uppsalaforum

inspiration in the science of pharmacovigilance

Uppsala Monitoring Centre

WHO Collaborating Centre for International Drug Monitoring

CONTENTS

Pharmacovigilance's role in rapid access to safer drugs

The need to develop and rapidly deploy new treatments pushes the boundaries of traditional pharmacovigilance and demands new thinking and practice.

Welcome to Uppsala Forum 2016

How can pharmacovigilance contribute to the safety of new drugs when rapid access is of paramount importance?

Uppsala Monitoring Centre (UMC) is delighted to welcome the group of international expert speakers and the distinguished audience to our fourth biennial research conference *Pharmacovigilance´s role in rapid access to safer drugs*.

During the conference, we will discuss the challenges that we face in trying to address the need for faster access to new drugs, while remaining as vigilant as ever in our efforts to minimise risks to patients.

Uppsala Forum is the premier venue for both cutting-edge research and for finding ways to use it in practice. Here, the focus lies on research on one hand, and on practice/policy on the other. Integrating these two areas provides opportunities for exchange on how to use evidence to increase drug safety in many settings, identify new relevant research questions, and develop new collaborations across sectors.

PROGRAMME

Monday, May 30

Chairs: Jennifer Wall and Dr Gerald Dal Pan

9:00-9:30 **Welcome**
Agile pharmacovigilance, is that possible?

Dr Marie Lindquist
Director & CEO, Uppsala Monitoring Centre (UMC), Sweden

9:30-10:30 **Ethical and methodological considerations for pharmacovigilance with accelerated release of medicines**

Dr Alex John London
Professor of Philosophy & Director, Center for Ethics and Policy, Carnegie Mellon University, USA

10:30-11:00 **Coffee break**

11:00-12:00 **Deployment of pharmacovigilance during mass drug administration in Sierra Leone**

Wiltshire Johnson
Registrar & CEO, Pharmacy Board of Sierra Leone, Sierra Leone

12:00-13:00 **Drug repurposing: Benefits and risks in using existing medicines in new indications**

Dr Noel Southall
Research Scientist, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), USA

13:00-14:00 **Lunch**

14:00-15:00 **Rapid Fire Talks**

Drug structures that cause Stevens-Johnson syndrome
Tomas Bergvall (UMC, Sweden)

Finding real-time adverse drug reactions in VigiBase
Dr Rebecca Chandler (UMC, Sweden)

The puberty of a medicine
Dr Agnes Kant (Lareb, Netherlands)

Application of STAMP (System-Theoretic Accident Model and Processes) for pharmaceutical safety, a.k.a. 'Plan B'
Dr Brian Edwards (NDA Regulatory Science, UK)

Rapid release of safer drugs for TB and MDR-TB: lessons learned from NIH-sponsored international clinical trials
Dr Jing Bao (National Institute of Allergy and Infectious Diseases, USA)

Exposure related variables and how they influence the occurrence of safety issues post approval
Alexandra Pacurariu (Medicines Evaluation Board, Netherlands)

15:00-15:30 **Coffee break**

15:30-16:30 **Patients? Pharmacovigilants!**

François Houÿez
Director, Treatment Information and Access & Policy Advisor, European Organisation for Rare Diseases (EURORDIS), France

16:30-17:00 **Opening of Open Space and Sticky Note assignment**

18:00 **Drinks and dinner at Norrlands Nation**

Tuesday, May 31

Chairs: Dr Pia Caduff, Dr Rebecca Chandler, and Tomas Bergvall

9:00-10:00 **The conceptualisation of an effective and safe Ebola vaccine in the midst of a pandemic**

Dr Andrea Marzi
Staff Scientist, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), USA

10:00-11:00 **When the heat is on: A debate on real-time, real-life drug surveillance**

Dr Alex Dodoo
Director, WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, Ghana

Dr Ralph Edwards
Senior Advisor & Professor of Medicine, Uppsala Monitoring Centre (UMC), Sweden

