18 April 2018 at Hotel Bloom, Brussels, Belgium

EMIF PUBLIC SYMPOSIUM:

LIBERATING EVIDENCE FROM EUROPEAN HEALTH DATA

The Achievements and Challenges of a Five Year IMI Project: EMIF

CONTENTS

Since the **Innovative Medicines Initiative** (IMI) began in 2008, it has funded many successful programmes to improve healthcare across the European Union (EU), and the **European Medical Information Framework** (EMIF) has been no exception. The accomplishments made through EMIF—especially in the areas of dementia, metabolic disorders, and data harmonization—have produced a proven model for collaboration and data management in medical research. In doing so, "EMIF is allowing research to happen at a speed and scale that was previously not possible," says Bart Vannieuwenhuyse, Co-Coordinator of the overall EMIF project and Senior Director at Janssen Clinical Innovation – Patient Data for Research (JCI-PDR).

The symposium brought together various stakeholders in the domain of (re)using health data for research to exchange views and experiences obtained in both past and ongoing large-scale projects. During this one-day meeting, a broad range of topics linked to the (re)use of health data were covered, including benefits and challenges, legal and ethical concerns, and the future of the European healthcare ecosystem.

EMIF has been an extraordinarily ambitious project, with big goals and big challenges. The purpose of this white paper is to highlight the achievements and challenges of the EMIF project so that others might learn and benefit.

A HIGH-LEVEL OVERVIEW OF EMIF: WHAT IS EMIF AND WHY WAS IT NEEDED?

CONTRIBUTORS

Bart Vannieuwenhuyse	Co-Coordinator, Overall EMIF Project, Senior Director of Janssen Clinical Innovation – Patient Data for Research (JCI-PDR)
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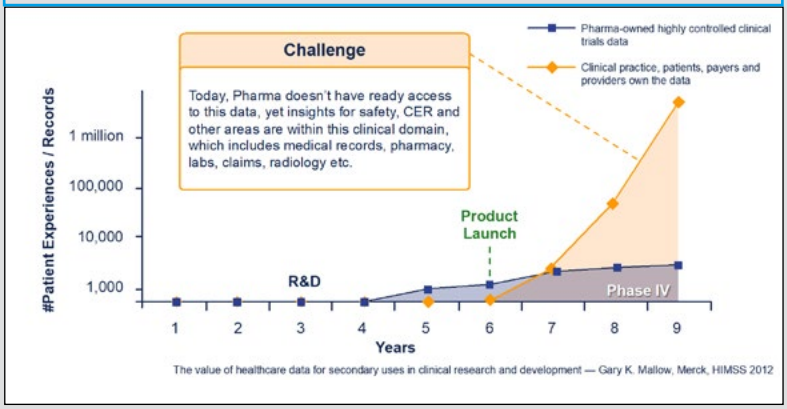
Dawn Waterworth	Co-Coordinator of EMIF-Metabolic, Director of Genetics, Cardiovascular, Metabolic and Dermatology, GSK

ACCESSING PATIENT-LEVEL DATA

The combination of rapidly increasing medical knowledge and advances in information technology is allowing researchers to use human health data in ways that were previously unimaginable. Increasingly, the challenge is to find and access data to fuel this research. Huge volumes of suitable data are already being collected and stored electronically in clinical practice databases. However, because this data exists in disparate locations and systems, it is generally used in isolation. It is also difficult to access due to technical, privacy, legal, and ethical issues related to data use and real-world data collection. New insights into diseases and treatments are being limited by our lack of access to this patient-centric data. According to Nigel Hughes, Co-Coordinator of EMIF-Platform, Janssen Pharma R&D, "There is a vast amount of information generated in healthcare. It's a treasure trove. It's almost a travesty that we cannot use this real world data to provide real world insights—it's almost unethical."

