



# Patient-Centered Approaches to R&D

**A PRISME Forum Special Interest Group**

Abstracts and Biographies

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# Table of Contents

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<b>Harnessing Real-World Data for Adaptive Healthcare .....</b>	<b>3</b>
Iain Buchan, <i>University of Manchester</i> .....	3
<b>A Vision for Real World Development and Real Examples in Practice .....</b>	<b>4</b>
Andy Black, <i>Kinapse</i> .....	4
<b>Primary Care-Record Access: Patient/Practitioner Co-production of the eHR .....</b>	<b>5</b>
Amir Hannan, <i>Haughton Thornley Medical Centres</i> .....	5
<b>The Evidence Evolution - a Pharma Perspective .....</b>	<b>6</b>
Andy Gaughan, <i>Payer and RWE Informatics at AZ</i> .....	6
<b>Patient-Centered Solutions for Translational Medicine .....</b>	<b>7</b>
Ilya Kupersmidt, <i>NextBio</i> .....	7
<b>Patient-Centered Observational Analytics .....</b>	<b>8</b>
Patrick Ryan, <i>Janssen Research and Development</i> .....	8
<b>The openEHR Foundation - Some Lessons of Experience in Standardising the EHR.....</b>	<b>9</b>
David Ingram, <i>The openEHR Foundation</i> .....	9
<b>Fact and Fiction in EHR data: the Lesson of Scylla and Charybdis .....</b>	<b>10</b>
Johan Van der Lei, <i>Erasmus Medical Center</i> .....	10
<b>eHRs and the European Union – Current Legislation and Future Directions .....</b>	<b>11</b>
Richard Fitton, <i>Tameside and Glossop PCT</i> .....	11

# Harnessing Real-World Data for Adaptive Healthcare

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Professor Buchan will explore the potential for patient and public health of building usefully-complex models of healthcare with real-world data. He will give examples of why the data alone are insufficient to build real-world evidence. He will put the case for large-scale and agile networking of datasets, models and people as the engine of real-world intelligence. Given these foundations, he will explore the implications for the biopharmaceutical industry innovating and operating in partnership with data-rich ecosystems of healthcare.

## Iain Buchan, *University of Manchester*

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Iain Buchan is Professor of Public Health Informatics at the University of Manchester, Director of the Northwest Institute for Bio-Health Informatics, Chief Scientific Officer for North West e-Health, and an honorary Consultant in Public Health in the English National Health Service.

He has backgrounds in clinical medicine, pharmacology, public health and computational statistics, and runs a multi-disciplinary team bridging health sciences, computer science, statistics, social science, and management science.

His work centres on harnessing routinely-collected health data and building usefully-complex models for developing care-services, improving clinical research and providing public health intelligence. He also drives informatics innovation to support personal and co-produced healthcare decision making.

# A Vision for Real World Development and Real Examples in Practice

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Andy Black will describe his perspectives on the opportunities and challenges in implementing new models for drug development and commercialisation in an evolving healthcare environment. He will draw on his experiences as a manager in the re-launch of GPRD at the MHRA, and in consulting to many R&D organisations in clinical development, medical affairs, regulatory affairs and pharmacovigilance. He will explain selected precedents for the use of real world evidence in the development and approval of medicines and suggest opportunities to innovate further in the use of real world methodologies.

## Andy Black, *Kinapse*

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Andy Black has over 20 years of life sciences sector experience in a career spanning surgery, management consulting and more recently co-founding and leading Kinapse, a specialist life sciences services business. His specialisations include process and organisation design and resource and performance management in R&D and outsourcing in clinical development, regulatory operations and pharmacovigilance.

Andy has worked extensively with many biopharma companies and also with the MHRA and EMA. At the MHRA, he helped to set up and re-launch GPRD, the world's largest longitudinal database of anonymised patient records, and a leading resource for public health research particularly for clinical research, pharmacoepidemiology and health outcomes applications.

Andy Black has led Kinapse's efforts in 'Real World Development' including publishing on the subject, initiating stakeholder forums and contributing to the Athenaeum Group. He graduated with distinction in surgery from Guy's Hospital Medical School, London and is a Fellow of the Royal College of Surgeons of England.

