Big Data in the Pharmaceutical Sector - Between Protection and Transparency: Opportunities and Legal Challenges

André S. Berne*

I. Introduction

Scientific Chair of the Conference:

Prof. Dr. iur. Claudia Seitz, M.A., Attorney-at-Law, University of Basel, Faculty of Law, Center for Life Sciences Law (CLSL)

Big Data in the health and pharmaceutical sector plays an important role in many ways and has already transformed various facets of the sector: These huge datasets are leading to new drug discoveries and improving clinical trials more efficiently, various devices allow researchers to monitor trial participants in real-time and healthcare professionals are enabled to predict and prevent illness in a better way. From personalised medicine to artificial intelligence, assisted diagnostics and genetic engineering, the possibilities, it seems, are endless. However, legal and regulatory challenges remain: especially the recent introduction of the General Data Protection Regulation (GDPR) brings with it significant regulatory challenges and further regulations must be expected. Against this background it was the aim of this conference to help navigate these challenges and to recognise opportunities. The scientists, medical practitioners and lawyers who attended the conference were encouraged to participate and establish a dialogue between the various stakeholders in order to raise important questions and find possible solutions.

The conference was opened by *Professor Dr. Claudia Seitz*, Assistant Professor for Health Law at the University of Basel, Faculty of Law, with a brief overview of the conference's concept. The participants were encouraged to actively participate in the discussion.

II. The Possibilities of Big Data in the Health Sector: Building a Personalized Health Network in Switzerland

Prof. Dr. Torsten Schwede, Vice Rector for Research and Professor for structural bioinformatics at the University of Basel and Director of the Personalized Health Informatics Group at the SIB Swiss Institute of Bioinformatics, held the keynote speech and presented the Swiss Personalized Health Network (SPHN).

He began his keynote by explaining that the costs of sequencing a human genome have decreased from \$100 Million in the year 2001 to less than \$1000 today, with the consequence that he expects tens of millions of human genomes to be sequenced by 2022 and that 80% of these would be sequenced in health care settings. Prof. Schwede pointed out that genetics are only one factor in the equation of the potential of big data in the health sector. The history of a patient, his/her activities, environmental exposure and life style choices influence his/her life. Access to real world data would be a great opportunity for science to find out why a treatment has a higher impact on one patient than on another, which would be the basis for a transformation of healthcare towards personalized prevention and precision medicine. To achieve this, Prof. Schwede posited that health-related data must be made interoperable and sharable for research.

To implement this aim in Switzerland, the SPHN initiative was founded with the goal of bringing Switzerland to the forefront of personalized health research by establishing nationwide interoperability of biomedical information. Switzerland is thus the first country where all (five) university hospitals across the country participate in such a project. Prof. Schwede pointed out that SPHN will, due to the federated structure of Switzerland, establish a dynamic network of distributed interoperable and sharable resources (including data, platforms, workflows and competences) on a national level. This mechanism, despite being technically complex, may from a governance perspective provide a model how data shar-

DOI: 10.21552/eplr/2019/1/9

* MLaw, LL.M., Attorney-at-law, Doctoral Candidate and Research Fellow with Prof. Dr. iur. Claudia Seitz, M.A., Center for Life Sciences Law (CLSL) at the University of Basel. For Correspondence: <andre.berne@unibas.ch>

ing for research may later be organized on an international level.

In closing, Prof. Schwede also described current challenges. Specifically, he raised questions concerning data collection, standardisation of data semantics and data formats. He also focused on data governance and legal issues of the general consent, such as what aspects it covers, how it can be revoked, and technical limitations for implementation. For example, in Switzerland consent must be given by a signature on paper because Swiss law does not stipulate an electronic signature. This limitation causes problems in the digitalization of processes for the electronic consent (the so-called e-consent), by which consent is given by clicking a button or by signature on a tablet computer. Overall, there are still significant legal and ethical challenges to be addressed before health-related data becomes interoperable and sharable for research nationwide. To address these challenges, close and good collaboration with specialized legal experts is crucial.

III. Transparency and Consent in the Era of Big Data Analysis, Personalized Medicine and Gene Therapies

Maria Chiara Atzori is Head Data Privacy Switzerland at Novartis in Basel and a member of the Novartis Data Privacy Leadership Team. In her presentation, she focused on transparency and consent in the era of big data analysis and personalized medicine.

