PRISME Forum

Pharmaceutical R&D Information Systems Management Executives

PRISME Forum

TECHNICAL MEETING

Understanding Disease through Mining Clinical Trial Data

PRISME Forum Chair:

Olivier Gien, *Sanofi*

PRISME Forum Technical Meeting Chair:

Thomas Lønborg-Jensen, *Novo Nordisk*

May 18 - 19, 2016

Prague, Czech Republic

Host: MSD

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PRISME Forum Spring 2016 Technical Meeting App:

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Meeting Venue

All sessions will be hosted by MSD at its Global Innovation Center located at Riverview, Svornosti 3321/2, Prague 5 - 150 00, Czech Republic

Hotel

Mamaison Riverside Hotel at Janáčkovo nábřeží 15, 150 00 Prague 5, Czech Republic

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PRISME Forum Technical Meeting Advisory Committee

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Chair, PRISME Forum
Global Head, Clinical IT, *Sanofi*

Nadir Ammour
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PRISME Forum Host

The PRISME Forum Technical Meeting Advisory Committee would like to thank MSD for hosting the 2016 Spring meeting.

PRISME Forum Statement of Compliance

"All meetings, working groups and communications will be open to all Members and any records thereof will be non-confidential and available for inspection by any Member. The Members acknowledge that discussing any commercially sensitive topics, including costs, volumes, inventories, sales level methods, channels of distribution, access to future products, markets, current or future prices, profitability, ***contract pricing or trading terms*** is prohibited. The Members of PRISME will strictly comply with all laws relevant to their activities, including US state and federal anti-trust laws and European competition laws."

THEME:
Understanding Disease through Mining Clinical Trial Data

BACKGROUND	Standard measures of human physiology are no longer enough to guide the next generation of medicines. Advances in technology are enabling the generation of new data types with finer granularity and more dimensions in information content. A deeper understanding of disease is arising from molecular data generated on bio-specimens from patients enrolled in clinical trials. Further understanding of disease and drug response may be achieved with continuous physiologic readouts using biosensor technologies. These data will drive target selection, patient stratification and understanding of therapeutic and adverse responses.
FOCUS	The agenda for this PRISME Forum Spring 2016 Technical Meeting will focus on relevant topics including: • Ability to capture novel data types in a clinical trial, e.g. biosensor data, smart phone data • Clinical Sample Data: Types and Analytical Methods/Models • Workflows and processes for enabling the integration of clinical and molecular data • Approaches that companies are following to enable broad re-use of data • Analysis environment for the primary and secondary use of such data • Bioethical (legal and privacy) and regulatory requirements for working with such data • Example of data management by a company in another industry with similar data challenges
MEETING OUTCOMES	PRISME Forum Members will be able to identify and define new clinical trials opportunities (including technologies, services and business models) that can impact R&D in their parent companies and find opportunities to partner to deliver pre-competitive capabilities that increase the effectiveness of their bio-pharma R&D.

PROGRAM

All sessions will be hosted by MSD at its campus located at Svornosti 3321/2, Prague 5 - 150 00

WEDNESDAY, May 18, 2016		
18:20	*Gather in the Mamaison Riverside Hotel lobby for departure to PRISME Forum Group Reception – prompt departure at 18:30*	
THURSDAY, May 19, 2016		
8:00	*Gather in the Mamaison Riverside Hotel lobby for departure to the meeting venue*	
8:30	*Check-in; poster installation*	
8:45	Welcome Notes	**Olivier Gien,** Chair, *PRISME Forum;* Global Head, Clinical IT, *Sanofi*
8:50	Introduction	**Thomas Lønborg-Jensen,** Technical Meeting Chair, *PRISME Forum*; VP, R&D Project Execution, *Novo Nordisk*
9:00	**SESSION I: Perspectives**	**Chair: Thomas Lønborg-Jensen,** Technical Meeting Chair, *PRISME Forum*; VP, R&D Project Execution, *Novo Nordisk*
9:00	Advanced Analytics with Trial Data: A Cross-industry view of Best Practices for Leveraging Internal Assets	**Jonathan Usuka,** Knowledge Expert, Pharmaceuticals & Medical Products, *McKinsey*
9:30	Code of Practice on Secondary Use of Medical Data in European Scientific Research Projects	**Anne Bahr,** R&D Privacy Officer, *Sanofi*
10:00	A Trustworthy Ecosystem for Reusing Health Data for Research	**Pascal Coorevits,** Professor, *Ghent University*; VP for Research, *EuroRec*
10:30	*Coffee Break*	
11:00	**SESSION II: Panel Discussion**	**Chair: Jim McGurk,** Sr. Director, Data Architecture, R&D Informatics, *Daiichi-Sankyo*
	Governance Models for Secondary Use of Human Data	**Katherine Tucker,** Senior Manager - Patient-level Data Sharing, *Roche*
	PROACT: Engaging Patients Through Innovative Governance	**Dónal Landers,** Senior Director Physician, *AstraZeneca*
	The Value of IT in Biomarker Execution: A Clinical User Story	**Rebecca Blanchard,** Exec. Director & Head of Clinical Genetics, *MSD* **Scott Thomas,** Director of IT, Translational Medicine, *MSD*
	Technology View: Analytics Informing Decisions	**Matej Adam,** *IBM Watson Health*
12:00	**SESSION III A: Posters**	**Chair: Peter Gamble,** Director, Research to Release, *MSD IT Global Innovation Center*
12:00	*Introductions - Poster Rotations (Three 15 minute rotations)*	
P1	Evolving Aspects of Anonymization in Data Re-Use	**Dave Handelsman,** Senior Director, Strategy and Product Development, *d-Wise* **Chris Olinger,** Chief Technology Officer, *d-Wise*
P2	Patient Engagement: The Intersection of Motivations, Activities and Physiology	**Peter Gamble,** Director**,** Research to Release, *MSD IT Global Innovation Center*
P3	Gaining Business Insight for Clinical Trials - Text Analytics for a Data-Driven Approach	**Jane Reed,** Head of Life Science Strategy, *Linguamatics*
P4	Mobile Solutions for (Diabetic) Clinical Trials	**Scott Dixon,** Global Vice President, eCOA Sales, *ERT* **Helle Ingemann Nielsen,** Project Manager - EDC Process Specialist, *Novo Nordisk*
P5	De-Identification of Clinical Trial Data at Novo Nordisk A/S to Enable Secondary Use of Anonymized Data for Research	**Adel Salem,** Senior Programmer, *Novo Nordisk*
P6	Biobanking for Secondary Use of Clinical Samples and Data	**Martin Urban,** Lead IT Business Consultant, *Boehringer Ingelheim*
12:50	*Lunch*	
14:00	**SESSION III B: Posters**	**Chair: Peter Gamble,** Director, Research to Release, *MSD IT Global Innovation Center*
14:00	*Poster Session (Remaining three 15 minute rotations)*	
14:45	**SESSION IV: Plenary Presentation**	**Chair: Nadir Ammour,** Domain Head, Patients & Partner Mgt, *Sanofi*
14:45	Anonymization and Sharing of Individual Patient Data from Clinical Studies	**Jason Coarse,** Biostatistician, *UCB*
15:15	**SESSION V: Keynote Presentation**	**Chair: Thomas Lønborg-Jensen,** Technical Meeting Chair, *PRISME Forum*; VP, R&D Project Execution, *Novo Nordisk*
15:15	*Legal, Regulatory & Ethical Issues in the Secondary Use of Genomics Data*	**Wendy Chung,** Director, Clinical Genetics Program, *Columbia University*
16:00	***Coffee Break & Preparations for* SESSION VI: Bringing It All Together –** *Table Captains will meet to frame the structure of the session A slide will provide clear instructions for the round-table discussion groups.*	
16:30	**SESSION VI: Bringing It All Together**	**Chair: David Sedlock,** Global Head, Research IT, *Takeda*
16:30	Table Discussions – Supervised by Table Captains *(Ammour, Gamble, Lønborg-Jensen, McGurk)*	
17:15	Plenary: Table Captains' Feedback	
17:45	Plenary: Discussion of readout; Determine next steps	
18:15	**Awards**	**Chair: Thomas Lønborg-Jensen**, *PRISME Forum / Novo Nordisk*
18:30	*Networking Reception at meeting venue (return to hotel at 19:30)*	