11:00-11:30 **Coffee break**

11:30-12:30 **Assessing the impact of pharmacovigilance: Predictors and correlates**

Dr Gerald Dal Pan
Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration (FDA), USA

12:30-13:30 **Lunch**

13:30-14:15 **Uncertainty and examples of reimbursement issues with accelerated release of drugs**

Dr Dyfrig Hughes
Professor of Pharmacoeconomics & Co-director, Centre for Health Economics and Medicines Evaluation, Bangor University, UK

14:30-15:00 **Accelerated release of HIV medicines: The challenges of a manufacturer**

Andreas Palmborg
Medical Advisor, Janssen Pharmaceuticals, Sweden

15:00-15:30 **Sharing the burden: How can marketing authorization holders support infrastructures needed with accelerated release of medicines**

Ingela Larsson
Cross sector country safety team lead Baltics & Nordics, Janssen Pharmaceuticals, Sweden

15:30-16:00 **Coffee break**

16:00-16:30 **Open Space groups**

16:30-17:00 **Highlights from Open Space and Uppsala Forum**

17:00-17:15 **Closing remarks**

Dr Ola Caster
Senior Researcher, Uppsala Monitoring Centre (UMC), Sweden

Gerald Dal Pan
MD, MHS

Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research

US Food and Drug Administration (FDA), USA

Dr Gerald J. Dal Pan, MD, MHS, currently serves as the director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the centre's programmes in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act, and other initiatives.

He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council for International Organization of Medical Sciences, and the International Conference on Harmonisation.

He received his MD at Columbia University College of Physicians and Surgeons, and his Master of Health Science in Clinical Epidemiology at the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the centre's Office of New Drugs. Before working at FDA, he was a faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

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Alexander Dodoo
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Director, WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance

Associate Professor, Centre for Tropical Clinical Pharmacology, School of Medicine and Dentistry, University of Ghana

Professor Alexander Dodoo is an Associate Professor at the Centre for Tropical Clinical Pharmacology, School of Medicine and Dentistry, University of Ghana. He is also the Director of the WHO Collaborating Centre for Advocacy and Training at the University of Ghana.

Professor Dodoo is an expert in medicine and vaccine safety and leads the continental efforts for safer medicine. He is a member of several global advisory committees on medicines and vaccines. The positions he holds include Chairman, Global Vaccine Safety Initiative, World Health Organization; Member, WHO Advisory Committee on the Safety of Medicinal Products; Member, World Health Organization's Expert Committee on Drug Dependence; and Member, Access and Product Management Advisory Committee, Medicines for Malaria Venture, Geneva. Professor Dodoo has been working closely with the Uppsala Monitoring Centre for several years and has led a very successful UMC-Africa operation since 2009, which has brought several African countries into membership of the WHO Programme for International Drug Monitoring (PIDM). He continues to be active in the activities of both the UMC and the WHO PIDM.

He is the author/co-author of various manuscripts and full papers in peer-reviewed journals and has one book published, titled "Healthy Secrets – a layperson's guide to health issues". He is married with three children – two boys and a girl, who are his best friends.

