

Clinical Trial Liaison (CTL) Team Helps Shorten Trial Enrollment Time

THERAPEUTIC AREA: Rare Disease
DISEASE STATE: ALS (Amyotrophic Lateral Sclerosis)
LIFECYCLE: Phase II Study

SITUATION

- US healthcare company with no footprint in Europe or APAC and little to no familiarity with regional key opinion leaders (KOLs)
- Was conducting a Phase II potential registrational study in rare disease with a global target enrollment of 228 patients
- Therapy was an investigational molecule demonstrating high potential to benefit patients
- Client was driven by a desire to address critical unmet medical needs and was seeking KOL endorsements
- Trial had experienced unanticipated operations issues during startup and unexpected regulatory delays in France, so was under pressure to accelerate study enrollment

STRATEGY

- Amplity identified obstacles to trial efficiency and progress
- We developed CTL role to support scientific engagement and site activation, gather insights, and aid study progress
- We recruited, trained and managed a team of highly experienced, well-connected, science-focused CTLs
- CTLs to collaborate closely with the client, the client’s third-party clinical research organization (CRO), and study teams to educate physicians, identify issues, and offer solutions
- Educate 150+ investigators and their teams in peer-to-peer education style, increasing enrollment rate and enhancing study team satisfaction, raising awareness of the company and therapy in US, EU, APAC and LATAM

RESULTS

- Participated in site initiation visits (SIV) and supported clinical research associate (CRA) implementation for 75 sites worldwide, ultimately managing 37 clinical sites in Europe, 17 sites in APAC, 13 sites in the US, and 8 sites in LATAM

Average number of patients expected per site was 3; top performing sites by number of patients randomized by site is shown to the right

Country	Number of Patients	Number of Sites
Poland	30	3
Italy	28	5
Spain	20	3
Australia	15	5

Region	Total Patients Enrolled
EU, APAC, LATAM	221
US	7
TOTAL	228

Figures by region demonstrate how patient potential for this study was significantly higher outside of the US

- From the start of site activation, site enrollments were completed in the US in 18 months and in the EU and APAC in 11 months.
- The CTL team also scheduled 5 investigator meetings.