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# Strategy for addressing equity of access to trials of and treatment with ATMPs

In line with Delivery of Advanced Therapy Clinical Trials at Scale across the UK: Milestone 69 Develop strategy to address patient equity of access to ATMP trials:
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## Aim

To explore and address issues of equitable access to clinical trials of advanced therapies (ATMPs) across the UK. This would be achieved through collaborative engagement with the public, industry partners and healthcare infrastructure bodies (encompassing both private and public stakeholders), providing recommendations for future clinical trials research and subsequent health technology adoption.

## Introduction

Equitable participation in clinical research is central to ensuring that the benefits of scientific and therapeutic innovation are distributed fairly across populations and is essential to ensure robust safety and effectiveness data linked to real-world outcomes. A lack of diversity in clinical trial populations fundamentally risks achievement of the goals of clinical research, spanning several dimensions; lack of generalisability from specified clinical trial populations to the broader condition-affected/ disease population of approved therapies, societal costs related to healthcare disparities across different demographics, fundamental failure to adequately recruit to trials leading to research waste and reinforcing medical mistrust (Bibbins-Domingo & Helman 2022). Additionally, we know that ancestral and ethnic differences in the general population can have a significant bearing on reactions to medicinal therapies in terms of efficacy and toxicity, thus inclusion of a diverse population will ensure that any related issues are discovered prior to the point of post-market surveillance.

Inequitable access at the point where novel therapies undergo investigation and evaluation is likely to persist through to the implementation stage (commission of an approved therapy and its adoption into clinical care). This risks the ingraining and amplifying of known, current health inequalities. The existence of inconsistencies in access to healthcare for particular UK demographics is well recognised, for example, the presence of ethnic disparities, and in response, the reduction of health inequalities forms a core strategic initiative of the NHS 10

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year plan. Thus, it is vital to tackle equitable access at the research level to mitigate the introduction of additional systemic barriers to receiving timely, effective healthcare, particularly where the standard of care is being changed through the adoption of new therapies, with particular reference to ATMPs.

In recent years, concerns have grown in the United Kingdom regarding the underrepresentation of certain groups—particularly ethnic minorities, older adults, children and those from socioeconomically deprived communities—in clinical trials (Hussain-Gambles et al., 2004; Treweek et al., 2020). It is important to note that these groups are not an exhaustive list and that the term under-served communities encompasses those who may be unconsciously excluded due to existing systemic and societal barriers, including but not limited to those with; neurodiversity, disability, impaired capacity to consent and in LGBTQ+ groupings. Addressing these disparities has become an explicit goal of the UK's research infrastructure, reflecting broader commitments to diversity and inclusion, including considerations of intersectionality, in healthcare innovation.

Within the field of advanced therapies, it has been widely recognised that given the complexities of manufacture, delivery and small patient numbers, at least initially, the issues surrounding equity of access to research opportunities and subsequently commissioned therapies is likely to be enhanced. Specifically, a report published by Genetic Alliance UK in 2023 illustrated the lack of concrete information available within the literature on equitable access to ATMP clinical trials in the UK and highlighted current gaps in data and knowledge in this area.

This strategy, in conjunction with the Genetic Alliance UK report, explores current knowledge on inequalities in ATMP clinical trials in the UK, combined with strategic recommendations for targeted action on equity. This document focusses on adult populations, but many of the recommendations made will be broadly applicable to paediatric populations and we further acknowledge that paediatric populations may require additional focused strategic objectives. A key element to successful implementation will be to identify and collaborate with existing third sector, clinical and industry networks working in this space to ensure relevance and that efforts are not duplicated.

## Underpinning Rationale

The broad identity of clinical trial participants in the UK does not reflect the demographic diversity of the population as shown across numerous studies. The NIHR (National Institute for Health and care Research) has reported persistent underrepresentation of ethnic minority groups and individuals from lower socioeconomic backgrounds across all clinical studies (NIHR, 2021). Similarly, women, older adults, and those with multiple comorbidities are less likely to be included in early-phase and precision medicine trials (Clark et al., 2019).

Limited diversity within clinical trial cohorts risks entrenching existing health inequalities, with the lack of broad representation having implications for both scientific validity and health equity. For instance, pharmacogenomic responses may vary by ancestry, meaning that new therapies could be less effective or carry different risk profiles for underrepresented communities (Agyemang et al., 2021). Whilst pharmacogenomic limitations are less likely to have significant impact for ATMPs, this example serves to highlight that restriction of clinical evaluations to homogenous populations not only risks strengthening inequalities that already exist but also risks adoption of expensive therapies that may not provide benefit across the intended population.

