Global Diversity Equity and Inclusion (DEI) Roadmap

Introduction

Clinical trials are generally conducted across multiple countries and world regions. A commitment to diverse, equitable, and inclusive recruitment requires research stakeholders to address this global context explicitly. However, the concept of 'global' DEI is understood in different ways by different stakeholders with different beneficiaries in mind. This roadmap sets out considerations to help stakeholders clarify their own organizational aims and objectives with respect to representation across their global portfolios.

We highlight three important distinctions:

1. **Different dimensions of diversity are of greater or lesser relevance in different contexts and countries.** In recent North American and European considerations of DEI, there has been a particular focus on questions of race and ethnicity,[1] in part because these factors act as a proxy for disadvantage and discrimination, and hence affect equitable access to healthcare and inclusion within research. However, race and ethnicity may not be as relevant in many other parts of the world – for example where populations are more homogenous with respect to geographic ancestry, or where other factors such as poverty, sex/gender, disability, caste, sexual orientation, or immigration status are much more clearly associated with lack of access to healthcare or representation in clinical trials. Alternatively, in some countries ethnic and cultural factors may be very important in terms of status and (dis)advantage, but the way in which differences are understood and can meaningfully be categorized may vary significantly between countries and world regions. This means that use of categories from one country, such as the US Office of Management and Budget

[1] That is not to discount an equally important focus on people with disabilities, sexual orientation and gender identity, children, older adults, socioeconomic status, geography, and others.

(OMB) categories of race and ethnicity,[2] will have limited relevance in other countries. Laws governing permissible categories of data collection vary substantially from country to country.

2. The driving forces behind organizational DEI initiatives can also differ. They may be based on **concern for social justice** (helping ensure that research is relevant to, and trusted by, all parts of society); the **opportunity to achieve better science** (through maximizing opportunities to detect differential responses); the need to meet **regulatory requirements** (in particular those in the US); or a combination of each of these. The relative weight attached to these motivations may be study-specific, depending on the nature of the research question, or population-specific, depending on the geography in which the study is sited. It will also depend on stakeholders' own wider organizational ethos and priorities.

3. In setting DEI policies, it is also crucial to clarify the **intended beneficiaries** of those policies. The US FDA has been particularly proactive in promoting recruitment to clinical trials that better reflect the demography and epidemiology of the US population in order to improve the representation of, and data about, the US population. Some stakeholders may use the same approach, based on US demography and epidemiology, when conducting multi-regional clinical trials (MRCTs) across multiple countries. However, this 'one size fits all' approach will not necessarily reflect the demography and epidemiology of the other countries where the trial is taking place or help achieve greater inclusion of disadvantaged populations in those countries. Nor will it help support greater inclusion and equity within the US itself. Local populations must always be included among the intended beneficiaries of any action taken to increase the diversity of clinical trial participation in their country.

[2] The Federal Register: The Daily Journal of The United States Government (2024). Available at: https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and (Accessed: 20 August 2024).

In light of different starting assumptions as to what is meant by attention to 'diversity' in MRCTs, we suggest that a common starting point when setting the overarching aim of a global DEI policy should be **to offer a fair opportunity to participate in research, coupled with a fair opportunity to benefit from research** (recognizing that forms of benefit will vary). Barriers to research participation, and to equitable access to needed healthcare, will take different forms in different countries. Stakeholders will take different views as to the extent of their responsibility to act proactively in response to those barriers. Commercial sponsors, philanthropic research funders, and national ministries of health, for example, are likely to frame their responsibilities regarding patients' equitable access to healthcare in different ways. This Global DEI Roadmap, therefore, distinguishes between actions that are regulatorily required, those that are standard good ethical practice, and those that are more aspirational in seeking proactively to enable more diverse, equitable, and inclusive participation in research. However, as an ethical threshold, all stakeholders must ensure that the approach they take to help meet the needs and requirements of DEI in one country (for example, in how they target recruitment in order to meet the regulatory requirements of the US FDA) does not lead to potentially exploitative recruitment practices in other countries. '*First, do no harm*' should be a guiding principle.[3]

Using the Roadmap

This Roadmap sets out a seven-stage process for designing MRCTs that takes account of different dimensions of diversity in different countries, and different drivers for equity and inclusion.