Ms Atzori explained that finding and providing the best personalized therapy for the patients requires starting a long journey that from big data collection and analysis leads towards being able to tailor therapies to the individuals. Along the journey from big data analysis to personalized medicine questions and concerns related to the use of personal data and health data in particular need to be addressed in different manner as the impact that the use of data has on the individual changes depending on stage of analysis. Subsequently, she demonstrated the multistep treatment process of a personalized therapy which requires careful monitoring of the chain of identity. While the treating physician would identify the patient, transplant coordinators would collect the patient's tissue samples on the basis of which a manufacturer would produce a personalized drug or treatment that would be subsequently be inserted in-

to the patient by infusion staff. Therefore, many players would be involved in the process of personalized medicine. Maintaining an accurate chain of identity from the collection of tissue until the infusion of the personalized medicine is essential to patient safety. If a patient received an infusion based on another person's cells, the consequences could be fatal. Besides, if the collection of information would fail for one patient, at least one other patient may also be affected. She concluded therefore, that certain patient's identifiers - for example, name and date of birth, as the most common identifiers - need to be known and controlled along the chain of treatment process, to confirm that the correct patient is getting the required procedure or the correct drug for treatment. One of the consequences of this process is that pharmaceutical companies that are used to basing their analysis on anonymous or pseudonymous data and build their internal processes on this requirement, have now to shift to a different paradigm, where the patient is known and the individual identity has to be protected according to new methods.

Accordingly, Ms Atzori argued that the identification and transparent communication to individuals of the legal ground for the processing of personal data along the journey from 'big' to 'personal' is crucial. However, consultations with regulatory authorities across Europe revealed the existence of divergent opinions with regard to the applicability of consent and different views on what the legal basis should be. Such an approach would result in the patient having to choose between giving his/her consent to a therapy or to completely reject the therapy thereby being forced in a so called situation of imbalance, where the patient is not empowered to have control on his/her choice. In particular, Ms Atzori stated that the choice of the legal basis is not a purely theoretical disquisition. Such choice is of crucial importance as it must be disclosed to the patient in a transparent manner and defines the frame for the applicability of certain rights and their limitations in case of conflicting obligations.

Ms Atzori argued that the new context require all players in the system, from patients to companies, regulators and law making bodies, to conduct an open discussion on how to address societal concerns around the use of health data for the advancement of medicine. In particular, it would be important to find consensus around the concept of risk of harm and fair processing according to the GDPR.

Ms Atzori concluded that the applicability of privacy principles and legal grounds for the processing of personal data in the new context must be ensured by means of the instruments provided by the GDPR. This process is currently hampered by a lack of harmonization among various players in the system and regulators across Europe with regard to the interpretation and meaning of key provisions. This impacts the transparency in regard to affected individuals and makes it difficult to focus and calibrate protective efforts according to the potential harm to individuals.

Marieke Jansen is Head Legal Cell and Gene Europe at Novartis in Basel. In her presentation, she focused on legal considerations regarding big data in CAR-T therapies.

Marieke Jansen began by enumerating the opportunities big data can offer such as delivering better treatments for patients, benefits to healthcare systems and society and to provide a more efficient development of new medicines. On the other hand, she evinced the challenges of big data and especially pointed out the lack of common standards and the lack of national and European guidance which makes it impossible to establish data transfer contracts which observe all aspects of national, European and international data privacy law. In particular, the fact that the purpose for which the data will be used must be clear at the moment of the patient's consent which makes the approach difficult. Later changes to the purposes require a subsequent consent of the patient.

Ms Jansen demonstrated the problem with the example of the CAR-T cell therapy, where genetically modified T cells are used in an innovative cancer immunotherapy using the patient's own blood cells as starting material. In this process the patient's T cells are extracted with a special filtration process (Leukapheresis), cryopreserved and sent to the manufacturing facility for reprogramming. In the facility, the T cells are genetically encoded using an inactive virus (viral vector) to recognize cancer cells and other specific antigen. As in nearly every production facility,

quality testing occurs prior to the release and shipment of the CAR-T cells back to the patient. After lymphodepleting chemotherapy to help the patient's body to accept the reprogrammed CAR-T cells, the latter are delivered into the patient's blood. The implementation of logistical controls would necessitate a rigorous chain of identity as the controlling electronic ordering system must maintain the chain of custody starting from the Leukapheresis to the transportation of the manufactured CAR-T cells in order to facilitate logistics and to ensure that patients are reinfused with their own cells.

