

Antibacterial Resistance Leadership Group (ARLG) MASTERMIND Study Proposal

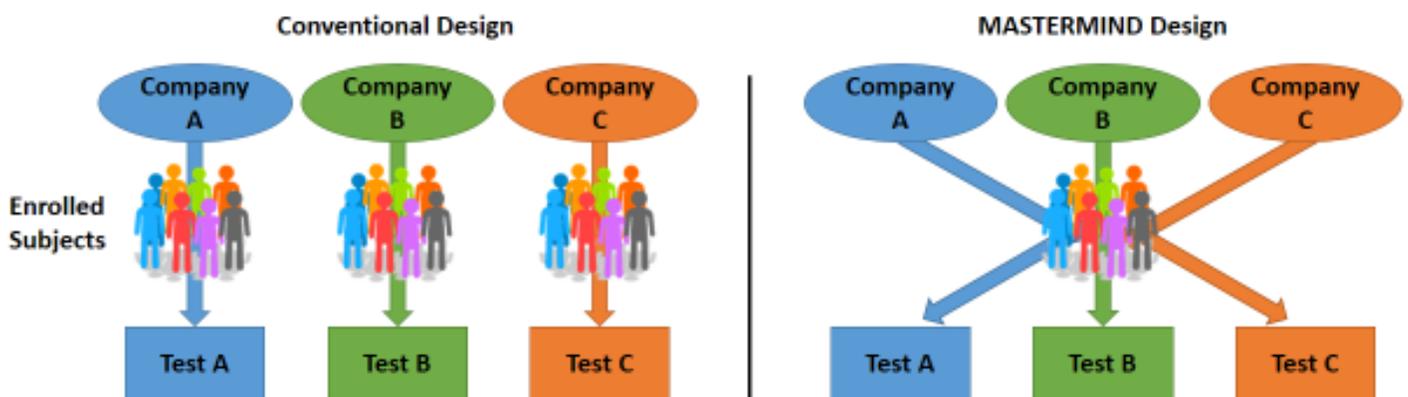
What is a MASTERMIND Study?

New diagnostics are urgently needed to address emerging antimicrobial resistance. The Antibacterial Resistance Leadership Group (ARLG) proposes a strategy called MASTERMIND (MASTER protocol for evaluating Multiple INfection Diagnostics) for advancement of infectious diseases diagnostics. The goal of this strategy is to generate the data necessary to support FDA clearance of new diagnostic tests by promoting research that might not have otherwise been feasible with conventional trial designs. MASTERMIND uses a single subject's sample(s) to evaluate multiple diagnostic tests at the same time, providing efficiencies of specimen collection and characterization. It also overcomes many of the monetary and logistical hurdles associated with clinical trials of new diagnostics¹. ARLG is bringing together infectious disease physicians, clinical microbiologists, statisticians, and diagnostic companies who are potentially interested in collaborating on MASTERMIND studies for specific diagnostic tests.

Targeted Diagnostics for a MASTERMIND Study:

- Bacterial bloodstream infection
- Bacterial urinary tract infection

What does a MASTERMIND Study look like¹?



Next Steps:

The purpose of this letter is to introduce the MASTERMIND concept and identify potential partners for a study focusing on bacterial bloodstream infection or bacterial urinary tract infection. ARLG will work in partnership with selected companies to plan study logistics and study initiation will begin once ARLG funding is available or through a cost sharing plan with industry partners. Ideally, the proposed study would serve as a pivotal, registrational study to support an application for FDA clearance. However, a

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test earlier in development that would still benefit from such a clinical study may also be considered.

Tests relevant to bloodstream infection include the following:

- Direct-from-blood pathogen detection
- Direct-from-blood antimicrobial susceptibility testing
- Rapid pathogen identification from positive blood culture bottles
- Rapid susceptibility testing from positive blood culture bottles
- Rapid blood culture

Tests relevant to urinary tract infection include the following:

- Rapid detection of the presence of infection
- Rapid differentiation of urinary tract infection from asymptomatic bacteriuria
- Direct-from-urine pathogen identification
- Direct-from-urine antimicrobial susceptibility testing

Benefits of involvement in an ARLG-sponsored MASTERMIND study include the following:

- Access to nationally renowned expertise (microbiology, infectious diseases, statistics, regulatory affairs)
- Access to an international network of clinical sites, coordinated by the Duke Clinical Research Institute (DCRI)
- Study costs may be defrayed by cost-sharing, involving multiple industry participants and the ARLG
- ARLG-managed coordination among participants
- Engagement with FDA throughout study planning and execution
- Full and complete access to study data pertaining to your test platform upon study completion

To learn more or discuss participation in a MASTERMIND study please contact:

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Reference:

1. Patel, R., Tsalik, E.L., Petzold, E., Fowler, V., Klausner, J.D. and Evans, S. MASTERMIND – Bringing Microbial Diagnostics to the Clinic. *Clin Infect Dis*. 2016, doi: 10.1093/cid/ciw788. Published by Oxford University Press.