Summary Report from the *DIA 2023 Global Annual Meeting* Diversity, Equity, and Inclusion DIAmond Session and Solution Room

Introduction

In the realm of life sciences research and development, progress is measured not solely by groundbreaking treatments, but also by the ability to ensure that these innovations reach every corner of our society. Picture a medical breakthrough that could save lives but is only tested on a narrow slice of the population. This is the critical issue we face in the realm of clinical trials, a lack of diversity that has far-reaching implications for healthcare and patient outcomes.

The United States Food and Drug Administration's (FDA) 2020 final guidance on "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs", their 2022 Draft Guidance on "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials", and the 2022 Food and Drug Omnibus Reform Act (FDORA) significantly changed and influenced the United States' landscape for diversity in clinical trials. DIA's *2023 Global Annual Meeting* featured an essential DIAmond Session, which underscored the critical importance of diversity in clinical research and included perspectives from FDA, Health Canada (HC), industry, a patient advocate, and academia. A Solution Room followed the DIAmond Session, providing participants with the opportunity to delve deeper and collaborate on identifying actionable steps to advance efforts in the right direction.

DEI DIAmond Session Key Takeaways

FDA

The FDA discussed their unwavering commitment to diversity, equity, and inclusion (DEI) as a top priority in increasing diverse representation in clinical trials. One notable development is the establishment of the Diversity Plan Implementation Committee (DPIC) to ensure that everyone is at the table when moving DEI policies forward. Furthermore, FDORA and statutory requirements now mandate diversity plans within 180 days after the release of the final DEI guidance on diversity plans, underlining the urgency of this initiative. An essential theme that emerged was the collaborative "It takes a village" concept, emphasizing the collective effort required to achieve meaningful progress. In June 2022, the FDA received an impressive response, with over 100 diversity plans submitted, predominantly in the field of oncology. Currently, the team is diligently reviewing these plans and providing constructive feedback to the sponsors. Additionally, they plan to publish a paper outlining the valuable lessons learned from the diversity action plans they've received. A speaker introduced the "recipe concept," highlighting the initial challenge of lacking a specific roadmap. While there isn't a one-size-fits-all recipe, regulators are keen to accumulate experience and share lessons learned. They're counting on stakeholders to contribute diverse recipes and variations to help advance efforts and facilitate their growth.

HC

HC's Sex- and Gender-Based Analysis Plus (SGBA Plus) (2022-2026), a continuation from their first plan released in 2017, was highlighted to showcase how they are working to systematically integrate sex, gender, and diversity considerations into their research, legislation, policies, regulations, programs, and services to advance equity, diversity, and inclusion. In addition to SGBA Plus, HC discussed the importance of disaggregated data and of collecting the necessary data from clinical trials globally, emphasizing the need for global consensus on terminology. Furthermore, HC supports the proactive approach of understanding disease epidemiology to identify relevant patient characteristics for recruitment in clinical trials and systematically addressing barriers early in the planning process. This approach is seen as crucial for achieving equity in health product development.

Patient Engagement

At DIA, including the patient's voice is critical in sharing their experiences and perspectives, shedding light on the critical aspects for effectively driving diversity in clinical trials. The patient advocate and panelist stressed the importance of acknowledging and addressing implicit bias, imploring all stakeholders to leave it at the door. The advocate emphasized that true progress can only be made when biases are put aside. Building trust with underrepresented communities emerged as another central theme, highlighting the need for continuous efforts. The advocate underlined that healthcare professionals must actively invite historically underrepresented communities to participate in clinical trials, thereby rectifying the current disparity in participation. Notably, it was stressed that such communities should not be regarded as mere checkmarks on a diversity checklist; their participation should be meaningful, respectful, and attuned to their unique

needs and concerns. The patient advocate's perspective served as a powerful reminder of the pivotal role diversity and inclusivity play in shaping the future of clinical research and healthcare, fostering a more equitable and effective system.

