International Clinical Trial Networks

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Wellcome Trust

Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development

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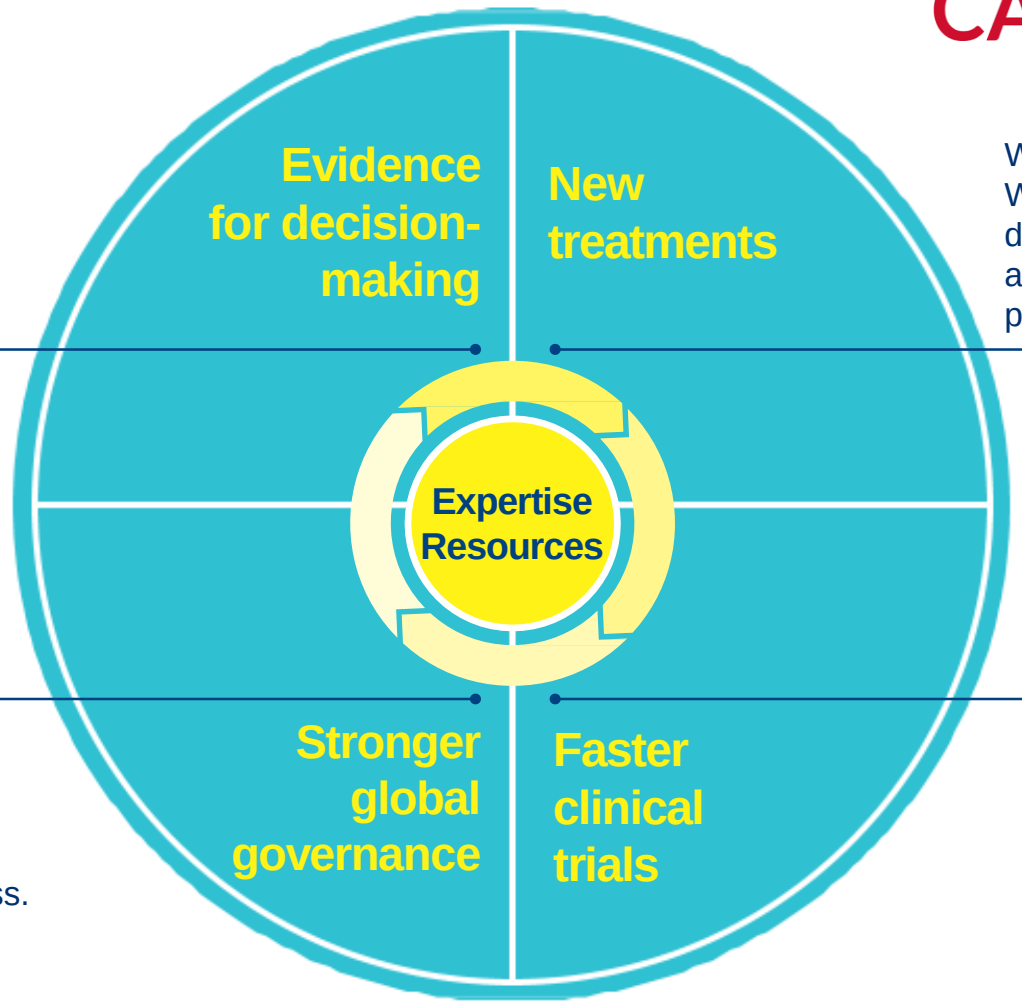
Wellcome is a global charitable foundation, both politically and financially independent

Wellcome's Drug-Resistant Infections Programme

Four pillars of the programme

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



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

Global scope

£175m ($225m) over 5 years

Wellcome is working with policy makers to support the development of a global framework to coordinate, monitor and evaluate progress.
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With partners around the world, Wellcome is building global clinical trial networks to innovate and standardise protocols and make trials more efficient.

