YOUR PAREXEL MUSCULOSKELETAL TEAM
MEET YOUR TEAM OF MUSCULOSKELETAL EXPERTS

Medical Imaging – Musculoskeletal Expertise

Peter Steiger, Ph.D., Vice President and Chief Scientific Officer, Medical Imaging

Sally (Sarah) Warner, Ph.D., CCD Senior Medical Director, Musculoskeletal Imaging

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Manish Sharma, M.D., DMRE, M.B., cMBA, Senior Director, Scientific and Medical Affairs

Rudresh R. Jarecha, D.N.B., D.M.R.E., Associate Medical Director

Prashant Bansal, Ph.D., Associate Medical Director

David Bennett, Ph.D., Associate Medical Director

William Palmer, M.D., Scientific Advisor

Felix Eckstein, M.D., Scientific Advisor

Didier Hans, Prof., Ph.D., M.B.A., Scientific Advisor

Jener Basilio, R.T., Medical Research Scientist

Anja Urbank, R.T., Senior Medical Research Scientist
PAREXEL Informatics has supported more than 178 musculoskeletal (MSK) imaging studies that include X-ray, computerized tomography (CT), magnetic resonance imaging (MRI), ultrasound, dual-energy X-ray absorptiometry (DXA), and quantitative computed tomography (QCT) imaging. PAREXEL also has extensive experience working with a full range of well-known MSK key opinion leaders (KOLs) and criteria authors as consultants and readers. Through thoughtful implementation of both expert independent review and automated analysis, PAREXEL has the proven capabilities to support all MSK indications. With a team of experienced in-house musculoskeletal imaging experts, including several radiologists, an MR physicist, and a dedicated MSK group, PAREXEL is fully equipped and optimally positioned to support your MSK trials.

The specific strengths of our musculoskeletal experts include:

- Ability to connect clinical and academic MSK experience to clinical trial practice
- Standardized global coverage with imaging specialists located across offices in the U.S., Japan, India, and Germany to oversee training, site visit, and site support needs, including machine calibration support and technologist training as needed
- Access to key opinion leaders (KOLs) as expert readers and trainers
- Sophisticated analysis platforms that have achieved KOL design approval
- Faster, reproducible, and more accurate analysis enabled by advanced monitoring and tracking tools
- Risk mitigation based on best practices gained through extensive trial management experience
Peter joined PAREXEL in 2014 and leads the medical and scientific team at PAREXEL Informatics Medical Imaging, which is comprised of a global team of over 30 MD, Ph.D., and scientists. He has a wealth of experience in the use of imaging in academic research, medical device development and clinical trials management. His responsibilities include both the oversight of the medical team as well as the expansion of PAREXEL’s Medical Imaging business into new areas.

**Work Experience**

Peter started his academic career at the University of California, San Francisco under the direction of Dr. Harry K. Genant, where he was involved in multiple publicly and privately funded research projects in skeletal radiology.

In 1990 Peter left academia to work at Hologic, Inc. As Chief Scientist, he was involved in the development of new product concepts and strategies, product development, planning and execution of clinical research for product validation, preparing regulatory submissions, and supporting the field service, marketing, and manufacturing departments. During his tenure at Hologic, Peter also created a division which provided image quality assurance services to pharmaceutical companies in support of clinical trials.

Later, Peter joined Synarc, Inc., a privately-held, venture-backed company for the support of imaging in clinical trials. During his tenure as CEO, Synarc grew to become one of the world’s leading dedicated providers of centralized imaging services, an organization with 350 employees in 5 countries.

Peter returned to the medical device industry when he joined Optasia Medical LTD. as CEO in 2006, and where he helped close an initial round of financing to help launch the company. Optasia Medical makes and sells FDA cleared software that is used in a point-of-care setting for the documentation of vertebral fractures.

Throughout his career, Peter has been actively engaged in research, has authored numerous papers and is regularly involved in research presented at scientific meetings.

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Education

Peter studied electrical engineering and computer science at the ETH in Zurich, Switzerland and received his Ph.D. degree in Biomedical Engineering for work on the quantification of subchondral bone loss in rheumatoid arthritis. His work for both his master’s and Ph.D. degrees included the development of hardware and software for the control and image processing needed for a special purpose high resolution computerized tomography (CT) scanner, which was built to characterize bone structure and bone quality.
Sally joined PAREXEL Informatics in 2006. She provides scientific expertise in study design, protocol standardization, and customization of analysis software tools for musculoskeletal clinical imaging trials. She is also responsible for quality and regulatory compliance of deliverables.