THE "BURNING PLATFORM" FOR LIFE SCIENCES

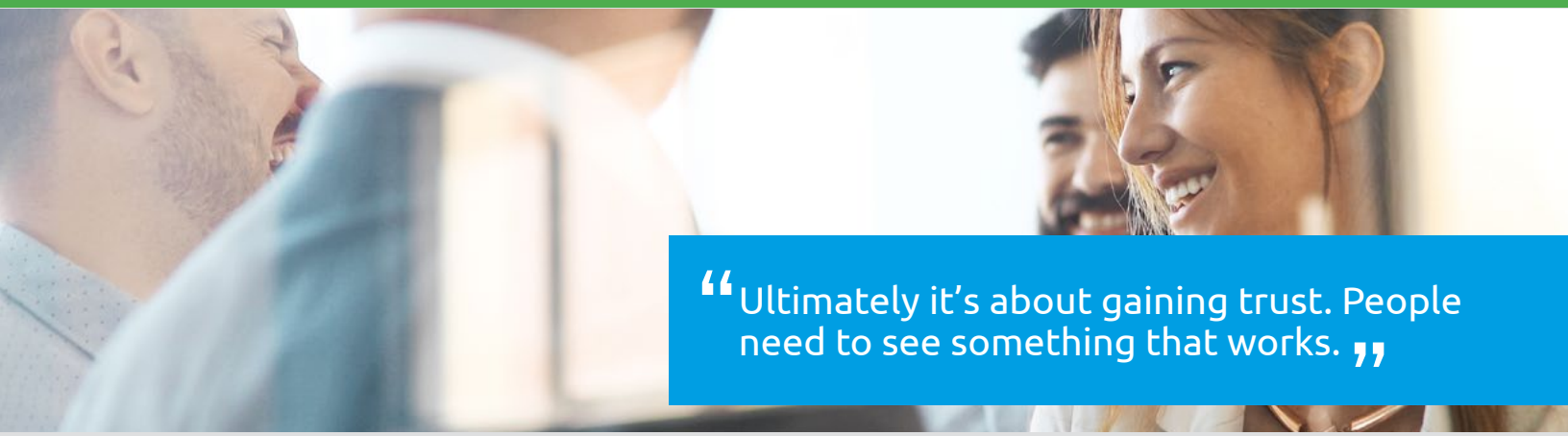


To help improve access to this patient-level data, EMIF was launched in January 2013. EMIF was a five-year IMI project tasked with improving access to, and use of, health data. To achieve this goal, a common Information Framework (EMIF-Platform) was developed to link up and facilitate access to diverse medical and research data sources within an appropriate governance framework.

TRUST IS KEY

The vision of EMIF was to enable and conduct novel research into human health by utilising human health data at an *unprecedented scale.*

However, the true potential of human health data will not be realised without the key ingredient of *trust*—no matter how powerful the technology or abundant the data. EMIF has put engendering trust at the centre of the programme's vision—a vision to create the European hub for healthcare data intelligence from which new insights into diseases and their treatment will flow. "Ultimately it's about gaining trust," says Hughes, and to gain trust, "people need to see something that works."



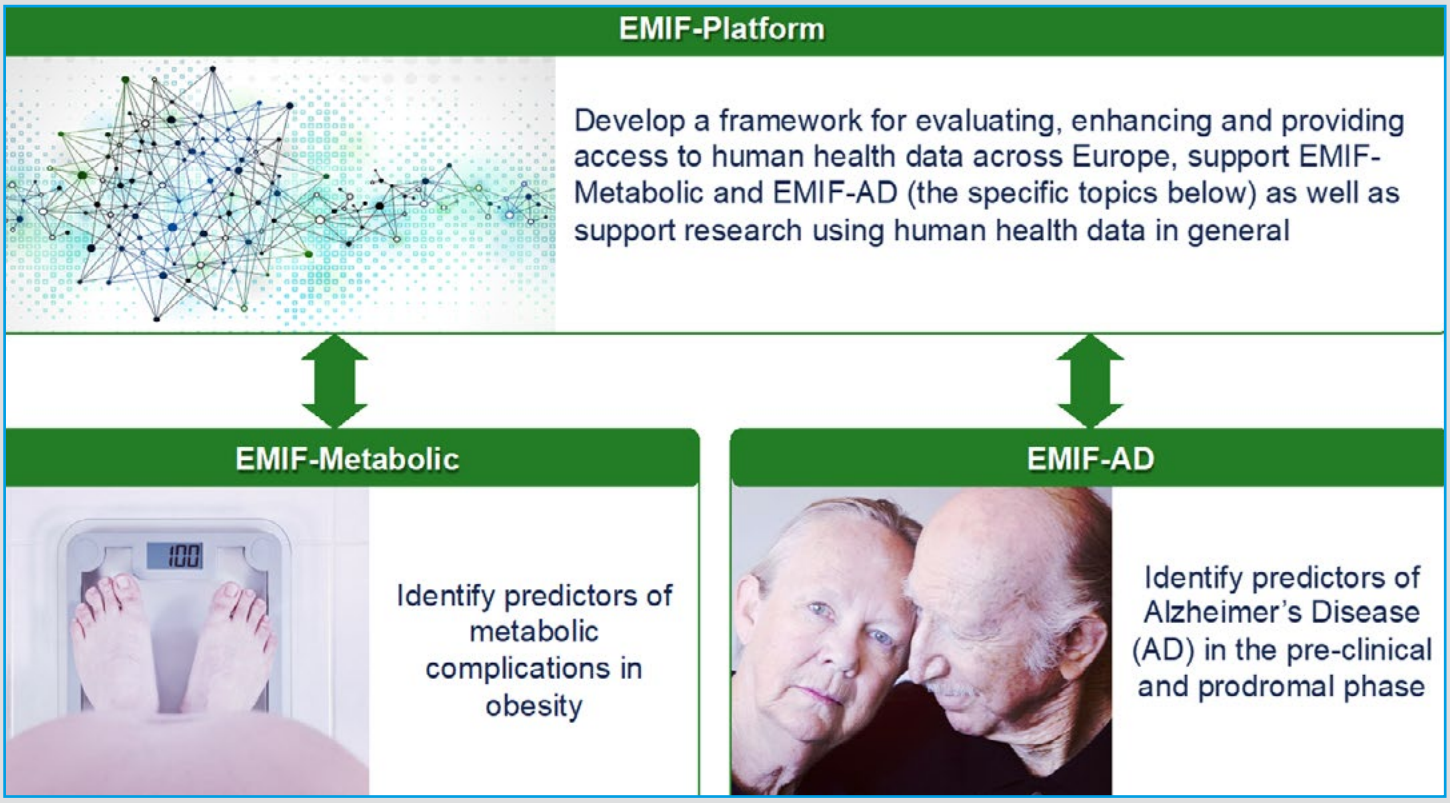
> "Ultimately it's about gaining trust. People need to see something that works."