In practise, such new grounds are explored without clear regulations and are causing grey areas to operate in. Especially the legal framework for providing out of specifications CAR-T in the EU is not clear; while the Directive 2001/83/EC¹ prohibits such an activity, the GMP ATMP Guidelines² allow such treatment. Furthermore, the off label prescription of these products was discussed. Normally a manufacturer would not have knowledge of particular details of any off label prescription. As these products however are individualized therapies, a manufacturer would be aware of any off label prescription. It is therefore a balancing act between the manufacturer only providing product that is within the label and the physician's independence of prescribing medication which should not be interfered with.

Ms Jansen concluded that the pharmaceutical sector and the national and European regulators need to work together to find a mutually acceptable solution in the light of the well-being of the patients.

IV. Big Data Applied to the Pharmaceutical Sector: Privacy vs. Data Protection in Light of the GDPR

Prof. Dr. Joaquín Cayón de las Cuevas, Professor of Health Law at the University of Cantabria in Santander and Director of the Research Group on Health Law and Bioethics at IDIVAL focused in his presentation on two main aspects. On the one hand, he explained the transition from privacy to data protection in the era of big data. On the other hand, he dealt with big data and health research in light of the GDPR.

He began his presentation by stating that data is no longer a mere reminder of the healthcare process

1 Directive 2001/83/EC of 6 November 2001 of the European Parliament and the Council on the Community code relating to medical products for human use OJ L 311/67, 28 November 2001.

2 Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products, points 11.53 & 11.54 <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2017_11_22_guidelines_gmp_for_atmps.pdf> accessed 27 March 2019.

but that it has become the main source of knowledge and progress in biomedicine. Therefore, big data would not only be the future but already the present.

Prof. Cayón de las Cuevas then demonstrated the opportunities big data provides in the healthcare and pharmaceutical sector. In this context, he showed examples demonstrating the problem of spurious correlations of statistics that do not have anything in common and demonstrated several examples. He subsequently stated that in the facilitating of health research it will become an unavoidable requirement to take advantage of these opportunities and that data sharing and re-using data for health research would be an ethical and scientific imperative.

Secondly, Prof. Cayón de las Cuevas emphasized that the fundamental right to privacy has usually been considered as the most prominent fundamental right to protect in health research but that the right to data protection is gaining relevance as a separate and different fundamental right. Therefore, all references to 'privacy' or to 'private life' contained in the Data Protection Directive of 1995 have disappeared in both the legislative text and the recitals of the GDPR. With reference to jurisdiction, he maintained that the two rights have a different scope because collecting personal data, by itself, does not fall under the scope of the right to privacy.³ Furthermore, the two rights would have different objects of protection since the right to privacy does not guarantee general access while the right to protection explicitly guarantees such access.⁴ In addition, the right to data protection involves positive obligations of the EU and Member States while the right to privacy was originally designed as a mere negative obligation of public authorities not to interfere with the private lives of individuals.⁵ Prof. Cayón de las Cuevas therefore noticed that the right to data protection relies on a more comprehensive and systematic approach while the right to privacy relies on a case by case approach. He concluded that the right to data protection as a whole is not an absolute right and that it must be weighed against other fundamental rights, in accordance with the principle of proportionality.

Thirdly, Prof. Cayón de las Cuevas explained that there cannot be a 'new' healthcare without big data. Furthermore, he highlighted that promoting big data requires research-friendly regulations. He therefore proposed a legal shift from the traditional 'Helsinki model' based on the primacy of privacy

through the consent of data subjects or the data anonymisation. In contrast, the new model should rely on the primacy of public interest. To this end, domestic regulations should take advantage of the new legal possibilities laid down by the GDPR such as the data pseudonymisation, the so-called 'broad consent' and the secondary use of collected data for scientific research purposes.

He concluded by quoting the International Bioethics Committee that big data is a common good of humankind⁶ and that big data should not be dealt with under perspective of the right to privacy but under the right to data protection, with two important legal challenges: implementing the GDPR on a national level in order to bring about a competitive environment for research in Europe and to interpret the GDPR according to this goal, leaving the 'Helsinki model' and fostering a new 'pro-research' approach.

V. Regulatory Challenges and Opportunities in the Age of Big Data

MD Nikolai C. Brun, PhD, Director of Division of the Medical Evaluation and Biostatistics Division at the Danish Medicines Agency and Chair of the HMA/EMA Joint Big Data Taskforce in Copenhagen focused his presentation on how large volumes of data can support decision-making and on the past and present findings of the HMA/EMA Joint Big Data Taskforce.

