



Data Transparency Conference

Demystifying Clinical Data Transparency:
Lessons learnt so far.



12-13 FEB 2019



BIP, Rue Royale 2-4,
1000 Brussels, Belgium

Conference Programme

Event Sponsor:



European Federation of Pharmaceutical
Industries and Associations

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Meet our Programme Committee



Sini Eskola



Isabelle Huys



**Christopher
Marshallsay**



**Benedikt
Van Nieuwenhove**



An Vijverman





DAY 1: full programme

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| 08h00 - 08h45 | Registration |
| 08h45 - 09h00 | Conference Opening |
| 09h00 - 10h15 | Session 1: Regulatory Aspects & Updates |
| | a. Overall introduction Speaker: Dr. Christopher Marshallsay, Grünenthal GmbH |
| | b. Update from EFPIA: reporting on how often data are being shared Speaker: Sini Eskola, EFPIA |
| 10h15 - 10h45 | Break |
| 10h45 - 13h00 | Session 2: Regulatory Aspects & Updates |
| | a. Use of Clinical Trial Data in HTA – The IQWiG Perspective Speaker: Dr. Cornelia Rüdiger, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) |
| | b. Compliance with EU CTR, MDR and GDPR and how it impacts Data Transparency Speaker: An Vijverman, Dewallens & Partners |
| | c. Data protection in reality Speaker: Isabelle Huys, KU Leuven |
| | d. Point of view of the regulator Speaker: Pieter Vankeerberghen, FAMHP |
| | e. Wrap up morning session & Q&A |
| 13h00 - 14h00 | Lunch |
| 14h00 - 15h30 | Session 3: How are the rules lived |
| | a. Watchdog initiative Speaker: Thomas Wicks, TrialScope, Inc. |
| | b. Clinical Data Transparency: Data use from an academic perspective Speakers: Sarah Lehmann, Technische Hochschule Köln |
| | c. Defining rules from an academic perspective Speaker: Prof. Frank Rademakers, UZ Leuven |
| 15h30 - 16h00 | Break |
| 16h00 - 17h15 | Session 4: Pro-active Approach |
| | a. Smart authoring of CSRs to reduce extra work during data sharing Speakers: Tracy Farrow, PPD & Sam Hamilton, Sam Hamilton Medical Writing Services Limited |
| | b. Practical challenges when implementing Data Transparency Speaker: Dr. Christopher Marshallsay, Grünenthal GmbH |
| | c. Q&A and Closing remarks Day 1 |
| 18h00 | Dinner |



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|---------------|--|
| 08h00 - 08h30 | Welcome Coffee |
| 08h30 - 10h30 | <p>Session 5: Anonymisation</p> <p>a. SHADOW: An Integrated Data and Document De-Identification Solution Speaker: Thomas Kalfas, GCE Solutions</p> <p>b. Implementing Policy 0070 and lessons learned from preparing 3 dossiers for publication Speaker: Dr. Sybille Eibert, Teva Pharmaceuticals International GmbH</p> <p>c. "Case Study: Experience implementing Policy 0070 Experience with unexpected data transparency" Speaker: Sascha Seidl, Merck</p> <p>d. Case Study: Experience implementing anonymisation Prof. Joris Vermeesch, UZ Leuven</p> |
| 10h30 - 11h00 | Break |
| 11h00 - 13h00 | <p>Session 6: Workshop around anonymisation</p> <p>a. Introduction to the anonymisation & redaction of documents Speaker: Tracy Farrow, PPD</p> <p>b. Exercise - Redaction of a subject narrative Speaker: Tracy Farrow, PPD</p> <p>c. Posting of redacted protocols and statistical analysis plans on ClinicalTrials.gov Speaker: Sybille Eibert, TEVA</p> <p>d. Wrap up morning session & Q&A</p> |
| 13h00 - 14h00 | Lunch |
| 14h00 - 15h30 | <p>Session 7: The future of Data Transparency - Panel discussion</p> <p>a. The future of Data Transparency? Speaker: Christopher Marshallsay, Grünenthal GmbH</p> <p>b. Panel Discussion with Representatives from pharma, biotech, academic, regulators, legal Speakers: Tracy Farrow, Dr. Christopher Marshallsay, Sybille Eibert, Sascha Seidl</p> |
| 15h30 - 16h00 | Closing Remarks |



