

# Community representation in research governance

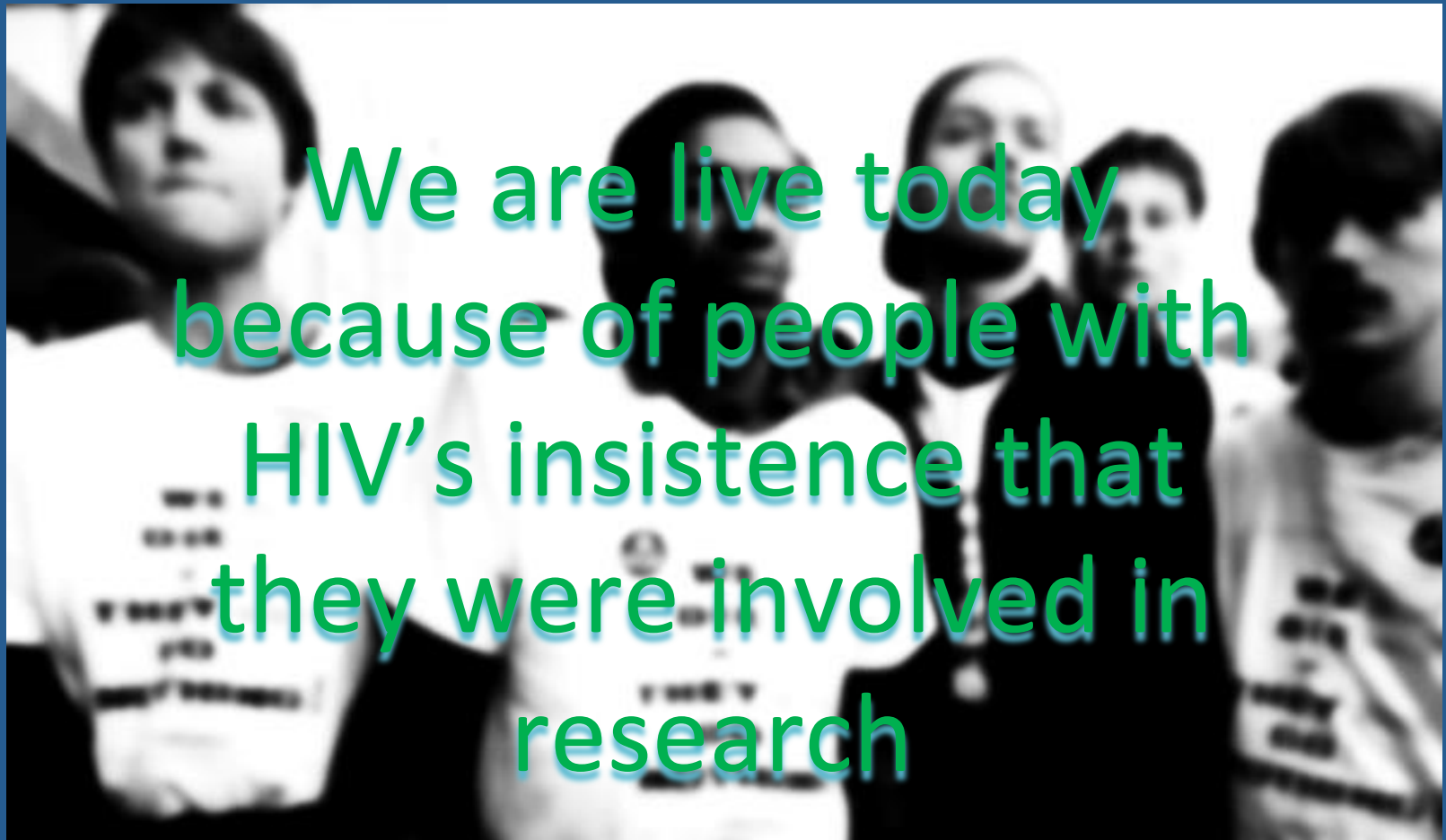
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# Community representation in research governance



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We are live today  
because of people with  
HIV's insistence that  
they were involved in  
research

# Overview

- Phase I and II trials
- Phase III trials
- Cohort studies and other trials
- Why, when and how
- Points of influence

