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Conversations with Underserved Communities to Address Health Inequality in Clinical Trials

A Call to ACT: Insights to Support Health Equality and Diversity in UK Clinical Trials.

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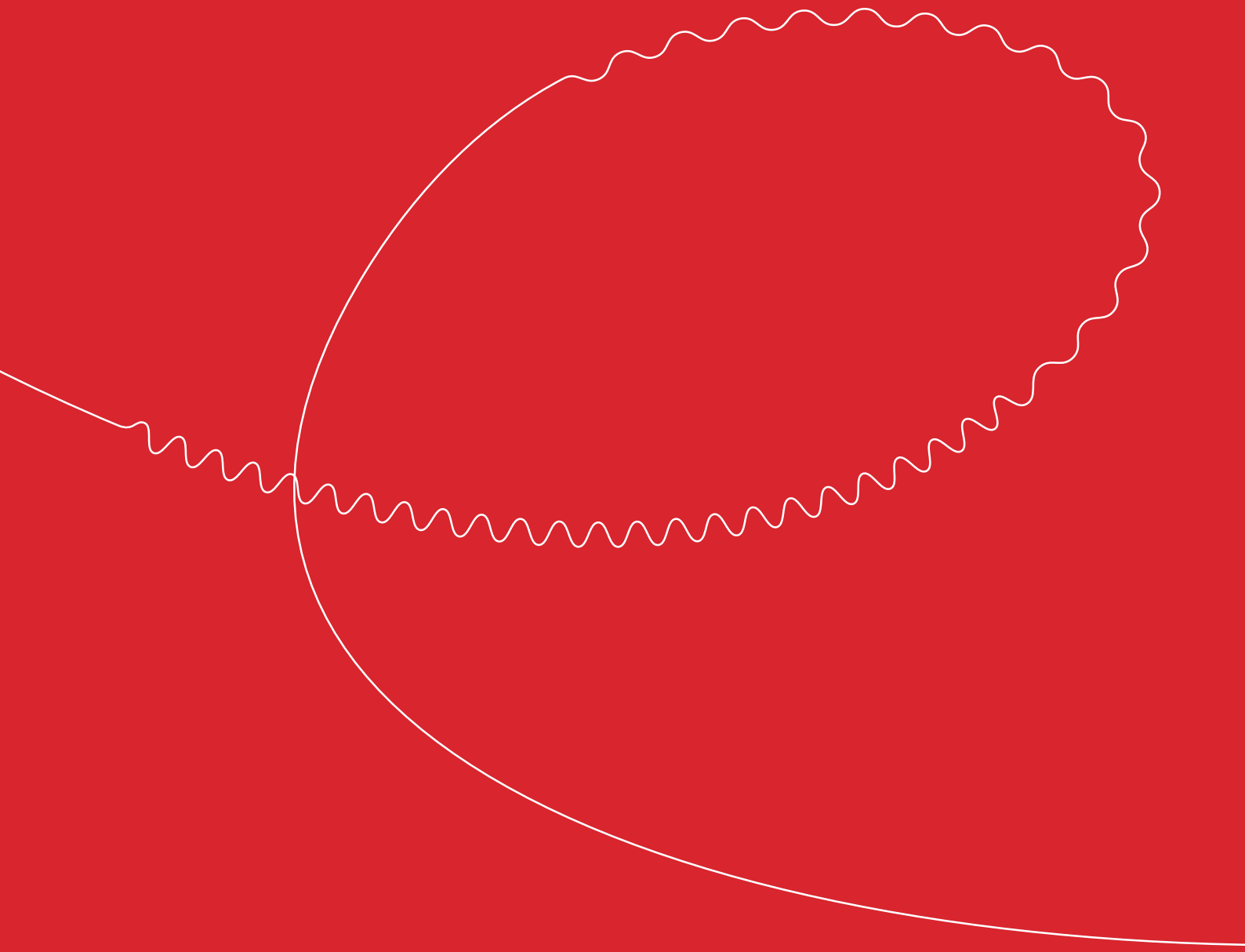

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Foreword

Moderna's Commitment to Advance Health Equity Through Inclusive Clinical Research

Across today's world, diversity and inclusion are values that are central to Governments, institutions and individuals. Whilst modern day societies continue to make progress on diversity and inclusion, we should not forget the role that our health and care systems play in ensuring everyone, no matter who they are, can prosper. The reality is that medical conditions don't discriminate. Medical diseases and conditions may affect all people differently, but they can still affect anyone.

