Enhancing Diversity in Oncology Clinical Trials: The Integral Role of Pharmacists

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TOPA
Tennessee Oncology Pharmacists Association

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Disclosures

- Dr. Pope has received a salary and stock options from Acclinate
- Dr. Pope has received a salary and stock options from AstraZeneca
- All of the financial relationships for this individual have been mitigated

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Learning Objectives

- **DEFINE** key terms related to clinical trial diversity, inclusive research, and health equity
- **DESCRIBE** current FDA guidance, legal requirements, and oncology organization recommendations related to improving participation of historically underrepresented racial and ethnic groups in clinical research
- **REVIEW** trust-based frameworks for optimizing clinical trial diversity and outreach to historically underrepresented communities
- **RECOGNIZE** the role of pharmacists in advancing clinical trial diversity efforts, based on various practice settings: community, health-system, industry

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Key Terms[1,2]

Diversity

Anything that **sets one apart from another**, including the full spectrum of human demographic differences as well as different ideas, backgrounds, and opinions

Inclusion

Implies a cultural and **environmental feeling of belonging and sense of uniqueness**; represents the extent to which one feels valued, respected, encouraged to fully participate

Equity

Fair treatment for all, while striving to identify and **eliminate inequities and barriers**

Health Equity

Everyone has a fair and just opportunity to be as healthy as possible; requires **removing obstacles** such as poverty, discrimination, and their consequences, and **eliminating health disparities** and determinants that adversely affect excluded or **marginalized groups**

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Why Is Applying A "Health Equity Lens" to Clinical Trials Important?[3,4]

It's the right thing to do for patients!
- Addresses key health disparities in historically underrepresented groups
- Improves access to life-prolonging medicines
- Representation in clinical trials should be reflective of real-world patient populations who actually use the drugs

Furthers understanding of how medicines work and answers scientific questions
- E.g., there may be differences in drug efficacy/safety based on biology and genetic make-up

Impacts timing of FDA approvals, availability of drugs, overall clinical development and business strategies
- E.g., potential for delayed/denied FDA drug approvals, based on lack of diversity in trials
- E.g., FDA may require post-market studies, due to lack of representation in pre-market trials

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Lack of Diversity in Clinical Trials[5,6]

People of color make up ~42% of the U.S. population, but are often underrepresented in clinical trials

Black or African-American	Hispanic or Latino Origin
13.4% Of US Population (Based on 2020 US Census)	**18.1%** Of US Population (Based on 2020 US Census)
8% Of Trial Participants (Based on 2020 FDA Drug Trials Snapshot)	**11%** Of Trial Participants (Based on 2020 FDA Drug Trials Snapshot)

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Lack of Diversity in Clinical Trials[7]

2022 FDA Drugs Snapshot

Average participation in clinical trials by subpopulation for 37 new drugs approved in 2022 (N=27,554)*

	White	Black/AA	Asian	Hispanic
Heart, Blood, Kidney, Endocrine	74.1%	3.6%	8.5%	13.1%
Autoimmune, Inflammatory, Lung	75.4%	5.3%	15.5%	10.2%
Infectious Disease	69.7%	22%	7%	23%
Neurological, Psychiatric	89%	3.7%	5.2%	6.7%
Cancers	78.1%	4%	11.5%	4.6%
Other	78.3%	8%	13%	12.5%

*Mean values are calculated based on demographic data reported per study ("NA" excluded); Combined percentages of all other races and ethnicities not shown adds up to 100% in the race and ethnicity categories, respectively

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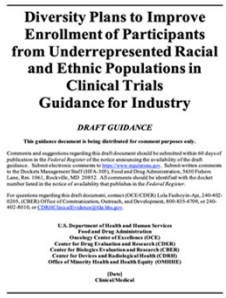
FDA Draft Guidance – April 2022[8]



Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

[Date]
Clinical/Medical

Recommends development of a **"Race & Ethnicity Diversity Plan"** prior to starting pivotal trials intended for marketing submission

