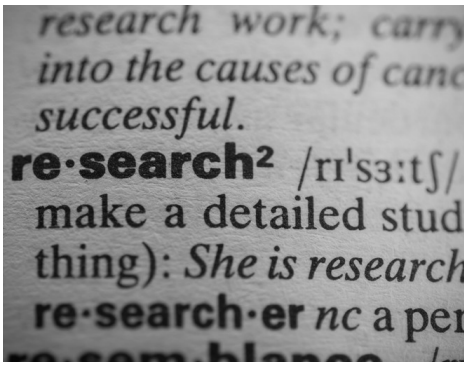

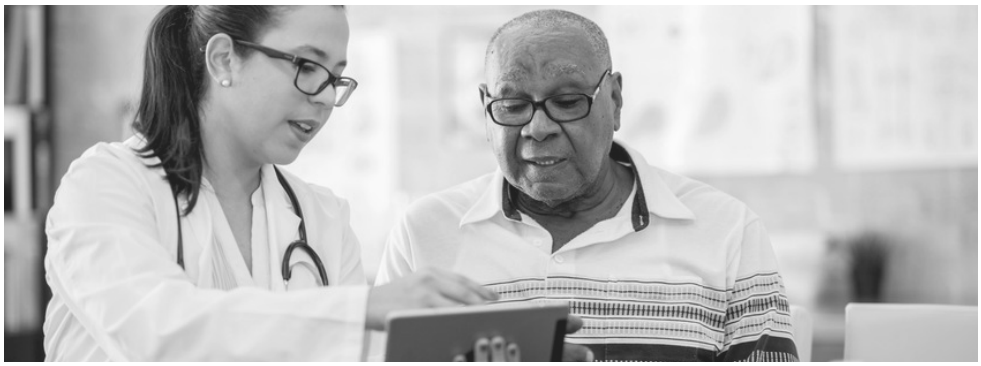

Novum
PHARMACEUTICAL RESEARCH SERVICES

CASE STUDY

NOVUM SUCCESSFULLY DELIVERS A COMPLEX LATE-PHASE SCABIES STUDY

OVERVIEW

Novum was awarded a phase III, randomized, double-blind, parallel-design, multiple-site study focused on comparing the equivalence of a test product to an existing brand-name drug for the treatment of scabies.

OBJECTIVES

Evaluate the therapeutic equivalence of the Test formulation to the marketed product, and compare the safety of Test and Reference treatments in patients with scabies.

CHALLENGES

- Managing a multinational patient enrollment strategy for 15 sites located in the United States, Puerto Rico and El Salvador.
- Gaining regulatory approval at each country's local ethics committee.
- Navigating nuances for the shipment of investigational products into each country.
- Experiencing delays in deliveries of investigational products due to regulatory constraints.
- Obtaining a Certificate for Provider Performed Microscopy (CLIA) under new state regulations.
- Overcoming harsh climate conditions and natural disasters such as Hurricanes Harvey, Irma, and most notably Hurricane Maria.

NOVUM'S APPROACH

Novum's team defined a specific plan for each country. The comprehensive strategic plan and innovative recruitment approach allowed for exceptionally rapid and effective recruitment, ahead of schedule. Moreover, Novum leveraged its strong relationship with Investigator Sites in each country to monitor the approval process in a timely fashion and track product shipments for the study. When delays in the delivery of investigational product occurred, Novum contracted Investigators visited the corresponding quarantine facility in order to expedite the release of the drugs.

State Laboratory regulations were amended around the time of site initiation. This led to the impossibility of launching at one of the sites, as they were unable to complete compliance process during the enrollment period. Yet Novum maintained regular communication with the site during this period, and made key introductions between the site's management and another site which had recently obtained CLIA under the new state regulations. Ultimately, Novum authorized two additional high-performing sites to over-enroll to compensate for the loss of enrollment at the uncertified site.

The project also faced risks from unprecedented natural disasters. Hurricanes Irma and Maria compromised communications and infrastructure, which halted recruitment and made monitoring and follow-up with the sites affected extremely difficult. Additionally, the internet and electricity across the island of Puerto Rico were infrequent and unpredictable. However, Novum's team went above and beyond, working outside of normal business hours to ensure quick responses whenever given a window. Novum Investigators were able to retain all enrolled subjects ahead of contracted timelines.

RESULTS

- Exceeded deadline expectations under harsh climate conditions and natural disasters.
- Created the study's final report three months ahead of schedule.
- Resolved challenges faced in local regulatory legislation considering the complexity of the study.
- Completed recruitment, screening and enrollment ahead of initial timelines set.
- Ensured the safety, monitoring and shipment of drugs at a multinational scale.
- Achieved all the study's objectives and goals.

The sponsor was extremely satisfied with the results and it has selected Novum as its quality CRO partner for subsequent studies.