**Work Experience**

Sally has nearly 20 years of experience in imaging for musculoskeletal research trials. Sally’s previous experience includes certification by the International Society for Clinical Densitometry (ISCD) as a clinical densitometrist and a dual-energy X-ray absorptiometry (DXA) technologist, as well as Radiology Practicing Technologist License in the state of Utah; making her perfectly suited to assist investigator sites in proper scan acquisition. She has held positions as senior research assistant at the University of Connecticut Health Center, research fellow at the University of Utah and senior research fellow in the department of Orthopaedics and Sports Medicine at the University of Washington. Sally’s musculoskeletal research has included the use of many different modalities for the assessment of bone metabolism including bone histomorphometry, 3-point bending, radiography, ultrasound (US), DXA, quantitative computed tomography (QCT), and high resolution computerized tomography (HrCT) imaging. During her tenure at PAREXEL, Sally has managed the medical and scientific aspects of imaging for more than 65 clinical trials in rheumatology (rheumatoid arthritis [RA], psoriatic arthritis [PsA], spondyloarthritis [SpA]), ankylosing spondylitis (AS) and osteoarthritis (OA), orthopedics and body composition. These trials have included the use of radiography, CT, Dual-energy computed tomography (DECT), QCT, DXA, US and magnetic resonance (MR) imaging with a variety of qualitative and quantitative assessments.

**Education**

Sarah received her B.A. in biology and exercise science from Skidmore College, a master’s degree in exercise physiology from the University of Connecticut and her Ph.D. from the University of Utah.
Ken joined PAREXEL in 2008 and has global responsibility for the medical imaging business. He provides operational, medical and technological leadership in support of imaging biomarkers in early-to-late-phase programs across various indications and therapeutic areas. Ken also works with other PAREXEL business units to provide technology solutions for the biopharmaceutical research market.

**Work Experience**
Prior to joining the PAREXEL family, Ken was co-founder of Synarc, Chief scientist and global director of product development at GE Healthcare, and spent nine years at Oregon Osteoporosis Center where he built and directed the biomarker laboratory operation.

**Education**
At the University of California, San Francisco, he received both his master’s and doctorate degrees in biomedical engineering and served as an assistant professor of radiology. Ken has had numerous articles published on rheumatology and osteoporosis.
Manish Sharma, M.D., DMRE, M.B., cMBA
Senior Director, Scientific and Medical Affairs

Manish is a senior director of scientific and medical affairs. He has over 12 years medical imaging and regulatory experience in the clinical research and pharmaceutical industry. He joined PAREXEL originally in 2007. Manish has been instrumental in designing medical strategy for regulatory submissions across several global regulatory agencies. He has closely worked with sponsors and regulatory agencies to define global biosimilar initiatives. He has supported development and registration pathways including study design, regulatory advice, endpoint selection and protocol development.

Work Experience
Manish is a radiologist with broad clinical radiology experience. He has been working in the Asia Pacific region for development of Central Review Systems with PACS and their customization for various assessment criteria. He has been instrumental in building review platforms including PACS and has supported its commercialization across the industry including hospitals, imaging facilities, and core labs.

Education
Manish has an excellent professional and educational background receiving his Bachelor of Medicine, Bachelor of Surgery in 2000, graduating first class. He went on to receive gold medals for both his Post Graduate Diploma in Medical Radiology and Electrology (2003) and his Doctor of Medicine degree (2004). He has obtained various honors and certifications throughout his professional career. In 2011, he has received HIPAA Compliance Training from John Hopkins and a Master Certificate in Business Management. He achieved an ICH GCP Certificate Training in 2012. In addition to this, Manish is fluent in English, Hindi, and Gujarati.
Rudresh is an associate medical director and Asia-Pacific medical head for PAREXEL Informatics, based in Hyderabad, India. He has been involved in the design and management of multiple musculoskeletal studies across various indications. Rudresh has served as an independent reviewer on trials, providing skilled medical data interpretations for clinical trials that rely on the results of medical imaging. Rudresh also has significant experience in leading and managing the imaging component of multiple musculoskeletal, oncology and women’s health imaging clinical trials. He supports sponsors and trials by acting as medical owner for trials and serving as a consultant to sponsors in protocol and charter development; independent reviewer training and oversight; and performing medical QC on the final data export. Additionally, he is an active member of the Quantitative Imaging Biomarkers Alliance (QIBA) volumetric working group and the Indian Radiology and Imaging Association (IRIA).