Submission of plan should occur to IND application, and discussion with FDA should occur no later than end of Phase 2 (for drug products)

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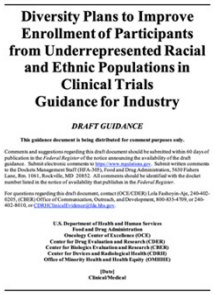
FDA Draft Guidance – April 2022 (cont.)[8]



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Office of Minority Health and Health Equity (OMHHE)

[Date]
Clinical/Medical

Recommended Components of Diversity Plan:

- Overview of disease in underrepresented racial/ethnic populations in the US, including any differential data/findings
- Scope of development program, including expected geographic locations that may address inclusion
- Goals for enrolling underrepresented populations, based on demographics and background research
- Specific plan to enroll diverse populations --- detailed operational measures, including sustained community engagement plan and metrics
- Status of efforts, including plan for post-marketing data collection if initial diversity goals not met

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Food and Drug Omnibus Reform Act (FDORA) – December 2022 *Sections 3601-3604* [9,10]

Includes laws related to clinical trial diversity, modernization, and diversity action plans. Calls on FDA to:

- Require submission of diversity action plans for all Phase 3 clinical studies of new drugs or pivotal trials, as appropriate
- Update current diversity plan guidance by Dec 2023, with considerations for sponsors to incorporate data disaggregated by age group, sex, racial/ethnic demographic characteristics, and potentially geographic location and socioeconomic status
- Update current guidance to include considerations for public posting by sponsors of key information from diversity action plans on company websites, with regular reports to FDA regarding progress
- Host public workshops to enhance clinical trial diversity
- Issue an annual summary report on progress to improve clinical trial diversity

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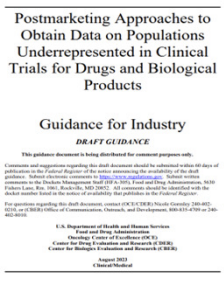
FDA Draft Guidance – August 2023[11,12]



Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products

Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
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Center for Biologics Evaluation and Research (CBER)

August 2023
Clinical/Medical

Outlines **post-marketing approaches** and considerations for enhancing clinical trial diversity

Key Takeaways:

- Pre-market diversity planning is STILL important
- Research sponsors have many options; there are various study design and statistical considerations for post-market data collections
- Tailored strategies are still needed, even in post-market setting

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American Association for Clinical Research (AACR) – Cancer Disparities Progress Report[13]

Barriers To Clinical Trial Participation for Racial/Ethnic Minorities Include:

Individual-Level: Lack of trial awareness, limited health literacy, mistrust, ancillary financial and travel burdens, social determinants

HCP-Level: Lack of trial awareness, implicit bias, cultural incompetence, limited staffing abilities

System/Structural-Level: Lack of trial availability (too much ex-US focus in oncology studies; US trials only conducted in high-volume academic centers; not enough decentralized considerations), trial complexity, time constraints, limited resources for patient and community engagement

Study Protocol-Level: Restrictive inclusion criteria, lack of RWE integration

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American Society of Clinical Oncology – Association of Community Cancer Centers (ASCO-ACCC)[14]

Joint Recommendations for Diversifying Oncology Clinical Trials

ASCO-ACCC Full Research Statement on Diversifying Clinical Trials

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American Society of Hematology (ASH)[15-17]

Endorsement of Indy Hematology Education Inc's 5-Step "DRIVE" Initiative to promote diversity in clinical research:

D: Diversity officer for clinical research studies

R: Ranking of clinical studies for diversity

I: Individual diversity, equity, inclusion, and access plan

V: Verification of study diversity

E: Elevate and enhance training of minority investigators and research team members

Recognition of financial burden to participation that primarily impacts minority patients, including limited/varying insurance coverage (inconsistent with Affordable Care Act mandate)

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National Comprehensive Cancer Network, American Cancer Society, National Minority Quality Forum (NCCN-ACS-NMQF) - *"Elevating Cancer Equity Working Group"*[18]

Developed "Equity Report Card" to help providers, payers, and accreditation entities advance equitable cancer care delivery

Includes 17 measurable practice changes.