First of all, Nikolai C. Brun recalled that although data privacy and data protection are mere European phenomena, discussions regarding research on big data occur on a worldwide level. Especially the United States of America and China, which are the main competitors of Europe in the sector of artificial intelligence and big data in health, don't heed data protection as much Europeans. He concluded that this very thought should be kept in mind in view of further developments in big data research.

3 ECJ, Joined Cases C-465/00, C-138/01 & C-139/01, ECLI:EU:C:2003:294 (Österreichischer Rundfunk u a) point 74.

4 ECtHR (Gaskin v UK), 1989.

5 ECtHR (Hämäläinen v Finland), 2014.

6 Report of the IBC on Big Data and Health, dated 15 September 2017 <<https://unesdoc.unesco.org/ark:/48223/pf0000248724>> accessed 27 March 2019.

Subsequently, he noted that big data offers the possibility to derive novel insights to support decision making but also brings together unknowns around data quality and hence the robustness of the evidence generated. Therefore, a regulatory strategy would be required to determine how and when the utilization of such data can bring value in the product life cycle. Accordingly, there is an urgent need to ensure the regulatory network has sufficient expertise to interpret and critically assess big data.

With this in mind, the HMA/EMA Joint Big Data Task Force was founded to describe the big data landscape from a regulatory perspective. The task force formed seven subgroups; six of them have already submitted their reports which have been combined into a summary report dated 13 February 2019.⁷ The seventh subgroup will submit its report in the first quarter of 2019. So far, the recommendations start with standardization in order to define and improve data quality and to enact actions to promote data sharing, access and to enable robust big data processing and analysis. The speaker added that now there needs to be a discussion about the sharing and access of data, of data standardization and of data quality. He pointed out that the law still strictly distinguishes between medical devices and drugs which would be of touch with reality because today's medical devices and drugs are so complex, that a clear distinction cannot always be made.

In the end, Nikolai C. Brun concluded that the current report sets out in some detail 'what' needs to be addressed but that the 'which', the 'how' and the 'when' will need further work. Therefore, the mandate of the EMA/HMA Joint Big Data Task Force has been extended. This would allow the data analytics group to complete their work and develop the scope for future work.

VI. Artificial Intelligence, Data Protection and Pharmaceutical Data

Prof. Dr. Claudia Seitz, M.A. (London), Attorney-at-law, and Assistant Professor for Health Law at the University of Basel, Faculty of Law, Center for Life

Sciences Law (CLSL) expounded in her presentation on the present and prospective legal challenges and opportunities regarding big data and artificial intelligence in the health and pharmaceutical sector. She focused on the insufficient legal regulations and solutions to various areas in data-related health and pharmaceutical data collections and processing.

To begin, Prof. Seitz gave a definition of what big data is and what it encompasses. She stated that digitalisation is a major trend in healthcare and that the mining of health-related data is on the rise and gave examples of how big data is collected. Afterwards, she distinguished between four different kinds of types and origins of health-related data: *voluntary* (collected through devices and software), *obligatory* (from insurances and health cards), *explored* (through patient-originated-research on the internet) and *inferred* (through assumptions from existing health data).

After offering a few examples of health-based big data and of how big data is collected in the health and pharmaceutical sector and especially in the area of genomics, Prof. Seitz went on to describe new opportunities arising through big data in healthcare such as personalized medicine or pharmaceutical research options. She also pointed out the EU Commission's positive point of view on possible opportunities and demonstrated a variety of initiatives coming forth from different agencies such as the EU Fundamental Rights Agency.

Hereupon, Prof. Seitz addressed the field of artificial intelligence and learning machines. She demonstrated that through algorithms, decisions are taken with ease thanks to predictive modelling methods, based on probability. She then presented an example for such an algorithm and showed where artificial intelligence is already being used in the health sector. Eventually, she presented the European Commission's Expert Group Draft on Ethical Guidelines for Trustworthy Artificial Intelligence, the Project AI4EU and the EU's Fundamental Rights Agency's work on artificial intelligence.

