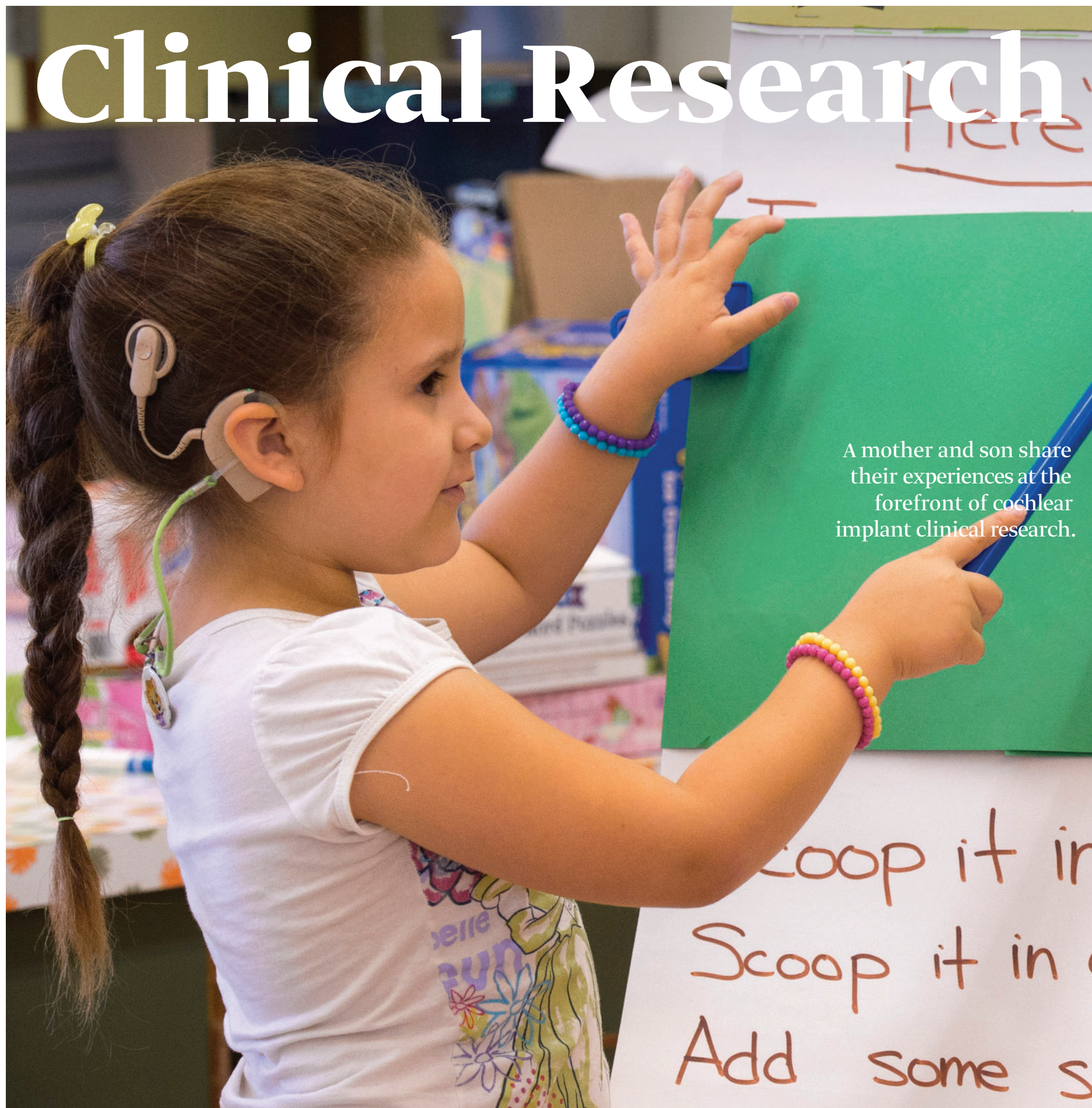


Clinical Research

A mother and son share their experiences at the forefront of cochlear implant clinical research.



A Salute to the Unsung Medical Heroes of Clinical Trials

Who are the individuals that participate in clinical trials, and what is being done to guide them along their crucial journey?

The number of promising new drugs and medical therapies grows annually as improvements are made in understanding, detecting and treating disease. But the success of these innovations — ultimately measured by improvements in the quality of patients' lives and by the availability of new treatments and cures for unmet medical needs — would not be possible without clinical trial volunteers. We call these brave

individuals medical heroes. They can be found everywhere, and we owe them our deepest gratitude.

