



Big Data for
Better Outcomes

**IN DATA WE TRUST:
TOWARDS OUTCOMES-BASED
HEALTHCARE IN EUROPE**

11 October 2018, Brussels

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Welcome

The Innovative Medicines Initiative's Big Data for Better Outcomes Programme invites you to join a discussion at the symposium *"In data we trust: towards outcomes-based healthcare in Europe"*.

In Europe, there is a considerable amount of patient and healthcare data available with much more on the horizon. These data sources are often siloed and represent only a partial record of a patient's experience in the healthcare system. When such different data sources are linked together, they offer a richer, more complete source of clinical patient data and have an enormous potential to make healthcare delivery more efficient, personalised and to improve health outcomes.

However, is there enough trust from all stakeholders to realise the full potential of Big Data? How can Big Data make healthcare systems sustainable? What steps can be taken to ensure that the use of Big Data will meet the expectations patients and citizens have of their healthcare system and improve health outcomes?

Together, we will try to find the answers.

12.00-1.00pm Networking lunch

Moderator: **Jacki Davis**

1.00-1.10pm Introduction

1.10-2.00pm Big Data: Exploring the VALUE & OPPORTUNITIES for healthcare systems, keynote speakers

Elias Mossialos, Professor of Health Policy, London School of Economics (LSE)

Lydia Makaroff, Director, European Cancer Patient Coalition (ECPC)

Carole Longson, Chief Scientific Officer, Association of the British Pharmaceutical Industry (ABPI) Discussion and Recommendations

2.00-3.00pm How can TRUST in the use of Big Data be strengthened to transform healthcare systems

There is huge potential for the use of Big Data in healthcare and several opportunities to realise this potential:

- Increasing transparency and improving understanding of how patient data is used;
- Protection from the wrongful use and data privacy breaches;
- Better governance, with a future-proof policy framework for big data and an interoperable health data infrastructure;
- Developing consumer digital skills;
- Building the case for the appropriate and responsible use of Big Data by commercial organisations.

What more can be done to build trust and safeguard the use of big data? How can stakeholders across Europe effectively leverage the opportunities to establish trust in using Big Data for healthcare?

Monika Lanzenberger, Head of Sector for Research Coordination, Unit H3 E-Health, Well-Being and Ageing, DG CONNECT, European Commission

Natacha Bolaños, Regional Coordinator, Lymphoma Coalition Europe, Harmony project Partner

Jacques Demotes, Director General, European Clinical Research Infrastructure Network (ECRIN)

Nigel Hughes, Scientific Director, Janssen Clinical Innovation, Coordinator, European Health Data Network (EHDN)

3.00-3.30pm Tea/coffee break

3.30-4.30pm THE FUTURE VISION where Big Data can unveil its full potential for healthcare systems

Today, health data collection is often duplicative, inconsistent, incomplete, uncoordinated and inefficient. By working more closely together, Big Data has the potential to transform healthcare across the entire treatment pathway, and for every stakeholder, with the ultimate outcome of improved patient care and value. In the future, what is the collective vision of a healthcare system that utilises the full potential of Big Data in order to improve outcomes? What are the roles of stakeholders in realising this ambition?

Michał Boni, Member of European Parliament, EPP, Poland

Andrzej Rys, Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission

Pieter van Galen, Patient Representative, European Multiple Sclerosis Platform

Salah-Dine Chibout, Global Head of Discovery & Investigative Safety / Global Head of Therapeutic Areas, Novartis Pharma AG, Chair EFPIA InnoMeds Priority Working Group

Sofia Wallström, Director-General, The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

4.30-4.50pm Reflections from the BD4BO project team

Lydia Makaroff, Director, European Cancer Patient Coalition (ECPC)

Shahid Hanif, Head of Health Data & Outcomes, Association of the British Pharmaceutical Industry (ABPI)

Thomas Allvin, Executive Director, Strategy and Healthcare Systems, European Federation of Pharmaceutical Industries and Associations (EFPIA)

5.00-6.00pm Networking reception

List of speakers (A-Z)

Allvin Thomas

Executive Director, Strategy and Healthcare Systems, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Bolaños Natacha

