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ISPOR Europe 2019

Digital Transformation of Healthcare: Changing Roles and Sharing Responsibilities

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ISPOR New Professional Event: Career Advice Across the Globe

"Unfortunately this Content is Unavailable in Your Region: What is the Impact of General Data Protection Regulation (GDPR) on the HEOR Community?"

ISPOR Europe 2019
Monday, November 4, 2019
14:30-15:30 | Location: Auditorium 10

Overview of Agenda

Time	Topic	Presenter
14:30 – 14:35	Welcome	Jason Cohen, MPP
14:35 – 14:40	Objectives, Overview of agenda	Dr. Elisabeth Oehrlein
14:40 – 14:50	Speaker: Berit Faber	Dr. Berit Faber
14:50 – 15:05	Speaker: Carl Asche	Dr. Carl Asche
15:05 – 15:20	Speaker: Jacco Keja	Dr. Jacco Keja
15:20 – 15:30	Q&A / Open Discussion	ALL

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Objectives & Overview

- This session will introduce New Professionals and graduating students to the European Union's General Data Protection Regulation (GDPR) and explore how it might impact outcomes researchers.
- The topic was selected through ISPOR Staff's collaboration with the New Professional Steering Committee members.
- Upon completion of the presentations there will be time for Q&A
- Join us at the CEE Reception tonight. For details search the mobile app and program.

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ISPOR New Professionals Overview

Presenter:
Elisabeth Oehrlein, PhD, MS
Senior Director, Research and Programs,
National Health Council
Washington, DC, USA &
ISPOR New Professional Steering Committee Chair

New Professional Overview

ISPOR New Professionals Network

- The ISPOR New Professionals Network is composed of recent graduates from HEOR related programs. The membership is available to former ISPOR student members and any new members who join that possess 3 years or less of experience in the HEOR field.
- Members will be eligible to renew for two additional years after they join before becoming standard ISPOR members. Current ISPOR members, paying the $150 Standard membership, are not eligible to downgrade their membership to New Professional.

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New Professional Steering Committee

New Professional Steering Committee Chair:

- **Elisabeth Oehrlein, MS, PhD,** Senior Director, Research and Programs, National Health Council, Washington, DC, USA

New Professional Steering Committee Members:

- **Blythe Adamson, MPH, PhD,** Senior Quantitative Scientist, Flatiron Health, New York, NY, USA
- **Sanket Shah, PhD, MD,** Manager, Stratevi, Boston, MA, USA
- **Ernest Law, RPh, PhD,** Senior Manager, Pfizer Inc., New York, NY, USA
- **Mark Bounthavong, MPH, PharmD,** Investigator, Veterans Affairs Health Economics Resource Center, Menlo Park, CA, USA

ISPOR Staff:

- **Jason A. Cohen, MPP,** Manager, Member Services (Students & New Professionals), ISPOR, Lawrenceville, NJ, USA

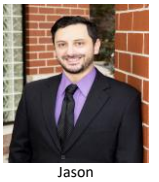

Elisabeth


Blythe


Sanket


Ernest


Mark


Jason

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Member Benefits Overview

Resources

- ISPOR *Value & Outcomes Spotlight*, the news journal of the Society;
- Electronic version of *Value in Health*, the peer-reviewed journal of the Society;
- Access to online educational opportunities including: “My Career Path” webinars, “My ISPOR Story” webinars, scientific webinars, and thought leadership videos;
- ISPOR Career Center;

At ISPOR Meetings

- Events during ISPOR conferences;
- Networking opportunities
- Access to the
- Eligible to participate in special interest groups / task forces;

Special Benefits

- Eligible to apply for ISPOR Meeting Travel Grants;
- Free online access to FormularyDecisions.com;

Email newprofessionals@ispor.org with questions or suggestions on how we can improve the member experience!

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In-Person Events

- Come visit the ISPOR Booth at 15.00 tomorrow for a Meet & Greet
- Reach out to a Steering Committee member if you're in town. We're in:
  - Boston, New York, San Francisco, Washington DC
- Upcoming December Happy Hour in Washington DC

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Introduction to Today's Topic

