LifeArc ARDT PPIE Strategy

1. Introduction

This document provides the strategic framework for Patient and Public Involvement and Engagement (PPIE) within the LifeArc Centre for Acceleration of Rare Disease Trials (ARDT). It describes how ARDT will work in partnership with people living with rare diseases (PLWRD), families, carers, and communities to shape priorities, improve trial design and delivery, and maximise impact.

The strategy is aligned to national best practice for public involvement and inclusive research. It is intended to be used alongside ARDT's operational documents, including Terms of Reference, standard operating procedures (SOPs) for meetings, reimbursement policy, and work package PPIE plans.

2. Background

Funded by LifeArc, the ARDT is a UK-wide collaboration between Newcastle University, Queen's University Belfast, and the University of Birmingham. ARDT addresses challenges in rare disease trials (such as small and dispersed patient populations, complex disease mechanisms and barriers to participation) by:

- Developing an integrated trial platform including a recruitment portal
- Strengthening and speeding up the delivery of trials
- Supporting the adoption of new treatments in the NHS.

Strategic partnerships with clinicians, academic researchers, policy makers, regulators, patient groups, patients and their families ensure trials are efficiently designed, patient-centred, and positioned for success.

3. How this strategy was developed

This strategy was co-developed with our Lived Experience Advisory Panel (LEAP) members, programme staff and work package leads. It integrates ARDT commitments and aligns with national guidance (UK Standards and NIHR Shared Commitments).
The strategy will be reviewed at least annually with LEAP members and updated in response to evaluation findings and contributor feedback.

4. Definitions

This strategy includes both involvement and engagement. Key definitions:

Involvement: Research being carried out 'with' or 'by' members of the public rather than merely 'to', 'about' or 'for' them. It is an active partnership between patients, carers and members of the public with researchers that influences and shapes research, and can accelerate and improve its impact.

Engagement: Two-way sharing and discussing research with the public, involving interaction and listening.

Underserved: groups of people who are not included in research as much as you would expect given their size in the population. They often have significant health needs, but there is not enough research focused on them. They may also respond to or engage with healthcare in different ways, but these differences are not properly studied or considered.

LEAP: Lived Experience Advisory Panel. A group that is an integral part of the ARDT project, comprising those with a rare disease themselves and the parents, carers, partners or other family members of a person with a rare disease.

PLWRD (People living with rare diseases): is generally treated as an inclusive term for the patient and their immediate support network (family/carers)

YPAG**:** Young Persons Advisory Group, children and young people (and families) affected by rare conditions.

PPIE Leads: ARDT staff from each of the three consortium partners who have responsibility for PPIE within the ARDT

5. Vision

In the ARDT programme, we want to embed meaningful, inclusive, and impactful PPIE across all aspects of the programme, ensuring that PLWRD are central to decision-making, trial design, delivery, and dissemination.

6. Values and principles

Our approach is grounded in co-production and the UK Standards for Public Involvement. We will:

- Share power and co-own decisions with PLWRD.
- Work together to build mutually respectful relationships.
- Be inclusive and accessible, removing practical, social and digital barriers.
- Support and learn through induction, training and mentoring public contributors (LEAP) and staff.
- Communicate clearly using plain language and timely feedback loops.
- Demonstrate and share impact using robust tracking

7. Strategic Objectives

- **Create and support a LEAP of PLWRD** and a YPAG with representatives from across the UK.

- **Embed PLWRD as co-designers and co-decision-makers across the ARDT governance and individual Work Packages**

- **Establish partnerships with community organisations** in order to reach underserved and marginalised people to support involvement, engagement and research participation opportunities in the ARDT.

- **Understand PLWRD expectations, ethical concerns, and trial participation experiences to inform all aspects of the ARDT work,** through structured sessions to gather people's views and experiences, making sure discussions help participants, LEAP colleagues and stakeholders understand key ideas such as different types of research, how research works from start to finish, and the different ways people can be involved (from giving feedback to working in partnership)

- **Embed the UK Standards for Public Involvement across all PPIE activity,** using the PIRIT tool to monitor and track involvement, and the GRIPP2 reporting framework to capture PPIE activities and outcomes. Work collaboratively with Genetic Alliance UK to evaluate and report on the impact of PPIE.

8. PPIE model and activities

(see Delivery plan in section 13 for timelines)

8.1 PPIE groups and representatives

- LEAP: 16 PLWRD (2 per WP) with representation across the UK nations, rare conditions and communities.
- YPAG: a UK-wide group for children and young people (and families) affected by rare conditions.
- Public Co-applicants: PLWRD and public members representing PLWRD charities and organisations.

8.2 Governance

There will be two elements of the governance of the ARDT and our PPIE activities:

1. Active LEAP and YPAG involvement on the ARDT Executive Board and Work package (WP) Management Groups to support the overall strategic direction and decision-making of the ARDT programme. We will ensure both groups will be embedded through defined roles, rotating representation options, and structured support. Terms of Reference and role descriptions will be maintained as controlled documents
2. Quarterly LEAP meetings and monthly PPIE Leads meetings to ensure effective processes and accountability of the PPIE activities within the ARDT programme. We will also work with the LifeArc PPIE Community of Practice to share learning.

8.3 PPIE integration across ARDT Work Packages

Each WP will include named LEAP member(s) and a PPIE plan aligned to this strategy. Typical activities in each WP will include:

- Attend and contribute to meetings and decision points.

