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WHITE PAPER

Shattering Barriers:
Advancing Healthcare Equity by Enhancing Diversity in Clinical Trials for a Future of Inclusive Innovation

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Executive Summary

Advancing healthcare equity requires increasing diversity in clinical trials, ensuring all individuals, regardless of demographic or socioeconomic background, have access to safe and effective medical treatments. This white paper focuses on ways to improve diversity in clinical trials as a key pathway to achieving healthcare equity. It consolidates insights from a panel discussion featuring Dr. Michelle Tarver, Acting Director of CDRH at the FDA, alongside RQM+ experts. The paper outlines RQM+'s recommendations for strategic and tactical approaches to enhance diversity in trials, recognizing that diverse representation is crucial for understanding the safety, performance, and effectiveness of medical devices and in vitro diagnostics (IVDs) across all populations. Structured around key areas such as the FDA's perspective on healthcare equity and RQM+'s actionable strategies for meeting regulatory expectations, this paper is grounded in industry best practices and FDA guidance on diversity action plans and enhancing trial populations[1-6]. By focusing on these areas, it provides a roadmap for stakeholders to increase diversity in clinical trials, advancing the broader goal of health equity in healthcare.

Introduction

Advancing healthcare equity begins with understanding and addressing disparities in healthcare outcomes, achievable (in part) through diverse and representative clinical trials. While clinical trials confirm expected outcomes, increasing diversity uncovers critical insights into how effectively medical devices/IVDs perform across different populations. This transparency is essential for identifying inequities and driving post-trial improvements. Ensuring that trials reflect the full spectrum of patient diversity lays the foundation for actionable improvements in both device design and healthcare delivery, contributing to equitable health outcomes for all.

The World Health Organization (WHO) defines health equity as the "absence of unfair and avoidable differences in health among population groups," underscoring the need for inclusive clinical research that meets the varied needs of diverse communities. Without justifiably sufficient diverse representation, the safety and effectiveness of devices cannot be assured for all populations. The International Medical Device Regulators Forum (IMDRF) emphasizes factors like age, sex, ethnicity, race, and socioeconomic status as crucial when evaluating device safety, effectiveness and performance[7]. Addressing these factors in clinical trials is vital for reducing healthcare disparities.

RQM+, a leading contract research organization (CRO) in the medical device and IVD industry, stresses the importance of diversity in clinical research. In a recent blog post on healthcare equity, we highlighted how increasing diversity in trials can help overcome systemic barriers to equitable healthcare[8]. This white paper outlines strategic approaches to enhance diversity in medical device/IVD trials, drawing from FDA guidance and industry best practices, with the goal of advancing healthcare equity through inclusive research practices.

DISCUSSION SECTION 1

FDA Perspective on Advancing Healthcare Equity via Improved Diversity in Clinical Trials

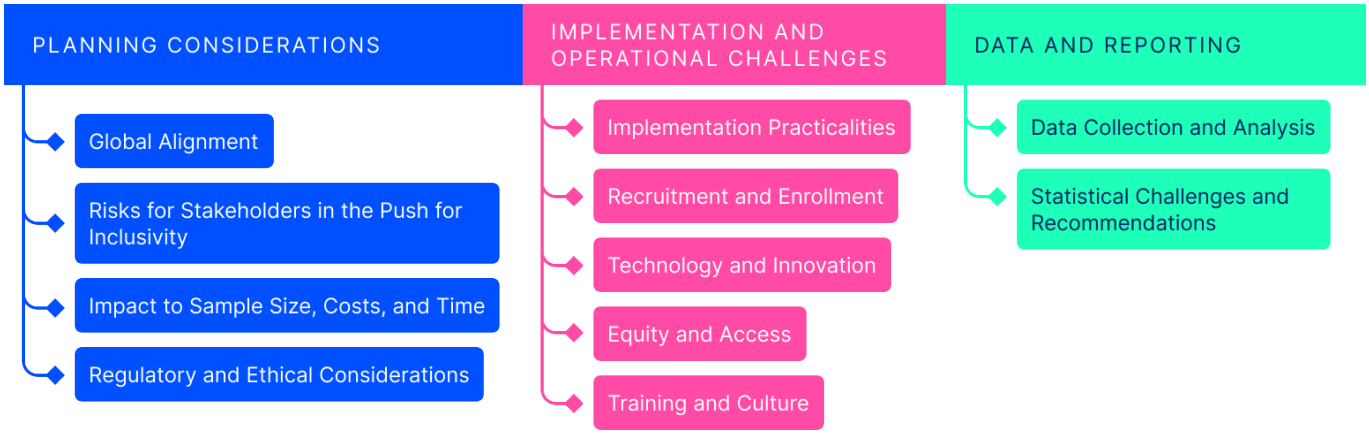
Achieving healthcare equity requires diverse representation in clinical studies to ensure that medical devices and IVDs are tested on populations reflective of their intended use. The FDA has long emphasized diversity in clinical trials, with a renewed focus following the 2018 guidance on the Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies[1-5]. A significant advancement is the requirement for Diversity Action Plans (DAPs), which mandate that sponsors ensure participant demographics align with the intended use population through clear diversity goals and strategies[3-6]. The FDA supports this with public workshops, like the November 2023 event on equitable clinical trials, and requires annual summary reports to promote transparency and accountability. Additionally, the FDA's "Home as a Healthcare Hub" initiative leverages telemedicine, remote monitoring, and virtual consultations to reduce access barriers, making trials more inclusive for underrepresented populations.

