RxE2®
Pharmacists Unbound

Diversity Now Protocol

Powered by RxE2

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DIVERSITY NOW PROTOCOL

This plan provides a pharmacist-centered approach for compliance with Section V Categories 4 and 5 of the US Food and Drug Administration's industry guidance[1] (hereinafter "FDA Guidance") for developing the required Race and Ethnicity Diversity Plan. RxE2 has the AI-enabled technology platform to comply with all necessary enrollment requirements. Our goal is to ensure the appropriate proportion of pre-determined populations are proactively referred and enrolled to better achieve necessary protocol requirements and clinical and patient outcomes. Based on the RxE2 model, pharmacists are engaged early to ensure that underrepresented populations are educated about clinical trials, and referred, recruited, and retained in clinical trials.

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[1] FDA Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials – Guidance for Industry, April 2022. Section V. Content of the Race and Ethnicity Diversity Plan (The Plan)

Section V Category 4: Specific plan of action to enroll and retain diverse participants

4.A. *Describe in detail the operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants in the planned trial(s) or studies, and the planned use of data to characterize safety, efficacy, and optimal dosage in these participants, when applicable.*

Traditionally, informing patients about clinical trial opportunities has been the role of clinical staff and doctors. However, as decentralized trials become more prevalent and racial and ethnic diversity among participants increases, enrolling and retaining patients in clinical trials outside of the clinical setting requires more than providing study documentation; it is also necessary to have a trusting relationship. In many underrepresented communities, the community pharmacist is the most trusted and accessible healthcare provider. Local pharmacists are fundamental to diversifying clinical trials because, as medication experts, they already play a central role in community healthcare. They can provide the necessary information to encourage participation and understand patient needs and the social determinants of health (SDoHs) that often prevent enrollment.

Involving state-licensed pharmacists at the beginning of a clinical trial can offer a larger and more diverse pool of potential participants, as pharmacists can provide the qualifying patient data. This includes disease stage, other drugs being taken that may preclude participation, SDoHs, and the logistical issues that often prevent participation, for example, transportation.

Pharmacists communicate with participants via regular visits and calls throughout the trial, providing counseling and answering patient questions. This is especially valuable in underrepresented populations where the pharmacist is the primary healthcare provider. During these counseling sessions, an Institutional Review Board (IRB)-approved questionnaire may be used to collect objective and subjective data. This can support real-time feedback to clinicians and better characterize safety, efficacy, and optimal dosage. Additionally, providing patient feedback to clinicians helps proactively address the causes of participant withdrawal and increases retention.

The trusting relationship between pharmacists and patients solidifies protocol compliance and completion. This is enhanced by pharmacist counseling to ensure adherence and persistence, leading to better patient outcomes and, ultimately, trial outcomes. Real-time adjustments to patient needs can then be made that also lead to better patient retention rates, noting that patient retention without adherence and persistence is not of value.

For details on the specific steps to fulfilling patient enrollment requirements, refer to Category 4.C. below.

4.B. *Describe specific trial enrollment and retention strategies, including but not limited to:*

> ***i.*** *Site location and access (e.g., language assistance for persons with limited English proficiency, reasonable modifications for persons with disabilities, and other issues such as transportation).*

Local community pharmacies already have these services available. Clinical sites cannot readily be moved to diverse populations. However, diverse participating pharmacies can be chosen near clinical sites, potentially providing a more accessible study location than the clinic and assisting patients with SDoHs.

State-licensed pharmacists meet all state requirements for telehealth/telepharmacy; they are licensed to dispense investigational medication and counsel and meet all state dispensing, labeling, and counseling laws.

While decentralized clinical trials (DCTs) may be based anywhere, licensing is state-specific, requiring healthcare professionals to be licensed in the state where the patient resides.