- Preparing for public involvement activities, including meetings, events, and conferences, where required.
- Review and co-develop participant-facing materials.
- Co-design recruitment and retention approaches.
- Advise on outcome selection, feasibility, burden and acceptability.
- Interpret findings and co-author outputs where appropriate.
- Support the sharing of research findings through presentations and plain-language materials

LEAP activity within each of the Work Packages (WP)

See section 13 for full delivery plan

Work Package	Centre	Main objectives	PPIE activities	Measures of success
WP1 – Facilitating trial recruitment	Newcastle	Develop a recruitment platform and portal for rare disease trials Develop pre-screening approaches using existing data/registries.	• Co-design patient-facing interface and content • Advise on data/registry communications • User-test portal • Co-create recruitment materials and accessibility checks.	• Usability and accessibility metrics • Documented changes attributable to PPIE • Recruitment reach/diversity metrics.
WP2 – Inclusive Patient Reported Outcomes (PROs)	Birmingham	Develop guidance to support inclusive PRO use in rare disease trials.	• Attending work package (WP) meetings and sharing their views and feedback during discussions. • Contributing to and reviewing WP documents, including participant-facing materials, study findings, manuscripts, and reports. • Supporting the development of documents, such as interview topic guides. • Helping to shape the focus of systematic reviews undertaken within the WP. • Contributing to the co-authoring of manuscripts where appropriate. • Supporting the sharing of findings by participating in dissemination	• Guidance reflects lived experience • Documented changes attributable to PPIE • Co-authored outputs

			activities, including attending and presenting at relevant conferences and meetings.	
WP3 – Innovative trial design & delivery	Birmingham	Support design and delivery of rare disease trials.	• Support trial adoption decisions • Shape trial design, including recruitment, data collection and participant support • Co-develop participant materials • Co-develop dissemination materials	• Protocol/material changes attributable to PPIE • Trial participant experience and feedback.
WP4 – Accelerating trial delivery	Birmingham	Improve and speed up rare disease trial delivery Build a UK research delivery network. Support the development of a participant facilitator role in delivery sites	• Identify barriers/enablers to delivery • Co-design participant and carer support model • Advise on delivery network priorities. • Advise on barriers and facilitators to participation in clinical trials • Co-develop participant facilitator role	• Support model implemented and evaluated; network outputs; barrier reduction actions. • Implementation of participant facilitator role in selected NHS sites
WP5 – Regulatory and implementation	Belfast	Improve adoption of new treatments in the NHS and regulatory readiness.	• Co-design deliberative workshops/citizens' juries • Advise on barriers/enablers to NHS adoption and risk–benefit communication • Inform implementation pathways.	• Document evidence of influence on adoption/implementation planning • Workshop recommendations adopted

	Work Packages that span across ARDT			
Work Package	**Centre**	**Main objectives**	**PPIE activities**	**Measures of success**
WPA - PPIE	Newcastle	Support meaningful and effective PPIE across ARDT	• Involvement in PPIE activities across ARDT • Share updates and experience of involvement within LEAP meetings • Provide support, induction and training of LEAP and YPAG members Co-produce research projects exploring involvement of PLWRD in research	• Positive experiences of LEAP and YPAG members • Evaluation of ARDT PPIE activities (Genetic Alliance)
WPB – Equality, Diversity & Inclusion	Belfast	Embed EDI principles throughout ARDT, its research and activities	• Co-develop EDI strategy • Advise on research on barriers to participation and retention in rare disease trials • Support outreach and engagement events • LEAP members will play an active role in the Research culture and EDI committee	• Documented changes attributable to PPIE • Co-authorship of outputs • Attendance to outreach events
WPC – Capacity building	Belfast	Develop training and support development of ARDT researchers (and partners?)	• Co-develop PPIE and EDI training for researchers • With WPA, co-develop training for LEAP and YPAG members • LEAP members will play an active role in the Research culture and EDI committee	• Completion of training courses

9. Equality, diversity, inclusion and underserved communities

ARDT will improve inclusion by applying NIHR Research Inclusion guidance and partnering with community organisations to identify and remove barriers to involvement both in the work of the ARDT and in the trials that it supports.

Our commitments:

- Use transparent, fair recruitment processes for PPIE roles.
- Work with community and voluntary sector partners to reach underserved groups.
- Provide accessible and culturally appropriate materials, with translation and interpretation where needed.
- Offer hybrid and flexible involvement options and support digital inclusion.
- Collect equality monitoring data voluntarily and use it to improve representativeness.

10. Support, learning and reimbursement

ARDT will provide practical and developmental support for LEAP and YPAG members and ARDT staff to enable meaningful involvement.

- Induction for all new contributors.
- Annual training and learning needs assessment for LEAP and YPAG members.
- Co-designed training programme to enable meaningful involvement of LEAP and YPAG members in ARDT activities.
- Meeting support (pre-briefs/debriefs, plain language materials, jargon-busting).
- A dedicated named contact person in each of the three consortium partners.
- Peer support/mentoring routes.
- Reimbursement and recognition in line with ARDT policy (as outlined in the Letter of engagement)

11. Communications and engagement

ARDT will communicate clearly, using plain language and accessible formats, and ensure LEAP and YPAG members receive timely feedback on how their input influenced decisions.

We will provide:

- Accessible outputs (plain-language summaries; Easy Read where appropriate; audio/video; large print).
- Regular feedback loops to LEAP members and communities, including asking for feedback from people who choose to leave LEAP
- Two-way public engagement through events and partner channels.
- Clear routes for concerns/complaints, code of conduct and meeting SOPs.

How we will measure this:

- Contributor feedback on communications quality and timeliness.

