DR. BILL BYROM

At the Forefront of eClinical Technology

Bill Byrom, Ph.D., has spent a significant amount of his professional career working to understand how to better collect clinical trial data from patients. He has written the book on electronic patient reported outcomes (ePRO) — literally. In addition to writing too many papers and book chapters to count, Dr. Byrom, along with Brian Tiplady, wrote ePro: Electronic Solutions for Patient-Reported Data in 2010.

Through his writing and as senior director of product innovation at ICON Clinical Research, Dr. Byrom has contributed to the overall understanding of ePRO and its use in clinical trials.

In addition to his innovation role at ICON, Dr. Byrom currently serves as the vice director for the ePRO Consortium (Critical Path Institute) where he has led industrywide collaborations to push forward current thinking on the regulatory and scientific areas of electronic clinical outcome assessment (eCOA). His research includes demonstrating the viability of bring your own device (BYOD) patient-centric tools, thorough investigation of wearables and their application in 21st century research and medicine, and new ways to recruit, motivate, monitor, and interact with patients in clinical trials.

CREATIVE. STRATEGIC THINKER.

Dr. Bill Byrom has been driving ePRO from the early days, and he is now pushing forward current thinking on the regulatory and scientific areas of eCOA.

Driven to collaborate by OTHER PERSPECTIVES

In recent years, he has helped to evaluate how patients can be supported in reporting ePRO data from home. Dr. Byrom not only researched operational aspects of BYOD, but also regulatory and scientific aspects championing ePRO and BYOD within clinical trials, including cutting edge primary research to support the validity of the approach..

He has not only done considerable work to advance the techniques of ePRO and associated technologies, but Dr. Byrom has also advocated and facilitated their increased use within clinical studies. Colleagues say one of his many strengths is his ability to take scientific and theoretical theories and translate them into practical application.

Those who have worked with Dr. Byrom say they admire the way he constantly seeks new ways to improve clinical research, especially in areas using technology. He has excellent communication skills and a strong lead-by-example work ethic. These attributes have enabled him to pull together teams of top thinkers from a variety of biopharma companies, academia, and even competing companies.

Dr. Byrom says one of his goals is to drive innovative approaches within clinical drug development and commercialization, and to operationalize these approaches to enable use at scale within clinical trials and real-world evidence studies.

Another of his goals is to drive the industry's adoption and use of wearable devices. As vice director of the ePRO Consortium, he is leading a consensus group that is developing recommendations for evidence needed to support the selection of wearable devices for use in regulatory submission trials and to support endpoints derived from their data.

"I'm passionate about leveraging smartphone sensors within patient apps, remote collection of data using wearables and shareables — such as commercial health kiosks — and leveraging existing technology in novel ways," he says. "Currently, I'm looking at how we can use motion-based gaming platforms such as Microsoft Xbox to collect movement and mobility endpoints from the 3D coordinates of body joints tracked using the gaming platform during tests conducted by the patient."

He says he has a desire to continually improve how clinical data are collected to see patients benefit from these improvements. His overall goal is to leverage technology in novel ways to make trial participation easier, more engaging, and to provide richer and more informative data that generates deeper insights for researchers and healthcare providers.

He wants to be remembered for bringing forward creative eClinical solutions to improve the conduct of clinical trials. Dr. Byrom is dedicated to delivering the scientific work needed to help drive the increased adoption of wearable, mobile, and telemedicine technology in trials that ultimately helps patients to become partners in research and addresses their medical needs. PV

Getting to know...

Bill Byrom, Ph.D.

TITLE: Senior Director of Product Innovation
COMPANY: ICON Clinical Research
EDUCATION: BSc, Mathematics with Statistics, University of Nottingham; PhD, University of Strathclyde
FAMILY: Wife, Tina; two teenage daughters, Charlotte and Sophie
HOBBIES: Road cycling, walking his dogs with the family, and watching live indie rock music in his hometown of Nottingham, England
BUCKET LIST: Complete a triathlon
AWARDS/HONORS: PharmaVOICE 100, 2008; Stevie Business Award: Selling Power Sales Excellence Award for innovative sales training program, 2006; Nottingham Girls' and Ladies' Football League, Manager of the Season, 2011
ASSOCIATIONS: The Critical Path Institute's ePRO Consortium; eClinical Forum; DIA Study Endpoints Community; ISPOR; Centre For Business Intelligence Medical Adherence Consortium
SOCIAL MEDIA:
TWEET AT: @billbyrom

CALM. PROBLEM-SOLVER.

