Research report

The Current Status and Future Prospects for Real-World Data Research in Finland: A Qualitative Survey

Tero Ylisaukko-oja, *PhD*, CEO
Hanna Ventola, *MSc*, Scientific Project Manager

MedEngine Oy
2018

MedENGINE

Table of contents

Contact Information

Tero Ylisaukko-oja, *PhD*
CEO, Founder
tero@medengine.fi
+ 358 40 910 2975

Hanna Ventola, *MSc*
Scientific Project Manager
hanna@medengine.fi
+ 358 40 024 0858

MedEngine Oy (www.medengine.fi) is a medical science agency which is built upon extensive academic expertise and years of experience in the pharmaceutical and health-tech industries. MedEngine provides expert scientific research, fully customized medical communications, and tailored medical advisory services to pharmaceutical and health-tech companies.

Abbreviations

CAGR	Compound annual growth rate
PASS	Post-authorization safety study
PIF	Pharma Industry Finland
PRO	Patient-reported outcomes
RWD	Real-world data
RWE	Real-world evidence

1 Introduction

Real-world data (RWD) is, by definition, data that is collected outside traditional clinical trials. Real-world evidence (RWE) is evidence derived from aggregation and analysis of RWD. Such evidence may help design better clinical trials, demonstrate the value of the product to payers, identify rare safety signals, and make better commercial decisions, just to mention a few.

Pharma Industry Research Foundation has assigned MedEngine to perform a qualitative survey to evaluate RWD research in Finland. The objective was to estimate current and future investments, applications of data, research environment, and future prospects of RWD research. The survey was based on interviews of 20 selected professionals from the pharmaceutical, health technology and healthcare industries. In addition, results from an online survey performed by Pharma Industry Finland (PIF) in Spring 2018 were used in the analyses.

Based on this survey, Finland is in a good position to begin building a globally competitive ecosystem for RWE. However, much work needs to be done to be successful in the highly competitive market place. The most important steps needed are to:

- Finalize the legislative act on the secondary use of health and social data and other related legislation, such as updated biobank act.
- Ensure sufficient interest and expertise in RWD research among healthcare professionals, as well as time and resources within healthcare organizations.
- Make sure that there are a sufficient number of data scientists with expertise in health data analytics.
- Improve data sources: functional data lakes of primary and secondary data, as well as high-quality clinical quality registries, are essential.
- Generate better understanding of the global operations and strategies of pharmaceutical industry.
- Actively promote internationally the possibilities of RWD research in Finland.

RWE has the potential to transform activities throughout the product lifecycle, from pre-clinical to clinical development and during the post-marketing phase. Therefore, it holds significant commercial value for the future. The commercial implications include potential investments in Finland, but also involve creation of more cost-

effective drug development processes, new pricing models and better targeted, and thus more valuable, treatments.

RWE also has the potential to help in management and development of healthcare practices, increase academic output, and improve the medical expertise of Finnish healthcare professionals. Therefore, increased RWE activity helps Finland to stay at the forefront of medical research and maintain its high quality of healthcare.

2 Methods

To understand real-world data (RWD) research utilization, capabilities, operational environment, investments, and future prospects of RWD research in Finland, we surveyed 20 selected professionals from the pharmaceutical (n=14), health technology (n=4), and healthcare industries (n=2). The semi-structured interviews were conducted either as face-to-face meetings (75% of the interviews) or over the phone (25%). The interviews were conducted in June–September of 2018. In addition to interviews, selected results from an online survey performed by PIF are presented in this report. Invitation to the online survey was sent to 40 PIF member companies in Spring 2018. Total number of replies was 21.

3. Current use of RWE in Finland

Pharmaceutical industry as a driving force in RWE

Real-world evidence is clearly one of the current megatrends in the pharmaceutical industry. Most of the survey participants working in the pharmaceutical industry stated that RWE is among the main focus areas within their company. The concept of RWE is probably not that widely-established in the health technology or diagnostic industries: some of the companies from these sectors declined the invitation to participate this survey because the topic was not in their interest. On the other hand, for some health technology companies RWE is clearly a major focus area. It is generally well accepted, however, that the pharmaceutical industry is the main driving force in establishing and implementing RWE into health care.