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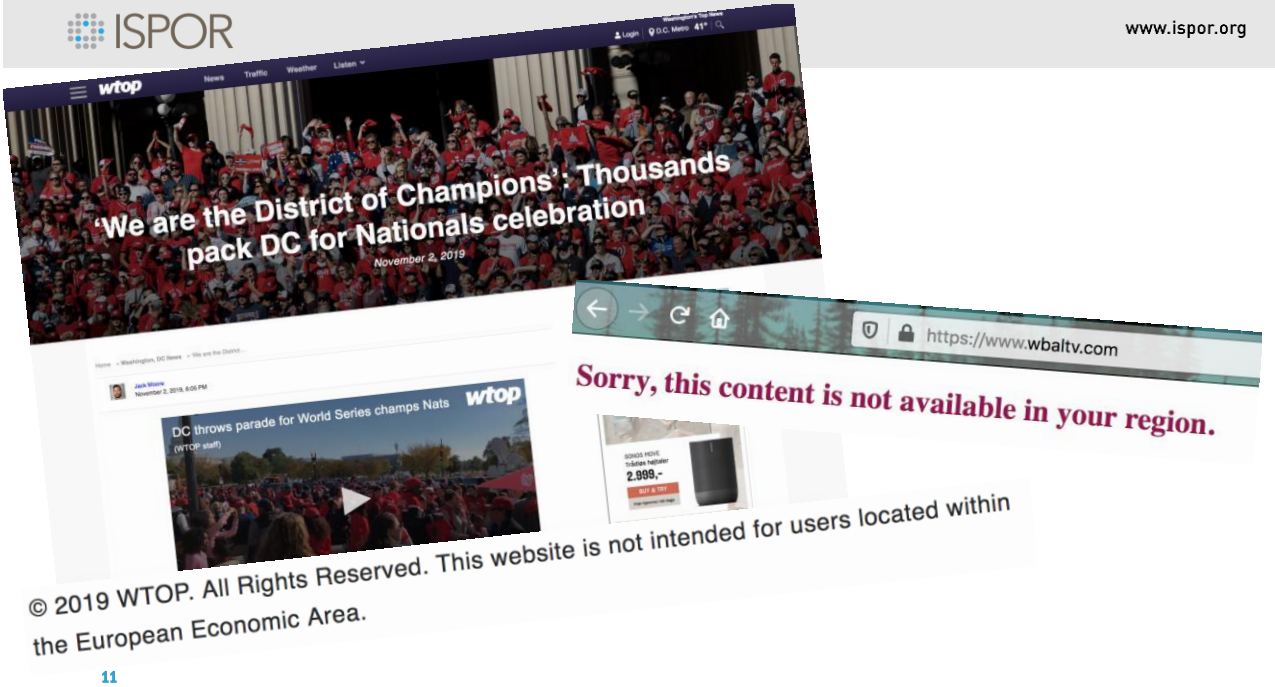
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'We are the District of Champions': Thousands pack DC for Nationals celebration
November 2, 2019
DC throws parade for World Series champs Nats
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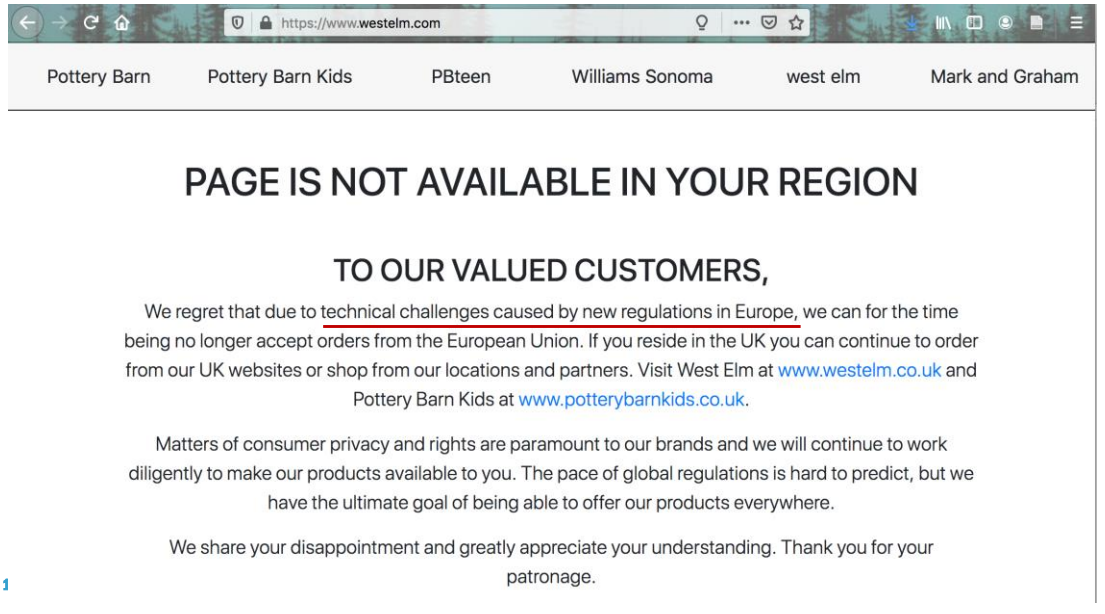
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We regret that due to technical challenges caused by new regulations in Europe, we can for the time being no longer accept orders from the European Union. If you reside in the UK you can continue to order from our UK websites or shop from our locations and partners. Visit West Elm at www.westelm.co.uk and Pottery Barn Kids at www.potterybarnkids.co.uk.
Matters of consumer privacy and rights are paramount to our brands and we will continue to work diligently to make our products available to you. The pace of global regulations is hard to predict, but we have the ultimate goal of being able to offer our products everywhere.
We share your disappointment and greatly appreciate your understanding. Thank you for your patronage.