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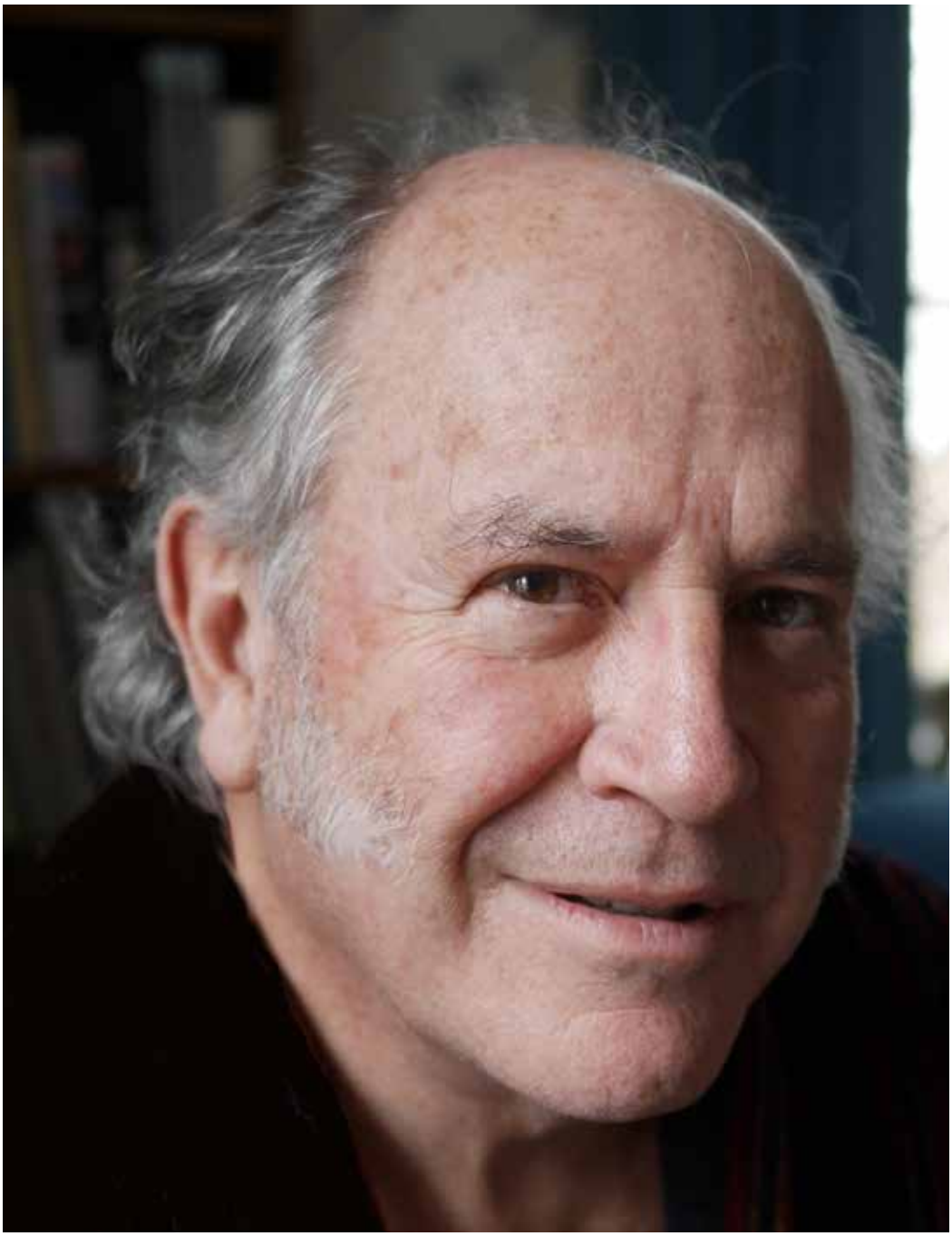

I. Ralph Edwards

MB ChB, MRCS, LRCP (London), MRCP (UK), FRCP (London), FRCP (Edinburgh), FRACP

Senior Advisor & Professor of Medicine

Uppsala Monitoring Centre, Sweden

Dr I. Ralph Edwards, senior advisor and Professor of Medicine at Uppsala Monitoring Centre, trained in general internal medicine and clinical pharmacology. He has been a practicing specialist physician in acute internal medicine, and has worked in clinical toxicology in the fields of drug abuse, acute and chronic poisoning, toxicity from industrial chemicals, and adverse drug reactions.

He worked in the United Kingdom between 1967-1975, holding various posts at the University of Sheffield Medical School and United Sheffield Hospitals, and between 1975-1978 at the University of Leicester Medical School and Hospitals.