Dr. Susan Atkinson exemplifies an executive who develops other leaders and derives personal satisfaction from her teams' progress.

DR. SUSAN ATKINSON

Practical Innovator

Driven to collaborate by

HONEST IDEAS

For Susan Atkinson, Ph.D., her job is very much a calling. It's about doing work that matters to those she collaborates alongside, to the company she innovates for, and to the patients who receive benefits from the drugs they are developing.

As senior VP of global biometrics for PPD, Dr. Atkinson oversees the company's global patient data acquisition, cleaning, analysis and reporting for all phases of its clinical trial data, leads the clinical supplies and randomization services and plays a strategic role in PPD's innovation efforts.

"Real innovation brings value when it's applied to a practical problem with an enterprise mindset," she says. "There is an abundance of data in clinical R&D. The tools to acquire and analyze these data sets are becoming more accessible. The ability to warehouse — organize and store data — is increasing. My role in innovation is to connect these tools and approaches to business problems that need solving. And in reverse, it is to take a business problem and look at it from a fresh perspective and see how other solutions can be extrapolated to the problem at hand."

Since joining PPD in 1991 as a senior biostatistician, Dr. Atkinson has risen through the ranks of the CRO to her current leadership role to which she brings vast expertise in statistical analysis, clinical trial design, regulatory submission strategies, and knowledge of eClinical trial technologies.

Increasingly, Dr. Atkinson believes traditional boundaries of the clinical trial R&D model are being challenged by a much-needed focus of putting the patient first. To stay relevant, clinical trial protocols must be innovated with the patient's view in mind and data collection methods must continue to evolve in support. A natural puzzle-solver, Dr. Atkinson loves the challenge of analyzing a situation, considering options, and putting together new solutions.

Colleagues describe Dr. Atkinson as an inspiring leader, incredibly intelligent, ethical, sincere, compassionate, and a visionary leader during times of change. She has a skill for grasping complex concepts and distilling them down to develop creative strategies.

She describes success as sustainable business growth amid challenging times. She says many leaders thrive during the good times; it's those leaders who steer people through the rougher times who really stand out. Her colleagues say she has the talent to take the worst situation and reframe it to what it could be.

Dr. Atkinson sets high expectations for her teams and for herself. The environment she creates is fair and respectful, and one in which people come first. This balance breeds motivation and inspires those around her to reach their goals.

Leadership to Dr. Atkinson is about encouraging others to do the right thing — with integrity, a high personal standard of quality, deep domain knowledge, and driven by data — for the right reason and at the right time. She encourages her people to draw on situational awareness, collaborative skills, and team dynamics.

Dr. Atkinson particularly enjoys working on the integration of acquisitions, where the skills of collaboration and teamwork are leveraged to build something that is greater than the sum of its parts.

When challenges arise, she keeps teams focused on the purpose and vision behind what they are working on. And she helps others to see that a challenge is really an opportunity — to grow personally, question the status quo, and improve operations to benefit patients.

Collaboration is important to Dr. Atkinson, who runs a large and diverse global operation by pulling her teams together and aligning their vision on the goal at hand.

She would like to be remembered by others who feel that they are better leaders because of her input. Her hope is that the teams she has assembled will build on the foundations she has instilled of quality, innovation, and collaboration to soar to new heights, doing even greater things in the areas of research and development.

Dr. Atkinson inspires others by remaining focused and humble amid an intense and often demanding industry. She mentors both officially and unofficially within PPD and the nonprofit organizations she is involved with. Colleagues note that Dr. Atkinson encourages others to reach their full potential by remaining genuine and having a sincere interest in understanding and listening to their concerns.

In addition to mentoring others, Dr. Atkinson helped to develop a leadership training program.

"Leaders have to share and develop others; otherwise, they are just managers or individual contributors," she says. "I find that I grow and develop just as much in these mentoring engagements as does the mentee. The more I mentor, the more challenged I am to clarify my thinking and evaluate approaches from different perspectives." PV

Getting to know...