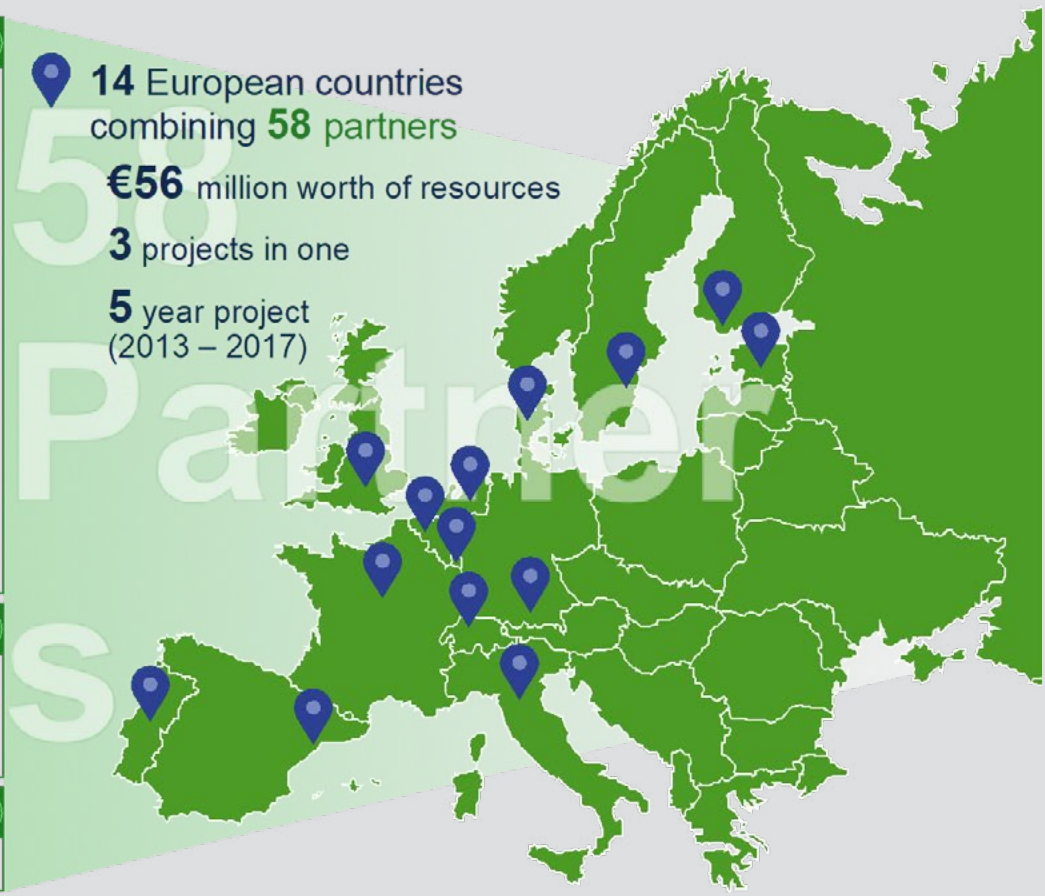
To demonstrate the validity of the principle and to ensure immediate applicability, EMIF included two specific therapeutic research topics that helped guide the development of the Information Framework: the onset of Alzheimer's disease (EMIF-AD) and the metabolic complications of obesity (EMIF-Metabolic).

COLLABORATION

Many meaningful discoveries and advancements are not possible if researchers don't have the infrastructure to reach beyond their own field. Waterworth explains that, in order to get the full value from research, we need to seek out a variety of perspectives. "The lesson [learned from EMIF] is that you have to reach outside your discipline," she says. EMIF has provided the unique opportunity for researchers across Europe to do exactly that.

Over the past five years (2013–2017), EMIF has brought together academic centres of excellence, subject matter experts, industry life sciences companies, and a patient organization. We have combined 57 partners across 14 European countries with €56 million worth of resources, focusing on three major projects.





SHAPING THE EUROPEAN HEALTH DATA ECOSYSTEM: EMIF ACHIEVEMENTS

CONTRIBUTORS

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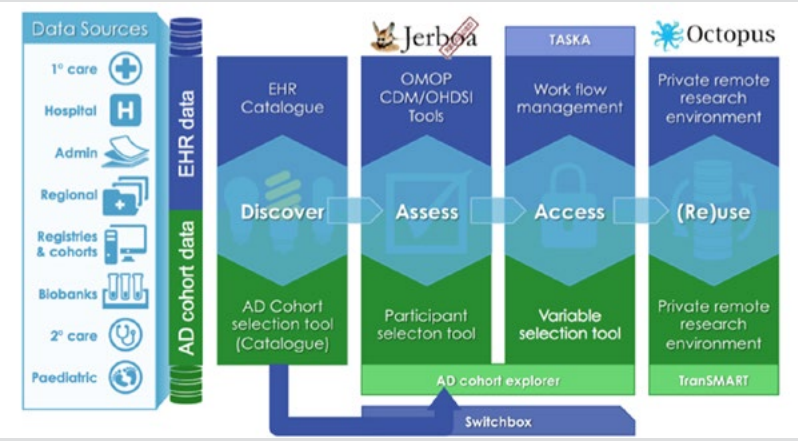
Peter Rijnbeek	Assistant Professor at Erasmus University Medical Center
Nemanja Vaci	University of Oxford
Adil Mardinoglu	Assistant Professor at KTH-Royal Institute of Technology and Chalmers University of Technology
Gerald Luscan	Pfizer