- Accessibility audits of materials.
- Reach metrics for engagement in ARDT outputs and events (attendance, downloads, engagement).

12. Monitoring, evaluation and reporting

ARDT will evidence the quality and impact of our PPIE activities according to the UK Standards for Public Involvement using pragmatic tracking tools and recognised reporting standards (PIRIT and GRIPP2).

12.1 Tools

- PIRIT: plan and track PPIE activity and its influence on research.
- GRIPP2: report PPIE consistently in outputs and publications.

12.2 Success measures

We will assess the success of our PPIE activities through an evaluation conducted by Genetic Alliance. The evaluation will look at:

- Activity: number and type of PPIE activities per WP, recorded in PIRIT.
- Reach and inclusion: LEAP and YPAG diversity and evidence of inclusion actions.
- Quality: contributor experience surveys and qualitative feedback.
- Influence: documented changes to protocols, materials, recruitment, outcomes and implementation plans.
- Outcomes: indicators of improved feasibility, recruitment/retention and participant experience.

This table defines what success looks like for each UK Standard-aligned aim, how it will be measured, and how it will be monitored.

Strategic aim (UK Standard)	Success criteria (what good looks like)	Measured by (evidence/data)	Monitoring and accountability
Inclusive opportunities	Accessible opportunities; representation reflects the diversity of PLWRD; underserved groups reached; adjustments and hybrid options routinely offered.	Voluntary equality monitoring; contributor profile; accessibility audits; reach of partnerships and engagement; contributor/community feedback.	Quarterly review by PPIE Management Team; annual review with LEAP/YPAG; reported to Executive Board and Scientific Steering Group.
Working together	Clear roles and shared ways of working; contributors report meaningful influence; collaboration effective across WPs and partners.	Terms of Reference; role descriptions; meeting participation; contributor surveys/interviews; co-designed outputs and decisions logged.	Quarterly pulse checks; action log reviewed by WPA Team; escalations to Executive Board as needed.
Support and learning	All new contributors inducted; learning needs assessed annually; training offered; barriers to involvement reduced.	Induction completion; training needs assessments; training attendance and evaluation; confidence measures; support actions recorded.	Biannual update to Scientific Steering Group; annual summary to External Advisory Group; improvement owned by PPIE Lead.
Governance	Public contributors are equal members of relevant committees; public voice influences decisions; resourcing is realistic and transparent.	Committee memberships; minutes evidencing influence; resource/budget review; governance self-assessment.	Quarterly governance review with chairs; annual strategy review; accountability through Executive Board.
Communications	Plain language and accessible communications; timely feedback to contributors; inclusive two-way engagement with communities.	Communications plan delivery; accessible outputs produced; feedback loop logs; engagement metrics; satisfaction surveys.	Quarterly comms dashboard; annual review with Comms lead; report to Executive Board.
Impact	Clear evidence of changes to research due to PPIE; learning shared; GRIPP2 used; PIRIT used across WPs.	PIRIT records; impact case studies; GRIPP2 in outputs; dissemination metrics; indicators of improved feasibility/recruitment/experience.	Annual impact report; quarterly review by PPIE Team; shared with LEAP/YPAG and partners.

12.3 Reporting and accountability

Progress will be reported quarterly to the ARDT Executive Board and Scientific Steering Group, and annually to the External Advisory Group. Annual reporting will include activity and impact summaries, EDI monitoring, and case studies of change.

13. Delivery Plan

Workstream	Milestone	Timeline	Owner	Outputs	Evidence/ metric
WPA	LEAP/YPAG members recruited and appointed to committees and WPs; role descriptions agreed	MS1-MS4 2024-2028	WPA + Exec/WP Chairs	Appointments; induction packs	Attendance; feedback
WPB	EDI strategy published	MS1-MS2 2024-2026	WPB Lead + WPA Lead	Partner MOUs; outreach plan	Diversity; outreach reach
WPC (PPIE training)	Training needs assessment and programme launch	MS1-MS2 2024-2026	WPC Lead + WPA	Training modules; resources	Training evaluation; confidence
WP1	Recruitment portal co-design and user testing	MS2 – MS6 2026 – 2029	WP1 Lead + LEAP	Test reports; improved interface	Usability; changes log
WP2	PRO workshop and guidance co-produced	MS2-MS4 2026-2028	WP2 Lead + LEAP	Guidance; topic guides	Outputs; dissemination
WP3	Trial design support integrated into candidate trials	MS3 2025–2027	WP3 Lead + LEAP	Materials; protocol inputs	Changes to the protocol and participant facing documents
WP4	Participant support	MS 3 2026–2027	WP4 Lead	Support toolkit	Evaluation outcomes

	model piloted				
WP5	Deliberative workshops / citizens' juries delivered	MS3 -MS6 2026–2029	WP5 Lead + WPA	Recommendations; summaries	Influence evidence
Evaluation	PIRIT tracking live; annual GRIPP2 reporting	MS 2 2026; annual	PPIE Team/ Genetic Alliance	Dashboards; annual report	Impact case studies

14. Infrastructure and Resources

A dedicated team of ARDT staff with PPIE expertise from each of the three consortium partners will lead and support PPIE activities. Each consortium partner has responsibility for one or more of the WPs. As such, PPIE activities within a WP will be led, supported and funded by the relevant partner.

15. Collaborators and Partners

ARDT will collaborate with rare disease charities, community organisations, NHS partners, regulators and NIHR infrastructures to strengthen PPIE reach, quality and impact. Partnerships will support inclusive recruitment, co-produced communications, and dissemination activities.