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Conference App

ISPOR MOBILE APP IS NOW LIVE

App Store Google play

Be sure to search and select: ISPOR Europe20

As a reminder you can also access the app via
2019 Conference Mobile App.

Both options allow users to create a personal
content and venue information; network and connect with attendees and exhibitors; view an attendees' list comprised of those who have provided consent* and search for presentation by title, author, or day.

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What is GDPR? Where did it come from? How might it impact researchers?

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Image from: https://blog.finjan.com/gdpr-social-media-marketing/

Speakers

- Berit Faber, LLM, Jurfast Project, Southern University of Denmark
- Carl Asche, PhD, Director of the Center for Outcomes Research at the *University of Illinois* College of Medicine at Peoria
- Jacco Keja, PhD, Vice President, Real-World Evidence Solutions, Global IQVIA

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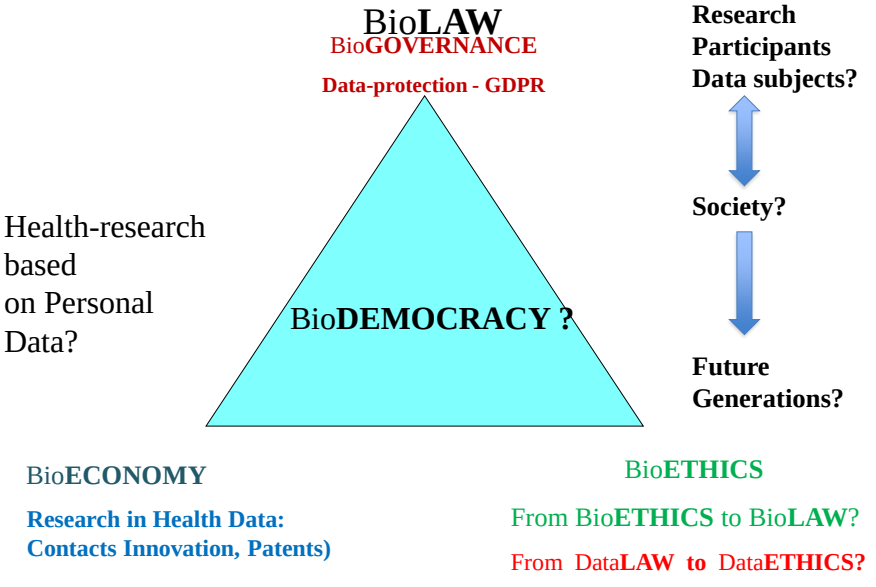
Presenter:
Berit A. Faber, LLM
JURFAST Project
University of Southern Denmark (SDU)
berit @ faber.net

Setting the Scene



Transparency

"The new biotechnologies within healthcare and medicine make the patient transparent to the system

We need to make the system transparent to the patients"

Prof. Mette Hartlev

Consent: Legal models tackling different scenarios

The Donor as a mining-area:
No restrictions/obligations towards donors and society
Researcher-heaven Pharma-heaven?
Laissez Faire – Opt out?

Donors are conscious drivers of the process
Patients' organisations
Opt in – layered consent, dynamic consent? Right to know Right not to know? Incidental findings? The right to know and the right not to know? Economic benefits?

How to combine the areas of protection in Biolaw and Data-protection:

Bioethics – data ethics?
The donor seen as a research project participant:

Human Rights, Bioethics Convention
Helsinki Declaration
EU regulation on medicinal trials
National regulation on research ethics

The donor seen as a data subject:
EU Regulation no. 679/2016 General Data Protection Regulation
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679

National supplementary legislation

Regulation (EU) 2016/679

Article 4: Definitions: 26 definitions of concepts used in GDPR
Personal data (1), processing (2) pseudonymization (5) controller (7), consent (11) Genetic Data (13) Biometric Data (14), "Data concerning Health" (15) Cross-border processing (23)

Article 5: Principles relating to processing of personal data
b)collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purpose
e) Storage Limitation: Personal data may be stored for longer periods than necessary for the purposes for which the personal data is processed.

Pitfalls: Anonymization - Pseudonymization

Anonymization
No Re-identification:
The link between the Data-subject and the data is Irrevocably broken

Pseudonymization
Re-identification is possible:
The link between the Data-subject and the data can be re-created

Important Contractual Caveats in relation to Personal Data and research collaborations

The Research Collaboration Contract Phase:

Elements of Legal Basis for the Contract:

Legal basis for research? (i.e. Ethics Approval)

Legal basis for handling personal data in the project?