Susan Atkinson, Ph.D.

TITLE: Senior VP, Global Biometrics
COMPANY: PPD
EDUCATION: BS, MS, PhD, University of North Carolina, Chapel Hill
FAMILY: Her husband, their grown children, and rescued German shephard
HOBBIES: Crocheting, quilting, yoga, reading
BUCKET LIST: Travel to numerous places she has yet to see — top of the list are Australia, New Zealand, Italy, and a safari in Africa
ASSOCIATIONS: American Statistical Association; CDISC; Board of Directors for local nonprofit, church membership and related ministries
SOCIAL MEDIA:

AMBER EATON

Connecting Passion and Conviction

An innovator and motivator, Amber Eaton is propelling MicroMass to new heights in its efforts to change patient and provider behavior.

In her role as VP and group account director at MicroMass Communications, Ms. Eaton is also cultivating an atmosphere where people matter and she is helping others to re-envision the future and take risks.

Ms. Eaton possesses a strong strategic vision as well as a penchant for the fine details, which have served her well in her role as the main agency point person for very large, exhaustive brand initiatives and specialized projects.

An innate passion for helping improve the patient experience helps to keep Ms. Eaton's ideas fresh and her interest high. She has created an environment that enables her colleagues to craft solutions that haven't been used before to solve client challenges.

According to Ms. Eaton, the industry is still tackling real-world barriers around prescription initiation and adherence. To win this battle, she says the industry must address both the clinical and psychosocial needs of patients along the treatment journey and that means bringing together pharma companies and external partners, including nurse educators, healthcare providers, specialty pharmacies, patient assistant teams, and advocacy groups to implement a whole patient approach.

This approach supplements conventional efforts with active motivation and skill-building programs to accelerate product awareness and adoption and drive optimal outcomes.

Ms. Eaton is working to ensure that MicroMass remains relevant and innovative in its thinking, pushes limits, constantly pressure tests ideas, and evolves to not only solve clients' challenges but has a true impact on patient outcomes. Her innovative approach to problem solving is taking MicroMass' behaviorally based solutions to the next level.

She can identify opportunities and adapt strategically to meet patient needs. In doing so, she builds the trust and respect of her clients, her peers, and her co-workers.

Ms. Eaton believes that people are motivated to do their best when they feel validated, appreciated, and understood.

"I've learned over the years that the growing pains I experienced in my career are powerful tools to share with others as they grow," she says, and admitting that it's important to go outside of one's comfort zone and not be afraid to take risks. "Taking the time to connect — sharing experiences, failures, fears, and goals — allows me to truly get to know others. When we share these types of connections, we intuitively want to work harder to meet common goals."

Challenges present an opportunity to teach and learn, she maintains. And Ms. Eaton and her team work together to break down the issues so they seem less overwhelming. Colleagues describe her as passionate, fearless, and insightful.

"I lean on my instincts to identify who I think likely has the answer and I push that person to speak up and be the leader the team needs at that moment," she says.

She empowers her team members to confidently lead and flourish on their own. Ms. Eaton believes leadership is about motivating and influencing others through one's own character, humility, and integrity, and inspiring them through passion and conviction toward a shared vision.

"Innovation thrives where there is an environment that ensures alignment on a shared goal, values different perspectives and experiences, empowers people, fosters collaboration, and forgives failure," she says. PV

PASSIONATE. PERSISTENT.

Amber Eaton's strategic vision and innovative approaches to solve patient-centric challenges are just two of her leadership tools of the trade.

Driven to collaborate by

PATIENT NEEDS

Getting to know...

Amber Eaton

TITLE: VP, Group Account Director
COMPANY: MicroMass Communications Inc.
EDUCATION: BA, Public and Interpersonal Communication, North Carolina State University, 2001
FAMILY: Husband, Eric; two sons, Cooper and Walker
HOBBIES: Spending time with family and friends, reading, traveling
SOCIAL MEDIA:
TWEET AT: @AmberSEaton1

DR. STEVE SHAK

A Pioneer in Precision Medicine

Steve Shak, M.D., has been a pioneer in personalized medicine for more than 30 years. With decades of discovering and developing breakthrough drugs and diagnostics, his contributions to medical science and patient care are innumerable. As a leader, he constantly challenges his teams to think innovatively and pushes clinicians and scientists to answer the most critical clinical questions.