## Primary Care-Record Access: Patient/Practitioner Co-production of the eHR

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In this session, Amir Hannan will explore how he has enabled over 1900 patients in his practice to get access to their health records. The issues that have enabled this to happen and some of the critical factors that have led to the change will be addressed. He will describe the behaviours adopted by patients as a result of getting access to their records and how we are now beginning to see the start of the co-production of the eHR. Finally an innovative approach to encouraging patients to “cleanse” their data will be presented; such an approach to curating the eHR would also support the needs of the research community.

### *Amir Hannan, Haughton Thornley Medical Centres*

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Dr. Amir Hannan is a full-time general practitioner at Haughton Thornley Medical Centres in Hyde, UK. Developing a “Partnership of Trust” between patient and clinician, the practice has enabled over 1,900 citizens to access their GP electronic health record on-line, helping them to self-care and become eMPOWERed.

Presently, Dr. Hannan is the Primary Care IT clinical lead, a member of the Health Informatics Clinical Advisory Team ([www.northwest.nhs.uk/HICAT](http://www.northwest.nhs.uk/HICAT)) and Map of Medicine clinical lead for NHS North-West. He is a member of the Clinical Leaders Network and an editorial board member for the Journal of Communication in Healthcare. He has set up an innovative health 2.0 website for his practice, [www.htmc.co.uk](http://www.htmc.co.uk) putting patients, managers and clinicians at the heart of healthcare, giving them “control” and enabling co-production of the eHR.

## The Evidence Evolution - a Pharma Perspective

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The presentation will describe the rapidly changing healthcare 'evidence landscape', with a focus on Real World Evidence, and look at how this change is impacting the development of healthcare solutions by Pharma. It will outline specific examples of how AstraZeneca is responding through the development of dedicated Real World Evidence capabilities, and the formation of strategic data partnerships to enhance our understanding of healthcare systems.

### *Andy Gaughan, Payer and RWE Informatics at AZ*

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Andy has a background in molecular biology and bioinformatics, starting out as a computational biologist at the Sanger Centre, Cambridge working on the Human Genome Project.

He began his Pharmaceutical career as a bioinformatician at AstraZeneca in 1997 and since then has performed various leadership roles across Discovery and Clinical, both in the Informatics/IS arena, and more recently in early and late phase Oncology Clinical Project Teams.

Andy is currently the Director of Payer and RWE Informatics at AZ, and is accountable for, amongst other things, the design and execution of AZ's Real World Data strategy.

# Patient-Centered Solutions for Translational Medicine

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Modern medicine is quickly transforming into an information-driven science. High-efficiency 'omics' data generation combined with clinical profiles of patients can potentially transform the current translational medicine paradigm. In this new scientific landscape the ability of organizations to rapidly and intelligently leverage complex omics and clinical data from internal, partner, and public sources is critical to the development of personalized therapies and better patient care. In this talk Ilya Kupershmidt will describe the challenges and solutions for aggregating, standardizing and analyzing large quantities of molecular, clinical and drug sensitivity data to enable discovery of biomarkers, optimization of clinical trials and development of more effective, targeted therapies.

## Ilya Kupershmidt, *NextBio*

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Ilya Kupershmidt is a cofounder and head of products at NextBio. He is responsible for defining the product vision and for leading a team of scientists who are developing the core scientific framework, content, as well as user-facing applications within the NextBio platform.

Prior to NextBio, Ilya Kupershmidt led the bioinformatics group at Silicon Genetics (developer of GeneSpring). He carried out his PhD thesis work in cancer genomics at KTH/Karolinska Institute in Stockholm, Sweden.

# Patient-Centered Observational Analytics

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*Patrick Ryan, Janssen Research and Development*

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Patrick Ryan, PhD is the Head of Epidemiology Analytics at Janssen Research and Development, where he has been leading efforts to develop and apply analysis methods to better understand the real-world effects of medical products. He also currently serves as a research investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership managed by the Foundation for the National Institutes of Health and chaired by the Food and Drug Administration. As part of this effort, he is conducting methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues.

Dr. Ryan received his undergraduate degrees in Computer Science and Operations Research at Cornell University, his Master of Engineering in Operations Research and Industrial Engineering at Cornell, and his PhD in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill. He has worked in various positions within the pharmaceutical industry at Pfizer and GlaxoSmithKline, and also in academia at the University of Arizona Arthritis Center.



