

10th Symposium

Organizers

Prof. Hartmut Derendorf
University of Florida

Prof. Daan J.A. Crommelin
Utrecht University

Prof. Ton de Boer
Utrecht University

The generous support of

University of Florida, College of Pharmacy

Boehringer Ingelheim Pharma

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Roche

Sanofi

is gratefully acknowledged.



Global Gator Club e.V.

New Developments in Clinical Pharmacy and Clinical Pharmacology

June 6, 2015

Utrecht, The Netherlands



Please send your updated contact information to

Nancy Burgos

nburgos@cop.ufl.edu

- 8:00-9:00** **Registration/Coffee**
Auditorium
Domplein 25
- 9:00-9:15** *Welcome*
Hartmut Derendorf
University of Florida
- 9:15** *The College of Pharmacy – Pathway to Preeminence; An Update*
Julie Johnson
University of Florida
- 9:30** *All You Always Wanted To Know About Your Host In 15 Minutes: The Department of Pharmaceutical Sciences at UU*
Daan Crommelin
University of Utrecht
- 9:45** *Pharmacogenomics: Translation to Clinical Practice*
Julie Johnson
University of Florida
- 10:15** *Immunosuppression in Kidney Transplantation*
Teun van Gelder
Erasmus Medical Center
- 10:30** **Break**
- 11:00** *Clinical Pharmacokinetics of Once Weekly Dulaglutide*
Amparo de la Peña
Chorus, Eli Lilly
- 11:15** *Personalized Medicine: Where Clinical Pharmacology Works*
Larry Lesko
University of Florida



Karen Sando, PharmD joined the faculty at the University of Florida College of Pharmacy in September 2010. She received her Pharm.D. from the University of Florida in 2008 and went on to complete a PGY-1 with an emphasis in ambulatory care at the University of Florida in 2009. Following residency, she worked as a clinical pharmacist at Shands Jacksonville

offering clinical pharmacy services in diabetes, anticoagulation, and pain management. Since joining the faculty at UF, Dr. Sando has co-coordinated the Pharmaceutical Skills Lab Course for 3rd year pharmacy students. She also teaches ambulatory care topics (osteoarthritis, rheumatoid arthritis, gastrointestinal diseases, diabetes, tobacco cessation) in the Pharmacotherapy course series in the UF COP curriculum. Dr. Sando maintains a practice site at UF Health Family Medicine at Old Town and supervises APPE students and directs a PGY-2 residency program in Ambulatory Care. She recently earned Board Certification as an Ambulatory Care Pharmacist (BCACP) in 2013 and has maintained certification as a Certified Diabetes Educator (CDE) since 2010. Her research interests include pharmacist impact on diabetes management, quality improvement in primary care, and scholarship of teaching and learning.



Paul Doering MS, is an Emeritus Distinguished Service Professor in the Department of Pharmacotherapy and Translational Research, the university's highest honor awarded to a faculty member. He was the first professor in the College of Pharmacy to be recognized in this way at the University of Florida, College of Pharmacy.

He is also Co-director of the statewide Drug Information and Pharmacy Resource Center. He is a past-president of his local pharmacy association. Doering has been recognized four times as Teacher of the Year. In March, 1990, he was awarded Fellowship status in the APhA's Academy of Pharmacy Practice and Management. In 1993, he received one of two Teaching Incentive Awards given to UF College of Pharmacy faculty.



Karen Whalen, Pharm.D., BCPS, CDE, FAPhA is Assistant Dean for Clinical Education and Clinical Professor in the Department of Pharmacotherapy and Translational Research at the University of Florida College of Pharmacy. She received her Doctor of Pharmacy degree with highest honors from the University of Florida. She then completed a Pharmacy Practice Residency at Moses Cone Hospital followed by a Primary Care Residency at James A. Haley Veterans' Hospital. In 2008, Dr. Whalen joined the faculty at the University of Florida, College of Pharmacy. She now serves as Director of the MS in Pharmacy with concentration in Medication Therapy Management degree program, as well as Director of the MS in Pharmacy with concentration in Clinical Pharmacy. Dr. Whalen is a Board Certified Pharmacotherapy Specialist and a Certified Diabetes Educator. She has practiced ambulatory care pharmacy in a variety of settings including an academic family medicine center, a nurse-managed rural health clinic, and a Veterans' Affairs Healthcare System. She is active in local, state and national pharmacy organizations, and is a past president of the Florida Pharmacy Association and a Fellow of the American Pharmacists Association.