Legal basis for Transfers to unsafe 3. countries?

Elements of legal basis and data safety: Consent, Data Management Plan, Dataflow in the project ? ? ? ?

The Innovation Phase:

Can governance and data safety play a role/pose restrictions in the Innovation phase ? ? ? ?

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Presenter:
Carl Asche, PhD
Professor & Director, Center for Outcomes Research
University of Illinois, Chicago
Chicago, IL, USA

ISSUE

- Healthcare systems stakeholders are looking to reduce inefficiencies, remove redundancies, personalize treatments, improve healthcare quality, and patient access, whilst trying to reduce healthcare costs.
- As of May 2018, European patients are protected by General Data Protection Regulation (GDPR).

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BACKGROUND

- General Data Protection Regulation (GDPR) .
- GDPR will be directly applicable in all EU Member States.

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GDPR FEATURES

- Worldwide territorial scope.
- Enhancements.
- One-stop shop.
- Sanctions.

WAYS BY WHICH GDPR WILL AFFECT THE HEALTHCARE INDUSTRY

SAFER PERSONAL DATA

- The GDPR mandates that data breaches must be reported.
- Concern that GDPR will severely impact ability to engage with customers and prospects.
- GDPR presents a great opportunity to build trust.

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DETAILED PATIENT PROFILES

- The data footprint of an individual is usually highly fragmented.
- Healthcare providers will have a more detailed view.
- GDPR enshrines the right to be forgotten, which could emerge as a barrier to improved diagnosis.
- Legal requirement for all healthcare providers to retain records for a prescribed period in case of query.
- The GDPR places a framework around this data.

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PUTTING PATIENTS IN CONTROL

- Healthcare is the one area of our lives that has remained highly sensitive and private.
- Some of the new data-subject rights also help customers feel in control.
- The framework is there to give the user control; but how?

USING NEW DATA SOURCES

- Research has found that healthcare is the industry the general public most trusts with its personal data.
- Technologies from social networking are increasingly being used to deliver patient care and support.

FROM DATA INSIGHTS TO BETTER PREVENTION

- The success of ERNs also depends on big data.
- The masses of data that healthcare organizations have been collecting for decades is still often unstructured and inaccessible.
- The GDPR is a reason for the health sector to be excited.

GDPR INTRODUCES IMPROVEMENTS

- Clear language
- Consent from the user
- More transparency
- Stronger rights
- Stronger enforcement

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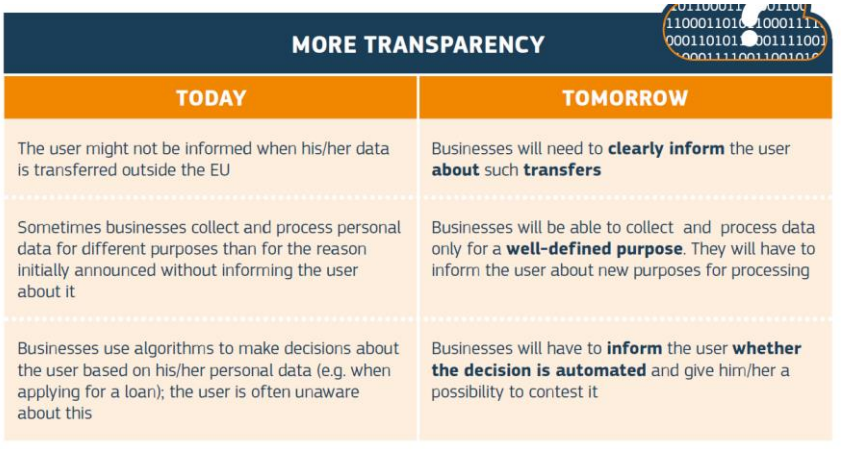
GDPR (excerpts from factsheet)



MORE TRANSPARENCY	
TODAY	**TOMORROW**
The user might not be informed when his/her data is transferred outside the EU	Businesses will need to **clearly inform** the user **about** such **transfers**
Sometimes businesses collect and process personal data for different purposes than for the reason initially announced without informing the user about it	Businesses will be able to collect and process data only for a **well-defined purpose**. They will have to inform the user about new purposes for processing
Businesses use algorithms to make decisions about the user based on his/her personal data (e.g. when applying for a loan); the user is often unaware about this	Businesses will have to **inform** the user **whether the decision is automated** and give him/her a possibility to contest it

