

# Worldwide's Dedication to ALS: From Terminal to Treatable

Amyotrophic lateral sclerosis (ALS) is a complex and invariably fatal neurodegenerative disease that presents multiple complications, including substantial heterogeneity in clinical presentation and relentless progression, which make study design and conduct particularly challenging. At Worldwide, we partner with sponsors, investigators, and stakeholders across the ALS community to advance clinical development programs exploring investigational disease-modifying therapies in ALS.

As a cornerstone of our therapeutic focus, our ALS-dedicated teams have mastered the complex operations of global ALS trials, executing with high data integrity and quality. Through our partnerships with ALS centers across the globe, we are helping to increase equity in access to investigational products and provide hope to more people living with ALS. We embrace “nothing about us without us” – that patients inform policy, and we use their experiences and perspectives to drive our solutions.

## Meet Your Team



Lucie Undus, MD, PhD  
Executive Director, Therapeutic  
Area Medical Lead



Tomislav Babic, MD, PhD  
Vice President, Scientific Solutions



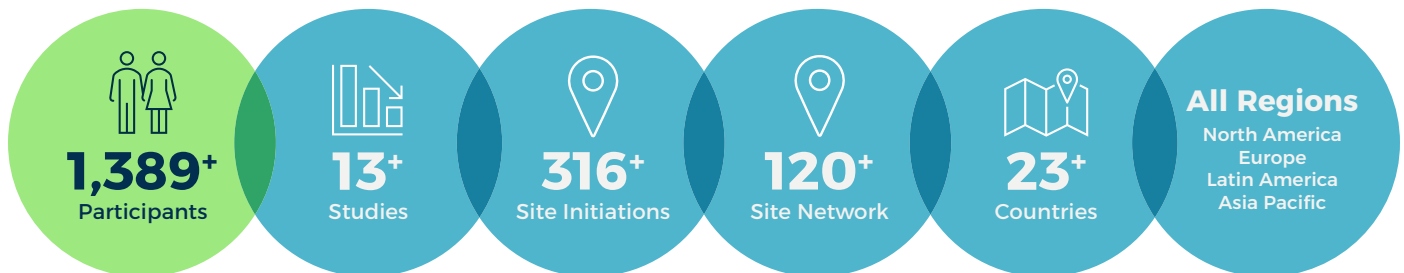
Jeanine Ronniger  
Senior Director, Project Management



Jeff Almrud, PhD  
Senior Director, Project Management

## Proven ALS Expertise

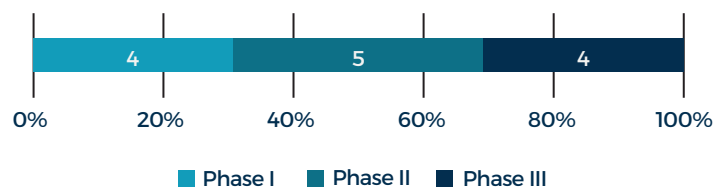
### Experience in the Last 5 Years



### IP Class & Route of Administration

- Small Molecule
  - Cellular Therapy
  - Antisense Oligonucleotide
  - Fusion Protein
  - Gene Therapy
  - mAb
- Oral
  - Intravenous
  - Intrathecal
  - Intramuscular
  - Subcutaneous

### Full-Service Trial Starts By Development Phase



## Worldwide's Differentiators



### **Comprehensive ALS Site Network**

We work independently with ALS-specialist care centers otherwise affiliated with recognized ALS consortia, such as NEALS, CALS, ENCALS/TRICALS, and PACTALS.



### **Champions of Patient Voice**

We actively incorporate lived experience from plwALS and cALS into our study design and operations. We were additionally the first CRO to join EUpALS as an industry member in 2021, serving as an industry partner to patient advocacy groups globally.



### **Active Key Opinion Leader (KOL) Network**

We have established relationships with ALS community leaders, including global KOLs who have joined Worldwide on our scientific advisory boards.



### **Broad ALS Experience Across the Team**

Our ALS team includes colleagues from across the ALS community with specific ongoing or prior engagements to ensure that we incorporate various stakeholder perspectives into our study conduct. Some areas of ALS experience include:

- Consortia monitoring team (NEALS)
- Investigator site staff (including 'The Neuro' at McGill University, Montreal)
- Biotech (with asset in Phase II and III for ALS)
- Neurologists responsible for care of plwALS including an NMD specialist



### **Contemporaneous Experience**

Our broad body of work in ALS commenced with our first trial, a cellular-based therapy, starting in 2017. Since then, all our clinical trials have been conducted under the auspices of the EMA/CHMP and FDA guidance to industry and the Airlie House consensus paper on ALS research.



### **Strong Relationships with Our ALS Site Network**

We have formed relationships with our ALS site network, which provides us with access to leading ALS care and research centers that we use to:

- Navigate the complex nuances of ALS trial competition.
- Take positive action towards equity in access to investigational products as part of the pharmaceutical options provided by the multidisciplinary care team.
- Allow access to KOLs and sites that are part of ALS consortia while maintaining independence and minimizing the requirement for study adoption.
- Navigate the research landscape, which includes early product screening initiatives, platform studies, and patient organization-sponsored research activities.

## Capabilities

Our ALS team is committed to providing excellence and support through the following capabilities:



Strategic engagement, including clinical development plans and regulatory procedures



Study design and optimization



Global clinical operations



Qualified vendor partners providing specialist services to ALS clinical trials:

- Spirometry
- Biomarkers
- Neuroimaging
- Speech analysis



Genetic screening and counselling support



Advanced Therapeutic Medicinal Products (ATMP) and complex study design support



**Worldwide**  
Clinical Trials

Our expertise in the ALS space speaks to our mission of uniting the ALS community for the successful conduct and optimal outcomes in these clinical trials.

**Contact us** to start the conversation for your next clinical ALS trial.