

→ A Clinical **ADVANTAGE**

From clinical trials to clinical development, these industry leaders are capitalizing on new technologies, solutions, and strategies to improve the patient experience and advance science.

CREATIVE. DEXTEROUS.

NAME: Sreedhar Tirunagari, M.D.

CURRENT POSITION: Senior Manager, Site Management Operations, MakroCare Clinical Research Ltd.

DATE AND PLACE OF BIRTH: Feb. 27, 1977; Hyderabad, India

EDUCATION: BAMS, M.D., PGDFM; NTR University of Health Sciences, India; Rajiv Gandhi University of Health Sciences, India

FIRST JOB: Medical doctor

ALTERNATIVE PROFESSION: Educational research; education for the underprivileged

PROFESSIONAL MENTORS: Mr. Mahesh Malneedi

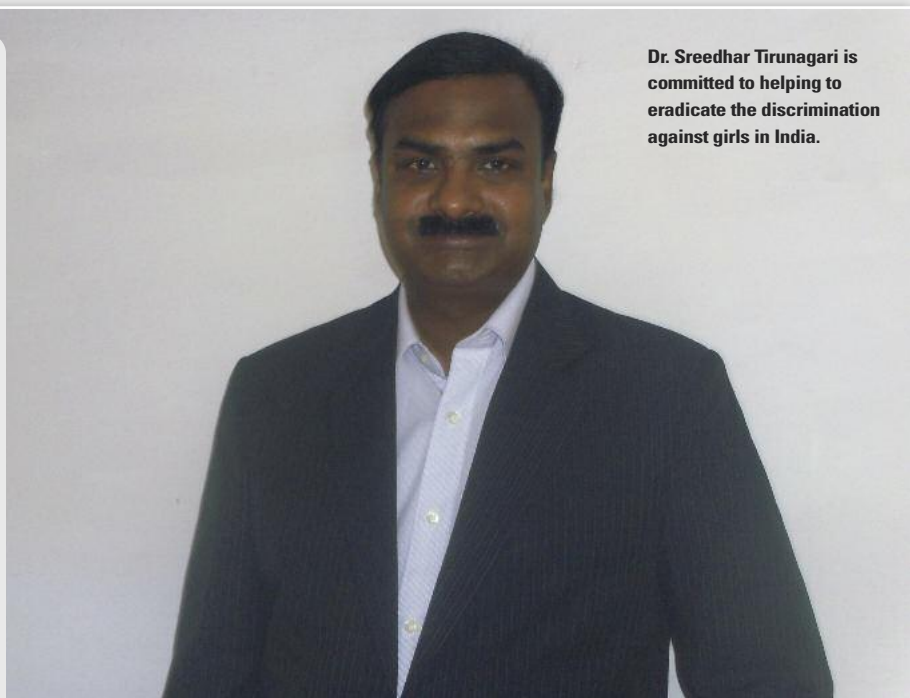
PROFESSIONAL ASSOCIATIONS: European Forum for Good Clinical Practice; Society for Clinical Data Management; Indian Society for Clinical Research; Principal Investigators Association; Regulatory Affairs Professionals; Public Responsibility in Medicine and Research; Centre for Information & Study on Clinical Research; Institute for Clinical Research; Pharmaceutical Development Institute

AWARDS AND HONORS: Best Employee of the year 2008, MaxNeemans International Ltd, India; Mother India Award for Health Excellence 2010; You Shine Award For Best Team Effort 2011, MakroCare Clinical Research; Platinum Award for Best Connector, Branch Out

GIVING BACK: Help a Girl Child; Speak for Kids

TWITTER ADDRESS: @sreedharsmail

CONNECTED VIA: LinkedIn, Twitter, Facebook



Dr. Sreedhar Tirunagari is committed to helping to eradicate the discrimination against girls in India.

Dr. Sreedhar TIRUNAGARI

Did You Know?

Dr. Sreedhar Tirunagari received awards for singing, painting, and acting from the governor of Andhra Pradesh India during his school days.