Work Experience
Before joining PAREXEL, Rudresh worked as a consultant radiologist where he was predominantly focused on musculoskeletal and oncology. He has experience with conventional and interventional radiology including general ultrasound (USG), computerized tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography–computed tomography (PET-CT). He has presented dozens of scientific exhibits, papers, and continues to lecture at various conferences and meetings.

Education
Rudresh earned a Diplomate of National Board (DNB) in Radiodiagnosis, working with Padmashree Prof. Kakarla SubbaRao. He has also received his Diploma in Medical Radiology and Electrology dealing with radiology physics (including MRI).
Prashant joined PAREXEL Informatics in 2013. He provides medical expertise in study design, protocol standardization, and customization of analysis software tools for imaging trials in the musculoskeletal, oncology, and ophthalmology therapeutic areas.

Work Experience
Prashant has nearly 10 years of experience in the application of multi-modality imaging for various therapeutic areas. Previously, he worked as a Senior Imaging Scientist at Pfizer’s multi-modality pre-clinical imaging laboratory in Andover, Massachusetts. He has extensive experience with X-ray based imaging modalities such as dual-energy X-ray absorptiometry (DXA) and computerized tomography (CT). He is also experienced in working with fluorescence and bioluminescence based optical imaging modalities. In his musculoskeletal research experience, Prashant has utilized various imaging modalities such as contrast–enhanced X-ray CT, DXA, peripheral quantitative computed tomography (pQCT) and micro-CT to interrogate changes in muscle, bone, cartilage, and body composition.

During his time at PAREXEL, Prashant has been managing the medical and scientific aspects of several imaging trials in the musculoskeletal therapeutic area. These trials encompass use of X-ray (DXA, CT), magnetic resonance (MR) based imaging modalities with a variety of qualitative and quantitative assessments.

Education
Prashant received a bachelor’s degree in Mechanical Engineering from Pune University in India, a master’s degree in Bioengineering from Penn State, University Park and a Ph.D. in Biomedical Engineering from Boston University. During his Ph.D., he developed contrast–enhanced X-ray CT imaging technology to image changes in proteoglycan content that may occur in early Osteoarthritis.

Prashant Bansal, Ph.D.
Associate Medical Director

Development Area:
MEDICAL IMAGING

Lead Therapeutic Area(s):
MUSCULOSKELETAL
ONCOLOGY
OPHTHALMOLOGY

Geographic Responsibility:
GLOBAL
David joined PAREXEL Informatics in 2014. David provides medical expertise in imaging protocol optimization and customization of analysis software tools for musculoskeletal clinical imaging trials.

**Work Experience**

David has 11 years’ experience in clinical and pre-clinical magnetic resonance imaging (MRI) in musculoskeletal and oncology diseases. David has held academic positions as a research fellow at both Worcester Polytechnic Institute at Harvard Medical School, McLean Hospital. David’s experience in MRI also includes teaching, serving as an MRI Physicist at a clinical MRI scanner manufacturer, and as an imaging scientist within the pharmaceutical industry.

David’s musculoskeletal imaging experience includes research on the use of diffusion-weighted MRI for assessing the characteristics of muscle in MDX mice (a model of Duchenne muscular dystrophy) and diffusion-tensor MRI to characterize human vertebral disc degeneration. Additionally, David’s musculoskeletal experience has included whole-body composition by magnetic resonance spectroscopy and analysis of leg muscle volume from MRI data.

**Education**

David received his B.S. and M.S. in electrical engineering from the University of Massachusetts and his Ph.D. in biomedical engineering from Worcester Polytechnic Institute in Worcester, Massachusetts. David maintains contacts with MRI academics through continued membership in the International Society for Magnetic Resonance In Medicine.
William Palmer, M.D.  
Scientific Advisor

William has been director of Musculoskeletal Imaging in the Department of Radiology at Massachusetts General Hospital (MGH) since 1999. William has served as a scientific advisor for PAREXEL Informatics since 2007, acting as an expert reader on musculoskeletal imaging trials and training radiologists to serve as independent readers on PAREXEL imaging trials. In addition, he has helped define the operational and medical management of rheumatology trials, and offers consultative services to PAREXEL’s sponsors from protocol development through submission.

