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REAL WORLD EVIDENCE
TALENT RESOURCING

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BEYOND TREATING PATIENTS: SECONDARY USES OF HEALTH AND SOCIAL DATA

Whether it be an encounter with a physician or nurse, a prescription for medication from a pharmacy, or admittance of a student loan—every contact that we have with health care personnel or the social security system generates data related to our health and well-being. Currently, **the Finnish Ministry of Social Affairs and Health** is preparing a law renewal to enhance the utilization of this ever-growing amount of information.

To get a better view of what is going on, we went to meet **Sirpa Soini**, Senior Legal Adviser at Helsinki Biobank, Academic Medical Centre of Helsinki (AMCH).

It was estimated already in 2012 that up to 30% of the total health budget may be spent—one way or another—on handling, collecting, looking for, or storing information. As our social and health care systems are undergoing a digital revolution, information that has previously been captured only in paper form can now be accessed electronically. We are now in a situation in which there is a constantly growing potential—but also need—to efficiently and more extensively utilize this vast amount of data to benefit the whole of society.

Secondary use of health care and social welfare data refers to use of information that has been collected in the course of providing health care or social welfare services for other purposes than direct patient care. Currently, the data collected during Finnish health care or social welfare processes can only have secondary use which is strictly limited to scientific and public authority purposes.

According to Soini, the renewal of the law is a necessity: it will help to secure that the invaluable data and information collected in our registers and databases will not be lost in unnecessarily heavy bureaucracy.

"The slow permission processes related to the utilization of health care data have been identified as one of the main barriers for the successful implementation of Finland's Health Sector Growth Strategy".

The law renewal, says Soini, will allow **greater flexibility in the utilization of data**, for example to support decision-making, knowledge-based management, or teaching. Besides scientific research, the law will be extended to also cover product development and innovation activities, allowing better utilization of data for commercial applications. The new law will adopt a broader concept of scientific research to ensure uniform interpretation of the law following the new EU Data Protection Regulation. However, pure marketing research is still out of the question, and the basis of development and innovation activities must be robust.

UNRAVELING BUREAUCRACY, IMPROVING SECURITY

According to Soini, the law renewal aims to unravel unnecessary and overlapping bureaucracy and bring all regulations related to the secondary utilization of health and social data under the same law. Currently, the rules regarding the utilization of health care data are spread between several different laws and the definition of scientific research has been relatively ambiguous.

"The scientific community has long been complaining that the current laws and regulations are too confusing and outdated", Soini states, "so it's about time that we actually do something about this."

Indeed, as Soini sees it, one of the most important revisions in the law is the "one-stop shop" principle planned for the research permits; instead of having to apply separate permissions from all different data owners, the **National Institute for Health and Welfare (THL)** will be responsible for all permission processes, including ethical evaluation, related to the secondary use of health and welfare data. This, in turn, is supposed to make permission processes related to data utilization faster and simpler, and allow more efficient utilization of the valuable data to benefit research and innovation purposes.

Besides more efficiently using data, the reform will also make the access to health and welfare data more secure. The data from different sources will from now on be combined and accessed via a single portal. **"In practice, the new law will make data processing and data linkage easier and more secure"**, Soini summarizes and continues with a laugh, "Perhaps we'll finally get rid of printed copies of patient health record data."

When talking about potential risks of the secondary use of healthcare data, Soini emphasizes the need for expertise to deal with the complicated real-world data. "The worst-case scenario would be that someone who doesn't fully understand the data will make correctly-looking but wrong conclusions from the data, and these conclusions are then used as a basis for decision-making or updating treatment practices, for example". New kind of expert services at the interface between registers and end-users could help to avoid this risk.

FUTURE ASPECTS

The law currently under reconstruction is likely to come into force next year. However, changes will not happen overnight. There is still no information on how quickly different registry keepers will be able to adapt their current practices or resources to meet the new regulations. Furthermore, the effects of the EU's new Data Protection Directive are so far unclear—and also the prices for data access are yet to be discussed.