Regional Coordinator, Lymphoma Coalition Europe, Harmony project Partner

Boni Michał

Member of European Parliament, EPP, Poland

Chibout Salah-Dine

Global Head of Discovery & Investigative Safety / Global Head of Therapeutic Areas, Novartis Pharma AG, Chair EFPIA InnoMeds Priority Working Group

Demotes Jacques

Director General, European Clinical Research Infrastructure Network (ECRIN)

van Galen Pieter

Patient Representative, European Multiple Sclerosis Platform

Hanif Shahid

Head of Health Data & Outcomes, Association of the British Pharmaceutical Industry (ABPI)

Hughes Nigel

Scientific Director, Janssen Clinical Innovation, Coordinator, European Health Data Network (EHDN)

Lanzenberger Monika

Head of Sector for Research Coordination, Unit H3 E-Health, Well-Being and Ageing, DG CONNECT, European Commission

Longson Carole

Chief Scientific Officer, Association of the British Pharmaceutical Industry (ABPI)

Makaroff Lydia

Director, European Cancer Patient Coalition (ECPC)

Mossialos Elias

Professor of Health Policy, London School of Economics (LSE)

Rys Andrzej

Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission

Wallström Sofia

Director-General, The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Biographies (A-Z)



Thomas ALLVIN

Executive Director, Strategy and Healthcare Systems, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Thomas is Executive Director for Strategy and Healthcare Systems at the European Federation of Pharmaceutical Industries and Associations (EFPIA), where he mainly works with policies for enabling healthcare reform towards more sustainable, outcomes-based systems, including facilitating access to health data needed for future healthcare models.

Before joining EFPIA, Thomas was Health Counsellor for Sweden to the European Union, responsible for Council negotiations on public health, pharmaceuticals and medical devices, and has a background in the Swedish Ministry of Health and the Swedish Parliament.



Natacha BOLAÑOS

*Regional Coordinator, Lymphoma Coalition Europe,
Harmony project Partner*

My relationship with patients began many years ago, after developing a career in classical ballet and learning about injuries and pain. That experience drove my interest in bringing the benefits of exercise interventions for patients undergoing cancer treatment and long-term survivors, with the aim to reduce the negative impact of some cancer-related side effects and preserve or improve their physical function and psychological wellbeing. I began volunteering for the Spanish Cancer Patients Group and found myself teaching patients, then caregivers, exercise professionals and even nurses about the benefits of exercise interventions to improve quality of life of cancer patients.

But I was committed to do more; I wanted to work for increasing access to multidisciplinary healthcare, decrease barriers and inequalities, among other challenges. I learned about how everyday people like me could use their voices to help influence lawmakers, administrators and educators about improving cancer care. I began then to use my knowledge to advocate for patients and their families, and progressively evolve to represent cancer patients at National and European Level. Since then I have been involved in providing the patient perspective to researchers, clinicians, regulators, policy makers and HTA bodies. I also moderate support forums and update educational resources in response to patient questions.

In June 2016, I was elected as Board Member for ECPC, European Cancer Patients Coalition, position held until October 2017, when I joined Lymphoma Coalition as a Regional Coordinator for Europe.

Now, I'm in charge of building and maintaining relationships with alliances to assure LCE's meaningful contribution with scientific groups and research projects as HARMONY, to oversee and act as a liaison between all patient organizations and partners working in the Lymphoma landscape in the region.



Michał BONI

Member of European Parliament, EPP, Poland

Member of the European Parliament since 2014, Vice-Chair of Delegation to the EU-Moldova Parliamentary Association Committee, Member of Committee on Civil Liberties, Justice and Home Affairs, Committee on Constitutional Affairs and Delegation to the Euronest Parliamentary Assembly, Substitute Member to Committee on Industry, Research and Energy and Delegation to the EU-Ukraine Parliamentary Association Committee.

Michał Boni holds a PhD from the University of Warsaw where he lectured in the Department of Polish Culture for many years. Involved in the 'Solidarity' underground movement since 1980 and a member of the national authorities of 'Solidarity' since 1989, he became Chairman of the Mazowsze Region Management Board in 1990.