Policy and advocacy efforts support the programme in its entirety

The current model of clinical research is inefficient from both a time and cost perspective

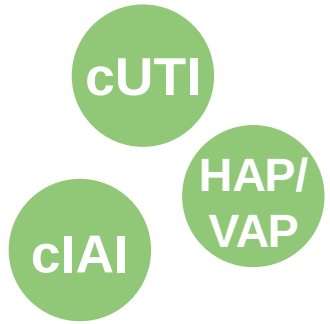
Single use networks of 50–300 sites

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

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

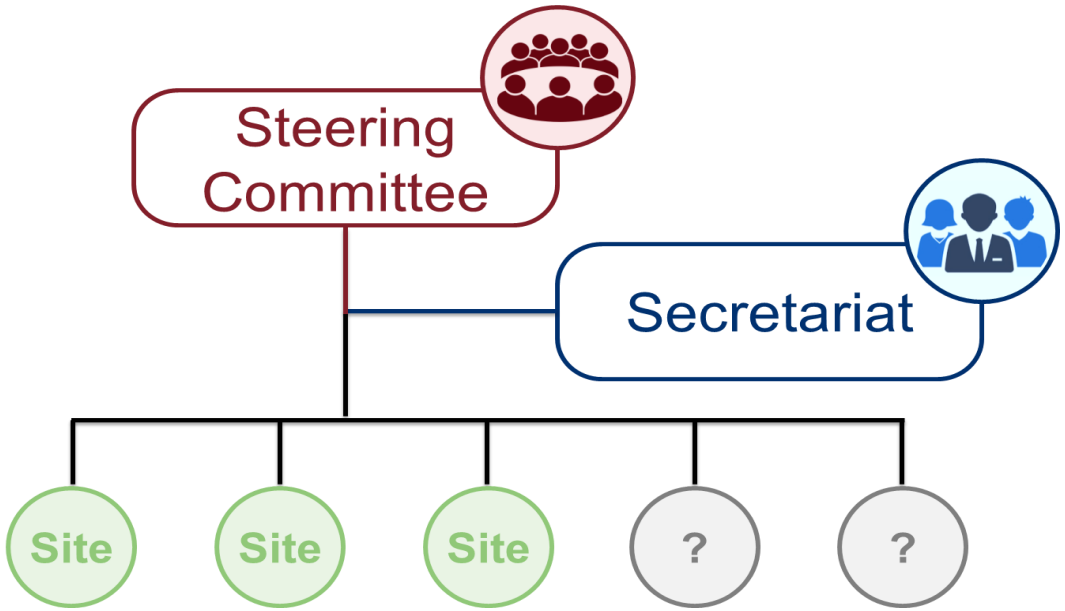
Investigators

- 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?



Addition of new sites meeting quality criteria

Secretariat responsibilities

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

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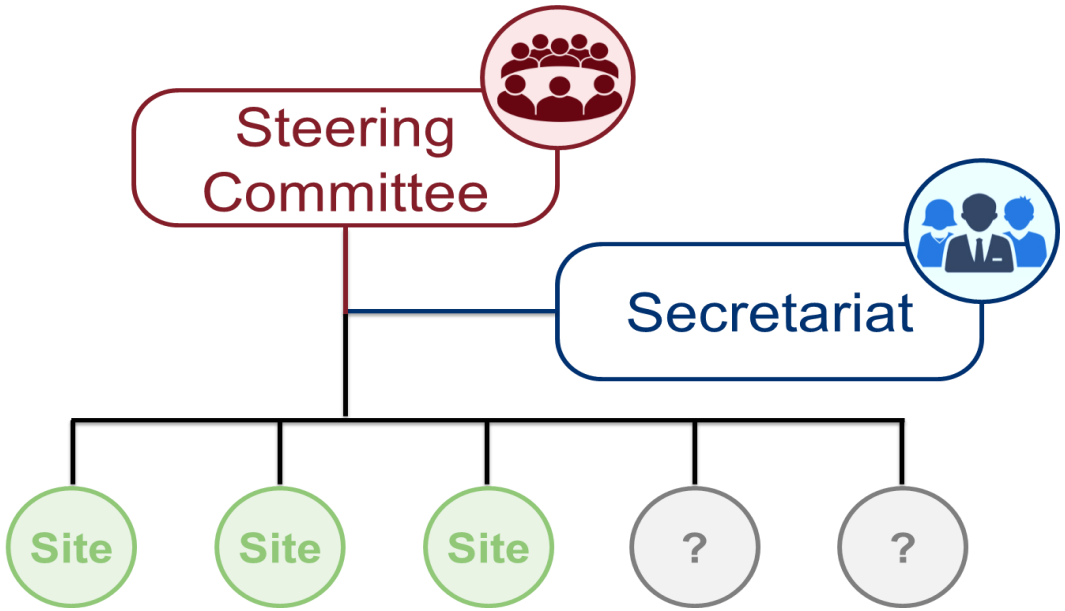