DISCUSSION SECTION 2

RQM+ Recommendations on Strategic and Tactical Considerations

Enhancing Diversity Across Clinical Trial Phases

Diversity can be enhanced at every stage of the clinical trial process and with it comes a host of new considerations. This roadmap highlights key focus areas for integrating diversity at every stage of the clinical trial process:



Planning Considerations

Global Alignment

While this paper focuses on FDA regulations, it's important to note that global regulatory trends, including IMDRF recommendations[7], also emphasize diversity in clinical trials. Agencies like the European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) prioritize diverse populations, with the FDA focusing on racial and ethnic diversity and the EMA on gender balance. Aligning trial designs with international standards not only ensures compliance but also positions medical devices and IVDs for global success, advancing health equity. Understanding regional differences is crucial for conducting effective multinational trials.

Risks for Stakeholders in the Push for Inclusivity

Failure to address diversity in clinical trials carries significant risks for stakeholders, including patients, sponsors, regulatory authorities, and healthcare providers. Neglecting diversity can unintentionally compromise patient safety, delay approvals, and increase regulatory scrutiny. The following table illustrates some of these risks.

Table 1: Risks associated with a failure to address diversity in clinical trials

Stakeholder	Risk	Discussion	Medical Device Example
Patients	Ineffective or Unsafe Therapies/Devices	Devices tested on homogeneous populations might not work well for diverse groups, potentially leading to reduced effectiveness or increased harm. These risks may differ in pre- and post-market studies.	St. Jude Medical Riata defibrillator leads experienced post-market insulation failures, raising concerns that initial trials did not adequately represent diverse demographics.[9] The data specifically highlighted that these issues were most prevalent among women.
	Misinformation	Overgeneralized results from trials lacking diversity can mislead clinicians and patients about treatment effectiveness, affecting clinical decisions.	The MAUDE database highlighted higher failure rates with orthopedic implants in minority populations, suggesting early clinical trials did not adequately capture device performance across diverse groups.[10,11]
Sponsors	Access to market & Regulatory Compliance	Failing to achieve diversity and inclusivity can delay approvals, increase scrutiny, and harm reputations.	Essure device (Bayer) faced significant post-market safety concerns, especially among minority women, leading to regulatory action, product withdrawal, and reputational damage.[12]
Regulatory Authorities	Post-Market Surveillance Gaps	Lack of diversity in pre-market trials can cause safety issues in underrepresented groups, necessitating costly post-market surveillance.	The Birmingham Hip Resurfacing (BHR) System (Smith & Nephew) faced post-market safety concerns with higher failure rates in women and smaller-bodied patients, which were not captured in pre-market trials, highlighting gaps in the pre-market studies.[13,14]
Healthcare Providers	Uncertainty in Treatment Application	Providers may be unsure about recommending treatments not tested in diverse populations, which could lead to hesitancy or misuse.	Early Transcatheter Aortic Valve Replacement (TAVR) trials for devices like the SAPIEN valve (Edwards Lifesciences) lacked sufficient data on outcomes in women and minority populations, leading to potential uncertainty among providers about device performance in these groups.[15]
	Patient Mistrust	Ignoring diverse community concerns during trials can increase mistrust, complicating future recruitment and adoption of new products.	After reports of higher complication rates with the DePuy ASR Hip Implants (Johnson & Johnson) among minority populations, patient mistrust made it harder to recruit diverse participants for future orthopedic device trials.[16,17]

Conversely, increasing diversity in clinical trials can also result in unexpected problems, therefore, the design of these trials needs to be carefully considered and planned. The following table discusses some of these risks with real-world examples.

