Clinical trials, climate harms and the response-ability to act

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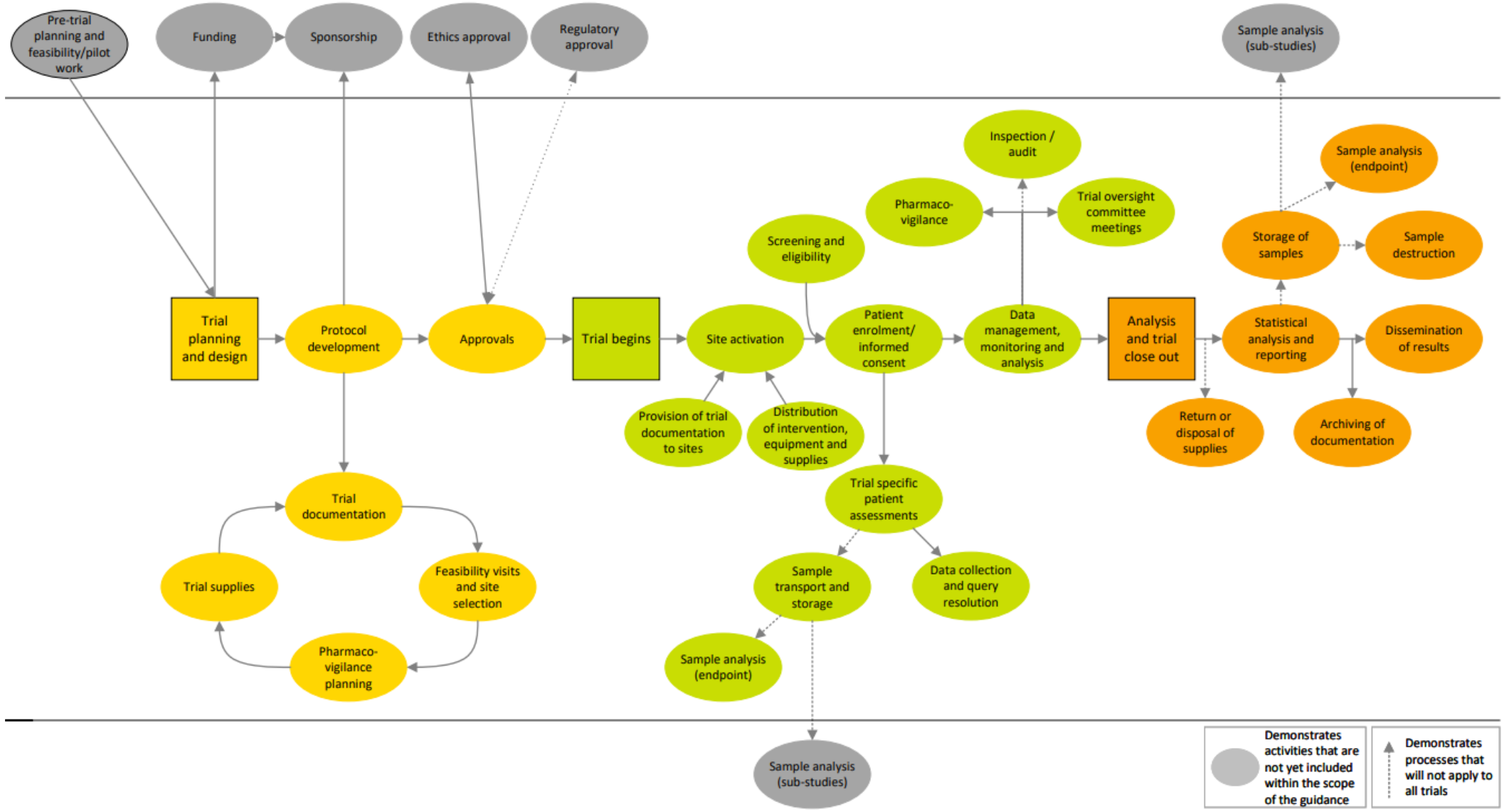
Format of talk

- What are clinical trials and their climate harms
- Why do we have a moral obligation to reduce these climate harms?
- Whose responsibility?
- This project: exploring responsibilities
- Recommendations