BIOS AND ABSTRACTS

PRISME Forum Chair: Olivier Gien

Global Head, Clinical IT, *Sanofi*

Olivier Gien, PhD, was elected as the Chairman of the PRISME Forum at the November 2014 PRISME Forum Business Meeting.

Dr. Gien is the Global Head of Clinical IT at Sanofi. He is a Chemical Engineer by training and holds a PhD in Organic Chemistry. His PhD work focused on leveraging Artificial Intelligence technologies and retrosynthetic analysis to build a system helping chemists in the design of synthetic routes.

Dr. Gien started his career in the Exploratory Unit of Sanofi's Hungarian affiliate in Budapest then took charge of Information Systems for Industrial Chemical development at Sanofi's Sisteron site. He led then Global Discovery Research Information Systems at Sanofi-Synthelabo, then Sanofi-Aventis in Montpellier, before taking on his new role in Paris area in 2010.

PRISME Forum Technical Meeting Chair: Thomas Lønborg-Jensen

VP, R&D Project Execution, *Novo Nordisk*

Thomas Lønborg-Jensen heads up the Project Execution unit within R&D in Novo Nordisk. He holds a Master's in Business Administration and Law and is additionally trained within computer science.

Throughout his professional life, Mr. Lønborg-Jensen has worked with IT projects in the beginning exploring different technical, functional, sales and managerial roles across industries. Since 2008, he has worked for Novo Nordisk as IT Project Manager and is today heading up the portfolio of Strategic IT projects within R&D.

SESSION I
PERSPECTIVES

Session Chair: Thomas Lønborg-Jensen

VP, R&D Project Execution, *Novo Nordisk*

Jonathan Usuka

Knowledge Expert, Pharmaceuticals & Medical Products, *McKinsey*

Jonathan Usuka, PhD, MBA, leads the Center for Analytics and Real World Evidence in McKinsey's pharmaceutical practice.

Before McKinsey, he led R&D Informatics for Research & Early Development at Celgene, and was an adjunct professor of Biotechnology Business at UCSD. Previously, Dr. Usuka was Director of Scientific Information Systems and head of Genome Informatics at Roche.

Dr. Usuka was an NIH Genomics fellow at Stanford University's School of Medicine, where he earned a PhD in Chemistry. He also holds an MBA in Healthcare Strategy from the Wharton School, University of Pennsylvania, and an AB from Princeton University. He is the author of 20+ peer reviewed publication in Science and Nature, and the inventor of several patents in genome sequencing and bioinformatics.

Advanced Analytics with Trial Data: A Cross-industry View of Best Practices for Leveraging Internal Assets

Anne Bahr

R&D Privacy Officer, *Sanofi*

Anne Bahr, PhD, is the R&D Privacy Officer in charge of compliance with Personal Data Protection regulations and guidelines within Sanofi. She is supporting clinical studies worldwide as well as international R&D projects, especially focusing on patient consent, ethics boards review and human biological sample management. She is the deputy of Sanofi's Chief Privacy Officer.

Dr. Bahr is also involved in the Human Biological Samples governance of the company as well as its Bioethics working groups. She also participates as an Ethics and Privacy expert in many collaborative projects (including 6 IMI projects [BD4BO, EHR4CR, eTRIKS, Predict-TB, SPRINTT, and WEB-RDAR], the European Commission working group on the "mHealth Personal Data Protection Code of Conduct" and represents Sanofi in the EFPIA Data Privacy working group). She has also been leading, in collaboration with the IMI Office, the development of a "Code of Practice on Secondary Use of Medical Data in Scientific Research Projects" and its related article.

Dr. Bahr holds a PhD in Molecular Biology from Strasbourg University and has been working in the field of Biomedical Research for more than 20 years. She joined the Sanofi group as a Hoechst-Marion-Roussel Bioinformatician in 2000, and then joined the Sanofi Privacy Office in 2007. She holds her current position since October 2013. She is an active member of the IPPC (International Pharmaceutical Privacy Consortium), the AFCDP (French Privacy Professionals Association), the LEEM (French association of drug developing companies) and the IAPP (International Privacy Professionals Association, from which she has been certified in December 2011 as a European Privacy Professional (CIPP/E).