Table 2: Risks and Real-World Examples in the Push for Inclusivity in Clinical Trials - A Comparative Analysis of Medical Device Trials

Stakeholder	Risk	Discussion	Medical Device Example
Patients	Risk of Insufficient Protection for Vulnerable Populations	Elderly or those with severe comorbidities need special consent and protections to avoid harm or exploitation in trials.	SAPIEN Transcatheter Heart Valve trials (Edwards Lifesciences) included elderly and high-risk patients, necessitating enhanced informed consent and tailored communication strategies (relative to other TAVR trials) to ensure their safety and understanding.[18]
Sponsors	Risk of Increased Costs and Extended Timelines	Recruiting diverse populations and using adaptive designs increase trial costs and extend timelines, delaying product launches.	The COAPT trial for MitraClip faced extended timelines and increased costs due to the complexity of managing high-risk patient groups, which included a broad and diverse participant pool in terms of comorbidities and surgical risks. However, while ethnic diversity was not a primary factor, the diversity of patient conditions and the associated logistical challenges certainly played a role in the trial's extended duration and increased expenses.[19]
	Risk of Inconclusive Data	Small subgroup sizes in diverse trials can lead to inconclusive data, necessitating further studies and potentially delay safety and effectiveness assessments.	Small sample sizes in subgroup analyses for the PROTECT AF trial (Boston Scientific) resulted in inconclusive data. This was observed for the WATCHMAN device where data variability in certain demographics (including those for women) led to the need for further studies for comprehensive assessments.[20]
Clinical Sites and Investigators	Risk of Operational Strain	Recruiting and managing diverse populations (with statistically powered sub-groups) adds logistical and resource challenges.	The SYNTAX Trial (1800 patients, 85 sites, 17 countries), led by Boston Scientific, faced operational strain due to complex logistics from coordinating multiple international sites and the challenge of managing diverse patient populations, which complicated data collection and analysis.[21(a),21(b)]
	Risk of Data Integrity Issues	Diverse populations and multi-site trials can complicate data collection, risking data integrity due to varying standards.	The Fantom II trial (28 sites, 8 countries), faced challenges related to standardizing data collection practices. For example, not all centers recorded a cine angiogram with the delivery balloon fully inflated[22]. This data variability, procedural variability and standard of care complexity, typical in large-scale international trials, can lead to concerns about how reliably the data could be aggregated and compared across diverse populations.
Regulatory Authorities	Risk of Balancing Rigor with Flexibility	Regulators face the challenge of balancing strict inclusivity standards with flexibility to ensure trial integrity and foster innovation.	The FDA's approval process for the Medtronic Harmony Transcatheter Pulmonary Valve faced challenges in balancing rigorous data standards with the need for inclusivity across diverse populations, particularly pediatric patients[23]. Due to the limited number of pediatric patients requiring pulmonary valve replacement, achieving large, diverse sample sizes was challenging. The FDA worked closely with Medtronic to ensure that the available data, though limited, was sufficient to demonstrate the device's safety and effectiveness across the target population. Additionally, real-world evidence (RWE) and post-market studies were incorporated into the approval strategy to address ongoing concerns about the representation of diverse populations.

Impact to Sample Size, Costs, and Time

Advancing diversity in clinical trials requires strategic planning to manage the impact on cost, time, and resources. Effective execution, especially with adaptive designs, can balance these demands with trial goals, potentially reducing long-term expenses while enhancing healthcare equity.

1. Pre-Trial considerations: Larger, more representative sample sizes introduce complexity, requiring additional outreach, culturally tailored materials, and incentives for underrepresented populations, which drives up costs and extends timelines.

2. Trial Design: Adaptive trial designs offer flexibility in managing sample sizes and progression but entail higher upfront costs due to simulations, planning, and technology needs. These investments can streamline trials by allowing mid-trial adjustments based on interim data, potentially reducing future expenses and accelerating market access. However, adaptive designs can also affect timelines, either speeding up or delaying completion depending on the adjustments.