Who are our heroes?

Medical heroes are mothers and fathers, siblings, children, friends and colleagues who have chosen to give the extraordinary gift of participation in clinical research. Their decision to participate is a selfless act, an altruistic gift.

Ultimately, future generations are the direct recipients of the gift

of participation. Medical heroes — through their participation and partnership with the clinical research enterprise — profoundly contribute to society's collective knowledge about the nature of disease, its progression and how, or how not, to treat it.

Why is education important?

For the vast majority of people, the idea of clinical trials is an unfamiliar concept. Most people are exposed to clinical trials

when faced with the abrupt and often unexpected prospect of a serious and debilitating illness for which no medication is available or adequate. This rush to navigate the unfamiliar terrain of clinical trials invariably feels like an overwhelming and confusing undertaking.

Sixteen years ago, the Center for Information and Study on Clinical Research Participation (CISCRP) was founded to provide outreach and education to those

individuals and their support network considering participation in clinical trials. Based in the Boston area, but with global reach, this nonprofit organization focuses its energy and resources on raising general awareness, educating patients and the public and enhancing study volunteer experiences during and after clinical trial participation. ■



Ken Getz
Founder and Chairman,
CISCRP

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PLEASE RECYCLE AFTER READING

Take Everett and Evelyn. Healthy. Moving forward together. And still as much in love as they were when they met in 1944—back when he was a paratrooper and she was a nurse.

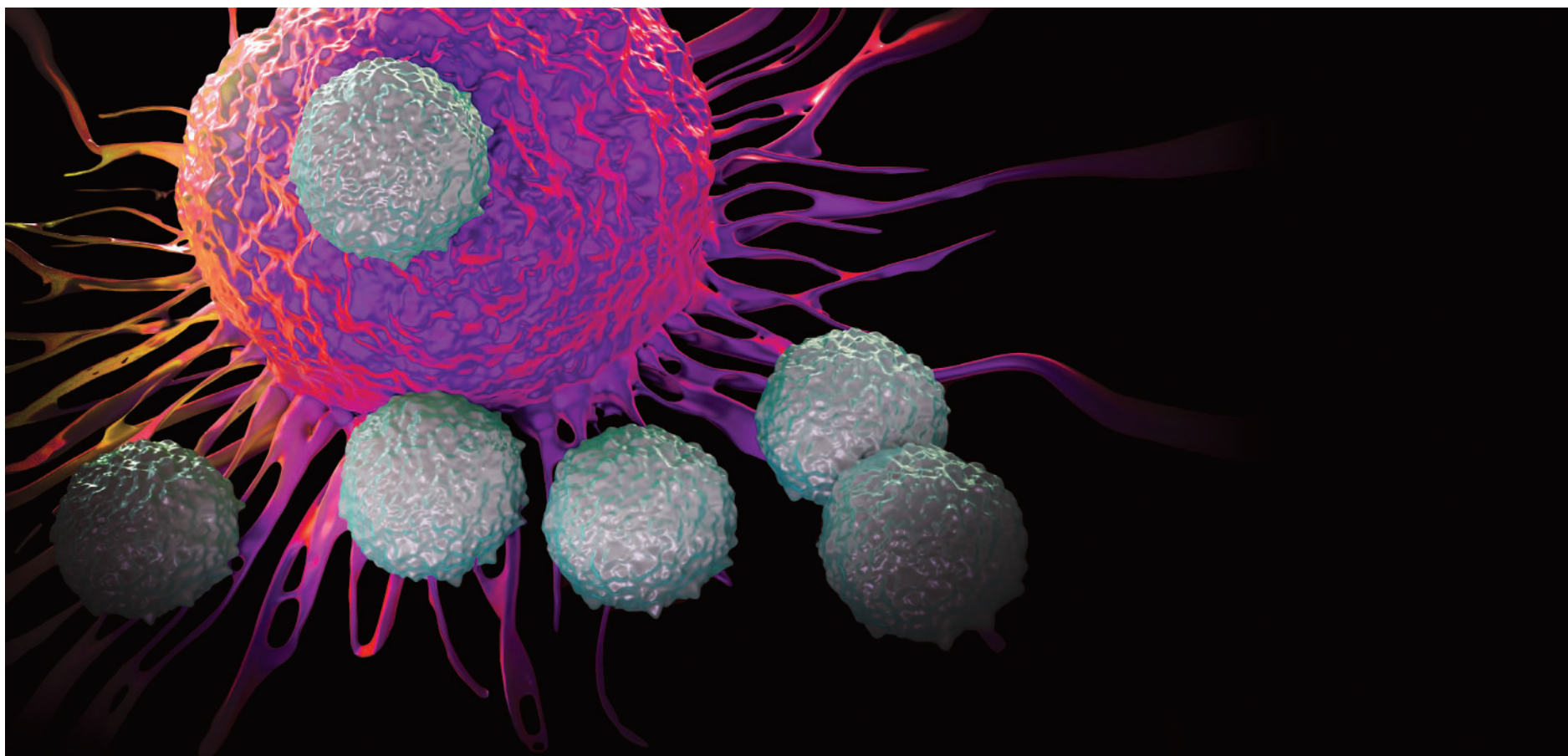
For more than a century, Merck has been inventing medicines and vaccines for many of the world's most challenging diseases. Today, we're inventing new ways to treat cancer, with more than 600 clinical studies underway. All in an effort to help keep people healthy, hopeful, and allow their relationships to endure for years to come.