DAY 1: Topic Descriptions

Session 1: Regulatory Aspects & Updates

a. Overall Introduction

Clinical data transparency is a rapidly evolving discipline. Key areas of change include the pending “go live” of the EU Clinical Trial Regulation; the May 2018 implementation of the EU General Data Protection Regulation; and ongoing discussion of the EMA policy 0070 requirements. This introductory session will briefly introduce the topic and highlight recent changes. Updates will be provided about various initiatives, including the EU and US initiatives to enforce clinical trial registration and results reporting in web-based registries; the Health Canada data transparency initiative; various data transparency monitoring initiatives; and the impact of Brexit on public disclosure. This session will combine a presentation with interactives quizzes and an exercise to enhance the topic understanding.

b. Update from EFPIA: reporting on how often data are being shared

Members of industry trade associations EFPIA (EU) and PhRMA (US) are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles: safeguarding the privacy of patients, respecting the integrity of national regulatory systems, maintaining incentives for investment in biomedical research. Clinical trial data is shared throughout the lifecycle of a medicine following these principle or by the legislative requirements. The presentation will explore the current experience on clinical trial data sharing in the evolving environment.

Session 2: Regulatory Aspects & Updates

a. Use of Clinical Trial Data in HTA – The IQWiG Perspective

Traditional publicly available sources provide insufficient information on trials of new drugs. Important information for the unbiased evaluation of clinical trials is provided by clinical study reports. This presentation will cover the problems of insufficient transparency for HTA and systematic reviewers and the gains from availability of clinical study reports for decision-making in health care.

b. Compliance with EU CTR, MDR and GDPR and how it impacts Data Transparency

Today many various obligations exist with regard to transparency on clinical trial data: such transparency rules are a.o. laid down in the EU Clinical Trials Regulation, in the EU Medical Devices Regulation and in the EU General Data Protection Regulation.

The purpose of this presentation is to give an overview of all those different transparency obligations (what they cover, what their implications are and how they must be complied with) and to explain how they can all be reconciled with each other.

c. Data protection in reality

The EU General Data Protection Framework (GDPR) provides important provisions to encourage the use of pseudonymised data and facilitate scientific research. However, lots of discretion is left to the Member States in relation to scientific research and the use of sensitive data which may influence efficient cross-border sharing in the EU. Participants are encouraged to discuss practical implications for stakeholders.

d. Point of view of the regulator

The presentation addresses our current point of view on data transparency and GDPR in clinical research.

Session 3: How are the rules lived

a. Watchdog initiative: Keeping Tabs on Transparency Advocates.

Keeping up with increasingly stringent disclosure regulations is challenging in and of itself. Meeting the expectations of transparency advocates, who judge sponsors based on their own criteria, ups the disclosure game. These advocates regularly publish their assessments of clinical trial sponsors' disclosure practices on tracking websites and in leading journals. This session explores advocates' perspectives and suggests strategies to respond to these assessments.

b. Clinical Data Transparency: Data use from an academic perspective

This presentation examines clinical data transparency aspects that are important in academia. It includes a case study which looked at what "real life" information could be extracted and analyzed from published EMA Policy 0070 documents.

c. Defining rules from an academic perspective

Big Data are a major buzz word in medicine today and held to provide the solution to several major issues and problems which medicine and health care are facing today. On the other hand the origin of big data is diversifying and requires the combination of several data sources, the EHR of the hospital being an important but not the only one. Structured documentation in the EHR is essential to create a rich and mineable data source but is often perceived as burdensome administration by care providers. On top of this patients and care providers have become more and more conscious of privacy issues when EHR data are being used for mining for different goals: while helping to improve health and health systems through the use of their health data is usually no problem, other uses and certainly commercial use is often regarded as inappropriate. This duality between privacy and sharing of data will remain a challenge in the GDPR era and require careful reflection and possibly legislation to be overcome.



