excelya

Case Study

Type:	Geography:	Study Type:	Client:
Pain	Europe	Phase III	Biotech

PROJECT TITLE:
A Comparative, Randomized, Double-blind, 3-arm parallel, Phase III Study to Evaluate the Efficacy and Safety of a Fixed Dose Combination of XXX (tablet) Taken Orally in Moderate to Severe Pain After Impacted Third Molar Extraction.

Objective 1
To evaluate **the efficacy** of a fixed dose combination of XXX in the treatment of pain in dental patients

Objective 2
To compare **the safety profile** of the respective individual active substances

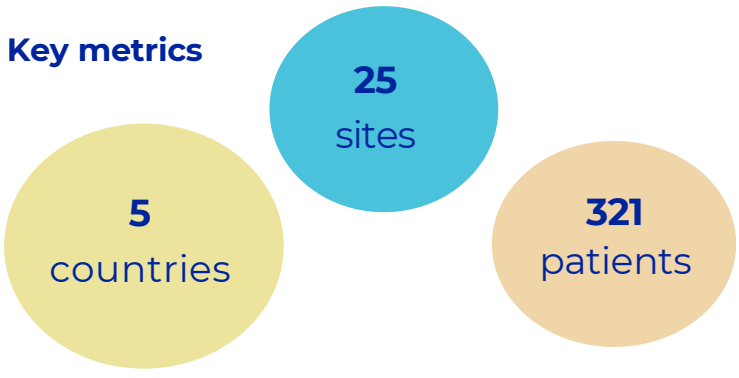
Study Challenges:

1) Patient recruitment: Low patient enrollment at the study start. Recruitment impacted by COVID and geopolitical conflict
2) IMP expired due to extension of study timelines
3) IMP management: Sites not used to IMP/NIMP management (Temperature/ Stock mgt)
4) Protocol Design: Different questionnaires (electronic & paper) to be completed in short time frame. Time consuming for patients, without dedicated resources available on site

Excelya Solutions:

1) Country expansion: Proactively preidentified and opened additional countries to counter recruitment disruption
2) Relabelling campaign: Close contacts with sites/on-site visits organised to ensure IMPs shipment for relabelling in due time
3) Protocol deviations related to IMP stockage closely followed-up. No IMP resupply to sites, with protocol deviations linked to IMP stockage
4) Site management: Focus on site training and engagement through flexible monitoring visits. Remote eCRF review and protocol deviation management

Key metrics



Impact for Client:
Ability to adapt strategy to keep the study and recruitment on track, despite all unprecedented macro challenges (namely COVID-19 and geopolitical).