The task of making sure everyone can live full and healthy lives begins with clinical research. When we conduct clinical research, we aim to understand the influence of biology, environment and lifestyle in the treatment response. This can differ amongst different populations. Therefore, we need to know that a new medicine or a vaccine has an acceptable safety and efficacy profile in the population it aims to treat.

Whilst this objective is one that the clinical research community aspires to, it is one that has not been easily achieved traditionally. A 2023 study of 407 UK clinical trials from 2016 – 2021 found that less than 10% of UK clinical trials were able to demonstrate how they recorded and reported the impact of their trial on different ethnic minority groups.[1]

At Moderna we understand the ethical responsibility and scientific imperative that we must ensure our clinical trials include people of all backgrounds and across numerous geographies. Our commitment to increasing diversity and representation in clinical trials is central to who we are as a company and our desire to ensure people of all backgrounds have access to the promising medicines of tomorrow. For us, representation is not merely a 'nice to have', but a fundamental part of our mission to deliver the greatest possible impact to people through mRNA medicines.

Moderna's 10-year strategic partnership with the UK Government that was signed in December 2022 provides us with a unique opportunity to deliver transformational change. As part of the strategic partnership, the Moderna Innovation and Technology Centre (MITC) will bring an innovative new vaccine research and manufacturing centre to the UK, that will be home to our pioneering mRNA technology.

Moderna is committed to tackling health inequalities in our clinical trials and to ensuring that our future treatments benefit those who need them the most. We are thinking deeply about how we can establish ourselves as an 'anchor institution' that is dedicated to reducing health inequalities across the UK. This involves not only acknowledging the barriers that underserved communities face in accessing research, but actively working to dismantle them.

Our approach is collaborative. We aim to bring together all partners involved in our clinical trials – from the Government and the NHS to researchers and representatives of the communities we aim to serve. Through active dialogue and collaboration, we can co-develop effective strategies to improve awareness of, and extend access to clinical trials.

This paper builds on Moderna's experience of reaching underserved communities through its clinical trials in the US and is a product of conversations with a wide range of stakeholders across the UK in 2023.[ii] We have listened carefully to experts and community champions alike. The feedback and insights we have gathered provide the foundation for developing a long-term action plan to improve representation in clinical research. Inclusion in clinical trials today ensures that innovative treatments address health inequalities tomorrow. We look forward to working with all partners old and new to overcome these barriers, and we invite you to join us in this vital mission.

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Introduction

This paper has been developed by Moderna and is non-promotional. It reflects Moderna's understanding of feedback provided through a written call for evidence on barriers and levers to support diversity and representation in clinical trials, as well as a meeting programme with UK community groups and research units between June and October 2023.

Conversations with Community Leaders

Improving representation in clinical research requires us to listen to the voices of those who represent the historically underrepresented communities we aim to serve. It also involves supporting, and empowering community leaders, including GPs, to educate their communities about the importance of scientific research and local clinical trial opportunities. In this paper, we present the barriers to clinical research access that community leaders have identified and present our understanding of their views on levers to tackle these barriers. Based on our findings, we are calling on partners to collaborate with us to ACT on improving diversity and representation in clinical trials by making sure research is Accessible, Convenient and Trusted.

Accessible

Improving Awareness of Clinical Trial Opportunities

The barrier:

The O'Shaughnessy Review into commercial clinical trials in the UK highlights the need to bring more clinical research into community healthcare settings like GP surgeries and pharmacies in the UK.[iii] Currently, only 10% of clinical trial activity in the UK takes place in primary care.[iv] Research has found that research centre based clinical trials will often be inaccessible to underserved communities and diverse populations[v] If information about the importance of scientific research and clinical trial participation is restricted to patients in hospital settings, it restricts the clinical trials opportunities available to people receiving care in care homes, community settings, at home, or in non-traditional settings.