The lack of inclusivity and diversity in clinical trials of all therapies has become a widely recognised issue, with multiple bodies such as NIHR, Association of the British Pharmaceutical Industry (ABPI), Association of Medical Research Charities (AMRC) and additional academic consortia such as Trial Forge, seeking to understand the innate nature of current inequalities and providing recommendations on how to address these for the clinical trial landscape.

**What ATMP trials are taking part in the UK and who is taking part?**

From 2017- 2025, a total of 348 ATMP trials have commenced within the UK. The vast majority of these trials are targeted at oncological disorders (38%) and delivered across approximately 115 clinical sites spanning 24 cities/ towns locations across the UK. The limited geographic spread of these clinical sites is highlighted in figure 1, which illustrates where in the UK sites are located alongside the relative number of trials at each location. A little over half (54%) of the towns shown here supported 5 or fewer ATMP trials. The areas supporting a higher number of ATMP trials tend to be major conurbations in England, Wales and Scotland and it is worth noting the dearth of ATMP trials in regions of the South West of England, Northern Scotland and the whole of Northern Ireland. The areas supporting the largest number of ATMP trials are Manchester and London.

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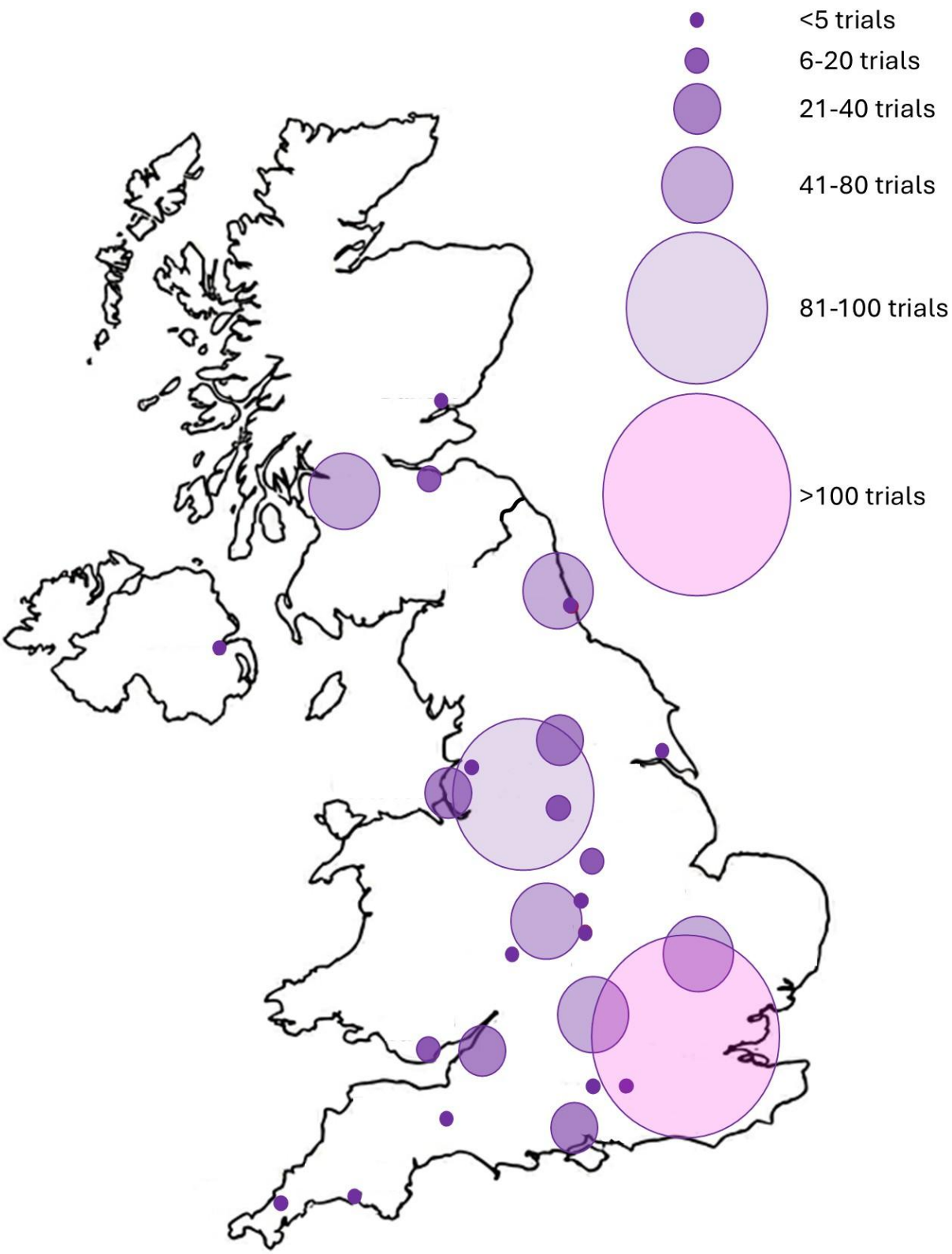
*Figure 1. Location of ATMP trials in the UK from 2017-2025*