Industry

A representative from the pharmaceutical industry emphasized the importance and significance of sponsors making a clear commitment to fostering diversity in clinical trials. An approach highlighted underscored the significance of building trust within communities by collaborating with community-based organizations, institutions of higher education, and professional groups. Notable initiatives include establishing diverse centers of excellence across the US, providing training for site staff, and introducing the research navigator role. Moreover, the panelist highlighted the importance of actively collaborating with historically black medical schools to operate clinical trials and the inclusion of a community advisory board to ensure that the patient voice is incorporated into their engagement efforts. Furthermore, they are supporting initiatives and sponsoring training for physicians of color to become principal investigators (PI) and launching an early talent training program to introduce community college and high school students to the clinical research profession. The panelist emphasized the importance of meeting potential participants where they are, addressing challenges that may impede participation. This includes initiatives to ease transportation barriers and co-sponsoring reimbursement for out-of-pocket travel costs. These actions collectively reflect a comprehensive approach to enhancing diversity and accessibility in clinical research.

Complexities and Challenges of Academia's Role in Increasing Diversity in Clinical Trials

In the academic sphere, a strong commitment to both researchers and their diverse communities was evident. The panelist from academia recognized that the rich tapestry of identities within the community is a wellspring of inspiration for pioneering research, innovative study ideas, and the development of clinical trials that serve the community's needs. It was noted that there was a need to advocate for a deep dive into these dynamics, urging researchers to ask crucial questions: Who is missing, and what do they require to ensure their full participation? The approach should encompass trying something new, alongside implementing evidence-based practices to drive meaningful change. The panelist emphasized that collaboration is a cornerstone, acknowledging that this collaborative process can take various forms to accommodate the unique needs of each stakeholder. Simultaneously, the importance of building capacity within and through these stakeholders, ultimately fostering a more inclusive, dynamic, and impactful academic research environment, was highlighted.

DEI Solution Room Outputs and Insights

Engaged Stakeholder Groups:

- Pharmaceutical and medical device companies and organizations
- Patients and patient advocacy groups
- Regulators
- Community engagement

Posed Questions:

- What are the current strategies to increase and advance diversity in clinical trials?
- What are the potential barriers, challenges, and unmet needs that organizations face when trying to implement these strategies and policies?
- How can we overcome the potential barriers or challenges you and your organizations face when trying to implement these strategies and policies?
- What are some successful and unsuccessful use cases and effective change management strategies to work towards greater efforts to increase diversity in clinical trials?

Q1: What are the current strategies to increase and advance diversity in clinical trials?

Patients and Patient Advocacy Groups:

- Improving Clinical Trial Access and Infrastructure:
    - Emphasize investing in new clinical trial sites to widen access.
    - Improve investigator site infrastructure for a more welcoming environment.
    - Ensure that investigators can communicate in multiple languages.
- Patient and Community Engagement:

  - Focus on the patient voice and gain their input early and often for clinical trials.
  - Partner with patients for co-design.
  - Include caregiver involvement input.
  - Identify quality patient advocacy groups.

Industry:

- Diverse Staffing and Investigators:
  - Hire and train diverse site staff and PIs.
- Clinical Trial Location and Access:
  - Conduct clinical trials in locations where patients are found, such as barbershops and small churches.
  - Utilize decentralized trials and digital health technologies to reduce barriers to participation.
- Early Diversity Planning and Measurement:
  - Initiate diversity action planning at an early stage.
  - Implement measurements for tracking progress.
  - Appoint specialists or officers for DEI.
  - Appoint a diversity spokesperson.
- Enhancing Patient Experience:
  - Introduce a "Patient Concierge" Model for patient assistance.
  - Offer help with digital data collection tools.
  - Obtain input from diverse patients before protocol design.
  - Engage patients in the design of clinical trials to build transparency and trust.
  - Develop more inclusive inclusion/exclusion criteria in trials.
  - Provide patient health literacy education regarding participation in clinical trials.
- Community Engagement and Education:
  - Promote public education on clinical trials and scientific literacy.