Even so, Soini sees that the development is currently moving in the right direction. More versatile utilization of data gives both public and private operators a plethora of new possibilities. Soini believes that this will encourage both new innovations as well as investments in Finland. "Our system has been relatively flexible before", she summarizes, "but unraveling unnecessary bureaucracy will definitely put Finland at the forefront of real-world data based research". ■

SIRPA SOINI

is the Senior Legal Adviser at Helsinki Biobank, Academic Medical Centre of Helsinki (AMCH). She is a specialist in biomedical law and regulation, and her core interests include public health, genomics, personalized medicine, and digital health.

TERO YLISAUKKO-OJA

TURKUCRC: REAL-WORLD DATA FROM BIRTH TO DEATH

The demand for **real-world data (RWD)** has increased dramatically in the pharmaceutical industry in recent years. The key challenge in RWD research is that there are very limited numbers of high-quality data sources with easy access to the data. The Centre for Clinical Informatics at the Turku Clinical Research Center (TurkuCRC) has built a unique solution to tackle this problem. We sat down with **Professor Tarja Laitinen** from Turku University Hospital to discuss the newly initiated strategic partnership between TurkuCRC and MedEngine, and the new possibilities it offers for RWD research.

Real world evidence (RWE), the evidence derived from aggregation and analysis of RWD, is essential throughout a medicinal product's life cycle. Such evidence may help design better clinical trials, demonstrate the value of the product to the payers, identify rare safety signals, and make better commercial decisions, just to mention few.

RWD is, by definition, data that is collected outside traditional clinical trials. Such data is typically collected for other than research purposes, e.g. for statistics, administration, or routine healthcare. That is why RWD is often incomplete, riddled with errors, and difficult to access. These are the key challenges that Professor Laitinen and her team have decided to tackle at Turku University Hospital. They have built a true big data solution that collects comprehensive data from health care records and other hospital databases, which can be accessed directly via electronic interface. At present, all secondary care data from the Southwestern Hospital District of Finland is included, but the reach is currently expanding to other areas as well.

"We have access to patient data from birth to death and that's why we can build a life-long phenotype for each patient", Professor Laitinen says.

This data is used as the basis of hospital management: it helps improve quality of care and in developing cost-effective processes. In addition to internal use of the data, TurkuCRC has recently started to collaborate with MedEngine to also provide data access to industry partners.

"Our strategic partnership with MedEngine is about building a service model that provides the possibility to find novel treatment protocols for cost-effective treatment using high-quality clinical and health-economic RWD", Professor Laitinen says. She remarks that there's a unique win-win situation in the industry collaboration: "The polished data that returns to the clinic will ultimately result in better targeted treatments, and subsequently better patient care and cost-effectiveness in treatment".

Despite availability of comprehensive data, study settings and data analyses are not always the easiest to set up in RWD research: "It is very important for us that MedEngine has exceptionally strong expertise in RWD research and biostatistics. It is also important to involve investigators from Turku University Hospital in the projects, because they have the best understanding of treatment practices at the clinic."

Finland has made major investments in the secondary use of health data, and TurkuCRC is the prime example of what the results can be in the best case. However, much effort is still needed in building the nationwide RWD ecosystem. This needs collaborative effort from public and private healthcare, research institutions, and the industry: "Finland stands a good chance of being among the leading countries in RWD research, but the international competition is tough. That's why we need to accelerate the development of our ecosystem." ■

3 REASONS TO UTILIZE TURKUCRC DATA VIA MEDENGINE

1 **UNIQUENESS:**
Exceptional resource of detailed clinical and health-economic RWD

2 **EASY AND FAST ACCESS:**
Turnkey service from study concept to finalized scientific publication, with unmatched timeliness

3 **RWE PROFICIENCY:**
A team of experienced RWE-scientists and statisticians, who seek the best approach to answer your research questions with the highest standards of medical research

PROFESSOR
TARJA LAITINEN

Chief Physician, MD, PhD, is the Head of Pulmonary Diseases at Turku University hospital (TYKS). Her special area of responsibility is the secondary use of health data.

