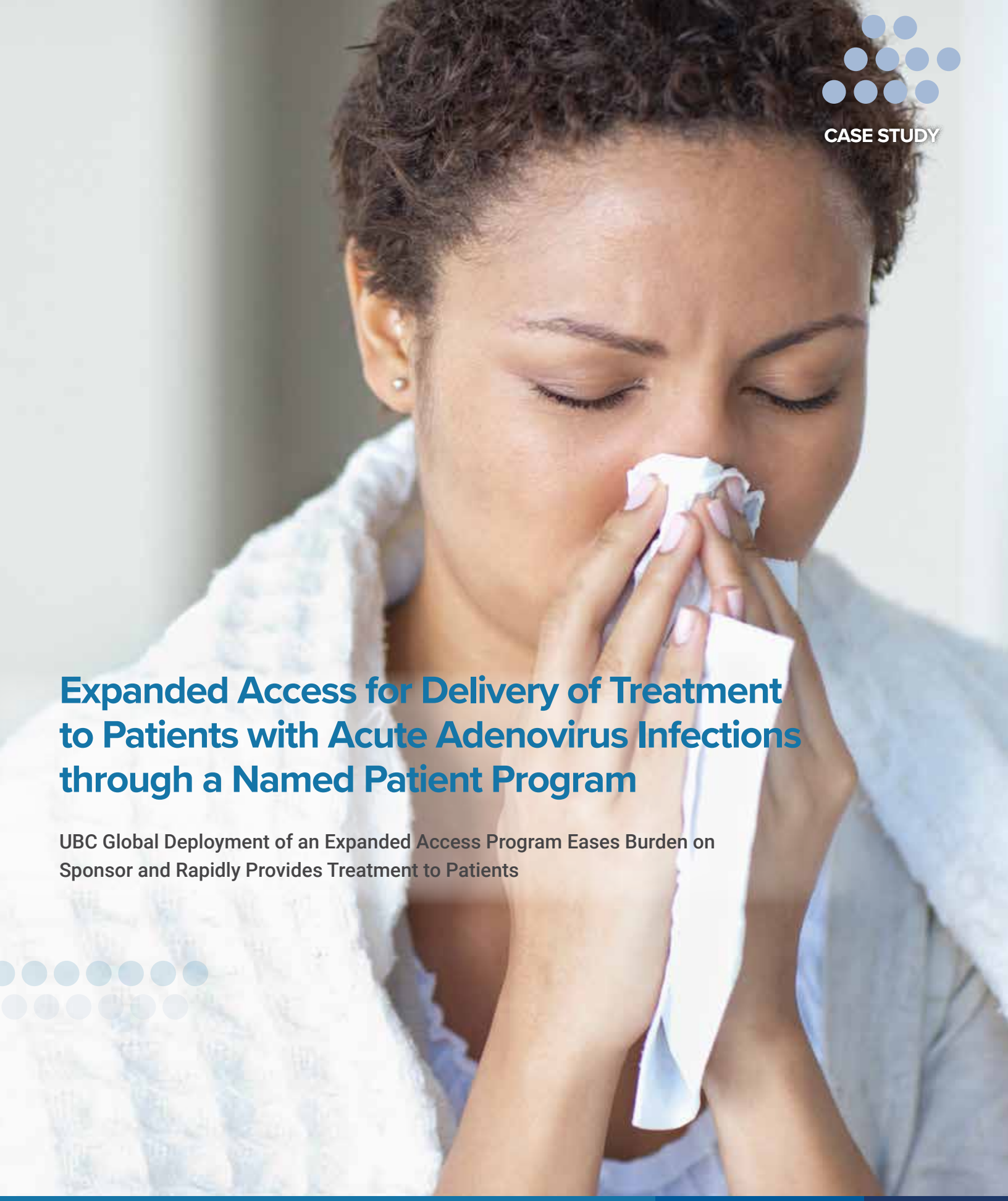

CASE STUDY

Expanded Access for Delivery of Treatment to Patients with Acute Adenovirus Infections through a Named Patient Program

UBC Global Deployment of an Expanded Access Program Eases Burden on Sponsor and Rapidly Provides Treatment to Patients

UBC®

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SITUATION

As breakthrough therapies are under development, particularly for diseases for which limited or no treatment is currently available, more patients are requesting access to medications in the window between the end of registrational trials and marketing approval. Often biopharmaceutical companies launch Expanded Access (EAP) or Compassionate Use Programs (CUP) to address this unmet need. The implementation of EAPs can be considered in a variety of stages and situations during the lifecycle of the drug. They can be considered in the early stages of product development where there is a likelihood of the product showing promising results for patients who cannot take part in clinical trials, or, once a clinical trial is fully enrolled, making the product available to patients until market approval. For sponsors, there are numerous operational logistics and regulatory approvals required in order to provide access to their medications through an EAP or CUP.

UBC was engaged to assume responsibilities for a named-patient EAP by a sponsor company that is developing a product to treat a rare infectious disease. Named-patient EAPs involve pre-approval access to treatments in response to requests by physicians on behalf of specific, or "named", patients before those medicines are licensed in the patient's home country. Whereas site-based EAPs are initiated by sponsor companies and allow physicians to offer the treatments to a cohort of patients, named-patient EAPs are limited only to the requested named patients. The sponsor had initiated the named-patient EAP but required dedicated operational support due to a high patient demand and the need to expand globally.

CHALLENGES

The named-patient EAP required expedited patient eligibility review and urgent drug shipment (within 48 hours) to an extremely sick patient population. The program initiated in the US and 9 countries in the EU with plans to expand to other countries based on the location of the requesting physicians and their patients.

SOLUTIONS

UBC designed and implemented a comprehensive operating infrastructure that was scalable as the program expanded, and required robust quality control management. The success of the program was a result of the following UBC solutions:

- Automated patient eligibility review, approval, and tracking process
- Dedicated multi-disciplinary global program team
- Dedicated 24/7 call center as the initial physician interface to support management of requests
- Rapid start-up methodology for participating physicians
- Seamless transition to site-based EAP design in the US

RESULTS

As a result of the above mentioned **patients first** solutions, UBC

- Provided patient eligibility decisions and managed expedited drug shipments within 48 hours of receipt of the request.
- Successfully processed > 1100 individual named patients
- Effectively handled the expansion of the program to 23 countries (USA, Canada, China, Czech Republic, Australia, Austria, Belgium, Denmark, France, Germany, Lithuania, India, Israel, Italy, Mexico, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland, United Kingdom)
- Subsequently launched a site-based EAP design in the US, activating 47 sites and enrolling over 352 patients

To learn more about our services and solutions related to EAP and CUP, please visit ubc.com or email us at contact@ubc.com.

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