Community Engagement:

- Engaging Diverse Communities:
  - Collaborate with grassroots organizations and reach out actively to diverse groups.
  - Attend events in various communities to engage potential participants.
  - Build trust and relationships within communities.
  - Expand the clinical research site beyond traditional research centers into different communities to enhance participant diversity.
- Transparency and Education:
  - Be transparent about the definition of diversity and the importance of clinical trials.
  - Consider the intersectionality of diversity factors, including race, gender, income, genetics, etc.
  - Advocate for a community regulator to enhance visibility.
- Stakeholder Collaboration:
  - Encourage collaboration and communication among stakeholders.
- Community Investment and Visibility:
  - Ensure sustained investment in community engagement.
  - Promote the visibility of pharmaceutical companies within communities.

Regulators:

- Leveraging Technology and Data:
  - Utilize artificial intelligence (AI) for improved clinical trial diversity assessment.
  - Implement regulations like FDORA to disaggregate data and adhere to pediatric legislation/regulation.
- Community Awareness and Capacity Building:
  - Raise community awareness and build capacity.
- Promoting Transparency and Education:
  - Promote transparency by providing training and educational materials.
  - Discuss DEI plans and requirements for grant funding.
- Guidelines and Regulatory Compliance:

- Utilize ICH platforms for global considerations and guidances, such as the 2020 FDA guidance for enhancing the diversity of clinical trial populations, the 2021 FDA diversity action plan guidance, and insights from guidance on the inclusion of pregnant individuals.

Q2: What are the potential barriers, challenges, and unmet needs that organizations face when trying to implement these strategies and policies? And Q3: How can we overcome the potential barriers or challenges you and your organizations face when trying to implement these strategies and policies?

Community Engagement and Trust	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Lack of patient voice and historical injustices leading to community mistrust.	Establish transparent, ongoing communication and collaboration with patient advocacy groups, local community leaders, and organizations (e.g., health centers, social services organizations, etc.). Conduct community programs to address historical mistrust. Include patients in the design and decision-making processes.
Shortcomings in sustained engagement with communities over time.	Establish long-term relationships with communities through continuous outreach and involvement. Invest in community liaisons and advocates.
Challenges reaching hard-to-reach populations.	Work with locally trusted community leaders and organizations to genuinely engage hard-to-reach populations. Develop specialized outreach and engagement strategies.
Articulating the importance of community engagement and overcoming internal policies that hinder opportunities to engage communities.	Utilize data and statistics to illustrate the impact of diverse participation in clinical trials and the importance of community engagement. Educate colleagues on the importance, impact, and value of community engagement. Review and update existing internal policies that hinder opportunities to engage communities.

Data Collection and Reporting	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Organizations lack data to drive strategic decisions.	Establish well-defined goals and targets, informed by data, that are effectively communicated and consistently measured. Establish a reliable and consistent resource for gathering data on specific indications to make data-driven strategic decisions for effective planning and targeting.
Insufficient expertise in using digital data collection tools.	Offer training and support for both patients and site staff in using digital tools.

	Create user-friendly interfaces and provide assistance at trial sites.
Biased data sources.	Implement rigorous data quality control measures. Identify the sources that introduce bias and errors in data management.
Incomplete data collection for certain categories or populations.	Review and expand inclusion/exclusion criteria to encompass diverse populations. Conduct outreach to underrepresented groups. Start with epidemiology data and/or real-world data before determining the scope of study participants. Connecting and validating data to ensure that the implemented solutions effectively impact diversity in clinical trials.
Gaps and inconsistencies in country requirements for data collection.	Collaborate with regulatory agencies to harmonize data collection requirements. Standardize data collection practices. Standardize terminology of race and ethnicity categories. Promote data-sharing initiatives and collaborations.
Limited data on social determinants of health (SDOH).	Enhance data collection methods to include SDOH metrics. Collaborate with healthcare systems and organizations to access relevant data.