3. Trial Execution: Technology investments are crucial for managing these complexities. Advanced statistical methods and adaptive designs require significant spending on software, infrastructure, and training. Despite the costs, these investments facilitate efficient trials that adapt to real-world conditions, benefiting both sponsors and patients. Extended recruitment phases and complex data analysis can prolong study timelines and cause delays in regulatory review and data interpretation, particularly with real-time adjustments. Post-market study requirements from conditional approvals further extend data collection and increase long-term resource demands.

Regulatory and Ethical Considerations

Regulatory compliance and ethical integrity are fundamental to conducting inclusive trials. This requires a deep understanding of guidelines from regulatory authorities and a commitment to protecting vulnerable populations.

1. Conditional Approvals and Regulatory Flexibility: Regulatory authorities, such as the FDA, balance the need for early access to life-saving devices with the risks of incomplete trial data. Conditional approvals paired with rigorous post-market commitments allow for timely access while addressing data gaps, ensuring patient safety without delaying innovation.

2. Ethical Safeguards for Vulnerable Populations: Ethical integrity is crucial, particularly when involving vulnerable populations like children or socioeconomically disadvantaged groups. Tailored consent processes, using simplified language and visual aids, enhance participant understanding and retention. Ongoing ethical assessments ensure protection and trust, aligning with regulatory expectations to safeguard those most at risk.

3. Ongoing Ethical Responsibilities: Ethical standards must be continuously reassessed throughout the trial, beyond initial IRB/EC approvals. This includes evaluating consent procedures for vulnerable groups and ensuring adaptive trial designs do not compromise ethical obligations. Ethical reviews must adapt to evolving trial conditions, especially in studies driven by interim findings.

Implementation and Operational Challenges

Implementation Practicalities

Implementing diversity-focused clinical trials requires actionable solutions that can be tailored across various settings. Successful implementation involves addressing recruitment, logistics, and trial design challenges. This section offers strategies to overcome these hurdles, ensuring effective execution.

1. Strategic Approaches to Overcoming Barriers: Setting clear inclusion goals and monitoring progress are vital. Engaging trial sites and patients early in the feasibility phase helps identify potential barriers and aligns with standard care practices.

2. Adaptations for Different Trial Settings: Develop culturally tailored recruitment materials with input from community leaders to effectively engage target populations. Partner with local organizations like health centers, religious institutions, and advocacy groups to enhance recruitment and achieve strong return on investment. Provide support services like transportation, childcare, and flexible scheduling to remove participation barriers. Collaborate with Patient Advocacy Groups (PAGs) to extend outreach and logistical support. Real-world examples include the NIH's All of Us Research Program[24], which partnered with community health centers to improve diversity, and the STRIDE Study[25], which partnered with senior centers to reduce participation barriers.

3. Trial Design: Flexible trial designs, such as adaptive studies and phased data collection, accommodate diverse populations without compromising integrity. Integrate diversity goals early and collaborate with diverse healthcare providers to avoid bias and ensure representative samples.

4. Flexibility in Approach and Addressing Access Challenges: Flexibility and a willingness to revise strategies based on feedback are essential. Engage new investigators, utilize digital platforms, and employ targeted outreach campaigns to address access limitations. Digital health technologies and mobile platforms can further enhance diversity by making participation more accessible.

Recruitment and Enrollment

Recruiting a diverse participant pool is essential for trials to reflect the populations they aim to benefit, but it can significantly increase costs for sponsors, making upfront assessment critical. For instance, while a mechanical thrombectomy device may not vary in performance across demographics, clinical outcomes could differ due to factors like the length of deep vein thrombosis history, which may be delayed in certain patient groups. On the other hand, in case of laser- or light-based technologies, outcomes for which tend to be dependent on the melanin levels in skin and/or wounds may be race-/ethnicity-specific. Therefore, reviewing existing data such as the state of the art review in the EU-MDR clinical evaluation report to identify differences in device performance (or the lack thereof) is crucial for selecting the appropriate target populations. This research should guide recruitment strategies, ensuring alignment with regulatory expectations and the needs of diverse populations.

1. Overcoming Operational Challenges: Use targeted outreach, community partnerships, and patient navigators to connect with diverse communities. Partnering with Site Management Organizations (SMOs) can bring research to clinics that lack resources for clinical studies.