Learn more at Merck.com/InventingForLife

*Merck invents to
Keep Love Alive*

MERCK
INVENTING FOR LIFE

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FDA APPROVES HISTORIC CANCER BREAKTHROUGH

In a landmark decision, the FDA recently approved the first-of-its-kind CAR-T cell therapy created by Penn Medicine. This personalized cellular therapy genetically alters a patient's own immune cells to target and destroy their cancer. This treatment will transform the way the world battles cancer...and this is just the beginning. Learn more at **PennCancer.org** or call **800.789.PENN** (7366).

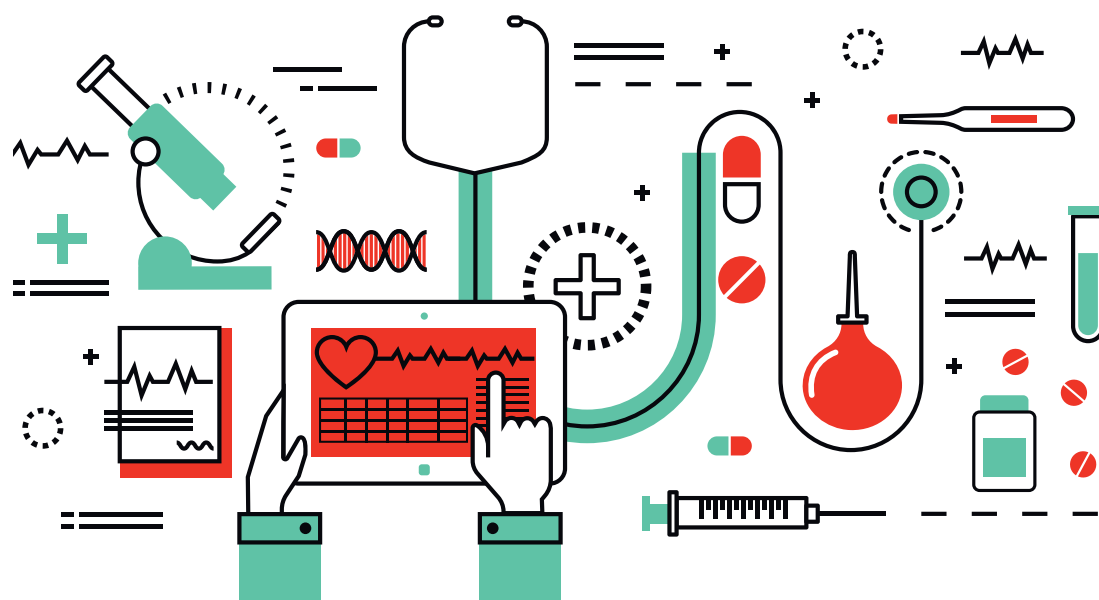
Your life is worth Penn Medicine.



Penn Medicine
Abramson Cancer Center

Encouraging Education Before Participation

We need more participants in clinical trials, but before you or a loved one signs up, it's important to weigh the pros and cons.



Your decision to participate in a clinical trial is very important — one that must be taken seriously and requires you to do your homework and gather as much information as you can.

Most people begin the process of learning about clinical trials when it is very difficult to do so. Facing a sudden and often unexpected diagnosis, people gather information and make decisions quickly — sometimes hastily — at the same time they are adjusting to their new reality.