Code of Practice on Secondary Use of Medical Data in European Scientific Research Projects

Anne Bahr[1], Irene Schlünder[2]
[1]Sanofi; [2]TMF

At the time of Translational Medicine, Digital Health and Big Data, compliance with personal data protection rules becomes essential. In order to better support Sanofi in this matter and align requirements among various actors of the Health sector, it was decided to jointly develop a common 'Code of Practice' dealing with the secondary use of health data.

The development of the Code has been funded by the EHR4CR and eTRIKS projects, in the context of the European Innovative Medicines Initiative (IMI). As many others, these projects encounter very similar problems with regard to the need for a common framework to protect patient privacy when sharing research data. It is obvious that the European legal framework is being implemented differently across Europe and that there are many open questions to be answered to ensure that researchers can share data and comply with the requirements without being data protection experts.

The Code attempts to resolve issues in a way that balances the need to make research possible and the need to protect patients' privacy at its best. It is based on the conviction that clear standards and implementable rules for researchers are urgently needed to facilitate collaborative research in Europe.

Pascal Coorevits

Professor, *Ghent University;* VP Research, *EuroRec*

Pascal Coorevits, PhD, is Vice President of Research at the European Institute for Health Records (the EuroRec Institute) and Visiting Professor of Medical Informatics and Statistics at the Ghent University, Faculty of Medicine and Health Sciences, Department of Public Health.

He is involved in several FP7 and H2020 eHealth projects. His primary research interests lie in the domain of Electronic Health Records (EHRs) and are oriented towards various aspects of quality labeling and certification of EHRs.

Dr. Coorevits holds a PhD from the Ghent University in Motor Rehabilitation and Physiotherapy.

A Trustworthy Ecosystem for Reusing Health Data for Research

The "Electronic Health Records for Clinical Research" (EHR4CR) project (2011-2016) has involved 37 academic and private partners (10 pharmaceutical companies) and has been one of the largest of the IMI PPPs in this area. The consortium also included 11 hospital sites in France, Germany, Poland, Switzerland and the United Kingdom. It was part-sponsored by the European Commission through the Innovative Medicines Initiative (IMI). The EHR4CR project has developed a robust and scalable platform that can utilise de-identified data from hospital Electronic Health Records systems (EHRs), in full compliance with the ethical, regulatory and data protection policies and requirements of each participating country. The EHR4CR platform supports distributed querying to assist in clinical trials feasibility assessment and patient recruitment. The platform can connect securely to the data within multiple hospital EHR systems and clinical data warehouses across Europe, to enable a trial sponsor to predict the number of eligible patients for a candidate clinical trial protocol, to assess its feasibility and to locate the most relevant hospital sites. Applications for internal use are offered to connected hospitals to assist them to efficiently identify and contact the patients who may be eligible for particular clinical trials. EHR4CR has shown that such a platform can significantly improve the efficiency of designing and conducting clinical trials, reducing time and costs, reducing administrative burdens, optimising protocol feasibility assessments, accelerating patient recruitment, making study conduct more efficient, enabling the participation of European hospitals in the more clinical trials and thereby potentially increasing research income.

The European Institute for Innovation through Health Data (i~HD) is a not-for-profit organization that has been established in 2015, arising in part out of the EHR4CR project, to develop and promote best practices in the governance, quality, semantic interoperability and uses of health data, including its reuse for research. An important role of i~HD is to provide independent governance oversight of clinical research platforms and their expanding networks of hospitals. Its inaugural conference was held on March 10th 2016 in Paris and brought together over 200 experts from across Europe (health ministries, insurers, pharma industry, healthcare providers, patient associations, health professional associations, the health ICT industry and standards bodies).

Custodix is now launching, as the first EHR4CR service provider, its operational platform InSite for Europe-wide deployment, to be governed by i~HD. An early adopter Champion Programme has been launched as a first step in building a pan-European network connected to the InSite Platform. The objectives are to start building a network and community of hospitals open to data re-use for research, to further validate and improve the technology and to refine the business model, creating a win for all stakeholders.

In this presentation it will be discussed how the EHR4CR project, the i~HD Institute and the InSite Champion Programme contribute towards creating a trustworthy ecosystem for reusing health data for research.

SESSION II
PANEL DISCUSSION

Session Chair: Jim McGurk

Senior Director, Data Architecture, R&D Informatics, *Daiichi-Sankyo*

James (Jim) McGurk, PhD, is Senior Director, Data Architecture, at Daiichi-Sankyo. His previous position involved development and implementation of master data management and governance for the Global R&D organization. He is also responsible for creating and implementing a 'Big Data' strategy; providing internal capabilities for accessing, managing and analyzing external/public data sources.

Dr. McGurk has more than 20 years' experience in software and system development in pharmaceutical discovery and development, as well as developing strategic directions driving architectural, software and hardware decisions. He holds a PhD in Neuroscience from The Rockefeller University.

PANELIST: Katherine Tucker

Senior Manager, Patient-level Data Sharing, *Roche*

Katherine Tucker has a background as a statistician and statistical programming manager in the pharmaceutical industry, with 20+ years' experience. She now works as a Senior Manager in Roche Biometrics Data Sharing group in the UK. She is also responsible for a team who delivers on all aspects of delivery of patient-level data requests for external researchers.

Ms. Tucker's team is also looking to take many of the learnings from external data sharing and use them to facilitate enhanced internal sharing of data within our organization. She was heavily involved in the creation of ClinicalStudyDataRequest.com or 'CSDR' with several other pharmaceutical companies, as well as an active member of industry bodies such as PhUSE, EFSPI, PSI, TransCelerate.

Governance Models for Secondary Use of Human Data

Transparency and sharing of clinical trial data for further research is a fast evolving area. It is an increasingly important topic for the pharmaceutical industry and other organizations who sponsor and conduct clinical trials (government agencies, academia, charities etc.). Drivers of these changes have come from several sources – for example, the scientific community/academia (e.g. Alltrials, BMJ Open Data Campaign, Institute of Medicine), regulators (e.g. EMA transparency policy 0070), the pharmaceutical industry (e.g. EFPIA-PhRMA "Principles for Responsible Clinical Trial Data Sharing").