THE ALLHAT TRIAL

(Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial)

Challenge

ALLHAT sought to include a diverse population in terms of race, gender, and age to address health disparities in hypertension and cardiovascular outcomes. Recruiting and retaining a diverse patient population presented logistical and cost challenges.

Solution

The trial employed community engagement strategies, including partnerships with local clinics and minority-serving institutions, to enhance recruitment of underrepresented populations.

Outcome

ALLHAT successfully enrolled over 40,000 participants, with 47% women and significant representation from African American and Hispanic communities. The results helped provide insights into effective treatments across diverse groups.

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2. Improving Data Management: Standardize protocols and centralize systems for data management, ensuring compliance with local regulations. Provide staff training on data entry procedures.

3. Maintaining Engagement and Retention: Personalized communication, flexible schedules, and non-coercive incentives enhance participant retention and long-term engagement.

Technology and Innovation

1. Leveraging Technological Solutions: Utilize electronic health records, mobile health apps, and telemedicine platforms for recruitment, engagement, and data management. Innovations like artificial intelligence (AI) can enhance recruitment strategies and data analysis.

2. Decentralized and Hybrid Models: Adopting decentralized and hybrid trial models increases accessibility by enabling remote participation, reducing travel, and broadening the participant pool. However, fully decentralized models may not be feasible for devices requiring in-person procedures, imaging, or assessments. Hybrid models that combine in-

person visits for key milestones with remote monitoring can improve participation without compromising data quality. For example, TAVR trials[26] have successfully combined in-person interventions with telemedicine for follow-up care, enhancing trial efficiency and patient satisfaction.

Equity and Access

Improving access to clinical trials is key to advancing health equity. This section discusses strategies to enhance access and ensure all communities benefit from medical advancements.

1. Flexible Trial Models and Onsite Support: Decentralized trials can improve accessibility, but practical implementation for medical devices and IVDs can be complex. Emphasize flexible trial models that reduce the burden of onsite visits rather than eliminating them entirely. Hybrid models that allow remote follow-ups while maintaining necessary in-person visits ensure accessibility without compromising oversight.
2. Tailored Support: Providing tailored support involves more than financial assistance; it requires rethinking consent processes and participant stipends. Implement creative solutions like video consent with simplified language and visuals, translated into multiple languages. Offer flexible compensation models that address specific participant needs, such as extra stipends for travel or childcare.
3. Creative Solutions: Increased diversity pushes for innovation. Research sites may need to adjust hiring practices and offer different compensation for staff working off-hours. Incentivizing off-hour work and hiring culturally competent coordinators enhance engagement and retention, ensuring more inclusive studies.

Training and Culture

1. Effective Training Programs: Develop training programs that include workshops on cultural competence, implicit bias, and inclusive practices. Provide resources for creating inclusive trial materials.
2. Measuring Progress: Track progress towards diversity and inclusion goals by monitoring recruitment and retention rates, diversity metrics, and participant feedback. Use dashboards to evaluate the effectiveness of diversity initiatives.

Data and Reporting

Data Collection and Analysis

Diverse clinical trials require accurate data collection to reflect the populations studied. Effective data management is crucial for identifying disparities and informing post-market

decisions. This section outlines best practices for data collection and analysis, focusing on data integrity and maximizing insights.

1. Enhancing Data Collection Methods: Collect accurate demographic data using standardized protocols. Use technology like Electronic Health Records ‘EHR’ and digital tools to streamline data collection, allowing real-time updates. Engage early with regulatory authorities and report demographic data transparently to build credibility. RWE enhances data robustness, offering deeper insights into long-term safety and effectiveness.

2. Managing Expectations: **Avoiding Overgeneralization**: Diverse participation is essential, but expectations regarding uniform effectiveness should be managed. Trial designs and statistical analyses must account for biological, environmental, and social variations, balancing the benefit-risk analysis.

3. Addressing Data Interpretation Complexity: Analyze data from diverse populations by accounting for factors like socioeconomic status and comorbidities in statistical models. Conduct multiple subgroup analyses with statistical corrections to avoid Type I errors. Collaborate with experienced biostatisticians during planning to address these complexities.

4. Best Practices for Data Collection: Consistency in data collection is crucial for reliable results. Employ standardized methods, provide thorough staff training, and implement rigorous quality control. Adhere to regional data privacy regulations (such as GDPR, HIPAA, etc.) to ensure data integrity.