From 1978-1981 he was Professor of Medicine at the University of Zimbabwe, consultant physician, Harare and Parirenyatwa Hospitals.

Between 1981-1990 Dr Edwards was director and CEO of the National Toxicology Group in New Zealand, and also a professor in Clinical Pharmacology at Otago University, as well as consultant physician at Dunedin Hospital. He was medical assessor for adverse drug reactions at the Ministry of Health New Zealand.

From 1985-1990 he was chairperson of the Advisory Group at WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. From 1990-2009, Dr Edwards was director of Uppsala Monitoring Centre.

He was also president of the International Society of Pharmacovigilance in 2000-2004, a member of the WHO Expert Advisory Group on Essential Drugs between 2000-2002, and a member of the WHO Expert Advisory Group on Narcotic and Psychotropic Drugs in 2002 and 2010.

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François Houÿez

Director, Treatment Information, and Access & Policy Advisor
European Organisation for Rare Diseases (EURORDIS)

Mr François Houÿez is working at the European Organisation for Rare Diseases (EURORDIS), where he is director of Treatment Information and Access, and policy advisor. He has been working as a patient advocate since the early 90s, first in HIV/AIDS advocacy, and then with a focus on rare diseases since 2003.

He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA) and has been appointed external expert for the evaluation of marketing authorisation applications.

Mr Houÿez is involved in the IMI-Web-RADR project (data mining tool for social media) and advisor to the SCOPE Joint Action Advisory Group (Strengthening Cooperation on Pharmacovigilance in Europe). Mr Houÿez also co-chairs the stakeholders' forum of the EUnetHTA2 Joint Action, leads the EURORDIS "Drug Information, Transparency and Access" task force, and is one of the trainers at the EURORDIS Summer School and European Patients' Academy (EUPATI).

He pioneered patient advocacy with the EMA as part of the first patients' delegation that engaged dialogue with the agency back in 1996, and has continuously been involved in the agency's activities over the last 17 years.

He has worked both as a volunteer and as an employee for a variety of patients' organisations at both national and international levels. Mr Houÿez is also a patient.

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Dyfrig Hughes
PhD, FFRPS, FBPhS, FLSW

Professor of Pharmacoeconomics & Co-director, Centre for Health Economics and Medicines Evaluation

Bangor University, UK

Dr Dyfrig Hughes is Professor of Pharmacoeconomics (personal chair, 2010) and Co-director of the Centre for Health Economics and Medicines Evaluation at Bangor University, Wales, United Kingdom.

Having registered as a pharmacist and researched in pharmacology (cardiovascular toxicology), he was subsequently awarded an NHS fellowship in health economics. His main research activities, which have led to over 100 publications, concern pharmaceutical economics and policy, health technology assessment and medication adherence.

Dr Hughes is also academic lead for Pharmacy and Medicines Management at the Betsi Cadwaladr University Health Board, one of Europe's largest health authorities, and has led the pharmacoeconomic activities of the All Wales Medicines Strategy Group, contributing to over 200 substantive HTA reports. He is member of the editorial boards of the journals PharmacoEconomics, and Pharmacoepidemiology and Drug Safety. He was founding president of the European Society for Patient Adherence, Compliance and Persistence (ESPACOMP) and was elected fellow of the Learned Society of Wales (2013), the British Pharmacological Society (2013), and the Faculty of the Royal Pharmaceutical Society (2014).

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Wiltshire Johnson

Registrar & CEO

Pharmacy Board of Sierra Leone, Sierra Leone

Pharmacist Wiltshire Christian Nicolai Johnson is registrar and CEO of the Pharmacy Board of Sierra Leone, the country's national drug regulatory authority. He is also a lecturer at the University of Sierra Leone's College of Medicine and Allied Health Sciences, Faculty of Pharmacy, were he currently acts as head of the Clinical Pharmacy and Therapeutics Department. Mr Johnson is a fellow of the West African Postgraduates College of Pharmacy (WAPCP) with head office in Lagos, Nigeria, and is the immediate past president and a current examiner for the college. He serves as a pharmacovigilance resource person and consultant for PVGSF in Africa.

