Citizen science and clinical trials

A New Frontier

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Citizen science in health research

Public contribution	People contribute questions, observations, knowledge or analysis to scientific inquiry.
Agreed influence	Explain which decisions contributors can make and what support they need.
Scientific purpose	Connect each contribution to a useful question, credible evidence and feedback.

Vohland et al. 2021; ECSA 2015. Roles vary across projects and should be described explicitly.

Different roles in a clinical study

Role	What it involves
Trial participant	Enrolment in a study under its protocol and consent arrangements.
Public research partner	Helping shape questions, materials, interpretation or sharing of findings.
Clinical research team	Protocol responsibilities, qualified oversight and scientific conduct.

One person may hold more than one role; agree the responsibilities and boundaries.

Friedman et al. 2010; NIHR 2024; Resnik 2019; WMA 2024.

Potential contributions to clinical research

Relevance	Help identify questions and outcomes that matter to potential participants.
Understandability	Review information sheets, questionnaires and other study materials.
Feasibility	Identify burdens, access barriers and practical difficulties in proposed procedures.

Evaluate the effects on recruitment, quality, time, trust and participant experience.

NIHR 2024. These are potential contributions, not guarantees of faster research or better clinical outcomes.

Public involvement and citizen science

PPI	Patient and public involvement can include active partnership across the research cycle.
Overlap	Citizen science and PPI may share contributions, collaboration and joint decisions.
Design choices	Describe actual influence, tasks, support and recognition when comparing approaches.

NIHR 2024; Vohland et al. 2021. Neither label alone establishes sustained participation, lower cost or greater influence.

STEP CHANGE health study protocol

Oxford study protocol (2023) within the EU-funded STEP CHANGE project

Non-alcoholic fatty liver disease (NAFLD): the protocol's original disease term.

Review questionnaires and diaries.

Co-analyse de-identified participant-experience data.

Help synthesise findings and prepare outputs.

Share findings; coauthor where contribution criteria are met.

Planned roles in a protocol. Clinical researchers retained data collection; clinical outcomes require separate evidence.

Shah et al. 2023; European Commission CORDIS, grant 101006386. STEP CHANGE ended in April 2024.

Ethics and responsibilities

Consent and choice	Explain roles, burdens and withdrawal without pressure.
Clinical responsibility	Use appropriate ethics review and qualified supervision.
Privacy and access	Agree data access and limit identifiable information.
Dual roles	Discuss conflicts when a contributor is also a study participant.
Recognition	Agree data responsibilities, acknowledgement and authorship criteria.

CIOMS 2016, Guidelines 7-9 and 12; Resnik 2019; WMA 2024.

Support for sustained participation

Time and resources	Budget for coordination, training, accessible materials and appropriate reimbursement.
Quality and support	Practise procedures, review records and document uncertainty or missing information.
Continuity	Agree realistic commitments, regular feedback and a way to resolve concerns.

NIHR 2024; ECSA 2015; Vohland et al. 2021. Participation needs ongoing support.

Questions for future projects

Research priorities	Which questions and outcomes do patients and communities consider important?
Methods and burdens	How can contributors help identify procedures that are understandable and feasible?
Evaluation	What changed, for whom, at what cost, and with which remaining limitations?

NIHR 2024; ECSA 2015; Friedman et al. 2010. Evaluate the contribution alongside scientific and ethical requirements.

Starting a responsible partnership

Begin with a useful question and the people affected.

Agree roles, influence, resources and safeguards.

Check the evidence and return findings to contributors.

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Educational reference edition. Original presentation: FERCAP 2024, Nepal. Sources and revision details follow.

Selected references 1

Vohland, K., Land-Zandstra, A., Ceccaroni, L., Lemmens, R., Perelló, J., Ponti, M., Samson, R., and Wagenknecht, K. (Eds.). (2021). The Science of Citizen Science. Springer.

https://doi.org/10.1007/978-3-030-58278-4

Friedman, L. M., Furberg, C. D., and DeMets, D. L. (2010). Fundamentals of Clinical Trials (4th ed.). Springer.

https://doi.org/10.1007/978-1-4419-1586-3

Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-related Research Involving Humans (4th ed.). CIOMS, in collaboration with WHO.

https://doi.org/10.56759/rgxl7405

These three works are in the presenters' original source list; editions were checked against the supplied PDFs.

Selected references 2

Resnik, D. B. (2019). Citizen Scientists as Human Subjects: Ethical Issues. Citizen Science: Theory and Practice, 4(1), Article 11, 1-7.

https://doi.org/10.5334/cstp.150

World Medical Association. (2024). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants. October 2024 revision.

https://www.wma.net/policies-post/wma-declaration-of-helsinki/

National Institute for Health and Care Research. (2024). Briefing notes for researchers: public involvement in NHS, health and social care research (Version 2.0, May 2024; first published 2021).

https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research

Resnik is an original source. WMA 2024 updates the original 2013 copy. NIHR supplies additional citation support.

Selected references 3

Shah, S. G. S., Barrado-Martín, Y., Marjot, T., Tomlinson, J. W., and Kiparoglou, V. (2023). Adopting a Citizen Science Approach in Translational Experimental Medicine Research in Non-alcoholic Fatty Liver Disease: A Study Protocol. Citizen Science: Theory and Practice, 8(1), Article 59.

https://doi.org/10.5334/cstp.555

European Commission CORDIS. (n.d.). STEP CHANGE: Science Transformation in EuroPe through Citizens involvement in HeAlth, coNservation and enerGy rEsearch (Grant agreement 101006386). Accessed 9 November 2026.

https://cordis.europa.eu/project/id/101006386

European Citizen Science Association. (2015). Ten Principles of Citizen Science. ECSA.

https://ecsa.citizen-science.net/10-principles/

Additional citation support for this revised reference edition; the presenters' original reading list is retained separately.