While at Genentech, Dr. Shak is credited with spearheading the discovery and development of multiple breakthrough products in the biotechnology industry — including Herceptin, approved in 1998 and the only targeted biologic therapy approved for treatment of HER2-positive breast cancer in the adjuvant and metastatic settings, and Pulmozyme, approved in 1993 as the first treatment that specifically improves lung function in CF patients.

In 2000, Dr. Shak co-founded Genomic Health with the goal of developing high-value diagnostics to enable more personalized cancer treatment decisions based on the genomic activity within a patient's individual tumor.

The company, which started 17 years ago with a small group of like-minded colleagues, has now grown into an organization with more than 840 employees worldwide serving more than 800,000 patients in more than 90 countries around the world.

Genomic Health is a provider of genomic-based diagnostic tests that help optimize cancer care. With its Oncotype IQ Genomic Intelligence Platform, the company is applying its scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, saving the U.S. healthcare system more than $3.5 billion.

Under Dr. Shak's leadership, Genomic Health has revolutionized the quality of treatment decisions for cancer patients and made precision medicine a reality for hundreds of thousands of patients worldwide. In 2004, he played an instrumental role in the launch of the company's first product, the Oncotype DX Breast Recurrence Score, which quantifies the likelihood of breast cancer recurrence for early-stage breast cancer patients and predicts chemotherapy benefit to help inform decisions about treatment and improve patient outcomes.

Dr. Shak believes in the power of data to help guide treatment decisions. He has made it a mission to foster a team dedicated to building an unmatched database of scientific evidence supporting the use of Genomic Health's products. He led a collaboration with the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program to gain important clinical insights from patients whose treatment information and outcomes has been gathered and tracked by the government registries.

Partnering with SEER, Dr. Shak helped pioneer a new model for government and industry working alongside one another, using big data to improve breast cancer diagnosis and treatment.

Colleagues say Dr. Shak's leadership style is infectious. He consistently and passionately facilitates the connection of everyone at Genomic Health to that common mission, which is to help patients receive optimal treatment and experience better outcomes.

Dr. Shak has been recognized on multiple occasions for his impact in optimizing cancer research and care, and in bringing the patient voice into product development. In 2009, he received CancerCare's Beacon Award, in recognition of genomic innovations in diagnostics for breast cancer. In 2015, he received the Physician of Impact Award from Susan G. Komen honoring him for his commitment to raising awareness and saving the lives of breast cancer patients.

Dr. Shak says his most challenging assignment has been transitioning his skills in scientific innovation and drug development into becoming a transformational leader who inspires innovation in others.

"I try to ask good questions and look at strategy and decisions in the context of near- and long-term considerations and the larger industry and healthcare ecosystem," he says. "I try to inspire by providing opportunities for others to excel and make a difference."

Dr. Shak would like to be remembered as someone who has made a difference in the lives of patients and colleagues. And it appears as if he already has. PV

Getting to know...

Steven Shak, M.D.

TITLE: Co-founder and Chief Scientific Officer
COMPANY: Genomic Health Inc.
EDUCATION: BA, Chemistry, Amherst College; MD, New York University School of Medicine; Postdoctoral training, Bellevue Hospital, New York, and University of California, San Francisco
FAMILY: Parents; wife, Gail; daughter, Linda; son, Joshua (Emma)
HOBBIES: Cycling
BUCKET LIST: Give back to others
INDUSTRY AWARDS/HONORS: Susan B. Komen Greater NYC Physician of Impact Award, 2015; The Solomon A. Berson Alumni Achievement Award in Clinical Science from NYU School of Medicine, 2010; CancerCare's Beacon Award, 2009; NYU Biotechnology Award, 2001; Prix Gallien, Portugal for Pulmozyme Discovery, 1995; Parenting Achievement Award, Parenting Magazine, 1995; Distinguished Corporate Scientist Award, Cystic Fibrosis Foundation, 1993; CF Achievement Award, Cystic Fibrosis Research, 1992
ASSOCIATIONS: American Society of Clinical Oncology
SOCIAL MEDIA:

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ACCOMPLISHING A BIG AND IMPORTANT GOAL

CARING. CURIOUS.