Statistical Challenges and Recommendations

Incorporating diverse populations into clinical trials presents statistical challenges that require careful management to ensure valid and reliable results. Effective outcomes depend on meticulous planning and the strategic use of advanced statistical methods. The following table outlines the key challenges in diversity-focused trials and offers strategies for addressing them.

Table 3: Typical Statistical Challenges and Recommendations

Statistical Challenge	Recommendation
Power and Sample Size Calculations	Ensure accurate power calculations to determine appropriate sample sizes for detecting true effects across populations.
Data Complexity and Advanced Methods	Use hierarchical modeling or Bayesian techniques to enhance subgroup precision, with careful interpretation.
Balancing Rigor with Feasibility	Balance statistical rigor with practical feasibility to ensure robust, achievable trials.
Adaptive Trial Designs	Employ adaptive designs with real-time data monitoring for resource optimization and data-driven decisions.
Risk of Misinterpretation	Maintain clear communication with stakeholders and regulatory authorities to mitigate risks.
Enrichment Strategies and Bias	Design enrichment strategies that enhance trial integrity while capturing diverse effects.
Statistical vs. Clinical Significance	Differentiate between statistical and clinical significance, particularly in exploratory analyses.
Post-Market Data Collection and Labeling	Leverage RWE and ongoing surveillance to refine understanding, consider the need for specific labelling and maintain product safety post commercialization.

The following table discusses statistical challenges and the corresponding solutions from some recent real world medical device trials.

Table 4: Key examples and insights into statistical challenges in diverse medical device trials

Trial Name Study Objective	Statistical Concern	Recommendation	Impact on Cost, Time, Resources
Absorb Bioresorbable Vascular Scaffold (BVS) Trials (ABSORB III)[27,28] Evaluate the safety and effectiveness of the Absorb BVS compared to standard metallic drug-eluting stents (DES) in treating coronary artery disease, focusing on target lesion failure at one year and long-term outcomes, including scaffold bioresorption.	Limited statistical power due to small sample size in subgroups. Difficulty in drawing conclusive results for diverse populations.	**Stratified Randomization:** Implement stratified randomization to better represent key demographic subgroups and enhance subgroup analysis.	Increases trial complexity, requiring additional resources for recruitment and data analysis. Post-market surveillance adds financial and operational burdens, delaying understanding of the device's performance and extending timelines for regulatory decisions.
BIOFLOW-V Trial[29,30] Assess the safety and effectiveness of the Orsiro DES versus the Xience DES in patients with coronary artery disease, comparing target lesion failure and major adverse cardiac events at one year.	Complexity in balancing subgroup analysis with overall trial integrity. Challenges in ensuring diversity without overburdening the trial.	**Adaptive Trial Design and Enrichment Strategies:** Use adaptive trial designs and enrichment strategies to ensure adequate subgroup representation while maintaining statistical power.	Results in higher costs and potential delays due to ongoing adjustments and complex design requirements.
REPRISE III Trial[31,32] Compare the LOTUS Edge TAVR system with the CoreValve system in patients with severe symptomatic aortic stenosis at high surgical risk, aiming to show non-inferiority or superiority in all-cause mortality, disabling stroke, and major adverse events at one year.	Granular data collection complicates analysis. Small subgroup sizes increase the risk of inconclusive findings.	**Bayesian Statistical Models:** Apply Bayesian models to incorporate prior data and enhance the reliability of subgroup analyses.	Increases analytical complexity, requiring more time and computational resources, and leads to higher data analysis costs.
EXCEL Trial[33,34] Compare percutaneous intervention (PCI) with the Xience stent to CABG in patients with left main coronary artery disease, demonstrating non-inferiority of PCI in major adverse cardiovascular (MACE) events at three years.	High risk of misinterpretation due to underpowered subgroup analyses. Logistical challenges in achieving diverse enrollment targets.	**Pre-Specified Subgroup Analyses and Collaboration:** Conduct pre-specified subgroup analyses and collaborate with regulatory authorities to align diversity levels and interpretative strategies.	Involves additional time and costs for targeted recruitment and collaboration with regulatory bodies.
SYNTAX Trial[35,36] Compare long-term outcomes of CABG versus PCI with the TAXUS Express2 DES in patients with complex coronary artery disease, focusing on rates of major adverse cardiovascular and cerebrovascular events (MACCE) over five years.	Risk of bias due to unbalanced subgroup representation. Difficulties in maintaining statistical power across diverse groups.	**Hierarchical Models and Post-hoc Analysis:** Utilize hierarchical models to control confounding factors and conduct post-hoc analyses to assess diversity impact on outcomes.	Requires increased computational resources and leads to longer timelines and additional costs for analysis.
PROTECT AF Trial[37,38] Determine if the WATCHMAN device is non-inferior to long-term warfarin therapy in patients with non-valvular atrial fibrillation at high stroke risk, focusing on stroke, systemic embolism, and cardiovascular death, while reducing bleeding risks.	Ethical and statistical challenges in ensuring sufficient representation of minority groups. Potential for type I errors in subgroup analyses.	**Adaptive Designs and Enriched Enrollment:** Implement adaptive designs and enriched enrollment focusing on high-risk populations while preserving overall trial validity.	Results in higher costs and extended trial duration due to complex design and enrollment strategies.
PARTNER Trial[39,40] Evaluate the safety and efficacy of the SAPIEN TAVR system in severe symptomatic aortic stenosis patients at high surgical risk, comparing outcomes to standard therapy or surgery in terms of all-cause mortality and major adverse events at one year.	Balancing statistical rigor with practical feasibility in recruiting diverse populations. Risk of inconclusive results due to small subgroup sizes.	**Integration of RWE and Registry Data:** Use RWE and registry data to complement trial findings and provide a comprehensive analysis.	Adds costs and time for integrating and analyzing RWE and registry data, increasing overall complexity.

