



ALS Signal: The Clinical Research Dashboard Helpful Definitions

Recruitment status: Tells you whether the trial is enrolling patients to participate, or whether it is full.

Target enrollment: Total number of patients who will take part in the study.

Trial phase: The Food and Drug Administration has set up clinical trial phases through which drugs are required to pass before they can be prescribed to those living with ALS. From 1-4, they vary depending on the goal of the study - starting at phase 1 with showing a drug is safe in people, to phase 3 when the goal is to show it is also effective, and beyond.

Trial duration: How long the trial will last.

Randomization: Process of assigning participants into trial groups. Usually, one or more groups will receive the treatment and another will receive a placebo or, if there is one, standard of care.

Open label trial: A trial in which all participants receive active treatment.

Open label extension: Add on to a trial design wherein after completion of the trial, all trial participants can have access to active treatment.

Crossover trial: A trial design where participants are assigned to two or more treatments one after another. For example one participant will receive an active drug followed by placebo, and another participant will receive a placebo followed by an active drug.

Route of administration: Describes how the drug is given to patients. For example, the drug could be taken by mouth (orally) or injected into a person's veins (intravenous, or IV).

Trial link: A hyperlink to the trial's registry listing with more detailed information about the trial.

By invitation: Trial recruitment is limited to invitation by investigators.

Patient-Centric Trial Design (PaCTD) rating: The I AM ALS Patient-Centric Trial Design rating system for clinical trials was created by the I AM ALS Clinical Trials Committee to outline criteria for humane trial design. This rating system allows for objective comparison of select features between trials as they relate to how they think about and incorporate patients. PaCTD ratings do not measure any aspect of the treatments being tested, including the science or effectiveness of a treatment. [Click on this link to learn more about the 9 Patient Standard rating criteria.](#)



Genetic target: Genetically caused ALS.

Sporadic/Unknown: All forms of ALS other than genetically caused ALS.

FDA approved for other indications: Drugs that are approved in the US for other diseases.

Approved outside USA: Drugs that are approved for other diseases in at least one country.

Supplement: Vitamins or supplements available over the counter.

Expanded access programs: These programs (also known as “compassionate use”) allow people who may be otherwise ineligible for trials to receive experimental treatments.

Remote trial: Trial where people can participate without in-person clinic visits. May require local lab visits.

Date listed: Date when the trial was first registered.