OPINION, **Q&A**

Designing autism-friendly trials: Q&A with Caroline Averius and Zachary Williams

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Clinical trials can't run without participants, but the demands of these trials — including traveling to clinics, tolerating tests and procedures, and keeping in touch for follow-up assessments — can be difficult for autistic people and their families to manage.

"There's no point in designing super complicated trials that no one wants to enroll in," says Caroline Averius, senior global patient partnership director at the pharmaceutical company **Roche**.

When Roche was preparing to run a new clinical trial involving people with autism, Averius turned to members of the autistic community to learn how to make the trial more participant-friendly. And to make sure that the research community, too, could benefit from what she learned, she teamed up with an international coalition of autism-focused organizations and advocates to compile her findings in a free, downloadable resource.

The end result is a **guidebook** that outlines best practices for designing and running clinical trials — and covers everything from advice about providing lunch vouchers to ways to enable participants to receive treatments after a trial has concluded. The team also wrote a **companion guide** for study participants that explains how trials can benefit the autistic community.

"If we start having trials that are genuinely positive experiences for people, that's going to be an overall benefit for the field," says autistic researcher **Zachary (Zack) Williams**, a medical and doctoral student at Vanderbilt University in Nashville, Tennessee, who collaborated with Averius on the book. "That's going to be what ends up changing lives for the better."

Averius and Williams spoke with *Spectrum* about some of the guidebook's recommendations and what they hope the field gets out of it.

This interview has been edited for length and clarity.

***Spectrum*: How did this project start?**

Caroline Averius: I met with Zack and other advocates first to discuss the idea. And I asked them if we were to create a guidebook, what should it look like? What should be the objectives? And what should we include?

S: How did they answer?

Zachary Williams: One of the key recommendations was to co-design clinical trials with members of the autism community. If you want to run a trial with people who are autistic and have gastrointestinal problems, then have some autistic people with gastrointestinal problems on the study team. And if your study involves folks who are autistic and minimally verbal, having caregivers involved in the design process may be useful, too.

We also included a lot of recommendations about things to do after the trial ends. So, for example, how do you appropriately follow up with participants and give them information about how to contact the study team if they have further questions?

S: Ah, rather than just saying, “See you later”?

ZW: Right. Participants need to be able to keep in touch about aftercare, possible side effects, things like that. Also, we think participants should have access to open-label extensions. This means after a randomized trial, the people who were in the placebo group have the opportunity to get the medication. It’s very expensive to continue to provide a treatment after a trial is over, but it’s one of the things that participants find very helpful. And they may be more likely to participate in a trial that does that.

There are also a lot of logistical things that researchers can do. People forget the value of things such as validating parking and making sure it’s easy to get in and out of the study site and find your way around.

S: It sounds like you were thinking a lot about the practical requirements of participating in a clinical trial.

CA: Yes, exactly. These are real people participating in trials. They have other things they need to do, like make lunches and take siblings to school. If they do join the trial, maybe that means they can’t make lunch on trial days, but at least they can get a voucher to have lunch at the trial site.

Also, entering a trial site for the first time can make people very nervous, because they don’t know what to expect. And we know this is extra challenging for autistic people. So researchers can do things to make that first visit easier. If I’m told ahead of time that I’m meeting with Zack — that he’s my investigator, and I have a photo of what he looks like, and he’s going to meet me for every site

visit — this can have a huge impact on the experience for the person participating in the trial.

ZW: The worst kind of trial experience is the one where you show up at a hospital that you have no idea how to get around, you can't find the study team, and your autistic kid — who is overwhelmed by change — has a meltdown in the lobby. There are definitely ways to make this whole experience better.

A lot of this information isn't necessarily new or groundbreaking, but putting it all in the same place, compiling it for investigators as a list of best practices, really allows it to be implemented in a much more robust way.

S: What resources did you include in the guidebook?

ZW: There's a section at the end of the guidebook that has resources our team curated from places such as University College London, the MIND Institute at the University of California, Davis, and other research institutions — things that would be helpful at visits, such as examples of consent documents, visual schedules, information packets for participants about doing blood draws or MRIs. Researchers can adapt the documents for their own studies as needed.

S: How do you hope the guidebook and participant explainer will change research?

ZW: I'm interested in increasing the volume of trials in the field of autism research. Autism research, in general, has an evidence problem: There is a lack of good evidence for a lot of our interventions, and that stems from a lack of funded trial research.

There are very simple trials researchers could run — really low-hanging fruit, such as whether certain types of antidepressants work to treat anxiety or depression in autistic people. And for many of these trials, the setup of the trial is essentially the same. Researchers are recruiting the same population and should have the same considerations. Our clinical trial guidebook is relevant for all of those kinds of investigations, and it can help make sure researchers are running these trials well.

S: How do you hope the guidebook and explainer affect trial participants?

CA: I hope that people see that by getting involved in research — not only as study participants, but also at the level of trial design — they can help focus the work on what's meaningful for them. Because if they're there from the start, they can shape it.

ZW: I hope we start performing trials in ways that make participants feel appreciated. And I hope people feel they can get involved in those trials, have good experiences and want to go back because their lives were actually improved by that work.

CA: Absolutely. People who are involved in research, they're doing it because they want to make a positive impact or difference in someone's life. And that's what we're all hoping for when we set up trials.

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