- **Starting prompts to clarify strategic commitments** with respect to the inclusion of underserved populations in research in other countries; to define epidemiology, by therapeutic area, across the countries where you intend to work; and, throughout, to keep in view key background considerations (e.g., business commitments; purposes of data collection; country capacity).
- **First ethics checkpoint to set out ethically important questions** to consider as part of country and site selection.

[3] Wright K, DeCormier Plosky W, Ahmed HR, White SA, Bierer BE. First, do no harm: a global perspective on diversity and inclusion in clinical trials. Nature Reviews Drug Discovery. 2024 May 8: 481-2, https://doi.org/10.1038/d41573-024-00078-4.

- **Prompt to consider country-specific regulatory requirements** or guidance with respect to diversity, and specification of minimum action in the absence of such requirements or guidance.
- **Scope to take further steps to support DEI** in recruitment, through proactive setting of targets in priority areas, and through supporting longer-term capacity strengthening.
- **Second ethics checkpoint to consider and review plans for community engagement**
- **Cross-reference to** the use of a program and/or indication-specific **Diversity Action Plan.**
- **Final ethics checkpoint to prompt users** to reassess commitments, track progress, and ensure accountability.

* Please note that, apart from the car and finish line, **all Ethics icons in the roadmap are [clickable]** and enable navigation between the image and the corresponding sections. Icons within the sections also allow you to return to the roadmap.


Ethics Icon(s)


Regulatory Environment


Scope for Further Steps


Diversity Action Plan

Representation in Research

Global Representation

Starting Point →

At strategic level, determine nature of organizational commitment to increasing DEI in other countries, beyond any regulatory requirements. Populations in other countries must not be exploited to meet US-specific diversity requirements.

By therapeutic area, define epidemiology/patient need across all the countries where you intend to work, identifying scope for variation 1) by biology (e.g., age/sex) and 2) by environment/ context (e.g., social determinants of health).

At all points, keep in view synergies and tensions with:

1. Organizational Business Commitments
2. DEI Data Collection Purposes
3. Country/Site Clinical Research Capacity

Document early considerations in advance of developing program or indication-specific DAPs.

Scope for Further Steps →

In line with organizational commitment to increasing DEI in other countries:

Work with relevant authorities in one or more partner countries to understand their DEI priorities, identify currently disadvantaged populations and set goals (e.g., by sex/gender or income) to increase participation.

Work with in-country partners to strengthen clinical research capacity to address systemic barriers to diverse participation.

Diversity Action Plan (DAP) →

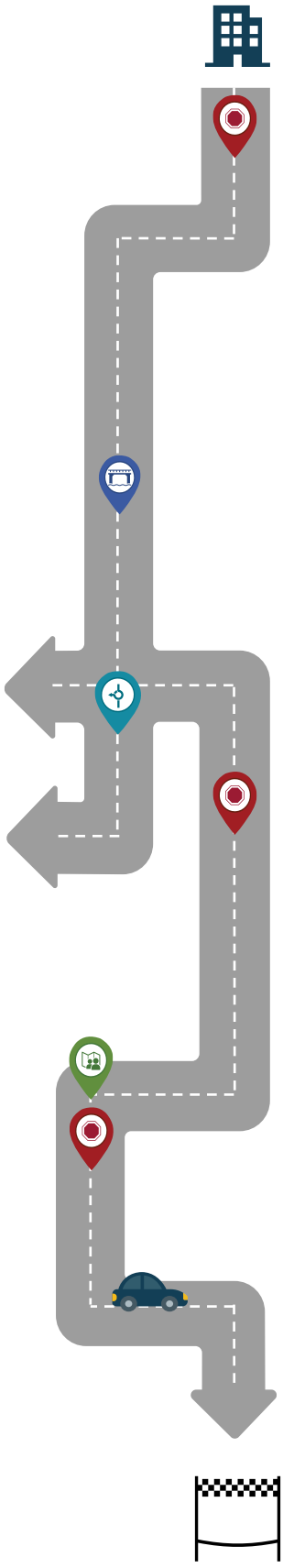
Use the program or indication-specific DAP to capture global DEI actions as well as FDA-mandated elements.

