OCT CLINICAL

Dr. Reddy's

Case Study:
Dr. Reddy's & OCT Clinical

How to Enroll 612 Patients in a Neurology Study on Time and Within Budget Despite Hurdles Caused by the Pandemic

In June 2020 Dr. Reddy's, a leading Indian pharmaceutical manufacturer, in partnership with OCT Clinical, an Easter European CRO, launched a Ph3 neurology study. Despite pandemic-driven uncertainty, the enrollment target of 612 patients was reached within an impressive seven months, two weeks ahead of schedule.

Study details

This was a multicenter, prospective, double-blind, randomized, parallel-group comparative study. The aim of the project was to determine the efficacy and safety of the Ibuprofen + Chlorzoxazone (Dr Reddy's Laboratories Ltd., India) fixed-dose drug combination against a comparator in male and female patients aged 18-55 with acute nonspecific lower back pain. OCT Clinical was contracted as a CRO responsible for a wide range of activities, including medical writing, project management, site selection, medical monitoring, data management and statistics, study supplies logistics, and pharmacovigilance.

Dr. Reddy's Laboratories Ltd. is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses – Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology. Their major markets include – USA, India, Russia & CIS countries, and Europe.

Main challenges during the project

The study startup and recruitment coincided with the first wave of the COVID-19 pandemic, which forced a reassessment of clinical trial conduct and feasibility. The pandemic resulted in restrictions of visits to healthcare facilities, imposed social distancing requirements and limited investigators availability for clinical research activities. These limitations were particularly evident in public medical facilities. Another issue was travel restrictions, and anxiety among patients visiting research centers. Sponsors and investigators were strongly encouraged to find alternative approaches to maintain trial participant safety and study data integrity by the use of remote technologies such as remote monitoring visits, remote investigator meetings, and remote consultations with enrolled patients.

Strategy and solutions

The Sponsor and the CRO had to respond swiftly to the altered landscape during COVID-19 and accomplish the goals within required timelines without sacrificing quality and the safety of the subjects involved. All project plans were redesigned with consideration given to the environment caused by the pandemic.

It is important to note that none of the research sites refused to participate in remote visits or showed any reluctance toward remote interaction with CRAs. Regular online communication with the sites helped retain the motivation among investigators.
As a result of such a productive communication pattern among all the parties involved, the target of 612 patients was reached within the initially stipulated timelines.

Key drivers for success:

- Focus on research sites based on the experience OCT Clinical had in the past.
- Inclusion of site lockdown scenarios in the risk management plan.
- Timely replacement of sites that were put on lockdown, and additional involvement of private non-state sites that are prepared to work remotely, and those that are prepared to conduct face-to-face visits and begin patient recruitment in such difficult conditions.
- Active involvement of the entire clinical team during regular investigator meetings and staff consultations, resulting in timely settlement of all issues at research sites.

