There are enough antibiotic patients to sustain a clinical trial network

Estimated number of network-eligible patients by month*

- Complicated Intra-Abdominal Infection (cIAI)
- Complicated Urinary Tract Infection (cUTI)
- Hospital- and Ventilator-Acquired Pneumonia (HAP/VAP)

Number of patients per month

Number of patients required to sustain a permanently running network

FDA estimates of new Phase III trials over the next five years**

- 9 HAP/VAP
- 5 Acute bacterial skin and skin structure includes current trials
- 4 cIAI includes current trials
- 3 cUTI
- 7 Other potential indications

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*Based on our analysis of data on clinicaltrials.gov  
**Based on FDA rough estimates of current and future Phase III trial numbers
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How a network could make clinical trials more efficient

Spend months finding hospitals, signing contracts and creating own grouping of sites

Typically 1/3 hospitals won’t enrol any patients

Trial enrolls patients slowly at the start as hospitals and clinicians get used to the protocol.

Half the patients must be assigned to the control group, meaning that more are required which will increase the cost and time of the trial.

Connection between hospitals disappears

Plug straight into existing network

Network able to enrol patients quickly and reliably as it’s well honed.

By sharing control groups with other trials less patients are needed, reducing time and increasing speed.

Network ready for next trial

*Conceptual graphic not to scale.
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Clinical trial networks will improve the profitability of antibiotics

Financial life cycle of a typical antibiotic

Cumulative cash-flow vs Year

Break even points

C. Scenario B with additional savings from previous control group data

B. Scenario A with additional savings from trial sharing from a Continuous Master Protocols

A. Savings from Globally Connected Trial Sites

Baseline, as estimated by the Review on AMR

The above data was based on analysis published by the Review on Antimicrobial Resistance in the report "Securing New Drugs for Future Generations – the Pipeline of Antibiotics" (2015). In that report the Review showed how an average antibiotic developer spends about 14 years investing money in an antibiotic, before they start to get a return on their investment. At about year 23, a drug breaks even and then at about year 24 after the start of their research, the patent expires and sales revenue level off as the price goes down. Scenario A reflects savings against the base case scenario resulting from a Globally Connected Trial Site Network (this allows a shortening of set up time by a combined 4 months and reduces the cost of Phase II, III and Post Approval trials by 25%). Scenario B builds on scenario A, with a further reduction in trial costs of 25% due to the smaller control trials that would be needed with a Continuous Master Protocol. Scenario C builds on B, with a further reduction in trial costs by 25% owing to the savings that would be possible if clinical trials could use control data from previous trials to replace some contemporary data.
Clinical trial networks will improve the profitability of antibiotics

Financial life cycle of a typical antibiotic

Cumulative cash-flow

-700m -600m -500m -400m -300m -200m -100m 0 100m 200m 300m 400m 500m 600m 700m 0 4 8 12 16 20 24 28 32 $247m $190m $147m $70m

Year

Break even points

C. Scenario B with additional savings from previous control group data

20y 2m

B. Scenario A with additional savings from trial sharing from a Continuous Master Protocols

21y 1m

A. Savings from Globally Connected Trial Sites

21y 10m

Baseline, as estimated by the Review on AMR

23y 6m

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Sharing control groups would have reduced their required size by 62%

This was estimated by assuming that all trials running for a given indication would share a control group the size of the largest currently in use.

Control group saving by indication

- Complicated Intra-Abdominal Infections: 55%
- Hospital- and Ventilator-Acquired Pneumonia: 61%
- Complicated Urinary Tract Infections: 68%

Average: 68%

We included all phase II, III and post-approval trials in the given indications, that could have been tested in a contentious master protocol trial. This means that they were in adults with infections susceptible to first line treatments for the three given indications.
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