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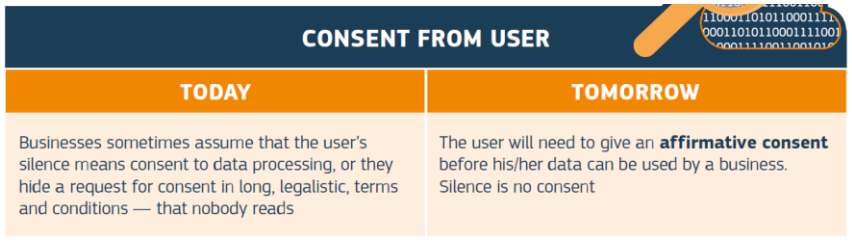
GDPR (excerpts from factsheet) (2)



CONSENT FROM USER	
TODAY	**TOMORROW**
Businesses sometimes assume that the user's silence means consent to data processing, or they hide a request for consent in long, legalistic, terms and conditions — that nobody reads	The user will need to give an **affirmative consent** before his/her data can be used by a business. Silence is no consent

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GDPR (excerpts from factsheet) (3)

STRONGER RIGHTS	
TODAY	**TOMORROW**
Often businesses do not inform users when there is a data breach, for instance when the data is stolen	Businesses will have to **inform** users without delay in case of harmful data breach
Often the user cannot take his/her data from a business and move it to another competing service	The user will be able to **move** his/her **data**, for instance to another social media platform
It can be difficult for the user to get a copy of the data businesses keep about him/her	The user will have the right to **access** and get a copy of his/her data, a business has on him/her
It may be difficult for a user to have his/her data deleted	Users will have a clearly defined **"right to be forgotten"** (right to erasure), with clear safeguards

Visit the European Commission's online guidance on data protection reform — available in all EU languages: europa.eu/dataprotection

BEWARE THE DOWNSIDE OF GDPR

- A couple of potential issues:

1. The GDPR may frighten organizations into being very careful about what data they collect and share. Will they be too conservative? Will it lead to less innovation?

2. GDPR gives individuals with the 'right to be forgotten'.

- If many individuals exercise this right, this can reduce our ability to obtain valid and precise estimates of the effectiveness and cost-effectiveness of many different types of healthcare interventions.

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ACCOUNTABILITY PRINCIPLE

1. Because of the "accountability principle", some organizations may be very conservative and not quick to share data with other parties.

➢ At the very least, researchers may need more time to acquire data and this will lead to delays in important discoveries.

RIGHT TO BE FORGOTTEN

➢ The right to **request erasure of personal data** ("the right to be forgotten") (Article 17) could lead to databases with fewer individuals.

➢ This may not lead to problems when researching the causes and treatment of common diseases, but it could lead to problems with researching uncommon subtypes or diseases.

➢ A database with fewer individuals will mean a reduced ability to:

- Identify causes of disease
- Estimate the effectiveness of a treatment
- Estimate the prognostic/predictive value of biomarkers
- Etc.

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RIGHT TO BE FORGOTTEN: BIASED

- If the persons who **request erasure of personal data** are different from others in "important" ways, this will result in biased results and conclusions.
- That is, these people may differ in:
  - their disease risk
  - the safety or effectiveness of a treatment
  - the prognostic/predictive value of a biomarker
  - etc
- Therefore, results based on these people will not generalizable to all people!
- Statistical adjustment may not correct this problem sufficiently.

WILLINGNESS TO SHARE (U.S.)?

Consumers with a chronic condition are more willing to share their tracked data

Survey question: How willing would you be to share the information tracked in your apps or devices for the following reasons?*

	Chronic disease	No chronic disease	Total
Blinded/anonymous contribution to an organization that does health care research	43%	34%	39%
Blinded/anonymous contribution to a device developer to improve device/program	44%	34%	40%
Share with emergency services if experiencing a sudden emergency situation	58%	46%	53%
Alert myself and share with family if in danger due to a fall or other health emergency situation	57%	48%	53%
Share with my doctors to help them provide better care to me	66%	52%	60%

*Chart shows the percentage of respondents who answered 4 or 5 on a 5-point scale, where 1 is "not at all willing" and 5 is "extremely willing."
Note: For the purposes of this research, a "chronic condition" is defined as any disease or health problem that has lasted for three or more months. Examples include arthritis, diabetes, cancer, heart disease, high blood pressure, high cholesterol, asthma, allergies, back pain, depression, alcohol or drug dependence, and others.
Source: Deloitte 2018 Survey of US Health Care Consumers.

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SIMILAR SITUATIONS IN HEALTHCARE

- If we conclude that policies like GDPR may severely affect healthcare research and healthcare, how can we convince people that it is better for them (and others) not to be forgotten?
- Can we learn from the experiences in other areas of healthcare?