Roche published its data sharing policy in 2013. It covered four aspects of transparency: posting to registries e.g. ClinicalTrials.gov, release of reports such as CSRs, publications in peer-reviewed journals and requests for patient-level data (PLD). Key considerations in creating the policy were that the information generated in Roche clinical trials should be used for the benefit of patients and society, ensuring necessary steps to protect patient privacy, respect for the role of regulatory authorities in making the benefit-risk decisions to determine access to new products and the right to protect commercially sensitive information.

In order to facilitate the sharing of PLD under the policy, Roche was one of the founder members, in January 2014, of ClinicalStudyDataRequest.com or 'CSDR', a multi-sponsor request site. Key elements of requesting PLD via CSDR are as follows: researchers need to create and submit a brief research proposal including studies required (assuming they are in-scope), rationale, hypothesis, statistical and publication plan etc. This research proposal is then reviewed and approved by an Independent Review Panel appointed by Wellcome Trust, a global UK-based medical charity. Once a data sharing agreement is signed, de-identified/anonymized datasets and redacted documents are shared via a secure portal which enables researchers to conduct their analyses and access data across multiple sponsors (if

requested). Requests via CSDR can be fulfilled without any kind of collaborative relationship between the researchers and sponsors, sometimes coined "sharing with strangers."

At Roche, the new capabilities we have built up in sharing data via CSDR are now proving important in shaping thinking on new governance models for more collaborative external sharing and even enhanced internal sharing within the company. Whilst these discussions are still ongoing, they will include a set of key principles, a decision making framework and scenarios/case studies. There are opportunities to gain greater insights into our data, clarity on responsibilities for both 'data users' and 'data providers', more efficient use of information, and potential for better tools and processes to enhance access and insights across the organization. Improved governance, systems and tools also need to come with a mindset which recognizes the value of increased transparency and access.

PANELIST: Dónal Landers

Senior Director Physician, *AstraZeneca*

Dónal Landers, MD, obtained his primary medical degree from Trinity College, Dublin (TCD). He worked in clinical medicine (Emergency Medicine, Medicine for the Elderly, HIV Medicine and Infectious Diseases) for several years as a clinical research registrar, during which time he completed an MBA from University College Dublin (UCD) before transitioning to hospital senior management at St. James's Hospital (TCD Academic Training Hospital). During this time Dónal also studied Computer Science at Dublin City University (DCU) and has published in both clinical and health informatics areas. Dónal co-founded his own health informatics business developing patient 'centric' mobile technology solutions, which enabled patients to collect and monitor their own health data. He was Sectoral Lead for Healthcare and Pharma in his role as a senior consultant in PwC's Strategy Advisory Services (SAS) and contributed to a number of their global publications (PwC Health Research Institute).

Dónal moved from PwC to AstraZeneca in 2010 and took up the role of Senior Research Physician. In his current role as Senior Director Physician in Early Clinical Development (ECD), he leads a large multidrug oncology 'umbrella' study in bladder cancer. He is a member of the Faculty of Pharmaceutical Medicine of the Royal College of Physicians and has completed his Pharmaceutical Medicine Specialist Training (PMST). He also holds a Postgraduate Certificate in Translational Medicine at the University of Manchester (UoM)..

PROACT: Engaging Patients Through Innovative Governance

Dónal, as part of his dual roles, leads the iDecide programme, a framework a clinical informatics R&D framework to support early decisions in Phase 1 studies. It leverages real-time patient information during an ongoing clinical study with the specific dual purpose:

- enabling early decision making in order to keep patients safe
- supporting effective adaptation of the clinical trial design, if required, for their benefit

Two key components of the iDecide programme are REACT (REal-time Analytics of Clinical Trials), which enables the real-time interpretation of information collected in the clinic during an ongoing study with the primary goal of keeping trial patients by closely monitoring the benefit-risk trajectory of a new AZ compound. The second, is PROACT (Patient Reported Outcomes About Clinical Tolerability), which enables our patients to collaborate and become co-scientists in their own clinical trial.

The development of PROACT required addressing significant cultural and legal issues and consumed as much time as the time taken to develop the actual system. The main challenges were misinterpretation and a misunderstanding of the Data Protection Act, the ICH E6 (Good Clinical Practice) guidelines and Data Privacy processes. These challenges were successfully addressed by seeking external legal counsel guidance, which in turn, led to changes to the AZ bioethics policy document and gave the green-light to patient engagement through the use of innovative smart technology. In addition, it demonstrated that clear and thoughtful reasoning that focuses on the care, safety and scientific understanding of the tolerability in patients in early clinical development can surmount entrenched religious beliefs.

PANELIST: Rebecca Blanchard

Head of Clinical Pharmacogenomics and Operations, *MSD*

Rebecca Blanchard, PhD, is the head of Clinical Pharmacogenomics and Operations within the Genetics and Pharmacogenomics department at Merck & Co., Inc.

Dr. Blanchard's career in academia and Merck has spanned preclinical, translational, and clinical development across multiple therapeutic areas. Her education includes a BS in Pharmacy from Albany College of Pharmacy and a PhD in Pharmaceutical Chemistry from the University of Utah in Salt Lake City, Utah. She completed postdoctoral studies at the Mayo Clinic with a focus on human pharmacogenetics. From 1998 through 2004 Rebecca was Assistant Professor at Fox Chase Cancer Center in Philadelphia where her NIH R01 funded-research focused on human pharmacogenetics with emphasis on human sulfotransferase and UDP-glucuronosyltransferase genes. In 2004, Dr. Blanchard joined Merck & Co., Inc. in Pennsylvania. She has held positions of increasing responsibility across Clinical Pharmacology, Clinical Oncology and Genetics and Pharmacogenomic departments within Merck. She has led several Drug Development teams across early and late stage development, with a recent focus on identification of predictive biomarkers for drug response.

In 2013, Dr. Blanchard accepted the position as Head of Clinical Pharmacogenomics, where she is responsible for the scientific strategy and execution of Merck's clinical pharmacogenomic efforts, biomarker sample management, and project management of Merck's genetic and genomic project portfolio.

