Trusting, Collaborating and Listening: Engaging Public and Communities with Vaccine Studies

Supporting better public health through ~~Good~~ Better Clinical Practice

8 October 2020

Scope

Our Purpose

To improve health globally by increasing the output of robust, reliable, and practice-informing clinical research by significantly reducing inefficiencies related to regulation of Good Clinical Practice (GCP) in the conduct of **randomised clinical trials**.

Our Focus

The Collaborative's primary focus is to support the (1) development and (2) utilisation of new guidance that promotes and enables rational, proportionate and critical application of Good Clinical Practice principles.

Our position

- Well-designed randomised clinical trials are essential to deliver **reliable results** that **inform practice.**
- Researchers must comply with a **complex system of regulations and guidelines** that aim to reduce risk, provide clarity and standardise approaches.
- But the over-interpretation of out-dated and confusing guidance has **driven up costs through waste, delay and failure.**
- **New, proportionate guidance is needed** to enable researchers to efficiently conduct the trials that are needed to improve patient care.

The benefits of a new approach to GCP

Improving GCP guidelines will ensure that clinical trials can...

- **Produce reliable results** – by highlighting key issues that influence results, encouraging a rational approach to safety monitoring, and providing clarity and consistency.
- **Ensure participant wellbeing** – by ensuring consent processes exist primarily to inform participants, and by considering appropriate ways to avoid, mitigate or monitor risk.
- **Foster innovation** – by emphasising the principles-led approach, allowing trialists to determine efficient & effective solutions, and by discouraging excessive, defensive practice

Challenges of trust, perception and priority

- Is less directive guidance open to more error or abuse?
- Who can judge what is rational, proportionate, adequate or appropriate?
- Do participants care if a trial is uninformative, if they are safe?
    - What about use of experimental treatments in routine care?

Working with all partners in clinical trials

Patients, participants & the public

Industry and CROs

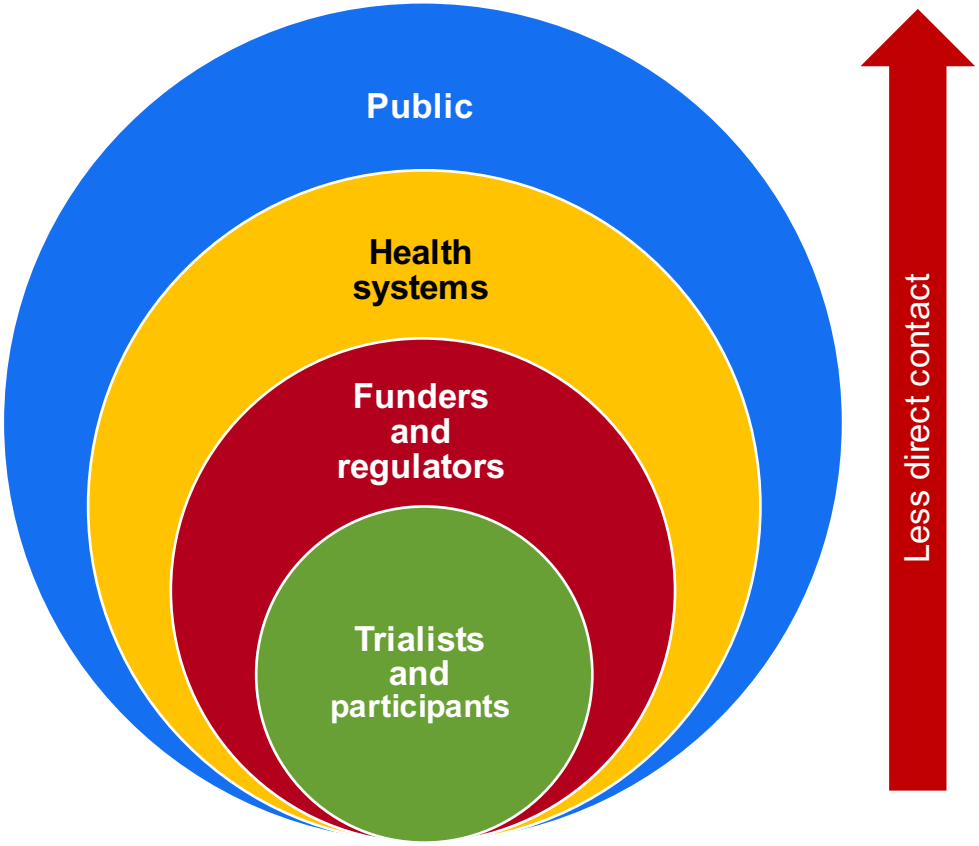
Academia

Clinical and health organisations

Regulators and Gov't

Funders

Engaging at grassroots for global impact



- Prioritising early engagement with trialists and clinical trial participants
- Clearer understanding of **practical** challenges and barriers
- **Credibility** with end-users of guidance

Guidance in isolation is insufficient

*Only possible with broad and open consultation

Thank you