DAY 1: Topic Descriptions

Session 4: Pro-active Approach

a. Smart authoring of CSRs to reduce extra work during data sharing

Writing interventional clinical study reports (CSRs) that are both fit for public disclosure, and fulfilling the current regulatory guidances presents challenges. CORE Reference (www.core-reference.org) is a time-saving tool to help you author CSRs that retain maximum clinical and regulatory utility, whilst minimising the effort needed for anonymisation. Learn about CORE Reference and how to use it in this session.

b. Practical challenges when implementing DT

This session will delve into the trials and tribulations when implementing from scratch clinical data transparency processes in a small/mid-sized pharmaceutical company. Key process components will be introduced, “must address” topics and pitfalls will be highlighted, lessons learned will be shared, and strategies to get buy-in from functional experts and management will be presented.

Session 5: Anonymisation

a. SHADOW: An Integrated Data and Document De-Identification Solution

SHADOW is an end-to-end data and document de-identification solution designed to assist Life Science companies address the challenges of data privacy and data sharing. This demonstration will show how SHADOW users can utilize PhUSE SDTM de-identification recommendations to produce de-identified datasets and leverage that data along with other next-generation de-identification strategies to produce a draft, de-identified CSR.

b. Implementing Policy 0070 and lessons learned from preparing 3 dossiers for publication

This session will cover the management of the Policy 0070 process, including the interaction with EMA. Qualitative risk assessment and the redaction of protected personal data as well as the identification and justification of commercially confidential information will be introduced. Some operational challenges will be covered as well, plus lessons learned shared for all aspects.

c. Case study: Implementing Policy 0070 at Merck

The presentation will provide best practices and share learnings about implementing a lean process to comply with Policy 0070 requirements and deliverables.

d. Case Study: Experience implementing anonymisation (Genotyping, etc.)

As many personal genomes are being sequenced, collaborative analysis of those genomes has become essential. However, analysis of personal genomic data raises important privacy and confidentiality issues. I will present our approaches to share and anonymize data: From centralized towards federated analysis of sequence variants from personal genomes.



Session 6: Workshop around anonymisation

a. Introduction to the anonymisation & redaction of documents

A practical guide to the background of regulatory public disclosure, data privacy and anonymisation processes supporting EMA's policy 0070 public disclosure of clinical submission documents including clinical document examples.

b. Exercise - Redaction of a subject narrative

A practical session during which you will apply what you have learnt in session a.

c. Posting of redacted protocols and statistical analysis plans on ClinicalTrials.gov

This short session will summarize the document posting requirements per the US Final Rule. Practical experience with defining what to redact and how to prepare the redacted documents will be shared.

Session 7: The future of Data Transparency - Panel discussion

a. The future of Data Transparency?

The pros and cons of in clinical trials (the benefits for science, for healthcare, for patients versus the costs, the issue of liability when data are shared, the risk of subject re-identification, the risk of data poaching, etc) have been extensively discussed. Initially, implementation of data transparency was an uphill battle. Today, data transparency is an accepted standard. This session will take a look into the future. Where will we be in 2025? What could new data transparency requirements be?

b. Panel Discussion with Representatives from pharma, biotech, academic, regulators, legal



Speakers



Sini Eskola

Director Regulatory Affairs at EFPIA

Sini Eskola is working as Director Regulatory, Drug Development and Manufacturing at European Federation of Pharmaceutical Industries and Associations (EFPIA) since February 2014. She has a degree in pharmaceutical sciences (MSc) from the University of Helsinki. In EFPIA her main focus areas are leading and coordinating the regulatory policy and advocacy activities on clinical trials and transparency, pharmacovigilance, regulatory information technology and environmental, health and safety aspects including pharmaceuticals in the environment.

She has previously worked over 5 years at AstraZeneca R&D Global Regulatory Affairs in Sweden and prior to that as an Executive Director of Finnish Pharmacists' Society. She has vast experience as practicing community pharmacist. Since 2011 she has been a member of the Executive Committee of Industrial Pharmacy Section of International Pharmaceutical Federation (2011-now).