PANELIST: Scott Thomas

Director of IT, Translational Medicine, *MSD*

As a Director in the MRL IT group at Merck, Scott Thomas is accountable for identifying innovative information and knowledge management solutions, providing stewardship of the Research and Developments information strategy and developing the department's information capability. Previously, over his twelve-year tenure at AstraZeneca, Mr. Thomas held positions of Senior Director IT/IS Solution Delivery, Global Director of Scientific Informatics and Discovery Information Site Director, R&D Boston. He spent two years abroad working on an international assignment in the UK, from 2006 to 2008.

Mr. Thomas has worked in the Pharmaceutical industry since 1992, and is currently based at the Boston site. Prior to joining Merck & Co., Inc. in April of 2014 he worked at AstraZeneca, Amgen, Vertex Pharmaceuticals and MDL Information Systems. His experience spans from Programmer/Analyst to Director of Scientific Informatics. His diverse experiences and perspective allow him to manage multi-disciplinary teams to solve complex information problems.

The Value of IT in Biomarker Execution: A Clinical User Story

Like many Pharma companies, Merck is increasingly leveraging biomarkers in a drug development and discovery. As use of biomarkers within a given development program becomes more complex, managing those complexities requires Information Technology solutions. This presentation will highlight a clinical "user story" related to Merck's biomarker efforts within our Keytruda clinical development program. Myriad biomarker assays are utilized to inform on predictive biomarkers of response, selecting oncology indications, identifying combination therapies and identifying new drug targets. These efforts require the ability to track and manage clinical biosamples, biomarker plans, a dashboard of biomarker assays for execution, and data. These IT challenges and some solutions will be presented.

PANELIST: Matej Adam

IBM Watson Health

Matej Adam is a health IT professional with 15+ years of experience in the field. He led the design and development of several national healthcare information projects. He also consulted with regional and national governments on e-health and health IT strategies to improve healthcare outcomes. Mr. Adam undertook transformation projects of patient safety and hospital processes through new technology deployment and defined IBM`s global healthcare provider solution strategy and portfolio.

Recently Mr. Adam joined Watson Health to define strategy in Healthcare and Life Sciences within CEE and support business across Europe in both public and private markets.

Technology View: Analytics Informing Decisions

Current work is focused on utilization of big data and cognitive systems across the continuum of human health. In this sense, this panel contribution will cover aspects of managing data lakes of clinical and other patient data along cloud data sharing across jurisdictions. We will also address population health data and population health management domains as well as cognitive and artificial intelligence technologies in healthcare and life sciences.

SESSION III
POSTERS

Session Chair: Peter Gamble

Director, Research to Release, *MSD IT Global Innovation Center*

Peter Gamble is the Research to Release Lead at the Global Innovation Center at Prague.

He began his career at Merck in 2008 as a member of the Strategy & Planning organization. He then joined Merck Research Labs IT, where he held IT Account Management responsibility for Clinical, Pharmacovigilance, and Regulatory Affairs. Prior to joining Merck, Mr. Gamble spent three years at Pfizer as Director, Global Business Technology and also worked as a Manager with Deloitte Consulting in the Strategic Information Technology Practice before resuming his Pharma IT career at Merck.

Mr. Gamble holds a Bachelor's of Science degree from the University of Notre Dame and an MBA from the University of Chicago Booth School of Business.

Dave Handelsman

Senior Director, Strategy and Product Development, *d-Wise*

Dave Handelsman is a healthcare and life sciences expert with more than 25 years of industry, software and management experience. He joined d-Wise in February 2014, and has overall responsibilities for charting the company's strategic growth and additionally serves as the Product Manager for d-Wise's industry-leading suite of data anonymization products.

Prior to joining d-Wise in February 2014, Mr. Handelsman established SAS as the leader for the life sciences industry's Clinical Trial Data Transparency initiatives. He has served as a founding member of the SAS Center for Health Analytics and Insight, where he led a team of experienced analysts charged with applying advanced analytics to address complex business and scientific challenges facing the healthcare and life sciences industries, and was SAS' recognized expert on clinical trials business issues.

Previous to SAS, Mr. Handelsman held management roles in the US and Germany with ClinTrials Research and Pharmaceutical Research Associates (PRA). During that time, he had spent the majority of his time both preparing clinical trial data for analysis and delivery to FDA, and managing teams charged with these tasks. Mr. Handelsman is currently the post-Chair of the Clinical Data Interchange Standards Consortium (CDISC) Advisory Council.

Chris Olinger

Chief Technology Officer, *d-Wise*

Chris Olinger, Chief Technology Officer, has 30 years of experience delivering software solutions. He leads the R&D organization at d-Wise within his remit as CTO and is the principal architect for the d-Wise portfolio of software solutions including Blur (data and CSR anonymization) and Reveal (enterprise SAS search). Prior to co-founding d-Wise, Mr. Olinger spent 14 years at SAS where he worked in a variety of capacities. As an R&D product manager, he led a team of developers charged with creating ODS, now a core component of SAS software used in nearly all SAS solutions.

Mr. Olinger has authored many technical papers and was a keynote speaker at the annual Pharmaceutical SAS User's Group conference. As CTO of d-Wise, his vision is to create a team with a balance of software and services capabilities whose core focus is delivering innovative and high quality solutions for customers.

P1: Evolving Aspects of Anonymization in Data Re-Use

The finalization of the EMA Policy 0070 guidance, the ongoing Transparency initiatives and the recognized value of aggregated clinical trial data mining has brought data anonymization and patient privacy to a critical inflection point. The biopharmaceutical industry is suddenly facing multiple simultaneous but subtly different versions of the same problem: How do we protect patient privacy while preparing data for sharing, advanced analysis and re-use? To complicate matters further, how backlogs of content are anonymized retrospectively (for example, as companies prepare submissions for late 2016, or add older clinical trials to clinical data repositories) is likely to be quite different from when anonymization is integrated into prospective clinical trial data delivery. Although the specific requirements of each anonymization strategy will vary, there are core technical and business process anonymization capabilities that can be readily applied today. Well-defined clinical data anonymization rules have been published by TransCelerate and PhUSE. National regulations are well-understood. The EMA anonymization implementation guidance provides clarity regarding regulatory expectations. These core capabilities form the anonymization framework that will comprehensively enable patient privacy to be protected even as data re-use continues to expand. This poster and the accompanying talk will describe the complex considerations regarding how to satisfy each data anonymization use case, and the core framework that will enable data anonymization to be comprehensively addressed.

