



## PRI Celebrates 40 Years of Clinical Research: Transcending Five Decades: 1975 - 2015

By: Charles S. Wilcox, Ph.D.

**D**o you remember, when you were a child, hearing so many adults say “seems like it all went by in-the-blink-of-an-eye”? For many of us long-term PRI Team members, that age-old cliché sure rings true today. All of us here at Pharmacology Research Institute [PRI] are truly excited to be commemorating and celebrating forty [40!] years of being on the leading-edge of clinical research!

Over these past 40 years, thanks to so many of you, we have conducted more than **800 clinical research studies** involving more than **22,000 study participants**, leading to a remarkable number of new medicines improving the lives of millions of people: enabling them to return to work, avoid additional doctors’ visits, feel better and live longer!

The technological advancements introduced and embraced since 1975 are a huge story unto themselves, particularly over these last ten years. Amazingly and inspiringly, the medical research field has followed a similar path of innovation and advancement! Operationally, we’ve seen the “miraculous”

fax technology come and (almost) go. We have on-line scheduling, e-mailed communiques, text messaging, real-time stipend (transportation reimbursement) payments for study participation and, for many study participants, hand-written diaries have been replaced by iPads and eTablets. Diagnostically, CT-scans have, in many studies, been replaced with MRIs and/or PET-scans, facilitating both earlier and more accurate diagnoses pertaining to memory loss.

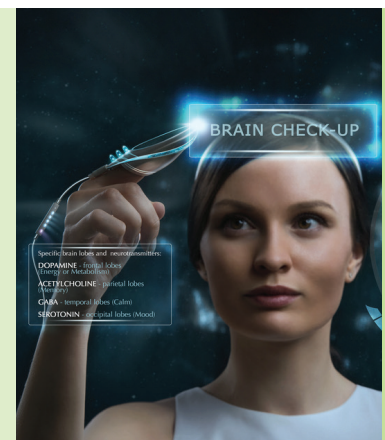
There have been major strides forward in the field of personalized medicine. Personalized medicine presents a new set of tools to help diagnose and treat patients based on our rapidly growing understanding of the genetic and molecular basis of diseases. Recently, PRI published a widely-cited paper pertaining to genotyping and smoking cessation, reporting the results of 76 smokers as carriers versus non-carriers of the A1 allele. This same type of genotyping has been a key focus in the field of Memory Loss research – including Mild Cognitive Impairment [“MCI” – or “Prodromal Alzheimer’s disease”] and Alzheimer’s disease as well.

In harmony with the advancements in imaging, biomarkers and a heightened awareness of the benefits associated with the earliest interventions possible, the scientific opportunities and the promise of more than 100 new (memory loss-related) medicines in development gives all of us good reason for hope and optimism! All of this is underscored by the thousands and thousands of study participants willing and able to participate in these vitally important research studies. Yes, they are hoping to help/benefit themselves, their caregivers and their loved ones as a result of their participation; moreover, they are helping “their fellow mankind” and literally millions of people around the world as well. To each and every one of you – we say **Thank YOU!!**

All of us here at PRI are very proud of our past and truly excited by the scientific opportunities here today and on the horizon for tomorrow. We look forward to continuing to work with many of you to make the world a healthier and happier place, one day and one person at a time!

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# AT PRI... IT'S ALL ABOUT YOU!

## Overcoming the Obstacles... to Participate in Clinical Trials for Alzheimer's Dementia

By: Nader Oskooilar, M.D., Ph.D.

**A**lzheimer's dementia is a devastating illness. Among its tolls is the patient's partial or full loss of insight into the illness. This, and other possible physical, mental, or social limitations that might afflict the patient, can all be obstacles to seeking proper medical care and management.

If the patient lives in his/her home, the caregivers (spouse, children, relatives, or others), could well be stressed and possibly overwhelmed by the caretaking demands of the Alzheimer's patient. The patient's

insight, mobility, and capacity for decision-making are compromised. The loved ones, perhaps rightfully, consider the illness as a declining one-way journey, with little hope for effective treatment or recovery. They feel overburdened by the ongoing care, and occasionally covertly resent the whole process.

As a result, the patient and the supporting caregivers may not be very motivated to seek out and participate in clinical trials for Alzheimer's dementia (AD). This reluctance is understandable. After all, the family/caregivers do not, at times, feel optimistic about the trials. They also hesitate to invest the extra effort to convince the patient to cooperate and to bring the patient in for study visits. There could be additional worries about the trial drug and the potential, whether remote or temporary, side effects, and the uncertainty of the double-blind nature of most clinical trials.