KAISA OKSANEN

KNOWLEDGE-BASED MANAGEMENT: SUPPORTING HEALTH-RELATED DECISION-MAKING

The current trend towards a **data-driven** world is affecting everyone—including the pharmaceutical industry. As the volume and complexity of medical data grows and analytics methods continue developing, companies become more and more dependent on their ability to transform data into information that can be utilized in **knowledge-based management, or KM.** To get an insider's view into knowledge-based management in pharma, we had a chat with Miika Linna, research manager and health economist at Aalto University and Health Economics and Outcomes Research Advisor at MedEngine.

When asked to briefly define 'knowledge-based management', Linna bursts into laughter. "That's about as difficult as asking me to define 'management' in a couple of words" he says, but quickly continues "Simply put, knowledge-based management is decision-making based on facts and evidence".

According to Linna, healthcare-related data has long been collected and utilized to support various levels of management in healthcare organizations and pharma companies. Knowledge can be used to guide everyday actions, but it can also support strategic planning, developing successful operational models, as well as external reporting or communications with authorities. A common health economic evaluation of what has been done, to whom, and at what cost, is often combined with data related to patient outcomes.

At the moment, use of real-world data (RWD) is not very well-developed in most healthcare organizations. Pharmaceutical companies, however, seem to be well aware of the importance of data-driven management. According to Linna, pharma has actually been one of the first industries having to prove both true effectiveness and cost-effectiveness of their products.

For the pharma industry and healthcare organizations knowledge-based management provides a way to collect feedback on the market and on the product, and subsequently facilitate decision-making. However, knowledge, as such, is not nearly enough; it also has to be implemented into practice, which can sometimes prove to be tricky. Regardless, Linna thinks that this is likely to get easier as more healthcare and pharma professionals become better aware of the possibilities provided by the enriched information used in knowledge-based management.

Finland has several strengths supporting the implementation of data-driven management. Information on health care service utilization and health-related costs are readily available, and can be combined with other registry data using the Finnish personal identity code. The regional healthcare organizations are similar and not very fragmented, which allows them to be evaluated as a whole – or nearly, as occupational healthcare providers don't provide any information to national registries.

On a national level, Linna sees that there are several key elements that enable efficient transformation of data into information that can support management:

UNIFORM NATIONAL STANDARDS for collecting comparable data in a well-defined manner.

REMOVING REGULATORY BARRIERS that may prevent efficient data utilization, as in the currently ongoing renewal of the law regulating the secondary uses of health and social security data.

GOOD DATA ADMINISTRATION that makes possible the efficient handling and arranging of data.

EASY AND EFFORTLESS GENERATION OF DATA from the data source (e.g. user friendly interfaces).

In the future, Linna believes that as digital systems evolve and allow ever more efficient data collection and utilization, there will be a growing need for skills in knowledge-based management. Furthermore, tackling the increasingly complex data is likely to require third parties who are able to produce new analytic methods.

Linna is hopeful that the vital importance of the secondary use of health care and social welfare data in knowledge-based management has now been recognized nationally. For individual patients, knowledge-based management promises high-quality treatments that are safer and cost-efficient, "We gain health while protecting tax payers", he summarizes. ■

3 key benefits for pharma industry about knowledge based management:

SHOWING COST-EFFECTIVENESS: ensuring payers and regulatory authoritiesorgans about the effectiveness and cost-effectiveness of the drug.

GAINING CRITICAL INSIGHT related to the product.

Achieving important INFORMATION ON THE MARKET of the drug.

MIIKA LINNA

is a health economist who currently works as research manager at Aalto University, and as an external HEOR advisor at MedEngine. He has had a central role in developing and applying many of the Finnish national registries at the National Institute for Health and Welfare.

TERO YLISAUKKO-OJA

WHAT IS YOUR REAL-WORLD DATA STRATEGY?

The entire pharmaceutical industry is built on various forms of data and has recently invested substantial resources towards collecting and analyzing real-world data (RWD). RWD has traditionally been viewed as a tool to primarily support market access and demonstrate product value. But when such data is used beyond the traditional applications, throughout the product lifecycle and across different functions, its true potential begins to emerge. That is why every pharma company should have a clear real-world data strategy at both global and local levels.