Dr. Tirunagari, who says what matters to him most professionally is contributing daily to outcomes for his company.

Other professional areas that inspire Dr. Tirunagari include educational research. He maintains that India tends to focus on educating interns in business rather than involving them in research, and that there is a lack of innovation in the education system. One area that he believes is sorely lacking in the medical education curriculum is entrepreneurship of physicians.

Beyond the workplace, Dr. Tirunagari is committed to helping to eradicate discrimination against girls in India, and he contributes to organizations that seek to support and promote girls' rights, empowerment, and education.

He is generally committed to the rights of children and helping children from different backgrounds succeed at school. **PV**



Trials and Tributes

A respected medical doctor and clinician, Sreedhar Tirunagari, M.D., has made a name for himself in the often-overlooked area of clinical trial management.


Dr. Tirunagari is senior manager, site management operations, and clinical enrollment director, at MakroCare Clinical Research in India.

His strong governance and oversight have been recognized with a nomination for Clinical Trial Innovation Award at the 2nd Annual

Partnerships in Clinical Trials Awards ceremony in the United States.

With a deep interest in ultra-rare diseases, Dr. Tirunagari maintains the enrollment of patients in this complex area is one of the biggest challenges within the industry. Indeed, enrolling patients for clinical trials for acquired hemophilia in India has been his most challenging assignment to date.

Commitment to his profession and his company is a strong defining characteristic of



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Olivia MONTAÑO-TRITZ



A positive scientific catalyst, Olivia Montañó-Tritz manages and motivates daily with a can-do attitude.

Standard Bearer

A big picture perspective and strong attention to detail underscore Olivia Montañó-Tritz. She is having a significant impact on the high-quality standards of both Synteract and the industry as a whole. She has built an incredible data management department at Synteract, and is drawing on her well-rounded background to set new and improved standards.

She views change as opportunity and is always interested in learning new things to expand her knowledge base. For example, under her leadership the company recently implemented an upgrade to the proprietary EDC system, offering users an improved option for on-time delivery of quality data.

Always striving to attain best practices for Synteract, Ms. Montañó-Tritz consults with various departments to ensure new processes work efficiently for all parties involved. This is evi-

Gaynor ANDERS

Patient Persuasion

For more than 15 years and across more than 75 countries, Gaynor Anders has been involved in patient recruitment and retention for clinical trials.

Ms. Anders has vast knowledge and direct experience in most — if not all — therapeutic categories. She offers perspectives on both the dynamic regulatory and cultural environment and the business values within a recruitment strategy.

In particular, she is passionate about pediatric populations, including the most vulnerable patients. Her thoughtful approach to recruitment, which encourages site-based and patient-education wherever and whenever possible, has won her widespread respect.

Her commitment and passion for her work shines through in everything she does. Going forward, her goal is to carry on building on her years in the industry, helping clients to push the boundaries of innovation and technology in the area of patient recruitment and health communications.

Not only is she hugely successful in her field as an individual, she is also fully committed to training and mentoring her U.K. team, enabling them to provide clients with a service that is second-to-none.

Outgoing and persuasive, Ms. Anders' motto — lead the way, let others follow — is

Gaynor Anders is a dedicated and talented professional, with unsurpassed experience in the patient recruitment arena.



Did You Know?

Gaynor Anders is self-admittedly accident prone and is often in need of paramedic attention.



evident in all she does; she can engage with anyone and she often convinces members of her teams to go outside of their comfort zones to stretch their skill sets and reach new heights.

Ms. Anders is also committed to giving back to her community. Last year she supported the London Royal Parks Half Marathon for the Children's Heart Federation raising more than £800 (around \$1,230) in contributions. **PV**



OUTGOING. PERSUASIVE.