Beginning research

A good place to start the learning process is to address the common misconception that receiving treatment in clinical trials is the same as receiving medical treatment as a patient. When you're a study volunteer, you typically feel like a patient in a doctor's office. You're examined by a doctor, undergo lab tests and other common procedures and receive a medication. But the difference is that a doctor's primary goal is to help you feel better, whereas in a clinical trial, the principal investigator's primary goal is to see how you will react to a new drug

and determine whether that drug will be safe and medically useful.

This truth doesn't change the fact that many people feel better while on an investigational drug. Some investigational products prove to be far superior to the older drugs they will one day replace. Some drugs administered during clinical trials have not only improved but also saved thousands of lives. But the opposite is also true: some drugs administered during clinical trials have worsened people's conditions and have caused death.

Considering the outcomes

Each volunteer's outcome in a clinical trial depends not only on the specific study in which they participate, but also into which part of the study they are randomized. Subjects who get randomized into the control group will, at best, get a standard treatment that is already available at pharmacies and drugstores. But they may also get free screenings and exams, the camaraderie of people dealing with the same medical condition, the opportunity to be an active player in their own health care and the knowledge that they're helping to answer questions that can improve the health care of future generations.

Opting out

Only about six percent of people who suffer from severe and chronic illnesses participate in clinical trials each year. As a result, an increasing number of clinical trials are delayed because there are too few study volunteers available.

Often the protocol eligibility criteria exclude many patients from qualifying to participate in clinical trials. Some people choose not to participate for fear that they won't receive the experimental drug or that the risk of side effects and discomfort will be too great. Others are concerned about the inconvenience of having to periodically visit the research center and undergo a demanding schedule of procedures.

Opting in

The most common reason people choose to participate in clinical trials is to gain access to a promising new medical therapy. Yet a surprising number of people choose to participate in clinical trials even when they personally have little, if anything, to gain by doing so. Some volunteers get involved because they want to contribute to the advancement of medical knowledge or to help people suffering from an illness. A few do it

out of simple curiosity or because they believe study volunteers get better medical care and attention.

Some study volunteers participate primarily to earn extra money. Payment is most often used as an incentive to recruit healthy volunteers who derive no direct benefit from the research, such as in most phase I studies. Some choose to participate in clinical trials because they don't have health insurance and need help covering medical treatment costs. Study volunteers in clinical trials almost always get free medication, as well as physical exams and other medical services like blood tests and heart assessments.

Deciding to participate

People who participate in clinical trials often learn a great deal more about their illness and about other conditions (including underlying heart disease and diabetes) they may not have known about. Study-related x-rays, lab tests and physical exams have picked up unsuspected cases of many types of cancers early enough to be successfully treated by specialists. For some participants, the best end result of a clinical trial is that they start taking better care of their own health.

An important benefit for all clinical

volunteers is the opportunity to meet research professionals who can help introduce them to other patients suffering from similar illnesses. Volunteers also may meet scientists and professionals who can help them better understand their illness and can tell them about new treatment options under development. The many people whom you meet in a clinical trial can greatly enrich your knowledge.

At the Center for Information and Study on Clinical Research Participation (CISCRP), our motto is Education Before Participation. Our motto applies to everyone, including patients and their families, health professionals and the general public. Education Before Participation guides everything that we do, from the many educational print and digital materials that we publish and make available on our web site to the many live educational seminars — called AWARE for ALL programs — that we produce in major cities throughout North America and parts of Europe each year. These initiatives are all provided free-of-charge to patients and the public. ■

By Ken Getz, Founder and Chairman, CISCRP; Rachel Minnick, Senior Manager, CISCRP



*Acknowledging
leaders in*

Patient Engagement

In recognition of the pharmaceutical and biotechnology companies that are leading the way in returning study results in plain, easy-to-understand language to their clinical trial volunteers.

Thank you to the following companies – and those planning to join them soon – for the commitment they’ve made to each of their study volunteers around the world, and for the leadership that they’ve shown in engaging their patients as partners in their clinical research programs: AstraZeneca, Allergan, Bayer, Biogen, CSL Behring, Eisai, EMD Serono, Lilly, Novartis, Purdue, Roche, Shire and Takeda.

AstraZeneca

Allergan



Biogen

CSL Behring
Biotherapies for Life™



EMD
SERONO

Lilly

NOVARTIS



Shire



Since 2010, CISCRP has been assisting sponsor companies in returning clinical trial results to their study volunteers.

To learn more, go to www.CISCRP.org

Clinical Studies Are Building a Brighter Future for People With Deafness

Behind every drug or medical device is a group of patients willing to partake in clinical research that leads to insight and innovation.

