August 2022 Q3 Newsletter

Welcome to the ARLG Newsletter! Here, you will receive important updates from ARLG regarding recent events, grants, publications, and the committees that help us work toward our mission: to prioritize, design, and execute clinical research that will impact the prevention, diagnosis, and treatment of infections caused by antibiotic-resistant bacteria.

Get Involved with ARLG

ARLG continuously accepts proposals for clinical studies designed to prevent, diagnose, treat, or eradicate antibiotic-resistant bacterial pathogens. We also award grants and fellowships to qualified investigators. If you are interested in getting involved with ARLG, apply now or contact us for more information.

Submit a Proposal

Contact Us

ARLG DOOR Turns Data Into Knowledge Opens Opportunities to Improve Patient Treatment Plans

For doctors, the most important "real world" application of clinical trial data is to determine which therapeutic option is best for each patient. However, since randomized trial outcomes do not provide a clear way to review and compare data on patient-reported experiences, they often fail to provide the necessary evidence to inform day-to-day medical decision-making.



ARLG's Desirability of Outcome Ranking (DOOR) is a novel paradigm for the design, analysis, and interpretation of clinical trials that allows doctors to create better treatment strategies by giving them a way to review data and compare the risks and benefits of different interventional options. Doctors can then discuss the pros and cons for each option and tailor the strategy to fit the patient.



Scott Evans, PhD

Scott Evans, PhD, developed this innovative paradigm with support from members of ARLG's Statistical and Data Management Center (SDMC) Toshimitsu (Toshi) Hamasaki, Lauren Komarow, and Carol Hill. The goal of DOOR is to give doctors and researchers a method for informed therapeutic selection based on a comprehensive patient-centric benefit-risk evaluation. Researchers can apply DOOR's paradigm to the design, data monitoring, and analyses of any clinical trial or observational study to evaluate the patient experience and guide therapeutic decision-making.

DOOR helps improve the real world applications of clinical trial data by correcting the usual arithmetic of analyzing outcomes separately. Instead of using patients to analyze outcomes, DOOR uses outcomes to analyze patient experiences.

DOOR bases therapeutic evaluations on a comprehensive assessment of patient-centric benefits and harms, which helps doctors address the most important clinical questions on the comparative value of interventions as they pertain to specific patients.

By providing a way to transcend this obstacle, DOOR advances the goal for more research studies yielding practical data doctors and patients can use to answer real world questions.

Read more

ARLG Spotlight: Keri Baum and the Diversity, Equity, and Inclusion Working Group

Keri Baum Clinical Trials Project Leader II Duke Clinical Research Institute (DCRI)

About my role in the ARLG DEI Working Group

I am a clinical trial leader who also supports the ARLG Diversity, Equity, and Inclusion (DEI) Working Group. My role in the working group is



to implement efforts that fulfill our operational goal to facilitate the inclusion of underrepresented minorities in our research studies. We also seek the inclusion of diverse representation across the ARLG and the clinical trial teams we partner with.

In my role as an operational representative, I work to reinforce the importance of ethical clinical research practices in all stages of the project lifecycle, from planning to execution, participate in literature reviews, and develop and implement tools to be used at the operational level.

What is the ARLG DEI Working Group and what is its primary goal?

The Diversity, Equity and Inclusion Working Group is part of the ARLG Scientific Leadership Core (SLC). It was created to develop a framework to ensure implementation and full integration of principles of DEI throughout the Antibacterial Resistance Leadership Group.

Why is this work important?

It is imperative that we make every effort to ensure that the data from current and future clinical trials is generalizable and an accurate reflection of the population that will benefit most from our studies. Knowing more about the people affected by AR advances the scientific validity and enriches the social and clinical importance of what we do.

What do you like best about participating in the DEI working group?

This work has given me the opportunity to explore new ways to approach the systemic problem of underrepresentation at every level of research. Moreover, the information I have learned during my participation doesn't stop at the research level. This acumen is applicable to many aspects of diversity, equity, and inclusion within our larger society.

Read More

PFID Features Tori Kinamon in Faces of AMR Series



In June, the Partnership to Fight Infectious Disease (PFID) featured a profile of ARLG fellow Tori Kinamon whose journey surviving a methicillin-resistant Staphylococcus aureus (MRSA) infection inspired her to pursue a career as an infectious diseases physician and researcher.

Today, Tori is an MD Candidate at the <u>Duke University</u> <u>School of Medicine</u> and a recipient of the <u>FDA</u> <u>Antibacterial Drug Resistance (DOOR) Fellowship</u>. Her

profile is part of PFID's <u>Faces of AMR</u> series, which strives to raise awareness of antimicrobial resistance (AMR) by sharing stories of people who have battled this public health threat.

Read more

New Infographic for ARLG DOOR Now Available!

A new infographic is now available to help simplify ARLG's Desirability of Outcome Ranking (DOOR), an innovative method to help doctors and researchers design, analyze, and interpret clinical trials. They can use this information to compare the risks and benefits of different treatment options and create better strategies customized to fit their patients.