The lever:

Involving health care professionals as a conduit to clinical trials, including in recruitment strategies and advertising, is crucial. Evidence from community organisations found that GPs and pharmacists were trusted voices in communities.[vi] With this in mind, and as recommended in the O'Shaughnessy Review, clinical trial sponsors should work with a range of health care professionals to raise awareness of clinical trial opportunities amongst underserved communities.[vii] Improving awareness also involves enhancing communication between different areas of the health care system to ensure that relevant clinical trial opportunities are locally advertised, and successful recruitment practices among underserved communities and diverse populations are shared.

Reflecting a Diverse and Multilingual Britain

The barrier:

Moderna also recognises that health literacy, including language, is a significant barrier to clinical trial access. We acknowledge that health literacy extends beyond merely understanding health information, it is about empowering individuals, regardless of their background or educational level, to make informed decisions about their health.

If a certain level of English is a requirement for taking part in a clinical trial, this immediately denies access to 1 million people in the UK.[viii] However, language barriers aren't only a challenge for those who don't speak English as a first language. They also affect those who struggle with understanding the complex health information often used in the clinical trial recruitment process.

The lever:

Past success with multilingual approaches to clinical trials demonstrate the value of providing access to bilingual staff, multi-lingual materials and interpreters in including underserved communities in clinical trials.[ix] With the increasing familiarity of video calls and other non-written methods of communication, clinical trial research teams should leverage nontraditional channels of communication.[x] Trials should also consider sign language, age-appropriate language and easy-to-understand options for clinical trial materials.

> ***"We want to build clinical trials with communities, not just for them."***

Convenient

Bringing Clinical Trials Closer to Home

The barrier:

Access to clinical trials isn't only about where opportunities are advertised, but also about the travel requirements and logistical barriers they impose on clinical trial participants. Clinical trials conducted in large research centres or in a single central location can be inaccessible to those with work and family commitments that prevent them from travelling long distances.[xi] A 2014 study found that 89% of the UK population can access a community pharmacy within a 20-minute walk and that access was higher in areas of greatest deprivation.[xii] Local healthcare services should therefore play a significant role in planning and conducting future clinical trials.

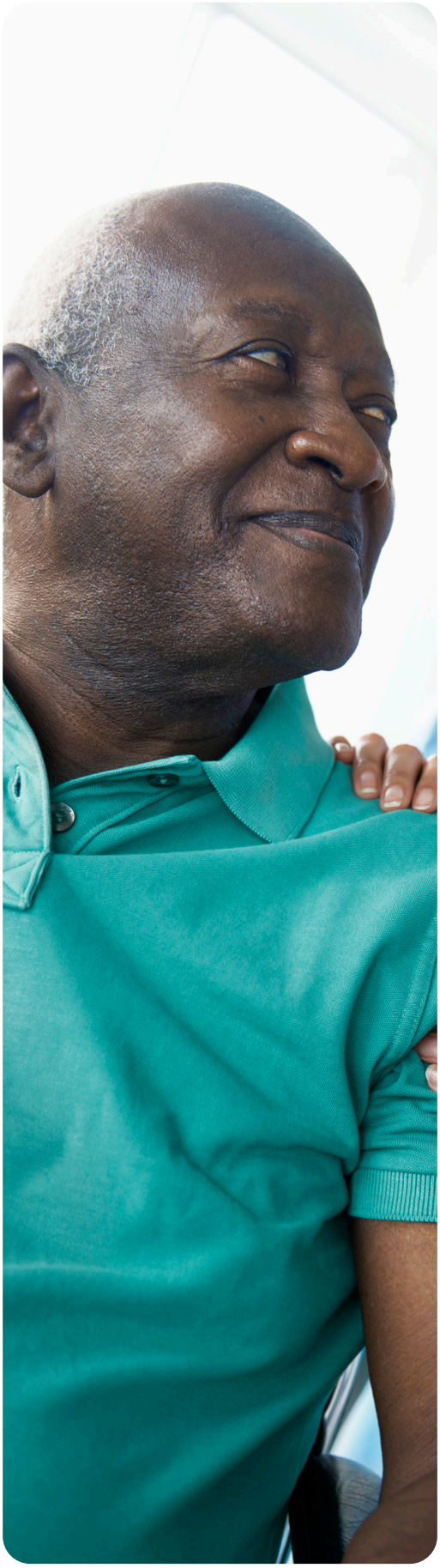
If clinical trial participation requires travelling long distances to large research centres, they will often exclude people who don't drive or don't have access to, or financial means to afford, suitable transport links. The accessibility and availability of parking at large research centres is also a potential barrier and should be considered before deciding the location of a clinical trial. Making clinical trials accessible to all, regardless of geographical location, should be a central consideration in how future clinical trials are designed and delivered.