We've all seen the viral videos online of children born deaf hearing their parent's voice for the first time and lighting up with glee or breaking into sobs at the foreign sensation of audibility. But what many of us do not realize is that behind that technology, be it a common hearing aid or a cochlear implant, were ambitious researchers and a brave group of patients willing to give it a shot in a clinical trial.

Today, hundreds of thousands of clinical trials and studies are ongoing,

and they may lead to the next big advancement in restoring lost hearing or improving the quality of life for those individuals living with it.

Living proof

Years ago, Sonia Morreale didn't hesitate to sign her son, Justin, then 8, up for a clinical study on how children who grow up with cochlear implants tend to fare in language and comprehension. "I wanted to know that information," she shares. "And I knew that it would help not just my own child,

but that [the researchers] would be giving this information to other parents."

As the results suggest, and as Justin demonstrates, growing up with cochlear implants isn't as limiting as many may suspect. Now age 16 and living with two cochlear implants to correct the genetic profound deafness he was born with, Justin has over a 4.0 GPA, is enrolled in AP and honors classes and is in the process of getting his driver's license.

From the moment she heard Justin cry at the sound of her voice after receiving his first cochlear

implant at age 2, Sonia knew the future held big things for her teenage son. "It gave me a lot of hope."

Selfless motivation

Dr. Laurie Eisenberg, professor of research otolaryngology at the Keck School of Medicine of USC, which conducts the study, says the Morreales' inspiring story is one of many she's seen in the 41 years she has worked in the field.

"Seeing a patient hear for the first time is always an emotional experience," Eisenberg explains. She notes that while some patients

may be hesitant to enroll in trials due to safety concerns or feeling inconvenienced about travel, those who do enroll are carrying out a selfless act.

"Many adults feel like, 'If I can help a child, then maybe it is worth it,'" Eisenberg says. "It's an intrinsic motivation that, 'My experience and involvement in science can help others.'"

Sonia put it simply: "I just think that, as a parent, I don't see any cons — I see only the opportunity for gain." ■

By Melinda Carter



**Our mission is clear.
We are pioneers in neuroscience.**

Biogen wishes to thank all of the heroes who have participated in clinical research studies. Your enormous contribution is helping to advance medical research and discover new treatments.

Biogen has the leading portfolio of medicines to treat multiple sclerosis as well as the first and only approved treatment for spinal muscular atrophy.

We are also at the forefront of research into new medicines for neurological diseases such as Alzheimer's and Parkinson's as well as neuromuscular diseases like amyotrophic lateral sclerosis.

Caring Deeply. Working Fearlessly. Changing Lives.™



www.biogen.com

What's Keeping Neonatal Treatment Stuck in the Last Century?

One doctor explores the reasons the medical community isn't advancing when it comes to developing drugs for newborns.

It was the year of the original Blackberry, Napster music downloads and AOL Instant Messaging — all ancient technology by today's standards. Yet 1998 was the most

recent year the FDA approved more than one drug therapy specifically for newborns. Since that time, there has only been one approved, and it is no longer in production.

Almost two decades represents an eternity in the fields of science, medicine and technology. So why don't we have more and newer drugs to improve survival for newborns?

Considering the obstacles

One obstacle is lack of clinical trials for premature newborns. Adequate funding, appropriate facilities and knowledgeable clinicians are necessary to begin studies. Parents must be willing to let their babies participate in research to test therapies designed expressly for newborns.

Meanwhile, clinicians are stuck scaling techniques, devices and drugs designed for adults to address the needs of premature newborns. The approach doesn't work. Although many adults may be big babies, babies are not little adults. Precision decreases and risk increases.

Catching up with Congress

Congress has introduced legislation to stimulate development of safe and effective drugs for neonates — the Promoting Life-Saving New Therapies for Neonates Act of 2017. But researchers will need young patients to study.

Increased awareness can help new parents understand that participating in a clinical trial isn't just for the very desperate or the terminally ill. Clinical trials allow people of all ages and stages of life to invest in the health of future generations.