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However, there is little easily accessible and readily available data that illustrates how many people have been recruited to these trials and, more importantly, there is little demographic information about those being recruited into ATMP trials and where they come from. Whilst data protection and privacy risks are increased in many ATMP trials where participants are identified from inherently rare populations, this is not true for all research involving ATMPs. Guidance from the international journal *Trials* features a recent editorial which sets out the journal's approach to making the concept of inclusive and diverse research at the forefront of investigators goals by mandating the inclusion of cohort demographic data or plans for the collection thereof in all trial reports and protocol publications (Treweek et al 2025).

To illustrate the issues of inclusivity and diversity and how that data is published, case study data from within Midland and Wales ATTC was collated. For one clinical site within the region, the available demographic and geographic information on participants recruited to ATMP trials was compiled and can be seen in Table 1. This data outlines the readily available and accessible data for three exemplar trials of gene therapy; namely age, sex and ethnicity. It was not possible to obtain information on socioeconomic or educational status. However, there was sufficient information to determine the distances the participants needed to travel from their homes for recruitment and follow-up assessment and for treatment (where these may be two different sites). From this data it can clearly be seen that participants are predominantly male and White British. While the demographics of the affected populations being studied in these trials may be skewed by sex and ancestry, the bias is still starkly evident. Further, the age data is commensurate with the particular populations being studied in these trials. However, it is also clear that participants are required to travel significant distances for both treatment and follow-up. Given that many ATMP therapy trials are still early phase, where multiple long-term visits are required for safety purposes, it is easy to see how this is burdensome on participants.

Whilst specific data on socioeconomic and educational status were unavailable for these trials, those involved in the recruitment and follow-up provided personal communications that these participants tend towards greater affluence with high level of education, reflective of the known recruited populations in other trials in this disease area. This is stated with the caveat that this is open to personal interpretation and unconscious bias, but exemplifies the ongoing problem around accessibility to diverse populations and the lack of systematic demographic data collection.

Although this is a very small snapshot of current ATMP clinical trial activity within the UK, it serves to illustrate the scale of the equity of access issues discussed in this strategy.

*Table 1. Representative demographic information on 3 gene therapies conducted within MW-ATTC region.*

| | | Distance of participant from recruitment site (miles) | Distance of participant from treatment site (miles) | Age (years) | Sex (% Male) | Ethnicity |
|---|---|---|---|---|---|---|
| **Trial 1** | **Mean** | 87.31 | 118.15 | 56.50 | 90 | 100% White British |
| | **Median** | 97.00 | 130.00 | 54.50 | | |
| **Trial 2** | **Mean** | 193.83 | 207.97 | 65.33 | 100 | 100% White British |
| | **Median** | 144.70 | 177.50 | 67.00 | | |
| **Trial 3** | **Mean** | 27.33 | 105.80 | 49.25 | 75 | 100% White British |
| | **Median** | 21.95 | 107.65 | 51.00 | | |

## Are ATMP trials different to clinical trials of small molecules or other non-pharmacological health interventions?

To date, most literature and evidence surrounding the issues of equity of access to clinical trials focusses on investigations of traditional small molecule/ chemical compounds (Investigational Medicinal Products) or non-pharmacological healthcare interventions, including medical devices. The only specific analysis of real-world data relating to equity of access to ATMP clinical trials that appears in the literature to date appears to be restricted to assessment of geographical access by continent, which does not provide more granular demographic analysis (Cornetta *et al.* 2018). However, given the known complexities of ATMP delivery and the requirements for co-location of trial sites with specialist centres with adequate infrastructure and technical and professional expertise, it is commonly accepted wisdom that the currently acknowledged equity issues facing traditional clinical trials will be amplified in the ATMP sphere.

