DRIVEN TO INNOVATE BY

PASSION

Kent THOELKE

Making a Difference Around the World

DRIVEN. THOUGHTFUL.

During his career in clinical research, Kent Thoelke has established an inspiring, industry-wide reputation for moving the current clinical drug development paradigm toward a more evidence-based strategy.

Kent Thoelke is a rare breed in the clinical trials industry. He combines broad and deep medical and therapeutic knowledge with practical operational experience and real-world common sense. He can explain the complexities of inclusion and exclusion criteria for a complex oncology trial, discuss the pros and cons and logistical hurdles of conducting trials in China, and describe the best way to validate the accrual rate on a global trial — all in a way that is understandable to someone with minimal clinical trial experience, without being boring to a knowledgeable veteran of the industry. And, Mr. Thoelke's colleagues say he does all of this while maintaining his sense of humor and down-to-earth attitude.

Part of Mr. Thoelke's appeal is his passion; he loves what he does and he imparts his enthusiasm and passion for being part of a system that brings medicines to patients who otherwise would never have access to novel therapies to everyone he meets.

"It's just such a cool job to be able to integrate drug development into changing lives globally," Mr. Thoelke says. "The global healthcare piece is pivotal to what drives me. At the same time, my specialty for a very long time was hematology and oncology. Cancer affects all us at some point in our lives, and I have personally been part of creating medications that have added years and saved lives of people, friends, and family members."

As PRA's executive VP of scientific and medical affairs, he leads the company's therapeutic expertise, medical informatics, and other key divisions. He empowers project teams and promotes the successful development of clients' products through scientific and strategic oversight.

During his career in clinical research and at PRA, Mr. Thoelke has established an inspiring, industry-wide reputation for leveraging data-driven and evidence-based decision making to enhance patient recruitment and site identification globally. He actively pursues novel technologies and strategies to move the current clinical drug development paradigm toward a more evidence-based strategy. Mr. Thoelke is all about data, and big data at that.

"I have a number of to-do's, one of which is trying to figure out how to leverage big data to help the drug development industry bring more drugs to market in a much more efficient system," he says.

Mr. Thoelke ensures that while his project teams are employing innovative, evidence-based trial approaches, he also strives to make the clinical trial experience as positive as possible for patients and to become a partner with them. He inspires everyone to promote quality patient care.

For example, Mr. Thoelke encourages his teams to educate patients about clinical trial participation and integrate them into the process, rather than using patients in a plug-and-play type of model.

What he teaches CRAs, project managers, and other team members is that at the end of everything they do — with every protocol, with every interaction — there's a person on the other side of the study report.

A true advocate for patients and quality research, he wants to make sure his teams don't get caught up only in charts and data and that they always remember that everyone is helping to save patients' lives.

"I try to instill in CRAs and everybody across the organization that each plays such a pivotal part in bringing drugs to market that change people's lives," he says. "Nobody has a small job. I try to convey to everybody that it's a great honor to be involved in a process that has such great outcomes. I want people to remember that it's not just a job. At the end of the day, there is a kid with cancer, there's a woman with diabetes, there's somebody who has a new orthotic limb. All of those advances came out of research and that's what we do and I love it."

Mr. Thoelke is also spearheading PRA's strategic initiative to expand operations in key markets, such as Asia, including China, Korea, and Singapore, as well as leveraging emerging markets in Africa and Latin America, to access target patient populations. His work in establishing resources and offices in emerging markets is a great example of the company's vision: to accelerate innovation and new drug development by offering the global life-sciences community access to R&D platforms with world-class capabilities and unparalleled capacities.

Under Mr. Thoelke's guidance and leadership, PRA recently formed a joint venture — WuXiPRA — with a leading CRO in China to provide clinical services for all major territories. The company now has 150-plus staff in 16 cities along with offices in Beijing, Shanghai, and Guangzhou. Additionally, he serves on the board of directors of PRA's joint venture and leads the interim management team.

Mr. Thoelke serves on the scientific advisory board of The Geneva Foundation, which provides access and support to U.S. military hospitals and physicians and patients for participation in clinical trials.

On a local level, Mr. Thoelke is involved with the GSBA, a Seattle-based organization that provides scholarships for at-risk LGBT (lesbian, gay, bisexual, transgender) youth. This year, he established a scholarship in memory of his father, who died of glioblastoma. PV

Getting to Know...