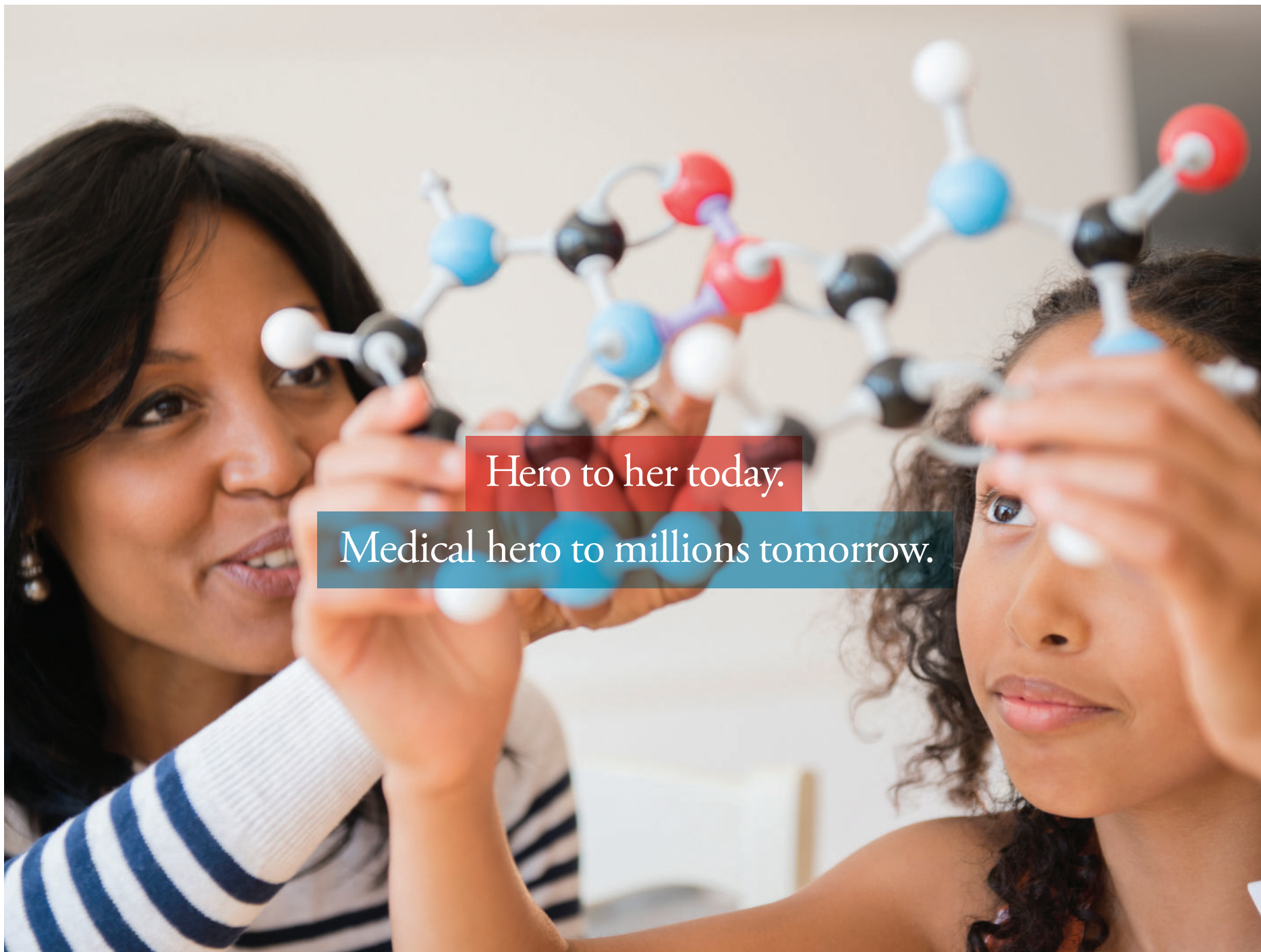
Parents often describe their newborn as a gift. We must see clinical trial participation as a gift that keeps giving, protecting these precious newborns, providing appropriate therapies and allowing them to thrive. ■

By Mitchell Goldstein, M.D., Medical Director, National Coalition for Infant Health

*Before it became a medicine,
It was 5,000 researched compounds.
87 different protein structures.
500,000 lab tests.
1,600 scientists.
80-hour workweeks.
12 years of breakthroughs and setbacks.
36 clinical trials.
8,500 patient volunteers.
And more problems to solve than we could count.
Before it became a medicine,
It was an idea in the mind of a Pfizer scientist.
Now it's a medicine
That saves lives every day.*



Driven to discover the cure



Hero to her today.

Medical hero to millions tomorrow.

To all clinical research volunteers, thank you.

A sincere thank you to all of the men and women who take part in clinical research studies each year. By volunteering today, you become a medical hero forever. For more information about clinical research, please visit CISCRP.org.

