Volunteer Infection Studies

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Head of Vaccine Priority Area, Wellcome Trust AMS 6th February 2018



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
- <u>Accelerate vaccine development</u>
- 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, coinfections, 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

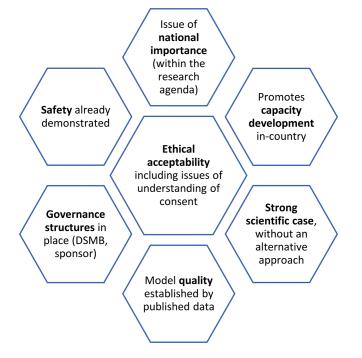


- We intend to support a holistic and coordinated approach to build capacity for CHIM, including ethics, regulatory, engagement, terminology, comparability etc...
- Supporting a review of ethical and regulatory challenges in endemic areas
- Developing Funders Principles which will be informed by discussions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







Thank you

Any comments or questions?

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