The infographic, which was created by Helen Boucher, MD, FACP, FIDSA, and Jessica Howard-Anderson, MD, MSc, helps to show how DOOR uses ordinal categories to classify clinical outcomes while taking harms and benefits into account. This yields a more informative and pragmatic benefit-risk evaluation.

DOOR was developed by Scott Evans, PhD, with support from members of ARLG's Statistical and Data Management Center (SDMC). It is being used in several current studies as well as many completed studies including CRACKLE I, PROVIDE, and SCOUT-CAP.



Read More

Events

IDWeek 2022 Registration and Late Breaker Abstract Submission Deadline

Get ready! IDWeek 2022 will take place October 19-23 in Washington, D.C. and online. The event will feature 140 scientific sessions on a variety of interesting topics. Registration is currently open for upcoming in-person and virtual events.

Don't forget to submit your late breaker abstract **before the August 17 deadline**.



Learn more

ARLG Grand Rounds 2022

Tune in for ARLG's 2022 upcoming Grand Round Series. This year will feature an exciting variety of speakers and topics. Don't miss the next event:

Date Topic Speaker

August 5, 2022 ARLG FAST Trial

Ritu Banerjee, MD, PhD Professor, Pediatric Infectious Diseases Director, Antibiotic Stewardship Program Vanderbilt University Medical Center You can check out ARLG's event page for ongoing updates about each session and how to attend.

Learn more



Study Milestones

View recent ARLG study updates.

RADICAL-3

Rapid Diagnostic
in Categorizing Acute
Lung Infections

Study Design

REPORT-ABC

Rapid REPORTing of Antimicrobial resistance from Blood Cultures Analysis Complete Manuscript in Progress

CRACKLE II

Consortium on
Resistance against
Carbapenems in *Klebsiella*pneumonia and other
Enterobacteriaceae

Lay Summary of Results

DICON I

Refers to the Duke Infection CONtrol Network which provides access to the community hospitals doing research

Lay Summary of Results

Go to the ARLG Studies page for more milestones and updates!

Learn More



Recent Publications

View the following recent ARLG publications.

Howard-Anderson J, Dai W, Yahav D, Hamasaki T, Turjeman A, Koppel F, Franceschini E, Hill C, Sund Z, Chambers HF, Fowler VG Jr., Boucher HW, Evans SR, Paul M, Holland TL, Doernberg SB; on behalf of the Antibacterial Resistance Leadership Group. A Desirability of Outcome Ranking (DOOR) Analysis of a Randomized Clinical Trial Comparing Seven Versus Fourteen Days of Antibiotics for Uncomplicated Gram-Negative Bloodstream Infection. Open Forum Infect Dis. 2022. ofac140, https://doi.org/10.1093/ofid/ofac140.

Patel R, Polage CR, Dien Bard J, May L, Lee F, Fabre V, Hayden MK, Doernberg SDB, Haake DA, Trautner BW, Grigoryan L, Tsalik EL, Hanson KE; on behalf of the Antibacterial Resistance Leadership Group and the Infectious Diseases Society of America. Envisioning Future Urinary Tract Infection Diagnostics. Clin Infect Dis. 2022 Apr 9;74(7):1284-1292. doi: 10.1093/cid/ciab749.

Jacobs JL, Bain W, Naqvi A, Staines B, Castanha PMS, Yang H, Boltz VF, Barratt-Boyes S, Marques ETA, Mitchell SL, Methe B, Olonisakin TF, Haidar G, Burke TW, Petzold E, Denny T, Woods CW, McVerry BJ, Lee JS, Watkins SC, St. Croix CM, Morris A, Kearney MF, Ladinsky MS, Bjorkman PJ, Kitsios GD, Mellors JW. Severe Acute Respiratory Syndrome Coronavirus 2 Viremia Is Associated With Coronavirus Disease 2019 Severity and Predicts Clinical Outcomes. Clin Infect Dis. 2022 May 3;74(9):1525-1533. doi: 10.1093/cid/ciab686.

Nordstrom HR, Evans DR, Finney AG, Westbrook KJ, Zamora PF, Iovleva A, Yassin MH, Bomberger JM, Shields RK, Doi Y, Van Tyne D. Genomic and functional characterization of Pseudomonas aeruginosa-targeting bacteriophages isolated from hospital wastewater. iScience. 2022 May 10;25(6):104372. doi: 10.1016/j.isci.2022.104372. eCollection 2022 Jun 17.

Turner NA, Zaharoff S, King H, Evans S, Hamasaki T, Lodise T, Riccobene T, Patel R, Doernberg SB, Ghazaryan V, Beresnev T, Fowler VG Jr, Holland TL; on behalf of the Antibacterial Resistance Leadership Group. Dalbavancin as an Option for Treatment of S.

aureus Bacteremia (DOTS): Study Protocol for a Phase 2b, Multicenter, Randomized, Open-label Clinical Trials. 2022 May 16;23(1):407. doi:10.1186/s13063-022-06370-1.

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