16. Appendix

16.1 LEAP shared principles

16.2 ARDT LEAP Integration and Engagement plan

16.3 Letter of engagement

16.4 LEAP quarterly meeting Terms of Reference

16.5 SOP for meetings including LEAP members

16. 6 LifeArc ARDT PPIE contacts

Working Together: CLEAR Principles

C 

Confidentiality and Conflicts of Interest

We ask everyone to treat anything shared in meetings—whether personal stories or research details—as private. You might be asked to sign a short confidentiality form. If you have any relevant personal or professional links, please let us know using the LEAP interests form.

L 

Listening and taking part

Everyone's voice matters, and we want to make sure everyone feels heard and respected. This space is for sharing thoughts and ideas that help shape and improve the work we're doing together.

If there's something personal about your care that you'd like to talk about, we can help point you to the right place—but this group is focused on the project we're working on as a team. In online meetings, we encourage everyone to have cameras on and to join in by speaking when you can—but we understand that's not always possible. Just let us know what works best for you.

E 

Equality

We are strongly committed to the promotion of equality, diversity and inclusion for all. We all play a part in creating a space that's respectful, kind, and open to different perspectives. If anything ever feels uncomfortable or not in line with these values, please feel free to speak to someone on the team. We're here to support each other and make sure this is a positive space for everyone.

A 

Accessibility

We will provide you with the information that you need, so you are prepared for the activity. We want to make sure your accessibility needs are met. Ahead of the activity, if you have any access requirements please inform your PPIE contact person. We also collect accessibility information yearly through our accessibility form to help us plan and ensure ongoing support

R 

Respect

We want everyone to feel heard and valued in our meetings. That means giving each other space to speak, listening with care, and avoiding talking over one another. To help things run smoothly, it's helpful if everyone can take a bit of time to look over any materials shared in advance. We also encourage those leading the sessions to keep things on track and make sure everyone has a chance to join in.

LEAP Integration and Engagement Plan

Overview

The LEAP (Lived Experience Advisory Panel) will be engaged across the project through regular meetings, integration with Work Packages (WPs), and participation in additional activities. This plan outlines the proposed structure for LEAP engagement, aiming to ensure meaningful involvement while maintaining sustainability.

1. **LEAP Meetings**

- Frequency: Quarterly (3 online meetings per year, 1-2 hours each) plus 1 in-person meeting per year.
- Purpose: Provide feedback, share experiences, discuss training, and cover other standing agenda items.
- Chairing: Meetings to be chaired by Christine Collins (Work Package A Belfast centre lead) and Kerry Leeson Beevers (Chief Executive Alström Syndrome UK) initially. LEAP may appoint its own chair(s) in due course if preferred.
- LEAP members will be invited to contribute to agenda setting to support co-production.

Additional Support:

- One-to-one calls with Work Package A (WPA) members or allocated WP leads will be offered if LEAP members find them useful.

2. **Integration with Work Packages**

- LEAP members are being allocated to WPs based on preferences outlined in their forms and best fit.
- Each WP will have 2 LEAP members, attending (at least) quarterly WP meetings and contributing to project activities.
- A confidentiality agreement may be required where sensitive or confidential information is shared.

LEAP members will also be assigned to:

- Research Culture and EDI group (WPB/C)
- YPAG (Young People's Advisory Group) support (WPA)
- Executive Board
- Other committees/boards as developed

Engagement Expectations:

WP leads will engage with their LEAP members to agree on:

- Expectations from both sides
- Meeting preparation needs
- Other requirements to ensure full integration
- Specify time commitment expectations

Meeting Frequency:

- Minimum quarterly meetings, with the option for more frequent engagement if demand and capacity allow.
- Meetings should be arranged so that LEAP members can contribute meaningfully even if attending flexibly or on an ad-hoc basis, and attendance is not required at every session. Clear agendas shared in advance will support LEAP member choosing which meetings to priorities.
- A Meeting SOP will be prepared to ensure consistent LEAP involvement across all WPs.
- Post-activity feedback forms will be used to support continuous improvement.

Objective:

- To integrate LEAP members meaningfully without imposing excessive time commitments.
- To enable LEAP contributions beyond meeting attendance while remaining sustainable within budget.

3. Additional Work

For activities requiring input from a broader range of LEAP members, WPs will submit an interest form outlining:

- Scope of work
- Expectations
- Agreed timeline for input

These forms will be shared with the LEAP after review by WPA and discussed by email or at quarterly LEAP meetings wherever possible and practical.

4. Training and Capacity Building

- LEAP will be consulted on and offered training to support participation in project activities, coordinated by WPA.

- Opportunities may also be provided for LEAP members to train and present to WP members where appropriate.
- Some core training may be mandatory. Where training is optional, members can choose which sessions are most relevant to their role and interest. Choosing not to attend will not impact access to future training

5. Payments and Budget

- The centre leading an activity requiring LEAP members' time will process LEAP payments for that activity, including preparation or reviewing time online/at home.
- If a centre's PPIE budget is depleted, responsibility for future payments will be discussed and reallocated across centres.
- ARDT LifeArc WPA recognises that LEAP members also contribute time outside formal meetings, including reviewing emails, polls and materials. We will follow NIHR guidance on payment rates, which covers reimbursement for all agreed tasks and time commitments.

Letter of Engagement (template)

Dear [name],

We would like to thank you for agreeing to be part of our Lived Experience Advisory Panel (LEAP). This is a letter of engagement to enable you, as a part of the LEAP, to be engaged across the project through regular meetings, integration with Work Packages (WPs), and participation in additional activities. This letter is not intended to be a contract, but to ensure shared understanding.