Sascha Seidl

Associate Director, Clinical Trial Transparency at Merck KGaA

Sascha Seidl started his Clinical Research career in the clinical operations group of a small CRO over 10 years ago. He currently holds the position "Associate Director Clinical Trial Transparency" at Merck KGaA, Darmstadt, Germany. Sascha currently manages Merck's "Responsible Data Sharing" activities and developed several Merck Quality Documents and Processes for various clinical trial data disclosure deliverables. He is a member of the TransCelerate Placebo and Standard of Care initiative and participated in all EMA EU Portal User Acceptance Testings. Sascha holds a MSc degree in Biology from University of Muenster and is a certified Clinical Research Associate/Clinical Data Manager from mibeg Institut Medizin, Cologne, and a Lean & Six Sigma green belt.



Dr. Sybille Eibert

Senior Manager Medical Writing Lead and clinical trial transparency expert at Teva Pharmaceuticals International GmbH

Sybille has a PhD in immunology and currently is a Senior Manager Transparency & Disclosure at Teva Pharmaceuticals International GmbH (Basel, Switzerland). Her main focus there is the implementation of new transparency requirements such as EMA Policy 0070. Between 2004 and 2016 she assumed various medical writing roles at Boehringer Ingelheim in Germany and for 1 year in China.

She also has 7 years' experience as a medical writing team leader and enjoys mentoring junior colleagues. Her expertise includes the management of medical writing and transparency projects, the writing of regulatory clinical documents, the development of processes, and the provision of internal and external training on a wide range of topics.



**Dr. Christopher
Marshallsay**

Head Medical Writing and Public Disclosure (GI-DD-DSC-MW) at Grünenthal

A PhD biochemist, currently working as Director, Head Medical Writing and Public Disclosure at Grünenthal (Aachen, Germany). He has 20 years' experience in various roles in clinical development (i.e., in pharmacokinetics, medical writing, clinical trial disclosure, and as department/function head) whilst located in Aachen, Frankfurt, and Paris. He has previously worked at Ciba-Geigy, Aventis, and Sanofi. He is an expert in continuous improvement and an experienced lecturer/workshop leader.



Tracy Farrow

Senior Director Medical Writing at PPD

Tracy is currently Senior Director, Medical Writing for PPD where she is responsible for EMEA and APAC medical writing and PPD's global data transparency initiative. Tracy has more than 25 years of Biomedical Science experience. Before PPD she worked for ClinTec International as Manager, Medical Writing Services; and Pfizer as Medical Writing Therapeutic Area Lead, and Quality Manager for Data Management where she was responsible for data privacy training, audit management, SOP and best practice development.

She lectured in Intermediate Laboratory Data Management for the Association for Clinical Data Management for a number of years as part of their professional development program. She attained her 2.1 (Hons) GI Biol in Biochemistry in 1993 after gaining two Higher National Certificates in Haematology and Chemistry. From May 2014, Tracy has been a member of the EMWA-AMWA Budapest Working Group Oversight Review Team, with special responsibility for the area of transparency and public disclosure in relation to clinical-regulatory documents.



Sarah Lehmann

M.Sc., Junior Medical Affairs Manager at Grünenthal GmbH

Sarah obtained a master degree in drug discovery and development (M.Sc.) from TH Köln (University of Applied Sciences) and University of Cologne in 2018. She completed her thesis at Grünenthal (Aachen, Germany) under the supervision of Prof. Yvonne-Beatrice Böhler, MD, MBA and Dr. René Allard. The M.Sc. work has been accepted for an ISPOR presentation entitled "The EMA Clinical Data Website: A Conceptual Exploratory Approach To Benchmark Clinical Development Indicators In Marketing Authorizations" at the European Annual Meeting in Barcelona November 2018.



Dr. Sam Hamilton

Director at Sam Hamilton Medical Writing Services Limited

Sam Hamilton is a postdoctoral virologist and director of her UK-based medical writing consultancy. With over 24 years in clinical and regulatory medical writing roles in the pharmaceutical industry, Sam headed UK Medical Writing for a large CRO until setting up on her own in 2006. Sam has a special interest in the area of public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. CORE Reference is the only known open-access resource that pinpoints the sections in an ICH E3-compliant CSR that are potentially affected by public disclosure.