He served as Minister of Labour and Social Policy in 1991 and from 1992 until 1993 as Secretary of State in the same ministry responsible for labour market policy. Between 1998 and 2001, he was the Chief Advisor to the Minister of Labour and Social Policy. From 2008 he served as Minister - Head of Strategic Advisors to the Prime Minister Donald Tusk and from 2011 until 2013 as Minister of Administration and Digitalization of Poland.

In 2016, Michał Boni was awarded a MEP award in category research and innovation.



Salah-Dine CHIBOUT

Global Head of Discovery & Investigative Safety /
Global Head of Therapeutic Areas, Novartis Pharma AG,
Chair EFPIA InnoMeds Priority Working Group

Salah-Dine has more than 25 years of experience in drug development and he obtained a PhD in Molecular Immunology from the Biozentrum in Basel, Switzerland. He joined the Toxicology Department in 1990 and had increasing responsibilities in Sandoz and then Novartis. He created the discovery and investigative safety group which is responsible globally to investigate all drugs side effects from Discovery to Market. From 2008 to 2010 he was Deputy Head of Translational Sciences in Europe.

Since 2010 he has been responsible for the therapeutic areas in Pre-clinical safety. He is also responsible for defining all regulatory required toxicity studies, to generate all relevant regulatory documents and ensure efficient health authorities interactions.

Salah-Dine is responsible for a global organization operating from Cambridge, East Hanover (USA) and Basle (Switzerland).

In addition, Salah-Dine is responsible for the IMI public-private partnerships for Novartis. He is representing Novartis at the EFPIA Science and Innovation Board and is the Chair of the InnoMeds group. He has been involved in IMI for the last 10 years.



Jacques DEMOTES

Director General, European Clinical Research
Infrastructure Network (ECRIN)

Jacques Demotes is the director general of the European Clinical Research Infrastructure Network (ECRIN), which he founded in 2004. In this role, he is responsible for the strategy and overall management of the infrastructure with the support of the ECRIN Management Office (located in Paris, France), the ECRIN European Correspondents (located in each Member / Observer country), and ECRIN's Scientific Partners (i.e., national networks of clinical trial units).

A neurologist and professor of cell biology, Demotes is an advisor to the biology and health research department at the French Ministry of Higher Education and Research. While at ECRIN, he has contributed to numerous initiatives and collaborative projects related to multinational clinical trials. In particular, he chaired the working group that drafted the Organisation for Economic Co-operation and Development (OECD) Council Recommendation on the Governance of Clinical Trials.

Prior to ECRIN, he worked as a clinical neurologist and basic neuroscientist, then as director of the clinical investigation centre in Bordeaux.

Demotes received his MD (with a specialisation in neurology), a PhD in neuroscience, a Master of Science (MS) in neuroscience, and a Bachelor of Arts (BA) in mathematics and computer science from the University of Bordeaux. He also received an MBA from IAE Paris, and completed a training course in science policy with the Institute of Advanced Studies in Science and Technology in Paris.



Pieter van GALEN

Patient Representative, European Multiple Sclerosis Platform

Pieter van Galen, 42 years old, of Dutch nationality, runs a training and change management consultancy in Brussels, which specializes in communications and software. He is fluent in several languages, travels extensively and speaks regularly to the wider community about his life with multiple sclerosis. Pieter has been living in Belgium for 18 years and enjoys the international environment of Brussels.

Pieter was finally diagnosed with a mild form of multiple sclerosis in 2006; prior to this, his symptoms had remained unrecognized for 15 years. His symptoms were mostly stabilized due to treatment, but now he's suffering from mobility problems and is currently diagnosed with secondary progressive multiple sclerosis. He is participating in a trail study and he tries to stay positive about the future.