US Diversity Action Plans	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
The development of robust diversity action plans.	Institutionalize standards for diversity action plans at the company level. Establish and delegate ownership at every organizational level for the development and execution of a targeted diversity action plan. Create comprehensive diversity action plans that include clear objectives and timelines. Engage with the regulators early to gain feedback. Regularly assess and adapt these plans based on results and feedback.

Terminology	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Global differences in the definition of diversity and the diverse patient populations.	Development of universal guidelines for diversity metrics and definitions. Promote cultural competency training for global teams.

Clinical Sites	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Patients' limited ability to travel to trial sites.	Offer decentralized trials and remote participation options. Provide transportation assistance and flexible scheduling for participants. Gain insights on the root causes and barriers to participation.
Geographical and socioeconomic disparities, language barriers, and lack of cultural awareness.	Establish more trial sites in diverse locations. Hire diverse staff who can relate to the communities they serve. Engage in cultural sensitivity training and share best practices and case studies to assist site staff. Ensure that site staff are multilingual or provide interpreter services. Offer study materials in multiple languages.
Costs, reimbursement, and clinical trial participation.	Assess the consequences of the IRS mandate that compels research institutions to report compensation of $600 or more per year to clinical trial participants using Form 1099, as it could potentially present challenges for future participants. Develop support programs. Advocate for reimbursement policies and note that the reimbursement of expenses is not considered compensation.
Implicit bias in trial processes.	Conduct regular bias training for trial staff and researchers. Use objective, standardized criteria in participant selection.

Organizational Challenges	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Budget constraints.	Advocate for increased funding for diversity initiatives. Increase funding for studies that prioritize inclusiveness. Seek partnerships with government agencies and philanthropic organizations. Start at the top and evaluate what is needed.
Resistance to change.	Conduct education and awareness campaigns about the importance of diversity in clinical trials. Engage in open dialogue with all stakeholders to address concerns and facilitate change. Conduct organizational change management and culture-building efforts. Convey to leadership the actions taken and the results obtained.

The need for cross-functional clinical trial diversity workstreams across research and development, medical, and commercial sectors.	Establish dedicated diversity teams with cross-functional representation. Develop clear communication channels between different sectors.
A more diverse workforce within the pharmaceutical and medical device industry.	Implement diversity hiring initiatives. Offer diversity and inclusion training.
High turnover and burnout.	Foster a supportive and inclusive work environment. Conduct exit interviews. Maintain comprehensive documentation of all processes, procedures, and workflows. Cross-train employees. Create a feedback mechanism that allows team members to express concerns, offer suggestions, and provide input.
Inclusion of diverse patient advisors on clinical trial design teams.	Actively seek out diverse patient advisors and include them in the design process. Create channels for patient input in decision-making.
Approvals from legal departments to compensate patients for participating in trial design teams.	Work with legal departments to establish clear policies and guidelines for compensating patient advisors. Advocate for the value of patient input in trial design teams.

General	
Barriers, Challenges, and Unmet Needs	**Insights on Overcoming Barriers**
Involvement of sponsors, community patient groups, and multistakeholders in addressing the unmet needs and challenges in working towards greater diversity in clinical trials.	Actively involve sponsors and multistakeholders in addressing these needs. Create collaborative partnerships to develop and implement solutions.
The necessity for forums for health authorities to discuss challenges in engaging communities and working towards greater diversity in clinical trials.	DIA to establish regular forums, conferences, or workshops for health authorities, sponsors, community engagement, and patient groups to discuss challenges, solutions, and best practices.

Q4: What are some successful and unsuccessful use cases and effective change management strategies to work towards greater efforts to increase diversity in clinical trials?