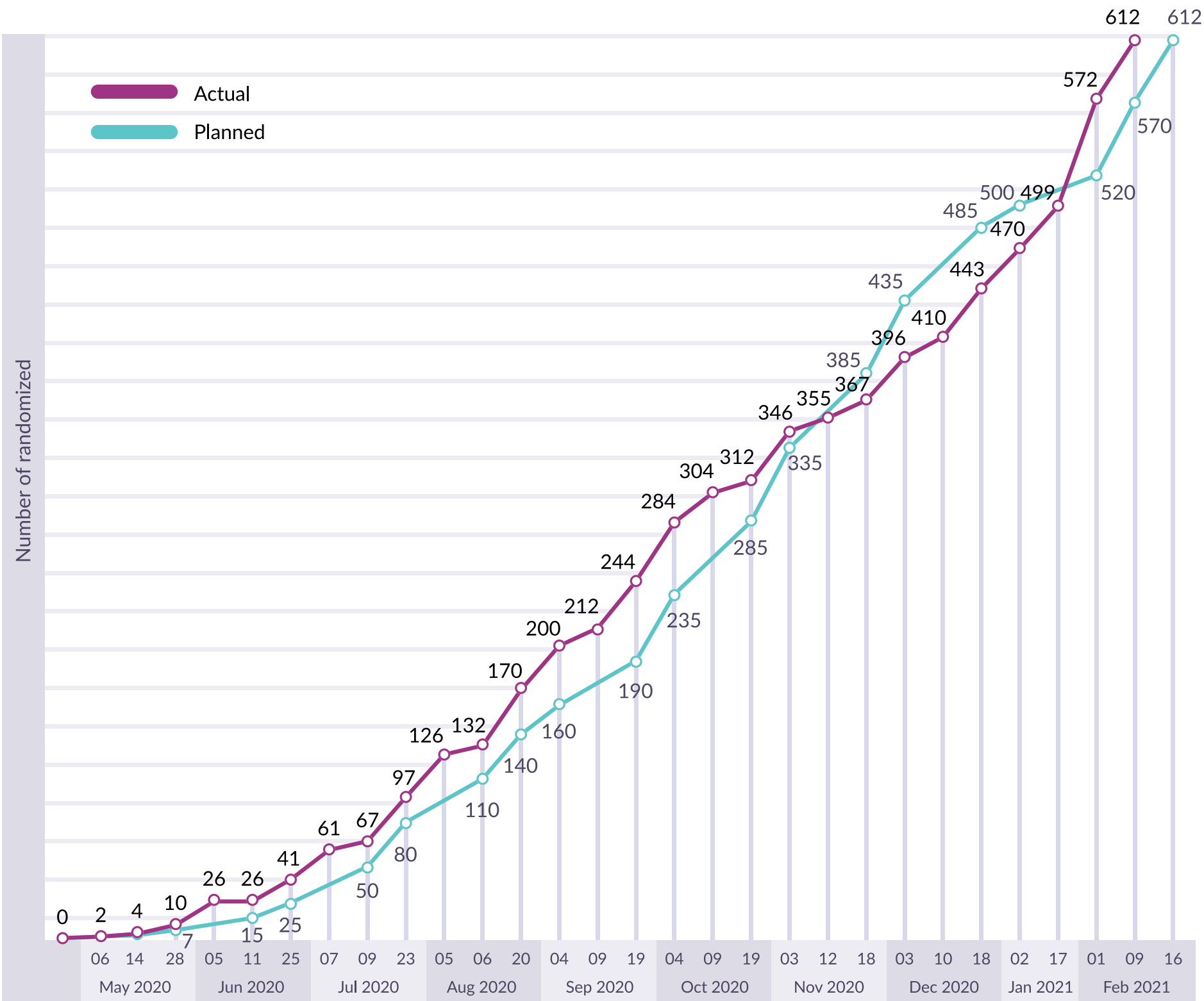
  “It is true that working with sites under these circumstances is more labor- and resource- consuming for the team,” **said Julia Stepanchuk, a project manager at the OCT Clinical CRO.** “Interaction with investigators, and hence resolving various issues – especially with new sites – was taking more time then usually. Nevertheless, our team has been very quick to adapt to the new reality and keep working hard to ensure the continuity of studies.”
- Implementation of remote site initiation visits, which helped to reduce the startup period and let the patient screening begin according to the timelines established in the contract.
- The development of guidance materials for the effective and efficient remote monitoring visits. All staff members were trained on the specifics of conducting such visits.

  “Each guideline is developed taking into account the specifics of a project and the number of checks that need to be done in each particular case: steps to be taken before, during, and after the visit, and what tools are required for a CRA to conduct a proper visit (audio, videos, photo),” **Stepanchuk explained.** “Prior to a visit, CRAs provide investigators with detailed information on what they need to deliver during the visit.”

- Involvement of sponsor representatives at the first remote visits. This was done to assure the sponsor that the site in question was properly prepared to participate in a monitoring visit, despite it being remote.

- A flexible approach in central monitoring, well-coordinated team activities and consultations with trial participants.

Number of randomized patients. Actual vs. Planned



Results

Regardless of the chaotic situation caused by the global pandemic, the project's clinical team managed to complete the recruitment within seven months. With enrollment starting in June 2020, the last patient was successfully randomized in February 2021. The tested drugs were studied at 28 research sites across several cities in Russia. With 612 study participants randomized out of 646 screened, the OCT Clinical team demonstrated an impressively low screen failure rate (34 subjects out of 646). There was no significant impact on the study budget due to effective financial management and re-allocation of on-site visit costs into remote visit costs. Besides that, several independent audits were successfully completed at five research centers at the peak of patient recruitment.

> "We are pleased with OCT Clinical's ability to maintain motivation among their employees and meet our recruitment goals within agreed timelines, especially during these tough pandemic months"
>
> **Alexander Khaymenov, MD, Ph.D., Head of Clinical Research at Dr. Reddy's Laboratories' representative office in Russia.**

Lessons learned

The success of the study in terms of achieving KPIs and major milestones can be attributed to several factors. Some of these practices could be considered also for regular practices n other clinical trials. Thus, in any complex situation, the process of site selection should mostly rely upon previous successful experience. Planning for additional backup sites (up to 25%) proved to be an effective mitigation tool. It is recommended that those involved to keep searching for new sites to be able to deal with all types of eventuality. Also important is to set recruitment deadlines for sites and investigators, while providing them with information about the numbers of enrollment at top-performing sites. Having followed this set of measures, the OCT Clinical team, even within the hurdles caused by the COVID-19 nightmare, managed to undertake all activities within the project on time and complete the recruitment of 612 subjects two weeks ahead of the initially agreed schedule.