Full list of practice recommendations are broken down into the following categories:

- Community Engagement
- Accessibility of Care and Social Determinants of Health
- Addressing Bias in Care Delivery
- Quality and Comprehensiveness of Care

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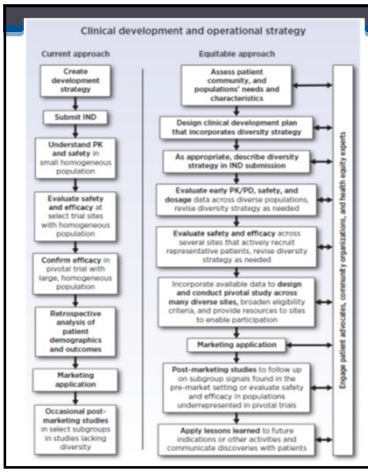

FDA, AACR, & Various Pharmaceutical Industry Stakeholders[19]

2023 Report on Driving Diversity & Inclusion in Cancer Drug Development

"Current Approach vs Equitable Approach"

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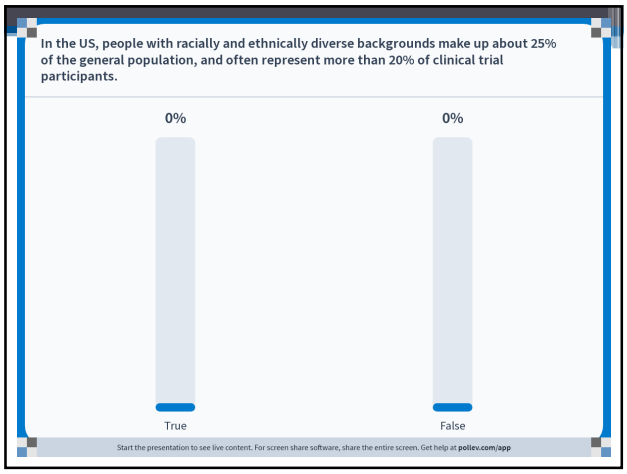

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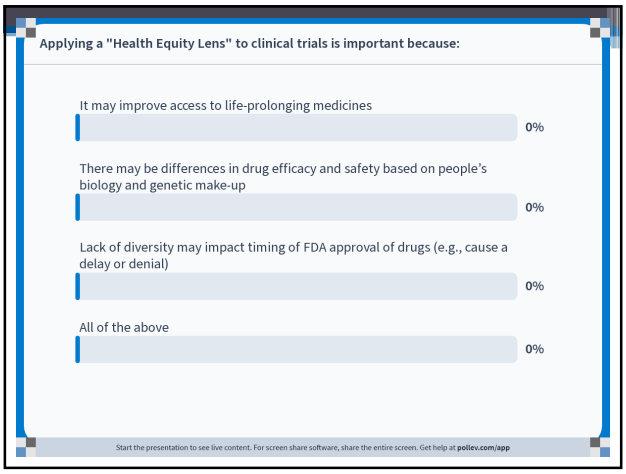

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Sections 3601-3604 of the 2022 Food and Drug Omnibus Reform Act (FDORA) require research sponsors to submit diversity action plans for Phase 1-4 studies (inclusive of first in human trials) to the FDA.

0% True

0% False

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According to the 2022 AACR Cancer Disparities Report, which of the following is not a barrier to clinical trial participation for historically underrepresented racial and ethnic groups?

- Easily accessible community clinics frequently serving as clinical trial sites 0%
- Limited health literacy 0%
- Implicit bias from clinical researchers and other healthcare providers 0%
- Restrictive inclusion criteria 0%

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What is Trust?[20]

Willingness of a party to be vulnerable to the actions of another party

- Expectation that the other will perform an action important to the trustor, regardless of ability to monitor or control that other party

Applies to clinical trial recruitment and retention, as there is inherent risk when deciding whether to participate

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Cognitive Trust vs. Affective Trust[21,22]

Cognitive Trust is based on:

logic, utility, rationality, competence, knowledge, evidence

vs.