Michael McKenzie, PhD is currently the Associate Dean for Student Affairs in the UF College of Pharmacy. He is a professor in the Department of Pharmacotherapy and Translational Research. In the past, he was the first clinical pharmacist to work with the pediatric service at Shands Hospital and Clinics in Gainesville, Florida. He initiated and taught an elective course in pediatric pharmacy for many years. He presently coordinates and teaches in an honors seminar course, "In Search of Magic Bullets," which is offered to UF honors students. His pharmacy education includes a B.S in Pharmacy degree from Samford University in Birmingham, Alabama, a Masters in Hospital Pharmacy degree from the University of Florida, and a Ph.D in Clinical Pharmacy from Purdue University in West Lafayette, Indiana. He completed an ASHP accredited hospital pharmacy residency at the University of Alabama Hospitals and Clinics in Birmingham. He is a member of the American Pharmacists Association, the American Association of Colleges of Pharmacy, the Florida Pharmaceutical Association, and the Florida Society of Health-System Pharmacists. He is a member of Rho Chi Honorary Pharmaceutical Society, and he has served as president of Phi Lambda Sigma, the national pharmacy leadership society.

11:45 Presentation of GlobalGator Award

Previous Awardees:

- 2013 William Riffie**
- 2011 Emil Pop**
- 2009 Willy Roth**
- 2007 Marcus Brewster**
- 2005 Hans Schreier**

12:15-13:15 Lunch

13:15 *System Pharmacology – Towards Precision Treatments*
Meindert Danhof
Leiden University

13:30 *Pharmaco-Metabolomics of Oncology Drugs*
Yusuke Tanigawara
Keio University

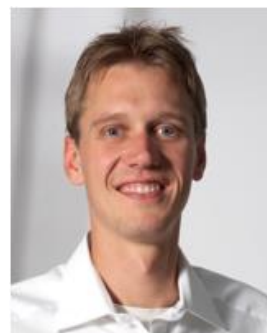
13:45 *Drugs from the Ocean: From Seaside to Bedside*
Hendrik Luesch
University of Florida

14:00 *Globally Networked Innovation: Vision for Addressing Affordability and Availability of New Medicines*
Rashmi Barbhaiya
Advinus Therapeutics

14:15 *How Informative Are Drug-Drug Interactions Of Gene-Drug Interactions And Vice Versa?*
Stephan Schmidt
University of Florida

14:30 *Pulmonary Fate of Inhaled Drugs – What Can We Learn From Plasma Pharmacokinetics?*
Benjamin Weber
Boehringer Ingelheim

- 14:45** *Systems Pharmacology Models to Understand Adverse Drug Events*
Mirjam Trame
 University of Florida
- 15:00** *Clinical Pharmacology of Protein-Engineered Antibody Constructs*
Bernd Meibohm
 University of Tennessee
- 15:15** **Break**
- 15:45** *Oxidative Stress and Formation of Kidney Stones*
Saeed Khan
 University of Florida
- 16:00** *Multidrug-Resistant Organisms – Spread and Prevention*
Nico Mutters
 University of Heidelberg
- 16:15** *Medication Therapy Management Research Projects in Germany with a Focus on: the WestGem-Study*
Olaf Rose
 University of Bonn; Elephantenapotheke, Steinfurt
- 16:30** *Advancing Pharmacy Practice: Inspiring Innovation Through Education*
Karen Whalen
 University of Florida
- 16:45** *Pharmacists for Tomorrow*
Michael McKenzie
 University of Florida
- 17:00** *Interprofessional Collaboration to Improve Quality of Care in the Elderly*
Karen Sando
 University of Florida



Nico Mutters, MD is a Specialist for Clinical Microbiology at the Department of Infectious Diseases at the Heidelberg University Hospital. The University Hospital is one of Germany's largest hospitals with 2,200 beds and 95,000 in-patients per year. Nico Mutters has degrees in medicine (studied at the Universities of Marburg, Leipzig, Amsterdam, Gainesville) and a Master's degree of Public Health, which he graduated as best student of the year. Nico Mutters is also part of the infection control

team, in which he is responsible for overall infection control management arrangements in the University Hospital, i.e. for major outbreak plans, notification procedures, patient isolation and disinfection policies, aseptic procedures and special problems due to multi-resistant organisms. Personal research interests include the epidemiology, control and prevention of health-care associated infections. He is particularly interested in transmission dynamics of multidrug-resistant organisms. He is also member of the steering committee of the European Committee on Infection Control (EUCIC) organized by ESCMID and was recently appointed Scientific Coordinator of EUCIC.