Sam is long-time supporter of EMWA serving in various roles over 12 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW; journal); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President of the Executive Committee (EC). Sam was elected an EMWA Lifetime Fellow in 2018 for her services to the association, and is currently MEW Section Editor for the “Regulatory Public Disclosure” Section and on the Advisory Panel of the Regulatory Public Disclosure Special Interest Group.



Prof. Isabelle Huys

Professor of Regulatory Sciences (Intellectual Property Rights and Regulatory Affairs) - Faculty of Pharmaceutical Sciences at KU Leuven

Prof. dr. Isabelle Huys is pharmacist by training and with PhD in pharmaceutical sciences (toxicology) and further specialisation in regulations on medicinal product development at KU Leuven, including intellectual property rights.

Her research focusses on access to medicines and therapies. The research program studies diverse legal and regulatory aspects along the continuum of a medicinal product life cycle, from medicinal product discovery, development, approval, reimbursement and market adoption. The research program focuses on all types of medicinal products (small molecules, biologicals, advanced therapy medicinal products (ATMPs)) and diagnostics. Topics include biobanking and access to (human) biological samples and data, the use of real-world data/evidence (RWE) in medicinal product development and market access, repurposing of medicines for other (e.g. cancer) indications, patient preferences in medicinal product development and evaluation, precision medicine and companion diagnostics, off-patent strategies of biological products and market access of biosimilar and drug shortages.

Isabelle Huys actively participated in several collaborative projects, bilateral university-industry, university-non-profit organisations, public-private partnerships of large scale (e.g. IMI, H2020). Isabelle Huys supervises PhD projects in this research program and publishes the research in diverse journals.



Prof. Joris Vermeesch

Chair of the Department of Human Genetics, Head of the Cytogenetics Lab and Coordinator of Genomics Core Leuven at the University of Leuven

Joris R. Vermeesch, Ph.D. Ir, is chair of the department of human genetics and heading the Constitutional Cytogenetics unit of the Center of Human Genetics. He is coordinating the genomic core Leuven. The laboratory has been pioneering applications for genome wide genetic analyses for preimplantation, prenatal and postnatal diagnosis. The laboratory has a special focus on structural variation detection and studies the mechanisms underlying chromosomal instability and rearrangements. He developed methods for single cell CNV detection and addresses questions about the

origins of chromosomal rearrangements and genomic instability by the genetic analysis of IVF embryos. The laboratory developed and translated novel methods for non-invasive prenatal and cancer testing. In collaboration with clinical geneticists, the laboratory actively seeks to define the molecular causes of developmental, mental and behavioural disturbances. The group invests in the new generation of sequencing technologies and is involved in research enabling whole genome analyses. The group is partner of the SymbioSys, a KULeuven center of excellence in computational biology and he is founder of the Leuven institute of genomics and Society (LIGAS). Prof. Vermeesch has published over 300 papers, H-index 51 and founder of a spin-off company Cartagena.



Thomas Kalfas

Global Head of Innovative Solutions for GCE

Mr. Kalfas is a Life Science professional of over 30 years. Leveraging an educational background in computer science and information systems and a natural gravitation toward systems development and process reengineering, Tom quickly ascended biostat programming and software development ranks, leading to the birth of his own consulting company where he had the opportunity to evaluate and enhance the systems and processes of Life Sciences companies of various sizes. Tom has won awards for his work in Life Sciences and has continuously enhanced the capabilities of his organizations. Throughout his career, Mr. Kalfas has served and/or led advisory committees and working groups focused on innovations, data standards, machine learning and artificial intelligence. Tom currently serves as the Global Head of Innovative Solutions for GCE where he has established and grown a distinguished, committed and extremely talented solutions development group to support GCE's mission to revolutionize Life Sciences with truly innovative service- and software-solutions.



**Prof. Frank E.
Rademakers**

**Directeur Medische Technologie en Innovatie - CMTO at
UZ Leuven**

Frank Rademakers is Chief Medical Technology and Innovation Officer at the University Hospitals Leuven, Belgium.