We are engaging you to deliver meaningful involvement while maintaining sustainability as outlined below:

1. **LEAP Meetings**
    - Frequency: Quarterly (3 online meetings per year, 1-2 hours each) plus 1 in-person meeting per year.
    - Purpose: Provide feedback, share experiences, discuss training, and cover other standing agenda items.
    - Chairing: Meetings to be chaired by Christine Collins (Work Package A Queen's University Belfast Centre lead) and Kerry Leeson Beevers (Chief Executive Alström Syndrome UK) initially. The LEAP may appoint its own chair(s) in due course if preferred.
    - LEAP members will be invited to contribute to agenda setting to support co-production.

Additional Support:

- One-to-one calls with Work Package A (WPA) members or allocated WP leads will be offered if LEAP members find them useful.

2. **Integration with Work Packages**
    - LEAP members are being allocated to WPs based on their expressed preferences, project need and best fit.

    Each WP will have up to 2 LEAP members, attending (at least) quarterly WP meetings and contributing to project activities.

    A confidentiality agreement and conflict of interest declaration may be required where sensitive or confidential information is shared.

LEAP members will also be assigned to:

Research Culture and EDI group (WPB/C)

YPAG (Young People's Advisory Group) support (WPA)

Executive Board

Other committees/boards as developed

Engagement Expectations:
WP leads will engage with their LEAP members to agree on:

- Expectations from both sides
- Meeting preparation needs
- Other requirements to ensure full integration
- Specify time commitment expectations

Meeting Frequency:

- Minimum quarterly meetings, with the option for more frequent engagement if demand and capacity allow.
- Meetings should be arranged so that LEAP members can contribute meaningfully even if attending flexibly or on an ad-hoc basis, and attendance is not required at every session. Clear agendas shared in advance will support LEAP member choosing which meetings to priorities.
- A meeting Standard Operating Procedure (SOP) will be followed to ensure consistent LEAP involvement across all WPs.
- Where appropriate post-activity feedback forms will be used to support continuous improvement.

Objective:

- To integrate LEAP members meaningfully without imposing excessive time commitments, ensuring WP deliverables are achieved through co-design with the LEAP.
- To enable LEAP contributions beyond meeting attendance while remaining sustainable within budget.

3. Additional Work

For activities requiring input from a broader range of LEAP members, WPs will submit an interest form outlining:

- Scope of work
- Expectations
- Agreed timeline for input

4. Training and Capacity Building

- LEAP will be consulted on and offered training to support participation in project activities, coordinated by WPA.
- Opportunities may also be provided for LEAP members to train and present to WP members where appropriate.
- Some core training may be mandatory. Where training is optional, members can choose which sessions are most relevant to their role and interest. Choosing not to attend will not impact access to future training

5. Payments and Budget

- ARDT LifeArc WPA recognises that LEAP members also contribute time outside formal meetings, including reviewing emails, polls and materials.
- Reimbursement will be offered for certain activities. Activities where the member has been asked to participate and involved, i.e. work package meetings, training, conferences, contributing to WP activities or other events will be reimbursed. Optional activities, activities that are for engagement or raising awareness that are shared for interest and awareness will not be eligible.
- We will follow NIHR guidance on payment rates, which covers reimbursement for all agreed tasks and time commitments (The payment rates below reflect the updated NIHR recommendations published on the 16th December 2025. These new rates will come into effect for our project from February 2026; previous rates have been applied for activities prior to this date).
    - £13.80 - For involvement in a task or activity such as reading and commenting on an abstract which equates to less than half an hour. For example, reviewing papers.
    - £27.50 - For involvement in a task or activity requiring little or no preparation and which equates to approximately one hour of activity or less. For example, participating in a focus group to provide feedback on a proposal.
    - £55 - For involvement in a task or activity likely to require some preparation and which equates to approximately two hours of activity. For example, a teleconference with related papers to read or review a few short documents.
    - £82.50 - For involvement in a task or activity where preparation is required and which equates to approximately half a day's activity. For example, participating in a meeting to interview a small number of candidates who have applied to join a committee or panel, participating in a focus group, or delivering training.

- £165 - For involvement in all-day meetings. For example, attending a committee or panel meeting as an observer prior to becoming an active public member of a committee/panel.
- £330 - For involvement in all-day meetings that require substantial preparation. For example, when chairing or co-chairing a meeting or when carrying out other discretionary work, which requires additional responsibilities.
- LEAP members will also be reimbursed for reasonable travel expenses where appropriate via BACS transfer, in line with institutional travel and expense policies.

- Time reimbursement will be made according to the LEAP member's preference, either via BACS or vouchers.
- Reimbursement will be processed monthly, it may take up to 6-8 weeks from receipt of claim form for reimbursement to be received by the LEAP member.
- Any total monthly reimbursement that does not end in of 0 or 5 pounds will be rounded up to the next 0 or 5 pounds due to institutional administrative restrictions. This rounding applies to both BACS and voucher reimbursement for activities/time and does not affect travel or other expense reimbursements.

6. Data Protection

- Any personal data collected during your involvement in the LEAP will be handled and stored in accordance with institutional policies and applicable data protection legislation.
- Data will be used solely for the purposes of this project and shared only with relevant project staff and committees as required.
- For full details can be seen in our institutional data protection polices here :
- https://www.ncl.ac.uk/data-protection/data-protection-policy/
- https://www.qub.ac.uk/about/Leadership-and-structure/information-compliance-unit/data-protection/
- The University of Birmingham Data Protection Policy

Acceptance of this offer indicates that you:

- Understand what your role is within this project.
- Confirm that you are participating in this LEAP as someone who is living with or caring for somebody with, a rare condition.
- Agree to the Code of Conduct (attached).