NAME: Gaynor Anders
CURRENT POSITION: VP, Head of Global Operations, MMG
DATE AND PLACE OF BIRTH: October 1976; Surrey, UK
FIRST JOB: Book publishing
FIRST INDUSTRY-RELATED JOB: Healthcare and biotech PR
ALTERNATIVE PROFESSION: Teacher
PROFESSIONAL MENTORS: John Benbrook
PROFESSIONAL ASSOCIATIONS: Institute of Clinical Research
GIVING BACK: Children's heart charities
WORDS TO LIVE BY: Lead the way; let others follow
TWITTER ADDRESS: @GaynorA_MMGC
CONNECTED VIA: LinkedIn, Twitter, Facebook

Did You Know?



Olivia Montañó-Tritz wrote poetry as a child and would get paid five cents a word for each published work.

denced by updated SOPs and detailed work instructions, implementation of CDASH and GCDMP standards, as well as inter-departmental harmony meetings to create solutions for ongoing challenges/inefficiencies. She uses creative problem solving to stay a step ahead of the industry's needs.

With her reports' best interests at heart, she continually provides opportunities for them to strengthen their skill sets, such as participation in bid defenses, software validation exercises, and presenting training topics and software demonstrations. She has also implemented an internal training program for data managers to prepare for the CCDM exam.

Diplomacy comes naturally to Ms. Montañó-Tritz, who has been told that she can deliver both bad news and constructive feedback and make it sound positive.

Ms. Montañó-Tritz would say her biggest accomplishment is mentoring others to achieve their own potential.

She helps motivate those who work for her to achieve more by supporting their ideas on improving processes. She takes the time out of her extremely busy day to speak with employees about work-related concerns, and she encourages a good work-life balance, urging her staff to take care of themselves and their families.

A compassionate individual, Ms. Montañó-Tritz helped organize an event at Synteract, where employees built tricycles for a local children's charity. **PV**



DIPLOMATIC. INNOVATIVE.

NAME: Olivia Denisa Montañó-Tritz
CURRENT POSITION: Senior Director, Clinical Data Management, Synteract Inc.
DATE AND PLACE OF BIRTH: October 1972; Phoenix
FIRST JOB: Cashier
FIRST INDUSTRY-RELATED JOB: In a lab at the University of Arizona in the water and soil Department
ALTERNATIVE PROFESSION: Kindergarten teacher
PROFESSIONAL ASSOCIATIONS: DIA; Society for Clinical Data Management; CDISC; CDASH
AWARDS AND HONORS: Individual in Services Pinnacle Award Nominee and Finalist, 2010; Individual in Bioscience Pinnacle Award Nominee and Finalist, 2011
GIVING BACK: Children's Hospital/Ronald McDonald House; Disabled Veterans
WORDS TO LIVE BY: "Your success and happiness lies in you. Resolve to keep happy, and your joy and you shall form an invincible host against difficulties." — Helen Keller



IT TAKES MORE THAN VISION TO BE AN INNOVATOR. IT TAKES GUTS.

Congratulations, Faruk, for being named to the PharmaVOICE 100 for 2012.

For a dozen years, Faruk Capan has been an innovator in healthcare marketing. He pioneered online patient communities, and helped take pharma marketing to new digital channels. And he continues to push forward while others stand still. That takes guts.

Intouch Solutions is proud to have Faruk lead us with his innovation and entrepreneurship.

If you have the guts to work in healthcare marketing — and want to work alongside Faruk and his great associates — visit us online. www.intouchsol.com/careers



Sheila ROCCHIO



Sheila Rocchio is bringing ePRO to the next level by introducing the widest range of ePRO modalities from handheld eDiaries, to the Web, to the first ePRO Smartphone app.

Did You Know?

Sheila Rocchio was the 1995 All-around Gymnastics National Champion, Division III.



An ePRO Pro

Sheila Rocchio, VP of marketing at PHT Corp., is successfully promoting the global adoption of ePRO technology to help researchers do science better and people lead healthier lives.