EMIF PLATFORM

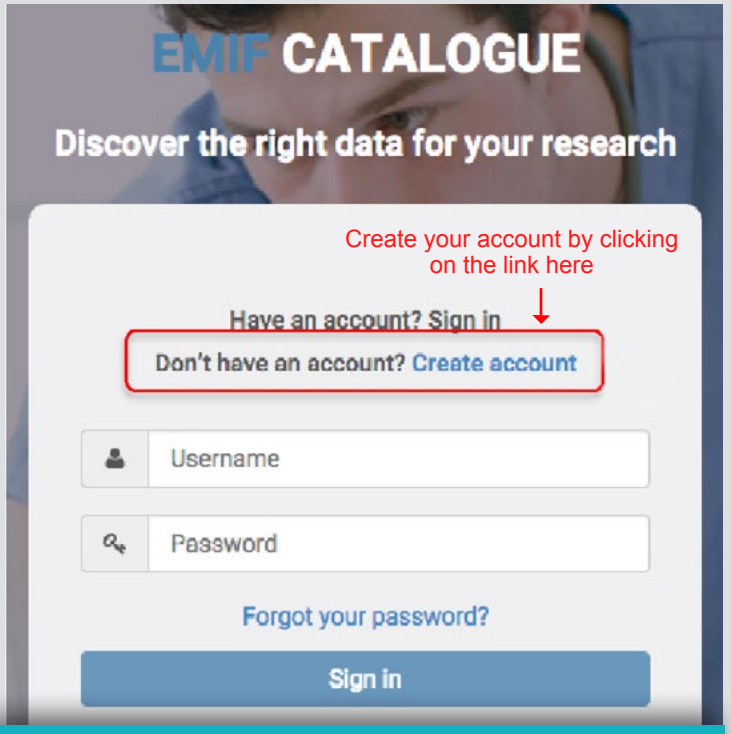
The goal was to build an integrated, efficient framework for consistent re-use and exploitation of currently available patient-level data to support novel research.

What did we achieve? There is now a working operational platform—an end-to-end solution reaching from catalogue to private remote research environment. It's a great achievement that will carry through into future projects (e.g., IMI2 EHDEN).



The platform contains data from more than 40 million subjects from six EU countries, as well as more than 60,000 subjects in AD cohorts and more than 94,000 subjects in metabolic cohorts.

The greatest legacy of EMIF-Platform will certainly be harmonization. Already, there are examples of how harmonizing data vastly improves its usability for research, such as the partnership with the Observational Health Data Sciences and Informatics (OHDSI) collaboration. But EMIF-Platform also focuses on *human* harmonization. The most powerful tool that we have available to overcome our most pressing human challenges, medical or otherwise, is one another. EMIF-Platform is already proving what's possible, and this is just the beginning.



You can now interact with the platform. It's in the public domain. To freely access it, all you need is to be a genuine researcher and set up an account—it's simple!

The EMIF Catalogue is the point of entry to the platform.

WHAT DID EMIF ACHIEVE?	LINK
Facilitated collaboration to make major breakthroughs in tool development, cohort development, and biomarker discovery	http://www.emif.eu/
Facilitated access to data from more than 40 million subjects from six EU countries	http://www.emif.eu/about/emif-platform#close
Worked with Erasmus Medical Centre to develop the European Observational Health Data Sciences and Informatics (OHDSI) Chapter	https://www.ohdsi.org/events/ohdsi-europe-symposium/
Adopted the OMOP common data model (CDM); while working to harmonize the 10 EU databases, also developed the CDM for EU implementation	https://www.ohdsi.org/data-standardization/the-common-data-model/
Created the Jerboa Reloaded extraction tool to support the data extraction and processing from the electronic health record (EHR) databases; Jerboa Reloaded is now open source	http://www.emif.eu/about/emif-platform#jerboa-reloaded
Disseminated publications (EMIF has been one of the most successful IMI projects when it comes to disseminating publications; still more to come)	http://www.emif.eu/results

EMIF-AD

Identify predictors of Alzheimer's Disease (AD) in the pre-clinical and prodromal phase

THE GOAL OF EMIF-AD

Our overall aim was to improve treatment opportunities for predementia Alzheimer's Disease (AD) by discovering diagnostic and prognostic markers and increasing understanding of AD pathophysiology.

WHAT HAVE WE LEARNED?