Identify [therapeutic area] diversity profiles for each country where planning trials.

(If applicable) Set initial priorities/ targets for more diverse trial representation in relevant countries.

Be explicit about how data relating to diversity in different countries are to be used: for tracking recruitment or for subgroup analysis.

Ensure that each DAP is clear about how you will address context-specific barriers.



Ethics Checkpoint 1 - Do No Harm →

Why are you considering selecting these countries/sites for this study? Clarify which criteria are being used by your organization to guide overall country and site selection.

What value will the study process and findings bring to local communities?

What is the post-trial access drug plan, and planned timeframe for local communities to access/afford the marketed product?

Will the work be sustainable given country capacity and organizational business priorities?

Regulatory Environment →

Follow any regulatory requirements or guidance in relevant country on DEI in clinical trial recruitment.

In absence of regulatory requirements, require sites to assess general DEI barriers and develop solutions (e.g., translations, reimbursements). Cover reasonable associated costs.

Ethics Checkpoint 2 - Meaningful Engagement →

How are local communities (including disadvantaged subgroups) in the country actively participating in shaping the organization's DEI planning and study design?

What measures are the organization implementing to address the expressed priorities of local communities.

Ethics Checkpoint 3 – Accountability →

What actions have you taken to broaden consideration for under-represented populations across the research lifecycle (e.g., eligibility criteria exclusions only for safety reasons; setting country-specific targets in more countries; use of post-marketing approaches)?

What actions have you taken to address barriers identified by participants, caregivers, communities, and countries (e.g., reimbursements; reduced or decentralized study visits; translation; local ambassadors)?

Can you consider further steps, as outlined above?

Do you have systems to track DEI progress, collect feedback, and assess if any harm was done?

Stage 1A: Starting Point – Strategy:

Ensure that the organizational Diversity, Equity, and Inclusion Policy explicitly addresses the global nature of the organization and sets out the broad nature of the commitment to DEI in the countries where you work, beyond any regulatory requirements of each jurisdiction. As an ethical threshold, this should make clear that countries outside the US must not be exploited in order to meet US-initiated requirements for diverse representation that reflects US epidemiology.

Some organizations may decide that, in the absence of specific regulatory requirements, it is not feasible for them to set proactive targets to reach specific underserved groups in other countries, as they would do for research within the US. Their organizational global DEI aims may instead be to work with local partners to reduce barriers to research participation without setting numerical targets.

Others may wish to be more proactive in setting targets to promote research participation within a country that is better aligned with the epidemiology of the relevant condition in that country. Initially, however, it may be challenging to set specific targets in every country where you work. It may be more feasible to begin with the organizational aim of taking more proactively inclusive and diverse approaches to recruitment in one partner country, in a limited number of countries, or in one therapeutic area (see examples below under ***Further Steps***). This may expand over time to additional countries or therapeutic areas, due to experience, response to regulatory change, or new guidance within partner countries.

Stage 1B: Starting Point – Epidemiology:

By therapeutic area, define the epidemiology/patient need across all the countries where you intend to work, identifying the scope for variation by biology (e.g., age, sex, common comorbidities) and by environment/context. This helps ensure the relevance and applicability of research across diverse populations. Understanding epidemiology identifies target populations and assesses disease prevalence globally. Being alert to the relevance of biological factors such as age, sex at birth, and common co-morbidities helps optimize intervention efficacy and safety for diverse patients. Accounting for environmental context enhances adaptability and the development of broadly applicable interventions.

Stage 1C: Aligning Policies and Capacity:

Having clarified strategy and defined epidemiology, consider how decisions about how to address DEI in different countries will be shaped by business commitments, data collection purposes, and site capacity, and the scope for synergies or tensions between all these.

