Public comments by pALS highlight barriers to participation in science and policy

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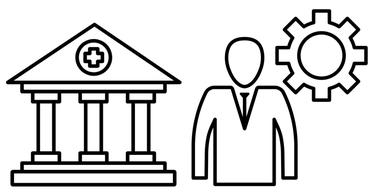
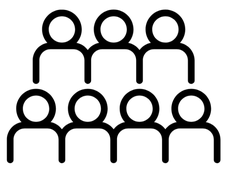
How we know matters



Current state: Institutions rely on expert led knowledge for decision-making



Challenge: May not align with the lived experience of affected people

Outcome: policies that fail to meet the community's needs

Public participation can complement institutional knowledge and embed people's needs in institutional processes
However, barriers to participation exist

ClinicalTrials.gov pALS[1] participate in scientific processes such as clinical trials

Regulations.gov *Your Voice in Federal Decision Making* pALS participate in policy making processes for ALS drug development (our main focus)

[1] pALS: Persons with ALS

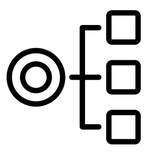
Study 1: pALS provide public comments on relevant policies.

RQ1: Can comments submitted by pALS on a federal platform reveal barriers to institutional participation?

Methods

Considerations Regarding Food And Drug Administration Review and Regulation of Drugs for the Treatment of Amyotrophic Lateral Sclerosis
Created by the **Food and Drug Administration**

Analyzed pALS comments on the FDA's guidance docket about drug development and evaluation



Conducted iterative inductive coding of 900 comments and developed themes

	Participation needs	Technological/scientific solution
Scientific Processes	Reducing placebos	• Cross-over trials, single-arm trials, parallel track • Historical data from prior trial as control
	Process efficiency	• Objective measurements (e.g., biomarkers) • Predictive modeling (e.g., AI)
	Expanded geographic reach	• E.g., mobile trial sites/ Remote data collection • Telemedicine/ Televisit for trial participation
Policy making Processes	Patient-centered trial design	• Community inputs for trial design • Community-sourced comment reviews
	Enhanced platform	• Increased platform usability • Transparent review of public comments

People face barriers to participation and respond by proposing technological solutions to address them in their comments

Example comment

"Utilize historical controls from PROACT and use data analytics to compare progression from each arm of a trial to how people progressed in other trials…Placebo trials in ALS are unethical, cruel and have proven to be of no use in finding any drug for ALS. Death as an endpoint is horrendous. We have ALSFRS and FVC which need to be used instead. Focus on the opinions of people living with ALS when considering guidance."

Needs
- Access to trials without placebos
- Endpoints short of death
- Community voice in policy-making

Solutions
- Historical controls from prior trials
- Cross-trial arm comparison analytics
- Functional and respiratory measures

Study 2: Do comments influence final policies? Institutions rarely provide feedback.

RQ2: Can AI trace the impact of public comments on institutional policies?

Methods

Compared draft/final FDA guidance + classified changes between draft/final versions as major/minor

Ground truth: Manually traced 30 sample comments to changes

Deployed an LLM to do the same tracing, then scored it against ground truth

	Sensitivity	Specificity	Takeaway
Major changes	0.70	0.66	AI traced most relevant comments but also flagged many irrelevant ones
Minor changes	0.13	0.91	AI rarely traced relevant comments, but rarely traced irrelevant ones either

- AI does well when comments closely mirror the policy wording
- AI struggles when tracing needs interpretative work
- Inferring meaning, context, or emotional intent is difficult for AI

Examples

Type	Comment AI failed to trace	Relevant policy change
Major	"Current clinical trials bar patients who have thyroid problems or diabetes. Where can they turn for treatment?"	Addition: "Broader inclusion criteria allow more rapid trial enrollment…An acceptable approach could include enrollment of a broad population with the conduct of the primary analysis…"
Minor	"*PLEASE HAVE SOME HUMANITY FOR THESE TERMINALLY ILL PEOPLE…*"	Addition: "patient" in "Sponsors should base eligibility for patient enrollment in effectiveness trials…"

- In both cases the human reviewer traced the comment to the policy change.
- Both comments require understanding the broader meaning of the request and the contextual relevance.