Mr Johnson studied at the University of Sierra Leone and the University of Bradford, UK. He was born in Uzbekistan in the former USSR, and is of Afro-Russian-Chinese decent. He received schooling in USA, Russia and Sierra Leone, and currently lives in Sierra Leone – his father's homeland.

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Ingela Larsson
MSc

Cross Sector Country Safety Team Lead, Baltics & Nordics

Janssen Pharmaceuticals, Sweden

Ms Ingela Larsson is currently working as a Cross Sector Country Safety Team Lead for the Baltic and Nordic countries in Johnson & Johnson/Janssen, Pharmaceutical Companies of J&J located in Sweden. She has a M.Sc. in Pharmacy from Uppsala University, Sweden.

In her role, Ms Larsson is responsible for the local pharmacovigilance activities in the countries she oversees. Her group collects reports from clinical trials, patients and consumers, health care personnel, and local health authorities. The reports are then assessed and entered in the global J&J safety database. The group is also responsible for reporting to local health authorities in the Baltic and Nordic countries.

Prior to her work in pharmacovigilance, Ms Larsson spent 20 years as a manager for local clinical trial groups in Janssen, Pfizer, and Schering-Plough, performing phase I-IV clinical trials in different therapeutic areas. She has also worked as global trial manager for the Swedish pharmaceutical company Pharmacia, setting up the global clinical programme for development compounds intended for intensive care use.

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Marie Lindquist

MSc Pharm, PhD Med, Hon FRCP

Director & CEO

Uppsala Monitoring Centre, Sweden

Dr Marie Lindquist is director and CEO of Uppsala Monitoring Centre (UMC) in Uppsala, Sweden. UMC is a non-profit foundation providing scientific services and products, and conducting research in the area of pharmacovigilance and patient safety. UMC is also a collaborating centre to the World Health Organization (WHO), providing scientific leadership and operational support to the WHO Programme for International Drug Monitoring – a global network of national pharmacovigilance centres in more than 100 countries.

Dr Lindquist has the overall responsibility for the scientific and professional activities of the centre, its management, matters relating to the WHO programme, and relationships with other organisations.

In her professional role she monitors global pharmacovigilance developments and politics, and creates strategic plans for implementation and follow-up. She represents UMC and WHO in international harmonisation, terminology and classification efforts.

Marie has had practical, hands-on experience of every aspect of UMC's scientific work, including data management, classifications and terminologies, signal detection methodology, and research in many areas of drug safety. She has also been actively involved in most of the UMC IT development over the years, ranging from setting up drug safety-related databases to administrative support systems.

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Alex John London
PhD

Professor of Philosophy & Director, Center for Ethics and Policy

Carnegie Mellon University, USA

Dr Alex John London is Professor of Philosophy, and Director of the Center for Ethics and Policy at Carnegie Mellon University. Professor London is an elected Fellow of the Hastings Center whose work deals with foundational ethical and methodological issues in research with human participants.

His papers have appeared in Mind, Science, The Lancet, PLoS Medicine, Statistics In Medicine, The Hastings Center Report, and numerous other journals and collections. He is co-editor of Ethical Issues in Modern Medicine, one of the most widely used textbooks in medical ethics.

Since 2012 he has been a member of the Working Group on the Revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects. Since 2007 he has been a member of the ethics working group of the US HIV Prevention Trials Network, where he was part of the group that drafted the HIV Prevention Trials Network Ethics Guidance for Research. In January 2016 he was appointed to the US Institute of Medicine (IOM) Committee on Clinical Trials During the 2014-2015 Ebola Outbreak.