The lever:

The convenience of clinical trials impacts how accessible they are to underserved communities. When setting up a clinical trial, clinical trial teams should consider whether a clinical trial is accessible for those who live in remote locations, have irregular work patterns or additional family commitments.

> ***Together, we can build a future where clinical trials are accessible to all.***

Clinical trial teams should also consider whether they could conduct clinical trials in care homes or other care services which support individuals with physical disabilities. For older adults and for those with physical disabilities, clinical trial participation will often depend on the support of a carer or family member. Clinical trial teams should consider how they can reduce the burden of clinical trial participation on carers and family members, including reducing travel time and accommodating existing work and family commitments.



Trusted

Building Trust in Clinical Trials

The barrier:

A common finding in existing research on clinical trials is mistrust of new treatments and clinical trials among diverse populations and underserved communities.[xiii] This often stems from fear that a new treatment could be harmful to their health.[xiv] Studies have also shown that hesitation in clinical trial participation also often derives from questions about how participation in a clinical trial relates to religious beliefs.[xv] Several community organisations and groups identified a lack of understanding about clinical trials, and misinformation as key barriers to participation.[xvi] People often rely on informal networks, such as family, friends, community and faith leaders and trusted health professionals for information. It is vital that these informal networks are involved in discussions about the value of scientific research and potential clinical trial opportunities.

> ***"Inclusion in clinical trials today ensures that innovative treatments address health inequalities tomorrow."***

The lever:

Firstly, in order to improve participation, it's essential that information about clinical trials is visible and comes from trusted sources, for example community pharmacists or community leaders. Transparency about the purpose of research and the opportunities they present is critical in overcoming barriers to participation. Researchers need to be transparent about the purpose of their research, making sure participants feel valued and safe. Organisers should work with service providers to ensure inclusive and diverse delivery of care more widely. Those running clinical trials should highlight their commitment to involving all individuals, evidencing previous and current relationships with and involvement of diverse populations and underserved groups.

Secondly, the inclusion of underserved groups in clinical trial research should also extend to those undertaking the research. Having Principal Investigators (PIs) leading clinical trials who are representative of diverse populations and underserved groups is crucial in encouraging trust in research participation. Ensuring that future generations of trial scientists in the UK are representative of our diverse population is vital to embedding principles of inclusion into the design and delivery of clinical trials.

Improving Relationships with Diverse Communities and Underserved Groups

The barrier:

One community group stated a concern that members of their community would avoid a clinical trial if they had a limited sense of how their participation would impact clinical trial design or future health outcomes for their community.[xvii] In light of these experiences, trust in clinical trials should be viewed as a social determinant of people's health outcomes and should be a fundamental consideration in future clinical trials design in the UK.

The lever:

People from diverse backgrounds and underserved communities should feel confident in how clinical trials may benefit them and their communities. They should be included as a valued thought partner in trial design and involved in how its results are shared. Research shows that partnerships with community groups improve the inclusion of diverse populations and underserved communities.[xviii] This approach should be central to clinical trial design and planning.

Clinical trial teams including PIs should also engage the broader patient and public involvement infrastructure of the NHS with the goal of increasing participation of diverse populations and underrepresented groups in clinical trials. These networks will often have longstanding relationships with community groups and will be involved in relevant campaigns around disease awareness and health literacy. Situating clinical trial opportunities within these broader conversations is key to engendering confidence in clinical trial participation, and to ensuring that clinical trials leave a long-term positive legacy within a particular community.