Turning her attention to international legal frameworks, Prof. Seitz addressed the aforementioned topics, through the prisms of the UNESCO Declaration on the Human Genome and Human Rights, the European Convention on Human Rights, the Oviedo Convention for the Protection of Human Rights in the Field of Biomedicine and the Charter of Fundamental Rights of the EU. She also addressed the GDPR

⁷ HMA-EMA Joint Big Data Taskforce, Summary Report, 13 February 2019, EMA/105321/2019 <https://www.ema.europa.eu/en/documents/minutes/hma-ema-joint-task-force-big-data-summary-report_en.pdf> accessed 27 March 2019.

and how genetic data fits into the concept of personal data, as it is special sensitive information. Ultimately, she raised further questions for consideration, e.g. regarding the patient's 'right not to know', the extents of consent and the precautions to take regarding the misuse of data.

To conclude, Prof. Seitz addressed issues in competition law that shouldn't be underestimated. For instance, new players like Google or Amazon are collecting data and using artificial intelligence – raising the question of market dominance. In the end, the areas of data protection, competition and consumer protection would also overlap and should be carefully weighed out.

VII. The CJEU's Case Law on Clinical Trial Data Transparency and Commercial Confidentiality

Prof. Dr. Timo Minssen, Professor of Law and Founding Director of the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen focused his presentation on selected problem areas resulting from tensions at the interface of increased clinical trials data transparency and the pharmaceutical companies' need to protect commercially confidential information (CCI).

Prof. Minssen presented the new Regulation on Clinical Trials on Medicinal Products for Human Use (CTR)⁸ which obliges pharmaceutical companies and academic researchers to disclose end-results of clinical trials and comprehensive clinical study reports in a publicly accessible EU database. Such data shall be *prima facie* publicly accessible unless documents are considered as (*inter alia*) CCI. In this context, Prof. Minssen explained Policy/0043 of the European Medicines Agency (EMA)⁹ which aimed to concretize the Regulation regarding the access to documents of EU Institutions, Bodies and Agencies (Regulation No 1049/2001)¹⁰ in the area on access to EMA documents. While the EMA was initially criticized by generics and biosimilar producers for being too reluctant in disclosing data due to CCI, it increasingly applied a pro-transparency approach in recent years. Within this context, the General Court of the European Union (EGC) dismissed several cases in 2018 where pharmaceutical companies claimed an infringement of CCI's by the EMA by disclosing clinical trial information to third parties. The EGC decided that the respective

claimants failed to provide concrete evidence that the disclosure would undermine commercial interests¹¹ and therefore confirmed principally EMA's transparency approach. But, Prof. Minssen evinced that in these cases the EGC also gave guidance on what constitutes 'CCI' and described this approach.

This case law has become instructive - not only for disclosures under Policy/0043 but also under the new Policy/0070 described further below - because Art. 81 (4) CTR provides that the information of clinical trials in the EU database, which is in principle publically accessible by default, might exceptionally be not publically available because of *inter alia* protection of CCI which overrides public interest in disclosure. Those cases might therefore facilitate the application of the exemption of disclosure and provide a veritable roadmap on how to successfully argue for the protection of CCI. Prof. Minssen summarized that in principle, the CTR aims at providing publicly available information from the EU database by increasing transparency of clinical trials and their results. However, the CTR's disclosure rules would attempt to strike a reasonable balance between patient's, doctor's and the public's needs to extensive and timely information about clinical trials and the developers' and researchers' need to protect their investments.

Considering the new regulations of the CTR, the EMA submitted its Policy/0070¹² aligned the Policy/0043¹³ in accordance and, in particular, released an Appendix on Disclosure Rules (ADR).¹⁴ Prof.

8 Regulation EU/536/2014 of 16 April 2014 of the European Parliament and the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ 158/1, 27 May 2014.

9 European Medicines Agency Policy on Access to Documents, EMA/110196/2006 30 November 2010.

10 Regulation EC/1049/2001 of 30 May 2001 of the European Parliament and the Council regarding public access to European Parliament, Council, and Commission Documents, OJ L 145/43, 31 May 2001.

11 EGC, Case T-235/15, ECLI:EU:T:2018:65, (Pari Pharma/EMA); EGC, Case T-718/15, ECLI:EU:T:2018:66, (PTC Therapeutics International/EMA); EGC, Case T-729/15, ECLI:EU:T:2018:67, (MSD Animal Health Innovation and Intervet International/EMA); EGC, Case T-33/17, ECLI:EU:T:2018:595, (Amicus Therapeutics /EMA).