He was trained as a cardiologist at the University of Antwerp with a keen interest in physiology of the heart and ventricular mechanics. His research in this field uses different imaging modalities, one of them being cardiac magnetic resonance which he introduced in Belgian cardiology. He did his PhD on this topic at Johns Hopkins, MD, USA.

He moved from Antwerp to Leuven in 1998 where he joined the cardiology department for non-invasive cardiac imaging.

He was always interested and active in representation and management and became CMO of the University Hospitals Leuven in 2005 where he co-organized the first JCI accreditation in Belgium.

He is also responsible for the Pharmacy and IT at UZ Leuven and heads the steering group for GDPR implementation.



Dr. Cornelia Rüdiger

**Dept. Drug Assessment at Institut für Qualität und
Wirtschaftlichkeit im Gesundheitswesen (IQWiG)**

Dr. Cornelia Rüdiger is Research Associate with supervisory responsibilities at the Department of Drug Assessment at the German Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG). At IQWiG she is responsible for the scientific assessment of pharmaceuticals, the development of assessment methods as well as the Institute's collaboration with external parties.

Prior to joining IQWiG in 2012, Cornelia Rüdiger worked in market access consulting for about 6 years with a focus on pricing & reimbursement and outcomes research. Before moving to market access she was involved in basic research in the areas of neurobiochemistry and molecular biology at the universities in Tübingen and Milan. Cornelia Rüdiger holds a Diploma in Nutritional Sciences from the University of Gießen and a Dr. rer. nat. from the University of Tübingen, Germany.



Thomas Wicks

Chief Strategy Officer – TrialScope, Inc.

Thomas is responsible for the strategy of TrialScope's clinical trial disclosure and transparency solutions. He has more than 19 years of experience with performance and content management solutions, specializing in applications for life sciences such as clinical trial disclosure, structured product labelling and submissions management. Thomas has been focused on trial transparency since 2007.



An Vijverman

Lawyer-Partner at Dewallens & Partners

An Vijverman is a partner with the law firm Dewallens & partners, a specialized law firm operating exclusively in health law. Within health law An specialises in privacy legislation (data protection which nowadays obviously mainly includes legal assistance on GDPR-compliance), eHealth, RIZIV/ INAMI procedures (national sickness and invalidity insurance institute), pharmaceutical law, medical devices, medical apps and life sciences. The assistance of pharmaceutical companies and companies active in biotechnology, medical devices, pharmaceutical research (CRO's), medtech and healthcare ICT is at the core of her practice.

Through her dedication Dewallens & partners became the Belgian member of the Alliance of European Life Sciences Law Firms in 2015.

An has authored a wide variety of publications on various aspects of health law. In 2013 she published her book called "Het elektronisch medisch dossier. Praktische en juridische knelpunten" (The electronic medical file. Practical and legal issues). Each year she also publishes the "Chapter for Belgium in "Getting the Deal Through – Life Sciences" and she has co-authored the book "Chapters on Pharmaceutical Law". She has also written the chapters "Experiments on the human being", "Medicinal products" and "Medical devices" in the Belgian Manual on Health Law (2014).

An also regularly lectures on issues of healthcare law. She teaches various courses of health law (mainly focused on privacy law) at Ehsal Management School, Brussels and at the Antwerp Health Law and Ethics Chair (AHLEC) at the UAntwerpen and as a trainer she is attached to the European Centre for Clinical Research Training.