Olaf Rose, PharmD studied Pharmacy in Münster, Germany and worked as a research fellow for Bayer-Yakuhin in Japan. He graduated with his Pharm.D. at the UF in 2009 and was distinguished with the 'professional leadership award' of the UF. Rose is initiator of the WestGem-Study, an European-Union funded project to show the efficacy of Medication Therapy Management regarding quality of therapy, quality of life and costs, integrating several

Universities, professions, study centers and specialized pharmacists. He is involved in several further studies and research activities in this field. Rose is editor of manifold Pharmacotherapy- literature and promoting Clinical Pharmacy with lectures, articles and a monthly series about patient-oriented pharmacy together with Hartmut Derendorf in Germany. Rose is owner of 3 community pharmacies and lives in Münster, Germany.



Bernd Meibohm, PhD, FCP is a Professor of Pharmaceutical Sciences and Associate Dean for Research and Graduate Programs at the College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN. He received his B.S. in pharmacy and Ph.D. in pharmaceutics from the Technical University Carolo-Wilhelmina, Braunschweig, Germany. Dr. Meibohm's scientific interests include pulmonary infectious and inflammatory diseases, pediatric pharmacotherapy and the application of quantitative modeling and simulation techniques in preclinical and clinical drug development, with specific focus on therapeutic proteins. Dr. Meibohm is a Fellow of the American

Association of Pharmaceutical Scientists (AAPS) and the American College of Clinical Pharmacology (ACCP). He was the 2010 Chair for the 'Pharmacokinetics, Pharmacodynamics and Drug Metabolism' (PPDM) section of AAPS, and currently serves as President for the American College of Clinical Pharmacology (ACCP). Dr. Meibohm is also serving as associate editor for *The AAPS Journal*, and is a member of the editorial boards of the *Journal of Clinical Pharmacology*, *Clinical Pharmacokinetics*, *the Journal of Pediatric Pharmacology and Therapeutics*, the *Journal of Pharmacokinetics and Pharmacodynamics*, *Frontiers in Obstetric and Pediatric Pharmacology*, *Les Annales Pharmaceutiques Françaises* and *Die Pharmazie*.



Saeed R. Khan, PhD earned his Ph.D. from the University of Florida. After a postdoctoral fellowship at the University of Adelaide, Australia, Dr. Khan joined University of Florida as Research Fellow in the Department of Pathology in 1978. He is currently Professor of Pathology, Immunology and Laboratory Medicine, Finlayson Professor of Urologic Research and Director of Center for the Study of Lithiasis in University of Florida College of Medicine. Dr. Khan has published over 400 scholarly articles, including

reviews, book chapters and more than 150 refereed articles. He has had significant involvement in national and international professional associations, serving as President of the Florida Society for Microscopy; President of the ROCK (Research on Calculus Kinetics) Society as well as member of Advisory Boards of International Symposia on Urolithiasis held every 4 years as well as European Urolithiasis Symposia held every two years. Dr. Khan was awarded the University of Florida Research Achievement Award, College of Medicine Faculty Research Prize in Basic Science as well as the University of Florida Research Foundation Professorship. He has recently been appointed as Finlayson Professor of Urologic Research in the Department of Urology.