EXAMPLE 1: ORGAN DONATION

- Some people choose not to register to donate their organs after they die; plus family members refuse it
- This reduces the number of available organs, which increases waiting time for an organ
- Result: poorer health and/or an earlier death
- Question: what can be done?
- Policy options include:
  1) Require everyone to donate their organs
  2) Give donor refusers a lower priority for organs
  3) Do not give donor refusers any organ
  4) Provide incentives
  5) Provide better health education

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EXAMPLE 2: VACCINATIONS

- Some people refuse to have their child vaccinated.
- Consequence: Their children's risk will increase
  - This will also reduce overall coverage, thereby reducing herd immunity and increasing the risk of disease in other children.
- Question: what can be done?

- Policy options:
  1) Mandatory vaccination
  2) Incentives/disincentives for vaccinations (e.g., ineligibility for other benefits)
  3) Better health education

MESSAGES

- GDPR may be a way forward from a societal standpoint but it could hamper advances in health.
- If you exercise your right to privacy, you may reduce your own future health (as well as the health of others).
- We will need ways to encourage people not to be forgotten.

1. Organisations need to gain the trust of others.
2. We need to apply incentives/disincentives to discourage people from opting out (ethically)

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Presenter:
Jacco Keja
IQVIA
VP consulting services RWE HEOR
London, UK

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"Unfortunately this Content is Unavailable in Your Region"

What is the Impact of General Data Protection Regulation (GDPR) on the HEOR Community?

Jacco Keja VP consulting services RWE HEOR

Disclaimer

My presentation is a personal view and does not represent that of my employer

Please note that this presentation **does not constitute legal advice**

Defined

EU DATA PROTECTION LANDSCAPE

Until **25 May 2018**

EU Data Protection Directive
(95/46/EC)

Transposed into local Data Protection Act in each EU Member State
+
Different local regulations but same framework

After **25 May 2018**

EU General Data Protection Regulation
(GDPR)

One single regulation for all the EU Member States – directly applicable, without the need to be transposed
+
Local derogations are possible – captured under national laws

Other legislation to be considered as part of the EU Data Protection Framework

1) **e-Privacy Directive**
   - Complements the Data Protection Directive / GDPR
   - Applies to electronic communication services
   - Will be replaced by the e-Privacy **Regulation** (2019)

2) **Directive on security of network and information systems (NIS Directive)**
   - EU-wide rules on cybersecurity with the objective to achieve a high common level of security of network and information systems within the EU
   - Transposition to national laws until 10 May 2018

What is the GDPR (General Data Protection Regulation)?

New European regulation

Directive 95/46/EC

Data protection directive with regard to the processing of personal data and on the free movement of such data - transposed to member state laws

REPLACED BY

GDPR

Regulation directly effective in member states without the need for implementing legislation.

Fully in force from May 25, 2018 in all EU countries

- Stronger rights for individuals
- Greater accountability requirements
- Increased scope
- **Strong sanctions and penalties for non-compliance: top fine is up to 4% worldwide group turnover**

It sets new standards for the collection, use, processing and transfer of the personally identifiable information of EuropeanUnion citizens.

What is the objective of GDPR?

General Data Protection Regulation provides a single set of rules for data protection across Europe.

GDPR seeks to expand the rights of individuals over how organizations use their personal data and to bring data protection law in line with how people's data is being used.

EU's desire to making data protection law identical throughout member states to give organisations more clarity over how they can behave.

It applies to all European Union member states and also any country or entity that transfers the personal data of EU citizens outside of the European Union.

MAIN DEFINITIONS

"GDPR is more about documentation than anything else"

The following definitions applied under the Data Protection Directive and **remain** under the GDPR

Personal Data	Processing	Special Categories of Data
Information relating to a natural person (data subject), identified or identifiable, directly or indirectly, by reference to an identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (eg. name, identification numbers, patient data)	Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (e.g. data management, access, transfer, storage)	Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic or biometric data (for the purpose of uniquely identifying a natural person), data concerning health, data concerning a natural person's sex life, sexual orientation (The general rule for these types of data is that processing is prohibited but there are exceptions such as explicit consent, need to process for carrying out obligations, to protect vital interests of the data subject, legal claims or public interest in the area of public health)

What is a Data Subject?