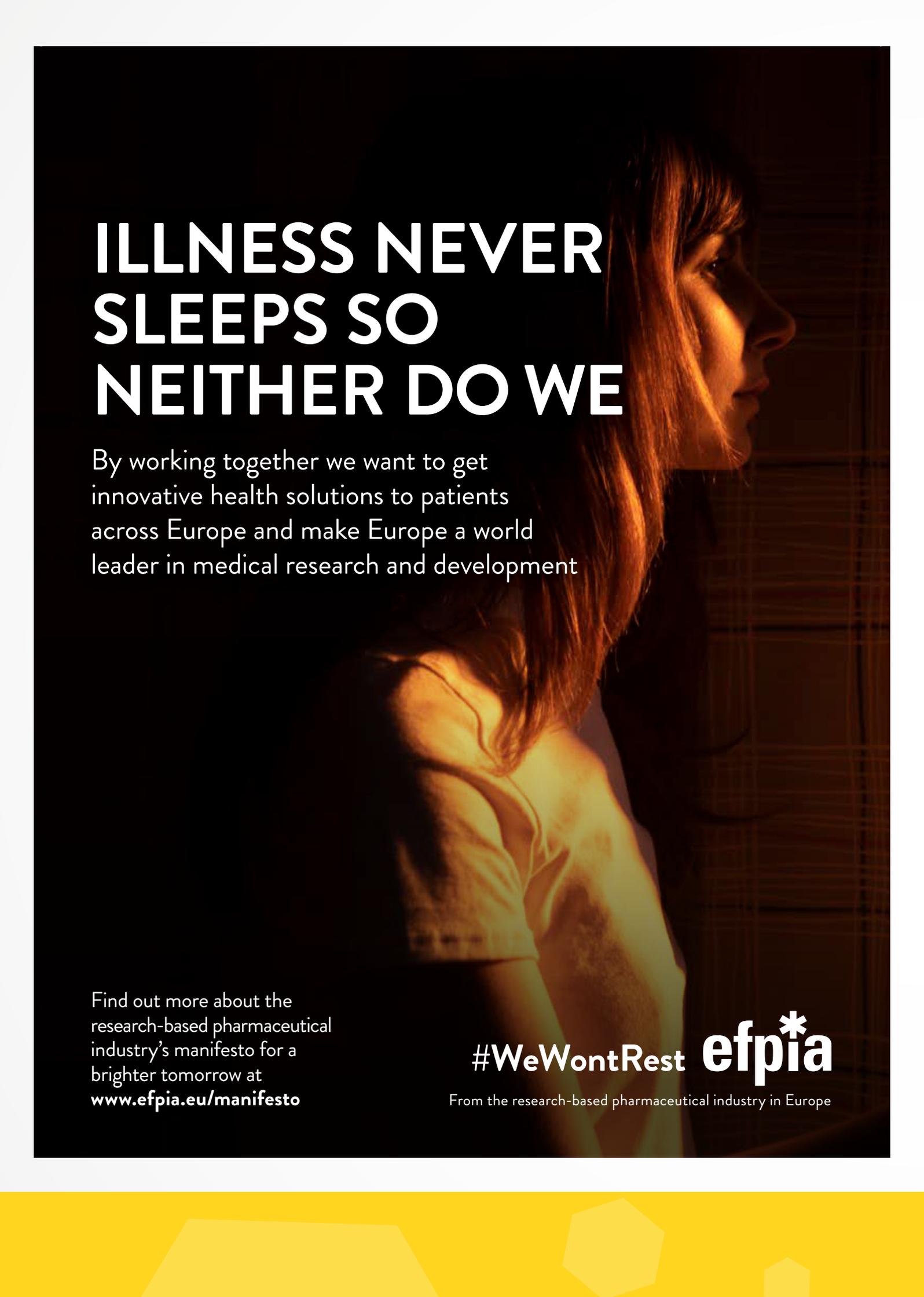
She is a member of the National Commission on the evaluation of the legislation concerning the interruption of pregnancy, of the editorial committee of the 'Tijdschrift voor Gezondheidsrecht/Revue de Droit de la Santé' (Journal for Health Law). Belgian Journal of Health law, of the Brussels Pharma Law Group and of the legal working group "e-health" at the FOD/SPF Public Health.



**Pieter
Vankeerberghen**

Head of R&D Department at the Belgian Federal Agency for medicines and health products:

Pieter Vankeerberghen studied pharmacy, obtained a Ph. D. in pharmaceutical sciences, obtained a master in Informatics and leads the R&D Department at the Belgian Federal agency for medicines and health products, with a focus on clinical trials with medicinal products and medical devices in the human domain.



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From the research-based pharmaceutical industry in Europe

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Lessons learnt so far.

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BIP, Rue Royale 2-4, 1000 Brussels, Belgium

Event Sponsor:

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