Thanks to Dr. Steve Shak's leadership and dedication, the biotechnology industry has evolved the treatment paradigm for cancer and made precision medicine a reality for hundreds of thousands of cancer patients worldwide.

DR. KENNETH KOBLAN

CNS Innovator and Collaborator

PASSIONATE. ENTREPRENEURIAL.

Dr. Kenneth Koblan drives innovation and creativity from the perspective of being a quantitative, objective scientist at heart.

A problem-solver by nature, Kenneth Koblan, Ph.D., is focused on driving innovation to develop medicines and solutions for patients struggling with psychiatric and neurologic disorders. In his role as head of global translational medicine and early development and head of discovery sciences at Sunovion, Dr. Koblan is using novel technology and quantitative methods and approaches from target identification to clinical trial end points, to bring new medicines to patients.

Passionate about central nervous system (CNS) development, Dr. Koblan joined Sunovion because of its core therapeutic focus in this area of research. He is using his abilities to organize and synthesize scientific data to address the challenges associated with studying mental health disorders and the brain, which present unique and unparalleled opportunities for innovation. Before joining Sunovion in 2011, he held scientific leadership roles at Merck Research Laboratories and Alnylam Pharmaceuticals.

With global healthcare needs evolving rapidly and the increasing prevalence of psychiatric and neurological disorders associated with aging populations, Dr. Koblan knows that while there is greater understanding of disorders of brain functioning, neuropsychiatric illnesses rank among the leading causes of disability worldwide.

For Dr. Koblan, a career-defining experience has been the opportunity to build the early clinical development and translational medicine groups at Sunovion and create innovative clinical trial designs in special patient populations. These trials have been translated into Phase III registration programs in the areas of ADHD and binge eating disorder.

Dr. Koblan continues to push Sunovion's pioneering systems-based approach to find new psychiatric drug candidates. He and his team have built an exciting library of compounds they continue to mine. They are characterizing the molecules based on their neurobehavioral effects in animal models, and then studying how these effects compare with known active agents.

This process allows for a better understanding of the range of possible therapeutic indications for new molecules and provides guidance for optimal pathways to take to early clinical development.

He recognizes that he has a major responsibility to fulfill for patients, noting that many of the larger pharmaceutical companies have retreated from drug development in many of the areas in which Sunovion is conducting research and development, particularly the fields of neurology and psychiatry, where the global disease burden is so significant.

He is optimistic about the future because of the boundaries being pushed by multiple factors, including patient-reported outcomes, patient-centric endpoints in clinical trials, and the elucidation of genetics of disease states, as well as novel modalities, for example cell-based therapies and a new generation of therapeutics.

He believes that evolving technologies, including regenerative medicine, have a transformative potential for patients. He is also excited by the possibilities of new computational chemistry and big data approaches, which have the potential to reduce the time and cost needed to attain the IND milestone. Additionally, to address the "inaccessibility" of the brain during clinical development, he is applying non-invasive imaging. He also continues to emphasize the use of cutting-edge translational approaches, such as new modeling and simulation techniques, and other methods for demonstrating the desired CNS activity and target engagement.

He encourages his team to take an entrepreneurial approach to accelerate timelines while maintaining high-quality standards. Dr. Koblan would like to be remembered as an innovator across the entire continuum of development, and for focusing on the genetics of early mental health that point toward the next generation of targets.

He is an active leader, who closely watches, acts, and teaches his teams and he puts a great deal of attention on getting the right people in the right roles and letting them do their jobs while providing oversight, so they can stay focused on critical objectives.

"I encourage each individual to have a single point of accountability and help teams focus on driving core timelines and objectives," he says. "At the same time, I drive toward collaboration and alliances with external partners, and embrace a global role working with my colleagues worldwide."

Dr. Koblan is a big believer in the power of cross-stakeholder collaborations and consortia, and he is a member of the Neuroscience Consortium of Massachusetts Life Sciences Center.

He is committed to developing the next generation of "drug hunters" in his group, fostering valued relationships, and working with people who have diverse skill sets and personalities. PV

Getting to know...

Kenneth Koblan, Ph.D.

TITLE: Head of Global Translational Medicine & Early Development (TMED) and Head of Discovery Sciences

COMPANY: Sunovion Pharmaceuticals Inc.