## What do we know about current barriers?

- **Structural and Institutional**
  Clinical trial recruitment often relies on secondary or tertiary care sites situated in major teaching hospitals, disproportionately accessible to those in urban or affluent populations (Gill et al., 2022). Limited engagement between research units and community health services reduces the likelihood that rural or socio-economically disadvantaged patients are invited to participate (Redwood et al., 2020). This is compounded in the ATMP sphere where delivery is limited to selected specialist centres, often located significant distances from a patient's home base.

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- **Socio-cultural and Linguistic Barriers**
  Language barriers, mistrust stemming from historical exploitation in research, and lack of culturally appropriate materials combine to influence the willingness of individuals to participate among ethnic minority communities (Hussain-Gambles et al., 2004; Redwood et al., 2011). This also holds true in rare disease communities (Mitchell and Butterworth 2025). Research design seldom includes co-production or community consultation processes that address these issues directly. Additionally, even when community inclusion is sought from the outset, the range of patient voices incorporated is often limited because the recruitment structures for public engagement mirror the same constraints and biases seen in research recruitment practices (Butt *et al.* 2025).

  ATMP research frequently includes complicated biological concepts that underpin both the therapeutic mechanism being studied and the potential risks that therapy may pose to the individual. These concepts are often beyond those covered in standard secondary education and thus remain outside the sphere of understanding for the general public. It therefore follows that information provided to participants and patients can prove impenetrable. A person unable to understand what is being asked of them, and the consequences of those activities, is less likely to engage with that research or therapy. Unlike traditional therapies, ATMPs constitute delivery of a cell, gene or tissue engineered product, often as a one-off therapy that once inside the body may not be able to be removed or switched off. Thus, the long-term implications of participating in trials of experimental ATMPs has further reaching consequences in terms of risk/benefit profiles than traditional pharmaceutical clinical trials might involve. When viewed in combination with the largely more complicated underpinning mechanisms of action of ATMPs, participants approached to take part in these trials have a large amount of complex information to understand and assimilate to make an informed, risk-based judgement on their potential involvement. It is vital that people approached to participate are supported to make informed decisions, with all the available information provided to them in clear and accessible formats. Here the goal should be engaging in shared decision-making processes, particularly where multiple options may be available to any given individual.

  The issues outlined above are further compounded by gate-keeping of information and the public's ability to source high quality, trusted information. With the advent of artificial intelligence (AI) in the activity of search engines, the possibility for members of the public finding erroneous information is high (Hoeyer K et al. 2024). High quality, accurate information, such as that contained in the peer-reviewed literature, can be subject to paywalls or remain inaccessible through complicated language use. Further, there is a risk with the increased use of AI-mediated patient focused platforms (Lamb 2025), that members of the public, already untrusting of the medical profession, may substitute expert opinion and

guidance for AI based programs to aid their decision making and disease monitoring. This has the potential to compound issues of inequity rather than resolving them.

- **Economic and Logistical Barriers**
  It is well documented that logistical and economic constraints such as transportation costs, time off work, and caregiving responsibilities also reduce clinical trial participation among individuals, particularly those on lower incomes. Again, these disparities become more acute when considering the delivery of ATMP trials is largely restricted to a small number of specialist centres.

  Despite recommendations for the use of specific initiatives featuring reimbursement for such costs, the mechanisms for implementing these are inconsistent (Treweek et al., 2018), poorly managed both temporally and administratively, or are poorly publicised to the people they meant to aid.

  Further, evidence suggests socioeconomic gradients play a role in the engagement of patients with medical specialists (Cookson et al., 2016), favouring those who are in more socio-economically advantaged strata, with more affluent populations engaging more with medical specialisms. As specialist care is the predominant route for participant identification and approach for potential participation in ATMP trials, it follows that socio-economically deprived individuals will be included less in research. There is further concern that this will follow through into uptake of any licensed and commissioned therapies. For instance, the uptake of new cancer immunotherapies at NHS organisations is often correlated with local infrastructure and research engagement, meaning patients in under-resourced regions may face delays or exclusions.