In partnership with the local pharmacy, RxE2 uses its AI-enabled technology platform to search pharmacy demographics and data to identify strategic locations and potential participants to contact about clinical trials. Because state-licensed pharmacists are embedded in the community, they must be language proficient to sustain their business; a pharmacy in a Spanish-speaking neighborhood, for example, must have Spanish-speaking staff. Most pharmacies have Americans with Disabilities Act accommodations for persons with disabilities. Additionally, pharmacies are already doing deliveries and addressing other factors that can prevent participants from enrolling and staying with clinical trials.

4.B.

ii. *Sustained community engagement (e.g., community advisory boards and navigators, community health workers, patient advocacy groups, local healthcare providers, etc.).*

Sustained community engagement is built into the local pharmacy. Community pharmacists have long-term relationships with their patients and with local healthcare providers. Many independent community pharmacies fill the role of clinics, and pharmacy technicians are becoming certified community health workers.

4.B.

iii. *Reducing burdens due to trial/study design/conduct (e.g., number/ frequency of study-related procedures, use of local laboratory/imaging, telehealth).*

In specific clinical trials, the state-licensed pharmacist is often more accessible than clinicians and can help with individual patient SDoHs that must be resolved to sustain clinical trial participation. For individual trials, RxE2 selects pharmacies with the necessary capabilities (e.g., collaborative practice agreements with local physicians, laboratories, imaging, telehealth/telepharmacy, etc.).

Pharmacists help solve SDoH burdens daily as the primary point of healthcare access and consistently help to address community needs. For example, questions of economic stability are offset by pharmacy involvement in 340B prescription pricing programs that help defray drug costs for eligible patients. Pharmacists also work within the community to provide translations and transportation and deliver drugs for housebound patients.

4.C. *Describe metrics to ensure that diverse participant enrollment goals are achieved and specify actions to be implemented during the conduct of the trial(s) or studies if planned enrollment goals are not met.*

The specific steps to fulfilling patient enrollment requirements are as follows:

01

Identify pharmacies in underrepresented areas

The RxE2 AI-enabled technology platform is used to identify pharmacies in geolocations with the necessary demographic and required trial components (e.g., social workers, certified healthcare workers, collaborative practice agreements with trial-specific practitioners, local clinics, laboratories, imaging sites, etc.). RxE2's model ensures the appropriate clinical trial population and pharmacies are engaged or disengaged using an AI-enabled database search based on the protocol's demographic requirements and selectively or randomly enrolled in waves.

02

Identify potential patients based on protocol requirements

Using the pharmacy prescription database stripped of patient-identifying information and uploaded by participating pharmacies, RxE2's AI-enabled technology platform matches the study protocol requirements, including study-entry criteria and enrollment goals for underrepresented racial and ethnic participants, to pharmacies with potential participants and identifies potentially qualified patients of the desired demographic characteristics. Multiple pharmacies are simultaneously polled to fulfill enrollment goals. RxE2 monitors enrollment status, initiating new waves of pharmacies until the patient population requirements are met. Stratification of race, ethnicity, and gender can be completed centrally and based on protocol requirements, maintaining blind sampling within the community pharmacy.

03

Initiate patient contact to determine interest in clinical trials

From the data generated by RxE2 in Step 2, a state-licensed pharmacist additionally incorporates patient SDoHs and then contacts potential clinical trial participants.

04

Perform inclusion/exclusion criteria for patients meeting the criteria

Pharmacists provide the initial screening for patient suitability based on protocol requirements. This may be as simple as administering an IRB-approved questionnaire in person or via telepharmacy.

05

Refer patients meeting the criteria to the Principal Investigator

Pharmacists introduce qualified potential participants to clinical site staff and assist with scheduling initial clinical screening. Pharmacists support patients throughout the transition to a new healthcare provider.

06

Monitor underrepresented population enrollment

RxE2 follows potential participant progress and study enrollment criteria adjusting accordingly to ensure protocol requirements are met. This includes registering more pharmacies, as needed, to refer more patients if necessary.

