The Importance of Diversity in Clinical Trials

By Esther Kwarteng

The primary purpose of clinical trials is to determine the safety and efficacy of medical treatments in the human body. The manifestation of disease, its progression, and the character of treatment may all present uniquely in subsets of the population, including those based on age, gender, racial and ethnic groups, lifestyle, and environment. Group underrepresentation in clinical trials can therefore result in the development of treatments that influence health disparities and inequalities across the United States.

In November 2020, the United States Food and Drug Administration (FDA) published a course of action outlining the various methods of enhancing diversity in clinical trial populations, by means of altering eligibility criteria, enrollment practices, and trial designs. The FDA recommends establishing eligibility criteria that encompass the population(s) for which the drug is designed, resulting in a representative sample. To broaden enrollment practices, the FDA suggests enrollment of participants who reflect clinically relevant populations, including but not limited to women, children and adolescents, older adult populations, and racial and ethnic minorities. Additionally, the FDA endorses the adaptation of practices to augment inclusiveness—such as working directly with communities to address their needs, implementing electronic communication, using mobile medical professionals, and promoting representation across all subgroups.¹

With the application of the FDA guidelines, stronger efforts can be made to combat not only the matter in question, but the larger predicament at hand—health disparities. Recognizing the inequality deeply rooted in this underrepresentation is important for the progression and potency of clinical trials for all people. Overcoming this impediment is a step toward health equity, essential to the advancement of medicine.

Letter from the Editor

Scientific progress benefits from having multiple ways to think about a problem. The way a person thinks stems from societal experiences in life—a cognitive model. Right now, in science, there isn’t an equal representation of cognitive models. Some groups are underrepresented within study populations and also amongst researchers. This absence limits the opportunities and directions for scientific progress. Over the next two months, we will highlight the efforts of underrepresented groups in science—not only at the bench, but in the clinical space too.

In medicine, when populations are underrepresented in studies and clinical trials, we hamper data collection for the population at large. This leads to unequal health outcomes. For our feature article this month, postbac Esther Kwarteng writes about the recently published FDA course of action for enhancing diversity in clinical trial populations.

Next month, we will continue with additional articles in support of underrepresented groups in science.

The rest of this issue includes information about giving virtual scientific talks—a much needed skill during this time—and an introduction to our new Institutes and Centers (IC) representative, Dr. Lauren Walling. In addition, many new announcements and events can be found within!

Your Editor in Chief,
Shana R. Spindler, PhD

Please send questions and comments to our editor at shana.spindler@nih.gov.
Recap: Components for (Virtually) Any Presentation
By Paul Elizalde

The COVID-19 pandemic has made in-person gatherings prohibitive for the past few months, and, even with vaccines available, will continue to prevent people from gathering for at least several more months. Because of this, we should be prepared to talk about our science (presentations, interviews, meetings, etc.) in a virtual setting—something that Mr. Scott Morgan, science communication consultant and director of The Scott Morgan Group, knows a lot about.

A frequent presenter at NICHD, Mr. Morgan offered a workshop entitled “Speaking (Virtually) About Science,” on December 2, 2020. He began by reviewing relevant tips for virtual interviewing, including employing side and front lighting, having a professional background, being enthusiastic, wearing bright colors, and using a “speakerphone voice.” Repetition, summaries, lighting, and enthusiasm are especially important in a virtual setting.

Mr. Morgan next stressed that—apart from unintended outbursts from unmuted participants—you will probably get very little feedback from a virtual audience (some might even have their cameras off). It is important for you to bring even more personal and vocal energy to your presentation to keep your audience engaged.

Visuals are important. Mr. Morgan emphasized the use of animations to keep your audience interested and spoon feeding your story through transitions. Cartoons and schematics can provide helpful illustrations. They are also useful reminders for your audience when you include them in multiple relevant slides so that viewers can reorient if they miss something.

Despite the drawbacks of virtual presentations, such as a lack of audience feedback, one benefit is that you can have all the notes you want (if they are not visible to your audience). Post-its and index cards around the edges of your computer can serve as prompts to control the rate and flow of information. Remember that you are central to your presentation—“an ambassador/spokesperson for your research.”

Mr. Morgan, an excellent presenter with a wealth of experience, ended his talk by exhorting his audience to “always end early.” I highly recommend attending his workshops in the future.