# Let's all argue about Ukcabavir!

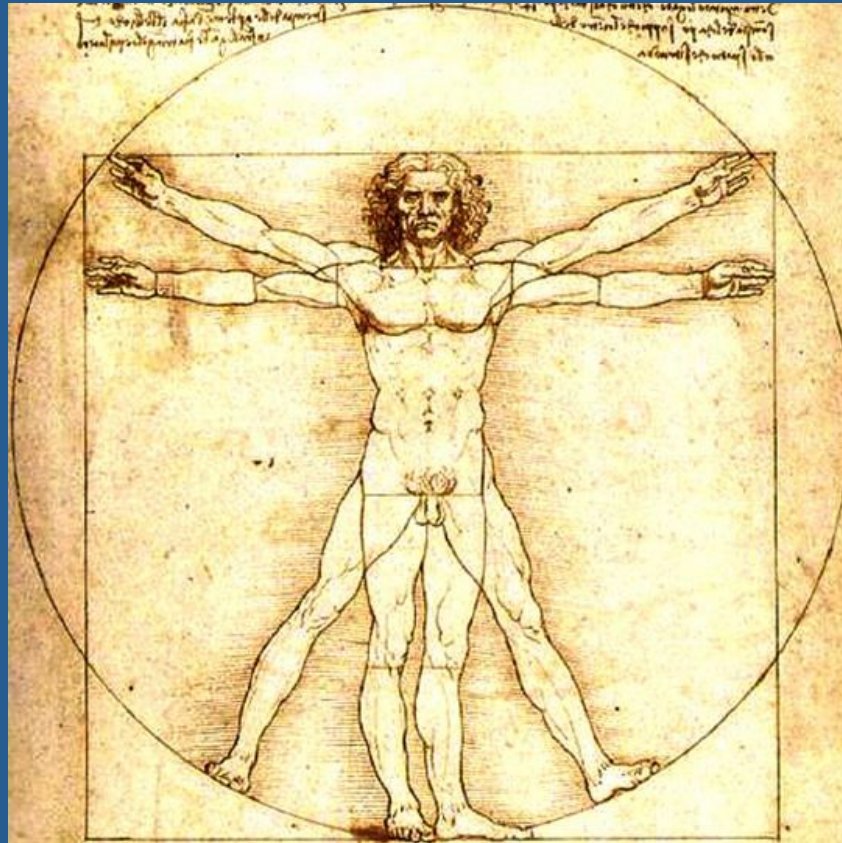
For each pair of statements about the experimental HIV drug Ukcabavir (ABC90210), decide which is more important...

# Phase I and II trials

- Phase I: about **safety** and **pharmokinetics**.
- Phase I: usually **but not always** in “healthy volunteers.”
- Phase II: about **safety** and **efficacy** (does it work?).
- Phase II: in people with condition to be treated.

# Phase I and II trials

Phase I studies - “First in man...” Why?



# Phase I and II trials

Safety of unborn children





# Phase III trials

- Phase III: about **safety** and **effectiveness** (in the study population).
- Phase III: in people with condition to be treated.
- Phase III: could include “special populations” like women (!), older people, children, people with viral hepatitis, people with TB.
- Non-inferiority studies: are similar to phase III trials in character.

# Cohort and other studies

- Cohort and observational studies: longitudinal (usually) prospective (looking forward) or retrospective (looking back), not randomised, answer questions with real world data, often messy data.
- Qualitative studies: look at thoughts, beliefs, feelings (subjective aspects), give depth and insight

# Research governance

- Ethics committee – external
- Sponsors – external
- Regulators – external
- Steering committee - oversight
- Management group - operational
- Data safety monitoring board – data integrity and safety
- Advisory groups – comment and advice

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What are the reasons why people with HIV should be involved in research?



# What are the reasons why people with HIV should be involved in research?

- Influence trial design – ask the right question... in the right way...for the right people
- Perspective
- Communication
- Safety
- Ethics
- Dialogues and relationships with researchers

What are the reasons why people with HIV should be involved in research?

SAFETY BEFORE DATA

SAFETY BEFORE MARKET

COMMON SENSE!

# 5 things you can direct

- The research question (hypothesis)
- How the research question is asked (methods)
- How the research question is explained (patient information needed for informed consent)
- Safety (methods and data monitoring)
- Communicating the study (existence, progress, scientific papers, non-scientific press and community engagement)