Ten years ago, most clinical research used inaccurate paper diaries to collect subject data. Ms. Rocchio began a mission to get biopharma companies to abolish paper and embrace ePRO to collect the voice of the patient directly and without distortion. Today, the FDA and EMA strongly suggest using ePRO for clinical research to collect patient data. Colleagues and customers give Ms. Rocchio credit for guiding regulators to advocate, and sponsors to adopt ePRO technology. She is bringing ePRO to the next level by introducing a wide range of ePRO modalities from handheld eDiaries, to the Web, to the first ePRO smartphone app.

A consummate marketer, Ms. Rocchio combines customer insights with engineering know-how. Her operational skills in the areas of corporate and product marketing, product management, strategic planning, and partnership development for business-to-business technology solutions are well-respected by her peers, colleagues, and team members.

She is adept at building and leading high-performance teams. She works closely with her team members to discuss long- and short-term career goals and think about how together they can achieve those goals in ways that are great for the individual and the company. It's important for her to be a mentor as developing mutually collaborative and supportive relationships is one of the most enjoyable things about work.

She draws as much inspiration from those

ENERGETIC. INTELLIGENT.

NAME: Sheila Rocchio

CURRENT POSITION: VP, Marketing, PHT Corp.

DATE AND PLACE OF BIRTH: May 1975; Boston

EDUCATION: MIT; MBA, Boston College

FIRST JOB: Consultant, American Management Systems

FIRST INDUSTRY-RELATED JOB: Summer intern, Domain Pharma

ALTERNATIVE PROFESSION: Author or screenplay writer because she enjoys telling stories

PROFESSIONAL MENTORS: Phil Lee; Steve Raymond; Linda Beneze; Valdo Arnera, her eldest sister

PROFESSIONAL ASSOCIATIONS: ePRO Consortium; eClinical Forum; DIA

AWARDS AND HONORS: Boston Business Journal's Pacesetters: SmartReports Mobile; finalist for Innovative Product of the Year at both the Massachusetts Innovation & Technology Exchange the Massachusetts Technology Leadership Council Product of the Year

GIVING BACK: Partners in Health; Brain Tumor Society

WORDS TO LIVE BY: Be the change you want to see in the world


TWITTER ADDRESS: @SheilaRocchio

CONNECTED VIA: LinkedIn, Facebook, Twitter

around her as she provides to them. She is positively influenced by her team members, who work so hard to make PHT and its clients successful, as well as by several key PHT executives, including Phil Lee, CEO; Steve Raymond, founder; and Valdo Arnera, general manager in Europe.

She also is inspired by her clients who are working on innovative new therapies that have the ability to dramatically improve health and treat disease.

Ms. Rocchio's goal is to continue to evolve the products and services that help researchers keep patient-driven e-data at the center of clinical research as well as help PHT expand its capabilities into new areas like disease management to help improve health outcomes. Next on her to-do wish list is to build a solution that actually works for weight management because of the seriousness of the problem in the United States for adults and increasingly for children.

She says she is extremely lucky to be inspired every day by her three children who are amazing, smart, and funny, and her husband who is smart, empathetic, and calm, and who helps her see the funny side of things. She also credits her dad, mother, sisters, colleagues, and friends, who are finding ways to do it all. 



Graham NICHOLLS

A Senior Statesman of Statisticians



Graham Nicholls is widely regarded as Almac's "resident genius."

Did You Know?

Graham Nicholls has played a leading role in providing randomization and drug supply strategies for more than 1,000 clinical trials.

Graham Nicholls represents all of the best qualities of a senior statistician: advanced knowledge with strong specializations, a consultative/customer-focused nature, a detailed-oriented approach, and leadership skills.

Mr. Nicholls' role as director of Almac Clinical Technologies' biostatistical department requires him to provide consultancy advice to clients, to listen carefully, interpret the

problem being described, and provide in a clear manner proactive solutions — with pros and cons — to solve the problem.

Mr. Nicholls has played a leading role in providing randomization and drug supply strategies for more than 1,000 clinical trials.