Clinical trials

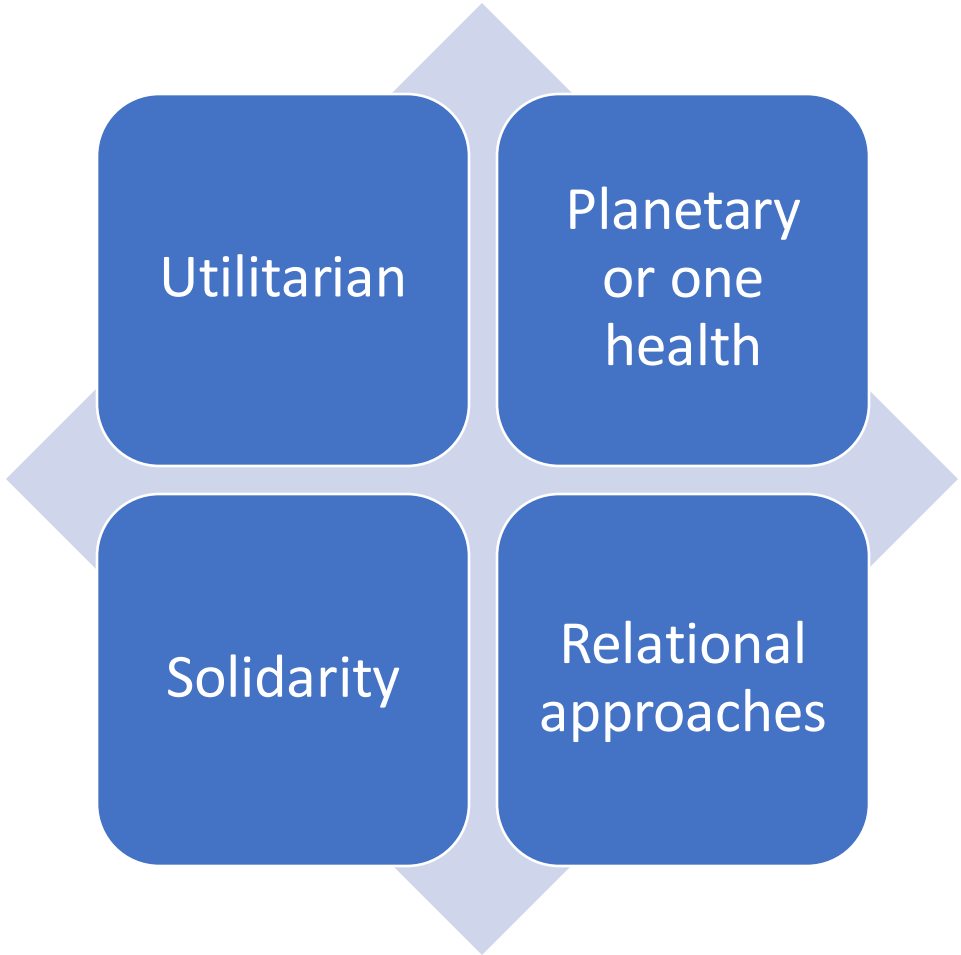
- Evaluate the safety & effectiveness of new medical treatments, procedures, interventions.
- Various types/complexity.
- In 2022, approx 38,000 new trials registered globally on clinicaltrials.gov.
- ~80-2000+ tonnes CO2eq each (80 tonnes=driving car 10x around the planet).
- Other env harms: hazardous/non-hazardous waste.



Griffiths J, Fox L, Williamson PR Quantifying the carbon footprint of clinical trials: guidance development and case studies *BMJ Open* 2024;**14:**e075755. doi: 10.1136/bmjopen-2023-075755

Moral obligation to reduce climate harms

- Multiple frameworks have been developed to argue a moral obligation to reduce climate harms.
- Not the topic of this presentation, but we need to be mindful of that each framework will shape how we think about responsibilities.



If a moral obligation exists, whose is responsible for ensuring it is addressed?

- Collective responsibilities:
  - **Young:** responsibilities are attributed proportionally to ability.
  - **Haraway**: being ‘response-able’–being able to respond.
- Given this, which actors are best positioned to reduce the emissions of clinical trials.

Iris Marion Young

Donna Haraway

This project

- WHO-commissioned project: to develop globally applicable recommendations for trial mitigation.
- Spoke to trial sponsors, primary investigators (PIs), contract research organisations, research site managers.
- Considered funders, research organisations, publishers, (inter)national regulators, ethics committees.
- 23 individuals. 12 countries represented
  - UK (n=8)
  - Kenya (n=3)
  - South Africa (n=2)
  - Malaysia (n=2)
  - The Netherlands, Germany, Brazil, India, Nepal, Zambia, Gabon, and Ethiopia)
- 15 men; 8 women.

1. Whose responsibility? Maximal preparedness

- Need to adhere to strict protocols to ensure trial efficacy, quality, safety.
- Leads to culture of nervousness/‘panic’.
- Trials conducted with maximum preparedness.
  - Frequent research site visits
  - Digital comms reduce flying, but lack of infrastructure at many LIMC sites
  - Evermore data collection ‘just in case’

2. Responsibility, capacity, trust & colonialism

- LMIC research sites lack capacity:
  - High site visit frequency
  - Flying samples to sponsor lab for processing
  - Flying engineers to fix broken machines.
- De-centralised trials increase capacity but are not easy:
  - Lack of sub-zero sample storage
  - Research site-based analyses inferior to host's lab?

- Difficult balance between building capacity (& co-benefits of less flying; de-colonisation of research); vs need to verify correct trial conduct.

3. Trial research site lack of ‘response-ability’*

- Research site managers constrained to reduce emissions:
  - Facilities often housed in larger institutions (no control over energy source).
  - Research sites must comply with stringent protocols that don’t include climate concerns.
  - No incentives provided to incorporate more expensive low-emission options in contracts.

*Term first used by sociologist Donna Harraway, but now used extensively in the sociological literature.