Section V Category 5: Status of meeting enrollment goals (as applicable)

5.A. *As the diversity plan is updated (when applicable), discuss the status of meeting enrollment goals. If the sponsor cannot achieve enrollment goals despite best efforts, discuss a plan and justification for collecting data in the post-marketing setting."*

With the RxE2 model, pharmacies in any region and patients of any demographic can be selectively reviewed to fulfill clinical trial enrollment goals. The RxE2 AI-enabled technology platform holds 4,000 and growing clinically integrated community pharmacies. This network is sufficient to satisfy the protocol requirements and provide a diverse population of clinical trial patients for almost any trial.

Additionally, the same modeling can be used in post-market studies. Community pharmacists can collect post-market data that has never previously been recorded because patients return to their pharmacies in daily life. Pharmacists can help distinguish drug effects from the noise of other medications because they continue working with patients after trial completion. This has been true since the Asheville Project (Cranor, Bunting, Christensen, 2003) was founded in 1997 and continues to this day, as seen in current research on pharmacist-led chronic disease management (McCarthy and Bateman, 2022; Como et al., 2020) and adverse drug responses (Lee et al., 2021). Filtering out that noise will help provide cleaner and more complete post-market data than can be achieved by study sites alone.

References

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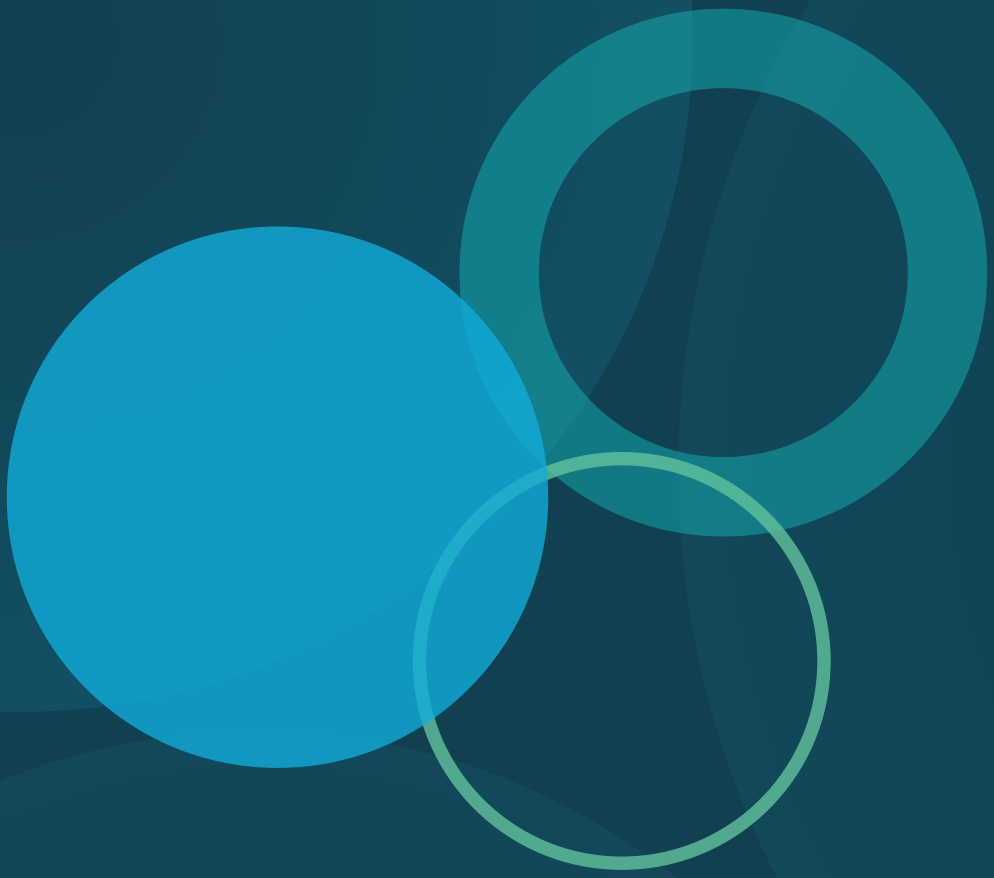

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