Work Experience
William joined the staff of the Radiology Department of Massachusetts General Hospital in 1991 and served as director of Clinical magnetic resonance imaging (MRI) from 1995 to 2000. His clinical and research interests have focused on inflammatory arthritis, degenerative joint disease, spinal disorders, and sports injuries. The majority of his publications are related to MRI and magnetic resonance (MR) arthrography. In addition to diagnostic image interpretation, his clinical practice at MGH incorporates extensive image-guided spine and joint intervention for pain management. He trains four to six musculoskeletal fellows per year. He serves as referee for more than ten clinical and scientific journals, lectures frequently at national and international meetings, and participates in several imaging and multidisciplinary societies. Currently, he is treasurer for the International Skeletal Society.

Education
He received his M.D. in 1984 from Yale University and completed residencies in internal medicine at the Hospital of the University of Pennsylvania in 1987 and in radiology at MGH in 1991. He is board-certified by both the American Board of Internal Medicine (1987) as well as the American Board of Radiology (1991).
Felix has been a scientific advisor for PAREXEL Informatics since 2012. He is an osteoarthritis and osteoporosis expert and has advised PAREXEL and sponsors on imaging based quantification of osteoarthritis, especially in the area of optimal image acquisition and analysis of magnetic resonance imaging (MRI) for cartilage morphology.

Felix is the Director of the Institute of Anatomy & Musculoskeletal Research at Paracelsus Private Medical University in Salzburg, Austria. In this role, he and his team teach anatomy and run a comprehensive postgraduate course to research the integration of imaging methods for understanding the morphology, function, and disease of musculoskeletal tissues, in particular osteoarthritis and osteoporosis.

Work Experience

In 2003, Felix founded Chondrometrics GmbH, a spinoff company from the Ludwig-Maximilians-University in Munich that produces and licenses software for cartilage segmentation and quality-controlled data analysis. The company provides image analysis service for academic researchers and the pharmaceutical industry.

Currently Felix serves as an associate editor of Cell Tissue Organs and Annals of Anatomy. He has served as president of the German Society of Biomechanics (DGfB) from 2002 to 2003, board member of the DGfB from 2000 to 2005, Secretary General of the Osteoarthritis Research Society (OARSI) in 2005 and 2006, and board member of OARSI between 2005 and 2010. In September 2010, at the World Congress of Osteoarthritis in Brussels, Felix was awarded the Clinical Research Award of OARSI. He has authored more than 150 peer-reviewed inter-national journal articles and more than 20 review articles and book chapters in the field of cartilage and bone research. He organized the first International Workshop of Osteoarthritis Imaging in 2007 in Ainring, Germany, and organized the fifth workshop in 2011 in Salzburg.
Education

Felix studied medicine in Freiburg and Heidelberg, Germany, where he graduated in 1991. In 1987, he received a scholarship from the German Academic Exchange Service (DAAD) to study medicine at Bristol University, UK and in 1988 earned a scholarship from the Dr. Carl Duisberg Stiftung to complete his doctoral thesis at the University of Innsbruck, Austria. In 1990, Felix completed electives at the Hotel Dieu in Paris (surgery) and at the Centre Gui de Chauliac in Montpellier, France (neurology).
Didier Hans, Prof., Ph.D., M.B.A.
Scientific Advisor

Didier has supported PAREXEL Informatics as a consultant for clinical trials and has assisted PAREXEL in developing tools for instrument quality-control management for dual-energy X-ray absorptiometry (DXA) imaging in clinical trials since 2009. Didier is the head of Research and Development in the Bone and Joint Department at the Center of Bone Disease at Lausanne University Hospital in Lausanne, Switzerland, where he teaches, researches, and performs clinical duties.

Didier teaches courses in DXA, ultrasound, body composition, and osteoporosis and lectures around the world. In addition, he is certified as a full clinician and technologist faculty for the International Society of Clinical Densitometry Bone Densitometry course, and is a member of the scientific committee of the International Osteoporosis Foundation. He has authored more than 120 articles and over 20 book chapters and serves as a reviewer and member of the editorial board for 10 international scientific journals, including Osteoporosis International, Journal of Bone and Mineral Research, Journal of Clinical Densitometry and Bone.