TIPS FOR VIRTUAL TALKS
1. Use lighting from front/side, not from the top or behind.
2. Use a headphone and microphone with your “speakerphone voice.”
3. Sit in front of a simple, professional background (no windows!).
4. Don’t use swivel chairs.
5. Wear bright colors and layer clothing.
6. Own your project.
7. Remember that the camera is a presence barometer (your audience can tell when you lose focus)—stay engaged.
8. Use notes.
9. Repeat, summarize, and keep your audience engaged!
10. End your talk early.
Meet Dr. Lauren Walling, Our New Basic Science Postdoc Rep

Our basic science representative is a postdoctoral fellow who serves on the NIH Fellows Committee (FelCom) on behalf of the institute's fellow population. Representative appointments last for 12 months and can be renewed for an additional year.

Responsibilities of the institute's representative include attending all scheduled FelCom meetings, participating on a subcommittee, disseminating information to the fellows in their institute, communicating fellows' concerns to the committee, and coordinating the distribution of information via subcommittees. In NICHD, our representatives also work closely with the Office of Education to plan events for all NICHD postdoctoral trainees.

If you would like more information about serving as a basic science or clinical postdoctoral representative, please contact Dr. Erin Walsh (erin.walsh@nih.gov) and for information about serving on a FelCom subcommittee, contact one of the committee chairs directly.

INTRODUCING LAUREN WALLING, PhD

I grew up in Syracuse, New York and graduated from Cornell University with a degree in biology. During my time at Cornell, I was very involved in undergraduate research in a microbiology lab, which inspired me to join the Microbiology and Immunology department at the University of Rochester for my PhD research. I completed my thesis work in the lab of Dr. Scott Butler, studying bacterial toxin-antitoxin systems. In 2018, I joined the lab of Dr. Gisela Storz here at NICHD to conduct my postdoctoral research on bacterial gene regulation by small RNAs in response to environmental stress. Apart from research, I am also passionate about training and mentoring young scientists and making science accessible to the community through public outreach.

In my free time, I volunteer with Guiding Eyes for the Blind to train future guide dogs and teach dog training classes for their volunteer puppy raisers in Montgomery County and DC. I also love any excuse to get outdoors—hiking, camping, sailing, or scuba diving.

I am very excited to serve as the basic science representative for NICHD to support our wonderful community of trainees. I hope that many of you will participate in the NICHD Fellows Advisory Committee, which is a great place to suggest new training or career development opportunities and voice any concerns you may have. Additionally, you can always reach out to me with any ideas or concerns; my email is lauren.walling@nih.gov.
February Announcements

DR. AISHA BURTON OKALA MAKES 1000 INSPIRING BLACK SCIENTISTS IN AMERICA LIST

Congratulations to Aisha Burton Okala, PhD, for being named one of 1000 inspiring black scientists in America, featured on the Cell Mentor website. Dr. Burton Okala is a postdoctoral fellow in the laboratory of Dr. Gisela “Gigi” Storz, where she studies the regulatory roles of small proteins on two component systems in E. coli. Following her postdoc, Dr. Burton Okala hopes to join the ranks of academia as a professor—and from the looks of it, she is well on her way!

THREE-MINUTE TALKS (TmT) COMPETITION DEADLINE TO ENTER: FEBRUARY 8

Don't miss your opportunity to enter the 2021 TmT Competition!

» Learn how to explain your research effectively to a broad scientific audience, in three minutes or less, with one-on-one professional training from public speaking coach Scott Morgan.

» Get the chance to win up to $1,000 for use towards approved training or scientific conference participation.

To enter, complete the submission form by Monday, February 8. The submission form, competition rules, and judging criteria are available at the NICHD TmT Webpage. Up to 10 DIR fellows (postbac, predoctoral, postdoctoral, visiting and clinical) are invited to compete for these science communication honors.

MANDATORY TRAINING FOR ALL TRAINEES: YOUR RIGHTS AND RESPONSIBILITIES AS AN NIH TRAINEE

OITE will provide a virtual mandatory training for all trainees (IRTAs and Visiting Fellows) regarding your rights and responsibilities as a trainee, especially around new policies at the NIH. The goal of this session is to provide you with information to make sure that you are safe while at the NIH, and that you know the policies and resources to set yourself up for personal and career success.

Research Fellows and Clinical Fellows are encouraged, but not required, to attend.