It is also important that diverse communities and underserved groups are informed of the results and impact of their clinical trial participation, including on the future use of innovative treatments. Clinical trial participants should also understand how their feedback and experience of a clinical trial will impact future clinical trial design and access for their community.

Mobilising our Learnings

Moderna's Five Point ACTion Plan

Moderna will **continue to learn from community groups** across the four nations of the UK to gain further understanding of how our clinical trials might reach everyone who could benefit from a new treatment. We want to build clinical trials *with* communities, not just for them.

Moderna will **continue to consider our ability to reach diverse participants** in decisions surrounding where to host our clinical trials in the UK and will incorporate data on historic recruitment amongst diverse populations and underserved communities into our decisions about clinical trial site locations.

Moderna will continue to strive towards clinical trials that are **Accessible, Convenient and Trusted** for and by diverse populations and underserved communities. This includes:

a. Championing accessible and health literate clinical trial materials through translation, the use of social media and targeted community engagements

b. Involving Healthcare professionals in our clinical trial recruitment and design

We will **work with key stakeholders across** the NHS and NIHR to map out what action they might take in making clinical trials more accessible to diverse populations and underserved communities. This will include concrete recommendations that local leaders can take to promote awareness of, and access to clinical trials in their local communities.

We are **committed to demonstrating our active engagement with diverse groups and underserved communities.** To this end, we will publish case studies detailing how their invaluable feedback has been incorporated into our clinical trial design. Additionally, we will provide clear outlines of how we are putting this feedback into action, and how we're forging lasting partnerships with these communities. Our aim is to make our UK clinical trials accessible and convenient for people of all backgrounds across the UK.

Your Support

We are encouraged by the desire of diverse groups and underserved communities to learn more about the opportunities afforded by clinical trials. We also recognise that this is a collective effort. Moderna's ongoing work will require partnership, collaboration, and action from a range of voices to ensure that clinical trial opportunities reach the communities currently underserved by clinical trials.

We appreciate the scale of this challenge. So, we will be action driven, starting by looking at the small steps we can all take to improve representation. We invite community groups, faith leaders, researchers, GP's, elected representatives, and the Government to join us in this mission. Whether you wish to start a conversation with your friends and family about clinical trials, or asking your GP about where you can find more information about clinical trial opportunities, no action is too small to matter. Together, we can build a future where clinical trials are accessible to all.

These conversations are a crucial starting point in ensuring that clinical trials are accessible to all and play a central role in tackling health inequalities in the future.

More Information

If you would like to hear more about Moderna's work to reach diverse populations and underserved communities through its clinical trials, or if would like to share the work you are doing to improve access to clinical trials, please email **Tony.Kerr@modernatx.com** and **Stuart.Carroll@modernatx.com.**

Appendix

A Call to ACT on Diversity in Clinical Trials

The O'Shaugnessy Review outlines how clinical trials give people early access to innovative treatments that could extend, improve, or save their lives.[xix] Clinical trials are how we prove that a new drug or medicine is effective in treating a disease.[xx] With this in mind, clinical trial participants in the UK should reflect the diversity of NHS patients who have a particular disease. Certain diseases are more prevalent in certain populations. Therefore, the clinical trials process for the relevant medicine should reflect the disease population. Inclusion in clinical trials today ensures that innovative treatments address health inequalities tomorrow.

Methodology and Disclaimer

This insights paper has been developed following a programme of engagement with community groups, research units and experts in health equality across the NHS between June and October 2023. This included individual meetings, the collation of responses to a call for evidence and a community roundtable which was hosted by Sir Stephen Timms MP in East Ham, London. The feedback received from this engagement programme has been supported by a review of relevant research on diversity and representation in clinical trials and relevant documents to the UK clinical trial landscape.

This insights paper collates feedback received from the following organisations and should not be taken as Moderna's own views:

- Caribbean African Health Network
- Hindu Council UK
- Centre for Ethnic Health Research
- LGBT Foundation
- Centre for Research Equity
- Trial Forge

Who is Currently 'Underserved' by Clinical Trials in the UK?