To overcome the possible barriers to participation in AD clinical trials, certain measures are at times helpful. First, it is probably crucial for the staff, especially the Principal Investigator/Physician of the trial, to be personally visible to the patient and the patient's family/caregivers; to educate them regarding the trial, to answer questions/

concerns, and to develop a genuine rapport and trust. Group discussions and one-to-one interactions with the patient and his/her trusted family members, can display the compassionate, credible and helpful intentions of the study and

the research team. Potential fears can be addressed, knowledge can be imparted, rapport established, and trust initiated or solidified based on transparency and empathetic supportive interactions.

The patient, with the support of his/her loved ones, is thus encouraged to consider the potential benefits of participating in clinical trials for Alzheimer's dementia. As of now, there is no known effective treatment to permanently stop the progression of the disease. Therefore, clinical trials are the leading edge treatments in this regard. Postponing participating in these trials, while a legitimate choice, allows the dementia process to further degenerate the brain. Additionally, participation in Alzheimer's dementia clinical trials, regardless of the potential effect of the trial drug, is able to give the patient a sense of accomplishment; the patient takes part in a medical and scientific endeavor that is meant to help or stop human suffering, even if for the future generations.

## Depressed? You Have Options!

By: Clifford R. Feldman, M.D., J.D.

**J**ohn had been feeling depressed for a while. He had taken antidepressant medications, but they didn't seem to help much. He had tried virtually every new medicine... but John was getting discouraged.

As he was driving to work, he heard Dr. Charles Wilcox of PRI on the radio. He listened intently about how PRI was running a study for patients with treatment resistant depression... so intently, that he had to endure a cacophony of car horns: he had failed to move up in traffic five feet! John had been reluctant to join a study. There was a lot of information he didn't know. Does a patient remain voluntary once the study has begun? Has the medication been tested for safety? What if I get side effects?

When he arrived at work, John called a friend to ask his thoughts about entering a clinical trial. His friend told him that he had been in a clinical trial a few years ago. He said that it felt nice to have the opportunity to take part in the approval process for a drug that could potentially help millions of people. He told John that the study medication he was given was eventually approved and marketed and is now widely used.

When John got home, he spoke with his wife about joining a study at PRI. His wife noted that John was unhappy with his current treatment, that PRI offered a new, different option, as well as the chance to help others. On the PRI website they learned that all PRI studies are totally voluntary and all study medications have completed Phase I testing for safety. Any and all possible medication side-effects must be reported to ascertain if they are, in fact, due to the medication. They decided that joining a study was the right thing for John. They called PRI and made an appointment.

The above vignette is fiction, but demonstrates how one may decide to enter a clinical trial. Clinical trials are vigorously monitored. PRI conducts many studies and provides personalized high quality medical and/or psychiatric care at no charge to the patient. Patients are assessed for studies that are most appropriate for them by Board Certified Physicians and Research Nurses. Patients keep their private medical doctors during the study period and many studies offer remuneration to the patient, as well as complimentary, time-limited aftercare.

## What's New at PRI?

By: Charles S. Wilcox, Ph.D.

### Adult ADHD

Attention Deficit Hyperactivity Disorder (a.k.a. ADHD) is characterized by persistent inattention and/or hyperactivity. The classic symptoms of inattention include distractibility, forgetfulness, procrastination and difficulty completing tasks. The widely recognized symptoms of hyperactivity/impulsivity include restlessness, impulsiveness and speaking at inappropriate times. While these symptoms are usually identified by the age of 12, it is estimated that somewhere between 30-to-60% of children with ADHD have symptoms which persist well into their adulthood. PRI, along with 60 other research centers all across North America, has been awarded two grants to evaluate the long-term effectiveness of a novel research medicine for Adults, ages 18-to-55, with ADHD over a one-year period. These programs enroll very quickly! If you're interested in learning more, we encourage you to call us today!

### Mild-to-Moderate Alzheimer's

As a leader in the field of Memory Loss-related clinical research since the 1970s, we're very fortunate here at PRI to be contacted about far more research opportunities than we could ever imagine being able to conduct. While we review each project thoroughly and confidentially, we always do so with one over-riding philosophy – "Would we choose this particular project for one of our family members?" We only conduct studies where our resounding collective answer is – YES! In 2015, more than ever before, with > 100 new chemical entities in some stage of clinical development, we believe we have some excellent programs here at PRI. For specific information, and or to schedule a complimentary consultation/evaluation, please call or e-mail us – at the PRI Office closest to you!

### Mild Cognitive Impairment – "MCI"

Amongst the many advances in the field of Memory Loss research is the increasingly widely-held belief that the biological changes, or "amyloid deposits" (plaques), neurofibrillary tangles and neuronal degeneration, are taking place over a number

of years, well before even that initial diagnosis of "early- or mild-Alzheimer's disease" is rendered. Mild Cognitive Impairment – or "MCI" – is characterized by subjective and objective evidence of cognitive decline, as compared with the usually accepted range of "normal-for-age," with only minimal impairments in one's activities of daily living. Yet – and this is vitally important – individuals with MCI progress onto a clinical diagnosis of Alzheimer's at a much higher rate than non-MCI healthy elderly subjects. If you or your loved one has concerns about, and/ or any signs or symptoms of, Mild Cognitive Impairment, we strongly encourage you to schedule a no-cost, confidential, one-on-one evaluation with our team here at PRI.