Peter Gamble

Director, Research to Release, *MSD IT Global Innovation Center*

P2: Patient Engagement: The Intersection of Motivations, Activities and Physiology

The Internet of Things provides us with an enormous amount of data about human activity and physiology. We can now 'see' how frequently people are walking and eating alongside their physiological responses such as heart rate, blood glucose and proteins from micturition or sweat.

However, our understanding of disease and the ability to collect a continuous stream of high quality data are rooted in human motivations and goals.

The IoT gives us a view into human activity but the underlying narratives remain hidden from its co-generators.

In this poster session we explore the following questions:

1. How does patient engagement matter to the understanding of disease?
2. What are the data collection gaps in linking human physiology, activity and motivations?
3. Where does Design Thinking apply?

and we offer some frameworks for design thinking approaches that are relevant to scientific discovery.

Jane Reed

Head of Life Science Strategy, *Linguamatics*

Dr. Jane Reed is the head of life science strategy at Linguamatics. She is responsible for developing the strategic vision for Linguamatics' growing product portfolio and business development in the life science domain.

Dr. Reed has extensive experience in life sciences informatics. She has worked for more than 15 years in vendor companies supplying data products, data integration and analysis and consultancy to pharma and biotech - with roles at Instem, BioWisdom, Incyte, and Hexagen.

P3: Gaining Business Insight for Clinical Trials - Text Analytics for a Data-Driven Approach

Clinical trials are one of the most expensive parts of the drug development process; thus one of the goals of clinical trial professionals is to increase efficiency along the process. Addressable bottlenecks include improving access to knowledge for site selection, patient populations, principal investigators, and key opinion leaders. In this presentation we will discuss the benefits of text analytics and natural language processing over internal and external clinical trial data to optimize clinical trial design and gain knowledge from legacy data.

Scott Dixon

Global Vice President, eCOA Sales, *ERT*

Scott Dixon is Vice President of Marketing and Strategy for ERT, establishing overall market leadership and product strategies across the full suite of solutions. He has over 25 years of experience in life sciences, clinical trials, data capture and reporting, and in leading strategy and product positioning.

Most recently, Mr. Dixon served as Senior Director, Global Product Strategy at Oracle. Prior roles include VP, OutcomeLogix Group, Global CRO Relations at PhaseForward, Chief Operations and Strategy Officer at Maaguzi, and other positions at Omnicom Group, eTrials, and Parexel.

Mr. Dixon holds a BS in Biochemistry from the University of Georgia.

Helle Ingemann Nielsen

Project Manager - EDC Process Specialist, *Novo Nordisk*

P4: Mobile Solutions for (Diabetic) Clinical Trials

Adel Salem

Senior Programmer, *Novo Nordisk*

Adel Salem is a Senior Programmer at Novo Nordisk A/S with over 19 years of experience in Statistical Programming, Data warehousing, Business Intelligence and Data Transparency.

He has developed the code for de-identification at Novo Nordisk where he is responsible for de-identifying clinical trial data requested by researchers.

P5: De-Identification of Clinical Trial Data at Novo Nordisk A/S to Enable Secondary Use of Anonymized Data for Research

Data transparency in the pharmaceutical industry is getting more focus. Sharing anonymized clinical trial data to be used in research is very important to help new research in the data, comparative analysis, building models and creating pooled databases for scientific research in specific therapeutic areas. The main concern in sharing clinical trial data is keeping the subject's privacy. For this reason, having a good anonymization and de-identification process is very crucial to keep the balance between the privacy of the subjects and the utility of the data.

Martin Urban

Lead IT Business Consultant, *Boehringer Ingelheim*

Martin Urban, PhD, is Lead IT Business Consultant for Translational Medicine and Clinical Pharmacology at Boehringer Ingelheim. In this role he provides support to Translational Medicine by helping to define and deliver services that build bridges between Research and Medicine.

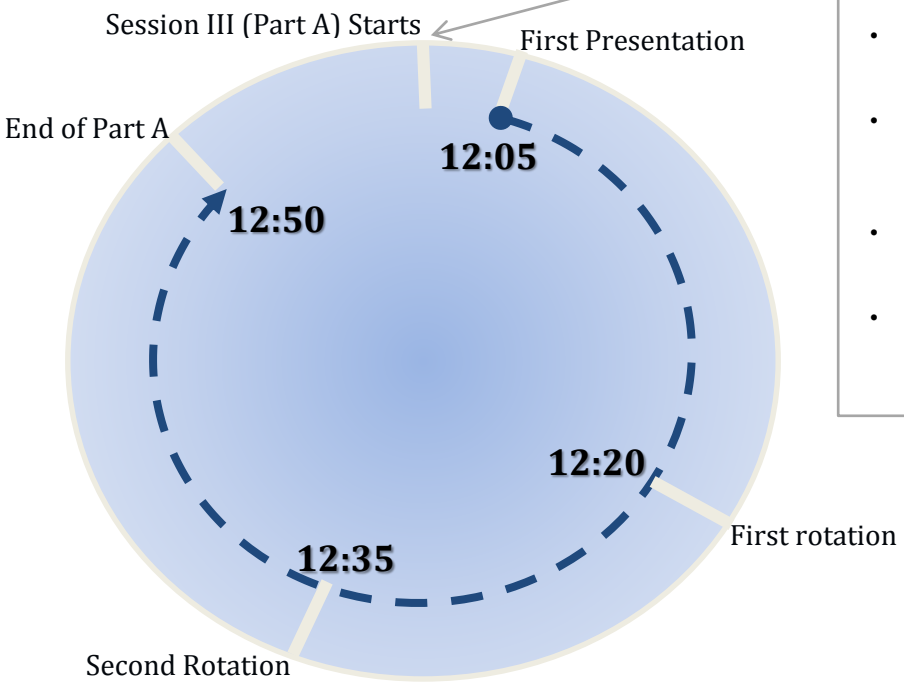
Dr. Urban has extensive experience in implementing validated computerized systems in Translational Medicine, having led the IT development programs for Biomarker and Pharmacogenomics strategy at Boehringer Ingelheim globally over the last 10 years. He is actively working on enhancing the Biobanking and Biospecimen capabilities for all clinical trial and preclinical trial research efforts while ensuring compliance to all applicable regulatory requirements.