Stage 1Ci: Organizational Business Commitments:

Conduct a landscaping of your organization's overarching Diversity, Equity, and Inclusion (DEI) commitments, alongside your organization's defined business commitments. Assess the alignment between these two types of commitments, to outline priorities and scope for global DEI planning. Issues to consider include:

- What are your aims, beyond meeting regulatory requirements?
- Whom are you aiming to benefit through your DEI policies?
- Is your business commitment to obtain regulatory approval from the US FDA? Do you expect to sell the product outside of the USA? Is your aim to get a product to market as quickly as possible? Do these business purposes conflict with DEI goals?
- Is leadership and all areas, offices, and departments fully on board with plans to promote DEI initiatives in other countries?

Stage 1Cii: DEI Data Collection Purposes

In considering the use of data and, in particular, the scope to aggregate data categories across countries in meaningful ways, be explicit about the purposes for which data relating to diversity are being collected because this will affect what you collect and how you collect it. Distinguish between the use of demographic data for subgroup analysis (i.e., for scientific reasons), and the use of demographic or socio-economic data to track more inclusive recruitment practices (i.e., for social justice reasons).

- Where data are being collected for the purposes of subgroup analysis (for example, with respect to sex at birth or age), they should be categorized and collected in ways that can be aggregated for analysis across sites and countries (recognizing any country-specific restrictions or requirements).
- Where data are being collected to map recruitment practices for particular sites or countries and help identify where barriers to recruitment may exist, it will be necessary for the categories used to be locally meaningful. In some cases, this may mean that data between sites and countries cannot readily be aggregated (for example where locally significant cultural or ethnic distinctions would be lost in aggregation).

Stage 1Ciii: Country/Site Clinical Research Capacity

The capacity to conduct high-quality research, both at the country and site level, is an important and often limiting factor in the location of clinical trials and in the ability to recruit diverse participants. Before committing to working in a particular country, sponsors need to have confidence in the adequacy of regulatory and ethical support, along with assurances as to logistical feasibility. Site selection within a particular country (including in certain locations within high-income countries) is similarly influenced by capacity concerns relating to factors such as the nature of the healthcare infrastructure, the clinical and clinical research workforce, laboratory capacity, and clinical record systems. There is a strong link between deprivation, lack of access to healthcare, and exclusion from research – and hence between the diversity of research participation and capacity strengthening of both health and research systems.

The MRCT Center's Diversity, Inclusion, and Equity in Clinical Research Toolkit includes a number of tools to support the inclusion of DEI considerations in site selection, including a feasibility decision tree, a feasibility questionnaire modification checklist, a site selection logic model, and site selection Key Performance Indicators (KPIs). The Society for Clinical Research Sites also offers a Diversity Site Assessment Tool to support individual sites in strengthening their ability to recruit diverse participants.

Site selection can further play an important role in intentional approaches to reaching new participants from underserved groups, for example by seeking to reach those unlikely to access major hospital sites or academic centers. Such an approach may

require a long-term commitment within a partner country. As part of such commitments, consider how you might work in partnership with local stakeholders to support the sustainable strengthening of capacity in research systems and infrastructure to support more diverse participation in research. A more detailed capacity-strengthening tool is forthcoming.

Stage 1D: Ethics Checkpoint 1 – Do No Harm

The Ethics Checkpoints serve as important backstops, prompting consideration of how the overriding requirement to 'Do No Harm' aligns with the organizational landscaping and initial GDEI planning, robust data collection practices, and selection of clinical research sites in various countries.

Ethics Checkpoint 1: Do No Harm

1Di. Why are you considering selecting these countries/sites for this study? Clarify which criteria are being used by your organization to guide overall country and site selection.

1Dii. What value will the study process and findings bring to local communities?

1Diii. What is the post-trial access drug plan, and the planned timeframe for when local communities can access/afford marketed products, including through country-specific pricing plans?