- Understand your role is focussed solely on participating in the LEAP, as outlined above. This does not create a partnership or representative position within the LifeArc organisation, or respective universities.
- In line with the organisation's guidelines, its logo and branding should only be used with prior agreement and permission and not used for business activities.
- May use the following statement to describe your role within the project : 'I'm pleased to contribute to this work in a personal capacity, sharing my lived experience of rare disease through my involvement with the LifeArc Centre for the Acceleration of Rare Disease Trials (ARDT). My contribution reflects personal perspectives and does not represent any professional role or organisational affiliation.'
- Appreciate that reimbursement on this project is provided as a recognition of contribution rather than as a wage or salary. It is intended as an acknowledgment and a gesture of thanks for the time and expertise offered. NIHR advise a 6-8 week timeline from receipt of the expense claim, but this may be shorter or longer depending on the time of year, method of reimbursement and organisation.
- Understand that if you currently receive state benefits, this may affect your benefit claim. We are unable to provide expert advice on the issue but can support you in the process of getting advice if needed.
- Understand that you are responsible for, and will account to the appropriate authorities for all the Tax liabilities to your home country (including notifying HM Revenue and Customs (HMRC) and/or the Department for Work & Pensions (DWP)) in respect of the payments made to you for your involvement in this project.

To accept this offer of engagement, please sign below and return to us via the following email: ARDTcentre@newcastle.ac.uk

LEAP member signature: X

LEAP member Name: X

Date: X

Many thanks,
Signature

LEAP quarterly meeting Terms of Reference

ARDT LEAP - Lived Experience Advisory Panel (LEAP) Terms of Reference (ToR)

1. Overview of ARDT

The Accelerating Rare Disease Trials (ARDT) programme brings together translational research centres, NHS partners, industry, and people living with rare conditions to improve how clinical trials for rare diseases are designed and delivered across the UK. Rare diseases affect around 3.5 million people in the UK, and while individually rare, collectively they represent a significant healthcare challenge. Clinical trials for rare conditions are often slow to set up, difficult to recruit for, and may not always reflect what matters most to patients and families.

ARDT aims to tackle these challenges by developing more efficient and inclusive approaches to trial design and delivery, enabling faster access to new treatments and improving outcomes for people living with rare conditions.

Lived experience is at the heart of this programme. The Lived Experience Advisory Panel (LEAP) ensures that the voices of people affected by rare diseases shape the direction, design, delivery, and dissemination of ARDT activities.

2. Purpose of the Lived Experience Advisory Panel (LEAP)

LEAP will provide advice, oversight and challenge to ensure that the needs, views, and priorities of people with lived experience of rare conditions are embedded across the ARDT programme. The group will work collaboratively with researchers, clinicians, funders and partners to promote patient-centred innovation in rare disease research and trial delivery.

3. Roles and Responsibilities

LEAP members will:

- Advise the ARDT leadership and work package teams on lived experience priorities, accessibility, and acceptability of proposed approaches.
- Contribute to shaping and refining research priorities, materials, and communications.
- Review and provide feedback on key documents, including surveys, information sheets, protocols, plain language summaries, and public-facing materials.
- Help ensure that equity, diversity and inclusion are considered at every stage.
- Contribute to interpreting findings and formulating recommendations that reflect lived experience perspectives.
- Support dissemination of ARDT outputs through accessible and meaningful communication.

- Champion collaboration, openness, and inclusive discussion within the panel and wider programme.

4. **Ways of Working**

Meetings

Frequency: LEAP will meet collectively approximately four times per year for the duration of the ARDT programme (2024–2029). It is expected that one of these meetings each year will be held in person. Members may also be invited to contribute to ad hoc work package discussions or document reviews between meetings.

Forum: Meetings may be held virtually or in-person, depending on accessibility, purpose, and availability of members. The preferred format for each meeting will be confirmed in advance**.**

Preparation and Commitment: LEAP members are expected to prepare for and participate actively in meetings. This may include up to 2 hours of preparation (e.g., reviewing materials) and up to 3 hours for meeting attendance per meeting. Additional time for feedback outside meetings will be specified per task.

Agenda and Pre-reading Materials: The ARDT coordination team will organise meetings, circulate discussion topics, and record meeting notes. Agendas will focus on specific challenges, opportunities, or programme updates and will be shared at least one week before each meeting, along with any pre-reading materials.

Absences: Members should notify the ARDT coordination team as soon as practicable, and ideally at least 10 working days in advance, if they are unable to attend a scheduled meeting. Members may not appoint an alternate or deputy.

Quorum: As the LEAP is an advisory body rather than a formal decision-making group, a strict quorum is not required. However, where matters relating to the operations or ongoing function of the LEAP are discussed, it is expected that at least half of the current members will be present. If a meeting has low attendance, any significant points of agreement or proposed changes will be followed up via email to confirm broader support across the full membership.

Reimbursement: Time spent preparing for and attending LEAP meetings, as well as reviewing documents outside of meetings, will be reimbursed at NIHR involvement rates via a voucher payment process or BACs transfer in line with NIHR recommendations, local institutional guidelines and the terms outlined in the LEAP engagement letter. Travel and other reasonable expenses for in-person meetings will be reimbursed via BACS transfer, in line with institutional travel and expense policies. Reimbursement caps for specific tasks will be communicated in advance where applicable.

