Welcome and Introduction

Professor Lynn Rochester

Wednesday 12th December 2018
Aims of the project

- This is a national project funded by the National Institute for Health Research (NIHR).
- The project aims to explore innovations in clinical trial design and delivery for under-represented groups.

Our vision:
Better healthcare through more inclusive research
Aims of the day

The aim of the day is to share our findings to date and invite input on progression. We will look at:

- Groups who are historically under-represented in standard clinical trials.
- Barriers and hurdles identified.
- Sharing examples of innovations in clinical trial design and delivery.
- Exploring where there may be any outstanding gaps in knowledge and findings and next steps.
Aims of the day continued

By the end of the day we want to find the answers to these questions:

Groups who are historically under-represented in standard clinical trials
What suggestions do you have for the way we refer to “under-represented groups”? (For example, what terminology can we use that is more inclusive? For example would “seldom heard from” work better for us?)

Barriers and hurdles identified
Of the barriers and hurdles we have presented, which do you agree and are there any you would remove or add?

Sharing examples of innovations in clinical trial design and delivery
Following on from what we’ve showcased today, what are the key opportunities for the CRN to explore and what have we missed?

Next Steps and a prioritised call to action
What would be your top three priorities over the coming year to enable us achieve our vision of better healthcare through more inclusive research?
Who you represent

- Public and patient groups and charities
- Practitioners and health professionals
- National Institute for Health Research and Clinical Research Network colleagues
- Lifesciences industry
- Funders
- Regulatory bodies
# Programme for the day

## Emerging Technology and Innovation

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>10:00 – 10:30</td>
<td>Registration</td>
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<tr>
<td>10:30 – 10:45</td>
<td>Welcome and introduction to the ETI</td>
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<tr>
<td></td>
<td>Professor Lynn Rochester, NIHR CRN Specialty Cluster E Lead and Professor of Human Movement Science, Newcastle University</td>
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<tr>
<td>10:45 – 11:00</td>
<td>Findings to date: What do we understand by underrepresentation and barriers? What innovations exist now?</td>
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<td>NIHRIO findings</td>
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<td>Jenny Williams, Information Specialist, NIHR Innovation Observatory, Newcastle University</td>
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<td>11:00 – 11:15</td>
<td>ETTI survey findings</td>
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<td>Professor Lynn Rochester</td>
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<td>11:15 – 11:30</td>
<td>Question and answer session</td>
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<td>Professor Lynn Rochester and Jenny Williams</td>
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<td>11:30 – 11:50</td>
<td>Break – Teas, coffees, refreshments and biscuits</td>
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## Case Studies: Experiences of clinical trials under-representation

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>12.00 – 12.20</td>
<td>Participant experience</td>
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<td>Professor Fiona Nolan, Clinical Professor of Mental Health Nursing, University of Essex and Francie Casey, Fashion Design Student, University of the Arts London</td>
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<tr>
<td>12.20 – 12.40</td>
<td>Researcher and clinician experience</td>
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<td>Professor Mike Wildham, Professor of Trials for Older People, Newcastle University</td>
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<td>12.40 – 1.00</td>
<td>Experience of delivery</td>
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<td>Wajid Khan, Senior Research Officer, South West Yorkshire Partnership NHS Foundation Trust</td>
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<td>1.00 – 1.15</td>
<td>Over to you: Q&amp;A panel</td>
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<td>An opportunity to ask case study speakers your questions</td>
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<td>1.15 – 2.00</td>
<td>Lunch and networking – Ada Salter Room 1 and 2</td>
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## Guiding future action

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<th>Time</th>
<th>Session</th>
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<td>2.00 onwards</td>
<td>Teas, coffees, refreshments and cake selection</td>
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<td>2:00 – 3:30</td>
<td>Have your say: Consultation session</td>
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<td>Professor Lynn Rochester</td>
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<td>3:30 – 3:45</td>
<td>Feedback and close</td>
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<td>Professor Lynn Rochester</td>
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Innovations in Clinical Trial Design and Delivery for under-represented groups

Workstream 1
Aim: Find key areas of under-representation and related barriers within clinical trials.
Findings: No cohesive definition of under-representation. However, literature suggests under-representation is context specific (e.g. group, indication, perceived barriers, etc.)

Workstream 2
Aim: Identify key areas of innovation
Findings: Patient and trial focused solutions that address context specific issues

Aim: Share findings and invite input on:
1. Groups who are under-represented in clinical trials
2. Barriers and hurdles
3. Innovations
4. Gaps in knowledge, findings and next steps

Project Initiation
(Autumn 2017)

Steering Group
Setting Objectives, Scope and Deliverables.

Horizon Scanning Reports
(Spring 2018)

Initiation Workshop
(Spring 2018)

Dissemination Workshop
(Winter 2018)

Practitioner & Patient Surveys
(Summer 2018)

Examples of Barriers
- Trial sites – infrastructure, staffing, geography
- Logistical complications
- Restrictive eligibility criteria

A need is identified

Is there a sufficiently consistent definition of “under-represented groups” in clinical trials across stakeholders?

14%
13%
12%
10%
9%

Our Stakeholders
- Public and Patient Groups and Charities
- Practitioners and Health Professionals
- NIHR and CRN
- Lifesciences Industry
- Funders
- Regulatory Bodies

VISION: Better healthcare through more inclusive research
Our ETI steering group

Many thanks to our steering group:

- Prof Lynn Rochester – National Specialty Cluster E Lead (Chair)
- Dr Lynne Corner – Director of Engagement, Newcastle University
- Prof Paul Dark – Chair in Critical Care Medicine, Manchester University
- Prof Alistair Hall – Clinical Director, CRN Yorkshire and Humber
- Prof Helen Hancock – Co. Director, RDS NE
- Dr Joanna Knee – Head of Research Operations, CRN RDD
- Rebecca Maier - Deputy Lead for Clinical Trials & Engagement
- Iain Mallet – Head of PPIE, NIHR CRNCC
- Prof Gail Mountain – Professor of Applied Dementia Research, Bradford University
- Dr Gary Nestor – Assistant National Specialty Cluster E Lead
- Amanda Tortice – Chief Operating Officer, CRN Yorkshire and the Humber
- Prof James Wason – Professor of Biostatistics, IHS BRG
- Prof Miles Witham – Professor of Trials for Older People, Newcastle University
Thank you

Professor Lynn Rochester

Wednesday 12th December 2018