- There is a pattern of MRI scan and AD diagnosis, which is new information.
- The Aβ1-42/1-40 (Aβ42/40) ratio is a better predictor of preclinical AD than Aβ1-42 alone. When we cross-validated Aβ42/40 with the Aβ-PET, we have a 90% concordance with PET, versus 75% with Aβ1-42.
- In preclinical AD, there is increased cerebrospinal fluid (CSF) neurofilament light, neurogranin, YKL-40.

NEXT STEPS

- Ongoing analyses multimodal biomarker discovery (MBD) study
- Risk score amyloid positivity
- Novel CSF tau and abeta markers
- Completion PreclinAD and 90+ studies

MORE FAIR THAN EVER BEFORE

The success of the EMIF initiative has brought medical research to a new level by making data more FAIR (Findable, Accessible, Interoperable, Reusable). One example of this is the EMIF-AD community in the EMIF Catalogue, which has recently been made available to the research community. Through the Catalogue, EMIF has not only made data on Alzheimer's Disease more visible, but has created tools to efficiently access and use that data by putting it in a common format. It has been an "enormously difficult task," Lovestone admits, but the Catalogue is already demonstrating value. So far, programmes in Europe have already made use of it, including the Dementias Platform UK (DPUK) and the European Prevention of Alzheimer's Dementia (EPAD), another programme funded through IMI.

Dementias Platform UK
Medical Research Council

EPAD
European Prevention of
Alzheimer's Dementia Consortium

EMIF-Metabolic

Identify predictors of metabolic complications in obesity

THE GOAL OF EMIF-METABOLIC

Our overall aim was to identify novel biomarkers for obesity-associated complications with a focus on insulin resistance, Type 2 diabetes (T2D), NAFLD/NASH, and cardiovascular disease (CVD).

WHAT HAVE WE LEARNED?

- Identified 9 amino acids significantly associated with impaired insulin secretion, as expressed by the disposition index (DI) in the baseline and at 5-year follow-up study of the METSIM (Finland) cohort
- Amino acids associated with a decrease in DI consistently associated with an increase in fasting and/or 2-hour glucose at baseline and follow-up studies, suggesting that these 9 amino acids are not only associated with insulin resistance shown by several previous studies, but also with impairment of insulin secretion
- Mannose identified as a marker of insulin resistance and hence risk of T2D
- Mannose also associated with increased risk of developing T2D and these complications, e.g., CHD and CVD
- Validation of 42 proteins identified 3 true adipokines (CCL18, S100A4 and MXRA5)
- Only CCL18 and S100A4 are increased in the circulation in concordance with WAT gene expression data
- Similar comparison with circulating TNFα or IL6 showed that the levels were higher in insulin resistance but with lower significance (p=0.05 and 0.06, respectively)
- NAFLD is very under-diagnosed in primary care (0.8% versus 20% actual), but prevalence and awareness of the condition is increasing
- A low-carbohydrate diet (LCD) improves liver fat metabolism in NAFLD patients

WHY HAS EMIF BEEN IMPORTANT FOR THE SUCCESSFUL OUTCOMES?

- Phenomics of extremely well characterized cohorts supported by large biological omics databases, including Systems Medicine, allowing precision medicine development
- EMIF Platform allowing access to large real-world data and epidemiology
- EFPIA contributions with broad expertise and also allowed early access to placebo-controlled large clinical databases
- AD topic allowed collaboration with a focus on dementia and insulin resistance—a common problem in diabetes

NEXT STEPS

- The metabolic topic has identified several novel biomarkers of risk of developing disease, which may also contribute to the pathogenesis of the disease and associated complications. This work needs to be continued!
- In vitro studies are ongoing to obtain more evidence to demonstrate that 9 amino acids impair insulin secretion in pancreatic beta-cells.
- We continue to identify more metabolites associated with impaired insulin secretion.
- Why is mannose related to insulin resistance and diabetic complications? Mannose is an insulin-regulated molecule, but we don't understand its role.

EMIF: THE CHALLENGES AND LESSONS LEARNED

CONTRIBUTORS

Bart Vannieuwenhuyse	Co-Coordinator, Overall EMIF Project, Senior Director of Janssen Clinical Innovation – Patient Data for Research (JCI-PDR)
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Nigel Hughes	Co-Coordinator of EMIF-Platform, Scientific Director of Janssen Clinical Innovation – Patient Data for Research (JCI-PDR)
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Johannes Streffer	Co-Coordinator of EMIF-AD, EFPIA lead of the AD topic, Director Experimental Medicine, Janssen

CULTURAL CHALLENGES

When EMIF started, it did not have a common goal and objective. We were three separate groups (Platform, AD, and Metabolic). We underestimated the cultural differences between the groups, and the project struggled in the beginning. Academics were used to solving problems for pharma, not working with them. Pharma was used to utilizing a formulaic approach to developing therapies, and deviating from this was culturally difficult. We also discovered that there were even more differences between the data custodians than between the academics and pharma. It was all very disruptive. We were trying to build the plane while we were flying it.

In many ways, the bumps in the road while building EMIF-Platform were more human than technological. "It's a socio-technical issue!" is something you may have heard if you've ever spoken with Johan van der Lei. Yes, the data is just ones and zeroes, but at the end of the day it's people's health data managed by universities, governments, and payers. That means access is also about relationships, laws, and the intended use of that data. Ultimately, it's about trust.

