Welcome

INCLUDE
Innovations in Clinical Trial Design and Delivery for the Underserved

Dr William van’t Hoff & Professor Lynn Rochester
Tuesday 23rd June 2020

https://www.ncl.ac.uk/medicalsciences/research/crn/researchinnovation
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>13:00-13:05</td>
<td>Registration and housekeeping</td>
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<td>Craig Smith, Flint Spark</td>
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<tr>
<td>13:05-13:10</td>
<td>Welcome</td>
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<td>Professor William van’t Hoff, Chief Executive Officer, NIHR Clinical Research</td>
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<td>Network</td>
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<td>13:10-13:20</td>
<td>What is INCLUDE all about? Phase II summary and aims of the day</td>
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<td>Professor Lynn Rochester, Specialty Cluster Lead, NIHR Clinical Research</td>
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<td>Network</td>
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<td>13:20-13:30</td>
<td>Session 1 – ETI Framework outline and implementation</td>
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<td>Bringing together the NIHR for the underserved</td>
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<td>Laurie Olive, Head of Public Engagement, NIHR Clinical Research Network</td>
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<td>13:30-13:40</td>
<td>Example of implementation: Ensuring that COVID-19 research is inclusive:</td>
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<td>Guidance from the NIHR INCLUDE project</td>
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<td>Professor Miles Witham, Professor of Trials for Older People, Newcastle</td>
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<td>University</td>
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<td>13:40-13:55</td>
<td>Over to you: An opportunity to ask questions</td>
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<td>13:55-14:10</td>
<td>BREAK</td>
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<td>14:10-14:55</td>
<td>Session 2 – Dissemination and implementation</td>
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<td>How can we disseminate and implement INCLUDE and how can we measure impact?</td>
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<td>Group discussion</td>
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<td>14:55-15:00</td>
<td>Final comments: summing up, next steps and feedback</td>
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<td>Professor Lynn Rochester</td>
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The INCLUDE Vision

“Better healthcare through more inclusive research”

We define the underserved as ‘those inadequately provided with opportunities to participate in research’

Phase I - Scoping
• Researched the underserved in clinical trials, professionals working on trials and those taking part in them
• Collated the barriers and challenges that contribute
• Identified innovations in trial design and delivery to enhance inclusion

Phase II – Developing a Framework (including roadmap and objectives with work streams)
• Produced the Framework: a roadmap suggesting intervention points to improve inclusion and core objectives and work streams
• Identified the importance of working with funders, regulators and other stakeholders to implement INCLUDE
• Working with stakeholders to decide routes to implementation and ways to evidence impact

Phase III – Implementation and Evidence
INCLUDE Framework

Involved stakeholders: Patients, public, funders, clinicians, researchers, regulators, industry, policymakers

Checkpoints for decision-making processes

Collaborative, iterative engagement with stakeholders in prioritisation, design and delivery

Tools and processes:
- Building community-partnered participatory research over the long term
- Training resources for stakeholders
- Infrastructure and systems to recruit and retain participants from underserved groups
- Removing funding, policy and regulatory barriers to inclusion

NIHR National Institute for Health Research
INCLUDE Framework

Core Objectives

- Develop Community Partnered Participatory Research building long-term relationships and opportunities for participation for underserved groups.
- Develop tailored training resources to design & deliver trials for underserved groups.
- Develop infrastructure & systems to reach, engage, recruit & retain underserved groups.
- Work with funders, regulators and other stakeholders to remove barriers to including underserved groups in clinical trials.

Workstreams

- W1 Communications & training
- W2 Infrastructure, people & processes
- W3 Design tools
- W4 Funder & regulatory landscape

Delivered by integrated approach
INCLUDE Stakeholders

- Practitioners and Health Professionals
- Charities, Participants, Families and Carers
- Funders
- NIHR and CRN
- Regulatory Bodies
- Life Sciences Industry

NIHR
National Institute for Health Research
INCLUDE Dissemination Framework

- Measuring Impact
- Stakeholder Identification and Engagement
- Sharing the INCLUDE Message
INCLUDE Workshop Aims and Objectives

• Driving awareness of INCLUDE – how can we do this?

• Influencing actions of stakeholders – how can we do this?

Let us know how we can make a difference where it matters
Thank you!

Contact Us:

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