1Div. Will the work be sustainable given country capacity and organizational business priorities?

There is a strong ethical case for promoting diverse, equitable, and inclusive approaches to participation in clinical trials. If research does not account for the needs and experiences of diverse populations (whether defined by geography or by other characteristics), then the

outcomes of research are less likely to be widely generalizable, relevant to people's needs, or feasible to deliver in different circumstances.

However, it is essential to recognize that greater inclusivity and diversity in clinical trial recruitment may also be a source of ethical concern, particularly in low-resource settings. The recognition that exclusion from research can be discriminatory (reducing opportunity for future benefit) must also be accompanied by an awareness of how, on the contrary, convenience recruitment for some kinds of studies may lead to the over-representation of economically disadvantaged participants despite the uncertainty of their ever being able to benefit from the findings. Research participation should be neither exploitative nor reserved for the privileged: the aim must be to offer a fair opportunity to participate, matched with a fair opportunity to benefit.

When planning and designing a study, and making choices about study sites, close attention must be paid from the very beginning to how any risks of exploitation may be minimized. Issues that are likely to be raised when protocols emphasizing diverse and inclusive recruitment criteria are submitted to research ethics committees (and which hence need thinking about from the start of the project) include:

- Concerns about **safety**, particularly in connection with groups traditionally classed as physically or socially vulnerable such as pregnant women, people living with multiple health conditions, or those unable to give consent for themselves; and
- Questions of **social justice**, for example asking why a particular study is taking place in this country and location; who is likely to benefit from study findings; and the likelihood of study participants themselves, and the wider communities from which they come, being able to access and afford effective interventions in the future. While these questions are of central importance in any study being conducted in low-resource settings, they become particularly acute when explicitly seeking to target groups who are currently under-represented in clinical research and/or who have inadequate access to healthcare.

Stage 2A: Assess the regulatory environment and tackle barriers

Once the groundwork is laid by assessing organizational DEI commitments, data collection purposes, and country site capacity and making initial GDEI plans, it is essential to further develop these plans by focusing on the regulatory environment in each country with respect to diversity, equity and inclusion. In the absence of specific regulatory requirements or national guidance on DEI, consider what action could be taken to remove general barriers to participation.

Stage 2A: Regulatory Environment	
2Ai. Follow any **regulatory requirements or guidance on** DEI in the relevant country in clinical trial recruitment.	2Aii. In absence of regulatory requirements, require sites to assess general DEI barriers and test solutions. Cover reasonable associated costs.

At present, only a limited number of jurisdictions actively require diversity in clinical trial recruitment, e.g.:

- Research conducted in the US must, by law, take account of diversity in recruitment practices. Under the Food and Drug Omnibus Reform Act 2022 (FDORA), clinical trial sponsors seeking US marketing approval for their products will soon be required to submit "diversity action plans" for many clinical trials, including phase 3 studies of new drugs and studies of interventional devices. The FDA is required to issue guidance within a year on the format and content of such plans "pertaining to the sponsor's goals for clinical study enrollment, disaggregated by age group, sex, race, geographic location, socioeconomic status, and ethnicity." Sponsors will not only be required to set out their enrollment goals in a format to be specified by the FDA but also to explain their rationale for selecting them and their plans for achieving them.

- Research conducted within the European Union must meet the requirements set out in the European Union Clinical Trials Regulation 536/2014, which came into force on 31 January 2022. One of the criteria to be assessed in authorising a trial is "the relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated". More specifically, the protocol must at least include "a justification for the gender and age allocation of subjects and, if a specific gender or age group is excluded from or under-represented in the clinical trials, an explanation of the reasons and justification."

Example 1: Company A has trial sites in over thirty countries. It takes the view that it is for individual countries, not for an international company, to set policy regarding more diverse and equitable inclusion in trials. It monitors partner countries closely to ensure that it is aware of policy changes. In the absence of such requirements, Company A sets its strategic policy to require all partner sites to work with local communities to identify and reduce barriers to participation. Although the details of such engagement and subsequent action are entrusted to the site level, Company A has an organizational commitment to covering the costs of ongoing community engagement, and of meeting reasonable additional costs associated with removing barriers, including funding transportation costs, interpreter services, and post-trial access to investigational medicines.