EDUCATION: BS, Biology, Massachusetts Institute of Technology; PhD, Biochemistry, Johns Hopkins University

HOBBIES: Woodworking, building furniture out of heirloom pieces of wood, fishing, rowing

BUCKET LIST: Riding the rapids at the base of the Grand Canyon

Driven to collaborate by

DIVERSE PERSPECTIVES

ELISE FELICIONE

Leading Transformational Change in R&D

As a founding member of Janssen's R&D innovation group, Elise Felicione helped establish a dedicated clinical trial innovation unit within Janssen, where she currently serves as the team lead and right-hand to the head of R&D Operations Innovation and oversees strategy and execution of a portfolio of initiatives that develop novel models and methods for clinical trial operations.

Ms. Felicione was instrumental in shaping a companywide strategy and roadmap for patient engagement in clinical R&D. During this time, she led an effort that tested several tried-and-true market research methods, including social listening, patient interviews, surveys, and simulated trials to seek direct patient insights and apply them to the design and conduct of clinical trials. This program, known as Patient Voice in Trial Design, won the 2017 Clinical & Research Excellence (CARE) Award for most patient-centric initiative.

"There were so many quick wins up for grabs that represented quantum leaps in patient engagement," Ms. Felicione says.

Another quick win and industry first volved use of a general patient satisfaction e survey in eight countries in a multinatio Phase III trial, creating the blueprint for systematic use of satisfaction surveys.

Colleagues remark that Ms. Felicione is a steadfast champion for open innovation and cross-industry collaboration.

Pharma R&D, Ms. Feliciosne says, needs to develop solutions and offer them up to other companies, developers, or entrepreneurs to further improve on. She also encourages a community-of-practice approach among the innovation units in other pharma companies.

"How to innovate in operations successfully is certainly not a trade-secret," she says. "We should all support one another.

"One of the best examples of collaboration and entrepreneur enabled innovation is electronic informed consent, or eConsent," she continues. "Informed consent has been prone to lengthy and highly technical paper forms for patient education and is prone to avoidable errors such as use of outdated versions. In parallel, a revolution in electronic learning systems and norms has taken place, which sparked a few brave entrepreneurs to develop eConsent technologies aimed at providing an interactive, educational experience for prospective clinical trial participants and electronic signing and archival capabilities."

Ms. Felicione and her team introduced eConsent technology into Janssen clinical trials in multiple countries around the globe while actively shaping policies and practices through cross-pharma organization TransCelerate and direct interactions with health authorities.

She attributes her success to her A++ team. "You need to attract and retain the best people, foster a teamwork culture, and inspire them that their work will change the world," she says. "They must also strive for measurable results in their projects."

She says partners and customers who share the same vision are important for helping to foster innovation.

"Innovation requires dedication: dedicated people; dedicated funding, organizational leadership that supports trying new things and has a tolerance for failure and prudent risk taking," Ms. Felicione says.

A career highlight for Ms. Felicione was being part of a clinical development program for a cervical cancer vaccine that ultimately was brought to market. Occasionally still to this day, when in a room full of children, she thinks how they have one less form of cancer to worry about thanks to this breakthrough.

Ms. Felicione is inspired by her mother, who bravely battles a devastating progressive brain disease.

She would like to be remembered for the impact her work has made. And she aims to inspire by communicating a cause, a reason, a mission that others can identify with, buy into, and then together, do something great. She views any situation, even adversity, as a gift, saying it teaches lessons, it helps you grow, and it has a purpose. "The glass is always half full," she says. PV

POSITIVE. ENERGETIC.

Elise Felicione challenges her team to think outside of the box to find patient-centered and technology solutions to improve clinical trials.

Getting to know...

Elise Cortner Felicione

TITLE: Senior Director, Research & Development Operations Innovation
COMPANY: Janssen, Pharmaceutical Companies of Johnson & Johnson
EDUCATION: BS, Molecular Biology and Biochemistry, University of Idaho; Master of Public Health, Epidemiology, Emory University; MBA, Drexel University
FAMILY: Carlos, Alessia, and Matthias Sattler
HOBBIES: Running, art, cooking, wine
BUCKET LIST: Becoming a sommelier
SOCIAL MEDIA:

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THE BRILLIANCE OF OTHERS