Shahid HANIF

Head of Health Data & Outcomes, Association of the British Pharmaceutical Industry (ABPI)

Shahid leads the ABPI's health data, digital and outcomes related activities. His role in the ABPI involves cross-functional working with our members, government bodies and relevant stakeholders and he represents our members externally, both in the UK and Europe, on policy in these areas including implementation of the ABPI's Big Data Road Map, the use of Real World Data and Evidence, activities relating to Stratified Medicine, and outcomes-based health systems. He is the industry work package lead for communications and outreach with healthcare system stakeholders as part of the Innovative Medicines Initiative 'Big Data for Better Outcomes' programme. Shahid holds a Doctorate in Molecular Biology, a Master's in Information Technology and Bachelors in Biochemistry from the University of Glasgow, with over thirteen years of experience in the industry working in R&D and Commercial functions.



Nigel HUGHES

Scientific Director, Janssen Clinical Innovation, Coordinator,
European Health Data Network (EHDN)

A former UK NHS healthcare & voluntary sector professional working in the pharmaceutical and diagnostics industry with a prior specialty in the blood borne virus market based on a professional heritage in the viral hepatitis, liver disease & HIV fields spanning thirty years, inclusive of ten years in the voluntary sector and being a Dept. of Health advisor. Formerly working for Roche, Gilead, Novartis, and now Janssen, he has focused previously on strategic marketing for new diagnostic solutions for personalized medicine via bio-informatic tools, health information technologies and biomarkers in infectious or chronic diseases, with an emphasis on real world data. He now works on the IMI European Medical Information Framework (EMIF) as the EFPIA Platform Co-Coordinator, developing digital cohorts, and integration of real world evidence programmes, and is the EFPIA Coordinator for the upcoming European Health Data Network (EHDN) IMI project. Married with two adult siblings, he lives in Belgium, in the countryside with his wife and ten cats.



Monika LANZENBERGER

Head of Sector for Research Coordination,
Unit H3 E-Health, Well-Being and Ageing,
DG CONNECT, European Commission

Monika Lanzenberger is the Head of Sector for Research Coordination at the European Commission, DG Communication Networks, Content and Technology, Unit for eHealth, Wellbeing and Ageing in Luxembourg. At the Vienna University of Technology, she teaches classes in Semantic Web technologies. She has been working at the European Research Council Executive in Brussels coordinating the evaluation panels of the Starting Grant Calls in Physics and Engineering. Until 2009 she was an assistant professor with the Faculty of Informatics, Institute of Software Technology and Interactive Systems. As a Post-Doc Fellow 2005-2006 at the NTNU, Trondheim, Norway and the Centre de Recherche Public Henri Tudor, Luxembourg, she has published about ontologies and shared vocabularies. She received her PhD in 2003 and her MSc in Computer Science from the Vienna University of Technology in 2001.



Carole LONGSON

Chief Scientific Officer, Association of the British Pharmaceutical Industry (ABPI)

Professor Carole Longson MBE was appointed Chief Scientific Officer at the UK Association of the British Pharmaceutical Industry (ABPI) in January 2018. She brings significant research, academic and pharmaceutical industry experience to the role, including seven years as a Research Lead at GlaxoSmithKline R&D.

Carole was a past member of the Scientific Advisory Committee for Innovative Medicines Initiative (IMI), the leading pan-European public-private partnership which funds health research and innovation. She also holds non-Executive Director and advisory roles in other scientific endeavours in the UK and abroad.

Carole has unparalleled insight into the fast-evolving medicines pipeline having spent the past 18 years at NICE where she has pioneered and led the organisation's technology appraisal programme. She is highly respected as a leader in HTA both in the UK and internationally.



Lydia MAKAROFF

Director, European Cancer Patient Coalition (ECPC)

Lydia Makaroff is the Director of the European Cancer Patient Coalition. She has over ten years international experience in non-communicable disease research and policy development in academia, the pharmaceutical industry, and the non-profit sector. She conducted medical research during her PhD at the Australian National University and as a senior post-doctoral fellow at the University of Washington. After working in Global Market Access at a pharmaceutical company, she joined the International Diabetes Federation as their Epidemiology and Public Health Manager. She has experience quantifying the impact of non-communicable diseases, monitoring national governments' commitments to health, providing tools to Member Organisations, writing policy papers, and working with the European Institutions to advocate for change. Lydia holds a PhD in immunology and a Masters' degree in Public Health.



