



# Volunteer Infection Studies

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# New strategic framework

**To be more focused and proactive in specific areas.**

By connecting experts from different disciplines, building partnerships, and leading advocacy, policy development, communications and public engagement.

Drug Resistant Infections, Our Planet Our Health, Education etc...

**Vaccines:** Explore how best to stimulate research, technology development and policy to address critical unmet needs.

# Vaccines Priority Area

– initiated Jan 2017



## Four ways we are taking action

*Initial focus*

1. A world prepared for epidemics (CEPI)
2. Innovation in vaccine development (CHIM)

## *Year 2 onwards*

3. Evidence for decision making
4. Increased vaccine expertise

# Not a broad funding scheme in the vaccines field

## Investigator led funding continues to fulfil that role

- Outcome / objective led
- Targeted research to deliver outcomes
- Commissioned work; targeted request for proposals
- Influence, advocate, catalyse partnerships

# Wellcome support for Volunteer Infection Studies

## Response mode

- Hypothesis-driven or product development through many different routes e.g.
- Collaborative awards
- Seed Awards
- Innovator Awards
- Investigator Awards
- Fellowships

## Vaccine Priority Area (Jan '17)

- Outcome-driven
- Accelerate vaccine development
- For and in endemic populations
- Holistic approach including ethics, regulations, community engagement, clinical capacity, comparability

# Expanding the use of Volunteer Infection Studies to endemic areas

## Why in endemic areas?

- Host-pathogen or host-vaccine interaction can be different in LMICs as compared to EU/US
- Genetics, infectious disease history, co-infections, immune status, and environmental factors can only be appropriately tested in the targeted settings.
- Potential benefits of the trial results in the country where the diseases occur
- Potential to accelerate vaccine development and inform decisions early in development

## Our initial approach:

- Wellcome has a long history of support for research capacity building in Africa and Asia



- We intend to support a **holistic and coordinated** approach to build capacity for CHIM, including ethics, regulatory, engagement, terminology, comparability etc...
- Supporting a review of ethical and regulatory challenges in endemic areas
- Developing Funders Principles which will be informed by discussions here today

# Why Funders Principles?

## Why Funders Principles?

- Funders have a responsibility to support innovation that promotes and sustains the public good
- These studies raise unique ethical concerns and carry a high burden of responsibility
- Precedent for this model – i.e. emerging technologies, data sharing, access to medicines (also a challenge – need to ensure coherence and not just a ‘proliferation of principles’).
- Complimentary to other international and local guidance
  - i.e. Recommendations made today, WHO guidance, Malawi framework
- Implementable – embed in the research practice



[Gordon et al, 2017]



Thank you

**Any comments or questions?**

<https://wellcome.ac.uk/what-we-do/our-work/vaccines>