17:15 *Marijuana: It's Not Just for Smoking Anymore*
Paul Doering
University of Florida

19:00 **Reception and Group Photo**

GatorFest

Janskerk
Janskerkhof 26,
Utrecht, Netherlands

Late Night: Nightcap

2013	9th Symposium	Garmisch-Partenkirchen, Germany
2011	8th Symposium	Graz, Austria
2009	7th Symposium	Stresa, Italy
2007	6th Symposium	Munich, Germany
2005	5th Symposium	Leuven, Belgium
2003	4th Symposium	Vienna, Austria
2001	3rd Symposium	Dresden, Germany
1999	2nd Symposium	Reims, France
1997	1st Symposium	Münster, Germany



Julie A. Johnson, PharmD, BCPS, FCCP, FAHA is Dean of the University of Florida College of Pharmacy, where she is also Distinguished Professor of Pharmacy and Medicine and Director of the UF Health Personalized Medicine Program. She received her B.S. in Pharmacy from the Ohio State University and her Pharm.D. from the University of Texas. She leads a hypertension pharmacogenomics

research group, funded under the NIH Pharmacogenomics Research Network, and another NIH-funded group in genomic medicine implementation that is part of the NIH IGNITE network. She is an internationally-recognized leader in the field of cardiovascular pharmacogenomics and genomic medicine, with over 220 peer reviewed publications. Dr. Johnson has served in many service and leadership capacities, including with the FDA, NIH, the American College of Clinical Pharmacy (ACCP), the American Heart Association, the American Society of Clinical Pharmacology and Therapeutics (ASCPT), among others. Dr. Johnson has received numerous awards including election to the Institute of Medicine (2014), the Leon I Goldberg Young Investigator Award from the ASCPT (2004), Paul Dawson Biotechnology Research Award, American Association of Colleges of Pharmacy (2007), the Therapeutic Frontiers Award (2009) and the Russell R Miller Award for Contributions to the Literature (2010), both from the ACCP; teaching awards and numerous others.



Daan J.A. Crommelin, PhD is emeritus-professor at the Department of Pharmaceutics at Utrecht University. Until December 2011 he was scientific director of the Dutch Top Institute Pharma in Leiden. He is adjunct professor at the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah. Crommelin is co-founder of OctoPlus, a Leiden based company specialized in the development of pharmaceutical (mainly protein based) product formulations and advanced drug delivery systems. He

published extensively and is on the editorial board of 10 peer reviewed journals in the pharmaceutical sciences. He is Editor-in-Chief of the AAPS book series 'Advances in the Pharmaceutical Sciences'. He also advises venture capital groups. He chaired the Board of Pharmaceutical Sciences of the International Pharmaceutical Federation (F.I.P.), was chair of the organizing committee of the Pharmaceutical Sciences World Conference 2007 in Amsterdam. He is past president of the European Federation of Pharmaceutical Sciences (EUFEPS) and past vice-chair of the scientific advisory board of the European Innovative Medicines Initiative (IMI).



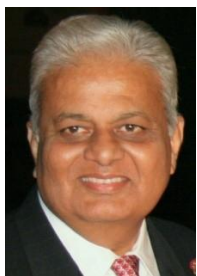
Benjamin Weber, PhD is a Senior Pharmacometrician in the Department of Translational Medicine and Clinical Pharmacology at Boehringer-Ingelheim in Biberach, Germany. He received a professional degree in Pharmacy from University of Tuebingen (Germany, 2008), a Master of Statistics (2012), and a Ph.D. in Pharmaceutical Sciences (2013) from the University of Florida in

2013. In his dissertation research, Benjamin developed a statistical method for equivalence testing of aerodynamic particle size distribution in close collaboration with the FDA. Before joining Boehringer-Ingelheim, Benjamin gained regulatory experience as an ORISE fellow at the Office of Generic Drugs, FDA and worked as a consultant for equivalence testing of aerodynamic particle size distribution for several pharmaceutical companies. He currently supports all phases of clinical drug development as lead pharmacometrician in respiratory therapeutic area. Benjamin is an expert in population pharmacokinetic/pharmacodynamics modeling, disease progress modeling, and time-to-event analysis. Moreover, Benjamin serves as mentor for a pharmacometrics PhD student at Boehringer-Ingelheim. Benjamin has been recognized by the College of Pharmacy and the International Center at the University of Florida for his teaching and scientific achievements.