Affective Trust is based on:

human emotions, social relations, personal goodwill, intrinsic value, genuine concern

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An "Integrated Model of Trust" for Clinical Trial Diversity[23]

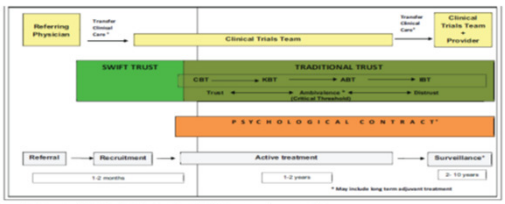

Figure 1. Integrated Model for building trust in clinical trials among diverse populations.
CBT: calculus-based trust; KBT: knowledge-based trust; ABT: affect-based trust; IBT: identification-based trust.
(a) The trust relationship is most vulnerable at the points of transfer of clinical care. At the referral stage, participants rely almost solely on the referring physician's recommendations. Transition to the surveillance phase requires participants to rapidly transition from weekly or monthly cancer center visits that include therapeutic interventions to treatment cessation and watchful waiting. Surveillance is primarily done in the community and linked to quarterly, semiannual, and ultimately yearly cancer center visits. In this phase, the participant must now assume an active surveillance role; (b) ambivalence mediates trust and distrust throughout all stages. It arises once a critical threshold of positive or negative attitudes toward an object or person is reached from serial participant–clinical trials team interactions; and (c) the psychological contract develops in parallel with the swift trust process during the latter phases of recruitment.

Integrated Model = Trust development that is framed through integrated clinical and business perspectives

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An "Affective Trust Framework" for Clinical Trial Diversity[24]

Inclusive Study Design
- Participant Selection
- Targeted Site Selection

Affective Community Engagement*
- Activation Points**
- Cultural Communications

Trust-Enabling Technology
- Digital Engagement
- Artificial Intelligence/Machine Learning Integration

*This should be a comprehensive strategy that starts before study kick-off, lasts the duration, and continues after study ends

**Activation Points = Persons or organizations within the community who can serve as trusted messengers regarding disease state awareness and clinical research information

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Trust that is based on logic, rationality, and evidence is called _____ Trust.

Affective 0%

Rational 0%

Cognitive 0%

Creative 0%

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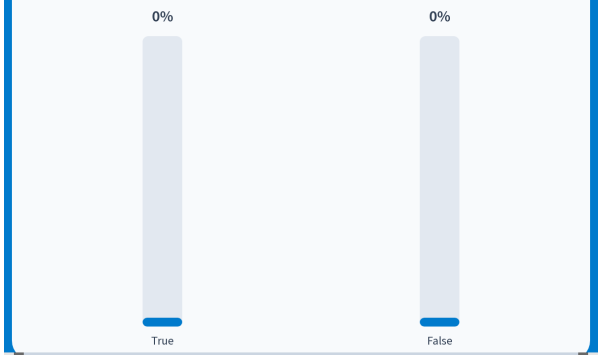
Swift Trust, Traditional Trust, and the Psychological Contract are key components of the "Integrated Trust Model" for improving clinical trial diversity.



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Three core pillars of the "Affective Trust Framework" for improving clinical trial diversity are:

Political Action, Sustained Community Engagement, Trust-Enabling Technology 0%

Reduced Recruitment Costs, Sustained Community Engagement, Limitless Technology 0%

Reduced Recruitment Costs, Exclusive Study Design, Limitless Technology 0%

Inclusive Study Design, Affective Community Engagement, Trust-Enabling Technology 0%

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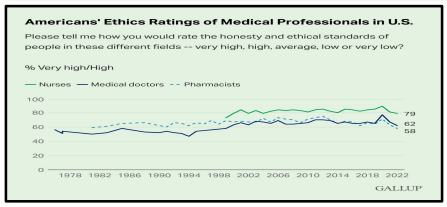
Pharmacists: Bridging the "Trust Gap"[25,26]