> "Listing the various achievements is not possible – but the main achievement, I believe, is that EMIF in many ways has been a trail-blazing project.
>
> It started a cultural and mind-set shift in both public and private partners around the opportunities and value of reusing data. But also the value of collaborations – between public and private, between countries, between various research teams, between experienced and young scientists, finally, between people each with their ambitions, backgrounds and experiences."
> *– Bart Vannieuwenhuyse*

THE SOCIO-TECHNICAL CONSTRUCT SOLUTION

The introduction of use cases forced us to understand each other, rather than act like we understood each other. The introduction of a common data model (CDM) helped harmonise not only data and technology but also people within EMIF. This is what we call "the socio-technical construct." EMIF was about having a new research operating system for Europe.

It was all quite challenging but a great learning experience. It is important that this learning propagates across other research teams (e.g., the European Health Data & Evidence Network, or EHDEN).

LESSONS LEARNED

- Collaboration, trust, and the harmonization of technology and people are key to success.
- Don't underestimate how long it can take to achieve a common view of the world.
    - We were a bit overly optimistic, thinking we could do things faster than was possible.
    - We underestimated the complexity of doing studies.
    - We had to learn the hard way the need to work on the common data models (CDMs).
    - We underestimated the degree to which the development of an infrastructure/platform like EMIF would disrupt the business models of the data custodians.

"The interdisciplinary and public-private partnership structure of EMIF allowed us to identify biomarkers for a range of complications of obesity and perform an epidemiological analysis of NAFLD/NASH in four primary care European datasets. The majority of current NAFLD/NASH knowledge is derived from small cohort studies, but we were able to deliver unique insights from real world data. Limitations of real world data were also evident, with BMI as a risk-based measure in primary care and lack of linkage between primary and tertiary care. However the uptake of the OMOP common data model across Europe galvanized by EMIF and OHDSI should enable more complete and a higher volume of health data to be available for answering important clinical and public health questions." *– Dawn Waterworth*

STAKEHOLDERS OF THE EUROPEAN HEALTH DATA ECOSYSTEM

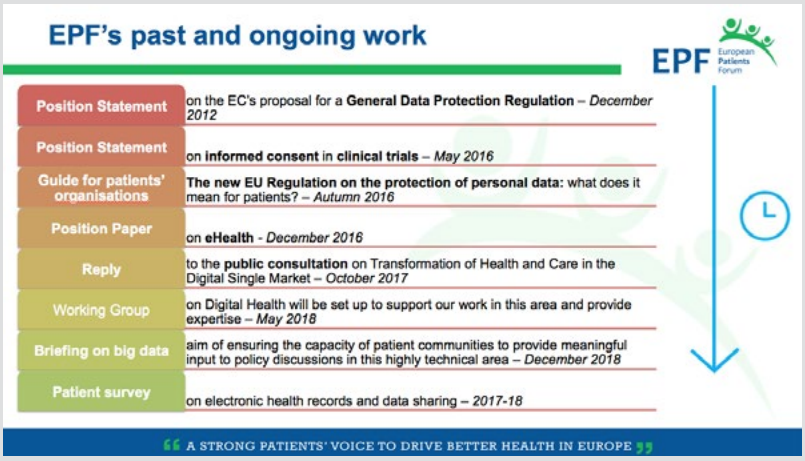
CONTRIBUTORS

Valentina Strammiello	Programme Manager, European Patients' Forum (EPF)
Nikolaus Forgó	Professor of IT- and IP Law, Head of the Department of Innovation and Digitalisation in Law, University of Vienna

THE PATIENT PERSPECTIVE ON RE-USE OF HEALTH DATA TO BENEFIT PATIENTS AND CIVIL SOCIETY

According to Valentina Strammiello, Programme Manager for the European Patients Forum (EPF), there is an increasing drive to improve collection, sharing, and use of patients' data in order to achieve better, more sustainable healthcare and advance health research. The only meaningful and valuable way to do this is together with patients.

Patient participation in decisions regarding health and genetic data is a matter of good governance. It's important that patients be involved at policy and programme level on questions of privacy in healthcare and health research. The ultimate goal is empowering patients as owners of their health and genetic data so that they can make decisions about their personal information.



Strammiello says that patients are generally comfortable with and willing to participate in the secure sharing of their anonymised health data. They recognise that this is of vital importance to advance health research, help other patients, and ultimately benefit society.

But patients do have privacy (anonymisation) and data security concerns. Unauthorised disclosure of personal health or genetic information could negatively impact a patient's personal and professional life. Patients' main fear is the fact that researchers and companies get their data. Patients think, "What will they do with my data? Can I trust them?"

This is why meaningful informed consent and transparency regarding the potential use of data is essential. Consent is not merely an exercise on paper. It is an empowering tool that allows patients to understand how they can contribute to research.

EPF European Patients Forum

OUR VISION

"All patients with chronic conditions in Europe have **equal** access to **high quality**, **patient-centred** health and related care."

OUR MISSION

"To be the collective, influential patient voice in European health and related policies and a driving force to advance patient empowerment and patient access in Europe."

We need to understand how to make healthcare systems more efficient and empower patients. It's not just about new medicines. It is about using the existing data to introduce efficiencies.