Dr. Urban's expertise includes demand and relationship management, business consultancy, project and program management and domain architecture. He holds a Master of Science in Medical Informatics (Dipl.-Inform. from University of Hildesheim, Germany) and a PhD in Human Biology (Dr.biol.hum. from Ulm University).

P6: Biobanking for Secondary Use of Clinical Samples and Data

There is a very strong non-linear growth in biobanking activity in the last decade but only very few publications can be found on data integration in biobanking literature. In order to utilize biobanking samples and the respective clinical trial data several internal and external compliance requirements and pre-requisites apply depending on the intended use. This poster will focus on a 'fit for purpose' concept and propose required building blocks for efficient biobanking and re-use of clinical trial data.

SESSION STRUCTURE



INSTRUCTIONS @12:00pm

- Session Chair (Peter Gamble) will invite participants to take their seats.
- Chair will open the session by introducing the presenters, their posters, along with the session structure and flow.
- PRISME Forum staff will ring the bell on each rotation (minute 13 of each presentation and then minute 15 at which time the presentation must end).
- Delegates are invited to identify the color of their badge and match to rotation called out loud by staff: "Rotation 1, 2, …n".
- Rotations will involve shift of participants' groups to the next poster on their right.

FIRST SET OF ROTATIONS:

ROTATION 1 - 12:05	ROTATION 2 - 12:20	ROTATION 3 - 12:35
P1 – Orange	P1 – Yellow	P1 – Red
P2 – White	P2 – Orange	P2 – Yellow
P3 – Turquoise	P3 – White	P3 – Orange
P4 – Purple	P4 – Turquoise	P4 – White
P5 – Red	P5 – Purple	P5 – Turquoise
P6 – Yellow	P6 – Red	P6 – Purple

BREAK FOR LUNCH 12:50

SECOND SET OF ROTATIONS:

ROTATION 4 - 14:00	ROTATION 5 - 14:15	ROTATION 6 - 14:30
P1 – Purple	P1 – Turquoise	P1 - White
P2 – Red	P2 – Purple	P2 – Turquoise
P3 – Yellow	P3 – Red	P3 – Purple
P4 – Orange	P4 – Yellow	P4 – Red
P5 – White	P5 – Orange	P5 – Yellow
P6 – Turquoise	P6 – White	P6 – Orange

POSTER ROTATIONS *(badge colors)*

ORANGE	
Beatrice Chapuzet	***Servier/Praxis***
M. Hall Gregg	***Pfizer***
John Koch	***MSD***
Dónal Landers	***AstraZeneca***
Thomas Løngborn-Jensen	***Novo Nordisk***
Jonathan Usuka	***McKinsey***
Ashok Upadhyay	***Otsuka***
WHITE	
Massimo de Francesco	***UCB***
Olivier Gien	***Sanofi***
James Hanly	***Bristol-Myers Squibb***
Henrik Lynge	***Novo Nordisk***
Jim McGurk	***Daiichi-Sankyo***
Alain Nanzer	***F. Hoffmann-La Roche***
Jianying Shi	***Ipsen***
TURQUOISE	
Matej Adam	***IBM***
David Christie	***Amgen***
Pascal Coorevits	***Ghent University***
Martin Erkens	***F. Hoffmann-La Roche***
Alex Schuleit	***H. Lundbeck***
Michael Shanler	***Gartner***
Scott Thomas	***MSD***
PURPLE	
Rebecca Blanchard	***MSD***
Wendy Chung	***Columbia University***
Joe Donahue	***GeneDx***
Andreas Friese	***Bayer***
Preben Klavsen	***H. Lundbeck***
Simon Roach	***GSK***
Jason Swift	***AstraZeneca***
RED	
John Apathy	***Celgene***
Anne Bahr	***Sanofi***
Jason Coarse	***UCB***
Edsel David	***Astellas***
Joel Ekstrom	***Ionis***
Philip Hajduk	***AbbVie***
Tomoyuki Matsunaga	***Takeda***
YELLOW	
Nadir Ammour	***Sanofi***
Dan Chapman	***UCB***
Sebastian Kloss	***Bayer***
Martin Leach	***Alexion***
David Sedlock	***Takeda***
Jens Noack Skærbæck	***Novo Nordisk***
Michael Stapleton	***MSD***
Katherine Tucker	***F. Hoffmann-La Roche***

SESSION IV
PLENARY PRESENTATION

Session Chair: Nadir Ammour

Domain Head, Patients & Partner Management, *Sanofi*

Nadir Ammour has first been involved in treating patients as an oral surgeon in public healthcare units. He has completed a certification on medical informatics in 1994 and achieved an MBA in 2000. His academic activities include a course on "innovation management within the pharmaceutical industry" at Reims Business School, in France.

Mr. Ammour held various global positions at Pfizer, and now at Sanofi, managing clinical development programs as well as developing, implementing and operating clinical systems on a global scale (mainly CTMS, RDC, eTMF, and ePRO).

He is now involved in strategic activities around clinical digitization with a focus on patient centric clinical development and healthcare solutions and services. Mr. Ammour is a member of the Executive Committee of the EHR4CR champion project.

Jason Coarse

Biostatistician, *UCB*

Jason Coarse is a biostatistician working with UCB's data transparency group to anonymize clinical data for secondary use. Additionally he holds roles as a clinical trial statistician as well as being the Crohn's disease statistical lead on the immunology data insight, analytics and evaluations team. Previously he held the role of clinical trial reporting lead, collecting and posting study trial properties and final results on the ClinicalTrials.gov website.

Linked Data at Work in Translational Science

A lot of companies are facing the challenge of linking and characterizing biomedical data of human studies, biological specimens, cell lines, microarrays and other research data to enhance resource sharing which ultimately accelerates experimentation and encourages interdisciplinary collaboration.