Within the industry, he is considered as one of the premier thought leaders in IVR/IWR implementation of randomization and drug management. Patient randomization is the foundation on which successful trials are constructed, as it is the key to patient blinding, drug assignment, and medicine management throughout a clinical trial.

Within Almac, Mr. Nicholls is widely regarded as a "resident genius" and a leader of the clinical staff. He is responsible for directing all biostatistical matters relating to clinical trials and for ensuring that employees are trained in the principles of clinical trial designs, maintaining the study blind, and optimizing the supply chain for clients.


Mr. Nicholls' track record in the field is impressive. He has spoken at more than 25 conferences and published several articles since 2005 on a variety of topics, including IVR/IWR randomization and drug supply management

DETAIL-ORIENTED. CUSTOMER-FOCUSED.

- NAME:** Graham Nicholls
- CURRENT POSITION:** Director Biostatistics, Almac Clinical Technologies
- DATE AND PLACE OF BIRTH:** February 1973; England
- EDUCATION:** B.Sc., The University of Newcastle-upon-Tyne; M.Sc., The University of Reading
- FIRST JOB:** Restaurant waiter
- FIRST INDUSTRY-RELATED JOB:** Research fellow, Medical and Pharmaceutical Statistics (MPS) Research Unit, The University of Reading
- PROFESSIONAL ASSOCIATIONS:** DIA; PSI
- GIVING BACK:** Organizations for life-threatening diseases
- CONNECTED VIA:** Facebook

methodologies, implementation of adaptive trial designs, clinical trial supplies simulation and forecasting, and other topics related to clinical trial implementation. At the 2012 annual DIA conference, he spoke on the topic of supply considerations for adaptive trial designs.

Working directly with clients on a consultative basis relating to complex and dynamic randomization strategies, Mr. Nicholls has influenced the design and results of trials for almost every one of the top 100 firms in the biopharmaceutical industry as well as dozens of smaller firms.

Mr. Nicholls also has served on working groups and meetings with regulatory authorities, such as the FDA and EMA, and is recognized as a leading voice in regulatory consideration relating to trial randomization. 



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Pat Mitchell



Bonnie St. John



Noreen Fraser

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Bonnie St. John, Author and Olympic Athlete

Noreen Fraser, Founder of the Noreen Fraser Foundation

Dr. Sreedhar TIRUNAGARI

Site Insights

Combining a background in medicine with experience in clinical research and site management, Sreedhar Tirunagari, M.D., has deep insights into a complex aspect of drug development — clinical trials.

Dr. Tirunagari has strong knowledge of clinical operation, site management operations, patient recruitment and retention services, and has successfully managed global clinical trials in diversified therapeutic areas.

These experiences have given him a comprehensive understanding of global healthcare systems, good outcomes research practices, and pharmaco-economic guidelines around the world.

In the more than 20 clinical trial projects Dr. Tirunagari has overseen, he has been instrumental in providing oversight in the preparation of project-specific feasibility reports in liaison with the corresponding business team.

He has handled e-site identification, evaluation, liaison, and development at locations across India as well as in Singapore, Malaysia, Thailand, and Indonesia.

Getting Personal with

DR. SREEDHAR TIRUNAGARI

FAMILY: Wife; three children

HOBBIES: Music; painting; professional networking

FAVORITE BOOK: Charaka Samhitha

FAVORITE MOVIE: Business Man

LIFE LESSONS: Listen to people

MOST UNUSUAL PLACE VISITED: Mortuary

UNDER THE CLOAK OF INVISIBILITY: Remain on Earth to know the secrets of nature

A widely published expert, Dr. Tirunagari is well-respected in India's alternative system of medicine, Ayurveda, and has written on areas ranging from osteoarthritis, tension headaches, anemia, and chronic ulcers.

Dr. Tirunagari is a member of more than 75 scientific and professional bodies, including the European Forum for Good Clinical Practice, the Society for Clinical Data Management, the Indian Society for Clinical Research, the Centre for Information & Study on Clinical Research, the Institute for Clinical Research, CDISC, HL7, and the Regulatory Affairs Professional Society. **PV**

Dr. Sreedhar Tirunagari has a comprehensive understanding of global healthcare systems, good outcomes research practices, and pharmaco-economic guidelines around the world.