Addition of new sites meeting quality criteria

Minimum Viable Model for ICTN

Objectives	▪ Lead evidence-based clinical trials on DRI in the region
Geography	▪ Founder members from institutions and sites in: – Singapore – Cambodia – Myanmar – Thailand – Laos – Nepal – Vietnam – Indonesia – [India]
Trial type	✓ Preventive ✓ Screening/Diagnosis ✓ Treatment ✓ QOL ✓ Health economics
Trial initiation	✓ IIT ✓ Company initiated
Disease scope	✓ DRI ✓ Infectious disease ✓ Outside of infectious diseases
Level of centralisation	▪ Minimum

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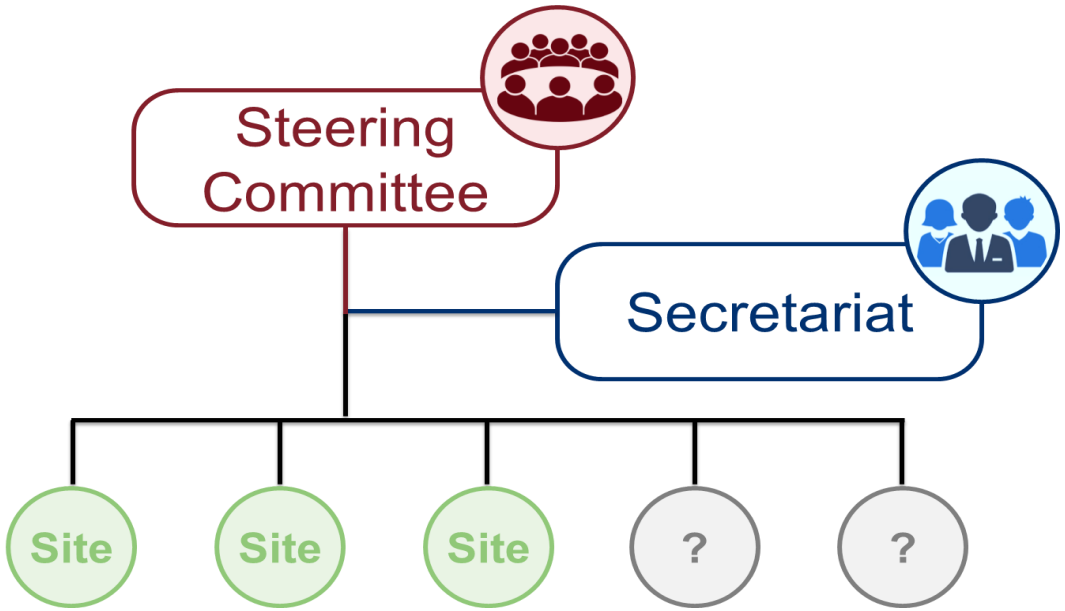