*Participation is tracked by the NICHD Office of Education.*

If you have successfully completed this training in the past (it was offered virtually on Nov–Dec of 2020), you do not need to attend again. This is only for trainees who have never taken the training or have not successfully completed it. We will offer this session monthly.

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MANDATORY TRAINING FOR ALL TRAINEES: YOUR RIGHTS AND RESPONSIBILITIES AS AN NIH TRAINEE, CONTINUED

See below for dates/times. Please register using your NIH email. Non-NIH email registrations will be deleted. You only need to attend one session.

» February 10, 2021, 10:00–11:00 a.m.
   Registration: https://nih.zoomgov.com/webinar/register/WN_YtU8qoTvTwOowd_CnPsb1w

» March 23, 2021, 10:00–11:00 a.m.
   Registration: https://nih.zoomgov.com/webinar/register/WN_Idem9zCeTCerjlfLOKYT_A

NIH GRANT WRITING COURSE

Are you planning to apply for a NIH research grant in 2021? There are various application due dates for NIH grants, and we are offering a virtual grant writing course that’s just for you!

In collaboration with three other institutes, we are offering an NIH Grant Writing Course for fellows this April and May. Led by Dr. Paula Gregory (Professor, Department of Genetics, Louisiana State University), this course will help students prepare a successful NIH grant proposal, with special emphasis on the career transition “K” grant series. With high reviews from past participants, NHGRI has offered this course for several years, and as a result, many of their fellows have been awarded NIH grants!

The classes will combine didactic presentations with group discussions, assignments, and proposal writing. A distance-learning component will allow you to submit writings between the virtual meetings and receive edits and valuable feedback. Participants will also conduct an NIH mock study section. During the process of scoring real grant applications, trainees will learn about the review process and the key aspects of a successful application.

Below is the schedule for this on-campus course (must attend all sessions):

» April 15: 1 p.m.–4 p.m.    » April 23: 9 a.m.–12 noon
» April 16: 9 a.m.–12 noon   » May 6: 1 p.m.–4 p.m.
» April 22: 11 a.m.–4 p.m.   » May 7: 9 a.m.–12 noon

There are four spots available for NICHD fellows. If you would like to join this course, please email Dr. Erin Walsh (erin.walsh@nih.gov) and indicate which NIH grant you are planning to apply for.

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NIH IPPCR COURSE ONLINE: REGISTRATION STILL OPEN
Interested in expanding your clinical research knowledge base in 2021? Registration for the 2020–2021 NIH Introduction to the Principles and Practice of Clinical Research (IPPCR) course is still open!

This free, self-paced, online course is open for registration until July 1, 2021. Graduate students, clinical fellows and post-doctoral fellows are encouraged to enroll now.

The IPPCR course is a lecture series from thought-leaders around the world covering:
- Study designs, measurement, and statistics
- Ethical, legal, monitoring, and regulatory considerations
- Preparation and implementation of clinical studies
- Communication of research findings and other topics

To register, please visit the IPPCR website at https://ocr.od.nih.gov/courses/ippcr.html. If you have any questions, please contact Rebecca Hwang at ippcr2@mail.nih.gov.

NIH PCP COURSE ONLINE: REGISTRATION STILL OPEN
Registration is still open for the 2020-2021 NIH Principles of Clinical Pharmacology (PCP) Course!

The PCP course is a free online lecture series covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. Topics covered in the course include pharmacokinetics, drug therapy in special populations, drug discovery and development, and pharmacogenomics.

The course is free, self-paced, and entirely online through the PCP website: https://ocr.od.nih.gov/courses/principles-clinical-pharmacology.html.

A certificate of completion is awarded to participants who achieve a passing score on the final exam.

The course will be of interest to graduate students, post-doctoral fellows, and clinical fellows interested in expanding their pharmacology knowledge base.

For additional information on the course, please visit the website above or contact Rebecca Hwang at odpcp@mail.nih.gov.

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NICHD ANNUAL POSTBAC COURSE: PROFESSIONAL DEVELOPMENT AND CAREER EXPLORATION
Our Annual Postbac Course launched on Wednesday, January 13, but it’s not too late to join our group!

Currently there are over 100 postbacs conducting clinical and basic science research in our intramural laboratories. During your one or two years of training here at the NICHD, we want you to have an enriched research experience, while at the same time growing more prepared and excited about your chosen career path.