DISQOVER uses an ontology-centric architecture to organize and visualize internal data in conjunction with third party and public data. It builds semantically linked data repositories allowing users to 'hop' from one data type to another.

The core search engine has been optimized and is now more powerful, more scalable and faster compared to traditional semantic web architectures. Users can search in different data types, follow links between data concepts while the data is being harnessed from many different heterogeneous data sources in a federated way. The intuitive visualization engine allows everybody to easily build complex semantic queries across healthcare and life sciences data from many different data sources. Results are stored in a reusable information network and can be visualized using lists, tables, tree-views, world maps, timelines, etc. depending on the data type or property.

At the end of the executed search, all search steps can be stored, exported, re-used or shared in multiple formats resulting in true collaboration across harmonized data fueling translational science. In the talk we will zoom in on the architecture and execute a demo delivering an answer to a real life scientific question.

SESSION V
KEYNOTE LECTURE

Session Chair: Thomas Lønborg-Jensen

VP, R&D Project Execution, *Novo Nordisk*

Wendy Chung

Director, Clinical Genetics Program, *Columbia University*

Wendy Chung, MD, PhD, is a clinical and molecular geneticist who directs the clinical genetics program at Columbia University and performs human genetic research. She is the Kennedy Family Associate Professor of Pediatrics and Medicine.

She received her BA in biochemistry and economics from Cornell University, her MD from Cornell University Medical College, and her PhD from The Rockefeller University in genetics. Dr. Chung directs NIH funded research programs in human genetics of obesity, breast cancer, pulmonary hypertension, and birth defects including congenital diaphragmatic hernia and congenital heart disease. She leads the Simons VIP study characterizing genetic forms of autism and tests novel treatments for autism in clinical trials and the SPARK study of autism.

Dr. Chung has authored over 250 peer reviewed papers and 50 reviews and chapters in medical texts. She was the recipient of the American Academy of Pediatrics Young Investigator Award, the Medical Achievement Award from Bonei Olam, and a career development award from Doris Duke.

Dr. Chung is renowned for her teaching and mentoring. She was the original plaintiff in the Supreme Court case that overturned the ability to patent genes and is a member of the National Advisory Council for Human Genome Research and the Genomics & Society Working Group and the Institute of Medicine Committee on Genetic Testing. Dr. Chung enjoys the challenges of genetics as a rapidly changing field of medicine and strives to facilitate the integration of genetic medicine into all areas of health care in a medically, scientifically, and ethically sound, accessible, and cost effective manner.

Legal, Regulatory & Ethical Issues in the Secondary Use of Genomics Data

Genomics is an important component of precision medicine and the ability to molecularly stratify disease and identify individuals at risk for future disease. Genomic data are and will be available on many patients through biobanks, research studies, clinical trials, and clinical genomic tests. However, it is unclear what data are available for various types of research and whether patients were consented for all desirable use cases of the data. Furthermore, with the proposed changes to the Common Rule, consent will be explicitly required for use of de-identified specimens that could have been previously used for research. We will discuss possible solutions for dealing with these challenges in both prospective studies and retrospective data.

SESSION VI
BRINGING IT ALL TOGETHER

Session Chair: David Sedlock

Global Head, Research IT, *Takeda*

David Sedlock, PhD, is currently the Global Head of Research IT at Takeda, Boston, responsible for the planning, development and management of the Informatics platforms supporting the company's drug discovery and early clinical programs. This includes application development, design, deployment, integration, and support for the various systems and services used by the Research scientific staff including bioinformatics, cheminformatics, LIMS, and GLP systems.

Dr. Sedlock received his PhD in Bacteriology/Biochemistry from the University of Wisconsin, Madison, and has been working in the pharmaceutical and biotech industries for the past 25+ years both as an R&D program director and an Informatics and IT business leader managing scientific and enterprise software systems at a global level.

ROUND TABLE DISCUSSION STRUCTURE

Session Objective: Create a preliminary draft of a topic proposal for review by the IMI DKM SGG or another relevant project organizing body.

Session Breakouts: The audience will be divided in four groups. The table captains will coordinate the groups' review, consideration and drafting advice for the next steps (on the basis of the day's proceedings and the instructions displayed on the big screen).

GROUP A

Nadir Ammour	Sanofi
John Apathy	Celgene
Edsel David	Astellas
Massimo de Francesco	UCB
Dave Handelsman	d-Wise
John Koch	MSD
Martin Leach	Alexion
David Sedlock	Takeda
Jens Noack Skærbæk	Novo Nordisk
Katherine Tucker	F. Hoffmann-La Roche
Ashok Upadhyay	Otsuka
Martin Urban	Boehringer Ingelheim
Jonathan Usuka	McKinsey

GROUP B

Peter Gamble	MSD
David Christie	Amgen
Pascal Coorevits	Ghent University
Olivier Gien	Sanofi
Philip Hajduk	Abbvie
James Hanly	Bristol-Myers Squibb
Dónal Landers	AstraZeneca
Henrik Lynge	Novo Nordisk
Tomoyuki Matsunaga	Takeda
Alain Nanzer	F. Hoffmann-La Roche
Simon Roach	GlaxoSmithKline
Jianying Shi	Ipsen
Scott Thomas	MSD

GROUP C

Jim McGurk	Daiichi-Sankyo
Matej Adam	IBM
Jason Coarse	UCB
Beatrice Chapuzet	Servier/Praxis
Wendy Chung	Columbia University
Scott Dixon	ERT
Preben Klavsen	H. Lundbeck
Sebastian Kloss	Bayer
Jane Reed	Linguamatics
Adel Salem	Novo Nordisk
Alex Schuleit	H. Lundbeck
Michael Shanler	Gartner
Michael Stapleton	MSD

GROUP D

Thomas Lønborg-Jensen	Novo Nordisk
Anne Bahr	Sanofi
Rebecca Blanchard	MSD
Dan Chapman	UCB
Joe Donahue	GeneDx
Joel Ekstrom	Ionis
Martin Erkens	F. Hoffmann-La Roche
Andreas Friese	Bayer
Hall Gregg	Pfizer
Helle Ingemann Nielsen	Novo Nordisk
Chris Olinger	d-Wise
Jason Swift	AstraZeneca

NOTES