4. Responsibility for ‘getting it right first time’

https://gettingitrightfirsttime.co.uk/

- Some PIs are using newer diagnostics during trial conduct that are not standardised.
- Presents obstacles in generating reproducible and valid data, and potentially wastes resources/emissions.

Recommendation 1: a good* trial is a sustainable one

- Sponsors, PIs, funders, journal editors share responsibility in ensuring:
  - Trials are well-designed from outset (appropriate RQs, no unnecessary duplication, efficient & well-designed methodology).
  - Testing and diagnostics must be standardised.

*good quality

Recommendation 2: resourcefulness

- Patient/participant safety is important, but some LMIC-based trial sites already mitigate emissions by accident due to a lack of resources.

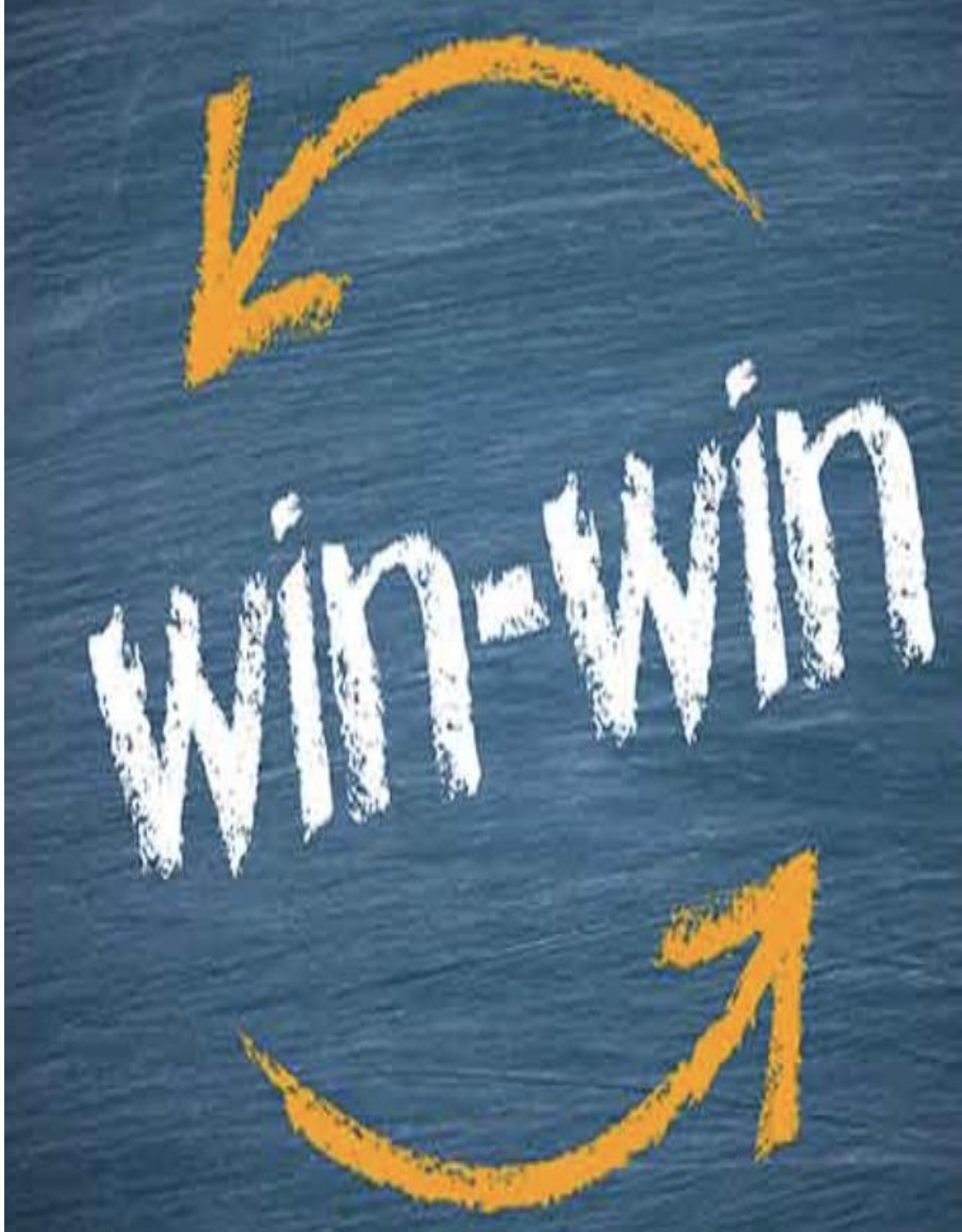
- Lessons can be learned: regarding how to move from maximal preparedness to **resourcefulness [ethical value]** without impacting trial safely.

Recommendation 3: co-benefits

- Sponsors, PIs, funders, RECs/IRB support investment:
  - renewable energy
  - digital infrastructures and capabilities
  - skilling workers through decentralised trials.
- e.g. some LMIC REC/IRBs require capacity building for approval.

- **Co-benefits:** promotion of socially just, de-colonised research processes.*

*though co-benefits are not a solution, but an uncertain process e.g. **rebound effects [whose responsibility? For another time]**



Thank you

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