Currently Didier serves as the immediate past president and a member of the Board of Directors for the International Society of Clinical Densitometry (ISCD). He is also an active member of several other international societies. In addition, he is one of the founders of Medimaps group, a medical technology company dedicated to building advanced solutions that improve care, treatment, and outcomes. Among several distinctions, Didier was the recipient of the ISCD clinician of the year award (2006) for distinguished services to the field of bone densitometry.

Work Experience

Didier has over 20 years of experience working in the musculoskeletal field, with particular emphasis in DXA, microarchitecture, and ultrasound imaging techniques. As a medical expert with radiology expertise, Didier has served both as a co-investigator for several clinical trials involving imaging for some of the world’s top pharmaceutical companies, and on the scientific advisory boards of diagnostic companies. As a musculoskeletal expert, Didier has been invited to present at more than 200 conferences and events on topics including osteoporosis, bone quality, and bone fractures, among other subjects.
Education

Didier earned a Ph.D. in human biology and medical physics with honors from Claude Bernard University in Lyon, France. He also earned his Masters of Science degree with honors in the area of DEA Acoustic, Signal and Image Processing and Ultrasound from Claude Bernard University. He recently completed his expertise with a Master of Business Administration (MBA) in entrepreneurship from HEC in Geneva, Switzerland.
Jener joined PAREXEL Informatics in 2014 as a Medical Research Scientist. He is a radiology technician by training with many years of experience in multiple imaging modalities, including computed tomography (CT) and magnetic resonance imaging (MRI). He has 10 years of experience in bone imaging, with a focus on rheumatoid arthritis, osteoporosis and osteoarthritis. Jener is specialized in OMERACT-RAMRIS (outcome measures in rheumatology clinical trials-rheumatoid arthritis MRI scoring system) and DCE-MRI (dynamic contrast-enhanced MRI) based image analysis. He has developed X-ray and MRI patient positioning devices for rheumatoid arthritis clinical trials.

Jener creates study-specific documents and guidelines, develops and implements study specific MR imaging protocols and manages reviews and reviewers. His client-directed tasks include charter development and presentations at investigator meetings and clients’ staff training.

Work Experience
In 2004, Jener joined Synarc, Inc., a privately-held, venture-backed company for the support of imaging in clinical trials. During his time at Synarc he developed a method for performing quality control on medical images in a clinical trial setting, Synarc’s proprietary quality control application.

Later, Jener joined Spire Sciences where he learned the OMERACT-RAMRIS to enhance performance in image-quality control in support of MRI scoring for clinical trials in rheumatoid arthritis. In 2013, Jener joined Image Analysis Ltd. as Image Application Specialist supporting business development, image logistics, image analysis, scoring, and reporting.

Education
Prior to joining PAREXEL, Jener received his degree in radiological diagnostics including Magnetic Resonance Imaging, from the College of St. Catherine, Minnesota. He is licensed as a Radiology Technologist (R.T.) in the American Registry of Radiology Technologist and California Radiologic Technologist.
Anja Urbank is a senior medical research scientist at PAREXEL Informatics in Berlin, Germany. Anja is a radiology technician by training. She has several years of experience in multiple imaging modalities, including conventional radiology, computed tomography (CT) and magnetic resonance imaging (MRI), nuclear medicine, and radiation therapy. She specializes in bone imaging, with a focus on arthritis including rheumatoid, osteoarthritis, psoriatic, and ankylosis spondylitis, as well as, visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT) imaging for diabetes. Anja develops study-specific documents and guidelines such as image acquisition guidelines, and manages reviews and reviewers. Her client-directed tasks include charter development and presentations at investigator meetings and clients’ staff training. She has published articles in several journals and has presented at conferences on imaging in clinical trials. Anja is fluent in German and English.

Work Experience
Prior to being promoted to a senior medical research scientist, Anja was a senior imaging research associate involved in overseeing imaging operations of several oncology, central nervous system (CNS), and musculoskeletal studies conducted with PAREXEL. Her responsibilities included image data collection, image preparation for independent review, site and monitor communication, and accurate delivery of imaging milestones.

Education
Trained Radiology Technician (R.T.) in radiological diagnostics, radiation therapy, and nuclear medicine.
WHEREVER YOUR JOURNEY TAKES YOU, WE’RE CLOSE BY.