The European Patients Forum (EPF), has been active in creating position statements, position papers, and guides for patient organisations on topics such as the impact of the GDPR on the protection of personal data, informed consent in clinical trials, eHealth, and data sharing (see next column).

HOW MIGHT WE DO CONSENT BETTER?

Giving informed consent is not an easy task. As a patient, you need to be health literate and have some legal expertise to understand what's written in these documents.

The informed consent concept is broken. It does not help the patient; it helps the scientist reduce liability. eConsent might help here, but again, it needs some kind of EU initiative from a legal and technology perspective. We have yet to see tools that help the patient.

It is also important to keep patients updated after the research has finished—we need to tell patients how their participation has benefited the healthcare world. For example, there is an interesting model where blood donors receive a text to tell them how their blood has been used to benefit patients.

There is no legal obstacle to sharing data. Patients want to be full partners in the process of data sharing. We should keep in touch with them and go back to them with the outcomes. Strammiello concludes that patient organisations have a key role to play in ensuring patients are informed, empowered, and involved in matters of consent. Patient organisations can ensure that patients' personal data is protected, but still offer the option for patients to share their data to advance health research and improve disease management.

DATA PROTECTION—LESSONS LEARNED FROM A LAWYER:

Nikolaus Forgó, Professor of IT- and IP Law, Head of the Department of Innovation and Digitalisation in Law, University of Vienna, presented on the subject of data protection under General Data Protection Regulation (GDPR). Some of the key messages included:

- Data protection law is a "weapon of mass destruction."
- Projects underestimate the complexity of legal requirements and, at the same time, use some kind of "fake law" as argument for not allowing research.
- Data protection authorities are more or less uninvolved so far.
- Ethics Committees speak about ethics, not necessarily about data protection law.
- Legal compliance is a task for the project's and the partner's top executives.
- The increased obligations, liability, paperwork, and contracts have not been welcomed.
- Data access committees are not always sufficiently governed by legal standards.
- Researchers need to know exactly how data flows in their projects and make data protection compliance a top priority.

GENERAL DATA PROTECTION REGULATION (GDPR) IS HERE

As of 25 May 2018, GDPR[1] is finally here, inciting panic for many.

THE HOPE:

- One continent, one law
- Fit for the Internet
- One size fits all

THE REALITY:

- No revolution
- Higher penalties
- Higher visibility
- More administration/documentation
- Some opportunities and reliefs

Forgó says that, broadly speaking, there's no need to panic. Take the opportunities that are in this law. Proactively share the issues faced when sharing medical data. Organise yourselves, speak out, and find best practices.

OPPORTUNITIES AND RELIEFS

GDPR does provide some reliefs. For example, Recital 33 allows for broad consent. Article 5(1)b, makes provision for research (without consent) on sensitive data in certain cases.

How necessary does scientific research need to be before it is acceptable to waive consent? That's up to national legislation, e.g., when it's in the public interest. Interestingly, Austria states it's not necessary for the science to be publicly funded. "Further processing for […] scientific […] purposes […] shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation') (as per Article 5(1)b)".

According to Article 89, Union or Member states can provide for "safeguards" and "derogations" where personal data are processed for scientific purposes. But what does this mean? Basically, we don't know yet. We need to work out what this means. Article 89 is the beginning, not the end.

1. Regulation (EU) 2016/679 of The European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation - GDPR)

We need to proactively share the issues faced when sharing medical data and encourage the Commission to draw up codes of conduct to help us understand what is permissible. Article 40 of GDPR specifically encourages the commission to create codes of conduct.

WHAT ARE THE NEXT STEPS?

- Unite
- Speak to your data protection officer (DPO)
- Communicate with the public
- Develop codes of conduct
- Speak to lawyers
- Speak to the Commission
- Take law enforcement and IT-security issues as core threats to your business model

FUTURE OF THE HEALTH DATA ECOSYSTEM

CONTRIBUTORS

Simon Lovestone	Co-Coordinator, Overall EMIF Project, Professor of Translational Neuroscience, Oxford University
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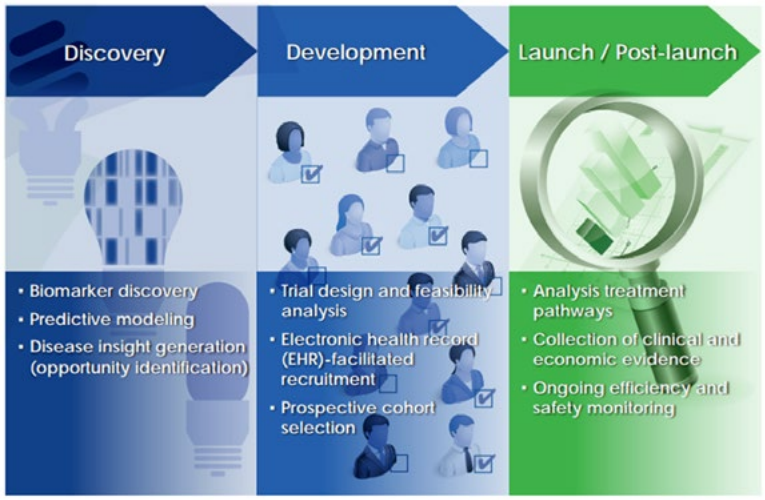
Bo Saxberg	President, DDO Strategic Services, LLC
Pierre Meulien	Executive Director of the Innovative Medicines Initiative

The final presentation evaluated the ten years of IMI, pointing to challenges, opportunities, and responses from numerous projects in the real-world data domain. IMI can rightfully be proud of a decade of heritage, including EMIF, which will support the developing programme of Big Data for Better Outcomes. IMI sees the convergence of opportunity to optimise and enhance clinical research, as well as improve the delivery and outcomes of healthcare. Through expanding partnerships and collaborations, as well as diversification of projects, IMI will have an increasing focus on "digital," but ultimately wants to co-create a harmonized and connected European clinical research powerhouse.

