

# **FDA's Path Toward Diversity in Clinical Trials: The DEPICT Act and Sponsor Responsibility**

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## I. INTRODUCTION

The Food and Drug Administration (FDA) is not a stranger in its intent to achieve more diversity in clinical trials. The FDA has been involved in evolving legislation which supports greater diversity in clinical trials. Additionally, the FDA has written numerous Guidances which are further testament to the commitment that the FDA holds in seeing a more diverse clinical trial population. Notwithstanding, there is work to be done in this sector, and with the introduction of the DEPICT Act in early 2022 and its passage in December 2022, the inclusion of sponsors in the diversity conversation will catalyze further change. Recommendations are provided for the facilitation of the requisites of the DEPICT Act as well as recognition of some of the challenges ahead.

## II. THE DEPICT ACT

In the newest iteration of an attempt to continue to strive for diversity, the DEPICT Act (Diverse and Equitable Participation in Clinical Trials Act) was passed by Congress in December 2022. The intent of the legislation is to provide more precise guidance to drug and device trial sponsors on how to collectively work toward more inclusion of under-represented populations such as racial and ethnic minority populations, and age and gender diversity. The DEPICT Act requires the FDA to require clinical trial sponsors to submit Diversity Action Plans with their protocols for Phase III or other pivotal trials. The

December 2022 law, gives the FDA until December 2023 to define what specifically is to be included in a Diversity Action plan. The legislation states:

The diversity plan SHALL include:

- The sponsor's goals for enrollment in the clinical study;
- The sponsor's rationale for such goals;
- An explanation of how the sponsor intends to meet those goals.

The legislation goes on to describe that the following information “may be” included as it pertains to a rationale for the sponsor’s enrollment goals:

- The prevalence in the United States of the disease or condition for which the drug or device is being investigated in the trial. The prevalence of any particular disease or condition must be broken down into percentages describing race and other characteristics such as age and sex.
- What is known about the disease or condition for which the drug or device is being investigated;
- Any relevant pharmacokinetic or pharmacogenetic data;
- An explanation for how the sponsor intended to meet these diversity inclusion goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel;
- Information about what is known about the patient population for such disease or condition.

The legislation leaves open many questions for sponsors and sites, about the way in which the action plans will be “adjudicated” and how any potential problems will be communicated.

### **III. SPONSOR RESPONSIBILITY UNDER THE DEPICT ACT**

The DEPICT Act, will require the FDA to issue regulations that will hold the sponsor accountable for the amount of diversity, or of lack of, in their clinical trial. One very important point taken from the DEPICT Act is the sponsor’s responsibility in cases

where the diversity goals set forth by the sponsor are estimated to not be feasible or not reachable. In these cases, the sponsor still has the responsibility to act and needs to communicate why these goals are not feasible. Thus, there is a sense of accountability for plans that are idealistic or unrealistic. Some possible “exceptions” are noted within the text of the legislation, leaving way for some exceptions in cases where the disease or condition being investigated in the clinical trial is rare or where it may be difficult to recruit participants.

Further guidance on the format and content of these “diversity action plans” is to be expected in the future.

## **IV. A CALL TO ACTION: HOW SITES CAN AMELIORATE LACK OF TRUST**

The following are some simple steps to begin bridging the gap between sites and the patient.

### **Awareness**

On the topic of ameliorating and bridging trust between patients and sites, awareness must first be introduced. Without awareness, it is not possible to even perceive the distrust that is occurring in the community. Understanding the causes of mistrust is pivotal to understanding certain points of view from varying members of the community. It is paramount to recognize the biases and inequities which were brought upon certain minority communities. This will inform where attention is needed and how to improve.

## Prejudices

Examining persisting prejudices is an important step. One study<sup>2</sup> describes that physicians may have unconscious biases which can unfortunately affect doctor-patient communication and medical care.

## Incorporation

If researchers are eager to enroll more diverse populations, it would be wonderful to have already made contact and be engaged in that community. Finding organizations such as churches, and other groups that are community-centered and community builders will enhance the approach to find a way into the community in which researchers are trying to bridge the gap.

## Transparency

During discussions with a physician, it is important to remain transparent and be forthcoming with information that may be of great importance to that community. Some common questions involve the time commitment required, the amount of payment, if any, and the company conducting the research.

## Inclusivity

The front lines of medical research need to be filled with individuals from diverse backgrounds to serve as a mirror of those we want to be enrolled in clinical trials. This means our research teams from the inside out need to be comprised of more minorities. Marketing materials should be representative to reach the widest percentage of the population, not merely the historical majority that have been enrolled in clinical trials.<sup>3</sup>

## V. THE GOOD NEWS

A number of changes have been encouraged to increase the inclusion of diverse groups and racial and ethnic groups are not the only groups benefiting from the FDA's vision for more diversity in clinical trials. Historically-excluded groups such as older populations, rare disease populations, and pregnant subjects, along with the recognition of sex, gender, identity, age, and disability have formed a part of efforts in previous Guidances from the FDA. However, LGBTQ plus individuals are also overdue for inclusion in trials.<sup>4</sup> Overall, this speaks of a trend with great momentum to rectify previous long standing lack of diversity within clinical trials.<sup>5</sup>

## VI. RECOMMENDATIONS

One place to start is with site staff. Site staff that “looks like” the participant and “speaks their first language” is more likely to bridge the trust gap. If sponsors want the population in clinical trials to be more diverse, some internal work needs to be done first or simultaneously, in order to lay down the foundation for successful recruitment.

The incorporation of translated advertisements into common submission materials is also a major step forward for sponsors. Those trial participants that do not speak English as a first language will have the same access to a clinical trial if the materials also reach them.

Lastly, by working with trusted community leaders like, for example, religious leaders, sponsors can build meaningful alliances..

It is important that stakeholders understand and have an awareness of historical biases that have

led us where we are today with regard to minority inclusion. Sensitivity and respect toward these populations are imperative in building or repairing the trust bridge. Transparency, along with kindness, is a good place to start in order to repair and build on new relationships that form along the way in a clinical trial.

With all these considerations in mind, researchers will be best equipped to take a deep dive into the rewards of what diversity and inclusion could finally look like.

## REFERENCES

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