

Clinical Trial Liaison Team Exceeds Global Trial Enrollment and Timeline

THERAPEUTIC AREA: Rare Disease

DISEASE STATE: Amyotrophic Lateral Sclerosis (ALS)

LIFECYCLE: Phase 2

SITUATION

- U.S. biopharmaceutical company with promising investigational molecule demonstrating **high potential** to benefit patients and address critical unmet medical need in ALS
- Phase 2 registrational study had immediate goal to enroll **221 patients in 12 months across Europe (EU), Asia Pacific (APAC), and Latin America (LATAM)**
- Sites were experiencing difficulties delaying trial enrollment:
 - Sites had experienced unanticipated operational issues during startup and unexpected regulatory delays
 - Client lacked the local, clinical experts needed to drive scientific exchange with trial sites

STRATEGY

- After careful consideration of current obstacles against trial efficiency and progress, Amplity customized the Clinical Trial Liaison (CTL) role to support the specific scientific engagement and educational requirements in line with the Client's needs and timeline:
 - CTLs would foster close collaboration with both the Client, their third-party clinical research organization (CRO), and site study teams
 - CTLs to educate healthcare professionals (HCPs) and site teams, identify issues, and gain insights to aid study progress
- Amplity's strategy included the recruitment, training, deployment, and ongoing coaching/management of highly experienced, well-connected, science-focused CTLs within 6 to 8 weeks

RESULTS

- Amplity's CTLs successfully built site relationships in line with their goals to raise awareness of the trial, the company, and the therapy area, ultimately **educating 150+ investigators** and their teams
- CTLs **recruited 221 patients across EU, APAC, and LATAM** effectively reaching the global target enrollment goal and **exceeding target enrollment timeline by 6 weeks**