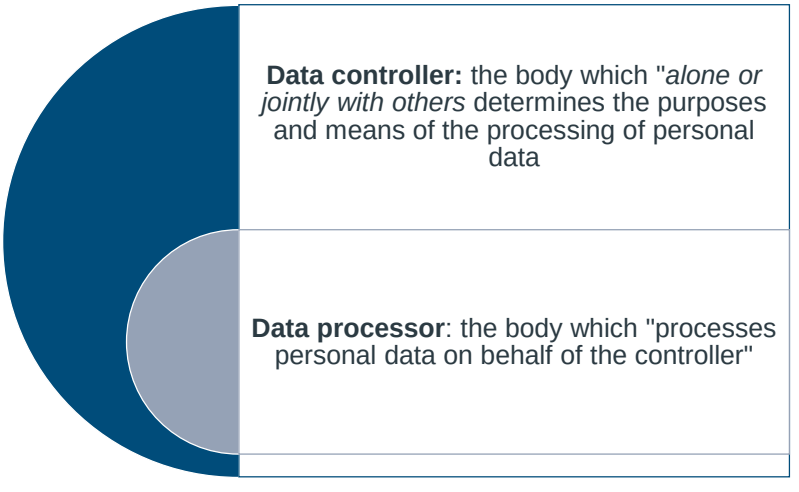
Data Subject:

- an identifiable natural person (data subject) is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;(Article 4(1) GDPR

In short everyone is considered a data subject

This includes employees, business contacts, health care professionals, patients, and any other individuals for whom we have personal data

Data Controller vs. Data Processor



This definition can be confusing in the data collection arena. For clarity, the controller has ultimate responsibility. The owner of the panel and sample is controller.

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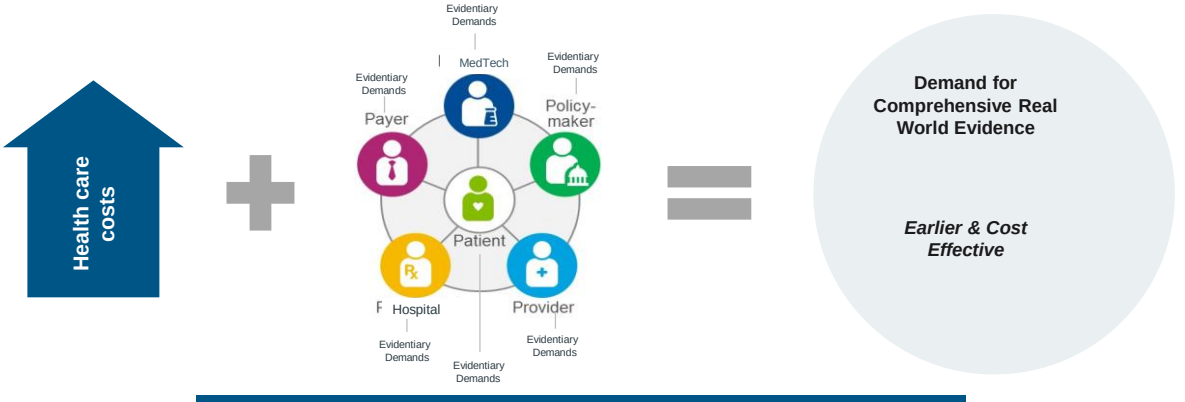
Hunger for Data

Demand: Healthcare system challenge

Stakeholders demand immediate, relevant evidence, collected efficiently at minimal cost



**Tighter Budgets + Networked Healthcare System =
Increased Demand for Comprehensive Evidence Development**

Supply: Applying predictive analytics to realise novel insight

Generating novel insight with complex data

- Healthcare data is rapidly growing in complexity:
  - New high-resolution data (e.g., biomarkers)
  - Newly linked data (e.g., across care settings)
- Richer data presents exciting opportunities but also challenges

Predictive analytics addresses many of these challenges enabling fresh opportunities to be realized

Driving clinical evidence-based decision-making

- Technology is driving improvements in diagnosis and targeted treatments (e.g., companion diagnostics)
- Pharma, payers and providers are increasingly partnering to develop and implement clinical decision-support tools

Predictive analytics is critical to the success of this technology

Real World Evidence & Genomics are pushing new boundaries

"If real world evidence can be validated and studied in a randomized way, it could be used to support new indications, or expanded labeling, for existing therapies"

Janet Woodcock, FDA

Regulators are using RWE for safety & epi now – and considering broader adoption

Regulators and Payers have differing data needs from RWE and genomics (approval alone is no guarantee of success)