In 2022, pharmacists were ranked as the 3rd most trusted professionals in the US



Pharmacists are ideal partners for building trust within historically excluded populations, connecting patients to research opportunities, and conducting clinical trials

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Advantages to Involving Community Pharmacists in the Clinical Trial Process & Diversity Efforts[26-28]

Access to patients and patient information
- Convenient locations (within 5-10 miles of most US households) and regular contact with patients
- Can raise awareness of clinical trials, share study information, and identify potential participants
- Real-world evidence from pharmacy databases can inform more inclusive study protocol designs

Knowledge of the community
- Well-respected members of the community
- Understand the health needs and concerns of communities in which they live, serve, and work --- including social determinants of health (SDOH) that impact their patients
- Can develop and implement study recruitment strategies tailored to community needs

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Advantages to Involving Community Pharmacists in the Clinical Trial Process & Diversity Efforts (cont.)[26-28]

Facilitating communication
- Serve as a bridge or connector between research sponsors, principal investigators, study sites and community members
- Can provide culturally- and community-tailored information about research opportunities

Providing care
- Provide care to patients throughout study duration, including administration of medications and follow-up (i.e., in-person and/or leveraging virtual care models)

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Community Pharmacies & Decentralized Clinical Trials[28-30,31]

Decentralized Clinical Trial (DCT)*

A clinical trial where some or all trial-related activities occur at locations other than a traditional clinical trial site

- Locations "other than a traditional trial site" may be a participant's home or a local healthcare facility
- May be fully decentralized or hybrid
- May leverage in-person and/or telehealth capabilities, and digital health technologies

*DCTs are also addressed in an FDA draft guidance and in section 3606 of FDORA

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Community Pharmacies & Decentralized Clinical Trials (cont.)[28-30,31]

- Depending on study protocol, some activities may be conducted by healthcare providers (HCPs) close to the participant's home but not part of the trial personnel, as long as it aligns with HCP's clinical training. Conversely, some trial-related activities may require specifically trained trial staff
- **In a recent consumer panel survey conducted by a national pharmacy retail chain:**
  - **32% of respondents said "ability to participate in a trial through my local pharmacy" would make it easier to be in a study**
  - **56% of respondents said they've be willing to participate in a trial through a national pharmacy retail chain**

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Proposed Steps for Improving Clinical Trial Diversity through Community/Retail Pharmacists[27]

1) Identify pharmacies within locations/communities that have been historically underrepresented and excluded
2) Identify potential participants that match study protocol requirements
   - i.e., use of AI-enabled technology to assess de-identified pharmacy prescription databases to find patients
3) Initiate patient contact to determine interest in clinical trials
4) Perform initial inclusion/exclusion criteria assessment
   - e.g., administration of an IRB-approved questionnaire in-person or via telehealth
5) Refer patients meeting the criteria to the principal investigator for further screening
6) Monitor enrollment of historically underrepresented patients and adjust approach, as needed

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Challenges for Clinical Trial Programs at Community/Retail Pharmacies[28,29,31]

- Clinical trial oversight, data quality, and data privacy concerns --- could compromise integrity of study results
- Potential conflicts of interest, particularly with retail chains that have a financial stake in revenue generation (i.e., they are publicly held entities and may compromise patient safety or data quality for financial gain)
- Operational hurdles --- limited infrastructure and staffing to support trials
- Barriers to participation that cannot be addressed by the pharmacist (e.g., inconveniences stemming from poor protocol design, a sponsor's responsibility)
- Business challenges related to venturing into a new market area
  - At least 4 national pharmacy retail chains have created clinical trial units since 2021. However, one major chain recently confirmed closure of its unit by 2024, due to reassessment/realignment of "long-term strategic business priorities"

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Health-Systems Pharmacists (Research-Focused*)[32,33]

- **An essential member of the research team, in a role that goes beyond traditional dispensing of medications**
- **Several opportunities exist for impacting clinical trial diversity within role**