### Treatment Resistant Depression

Although the above-referenced term "Treatment Resistant Depression – or TRD" has gained tremendous acceptance over the past ten-to-fifteen years, in many ways we believe it may connote and convey undue pessimism. Just as many times the first medicine used for a virus, infection or other ailment may not be the most effective, for millions of Americans the first and (often times) second antidepressant does not work very well. There are many classes of antidepressants and each one of us has our own unique biology, chemistry and (as noted within our opening article) our own individual genetic make-up too. TRD is usually defined as an inadequate response to an adequate dose and duration of treatment, with two different classes of antidepressant medication(s) during the same depressive episode. Not having the fully successful results and outcomes from the first medicine(s) is, of course, disappointing; however, there are many additional good treatment options! So, if your recent or current antidepressant has not enabled you to return to "being your 'prior, happier, self' again," enrollment in one of PRI's TRD studies may not only help you, your participation will help us to help millions of other people with "TRD."

### Depression Relapse Prevention

Depressive Disorders are long-term illnesses for millions of individuals and maintenance treatment is highly recommended to prevent a relapse in people with recurrent depression. We have a newly initiated study to evaluate the long-term maintenance of people treated with a just-recently-approved antidepressant, to test its effectiveness in the prevention of relapse. There is also an optional sub-study wherein we will be obtaining pharmacogenomic samples to study the contribution of genetic variances on the response(s) to this medication.

## PRI is Proud of our Partners including Home Instead and the Alzheimer's Association

By: Charles S. Wilcox, Ph.D.

Are you and/or your loved one age 65 or older and currently participating in one of our Memory Loss studies here at PRI? If so, you may be familiar with the nice folks at **Home Instead Senior Care®** and their *Transportation Services*. In harmony with **Home Instead's** expertise in assisting seniors with Memory Loss, Depression and Home Care, etc., this past September Home Instead provided a \$10,000.00 cash donation to **The Alzheimer's Association** – as shown (live) on national TV. Moreover, earlier this year, Home Instead's Senior Care Foundation also awarded the SoCal Chapter of the Alzheimer's Association a \$15,000.00 grant!

All of us here at PRI appreciate the *Transportation Services* provided, at no charge to our study participants, by the **Home Instead** team, and we salute them for their generosity in the global fight against Alzheimer's disease as well!

## The PRI Bulletin

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We are especially pleased to feature Jeffrey Litzinger, M.D. in this anniversary edition of *The PRI Bulletin!* Dr. Litzinger has been a key PRI Team Member (in our Los Alamitos office) for a number of years and his professional competence is rivaled only by his personal warmth and genuine caring for others. Born in Northern California and raised mainly in Reno, Nevada, Dr. Litzinger graduated from the University of Nevada, Reno in 1993 and subsequently graduated from the University of Nevada School of Medicine.

During the 1989 to 1993 time period, Dr. Litzinger served in the Army National Guard as Flight Medic...with one “very close call” in a helicopter and an emergency landing. Dr. Litzinger completed his residency in psychiatry at University of California, Irvine in 2002. Then, not yet finished serving our country, from 2002 to 2007 he was on Active Duty as a Psychiatrist for the U.S. Navy – where in the aftermath of Desert Storm, his working “long hours covering all the

different areas of psychiatry was essential.”

When asked what he enjoys about working as a PRI Research Team Member, Dr. Litzinger instantly flashed his infectious smile and immediately shared many reasons and examples! As a scientist, he “likes the ability to see objective evidence of what really works well for patients...” As a clinician, he enjoys “being able to help patients – regardless of their ability to pay – and to be able to work with people whom, often times, he (otherwise) would not be able to help...” Additionally, he noted that the research protocols have helped him to see how “many times encouraging research study participants to ‘stay the course, at least a little longer’ often times makes the difference in terms of achieving the desired level of therapeutic benefit, even if it means putting up with some transient side effects in order to meet that goal.” Dr. Litzinger has received accolades from more than a few PRI Study Participants who appreciated his sincere desire to inform, educate and empower people by helping them to better and more fully understand their own (personal) situation.

In harmony with Dr. Litzinger’s professional workload, as a devoted husband and dedicated dad – with a ten-year-old daughter and eight-year-old twins, he’s definitely busy all day **every** day! He enjoys wood-working and music... he plays bass guitar and is learning to play the drums too! All of us here at PRI respect and appreciate the opportunity to work with Dr. Litzinger!