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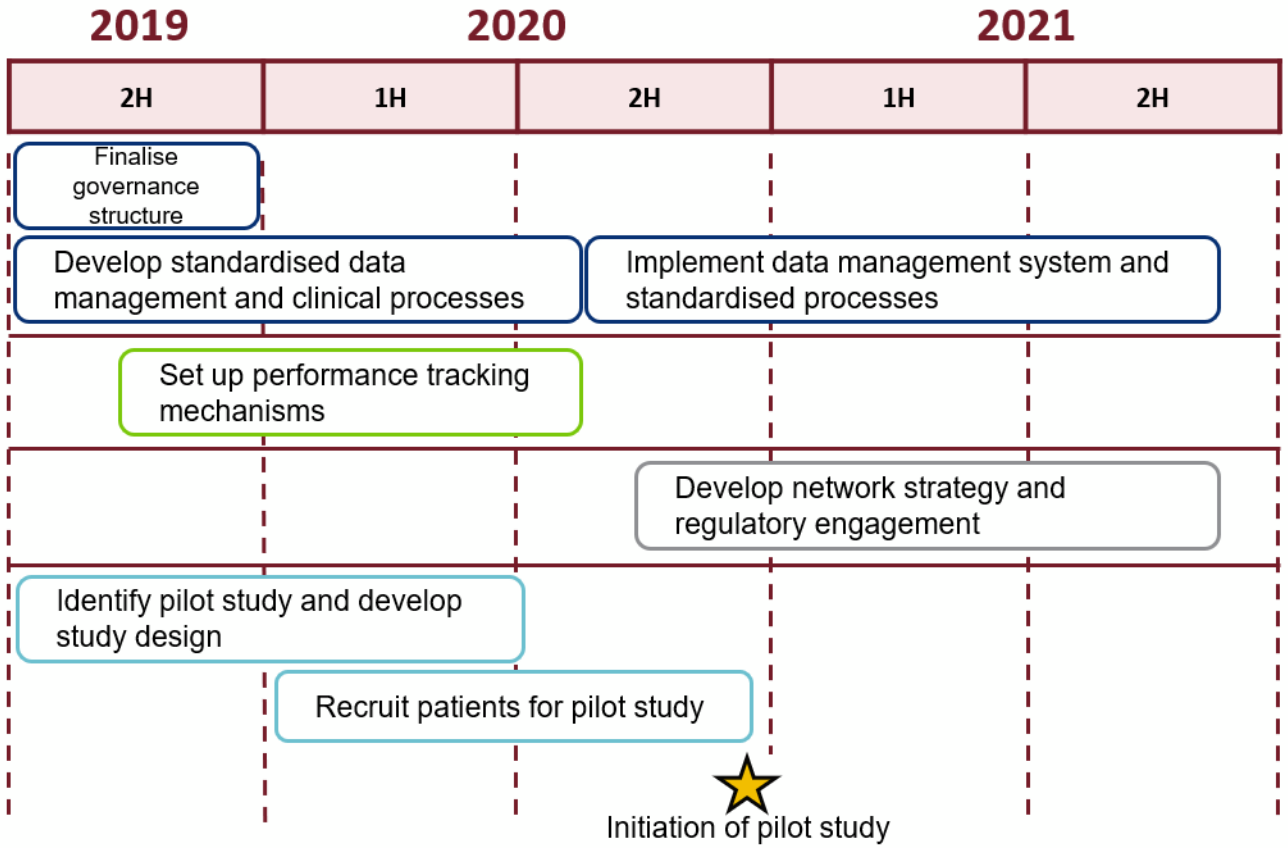