"Underserved communities" is a term identified by the NIHR INCLUDE project that captures the current inequalities in clinical trials in the UK. The INCLUDE project highlights several characteristics that could define underserved groups in clinical trials such as:[xxi]

- Lower inclusion in research than one would expect from population estimates.
- High healthcare burden that is not matched by the volume of research designed for the group.
- Important differences in how a group responds to or engages with healthcare interventions compared to other groups, with research neglecting to address these factors.

No list could exhaust every underserved group in every clinical trial in every disease area. However, there are several groups that the NIHR currently identifies as being generally underserved by the research landscape in the UK.:[xxii]

- Age extremes (e.g. under 18 and over 75)
- Women of childbearing age
- Different ethnic minority groups
- Male/female sex (depending on trial context)
- LGBTQ+/ sexual orientation
- Educational disadvantage
- People who are socio-economically disadvantaged, unemployed or on a low income

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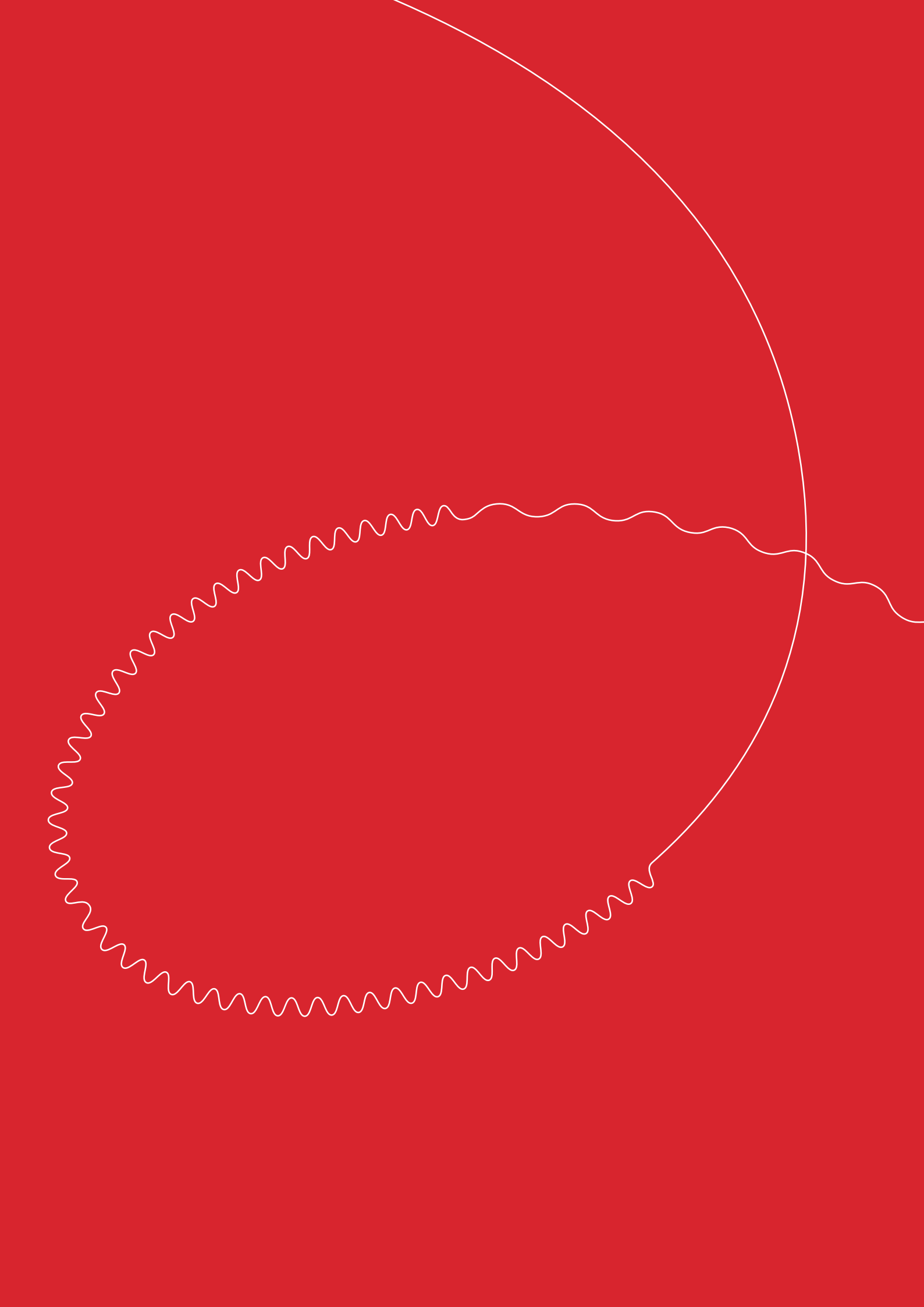