- Assists in background medication research on the study drug, including literature searches
- May write pharmacy section of study protocol (e.g., drug inventory, compounding, dispensing, record-keeping procedures)
- May write other protocol sections involving pharmacology, PK, drug exclusion criteria, adverse effects, and adherence monitoring
- May serve as a member of the institutional review board (IRB)

*Locations may be outpatient; primary "customers" are the principal study investigators

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Health-Systems Pharmacists (Research-Focused*) - cont. [32,33]

- Performs standard pharmacist tasks upon receipt of drug order for study medication from principal investigator
- Documents all processes and leads distribution of study drug including delivery to study location or patients' homes
- May meet face-to-face with patients during trial and afterward during transition-of-care period
- May collaborate with principal investigator on organization, analysis, and write-up of data related to study drug

*Locations may be outpatient; primary "customers" are the principal study investigators

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Industry Pharmacists & Clinical Trial Diversity[34,35]

- **Lack of trial diversity is not "just a Clinical Operations issue"**
- **Several opportunities exist for collaborating and impacting clinical trial diversity across various functions**

Clinical Development
- Study protocol development (including determination of population to be studied, diversity goals, and eligibility criteria)
- Selection of diverse principal investigators and advisory board participants
- Ensure proper data collection and interpretation
- Publish clinical study reports and manuscripts --- can ensure transparency of diversity data to external entities

Clinical Operations
- Diverse trial site and CRO selection/management (inclusive of training and monitoring)
- Other Clin Op responsibilities may include: site activation, screening and recruitment, study timeline management, study tracking regulatory/audit readiness…

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Industry Pharmacists & Clinical Trial Diversity (cont.)[34,35]

Regulatory Affairs
- Co-develop the clinical development and regulatory approval strategies/plans for trial diversity and communicate them to the FDA

Medical Affairs (Including Field Medical)
- Recommend new trial sites in racially/ethnically diverse geographic areas
- Identify up-and-coming racially/ethnically diverse key opinion leaders and investigators
- Regularly amplify reminders to sites re: importance of recruiting racially/ethnically diverse patients from their communities
- Bring insights re: opportunities and challenges with disease/trial education and diverse recruitment back to the clinical study team

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Industry Pharmacists & Clinical Trial Diversity (cont.)[34,35]

Patient Advocacy
- Facilitate connections with patient advocacy groups who focus on racially/ethnically diverse patients and complement community engagement efforts

Commercial/Marketing
- Enterprise business thinking --- leverage overall understanding of the business impact of reaching (or not reaching) trial diversity goals
- Conduct market research of real world-patient demographics by race, ethnicity and other subgroups (i.e., characterization of the "patient universe" or "patient funnel")

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A clinical trial where some or all trial-related activities occur at locations other than a traditional clinical trial site is referred to as a ____

- Localized Study Site (LSS) 0%
- Decentralized Clinical Trial (DCT) 0%
- Disseminated Clinical Trial (DCT) 0%
- Site-Evolved Study (SES) 0%

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Leveraging community pharmacies for clinical research activities may increase trial diversity because:

- Convenience of location makes trials more accessible to local, diverse communities 0%
- Pharmacists can reach out to patients directly and inform them of research opportunities 0%
- Real-world evidence from pharmacy databases can inform more inclusive study protocol designs 0%
- All of the above 0%

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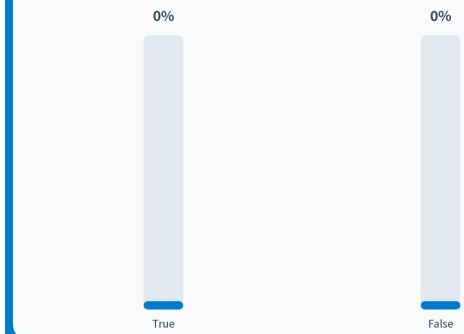
Industry pharmacists who work in Regulatory Affairs may influence clinical trial diversity by co-developing the clinical development and regulatory approval strategies/plans for study diversity and communicating them to the FDA



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