He has testified before the US Presidential Commission for the Study of Bioethical Issues, and served as an ethics expert in consultations with numerous national and international organizations, including the US National Institutes of Health, the World Health Organization, the World Medical Association, and the World Bank.

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Andrea Marzi
MSc, PhD

Staff Scientist

National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), USA

Dr Andrea Marzi is a Staff Scientist in the Disease Modeling and Transmission Section in the Laboratory of Virology at the Rocky Mountain Laboratories (RML), NIAID, NIH in Hamilton, Montana, USA.

Dr Marzi grew up in southern Germany and received her PhD in 2007 from the Friedrich-Alexander-University Erlangen, Germany, before joining Dr Heinz Feldmann's lab as a postdoc in Winnipeg, Canada. When Dr Feldmann moved his lab to the RML in Hamilton in summer 2008, she went with him to continue her research there.

Throughout her career she has worked with a number of viruses, including HIV, SARS-CoV, HCMV, and filoviruses, and has authored more than 60 publications. Her research interests include the mechanisms of virus entry, animal model development, and vaccines. Since 2007 she has primarily worked on vaccine development for hemorrhagic fever viruses and studied the pathogenesis of Ebola and Marburg viruses. Because of the nature of her work, she is very experienced with cell culture and animal work in high containment (BSL-4) laboratories.

In addition to her day-to-day research, Dr Marzi participated in the joined NIH/CDC Ebola virus outbreak response in Monrovia, Liberia in 2014, where she was part of a mobile lab team analyzing human blood samples for the presence of Ebola virus. Her vaccine research at RML, in particular the studies on the VSV-ZEBOV vaccine, has supported the ongoing Ebola virus vaccine efforts in West Africa.

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Andreas Palmborg
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Medical Advisor

Janssen Pharmaceuticals, Sweden

Andreas Palmborg is Nordic medical advisor at Janssen within Infectious Diseases, focusing on primarily HIV and MDR-Tb. He holds a MSc from the Karolinska Institute and has more than 10 years' experience from various positions within the pharmaceutical industry, including vaccines from his previous employer Crucell.

Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes).

Driven by a commitment to patients, Janssen Pharmaceuticals develops sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency.