In a profound presentation on the potential future application of RWD, Saxberg highlighted the need for longitudinal patient trajectories to fuel real-world research, and to be a corollary to randomized controlled trial (RCT) data. The requirements of precision medicine are multivariate in nature and indeed are reflective of real world studies beyond original RCTs, effectively cohortising patients in their care settings. This leads to a concept beyond today's RWD of "augmented" RWD (A-RWD), enabling greater granularity, but with minimal process change in the clinical workflow around a patient. Incorporating the "instrumented human" in an increasing wave of innovation, all these discussed components will have a significant impact on the market scenarios for the utilization, and ultimately valuation, of RWD.

While this phase of the EMIF project is coming to an end, this does not mean that we can stop striving for increased access to human health data. In fact, we find that this need is growing all the time. There are countless potential applications for real world data in life sciences and drug development, from discovery through development and into launch and post-launch. There will always be a need for improving life sciences research and bringing better and safer medicines to patients.



Potential applications for real world data in drug development.

As we wrap up the existing EMIF project, we are also working to create a sustainable environment where collaboration will continue to flourish. We are proud of the work that EMIF has accomplished to date, and we cannot wait to see where it leads in the future. EMIF has been a great success.

WHAT'S NEXT?

The European Health Data & Evidence Network (EHDEN) is a very aspirational project. It's being discussed right up to the European Commission, and it's all part of the digital marketplace that is being discussed and developed. We want to see an impact on the delivery of healthcare in the future based on the output from EHDEN. We hope this will accelerate the harmonization project across Europe. The International Consortium for Health Outcomes Measurement (ICHOM) and the National Institute for Health and Care Excellence (NICE) are part of the consortium.

The aim is to map 100 million health records across the EU via a common data model (OMOP CDM), supporting research, the BD4BO IMI2 programme, and outcomes-based healthcare. EHDEN will be an IMI consortium of 11 EFPIA partners and a public consortium of 11 partners, commencing circa October 2018. We will build on the strong foundation created by EMIF and continue that work in EHDEN.

We have an ambition to make a big change in European real world evidence (RWE) research. Join this journey to collaboratively generate the evidence that promotes better health decisions and better care.

Contact Nigel Hughes and/or Peter Rijnbeek for further information or about continuing to collaborate in the future.

EXECUTIVE SUMMARY

Launched in January 2013, EMIF was a five-year IMI project tasked with improving access to, and use of, health data. To achieve this goal, a common Information Framework (EMIF-Platform) was developed to link up and facilitate access to diverse medical and research data sources, within an appropriate governance framework. EMIF-Platform is a great achievement that will carry through into future projects (e.g., IMI2 EHDEN). This platform's greatest legacy will be harmonization—not only of data, but also of people. Collaboration has led to remarkable results in both the EMIF-AD and EMIF-Metabolic projects.

EMIF-AD has focused heavily on the re-use and enrichment of AD cohort data; this in turn delivered new insights into the pathophysiology of AD and helped to identify potential new AD biomarkers. In the case of EMIF-Metabolic, there was a shared interest with EMIF-AD to study the link between dementia and insulin resistance, and this kind of research was possible due to the collaboration with EMIF-Platform. Working together has enabled researchers to identify mannose as a new marker for insulin resistance and to answer critical questions about the risk factors that link to the progression of non-alcoholic fatty liver disease (NAFLD), cardiovascular disease (CVD), and heart failure.

Collaboration also has its challenges. The EMIF project taught us how long it can take for diverse groups to reach a common goal, objective, and world view when it comes to a project of this scope. These lessons learned will greatly benefit future large-scale collaborations.

Ultimately, everyone benefits from the re-use of health data. There is an increasing drive to improve collection, sharing, and use of patients' data in order to achieve better, more sustainable healthcare and advance health research. The ultimate goal is to empower patients as owners of their health and genetic data. Meaningful informed consent and transparency on the potential use of data is essential.

While the subject of data protection under General Data Protection Regulation (GDPR) is extremely complex, broadly speaking, we need to proactively share the issues faced when sharing medical data. By organising, speaking out, and finding best practices, we will determine a path forward.

The past ten years of IMI—including EMIF—have brought us both challenges and extraordinary opportunities. EMIF has succeeded in its vision of enabling and conducting novel research into human health by utilising human health data at an unprecedented scale, but our work is by no means finished. There will always be a need to improve life sciences research and bring better and safer medicines to patients. We hope you will join us in this continued work.

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