12 European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use, EMA/240810/2013, 2 October 2014.

13 European Medicines Agency Policy on Access to Documents, EMA/729522/2016, 4 October 2018.

14 Appendix, on Disclosure Rules, to the 'Functional Specifications for the EU Portal and EU Database to be Audited – EMA/42176/2014', EMA/228383/2015, Endorsed 2 October 2015.

Minssen added that the ADR would describe the approach to the application of the exceptions to public access to the database, set out in Art. 81 (4) CTR. Furthermore, they would specify rules, criteria and data to enable the system software to determine, automatically, when a particular data element or document should be made public and that rules would be designed to produce a consistent and predictable outcome to know what will be made public and when. With reference to a recent transparency report by the EMA, Prof. Minssen stated that there has been full compliance with Policy/0070 and that only 0.01% of all published pages have been redacted because of CCI. While this seems like a very successful transparency development, Prof. Minssen added that more studies are needed on these issues. It might be wise to add some caveat with regard to crucial biologics data which probably provide much room for CCI redactions.

He concluded that in the light of the EGC's decisions and EMA's recent Policy/0070, companies must refine their approach to submission of evidence to the EMA to limit inadvertent disclosure. The EGC's decisions did not focus on EMA's Policy/0070 but that this may only be a question of time. Therefore, companies should consider EMA's and EGC's guidance carefully when redacting documents. Ultimately, the pharmaceutical companies and the EMA might have settled into an uneasy truce on disclosure where some companies will continue to argue for redaction. Such a process may become distracting, expensive and time consuming for all parties.

VIII. Informational Self-determination: Patient's Individual and Global Perceptive

Philipp do Canto, Attorney-at-law in Zurich and Member of the Scientific Advisory Board of the Swiss Multiple Sclerosis Association Switzerland focused in his presentation on the chances and benefits that big data might bring for the diagnosis, observation, therapy and handling and in regards to multiple sclerosis.

After a short introduction on the goals and work of the Swiss Multiple Sclerosis Society, Mr do Canto explained what multiple sclerosis itself encompasses and especially what challenges still lie ahead, as there still exists no cure. Subsequently, he presented

the Swiss Multiple Sclerosis Society's pioneer project, the Swiss Multiple Sclerosis Registry. This new research network with a focus on interdisciplinary and patient-centred work welcomes new enrollees on a daily basis and builds the foundation for a citizen science platform study. Various information and inputs e.g. in the form of surveys, diaries and medical records feed into the multiple sclerosis research. Statistical results are gathered, for example in the area of symptoms having a large impact on the quality of life.

Next, Mr do Canto remarked on the rise of converging technologies and especially how public awareness was torn in two. On one hand, the press and media would try to dissuade the citizens from sharing their data – from their point of view sharing one's data for research and other purposes is precarious and risky. Academia and industry, on the other hand, would encourage this kind of sharing and call it vital. In-between, the patients' individual opinion would often be overlooked and more attention should be paid to them. There would be different positions as to what the patient really wants. But what he/she would want altogether, is the best possible therapy. For this purpose, the patient would need to share his/her medical history and other information with his practitioner. Surveillance is a key factor in healthcare and without the possibility of monitoring patients and tracing vital medication the patients' health is at stake. Of course, individual rights are not to be ignored, such as the interdiction of discrimination on grounds of a patient's genetic material.

Mr do Canto concluded that the best approach as of now would be a global one. The implementation of standardized mechanisms or tools to ensure the informational self-determination of the individual has high priority. Through transparency, compliance and good practice on an international level, a more collective view would be represented. As of today, there is a pressing need for debate and the current on-going clash of opinions is detrimental both to research and patient.

IX. The Access, Value, Lawful Use, Control and Ownership of Real World Data

Florian Zabel, Group Chief Privacy Officer at F. Hoffmann-La Roche in Basel focused his presentation on

the topic of real world data and put an emphasis on the access to it, its value, lawful use, control and ownership.

Mr Zabel at first presented a definition of real world data which can be summarized as data collected as part of routine healthcare practice as opposed to data generated through conventional clinical trials. He explained that real world data provides valuable insight on how approved diagnostics and medicines affect outcomes.

After a short exposition as to what sources feed into real world data, such as data recorded by professionals or individual-generated data, Mr Zabel addressed the four main areas of concern regarding access to and use of real world data: patient privacy which is a paramount problem, data quality and interoperability, transparency and finally legal and regulatory frameworks. Afterwards, he described the potential benefits arising from the use of real world data for different healthcare stakeholders, and what impact an electronic health record has within a dataset. He highlighted what consequences follow unstructured information within one single record. In the end, value lies in meaningful data at a large scale.