Conclusion

Advancing health equity by improving diversity in clinical trials is not just a regulatory requirement; it is a strategic imperative that drives medical innovation and ensures that medical innovations benefit everyone. As regulatory authorities increasingly emphasize inclusivity and real-world applicability, the design and execution of clinical trials must evolve to meet these demands. Inclusivity in trials is now a core element of both compliance and the broader pursuit of equitable healthcare.

At RQM+, we understand the challenges this ongoing shift presents, and we are here to help you navigate them efficiently. Our expertise in adaptive trial designs, advanced data collection methodologies, and strategies for recruiting diverse populations combined with our commitment (and process-based ability) to applying the latest best practices, enables us to craft tailored strategies that meet regulatory expectations while minimizing costs and optimizing timelines. We focus on building robust, compliant trials that generate reliable data across diverse populations without unnecessary delays or expenses.

By partnering with RQM+, you gain a trusted ally dedicated to ensuring your trials are inclusive, effective, and aligned with the broader goals of healthcare equity. Together, we can advance global healthcare and ensure that innovation benefits all communities, leaving no one behind.

Recommendations for medical device/IVD manufacturers

RQM+ encourages stakeholders to:

1. Develop and Implement Diversity Action Plans: Create and execute comprehensive plans for diverse participation in line with FDA guidance[1-5].
2. Explore Innovative Approaches to Access: Use digital health technologies and decentralized models to enhance trial accessibility.
3. Engage Early with Regulatory Authorities: Seek regulatory guidance to ensure compliance and promote health equity.
4. Keep Abreast of the Regulatory Landscape: As the regulatory landscape evolves, staying proactive and adaptable is essential. Continuous improvement and collaboration with regulatory bodies are crucial for maintaining compliance and advancing equity in clinical trials.

By addressing these areas, stakeholders can ensure that clinical research not only complies with regulatory requirements but also establishes new benchmarks for advancing healthcare equity across diverse populations.

Author Bio

Jaishankar Kutty leads regulatory and clinical strategy within the Trials Services Business Unit and across the RQM+ organization. His extensive background includes key strategic and operational roles in cardiovascular product development. Previously, as a clinical team leader (and lead reviewer) at BSI, he was instrumental in reviewing and CE marking numerous innovative structural heart devices under both MDR and MDD regulations. At RQM+, Jaishankar applies his unique EU notified body expertise and extensive product development industry experience to craft effective clinical and regulatory strategies. His responsibilities encompass designing clinical studies, conducting and analyzing retrospective data, performing biological safety evaluations, ensuring stringent compliance, and facilitating interactions with regulatory authorities to reinforce the evidentiary foundations for medical devices.

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