FROM DATA TO EVIDENCE

Real-world evidence (RWE), the evidence generated based on RWD, has great potential to answer to wealth of essential questions that people in the pharma industry are facing every day. However, the data that is collected for non-research purposes across healthcare systems, or even at patients' homes, is certainly not the easiest to tackle. That is why it is important to select the best data sources and ensure that the research team has strong experience in handling such datasets. When done properly, RWD projects can be run efficiently, even within months, and with reasonable costs.

For getting solid real-world evidence (RWE), correct interpretation of the results is as important as quality of data. It is important to recognize that real-world studies are set up differently than randomized controlled trials (RCT), and they also answer totally different questions. RWD is not intended to replace RCTs but the evidence from both study types are needed to arrive at a complete set of evidence.

Some of the key differences between RCTs and RWE are illustrated in Figure 1.

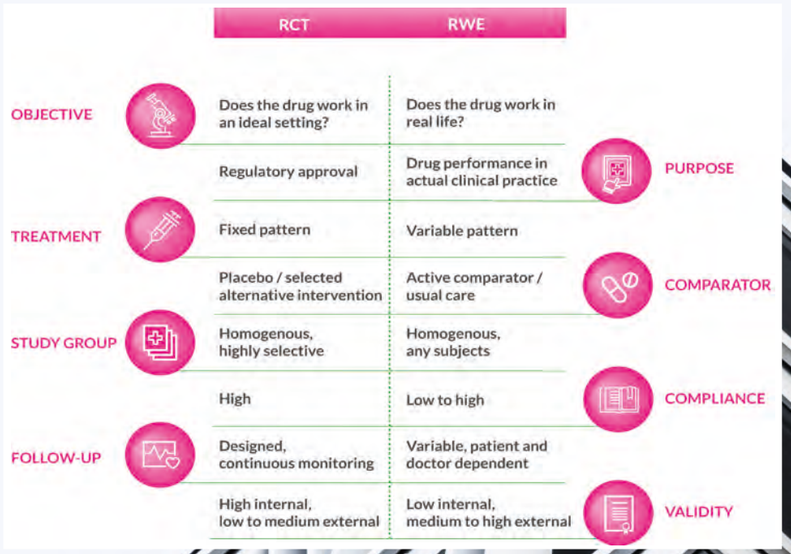

Figure 1. The key differences between RCTs and RWE.

CAPTURING THE VALUE

By itself, RWD is unlikely to be highly valuable for any company. It is the ability to generate exceptional insights, to implement the data to meaningful activities, and to make better business decisions, which generates the value for an organization. It has been estimated that with broad applications, the value of RWE can be as high as $1 billion annually for each of the largest pharma companies. Implementing a successful RWE strategy will definitely bring significant value also at the local level.

Market access, and to some extent medical affairs, has traditionally been the leader in RWD and continues to have a central role also in the future. But there are endless numbers of other applications for RWE within an organization; some of these are shown below.

R&D

- Trial optimization
- Target population
- Translational research

COMMERCIAL

- Therapy area insight
- Marketing strategy
- Marketing materials
- Forecasting
- Knowledge-based management

MARKET ACCESS

- Burden of disease/costs
- Demonstrating product value
- Risk-sharing models

MEDICAL AFFAIRS & SAFETY

- Medical Education Programs
- KOL relations
- Scientific publications
- Risk management
- Drug utilization/ monitoring
- Post-authorization safety

COMMUNICATION & EXTERNAL AFFAIRS

- Public affairs
- Public relations

BUILDING THE RWD STRATEGY

Here are some considerations you might want to take into account when designing your RWD strategy:

Be systematic. Take into account the product's current status, future needs, and the needs of different functions. Set up clear goals, timelines, and approaches. Work on long-term, and avoid *ad hoc*, projects.

The companies with the best data strategies are likely to be the leaders of the industry of tomorrow. Now is the time to move forward.

Design the data implementation. How will the data be converted into action? What are the key insights that you are looking for? These, and many other questions, need to be asked in the planning phase, not when the data is already generated. Think beyond traditional approaches to ensure maximum value of the data.

Set up the right team. Ensure that your team really knows where to get the right data and how to analyze and interpret it. The team should also have a strategic understanding of data implementation.

Learn by doing. There is enough talk of the promise of RWD, but you only learn by doing. First-hand experience is the only way to truly understand the value of the data for your organization. ■

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