  Lastly, in an age where the concept of decentralised trials is becoming increasingly popular with trial sponsors and patient populations alike, additional barriers that decentralisation may bring should be acknowledged. Whilst decentralisation may improve demographic reach in terms of who is able to take part through reduced requirements for travel and in person attendance, this does risk excluding those in digital or data poverty, so cannot be viewed as the only solution for achieving greater inclusivity and diversity It is essential that solutions aimed at improving inclusion do not risk marginalising other sectors of the population.

## Strategic Recommendations

- **Data**

  Fundamentally, to be able to understand how to address equity of access to ATMP clinical trials, it is important to know who is currently taking part in these trials and the demographics of historic trial cohorts. The depth and breadth of demographic data being collected and how, if at all, this is being shared for transparent assessment of equitable recruitment should be assessed. However, it should be explicitly acknowledged that there may be significant limitations as to what demographic data is currently collected. For example
  - as many ATMP trials are international in nature, the type of ethnicity data collected may be restricted to Clinical Data Interchange Standards Consortium (CDISC) recommended categories, which may be more skewed to North American populations and not include the type of granularity often seen in European census type demographic data. Further, for some specific ATMP trials, the therapies being investigated are for disorders which affect specific and distinct demographic populations (Sickle Cell for example which in the UK primarily affects people of Black African or Caribbean heritage)) or where the disease population itself lacks diversity within any given geographic location; for example, the best data available for Huntington's disease (HD), a rare neurodegenerative disease, demonstrates that for populations located in North America, demographic breakdown by ethnicity is predominantly Caucasian with 89.5% of the population identifying as white (Mendizabal *et al.* 2024). However, what is unclear, is whether non-white populations affected by HD are proportionally represented in clinical trials.

  The recommendations outlined below are not for the purpose of mandating diversity quotas in clinical trial protocols, but serve, in the first instance, to understand the breadth and depth of the issue of equitable access as it currently stands. Without knowing who is currently taking part in ATMP clinical trials, it is not possible to implement strategies to ensure that access to those trials is equitable across all demographics. These recommendations include:

  1. Explore the possibility of determining demographics (through scraping of currently available and accessible data) of ATMP clinical trial population in the UK to date to get an accurate picture of the scale of the problem of equity of access to ATMP trials. This recommendation is made with the acknowledgement that there are potential unknown limitations in the access to data to perform this analysis.
  2. Explore viability of systematic collection of demographic data in future ATMP trials, both investigator-led and commercially sponsored, acknowledging potential issues of data privacy, particularly for rare conditions. This would potentially include the need for input from NIHR and UK Health Research authority (HRA).

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- **Information**
  The provision and dissemination of accessible and high-quality information is key to engaging target populations in trial participation. This includes both information about ATMPs that the general public can access freely, and the targeted patient information required for recruitment. Accessible information should be available to the general public for those wanting to know more about ATMPs should they be offered the opportunity to take part in an ATMP clinical trial. Further, the information directly disseminated to those officially approached for inclusion in ATMP trials must be easily digestible and contain information relevant to the trial and relevant to the participant, within current regulatory frameworks.
  To produce information with the correct content and presented in the right way, it is advisable to work with both patient groups and the broader public to generate meaningful and relevant documentation.

  Recommendations for this include;

  1. Engage with a broad cross section of under-served communities to determine information needs regarding understanding ATMPs and best modes for disseminating that information.
  2. Identify trusted sources of reliable information on ATMP trials and how this is communicated or made accessible to target populations
  3. Explore the viability and practicality of an accessible registry for ATMP trials
  4. Assess current data sources in terms of digital equity and AI readiness
  5. Explore specific engagement with industry around the development of trial focused patient information and the barriers to simplification

- **Targeted Patient Engagement**
  The inclusion of those with lived experience is now increasingly recognised as a key tool in the development and delivery of clinical trials (Crocker *et al* 2018), that should be fully integrated at the earliest stages of clinical trial development and design, and right through the research lifecycle. It is important to recognise that high quality patient involvement results in a co-production style relationship as opposed to a consultative one and that approaches used for this are tailored to the communities being worked with. The voices of patient and members of the public are vital for identifying potential barriers to recruitment, retention and trial delivery. Additionally, the involvement of the lived experience from the very earliest stages promotes the inclusion of meaningful Patient Reported Outcomes (PROMS), which are gaining enhanced prominence in terms of importance for regulatory assessment. In particular, for communities where ATMPs offer previously unrealised benefits, but where medical mistrust remains high, such as Sickle Cell disease, engagement activities need to focus on regaining that trust.

