If you have ever taken a pill, received a childhood vaccine, taken a spoonful of cough syrup, or received any of the thousands of other benefits of modern medicine, then you have been on the receiving end of a clinical trial. Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. Nearly every man, woman, and child alive today has received a medical intervention that at some point was the subject of a clinical trial. More than 4000 experimental drug therapies are active today, and that number will continue to increase. Millions of Americans depend on medications, which is why researchers are devoted to exploring the best treatments available.

It is also why I chose to devote this issue of the AMWA Journal to clinical trials. Clinical trials are just one type of research that’s done before a new treatment becomes available to people. New medicines must first be discovered, purified, and tested in pre-clinical trials before researchers even consider clinical trials. According to the American Cancer Society, about 1000 potential medicines are tested before one makes it to clinical trials. On average, a new medicine to treat cancer has been studied in the laboratory for at least 6 years (and sometimes many more) before the first clinical trial is started.

One of the final stages of a long and careful research process, clinical trials are a key research tool for advancing medical knowledge and patient care. An important step in discovering new treatments for diseases as well as new ways to detect, diagnose, and reduce the risk of disease, clinical trials show researchers what does and does not work in people. Clinical trials also help researchers and doctors decide if the side effects of a new treatment are acceptable when weighed against the benefits. These studies also may show which medical approaches work best for certain illnesses or groups of people, providing the best data available for health care decision-making. Many of today’s advances are direct results of clinical studies, and because of the diligent work of researchers, people live longer and healthier lives. Diseases that affect millions, like diabetes or cancer, are at the forefront of medical development. These clinical studies are of particular importance to the general public because they serve to help a large proportion of the population.

Because of the vital importance of clinical trials in the advancement of medical science, in this issue we have gathered together several articles that touch on varied aspects of clinical trial design, implementation, and analysis. Laurie Endicott Thomas leads off this issue with some basic science—where all clinical research begins—by presenting the third in our science series on how cells communicate, discussing how cells respond to signals.

Lisa Ambrosini Vadola and Robin Whitsell help us move from basic science to study design by introducing the new National Institutes of Health—Food and Drug Administration Clinical Trial Protocol Template.

Helen Bridge and Thomas Schindler help us close the gap between trial objectives and statistical analysis by introducing us to the “estimand,” and William Sinkins helps us manage our statistical currency by showing us how to wisely “spend the alpha.”

Sandra Shpilberg gives us some guidance on how we can leverage social media for clinical trial patient recruitment.

Kristina Wasson-Blader shares some industry insight into the new clinical trial data sharing statements soon to be required by the International Committee of Medical Journal Editors.

Providing background for beginning medical writers, Lori Alexander reviews the book How to Write and Publish a Scientific Paper, 8th ed., and Laurie Endicott Thomas reminds us to describe our methods in our methods section.

Our Forum contributors Brian Bass, Mark Bowlby, Gail Flores, and Cathryn Evans provide clinical trials-related insights for our freelance colleagues.

Taking us Around the Career Block, Susan Towers provides a continuation of last issue’s introduction to gene therapy by discussing what it is, how it is different from CRISPR/Cas9, and why it is getting so much media hype.

Tami Ball gives us something to think about when considering the ethics of genetics.

continued on page 155
From the Editor continued from page 143

And Laurie Endicott Thomas wraps up our clinical trials theme by sharing her opinion on why we need more natural intelligence in peer review.

But that’s not all! In addition to these themed contributions, this issue also contains a pair of media reviews, a contribution in Practical Matters (Streamlined Notetaking: Writing Minutes and Meeting Deadlines, by Marie J. Temple, BA), another contribution In the Service of Good Writing, and AMWA News . . . including details of our new governance structure and our new president’s inaugural address.

I hope you will enjoy this special theme issue as much as we have enjoyed putting it together for you!

Yours in AMWA,
—Jim

References

CALENDAR OF MEETINGS

Alliance for Continuing Education in the Health Professions 43rd Annual Conference
January 20–23, 2018
Orlando, Florida
www.acehp.org

2018 European Meeting of the International Society for Medical Publication Professionals
January 23–24, 2018
London, United Kingdom
www.ismpp.org/european-meeting

17th Annual International Publications Planning Meeting
February 5–6, 2018
San Diego, California
https://healthcare-conferences.com/calendar.aspx

*AMWA members receive a 15% discount on registration. Use code “PMP313”*

American Association for the Advancement of Science Annual Meeting
February 15–19, 2018
Austin, Texas
meetings.aaas.org

American Pharmacists Association Annual Meeting & Exposition
March 16–19, 2018
Nashville, Tennessee
aphameeting.pharmacist.com

Canadian Science Writers’ Association
April 12–14, 2018
Vancouver, British Columbia
http://sciencewriters.ca/Annual-Conference-&-Meeting

Health Journalism 2018
April 12–15, 2018
Phoenix, Arizona
https://healthjournalism.org/calendar-details.php?id=1722

European Medical Writers Association
May 1–5, 2018
Barcelona, Spain
https://www.emwa.org/conferences/future-conferences/

Council of Science Editors Annual Meeting
May 5–8, 2018
New Orleans, Louisiana
https://www.councilscienceeditors.org/

DIA 2018 Global Annual Meeting
June 24–28, 2018
Boston, Massachusetts