Stage 2B: Assess Scope for Further Steps

In addition to meeting regulatory requirements and taking general steps to remove barriers, there may be scope for further proactive steps to support more diverse, equitable and inclusive participation in studies that include non-US sites, in line with the organization's strategic commitment to GDEI. This could include setting specific targets to increase participation by particular under-represented populations in one or more countries. It could also include supporting longer-term capacity strengthening in one or more partner countries in order to help achieve more diverse representation in the future.

Stage 2B: Assess Scope	
2Bi. Work with relevant authorities in one or more partner countries to identify underserved populations and set goals (e.g., by sex/gender or income level) to increase participation.	2Bii. Work with in-country partners to support targeted capacity strengthening to help address system systemic barriers to diverse recruitment over the longer term.

Example 2: Multi-national Company B has longstanding affiliations with a number of clinical research sites in Country C, a lower middle-income country with an established research infrastructure. Women, however, are not well represented within the research workforce in Country C and are significantly under-represented as participants in trials. Working with Country C partners, Company B sets as its strategic global DEI priority working with their sites in Country C to understand and address the barriers that prevent women taking part in trials, with the aim of achieving 50% representation of women within 5 years. A component of the strategic plan is to build capacity by recruiting and training women to enter the research workforce. Progress on this policy, and the increase in representation of women in the workforce and as participants in clinical trials, will be reviewed annually, with a view to exploring whether it is possible to extend lessons learned to other partner countries in the region.

Example 3: Company D has a wide portfolio of drug development, working with sites across multiple countries. It is aware that its cancer trials in low- and middle-income countries are only able to recruit relatively affluent patients – poorer patients are simply unable to access care, or only access services when their cancer is very advanced. Company D identifies cancer studies as a strategic global DEI priority, with a particular focus on socio-economic factors that hinder participation in research. It also recognizes that providing long-term support for sustainable research capacity strengthening will be necessary in order to achieve progress on this priority.

Stage 2C: Ethics Checkpoint 2 - Meaningful Engagement

As GDEI plans are further developed, with efforts to identify underserved populations and/or reduce barriers to clinical trial participation, it is essential to stop and reflect whether these steps have been taken with meaningful community engagement. Meaningful engagement with the communities where research is to take place is crucial: when identifying the most appropriate ways of meeting any national regulatory requirements for DEI; in seeking to remove barriers to participation; and in undertaking any further proactive steps to achieve broader participation.

Ethics Checkpoint 2: Meaningful Engagement

2Ci. In what ways are local communities (including underserved subgroups) in the country actively participating in shaping the organization's DEI initiatives and study design?

2Cii. What specific measures is the organization implementing to address the expressed needs and priorities of local communities during the study and DEI planning process?

The research team's engagement with local communities, across all aspects of the study aims, design and conduct, is always important. However, it takes on particular prominence when seeking to reach and recruit people or groups within the population who are marginalized or underserved. The development of respectful relationships between the research team and local communities that help shape the study, ensure it is relevant to local health needs, and provide transparency with respect to safety measures, will provide research ethics committees with important assurances that potentially vulnerable participants will not be exploited. The MRCT Center has developed a suite of resources to support effective and respectful engagement with participants and communities. Particular care will need to be taken to ensure that people who are disadvantaged within existing social structures have opportunity to have their voices heard. This may involve reaching out to local advocacy groups as well as national and local authorities.

Stage 3A: Diversity Action Plan

A Diversity Action Plan (DAP) is a strategic framework aimed at advancing diversity, equity, and inclusion within clinical trials, at the level of the specific study, program, or indication. DAPs must include specific elements mandated by the FDA for submission for US marketing approval but can also be used from early in the research lifecycle to document all relevant DEI considerations, including prompts relevant for promoting DEI in all countries where a study is taking place. The DAP encourages sponsors to consider a broad range of demographic factors, including race/ethnicity, sex, gender identity, age, socioeconomic status, disability, pregnancy, lactation, and co-morbidity.