Graham NICHOLLS

Statistically Speaking

Graham Nicholls' engaging, friendly, good-humored approach to training and leadership set him apart. As director of biostatistics at Almac Clinical Technologies, he leads a team of statisticians, but more importantly he is integral in how Almac manages studies for more than 250 clients, several of which have invited Mr. Nicholls to train their staff.

He believes one of the biggest challenges for the industry today is to develop preventive treatments for life-threatening illnesses, while continuing to bring to market medicines that save lives until true cures and preventions are discovered.

Before joining Almac, Mr. Nicholls spent nine years at Clinphone (now Perceptive Informatics) and two years as a statistician at GlaxoSmithKline.

Getting Personal with

GRAHAM NICHOLLS

HOBBIES: Playing badminton and squash; running; going to the gym

INSPIRED BY: Alexander Fleming, Einstein, Gandhi, Nelson Mandela

LIFE LESSONS: Never take anything for granted and to be always grateful for any success that comes his way

UNDER THE CLOAK OF INVISIBILITY: Eaves-drop on meetings of world leaders, great scientists, and mathematicians

While at Clinphone, Mr. Nicholls was a leader in the randomization and clinical trial management group, where he consulted on a variety of statistical matters relating to clinical trial design as well as software development for supplies forecasting, medicine management, adaptive trials, and other matters.

Mr. Nicholls holds a B.S.c (Honors, Class I) from the University of Newcastle and an M.S.c Biometry from the University of Reading. **PV**



Graham Nicholls is integral in how Almac manages studies for its clients, several of which have invited him to train their staff.

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Gaynor ANDERS

Making the Complex Easy

Amid the global financial pressures, it has never been more important to focus on return on investment, something that is most evident in pay-for-performance contracting.

As VP, head of global operations at MMG, Gaynor Anders is keenly aware of these challenges and is focused on helping clients navigate the minefield of what risks are worth taking and which are best avoided.

Ms. Anders is considered one of the most senior and seasoned health and clinical trial communications experts outside of the United States.

Well-respected as a senior strategist by pharmaceutical, biotechnology, and CRO clients alike, Ms. Anders combines industry knowledge of feasibility and patient recruitment/retention with outstanding healthcare communications expertise.

Getting Personal with GAYNOR ANDERS

FAMILY: Husband; son

HOBBIES: Cooking; going to the gym; reading; spending time with family and friends

READING LIST: Medical press; health news; fiction

FAVORITE BOOK: 1984 by George Orwell

FAVORITE MOVIE: 12 Angry Men

FAVORITE SMARTPHONE APPS: Running apps

INSPIRED BY: J.K. Rowling

LIFE LESSONS: Everything is negotiable.

UNDER THE CLOAK OF INVISIBILITY: David Beckham's changing room



Gaynor Anders combines communications, clinical trial, and therapeutic expertise with up-to-date unparalleled regulatory insights in more than 70 countries.

Her therapeutic expertise spans women's health, cardiology, gastroenterology, pain, CNS/mental health, oncology, and endocrinology to name but a few of the therapeutic categories in which she has experience.

In addition, her work within vulnerable patient populations, particularly the pediatric and mental health communities, is an inspiration to those around her. Patient recruitment has many inherent challenges, and these chal-

lenges are all the more so when specializing in pediatrics, particularly some orphan pediatric indications, which is why Ms. Anders' knowledge and insights are considered so valuable.

She draws on her vast communications, clinical trial, and therapeutic experience and unparalleled regulatory insight in more than 70 countries to develop complex but tailored communications programs that are executed all over the world. **PV**



As an expert in CDISC standards, Olivia Montaño-Tritz is able to provide information to clients in advance so their data are collected and submitted accurately from the start.