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Success in these areas should be viewed as dependent and continuous high-quality input from public representatives. Whilst the focus of this strategy seeks to engage members from under-served communities, it is important not to forget issues of intersectionality, where individual's ability to participate either in research or as people with lived experience, are often compounded by falling under more than one of the groupings who would be typically viewed as under-served and unconsciously excluded from research.

In consideration of the above, the following recommendations are suggested;

1. Engagement of diverse, condition agnostic, public and patient representatives to drive inclusive design of clinical trials, alongside the inclusion of those with specific lived experience. All engagement activities should be remunerated according to the NIHR public involvement standards, who have recently increased the minimum honorarium payment for PPI representatives.
2. Engage with specific patient populations and under-represented communities to explore specific barriers to engagement with ATMP trials. This should incorporate attention to those who may have intersectional lived experience and include understanding attitudes to the collection of demographic data.
3. Develop guidance for engaging with under-served communities though determining successful and current best practice, using published examples (Gafari et al 2024).
4. Aligning with strategic initiatives for raising awareness of ATMPs across the UK population, develop a plan for continuous community engagement with the aim of fostering trust in under-served and under-represented communities across the UK
5. Engage with specific disease communities to approach the concept of shared decision-making and the requirements for this from both community and healthcare provider perspectives.

- **Industry Engagement**

Currently, the majority of ATMP trials taking place in the UK are commercially sponsored. Although commercial trials adhere to the same regulatory frameworks as investigator-led trials, trials methods can differ. For many industry sponsors, time and budget are critical factors in determining where and how they choose to deliver their trials, with less emphasis put on the need for inclusive and diverse trial populations. To stimulate meaningful change in this area, it is essential that any recommendations are made in consultation with industry and their business needs. Further, it is of paramount importance that any incentives designed as an outcome from these strategic recommendations need to be aligned across all sectors in order to drive change at all levels in the UK ATMP trials ecosystem.

The proposed strategic recommendations to align with industry include:

1. Link with the Cell and Gene Therapy Catapult's Industry Advisory Group PPIE subgroup to
   i. Understand how commercial sponsors currently undertake PPIE for ATMP trials to be delivered in the UK
   ii. Discuss ways of standardising best practice in industry sponsored trials with reference to patient engagement, participant reimbursement etc.
   iii. Understand feasibility of demographic data collection and transparency from the industry perspective. The MHRA and HRA have recently completed a pilot of requesting and implementing Equity, Diversity and Inclusion plans within clinical trial applications, where results are shortly anticipated. However, there is currently no regulatory mandate for collection of demographic information or the public sharing of that data.

- **Trial Design**

The concept of clinical trial design extends beyond the fundamentals of the chosen analytical framework and sample size. Many of the aspects that go into trial design, such as participant identification, recruitment and retention strategies and informed consent processes, are not evidence based. Current practice largely follows anecdotal experience, not data grounded evidence. 'Studies within a Trial' (SWAT) methodology is something that can be used to generate evidence on what works best in terms of trial delivery (recruitment, retention and data collection). The early integration of the lived experience is key here and is especially relevant in the context of rare diseases and early phase/ proof of concept trials where, traditionally, recruitment may be more challenging. It is essential that issues of equitable access are considered as a fundamental part of the trial design process to ensure that strategies for addressing equity are fully integrated into trial processes.

To ensure that equity of access is considered from the inception of a clinical trial and is seamlessly incorporated into trial design the following recommendations are proposed:

1. Develop ATMP-specific equality action plan in line with STEP-UP (https://step-up-clinical-trials.co.uk/), NIHR and recent combined HRA/ MHRA initiative around submission of equity plans alongside regulatory submissions in an effort to reduce inequalities in research.
2. Promote use of methodological research such as Studies Within A Trial to gather evidence for strategies and initiatives to promote inclusion of underserved populations.
3. Investigate successful mechanisms for participant reimbursement/ expense coverage to understand what works best for the majority.
4. Investigate publicly available inclusion/ exclusion criteria of ATMP trials in the UK to assess for implicit bias in cohort definition.

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