Considering the stages above, the DAP serves as a tool to explicitly outline the purpose of data collection in each study—whether for scientific analysis or recruitment tracking. It offers a dedicated space to delve into site capacity considerations, aligning with the principles outlined in ethics checkpoints 1 (country site selection do no harm) and 2 (meaningful engagement).

Diversity Action Plan (DAP):

- Use the program or study-specific DAP to capture global DEI actions as well as FDA-mandated elements.
- Identify [therapeutic area] diversity profiles for each country where planning trials.
- (If applicable – see Further Steps above) Set initial priorities/targets for more diverse trial representation in those countries.
- Be explicit about how data relating to diversity in different countries are to be used, distinguishing between the use of demographic data to track more inclusive recruitment practices, and the use of demographic data for subgroup analysis.
- Ensure that each DAP is explicit about how you will address context-specific barriers.

Developing specific DAPs tailored for regulatory considerations becomes imperative to transform regulatory requirements into actionable strategies. While regulations establish a foundational framework, a customized DAP adapts these requirements.

Stage 3B: Ethics Checkpoint 3: Accountability

In the final stages of DAP planning, it's important to bring thinking back to accountability, ensuring that the plan aligns with the organization's goals and regulatory expectations. This involves a comprehensive review to verify if any adjustments are necessary based on feedback or changing circumstances. When practicable, a sponsor may also consider additional post marketing studies to fulfill diversity goals.[4]

Ethics Checkpoint 3: Accountability

3Bi. What actions have you taken to broaden consideration for under-represented populations across the research lifecycle? (e.g., eligibility criteria exclusions only for safety reasons; setting country-specific targets in more countries; use of post-marketing approaches?)

3Bii. What actions have you taken to address barriers identified by participants, caregivers, communities, and countries? (e.g., reimbursement arrangements; reduced or decentralized study visits/labs, translation and interpretation; information sessions; local champions/ambassadors).

3Biii. Can you consider further steps, as outlined above?

3Biv. Do you have systems to track DEI progress, collect feedback, and assess if any harm was done?

4 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-approaches-obtain-data-populations-underrepresented-clinical-trials-drugs-and

Ensuring concern for diversity is context-sensitive: Different aspects of diversity are of greater or lesser relevance in different contexts and countries, and this will affect choices regarding what aspects to prioritize in any given site. In low-income settings (including within wealthy countries), poverty and associated lack of access to healthcare present particularly high barriers to participation in research. In some countries, it remains very difficult for women to access research or take up roles within the research sector. In others, the prevalence of particular conditions may reinforce the importance of considering the impact of co-morbidities. Reaching out to under-represented sexual orientation or gender identity groups may be particularly challenging where national laws criminalize or actively discriminate against them.

Barriers: In addition to providing assurances that plans to recruit diverse participants are ethically justifiable, research teams will also need to identify and reduce barriers to participation. These may be practical barriers: e.g., the costs involved in taking time away from work, the distance to be travelled, the physical accessibility of the site, or lack of access to necessary technology. There may also be psychological barriers: e.g., lack of knowledge of what research is, or an inaccurate assumption by a person that they would not be a suitable participant.

Compensation: Ethical concerns about risks of 'undue inducement' to participate can sometimes lead to inadequate reimbursement of the actual costs of participation, creating unnecessary and unjustified barriers to diverse enrollment. Guidance issued by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) makes clear that: "Research participants should be reasonably reimbursed for costs directly incurred during the research, such as travel costs, and compensated reasonably for their inconvenience and time spent. Compensation can be monetary or non-monetary. The latter might include free health services unrelated to the research, medical insurance, educational materials, or other benefits." In May 2021, the MRCT Center hosted a webinar on Inducement or Fair Compensation to highlight the importance of ensuring that concerns about undue inducement do not, in practice, create injustice to participants and barriers to more diverse participation.