Elias MOSSIALOS

Professor of Health Policy, London School of Economics (LSE)

Elias Mossialos is Professor of Health Policy and Head of Department at LSE. He is also Professor in Health Policy and Management, Director of LSE Health, and Co-Director of the European Observatory on Health Systems and Policies and the Centre for Health Policy at Imperial College London.

He is associate editor of the Health Systems and Reform and European Heart Journal – Quality of Care & Clinical Outcomes. In 1995, he founded Eurohealth, a quarterly journal bridging academic scholarship and policy-making, and since 1998 he has been the Editor-in-Chief of the Health Systems in Transition reviews, published by the WHO.

Professor Mossialos founded LSE Health in 1996, currently LSE's largest research centre with 60 staff working on a wide range of research, combining technical competence with policy-mindedness. The Centre fosters the training of young researchers and funds several doctoral and post-doctoral students: The Centre has contributed more than £1.5 million of its own funds to support its PhD students.

Professor Mossialos established the MSc in International Health Policy at LSE in 1999, which attracted high quality students from more than 90 countries, and in 2009, a modular MSc in Health Economics, Policy and Management directed at mid-career professionals who lack the flexibility to participate in a traditional MSc programme. In 2014, in collaboration with the European Society of Cardiology, he established a modular MSc in Health Economics, Outcomes and Management. In 2014, he established an interdisciplinary MSc in Global Health, and in 2018 he will launch an executive master's programme in Global Health Policy in co-operation with the University of Chicago.



Andrzej RYŚ

Director for Health Systems, Medical Products and Innovation, DG SANTE, European Commission

Andrzej Ryś is a medical doctor specialized in radiology and public health and graduated from Jagiellonian University, Krakow, Poland. He acted as the Director of the School of Public Health at the Jagiellonian University until 1997 and continued his career as Director of Krakow's city Health Department. From 1999-2002, he was the Deputy Minister of Health in Poland and member of the Polish accession negotiators team. As of 2003, he directed the Center for Innovation and Technology Transfer at the Jagiellonian University. In 2006, Andrzej joined the European Commission as the Director for Public Health and Risk Assessment in the Directorate-General for Health and Consumers in Luxembourg. In 2011, he was appointed Director for Health Systems and Products in the Directorate-General for Health and Food Safety in Brussels.



Sofia WALLSTRÖM

Director-General, The Dental and Pharmaceutical Benefits Agency (TLV), Sweden

Since June 2013, Sofia Wallström is Director-General of the Swedish Dental and Pharmaceutical Benefits Agency.

In 2011, she was assigned by the Swedish government to lead a public inquiry into pricing, availability and conditions of the Swedish pharmaceutical and pharmacy market. She also has a background at the Government offices as Principal Secretary in the inquiry leading to the reform of the Dental Care Act.

In addition, she held positions as Group Manager and Director at the Department of Health and Medical Care of the Ministry of Health and Social Affairs, during which time her work included, amongst other things, the implementation of deregulating the Swedish pharmacy market.

Immediately prior to joining TLV, Sofia Wallström was County Director at the County Administrative Board of Västmanlands County.

The Dental and Pharmaceutical Benefits Agency, TLV, is a Swedish central government agency with responsibility to decide on price and reimbursement for outpatient pharmaceuticals. TLV determines the rules for subsidies of dental care and sets the retail margin for pharmacies. For pharmacies, TLV also contributes to oversight of quality of service and accessibility.



Jackie DAVIS

Jackie Davis is a leading commentator and analyst on European Union affairs. She is a very experienced journalist, speaker and moderator of high-level events both in Brussels and in EU national capitals, the editor of many publications, a regular broadcaster on television and radio news programmes and documentaries commenting on EU issues, and both a Senior Adviser and member of the Governing Board at the Brussels-based think tank, the European Policy Centre. She has been based in Brussels for more than 25 years, and was previously Communications Director of the European Policy Centre; launch editor and editor-in-chief of E!Sharp, a monthly magazine on EU affairs launched in 2001; the launch editor of European Voice, a Brussels-based weekly newspaper on EU affairs owned by The Economist Group, from 1995-2000 (which has now become Politico); and the Brussels correspondent of a British national newspaper.



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