



# THIEVON-WRIGHT

---

## CONSULTING GROUP

### FEATURES

#### STEVE SATEK JOINS TWCG

New Senior VP Joins Thievon-Wright Consulting Group

#### PI SPOTLIGHT

Inna Yuryev-Golger, M.D. - SPRI

#### THIEVON-WRIGHT CONSULTING GROUP MOVES INTO NEW OFFICE SPACE

#### REGULATORY CORNER WILLIAM M. TROETEL, PH.D.

FDA Issues Final Rule on Safety Information During Clinical Trials

### JOIN US AT THE CNS SUMMIT

NOV. 4-7, 2010  
BOCA RATON, FL

BOCA RATON  
RESORT & CLUB

### STEVE SATEK JOINS TWCG

NEW SENIOR VP JOINS THIEVON-WRIGHT CONSULTING GROUP

Thievon-Wright Consulting Group announces the newest addition to its consulting team. Steve Satek, a long-time business associate of TWCG president Lori Wright, and a former executive at Forenap Pharma (Rouffach, France) and Cognitive Drug Research (Chicago), has joined the consulting group as its senior vice president.

Satek, who holds a bachelor's degree in biochemistry and molecular biology as well as a master's degree in business administration, brings both scientific expertise and business acumen to his new position. Over the past 22 years, he has worked in labs, on the operational side of the clinical trials industry, and in business development and sales capacities in virtually every therapeutic area—most recently focusing on central nervous system research.



"My educational background is fairly scientific, which affords me the opportunity to really understand what we're doing and what we're selling," says Satek. "When we receive protocols, I can offer valuable input and understand the mechanisms of action."

Satek adds that he has a great deal of experience in virtually every operational function for clinical sites and CROs, including selling and operating Phase I units—a skill set he believes will fit well with the business strategy of Thievon-Wright Consulting Group.

"The capabilities within our network have expanded substantially," says Wright. "Our sites are branching out into new therapeutic areas and conducting more Phase I and Ib studies. We are thrilled to be able to bring someone on board who understands our long-term goals and who brings a complementary set of skills to our consulting team. He knows how to support sites and identify appropriate business opportunities."

Satek is based out of his home office in Chicago. While the specifics of his role are evolving, he says he will be collaborating with Wright and the other consultants to examine and develop the company's strategic direction.

"I'll be trying to procure studies for the entire network by following up on qualified leads and focusing on strategic relationships," adds Satek.

"Steve is a great addition to our consulting group," adds Wright. "Our investigators and our Sponsor and CRO clients are looking forward to working with him."

**PI SPOTLIGHT - INNA YURVEY-GOLGER, M.D. - SPRI**

Psychiatrist Inna Yuryev-Golger, M.D., principal investigator at the Brooklyn, New York-based Social Psychiatry Research Institute (SPRI), has been involved in more than 38 clinical research studies since joining SPRI in November of 2003. A native of Ukraine who came to the United States in 1988, Yuryev-Golger says she finds clinical research to be an extremely interesting field.

“To know about new drugs or find new indications for drugs that are well known to us is very interesting,” says Yuryev-Golger.

Dr. Yuryev-Golger earned a degree in general medicine at the Vladivostok Medical School in Russia. She then studied neurology and earned her doctor of medicine degree at Kharkov Medical School in Ukraine, after which she served for over a decade as a neurologist in Ukraine hospitals.

The desire to pursue psychiatry further led Yuryev-Golger to the U.S., where she completed residencies at the Creedmoor Psychiatric Center and Columbia Presbyterian Medical Center, both in New York. Before joining SPRI, Yuryev-Golger served as a psychiatrist at several New York hospitals and clinics. Today, Yuryev-Golger maintains a private psychiatric practice in addition to her role as principal investigator for SPRI.

“I am a general psychiatrist who sees all varieties of patients with psychiatric illnesses,” says Yuryev-Golger.

Some of Yuryev-Golger’s work at SPRI involves studies related to Alzheimer’s disease. “I think it is very important for us due to the aging population and the economic impact this detrimental disease has on the global community,” Yuryev-Golger explains, adding that her background in neurology comes into play at SPRI on studies related to pain management.

“We are also doing studies for post herpetic neuralgia,” she said. “It’s a chronic condition, and there is very little that can help. I believe it is very important to have some new medications for that problem.”

“Dr. Yuryev-Golger has brought tremendous expertise and professionalism to her work here at SPRI,” says Nick Vatakis, M.D., also a principal investigator at SPRI. “Her attention to detail and her deep commitment to patient safety are invaluable assets, and her background in neurology allows us to branch out into new therapeutic areas.”

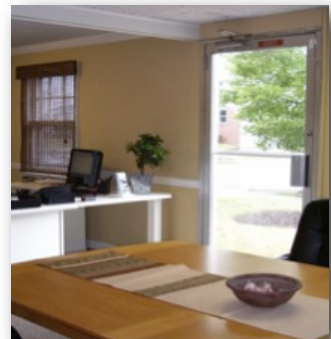
“My father was a neurologist and psychiatrist in Ukraine, which is probably why I fell in love with this field,” says Yuryev-Golger. “I am happy to be able to help develop medications that can help people with Alzheimer’s and other psychiatric and neurological issues receive better treatment.”

**THIEVON-WRIGHT CONSULTING GROUP MOVES INTO NEW OFFICE SPACE**

After many years of operating as a virtual company, TWCG has finally found the perfect space for their corporate headquarters. A small, quaint building adjacent to medical and dental offices became available last spring. After two months of renovations, the team moved into their new offices on Park Avenue in South Plainfield, New Jersey.



