International Clinical Trial Networks
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Wellcome Trust

Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development
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Wellcome is a global charitable foundation, both politically and financially independent.
Wellcome’s Drug-Resistant Infections Programme

Four pillars of the programme

- Evidence for decision-making
- New treatments
- Expertise and resources
- Stronger global governance
- Faster clinical trials

Global scope

Wellcome is creating a global portfolio of open research and data to help guide national and global strategies for tackling drug-resistant infections.

Wellcome is working with policymakers to support the development of a global framework to coordinate, monitor and evaluate progress.

Wellcome is working with partners, Wellcome is funding the development of potential new antibiotics, diagnostics and preventative approaches.

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Policy and advocacy efforts support the programme in its entirety

£175m ($225m) over 5 years
The current model of clinical research is inefficient from both a time and cost perspective.

- Single use networks of 50–300 sites
- High cost of building capacity and infrastructure
- Loss of capacity and expertise at trial completion
- Difficulties with patient recruitment
- Heterogeneity of trial site quality
- Individual studies for each indication

Indications: cUTI, HAP/VAP, cIAI
Wellcome’s proposed solutions
To use collaborative research networks and innovative trial designs to improve clinical trial efficiency

International clinical trial networks

• Improve and strengthen clinical trial capabilities in LMICs
• Provide a system to mitigate inefficiencies in the trial start-up phase and loss of experience at study conclusion
• Increased access to patients with drug-resistant infections

Platform to support continuous master protocol use

• Explore the potential for innovative trial design enabling use of a shared control group
• Creates enhanced efficiencies within a clinical trial network

Independent aspects but greater efficiencies could be realised if implemented jointly
International clinical trial networks
Creating a pilot clinical trial network anchored in SE Asia

• Flexible, scalable regional network of high quality sites
• Building on existing capacity
• Rapid access to Southeast Asian patient populations
• Interoperable with other regional networks
• Business oriented clinical research network
• Support both investigator-initiated and registrational studies
• Identified a nucleus of institutions and sites to work within initial regional network
• Network to launch with an initial trial to test and optimise network and inform scale-up
Benefits of an international clinical trial network

**Sponsors**
- Coordination and standardisation of sites
- Single contact entry point to network
- Facilitate parallel follow-on and optimisation studies
- Reduced costs of conducting trials

**Investigators**
- Access to a larger patient population
- Running of multiple studies simultaneously
- Reduced start-up time and costs
- Support for operational and administrative activities
- Platform to implement innovative trial designs

**Patients**
- Increased speed of treatment and to access drugs
- Potentially cheaper drugs due to reduced development costs
What will the pilot network look like?

**Secretariat responsibilities**
- Network strategy
- Pipeline management
- Regulatory engagement and MA
- Trial design and protocol development
- Site feasibility assessment
- Administration
- Trial performance management

Addition of new sites meeting quality criteria
What will the pilot network look like?

Minimum Viable Model for ICTN

- **Objectives**
  - Lead evidence-based clinical trials on DRI in the region
  - Founder members from institutions and sites in:
    - Singapore
    - Cambodia
    - Myanmar
    - Thailand
    - Laos
    - Nepal
    - Vietnam
    - Indonesia
    - [India]

- **Geography**
  - Preventive
  - Screening/Diagnosis
  - Treatment
  - QOL
  - Health economics

- **Trial type**
  - IIT
  - Company initiated
  - DRI
  - Infectious disease
  - Outside of infectious diseases

- **Disease scope**
  - Min mum

- **Level of centralisation**
  - Min mum

Addition of new sites meeting quality criteria
What will the pilot network look like?

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<td></td>
<td>Finalise governance structure</td>
<td>Develop standardised data management and clinical processes</td>
<td>Implement data management system and standardised processes</td>
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<td>Set up performance tracking mechanisms</td>
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<td>Develop network strategy and regulatory engagement</td>
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<td>Identify pilot study and develop study design</td>
<td>Recruit patients for pilot study</td>
<td>Initiation of pilot study</td>
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Potential challenges of developing an ICTN

- Governance structure and alignment on direction
- Cross border regulatory alignment
- Data management
- Independence of member sites
- Underuse of network between studies
- Funding, finance and sustainability
Innovative trial design
Clinical Trial Networks for Antibiotic Development:
Why they’re important and how they should be developed.

- A continuous disease-specific master protocol offers great potential to accelerate and reduce trial costs and improve the standard of data produced
- Applicable to initial drug registration studies
Continuous master protocols

- Clinical trial networks can be used to explore and test innovation in trial design to further accelerate clinical development
- Use of common control trial design allows for multiple studies to be run with a shared control group and staggered start and enrolment periods

Integration of clinical trial networks and use of common control trial design may introduce **cost savings of at least 30%**
Feasibility of continuous master protocols

- Standing networks can explore and further test additional innovations in clinical trial design
- Master protocols are especially beneficial for large standardised regulatory science studies
- Provide key benefits for supporting adult cUTI and HAP/VAP studies and paediatric studies
Conclusions

• Recent strengthening of pipeline demands a more efficient clinical development process
• Proposed initiatives will provide scientific, financial and developmental benefits
• Access to important population of patients with drug-resistant infections
• Improves the powering of studies and quality of data produced