5. **Membership and Conduct**

LEAP members will include people living with rare conditions, carers/family members, and representatives from rare disease organisations or communities.

The panel will aim to reflect diversity in lived experience, age, gender, geography, condition type, disability and background.

Participation of observers or guests at meetings is at the discretion of the co-chairs.

Documents and discussions should be treated in confidence unless otherwise agreed.

5.1 Use of Artificial Intelligence (AI)

LEAP members may use AI tools to assist with formatting, structuring, or wording their own feedback.

Members must not use AI to generate feedback, suggestions, or opinions on programme materials, draft documents, research data, meeting papers, or any confidential information.

All feedback provided by the LEAP should reflect the personal views, experiences, and perspectives of members.

Transparency, confidentiality, and ethical considerations must be observed when using AI in the context of LEAP activities.

For further detail refer to the LEAP AI policy

6. Term of Appointment

LEAP members will be appointed for an initial term of 12 months, with the possibility of extension until the end of the programme by mutual agreement.

Members may step down at any time by notifying the co-chairs and ARDT coordination team.

New members may be invited to join the panel as needed to ensure continued diversity of experience and representation.

7. Conflict of Interest

All LEAP members and co-chairs will be asked to complete a declaration of interests form upon joining the group.

Any potential or actual conflicts of interest must be declared at the earliest opportunity.

The co-chairs will maintain a log of interests and manage any conflicts in line with institutional policies.

Members with a conflict of interest on a specific topic may be asked to temporarily withdraw from discussions or decision-making on that topic.

8. **Confidentiality**

Any papers and documents provided to the LEAP should be treated in the strictest confidence and should not be shared outside the group unless explicitly agreed.

9. **Review of Terms of Reference**

These Terms of Reference will be reviewed and agreed by the LEAP after the first meeting. They can be updated as needed to reflect the evolving role of the panel and the needs of the programme.

10. **LEAP Membership**

- Lived experience representatives – 15 members
- Two members of the WPA team (interim Co-Chairs) to support initial establishment of the group
- A current membership list will be maintained separately and updated as required.

Standard Operating Procedure (SOP)

Holding Meetings that include Lived Experience Advisory Panel (LEAP) members

1. Purpose

We are committed to meaningfully involving people with lived experience throughout the Acceleration of Rare Disease Trials project. The LEAP's contributions and insights are highly valued and central to the way we work. We aim to create a positive, structured, inclusive and accessible approach that supports meaningful engagement and ensures lived experience helps shape and deliver the project effectively.

2. Scope

This SOP applies to all meetings involving our LEAP members (public contributors) across the research programme and work packages.

3. Roles and Responsibilities

Role	Responsibility
Meeting Lead / Chair	Prepare agenda, ensure inclusive participation, timekeeping, and adherence to ground rules, awareness of accessibility requirements of all participants and provide support where needed
Meeting Coordinator / Admin	Handle logistics, invitations, setup, sharing of any pre-meeting reading, hospitality or technical support, and expense claims
LEAP members	Undertake appropriate preparation/pre-reading in advance of meetings. Provide input and share experiences, communicate clearly, respect contributions, request support if needed, follow up on agreed actions
Researchers / Staff	Undertake appropriate preparation/pre-reading in advance of meetings. Provide input and shared experiences, communicate clearly, respect contributions, request support if needed, follow up on agreed actions

(Aligns with NIHR Public Contributor Roles Framework https://www.nihr.ac.uk/nihr-public-contributor-roles-framework)

4. General Principles (Apply to all meetings for all participants)

- Communicate clearly and avoid jargon, ensuring that language is accessible to all participants.
- Refer to and uphold the shared principles of the LEAP group throughout the meeting.
- Meeting recordings: If the meeting is to be recorded, inform participants 1 week in advance stating the purpose (e.g., to assist with minute-taking). At the start of the

meeting, remind participants and seek verbal consent before recording begins. Where possible, share pre-reading materials at least one week in advance to allow sufficient time for review.

- Notify participants of the meeting as early as possible and at least two weeks ahead of time to support planning and accessibility.

5. Online / Virtual Meetings

5.1 Pre-Meeting Planning

- Select reliable secure and accessible meeting platforms such as MS Teams or Zoom. Share joining links (as part of the calendar invite) at least two weeks in advance, or earlier if possible.
- While most participants are familiar with these platforms, it's helpful to offer brief guidance, especially as software features are frequently updated.
- Distribute meeting materials including agenda, one week prior and if relevant include a glossary for any acronyms used. If there are multiple documents to review, consider allowing additional time.
- If the meeting is going to be recorded, inform the participants of the intent (e.g. to assist with minute taking) one week prior to the meeting.
- Accessibility needs should be respected. WPA administrative team will share the attending-LEAP accessibility requirements with the meeting organiser, ahead of the meeting to ensure accessibility requirements are catered for – e.g. having enough comfort breaks etc.

5.2 During the Meeting

- Use large font sizes, preferably size 12 or 14 for A4 documents and enable captions during presentations to support readability and accessibility. Always check with the group or individual LEAP members to ensure audio and visual content is clear and accessible (refer to accessibility preferences provided by LEAP in WPA).
- Welcome all participants and remind them if the meeting will be recorded and why and seek verbal consent. Enable real-time captioning if needed.
- Reinforce the LEAP group's shared principles, for example by including them as a slide in the presentation.
- Set clear participation guidelines, such as muting when not speaking and using the "raise hand" feature or chat for questions and comments.
- Ensure the chair monitors both verbal and chat contributions, and that remote participants are actively acknowledged and included.
- Offer regular short comfort breaks to help manage screen fatigue and accommodate health conditions.
- Avoid jargon and acronyms, and present slides using plain, accessible language.
- Recognise that members may experience emotional labour. Meeting leads should check in with participants as appropriate and provide signposting to relevant support or mental health resources.

