Workshop Programme

Data Protection in Health Research:

A dialogue among data protection authorities, manufacturers of medicinal products and medical technologies, and other stakeholders

Tuesday, 27 November 2018

IPMPC & MedTech Europe Workshop

Hilton Brussels Grand Place, Carrefour de l'Europe 3, 1000 Brussels (*i.e.* Gare Centrale)

Workshop Materials are available at:
https://www.ipmpc.org/dpa-workshop

IPMPC
International Pharmaceutical & Medical Device Privacy Consortium

MedTech Europe
from diagnosis to cure

9.30 – 10.00		**Coffee & Networking**
10.00 – 10.15		**Welcome and Overview for the Day** Patrice Ettinger *(Chief Privacy Officer, Pfizer)*, Chair of IPMPC Board of Directors Chantal Vets *(Legal Director, OUS Data Protection and Privacy Program, Medtronic),* Chair of MedTech Europe's Data Protection Committee

Session Descriptions

10.15 – 11.45	Large Group Breakout	**Clinical Trials** Moderated by Cecilia Alvarez (*European Data Protection Officer Lead, Pfizer)*, IPMPC European Working Group Chair Panellists • Céline Deswarte *(European Data Protection Officer, Boston Scientific*) • Jeppe Manuel *(R&D Personal Data Protection Specialist, Novo Nordisk*) *The application of the concepts of "controller" and "processor" is key to determining a party's data protection obligations under the GDPR. Therefore, an examination of the application of the GDPR to clinical trials must begin by identifying the appropriate characterization of the roles of the parties involved. For example, what is the appropriate characterization of the role of the trial sponsor versus the trial site? From there, consideration must be given to the legal basis for the processing of data collected for the trial. Traditionally, consent has been relied upon as the legal basis for processing of data in this context. Is this still appropriate in light of the limitations specified in the GDPR on validity of consent and the right of the individual to revoke consent? Moreover, since the GDPR prohibits the processing of*

		sensitive personal data, including health data, absent an applicable derogation, what is the appropriate derogation to rely upon in the context of clinical research? *The legal basis for processing is just one of the elements that must be included in a notice to data subjects prior to data processing. The data retention period, the rights of the individual concerning, e.g., data access, rights related to revocation of consent/objection to processing, possibility of international transfers and the legal mechanism to be relied upon for such transfers must each be explained. Each of these issues raises questions as to what is permissible under the GDPR and what wording in a data protection notice would be acceptable. For example, how long is it permissible to retain data collected as part of a clinical trial? Is it permissible to inform trial participants that while they can choose to access their personal data at any time, should they choose to do so while their participation is ongoing, they will be withdrawn from the trial? These and other questions will be addressed during this session.*
This breakout session will run parallel to the large group breakout on ***Clinical Trials***	Small Group Breakout	**Convergence of Health Care Delivery, Quality Improvement, and R&D** Moderated by Christine Lee *(European Data Protection Officer, Abbott),* IPMPC European Working Group Vice-Chair and Vice-chair of MedTech Europe's Data Protection Committee Discussion Thought Leaders • Cynthia O'Donoghue *(Partner, Reed Smith)* • Olivier Proust *(Partner, Fieldfisher)* • Chantal Vets *(Legal Director, OUS Data Protection and Privacy Program, Medtronic*) • Erik Vollebregt *(Partner, Axon Lawyers)* *The learning health care system focuses on ongoing system improvement through capture of data at the clinical encounter and use of that data to improve care. Improving care can take a variety of forms, from using real-time clinical data to improve clinical decision-making, to use of data to improve health care diagnostic and treatment technologies. The blurring of the line between health care provider and health care product manufacturer also has implications for data protection. For example, when is an organization providing medical device support and related services a "processor" versus a "controller"? How can relationships among health care entities be structured to realize the promise of the learning health care system? This session will examine these issues.*
11.45 – 12.00	**Coffee Break**	
12.00 – 13.30	Large Group Breakout	**Future Research Using Clinical Trials Samples and Data** Moderated by Pierre-Yves Lastic *(Deputy Head, Global Privacy Office, Sano*fi), IPMPC Board Member Panellists • Nacéra Bekhat *(Legal Officer, CNIL)* • Stephen Roberts *(Research Regulation Specialist, UK Health Research Authority)* • Chantal Vets *(Legal Director, OUS Data Protection and Privacy Program, Medtronic)* • Anne Vidal *(Legal Officer, CNIL)* *Recital 33 of the GDPR states that "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose." However, the European Data Protection Board has opined that "when special categories of data are processed on the basis of explicit consent, applying the flexible approach of Recital 33 will be subject to a stricter interpretation and requires a high degree of scrutiny."* *This session will explore the potential legal bases that could be relied upon for future research, as well as notice requirements and data subjects' rights in this context. Anonymization, as a possible option for using data for secondary research, will be discussed, including what notices and options must be provided to data subjects prior to data anonymization.*

