The Impact of FDORA on Clinical Trial Diversity

It has been a little over a year since the FDA Omnibus Reform Act (FDORA) was signed into law. In many ways, the industry's perspective on diversity has changed significantly. Yet in other ways, we are still facing the same old problems. In other words, regardless of an industry-wide acknowledgement of the importance of more diverse clinical research, the same barriers to diverse participation still exist — such as social determinants of health — and research is only able to do so much to overcome them. So, what exactly is FDORA's impact on trial diversity, and what should sponsors do next to drive this positive impact toward ongoing meaningful change?

FDORA and Diversity: A Snapshot of What Has Changed

FDORA includes guidance on a wide range of clinical trial processes — from decentralized clinical trials (DCTs) to bioresearch monitoring (BIMO) inspections. The new FDA requirements for improved diversity in clinical research, however, emerge as top of mind for sponsors. Notably, the FDA's guidance expands the definition of diversity beyond racial and ethnic markers (to include sex, gender identity, age, socioeconomic status, and disability among other indicators) and builds in a requirement for clinical trial diversity action plans (which must detail enrollment goals, goal reasoning, and achievement strategy).

FDORA Aligns With Advances in Precision Medicine

FDORA's expansion of diversity definitions and front-end diversity planning is clearly in alignment with advances in precision medicine. Individual people respond differently (to varying degrees) to the same course of treatment, and

there is still much work to be done in recognizing and honing in on the social determinants of health that may impact outcomes, such as human behavior, social circumstances, environmental exposures, and healthcare.[1] A better representation of diverse populations in clinical trials can contribute to ongoing advances in precision medicine, perhaps identifying additional factors such as genetic and molecular profiles affecting those outcomes.

FDORA Has Already Impacted Trial Diversity — We Need That to Continue

Thanks to FDORA, diversity is now front and center for the clinical trial space. Even as early as feasibility planning, CROs, sites, and vendors are now being asked about existing database diversity and plans for increasing it.

Sponsors are getting more creative with study models and methods, choosing sites based on diversity qualifications — even selecting healthcare-first sites in some cases. There is also an increased focus on DCT solutions that provide expanded access to a more diverse patient pool, and there's more of an emphasis on nurturing patient relationships and making studies more patient friendly.

As sponsors continue to optimize trial diversity efforts, one of the biggest factors that will enable additional change and flexibility will be the emergence of better and clearer post-FDORA guidance on more creative research models and methods — including more collaboration with payors to shorten the time between approval and coverage.

Ongoing Sponsor Hurdles — and Some Solutions

Even with all this positive change, several ongoing hurdles to achieving ideal diverse trial participation remain, including:

- Health literacy challenges leading to a lack of trust (e.g., patients don't want their data used)
- Language barriers (e.g., better facilitation of multiple languages in ICF, study material translations, access to translators)
- Adequate compensation (e.g., covering time off, childcare)
- Physical access (e.g., facilitating site visits, offering DCT and hybrid options, coordination with local providers)

On top of this, additional regulatory hurdles persist, such as multistate licensure and DCT issues and evolving DCT guidelines — including the FDORA mandate that the Secretary will issue a draft guidance to provide clarifying recommendations on use of decentralized trials. This guidance is still forthcoming as of the writing of this article.

The good news is that some of the trial diversity challenges may be addressed by mirroring strategies used to address social determinants of health. For example, supporting after hours and weekend study visits, offering travel solutions to accommodate mobility challenges, and ensuring all patient-facing materials are written in appropriate reading levels and languages could improve clinical trial participant diversity.

Additionally, sponsors can take several steps right now to make a difference in their enrollment diversity, such as:

- Approach trial design from the perspective of the participant
- Keep prioritizing compliance and data integrity, but prioritize patient experience first and foremost
- Proactively create accessibility solutions
- Move away from an attachment to "the way things have always been done" and augment existing solutions with new ones

What About AI?

Regulatory bodies are still playing catch-up with when and how AI can be used for clinical trial enrollment. However, innovations continue to move forward, including LLMs (large language models) that translate massive amounts of patient data into manageable EHR data that can be easily analyzed as part of an automated patient selection process.

It's important to note though that regulators aren't the only ones playing catch-up in this sphere. Sponsors and site staff are acclimating, as well. The ultimate impact of AI on more diverse enrollment is yet to be determined, but it holds much promise.

What's Next?

The industry is changing. Maybe not as fast as we'd like it to, but progress is being made. However, progress will only continue if we all keep diversity top of mind and remain open to new, creative ways to make research more accessible for everyone.

Looking for more concrete steps you can take to increase diversity in your trial? Read our blog or contact our team.

CONTACT US

Reference

[1] Naithani, N., Sinha, S., Misra, P., et al. Precision medicine: Concept and tools. Med J Armed Forces India. Published 2021 July.

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