Mirjam Trame, PharmD, PhD joined the University of Florida as an Assistant Professor at the Center for Pharmacometrics and Systems Pharmacology in Lake Nona (Orlando) in May 2014. She holds an Adjunct Faculty appointment at the Translational Research Institute for Metabolism and Diabetes at Florida Hospital, Orlando. She received her B.S. from the Westfälische-Wilhelms Universität in Münster, Germany in 2006 and her license to practice as a

pharmacist in Germany in 2007. She earned her Pharm.D. degree from the University of Florida in 2010 and her Ph.D. in Clinical Pharmacology and Pharmacokinetic-Pharmacodynamic (PK/PD) modeling from the Westfälische-Wilhelms Universität in Münster, Germany in 2011. In addition, she was awarded for with the ACoP 2013 Trainee Award to predict potential QT liability based on Phase I dECG data. Her research interest include the application of quantitative analysis tools (pharmacometrics and systems pharmacology) to address clinically relevant research questions in the area of diabetes, obesity, antithrombotic therapy, neurodegenerative diseases, rare diseases, pediatrics, cardiovascular safety, cystic fibrosis, and translational research.



Rashmi H. Barbhaiya, PhD is a Pharmaceutical Executive with over 30 years of experience in Pharmaceutical R&D. He is one of the founders, CEO and Managing Director of Advinus Therapeutics, a research-based pharma company located in Bangalore and Pune, India. Dr. Barbhaiya started his industrial pharmaceutical career in 1980 with Bristol-Myers Company in United States.. In the year 2005, he co-founded Advinus Therapeutics Pvt Ltd. Advinus is created to address fundamental issues of R& D productivity, speed, efficiency and cost – a center for frugal innovation. He obtained Ph.D. degree in Clinical Pharmacology from the St. Bartholomew’s Hospital Medical College, University of London. He continued his education through post-doctoral training at the University of Florida and University of Wisconsin. His scientific contributions have resulted in over 150 publications.. Dr. Barbhaiya has received a number of awards for his scientific contributions including AAPS Fellow, AAPS Meritorious Manuscript Award, AAiPS Outstanding Achievement Award, Ranbaxy Award for Excellence in Pharmaceutical Research, India Life Sciences Person of the Year 2007 by Burrill & Company and BioSpectrum Entrepreneur of the Year 2010



Stephan Schmidt, PhD received his Ph.D. from the University of Florida under the supervision of Dr. Hartmut Derendorf in 2008, before completing a 3 year postdoctoral fellowship under the supervision of Prof. Meindert Danhof in the Division of Pharmacology at the Leiden/Amsterdam Center for Drug Research in The Netherlands. During his postdoctoral fellowship, Dr. Schmidt was also a member of the Dutch Top Institute Pharma PK-PD modeling platform. His research focuses on the application of quantitative (pharmacometrics and systems pharmacology) tools to address clinically relevant research questions in the area of antimicrobial chemotherapy, pediatrics, diabetes, cardiovascular safety and post-menopausal osteoporosis. Dr. Schmidt published his work in more than 10 peer-reviewed journals. Dr. Schmidt received the Paul Ehrlich Society for Chemotherapy Thesis Award in 2010, the University of Florida Clinical Translational Science Institute Junior Faculty Pilot Program Award in 2012, the University of Florida Excellence Award for Assistant Professors in 2013 and was named International Educator of the Year (Junior Faculty Category) of the College of Pharmacy at the University of Florida in 2014.



Teun van Gelder, MD is an internist-nephrologist and clinical pharmacologist in the Departments of Hospital Pharmacy and Internal Medicine at the Erasmus Medical Center in Rotterdam, the Netherlands. He was trained in internal medicine and nephrology at the Erasmus Medical Center, and completed his thesis in 1996 on the use of anti-interleukin-2 receptor monoclonal antibodies in solid organ transplantation. As a post-doctoral scientist, he worked in the Transplantation Immunology Laboratory of Dr. Randall E. Morris at Stanford University (1998-2000), and was awarded the Young Investigator Award from the American Society for Transplantation for his work during this time. Prof. Dr. van Gelder’s current research at the Erasmus Medical Center is focused on clinical pharmacology and therapeutic drug monitoring. In 2010 he was appointed Professor in Clinical Pharmacology. He is the chairman of the Dutch Society for Clinical Pharmacology & Biopharmacy and the secretary of the Dutch Society for Transplantation



Amparo de la Peña, PhD received a BS in Chemistry and a Pharmaceutical Chemist degree from the University of the Republic, Uruguay; and a doctorate in Pharmaceutics from the University of Florida, Gainesville under Dr. Derendorf’s guidance. She joined Lilly as a PK/PD scientist in the year 2000 and has contributed to the development of drugs in several therapeutic areas, including anti-infectives, diabetes and neuroscience. Amparo has authored more than 30 publications in US and international peer-reviewed journals. She currently works at Chorus; a division of Eli Lilly which evaluates drugs from early phase to proof of concept, as a Research Advisor for PK/PD. In her free time, she writes non-scientific prose and mothers her very energetic boys.