This breakout session will run parallel to the large group breakout on ***Future Research Using Clinical Trials Samples and Data***	Small Group Breakout	**Biological Samples** Moderated by Peter Blenkinsop, IPMPC Secretariat Panellists • Muriel Gazin *(Clinical Project Manager, Biocartis)* • Vassilis Karantounias *(Of-counsel, CMS)* • Carine Malcus *(Director, Global Clinical Affairs, Immunoassays, Molecular Biology and Global Bioethics Compliance, bioMérieux)* *Biological samples and associated clinical data may be obtained as part of an individual's research participation or as part of clinical care. When samples are used for research purposes, researchers are faced with questions such as (i) when is research using biological samples considered research on anonymous information versus research using personal data; (ii) what legal bases can be relied upon to conduct research using biological samples; (iii) what rights do individuals have with respect to, e.g., notice and access – for example, how should the right of access be interpreted in the context of research results of uncertain clinical significance; (iv) what special requirements apply to collection, use, and transfers of biological samples for research purposes. This session will explore these issues.*
13.30 – 14.30	**Lunch**	
14.30 – 16.00	Plenary Session	**Research Using Real-World Data** Moderated by Nick Tyler *(Group Data Protection Officer and Global Lead, Data Privacy, Takeda),* IPMPC Board Member Panellists • Mariann Karcza *(Policy Officer – Legal Expert and Internal Control Coordinator, Health Directorate at Directorate-General Research and Innovation, European Commission)* • Meni Styliadou *(Vice President, Government Affairs and Public Policy, Takeda)* • Jonathan Truelove *(Vice President, General Counsel – International, Genomic Health)* *Real-world data (RWD) refers to the collection of data on the effects of health interventions outside of controlled trials. There are a variety of sources of RWD, including the following:* ▪ *Patient registries are used to collect data on a category of patients over time. The criteria for inclusion in a patient registry may be defined by a particular disease or condition, or use of a particular product. Patient registries can play a role in monitoring the safety of medicines and medical devices. Electronic health records are used by health care providers to record routine clinical and laboratory observations.* ▪ *Pharmacy and insurance databases are used for billing and health care administration purposes.* ▪ *Social media allow patients to share information with other users of a social network. Some social networks are focused on specific patient communities.* *Each of these sources of RWD presents its own challenges in terms of notice and providing data subjects with an effective means to exercise their data protection rights. This session will explore the appropriate legal bases for data processing in a variety of different RWD scenarios, how notice can be provided, and means for effectuating data subjects' rights. The session will explore whether the type of research in question – for example, research for product development purposes versus cost-effectiveness research – might impact the answers to these questions.*
16.00 – 16.15	**Coffee Break**	

16.15 – 17.45	Plenary Session	**Big Data and Data Analytics** Moderated by Stan Crosley, IPMPC Secretariat Panellists • Xenofon Kontargyris *(Legal Counsel, Data Protection & Privacy, Olympus)* • Elsa Papadopoulou *(Legal Officer, Health Directorate at Directorate-General Research and Innovation, European Commission)* • Martijn ten Bloemendal *(European Regional Privacy Counsel, AbbVie)* *A goal of Big Data in health care is to gain insights into patient treatment using a mix of health information sources from across the healthcare ecosystem. Big Data may combine clinical data, claims data, genomic/proteomic/epigenomic data, product support data, and user-generated data from apps and devices. Through analysis of these combined datasets with powerful computers, a goal is to develop more targeted health care interventions.* *Big Data in health care necessarily involves amassing very large quantities of potentially sensitive data. Can this data be effectively anonymized? How do the needs of Big Data align with the requirement to minimize processing of personal data?*
17.45 – 18.00		**Concluding Remarks** Willy Vanbuggenhout *(Chief Privacy Officer, Johnson & Johnson),* IPMPC Board Vice-Chair

Please Join us for Cocktails & Networking Reception Immediately following the Workshop