The year’s course will be entirely virtual and will be held on Wednesdays, from 1 to 2 p.m. The intent is to create a comfortable environment within a small group of peers to help postbacs improve their analytical skills as scientists, while expanding their knowledge of biomedical research and its relevance to human health. This course also focuses on professional development: learning how to present your science, exploring different career trajectories, meeting physicians and scientists from various clinical or research settings, and preparing for the medical or graduate school application cycle (including interviews!).

You’ll hear from a senior NICHD postdoc; a panel of physicians will share their personal and professional experiences in practicing as a pediatrician; and there will be a “Meet the Scientist” series where scientist in clinical, basic science, and industry laboratories will share their career journeys.

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**NICHD ANNUAL POSTBAC COURSE, CONTINUED**

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<td>Journal Club Session: Cloning a Gene—How to, and Practical Applications</td>
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<tr>
<td>To Be Announced</td>
<td>The Graduate School Personal Statement</td>
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Stay-tuned for the final schedule, which will be announced by email soon.

**Enrollment in this course will be limited to 25 students to allow maximum participation and interaction with the instructors.** At the end of the course, we will offer a certificate of recognition for all postbacs who attend at least seven sessions.

If you are interested in joining the class, please email Monica Cooper (*cooperm@mail.nih.gov*) to register, and let her know which sessions you plan to attend.

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INTERESTED IN CONDUCTING A LITERATURE REVIEW?
There are many types of reviews—narrative, rapid, scoping, and systematic—all with different methodologies to use. The NIH Library’s Systematic Review Service can help you select the best type of review and methodology to use for your research. We offer software, classes, consultations, and resources to guide you through the entire process.

New at the NIH Library: Covidence Software
The NIH Library now offers Covidence, an online tool for managing and streamlining your systematic review. Covidence can help you screen and administer citations, conduct data extraction, and perform critical appraisal. Contact Alicia Livinski, alicia.livinski@nih.gov, to request access and for assistance with using Covidence.

Classes
The NIH Library is offering a series of one-hour webinars on systematic reviews. The February calendar of classes on systematic reviews may be found on the NIH Library website.

Consultations
NIH Librarians are available to help you select the appropriate type of review for your needs, and then identify and complete the steps of your review, conduct the literature search, and edit the final manuscript. Schedule a consultation to get started today.

Databases
The NIH Library provides access to the three primary databases used for most systematic reviews, and others are sometimes necessary. Talk to a NIH Librarian to learn more about each database, including relevant search functions.

Cochrane Library
Contains high-quality, independent evidence to inform health care decision-making, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials (CENTRAL), a curated registry of randomized and quasi-randomized controlled trials conducted worldwide.

Embase
Allows users to build comprehensive literature searches through its extensive, deeply indexed database and flexible search options. By applying the PICO (Patient or Problem; Intervention; Comparison or Control; and Outcome) framework, users can structure searches that address clinical questions.

PubMed/MEDLINE
Features advanced search functions and filters to find literature for your systematic review.

To stay up to date on NIH Library classes, events, resources, and services, subscribe to our e-news.
February Events

WEDNESDAY, FEBRUARY 10, 1–2PM
Annual Postbac Course: “Meet the Scientist: Basic Science Research”
*Gisela Storz, PhD & Matthias Machner, PhD*

If you are interested in joining the class, please email Monica Cooper at cooperm@mail.nih.gov.

THURSDAY, FEBRUARY 11
Three-Minute Talks (TmT) Competition: “Speaking About Science” Workshop
*Scott Morgan*

Join us to learn about:
» Scientific storytelling with only one slide
» Speaking in plain language while addressing the human health relevance for your research
» Creating effective visual aids

The deadline to enter the 2021 TmT Competition is **Monday, February 8**. Please visit the [NICHD TmT Webpage](#) for submission forms and more information.

WEDNESDAY, FEBRUARY 17, 12–1PM
Annual Postbac Course: “Meet the Physician”
*Physician Panel*

*Please note that this session will begin at 12 noon*

If you are interested in joining the class, please email Monica Cooper at cooperm@mail.nih.gov.

ONGOING EVENTS AROUND CAMPUS

NIH-Wide Office of Intramural Training and Education (OITE) Events
For more information and registration, please visit [Upcoming OITE Events](#).

NIH Library Training and Events
For more information and registration, please visit the [NIH Library Calendar](#).