Larry Lesko, PhD is Professor of Pharmaceutics and Director of the Center for Pharmacometrics and Systems Pharmacology in the University of Florida, College of Pharmacy at Lake Nona (Orlando). Dr. Lesko co-authored numerous Guidance for Industry including “Clinical Pharmacogenomics: Premarketing Evaluation in Early Clinical Trials” and “Pharmacogenomics Data Submissions”. He also started a Division of Pharmacometrics that is

responsible for quantitative analysis of dose-response and PK-PD relationships to support drug labels and NDA approvals, and the development of drug-disease models to support clinical trial simulations. Dr. Lesko has published more than 200 peer-reviewed manuscripts and is a frequent invited national and international speaker. In 2011, he received the Gary Neil Prize for Innovation in Drug Development from the American Society of Clinical Pharmacology and Therapeutics (ASCPT). Dr. Lesko also was honored with the Rawls-Palmer Progress in Medicine award from ASCPT, the Coriell Scientific Leadership Award for Personalized Medicine, the University of North Carolina Institute for Pharmacogenomics and Individualized Therapy Award for Clinical Service, and the Nathaniel B. Kwit Distinguished Service Award for Clinical Pharmacology from the American College of Clinical Pharmacology. His hobbies include riding motorcycles and underwater photography. He is a Divemaster certified by the Professional Association of Dive Instructors.



Yusuke Tanigawara, PhD is Professor of Clinical Pharmacokinetics and Pharmacodynamics, Keio University School of Medicine, Tokyo, Japan. He is an Adjunct Faculty of University of Florida, College of Pharmacy. He received his Ph. D. in pharmaceutical sciences from Kyoto University in 1983. His research interests include pharmaco-kinetics, pharmaco-dynamics and optimal dosing algorithms for

personalized medicine. He has been studying clinical pharmacokinetics and pharmacodynamics mainly for oncology drugs and antimicrobial agents. His modeling and simulation studies on population pharmacokinetics and pharmacodynamics were applied to new drug development as well as rational use for patient care. Recently, he also investigates pharmacogenomics as a factor causing individual variation in drug response, and multi-omics biomarkers by means of proteomics and metabolomics. He is distinguished as one of the “*ISI Highly Cited Researchers.*”



Meindert Danhof, PharmD, PhD is Professor of Pharmacology and former Scientific Director of the Leiden Academic Center for Drug Research (LACDR) at Leiden University in the Netherlands. He is President of the European Federation of Pharmaceutical Sciences (EUFEPS). Meindert Danhof's research is on novel concepts of systems pharmacology, interfacing concepts

from systems biology with quantitative pharmacology. He is (co-) author of 420 publications in peer reviewed international scientific journals. He has been the mentor of 58 PhD students graduating between 1990 and 2014 and 16 post-doctoral research fellows. Meindert Danhof has received numerous awards including , the “Rawls Palmer Award” of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) in 2004, the Distinguished Investigator Award of the American College of Clinical Pharmacology (ACCP) in 2006, the “Research Achievement Award in Pharmacokinetics, Pharmacodynamics and Drug Metabolism” of the American Association of Pharmaceutical Scientist (AAPS) in 2010. In 2014 he became Knight of the Order of the Netherlands Lion.



Hendrik Luesch, PhD received his *Diplom* in Chemistry at the University of Siegen (Germany) in 1997. He studied marine natural products chemistry at the University of Hawaii at Manoa and obtained his Ph.D. with Professor Richard E. Moore in 2002. He undertook three years of postdoctoral studies as an Irving S. Sigal Fellow at The Scripps Research Institute with Professor Peter G. Schultz in functional genomics. Since 2005 he is faculty at the University of Florida and currently Associate Professor of Medicinal Chemistry, leading a multidisciplinary marine natural products drug discovery and development program.