

# CASE STUDY

## Gastroenterology (Celiac Disease) Case Study

### Background

A **Phase 2b randomized, double-blind, placebo-controlled, multi-center study** to evaluate **efficacy** and **tolerability** in **celiac disease** subjects experiencing symptoms despite gluten-free diet.

**10 countries in Europe, 50 sites.**

### Engagement

- Full Service

### Challenge

- **Rescue study from CRO**
- Very high screen failure rate
- Slow sites activation rate
- Client unsatisfied with the project performance

### Optimapharm solution

- Implementation of **protocol amendment** to reduce SF rate
- Rapid global **feasibility** targeted to **30 countries (Europe, APAC, US, Canada)**, allowing to expand the project **from 10 to 21 countries (Europe + APAC)**, from **50 to more than 120 sites**
- Implementing **tailored recruitment booster activities** (incl. an online campaign via dedicated recruitment vendor, referral system, patient advocacy groups involvement and many others)
- **Relying on good professional relationship** between PIs, site teams and our CRAs (responsive and collaborative environment)
- **Project team structure adjusted** to manage high scale study
- All processes reviewed and optimized **improving the project performance**

### Outcomes

- **Screen failure rate decreased**
- **Recruitment being back on track to hit agreed timeliness** (due to implemented activities and rapid sites activation)
- **Sites motivation** and study visibility increased
- **High Sponsor satisfaction** resulted in the **repeated business** for another GI study