Raising Standards

Olivia Montaño-Tritz joined Synteract, a full-service CRO, in 1999 as a clinical data coordinator and one of the company's first 30 employees.

Through strong technical acumen and

Olivia MONTAÑO-TRITZ

leadership she was promoted rapidly. Now senior director, clinical data management, Ms. Montaño-Tritz manages continued growth, development, and quality control of all data management operations and project deliverables to ensure performance meets both business and professional growth objectives.

She actively participates to raise industry standards. As a member of DIA she has been a subject matter expert in the EDC SIAC.

Ms. Montaño-Tritz also has contributed to several chapters for the SCDM manual's Good Clinical Data Management Practices and collaborated with CDISC as a subject matter expert on v1.1 of the CDASH guidelines and v.1 of the user guide to help drive industry standards.

Her expertise in CDISC standards also enables her to provide that information to clients in advance so their data are collected and submitted accurately from the start.

Getting Personal with OLIVIA MONTAÑO-TRITZ

FAMILY: Husband; son; twins on the way

HOBBIES: Gardening, art

READING LIST: Clinical trial industry-based articles and blogs

BUCKET LIST: To have a gallery showing one day

FAVORITE SMARTPHONE APP: Webex

INSPIRED BY: Her mother and father

MOST UNUSUAL PLACE VISITED: Tucson, Ariz.

She earned a specialized certificate in Clinical Trials Administration, she's a Certified Clinical Data Manager (CCDM), and she has recently achieved accreditation as a Certified Rave study builder.

Ms. Montaño-Tritz also has been nominated for the Athena awards, a women in business award. **PV**

Sheila ROCCHIO

An E-Champion

Sheila Rocchio has been instrumental in developing the ePRO industry from its infancy more than a decade ago when she began her career at PHT, as well as positioning the company as a market leader.

Ms. Rocchio developed the brand identity of PHT, for which it is now well-recognized, as well as spearheaded the development of new offerings, including the company's new Net-PRO Web diary tool.

To promote ePRO adoption she took the bold step of publishing PHT's proprietary tool for selecting the best ePRO modality for a clinical study, so any company can use it.

She is an experienced marketer, focusing on customer satisfaction and ease of use for patients, sites, and sponsors, and she never loses sight of what is important: improving clinical success and delivering better health outcomes.

To that note, Ms. Rocchio was extremely pleased when she received feedback from patients who shared that they liked using their LogPad and that the device helped them better manage their disease; they even asked if they could keep it after the trial had been completed.

Sheila Rocchio has been instrumental in developing the ePRO industry from its infancy more than a decade ago when she began her career at PHT.



Ms. Rocchio is a well-respected mentor and enjoys helping to shape her team member's careers. She also is generous with her time and supports several charities, including Partners in Health, whose founder Paul Farmer she finds to be inspirational, as well as the Brain Tumor Society, as her mother had brain cancer. **PV**

Getting Personal with SHEILA ROCCHIO

FAMILY: Husband; three boys, 5, 3, 10 months

HOBBIES: Running; yoga; reading; gardening; doing P90x

READING LIST: Unbroken by Laura Hillenbrand; Be Excellent at Anything by Tony Schwarz

FAVORITE BOOKS: To Kill a Mockingbird; All Creatures Great and Small

FAVORITE MOVIE: Return of the King

BUCKET LIST: Be on a float in the Rose Bowl or Macy's Thanksgiving Day Parade; go into space

FAVORITE SMARTPHONE APP: Angry Birds

INSPIRED BY: Her three children; her husband; her father and mother; sisters and friends; Phil Lee; Steve Raymond; Valdo Arnera

LIFE LESSONS: Never deny a generous impulse

MOST UNUSUAL PLACE VISITED: The middle of South Africa to do training at a Phase I site, Bloemfontein; she stayed at a hotel that was JR Tolkien's Birthplace, called The Hobbit House

TIME TRAVEL: To the past to Hawaii in the early 1900s to travel around the islands on horseback and buy beachfront



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