- Reserve the final 10 minutes of the meeting to gather feedback on the meeting experience, either via Microsoft Form or by email. This is to avoid asking our members to complete a form in their own time.

5.3 After the Meeting

- Contact members to thank them for their involvement and reassure that reimbursement will be processed promptly.
- Process reimbursement.
- Circulate draft minutes or summary.

6. In-Person/ Hybrid Meetings

6.1 Pre-Meeting Planning

- Confirm a date with the LEAP members for the meeting via a poll or email. If possible, offer at least 3 dates with different timings.
- Ensure that the venue is accessible (e.g. ramps, lifts, toilets) and also has a quiet dark space/ prayer room as required. Provide maps (venue and parking location) and contact details.
- Share possible dates as early as possible, and once confirmed send invitations at least 2–3 weeks in advance.
- Share a plain-language agenda and any relevant materials (e.g. glossary) at least one week prior to the meeting. For in-person meetings, ensure hard copies are available. If there is any preparatory reading required, provide it at least two weeks in advance.
- Ensure that any shared literature is accessible e.g. readable font size.
- Reiterate honorarium and expenses offered for the meeting.
- Check with PPIE coordinators/ project managers about dietary requirements and arrange refreshments accordingly.
- Offer guidance on routes, reimburse parking and transport, reserve accessible parking spaces if possible.
- Accessibility needs should be respected. WPA administrative team will share the LEAP accessibility requirements of the attendees with the meeting organiser, ahead of the meeting to ensure accessibility requirements are catered for – e.g. having enough comfort breaks etc.

6.2 During the Meeting

- Begin by welcoming everyone and requesting consent to record the meeting for minute-taking purposes (if required).
- If there are new attendees, allow time for introductions and cover basic housekeeping (e.g., fire exits and fire alarm procedures).
- Reiterate the shared principles of the LEAP group—this could be done by sharing this as a presentation slide or hard copies.

- Ensure inclusive participation—particularly giving space for LEAP members to share their views.
- Ensure the room is comfortable and accessible for all, be mindful of the screen brightness when sharing presentations.
- Use plain, accessible language; avoid acronyms where possible or explain them clearly when used. Encourage questions throughout. For meetings longer than an hour, schedule short comfort breaks.
- Recognise that members may experience emotional labour. Meeting leads should check in with participants as appropriate and provide signposting to relevant support or mental health resources.
- If possible, invite feedback on meeting experience before leaving the venue via short feedback survey or verbally.

6.3 After the Meeting

- Share draft minutes or a summary of the meeting as soon as possible, and always ahead of the next meeting and feedback forms if not already completed.
- Confirm and communicate action items along with assigned responsibilities/due dates.
- Ensure reimbursements are processed promptly.
- If presenting a research project proposal to the LEAP, ensure that an Impact Form is completed—to capture feedback on how the LEAP's input has supported the co-development, co-design, and delivery of the project.

7. Monitoring and Review

- Review SOP annually or following updated PPIE guidance.
- Adapt based on participant needs and technological developments.

LifeArc ARDT PPIE contacts

1. **General enquires**
   For general LEAP/WPA queries if unsure who to contact.

   Email : ardtcentre@newcastle.ac.uk -
   Contact:
   - Molly Gilmour
   - Amber Hart

2. **LEAP meetings**
   For queries about LEAP quarterly meetings and activities.

   Email: ardtcentre@newcastle.ac.uk
   Contacts :
   - Molly Gilmour
   - Amber Hart

   LEAP meeting co-chairs:
   - Kerry Leeson-Beavers - kerry.leeson@alstrom.org.uk
   - Christine Collins - c.collins@qub.ac.uk

3. **LEAP and WPA/PPIE queries**
   For overall WPA and LEAP queries.

Role	Name	Email
WPA/PPIE lead	Cathy Turner	catherine.turner@newcastle.ac.uk
Belfast lead	Christine Collins	c.collins@qub.ac.uk
Birmingham lead	Steven Blackburn	s.blackburn.1@bham.ac.uk

4. **PPIE queries (by Work Package)**
   For queries related to work packages activities or meetings including finance/reimbursement questions.

Work Package	***Contact***	***Emails***
WP1, WPA	Molly Gilmour, Amber Hart	ARDTcentre@newcastle.ac.uk / Amber.Hart@newcastle.ac.uk /
WP2, WP3, WP4	Shilpa Pius, Laura Wyatt	s.pius@bham.ac.uk/ l.a.wyatt@bham.ac.uk / centreardt@contacts.bham.ac.uk
WP5, WPB, WPC	Kerry Longmore, Sarah Scullion	k.longmore@qub.ac.uk / Sarah.Scullion@qub.ac.uk

Full Contact list

Name	Organisation	Email
Amber Hart	Newcastle University	amber.hart@newcastle.ac.uk
Amy Hunter	Genetic Alliance	amy.hunter@geneticalliance.org.uk
Cathy Turner	Newcastle University	catherine.turner@newcastle.ac.uk
Christine Collins	Queens University Belfast	c.collins@qub.ac.uk
Kerry Leeson-Beavers	Alström Syndrome UK	kerry.leeson@alstrom.org.uk
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