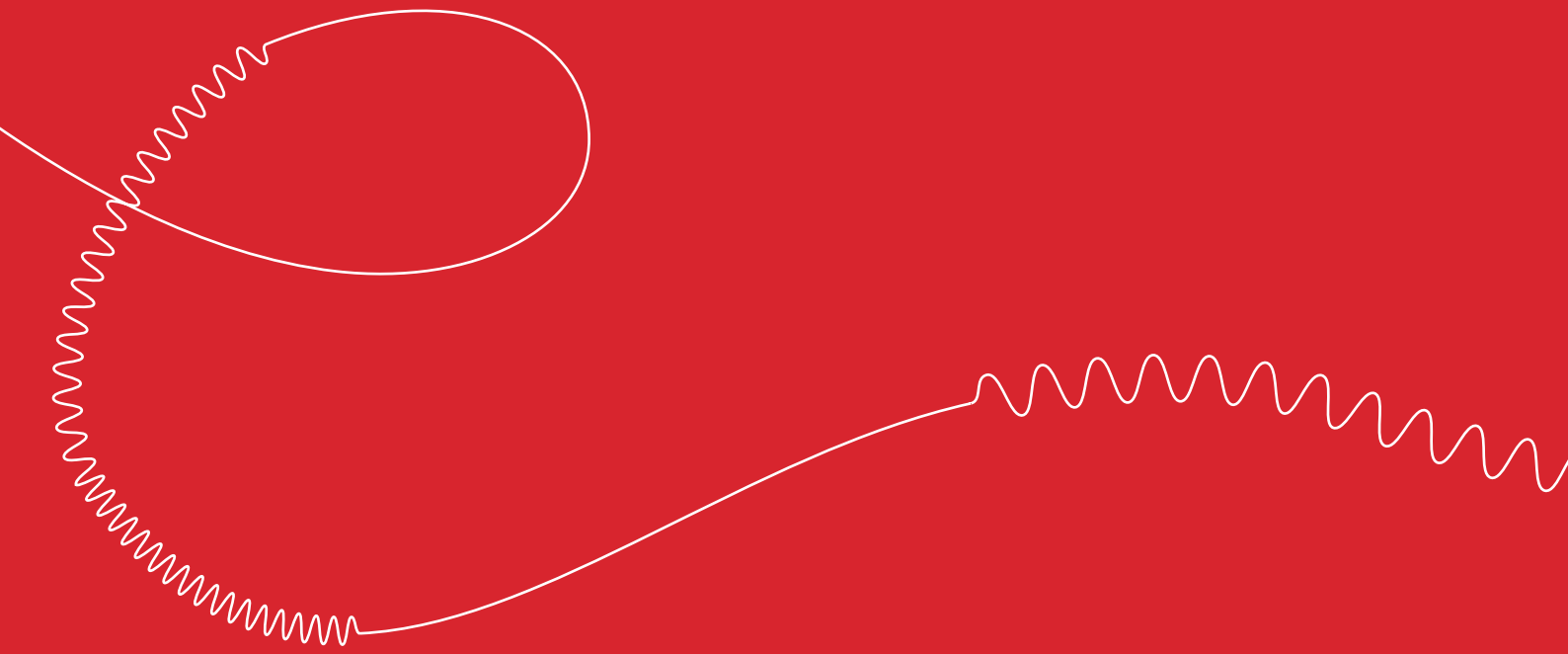

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