Organizational and Cultural Strategies:

- Strong Allyship
    - Building internal allies who support initiatives to increase diversity in clinical trials.
        - Implementation: Develop training programs and awareness campaigns to educate staff and leadership about the importance of diversity initiatives.
- Honest and Critical Assessment
    - Conducting honest and critical self-assessment as an organization.
        - Implementation: Encourage regular self-assessment and audits to identify areas for improvement in diversity efforts.

- Honest Conversations
    - Fostering open and honest dialogues.
        - Implementation: Create platforms and forums for open discussions, allowing employees and stakeholders to voice concerns and suggest solutions.

Technological and Access-Related Strategies:

Addressing Tech and Access

- Addressing the gap between technology and access, considering factors like Bring Your Own Device (BYOD) versus provisioning and internet access.
    - Implementation: Invest in technology infrastructure that supports remote participation and ensures equitable access for all participants.

Clinical Trial Infrastructure and Operations Strategies:

Permanent and Sustained Trial Infrastructure

- Establishing permanent and sustained trial infrastructure in communities.
    - Implementation: Develop long-term community partnerships and sustainable trial sites that support ongoing diversity initiatives.
- Decentralized Trials
    - Decentralizing trials, focusing on process, technology, and design changes.
        - Implementation: Implement gradual process changes, technology upgrades, and pilot programs to test decentralized trial models.
- Teaching Clinical Operations Teams
    - Training clinical operations teams to help sites tailor recruitment plans.
        - Implementation: Offer specialized training to clinical operations teams to equip them with the skills and knowledge needed to tailor recruitment plans effectively.
- Developing Guidance
    - Developing guidance for diversity initiatives.
        - Implementation: Collaborate with experts to create clear, actionable guidance for implementing diversity initiatives.

Change Management Strategies:

- Handholding
    - Providing support and guidance to stakeholders during the change management process.
        - Implementation: Create change management teams or specialists to guide stakeholders through transitions. Develop toolkits, resources, and best practices for change management.
- Funding Incentives
    - Providing financial incentives to encourage change.
        - Implementation: Allocate budgets and incentives specifically for diversity initiatives. Reward successful diversity efforts with recognition and financial bonuses.
- Mechanisms for Feedback
    - Establishing mechanisms for collecting feedback from diverse stakeholders.
        - Implementation: Set up regular surveys, focus groups, and forums for collecting feedback from employees, patients, and other stakeholders. Utilize online platforms and technology to facilitate easy feedback collection.
- Feedback from Regulators on US Diversity Action Plans
    - Receiving and responding to feedback on diversity action plans.
        - Implementation: Collaborate with internal cross-functional areas to review feedback from the regulators to refine and improve diversity action plans.
- Diverse, Clear Leadership
    - Ensuring diverse and clear leadership endorsement for diversity initiatives.
        - Implementation: Ensure leadership endorsements are visible and consistently communicated. Encourage leadership diversity to demonstrate commitment to inclusivity.
- Metrics and Continuous Feedback
    - Implementing metrics for tracking progress and incorporating continuous feedback.

        - Implementation: Define clear metrics for diversity success and use dashboards and reports to communicate progress. Promote a culture of continuous feedback and adaptation in response to changing needs.
- Pivoting and Responding
    - Being flexible and responsive to changing circumstances and outcomes.
        - Implementation: Encourage colleagues to be flexible and proactive in adapting to changing circumstances, including shifts in patient populations and societal changes.

Final Thoughts

Tackling DEI challenges in clinical research is complex but necessary for systemic change. The key takeaways from the DIAmond session and Solution Room include the need for a willingness to adapt, embrace experimentation, and learn from failures. The approach should involve a broad spectrum of participants, including industry, academia, regulators, and patient communities. Self-reflection and focusing on the long-term benefits of the system are essential. Collaboration is crucial, but it should be tailored to the unique needs of each stakeholder. Lastly, achieving meaningful representation in trials requires a conscious, collective effort from everyone involved, recognizing that each drug development program may require different approaches to DEI.

DIAmond Session Speakers

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Solution Room Participants

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