Potential challenges of developing an ICTN

Governance structure and alignment on direction

Cross border regulatory alignment

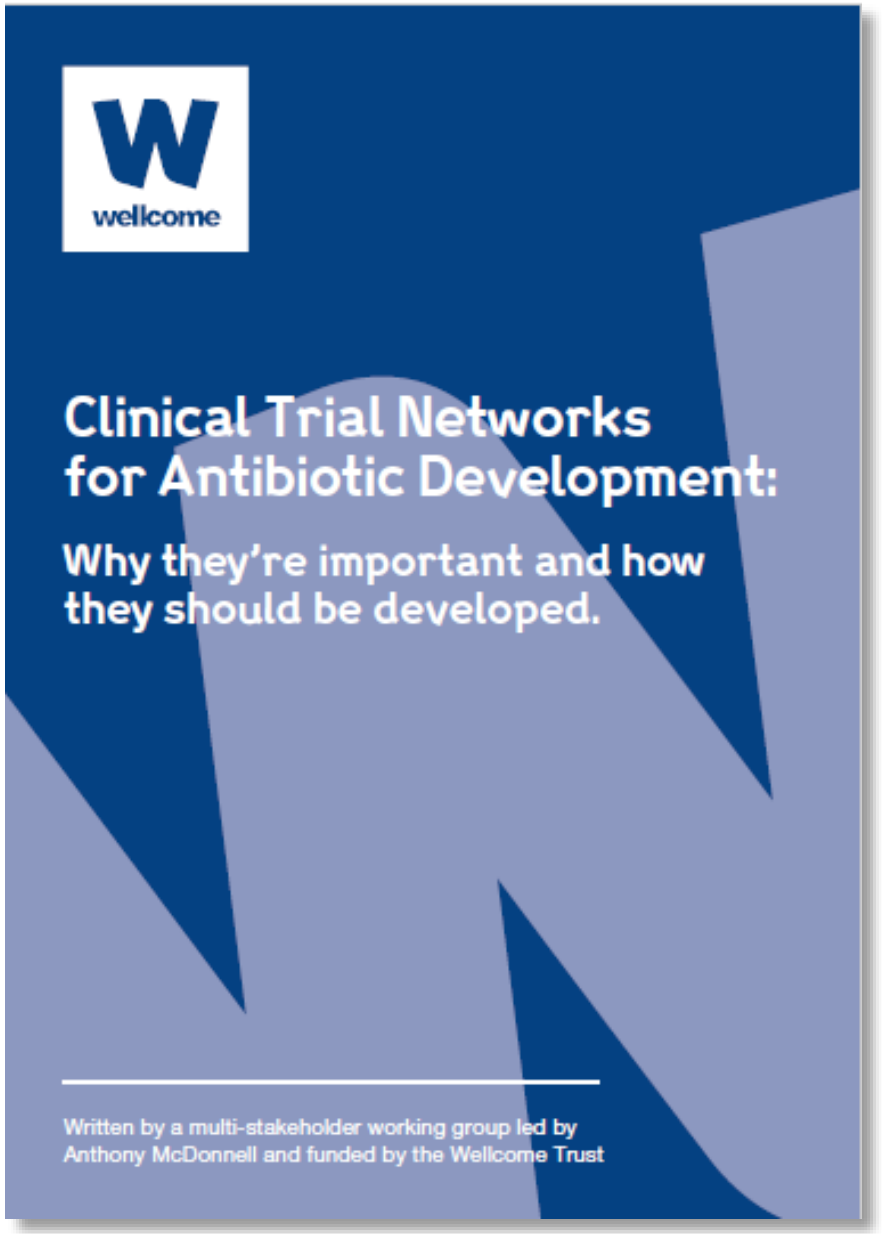
Data management

Independence of member sites

Underuse of network between studies

Funding, finance and sustainability

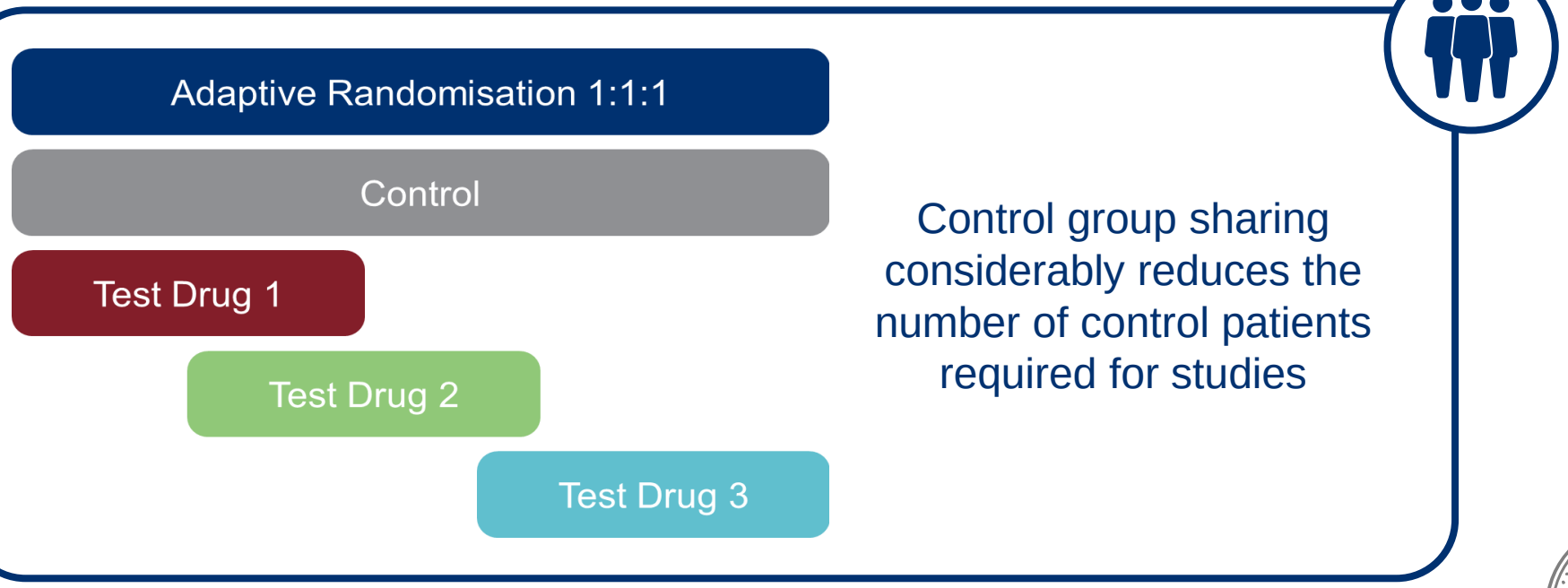
Innovative trial design



- 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

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