Florian Zabel then went on to present considerations for the lawful use, control and ownership of real world data. He set off describing the goal of data protection laws – protecting the individual's rights and personal freedom – and continued with a description of regulations regarding privacy principles and lawfulness of processing. He then stated how the Clinical Trial Regulation¹⁵ and the GDPR interact and that the consent foreseen in the former must not be confused as a legal ground for the processing of personal data under the latter. He concluded that the same principles should be applicable to real world data.

Afterwards, Mr Zabel addressed the need to respect data protection laws regarding any personal data. In particular data sets ought to be treated the same way as identifiable data if there is a risk of re-identification in particular due to sharing or publishing. However, individual rights cannot possibly be granted to anonymised data.

Before addressing that property rights beyond data privacy wouldn't apply and are not truly appropriate in this sector, Florian Zabel expounded upon a decision from the Austrian Data Protection Authority dated 5 December 2018. In a nutshell, the Authority stated that anonymization should be considered

to be a deletion as it removes identifiers from data. Thus, anonymization would not be a use of data but a deletion of data. The Authority maintained that it is the data controller's discretion how to delete and therefore whether to anonymize personal data and that for the assessment if data is irreversibly anonymized, taking future technologies into account isn't required, independently from the chosen way to delete data.

In the end, Mr Zabel concluded that the role of real world data should become more preponderant, and that privacy rights must be respected. Additional rights to data aren't necessary and might prove impracticable, impeding advancement in multiple areas.

X. Conclusions

Pharmaceutical companies have dominated evidence generation in the pharmaceutical sector since the advent of randomized controlled clinical trials in the 1950s. This situation is gradually changing as health care systems begin to harness the potential of observational research based on data produced in routine clinical care.

Even though the conference presentations covered the main issues raised by big data in the pharmaceutical sector, each of the presentations were followed by a wide-ranging debate between the audience and speakers.

At the end of the conference, the speakers gathered for a panel discussion and were joined by *Tom Metcalfe*, Data Policy Leader within the Roche Pharma Personalised Healthcare Centre of Excellence in Basel and by *MD Dr. Alfred Wiesbauer*, Vice President of the Swiss Alliance of Rare Diseases ProRaris.

The panel discussion was opened by analysing the GDPR and concerns were raised regarding the application and implementation of the GDPR. Concerns regarding compliance with the GDPR and issues of interpretation in different jurisdictions and by different actors, such as ethical review boards lead to substantial additional expenditures for companies and researchers. Additionally, uncertainties in regard to how big data might be used for the benefit of the patient without violating the GDPR's provisions were

15 Cf (n 8).

also addressed. Concerns were also expressed that documents such as consent forms are becoming longer, more detailed and less easy for patients to interpret as a consequence of perceived risks related to the GDPR. The speakers and participants of the conference agreed that all concerned stakeholders (*inter alia* patients, researchers, companies, data protection authorities, ethic committees, etc.) need to talk to each other and to exchange their views. Thus, this conference was an excellent opportunity and first step to involve all stakeholders to discuss issues and questions, to get a common understanding and to have a good, open and useful discussion to find answers. Ultimately, the patients as well as the researchers, pharmaceutical companies and authorities which all act for the benefit of the patient on a different stage, would benefit from such discussion and consequential solution approaches. Patients would therefore benefit twice.

With its multi-stakeholder approach, the conference was able to provide speakers and audience with a 360 degree view of the issues raised by the emer-

gence of big data. With a focus on the practical and the theoretical, the event provided an excellent forum to begin the vital discussions which are now needed in this area. Otherwise, it would be time to think about alternative ways.

In conclusion, if we are to improve the legal and regulatory framework governing the areas, interdisciplinary discussions and collaborations like this are essential to further improve the legal framework. As well as benefiting regulators, researchers and industry, they allow us to think about improving patient care in an ethical way. This conference, which has been the first of its kind, has therefore demonstrated how important it is to solve the legal issues in the area of big data in the health and pharmaceutical sector in a timely manner. The conference was an important first step to implement a general discussion of all stakeholders. Accordingly, a repetition of the event would be more than welcome. This, hopefully, could spur the innovation in health care and create new treatments that contribute to the patients' health.