Lori Wright, President /CEO and Joanne Praul, Vice President of Finance are both working out of the new location along with Jill Pavel who is providing administrative support to the entire team. While the other members of the group continue to work remotely from home in New Jersey, Pennsylvania and Illinois, the space allows for frequent team meetings in the newly decorated conference room.



## REGULATORY CORNER - WILLIAM M. TROETEL, PH.D.

On September 28, 2010, the FDA issued a final rule that clarifies what safety information must be reported during clinical trials of investigational drugs and biologics. The rule becomes effective on March 28, 2011.

The new rule requires that certain safety information that previously had not been required to be reported to FDA be reported within 15 days of becoming aware of an occurrence. These reports include:

- Findings from clinical or epidemiological studies that suggest a significant risk to study participants
- Serious suspected adverse reactions that occur at a rate higher than expected
- Serious adverse events from bioavailability studies which determine what percentage and at what rate a drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug

The rule also provides examples of evidence that would suggest that an investigational product may be the cause of a safety problem. Under current regulations, drug sponsors often report all serious adverse events, even if there is little reason to believe the product caused the event. Such reporting complicates and delays the FDA's ability to detect a safety signal. The examples address when a single event should be reported or when there is need to wait for more than one occurrence.

In addition, the rule revises definitions and reporting standards so that they are more consistent with two international organizations, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences. The changes are designed to help ensure harmonized reporting of globally conducted clinical trials.

Along with this final rule, the FDA also issued a draft guidance for industry and investigators that provides information and advice about the new requirements and other information.

According to an FDA spokesperson, the final rule will expedite FDA's review of critical safety information and help the agency monitor the safety of investigational drugs and biologics. It is believed by the FDA that these changes will better protect patients and subjects who are enrolled in clinical trials.

### LORI WRIGHT

President & CEO  
Office: (908) 756-4411  
Cell: (908) 358-2402  
Email: lthievonwright@cnsites.com

### STEVE SATEK

Senior Vice President  
Office: (773) 293-4053  
Cell: (312) 560-6576  
Email: ssatek@cnsites.com

### SUSAN RICE

Vice President  
Business Development & Marketing  
Office/Cell: (908) 244-6449  
Email: srice@cnsites.com

### BARBARA SMALLWOOD

Vice President  
Business Development &  
Compliance Officer  
Office: (610) 942-4149  
Cell: (908) 334-6661  
Email: bsmallwood@cnsites.com

### JOANNE PRAUL

Vice President - Finance  
Office: (908) 756-4411  
Cell: (908) 255-2927  
Email: jpraul@cnsites.com

## CLIENT TESTIMONIALS

*"I have collaborated with Lori Wright and many of her investigators for over 10 years. I have always found Lori to be remarkably effective. She has a keen understanding of specific trial needs as well as the capabilities and capacity of the investigators she represents."*

**Steven Romano, M.D.**

*"Working with Lori Wright and the group of clinical research sites she represents is one of the easiest decisions I make when executing a CNS trial. The principal investigators are among the best in the industry and are able to make valuable contributions to development programs by thoughtfully considering scientific issues and generating quality data. Lori provides an operational advantage by ensuring capability prior to commitment, facilitating start up and remaining accountable through study close out."*

**Judith Dunn, Ph.D.**

# OUR NETWORK

For all your clinical trial needs, please contact us at Thievon-Wright Consulting Group. We will recommend the best sites depending upon the indication and study design, and provide feasibility feedback in a timely manner with expert investigator input.

**Clinilabs, Inc.**  
423 W. 55th Street, 4th Floor  
New York, NY 10019

Gary Zammit, PhD  
Howard Greenberg, MD  
Mardik Donikyan, DO

**Cognitive Research Center of NJ  
Atlantic Neuroscience Institute  
Overlook Hospital  
99 Beauvoir Avenue  
Summit, NJ 07902**

Michelle Papka, PhD  
Roger Kurlan, MD

**CRI Worldwide – Kirkbride Division  
111 N. 49th Street  
Philadelphia, PA 19139**

Daniel Gruener, MD  
Mark Novitsky, MD  
Richard Fruncillo, MD

**CRI Worldwide – Lourdes Hospital Division  
1113 Hospital Drive  
Suite 202  
Willingboro, NJ 08046**

Howard Hassman, DO  
David Krefetz, DO  
Steve Glass, MD

**Memory Enhancement Center  
4 Industrial Way West, 2nd Floor  
Eatontown, NJ 07724**

Joel Ross, MD

**Memory Enhancement Center of New Jersey  
9 Mule Road  
Suites 8 & 9  
Toms River, NJ 08757**

Sanjiv Sharma, MD

**Midwest Clinical Research Center  
One Elizabeth Place, Suite G-3  
Dayton, Ohio 45417**

Bernadette D'Souza, MD  
Jeffrey M. Bishop, MD

**Pacific Clinical Research Medical Group  
301 W. Huntington Drive  
Suite 400  
Arcadia, CA 91007**

Paul R. Miller, MD

**Pacific Clinical Research Medical Group  
1028 W. Town & Country Road  
Orange, CA 92868**

Charmaine Semeniuk, MD

**Pacific Clinical Research Medical Group  
1317 W. Foothill Blvd., Suite 200  
Upland, CA 91786**

Ai-Li Arias, MD

**SPRI  
3044 Coney Island Ave., Suite 201  
Brooklyn, NY 11235**

Nick G. Vatakis, MD  
Inna Yuryev-Golger, MD  
Zalman Starosta, MD

**St. Louis Clinical Trials, LC  
2639 Miami Street  
St. Louis, MO 63118**

Ricky S. Mofsen, DO

**The Hospital of Central Connecticut  
100 Grand Street  
New Britain, CT 06050**

Michael E. Balkunas, MD