# The openEHR Foundation - Some Lessons of Experience in Standardising the EHR

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Standardisation of both structure and content of the EHR has been a universally recognised Grand Challenge of the field of health informatics for several decades. This talk will briefly describe the research origins and development of the openEHR Foundation, which addresses this wicked challenge, in the context of change in the science, practice and organisation of medicine, co-evolving with successive eras of technological platforms. The barriers faced and the progress achieved will be discussed and a case made for greater focus on open source solutions, towards deeper understanding of the requirements, design and performance of more cost-effective, adaptable and sustainable clinical systems.

## David Ingram, *The openEHR Foundation*

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David Ingram is Emeritus Professor of Health Informatics at UCL, Director of Charing Systems Ltd and President of the openEHR Foundation.

David Ingram has held posts in industry, the National Health Service and University Medical Schools. After undergraduate physics at Oxford and several years in the medical engineering industry, he studied computer science and completed doctoral research on the mathematical modelling of biological systems, at University College London.

His first academic post was at The Medical College of St Bartholomew's Hospital, London, from 1975, where he was appointed Professor of Medical Informatics in 1990, the first in the UK. He returned to UCL to set up and lead a new Centre for Health Informatics and Multiprofessional Education (CHIME), of which he was the Director from 1995-2010. He participated, as partner and reviewer, of numerous EU and UK Research Council Health Informatics programmes and projects from 1985-2011, including coordinating the EU GEHR Project, which laid the foundations for standardised health record architecture and the openEHR community, internationally.

With colleagues at Bart's and UCL, he established the openEHR Foundation as a not-for-profit company, in 2002, to hold the IP in openEHR, and chaired it until his retirement from full-time academic work in 2011. With his UCL team he has recently established Charing Systems, a spinout company of UCL, providing services to developers and users of clinical systems to support integration within open-source platforms.

## Fact and Fiction in EHR data: the Lesson of Scylla and Charybdis

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For many years, researchers have argued that EHR data should be used for multiple purposes that include not only the delivery of care, but also purposes such as quality control, scientific research, or cost containment. The inherent limitations of the data contained in the EHR and the consequences of those limitations for re-use of data need to be better understood if appropriate and realistic use of the data is to be achieved. Possibly Greek mythology has one or two answers!

### Johan Van der Lei, *Erasmus Medical Center*

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Johan van der Lei received his MD in Amsterdam (1982) and his PhD (cum laude) in Rotterdam in 1990. His initial research focussed on understanding the requirements for successful introduction of information and communication technology in medical practice.

Currently, his interests are on the development, evaluation, use, and impact of computer-based patient records. He is heading the Department of Medical Informatics at the Erasmus Medical Center in Rotterdam.

## eHRs and the European Union – Current Legislation and Future Directions

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Richard Fitton's presentation will cover the past, present and future data protection data legislation in the United Kingdom and Europe. In particular, the increasing role of the data subject and the European Declaration on Human Rights will be addressed.

### Richard Fitton, *Tameside and Glossop PCT*

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Dr. Richard Fitton is a General Practitioner working for Tameside and Glossop PCT as salaried assistant and salaried assistant at Manor House Surgery, Glossop. In 1968 he assisted Tim De Dombal, a pioneer in medical IT at the Leeds University Department of Surgery, to write Algol programmes. Trained at Guy's Hospital in the early seventies, Dr. Fitton experienced the use of Lawrence Weed's Problem Oriented Record as the basis for the patient medical record.

Dr. Fitton has been a member of the National Care Record Development Board, the DoH Working Group on Copying Letters to Patients and the Bethesda, USA, roundtable conference on Electronic Health Records. He was a member of The Wellcome Trust consensus working group on the use of data for research.

Recent work has seen Dr. Fitton acting as a scientific advisor to the International Council of Compunetics and he is a member of the International Society of Urban Health. He has presented on the topic of record access to the World Health Organisation (WHO) Family of International Classification and has advised on the WHO's position on the ethics of record access. Dr. Fitton presented his work to the International Council of Urban Health in Nairobi in October 2009 and again to the ICUH at the New York Academy of Medicine in October 2010.