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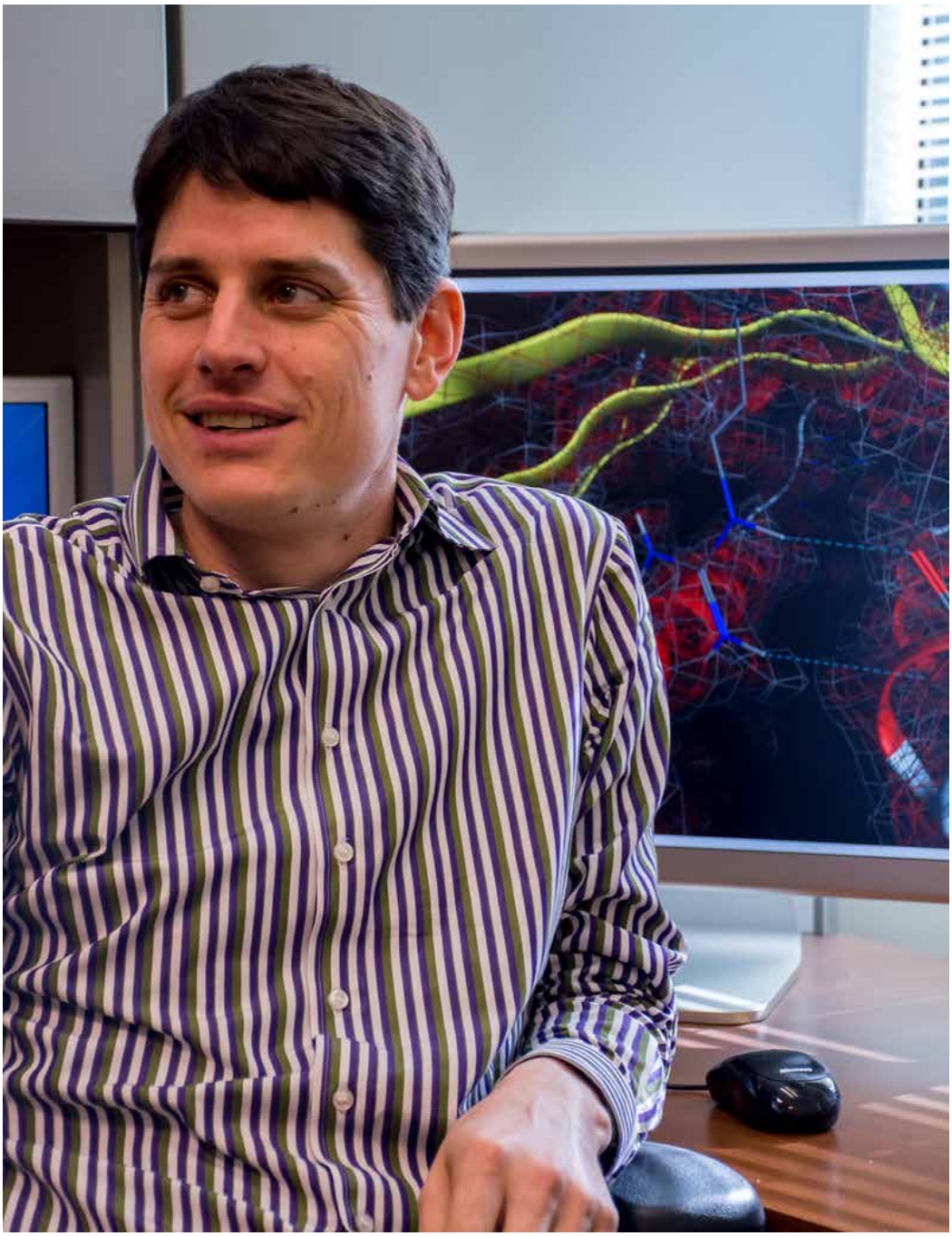

Noel Southall

PhD Biophysics

Research Scientist

National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), USA

Dr Noel T. Southall works at the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS), where he develops software and provides informatics analysis for therapeutic project teams. Dr Southall earned his PhD in biophysics at the University of California, San Francisco. He has previously worked at Celera Genomics as the scientific lead for its decision-support software Seurat, which Schrödinger now markets for commercial distribution.

At NIH, he co-directed the development of the NCATS Pharmaceutical Collection, a tool for drug repurposing. Dr Southall developed the infrastructure, tools, and libraries to facilitate repurposing and has experience prosecuting leads, transitioning to clinical proof-of-concept studies, and generating new molecular entities starting from an existing drug. He is also involved in the development of the Global Ingredient Archival System, a joint project with the US Food and Drug Administration (FDA), to coordinate ingredient registration among national regulatory agencies.

Dr Southall works in a variety of therapeutic areas, but mostly focuses on novel therapeutic approaches for rare diseases, including rare cancers and several classes of neurodegenerative disorders. One particular rare disease focus for him has been lysosomal storage disorders. NCATS's development of tool compounds to probe this disease biology has opened entirely new avenues of research for neurodegeneration. The scientists in this field are only just beginning to understand the molecular targets involved and to be able to evaluate their drugability.

In recognition of this work, he received the NIH Director's Award in 2012 and participated in the White House Office of Science and Technology Policy's Open Science "Champions of Change" programme in 2013.

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NOTES

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About Uppsala Monitoring Centre

Uppsala Monitoring Centre advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture.

As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimize harm to patients, and offer products and services used by health authorities and life-science companies worldwide.

Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality. For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population.

INSPIRE. ENGAGE. TRANSFORM.

Uppsala Monitoring Centre

WHO Collaborating Centre for International Drug Monitoring