Kent Thoelke

TITLE: Executive VP, Scientific and Medical Affairs

COMPANY: PRA

EDUCATION: BA, Biology, Western Washington University

FAMILY: Husband, Kevin; mother and sister

HOBBIES: Traveling

ASSOCIATIONS: The Geneva Foundation

SOCIAL MEDIA:

Mary CLEGG
Smooth Operations

DRIVEN TO INNOVATE BY
EFFICIENCY

The glue and the grease. That's how one SynteractHCR staffer describes Mary Clegg.

An excellent leader, both fair-minded and motivating, Ms. Clegg has garnered the respect of SynteractHCR's clients and her colleagues by using her expertise to ensure that clinical trial activities are conducted to the highest industry standards.

In her role as senior director of clinical operations in the United States, she oversees U.S. clinical operations, clinical resourcing, and clinical trial management. Ms. Clegg switched her focus to integration efforts following the merger of Synteract and Harrison Clinical Research (HCR), becoming heavily involved in the process of planning and executing an expanded and integrated clinical operations department, a critical strategy for the company's planned globalization efforts.

She also established best practices and standards that all clinical operations staff must meet, and at the same time, helped both legacy Synteract and legacy HCR staff connect and engage as members of a combined team. The result is one commonly dedicated SynteractHCR clinical operations team that operates in unison despite being geographically dispersed.

The task of integration after the merger was a big hurdle, given the need to understand and blend differences across a now multinational and cross-cultural organization.

"It's been a challenge, but rewarding and right up my alley as this is exactly what I love to do," she says.

Her approach to projects is thorough: she evaluates the full picture, including goals, challenges, processes, resource staffing needs, timelines and so on; provides solutions to problems; and then decides what actions to take.

Ms. Clegg also has been instrumental in working with the technology department to identify and bring in new software applications to assist in more effectively managing clinical trials. One of her more challenging tasks has been to bring a new global CTMS system into the company, selecting the right solution, and adapting it to the way the company does business.

Ms. Clegg draws on her background as a registered nurse, clinical research associate, and operations professional in offering valuable input to the numerous continual improvements within the organization.

She has developed training materials and guidelines that have helped to educate not only SynteractHCR employees but also nurses and CRAs who have gone out into the industry in senior positions.

Ms. Clegg led the initiative to get FDA input at an earlier stage, ensuring monitoring guidelines met submissions deadlines, and has contributed to influencing guidelines for risk-based monitoring.

She has been a key advocate for monitoring ethics and has supported efforts to initiate risk-based monitoring within the organization, both of which help the output of more reliable data and cost-efficiencies.

With vast expertise on the operational side of the business, her next goal is to get some additional experience on the business side of things.

A motivating role model, Ms. Clegg's highly developed interpersonal and communication skills allow her to be successful in interacting with various personalities. She is a Jedi master when it comes to delivering potentially difficult messages, or when there is a need to bring different points of view closer together.

She is a great advocate for the development of staff within the department, strongly supporting the development of SynteractHCR's CRA Academy and Clinical Lead Training program, and she encourages mentoring and opportunities for employees to stretch their abilities.

Having started from the ground up as a coordinator, CRA, and then one of the first clinical managers at Synteract, she inspires by example.

"I look for and identify the positive in people and I think when they get positive reinforcement that inspires them to continue to grow and improve," she says.

She draws inspiration from her colleagues across the business, and the camaraderie and teamwork that prevail. She loves her job and is inspired every day to come to work.

She pays back the mentorship she has received from others — in particular her current manager and U.S. President Stewart Bieler, and Elaine Kelley, her previous manager and mentor at SynteractHCR — by helping those around her.

A well-balanced personal life matters to Ms. Clegg and she leads her team with a true sense of compassion, recognizing those who work for her need to balance the demands of work with obligations outside of the work environment.

Ms. Clegg continues to support the many charitable efforts in which SynteractHCR and specifically, her department has been and continues to be involved.

In 2012, the U.S. clinical operations department led the initiative to support the San Diego Rescue Mission, a non-profit organization committed to assisting the homeless in a transition from poverty to becoming contributing members of society. PV

OPTIMISTIC. THOROUGH.

Mary Clegg evaluates the full picture; is collaborative with team members and clients; and is always patient, thorough, and good at explaining clinical concepts with patients always in mind.

Getting to Know...

Mary Clegg

TITLE: Senior Director of US Clinical Operations, US

COMPANY: SynteractHCR

EDUCATION: RN, Palomar Community College

FIRST INDUSTRY JOB: Study coordinator for Scripps Clinic

FAMILY: Husband, four children

HOBBIES: Traveling, reading, watching sports, particularly football (Chargers fan)

BUCKET LIST: Return to college, walk the "Camino" through Spain

ASSOCIATIONS: Drug Information Association

SOCIAL MEDIA: