge of medical device development, but also pediatric patient recruitment and its associated complexities including anticipating and accommodating the needs of multi-national regulatory authorities.

Patient population and size

The subject sample in the clinical study is myopic children between the ages of 7 to <13 years (at the time of enrollment) randomized in a 2:1 ratio. Number of randomized patients participating is 145. Countries participating in the trial: Canada, Hong Kong, U.S. and Singapore.

Due to anticipation of future submission to the NMPA (Chinese Regulatory Authority), the requirement of at least 30% of the population from all sites to be native Chinese was also followed and metrics reported.

Fortrea

Timelines

- Start date: March 5, 2021
- LPI: September 2022
- LPO: December 2025
- End date: March 2026
- Enrollment rate: 13 subjects per month (varied by site)

Critical milestones

- 12 month interim analysis for determination of crossover/treatment change November 2023
- To prepare the sites for crossover, DM and CTL implemented document with set guidelines
- CTLs trained the CRAs, and the CRAs work 1:1 with the sites when their first crossover visit window is upcoming

Challenges

As well as the anticipated challenges of a trial involving children across multiple countries and sites, the trial also faced unforeseen challenges with both international ethics committees and COVID-19 shut downs and restrictions. These included:

- Site start-up in APAC countries (Hong Kong and Singapore) was extensive
- Hong Kong sites approved by CFDA were limited to 4 sites
- One Hong Kong site EC would not approve study design unless atropine was used as comparator and was not included in trial
- Many of the sites were research naïve optometry sites with no clinical trial experience
- Study start during COVID-19 shut down—impacted recruitment in Canada due to limitations to on-site visits
- High number of screen failures due to the inclusion/exclusion (I/E) criteria resulted in protocol amendment
- Defined variables involved as secondary endpoints at the beginning of the study, as well as well-established subgroups, therefore aiding in final analysis
- CRF data capture developed to help determine variables that may affect the Myopia progression and treatment response such as genetic or environmental factors

Demographic diversity breakdown

42% < 10 yrs | 58% ≥ 10 yrs

53% Native Chinese

	<10 years	≥10 years	Total
101—Canada	1	3	4
102—Canada	4	11	15
203—Hong Kong	19	31	50
204—Singapore	1	11	12
301—U.S. Chicago, IL	6	3	9
302—U.S. New York City, NY	7	2	9
303—U.S. Houston, TX	22	23	45
304—U.S. Fresno, CA		1	1
GRAND TOTALS	60	85	145

Successful outcome

Fortrea met the evolving needs of the trial by being agile with design and requests.

This challenging patient population meant that we expanded the countries in the study, and modified our strategy to recruit successfully and meet diversity requirements. We also updated inclusion/exclusion criteria to reduce screen failures, and leveraged Facebook to boost enrollment. We also worked with our Site network to ensure that they could accommodate children and their school schedules by running the studies during evening hours and on Saturdays.

The Data and Safety Monitoring Board (DSMB) charter was also modified to meet requests to outline expectations and ensure efficiencies in review.

Before the trial was completed, we were also able to provide data at the sponsors request to support industry meeting updates.

Fortrea
Together, exceptional is possible

LEARN MORE at fortrea.com

Fortrea