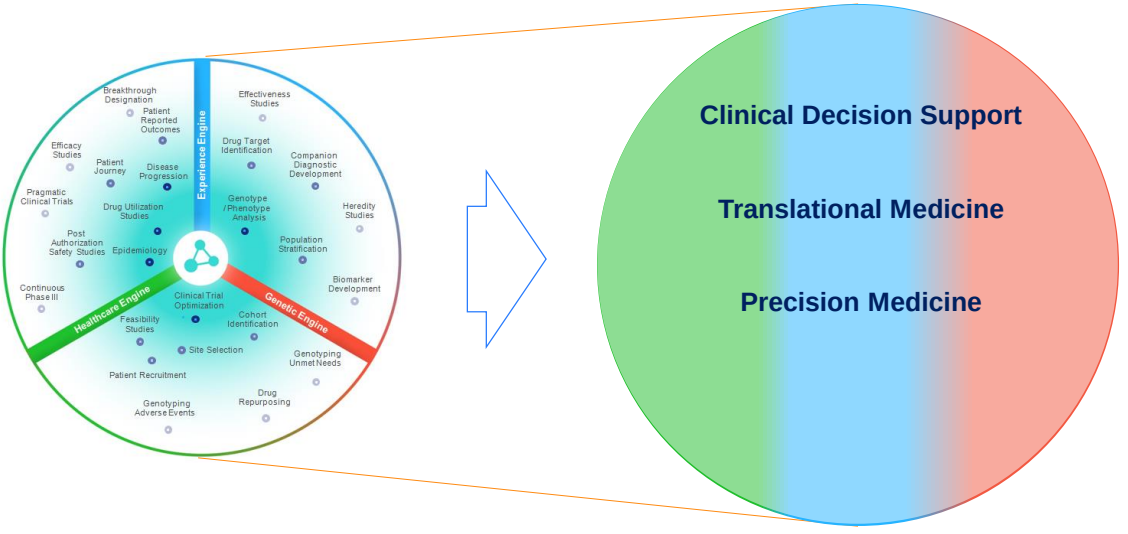
The issue is that health technology assessment (HTA) bodies wanted different data than EMA was using to approve the drugs, such as data on rare adverse events and long-term efficacy.

Michael Mezher - Regulatory Affairs Professionals Society

These technologies include high performance computing and machine learning to infer the complex associations between patient data, genetic factors, demographic data, disease progression, and treatment options.

Technology makes massive computing and storage capabilities accessible to many

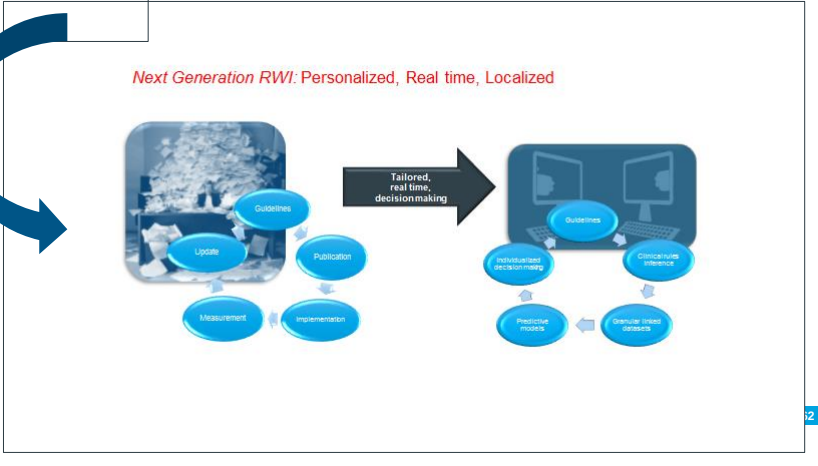
Precision medicine requires genomic, phenomic and care linkage



Challenges and solutions

" It is estimated that the **doubling time of medical knowledge** in 1950 was 50 years; in 1980, 7 years; and in 2010, 3.5 years. **In 2020 it is projected to be 0.2 years—just 73 days"** (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116346/)

Is GDPR the answer to the ask posed in **Trustworthy reuse of health data?** https://www.sciencedirect.com/science/article/abs/pii/S138650561200202X



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Case Biobanking

- **Derogations are allowed in the name of scientific research**

The GDPR and the research exemption: considerations on the necessary safeguards for research biobanks
Ciara Staunton ORCID: orcid.org/0000-0002-3185-440X[1],
Santa Slokenberga ORCID: orcid.org/0000-0002-5621-8485[2] &
Deborah Mascalzoni[3]
European Journal of Human Genetics
volume 27, pages1159–1167(2019)

Biobank research is based on long-term organised collections of data and samples that can potentially be used for very diverse research aims

Classical tool relates consent to strong governance
Secondary use

Challenge: individual rights, e.g. notification, restriction of processing, object?

Safeguards to be provided by member state law?

"This review makes it clear that a full implementation of the derogations as provided for under the GDPR may render the research unethical and not in line with individuals interests"

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status

General Data Protection Regulation shows results, but work needs to continue **Press release24 July 2019Brussels**

- **One continent, one law**: Today, all but three Member States – Greece, Portugal and Slovenia
- **Businesses are adapting their practices**: Compliance with the Regulation has helped companies increase the security of their data and develop privacy as a competitive advantage
- **Stronger role of data protection authorities**: The Regulation has given national data protection authorities more powers to enforce the rules, yet limited # of fines yet
- **EU rules as reference for stronger data protection standards across the globe**