Applications

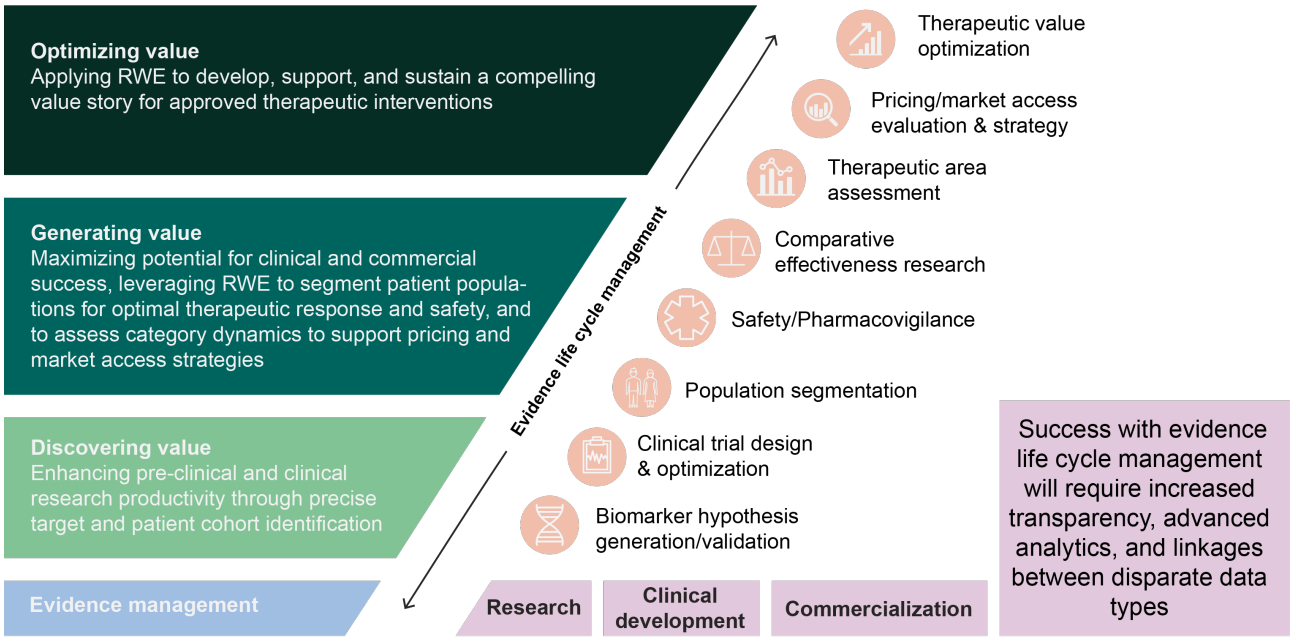
Traditionally, applications of RWE have been largely limited to HEOR/pricing analytics. This is also reflected in our survey; most companies stated that Market Access needs were typically the primary reason for conducting RWE research. The RWE projects are commonly led by Market Access or Medical Affairs departments, or by these functions jointly. Only one participant mentioned that RWE is generated primarily for commercial needs in their company.

Those survey participants who have a role in global R&D functions mentioned a wide spectrum of registry and biobank data use; these included target identification and validation in the drug discovery phase, clinical trial feasibilities and study subject identification, as well as post-authorization safety studies (PASS). RWD could potentially be a major competitive advantage for clinical trial feasibility studies, but the data access should be much more agile than it currently is. None of the participants had carried out patient-reported outcomes (PRO) studies. The current Finnish regulatory requirements for PRO studies are considered unclear and quite strict compared to practices elsewhere in Europe.

It is clear that with growing cost pressure on healthcare, new therapeutic approaches and a significant shift towards outcomes-based pricing, the importance of generating RWE for Market Access needs will increase in future. On the other hand, some companies have already started to use RWE effectively as a strategic asset in other parts of the value chain as well, for example through combination of medical

education, knowledge management, public relations, and various commercial activities. It was also highlighted in the interviews, that data should not be generated just for the needs of authorities, but it should be implemented effectively in collaboration with physicians at the clinics and within the company. Figure 1 illustrates how insights generated from RWE may affect decisions across the entire product life cycle, from R&D through commercialization (1).

Figure 1. Evidence life cycle management framework (adapted from 1).

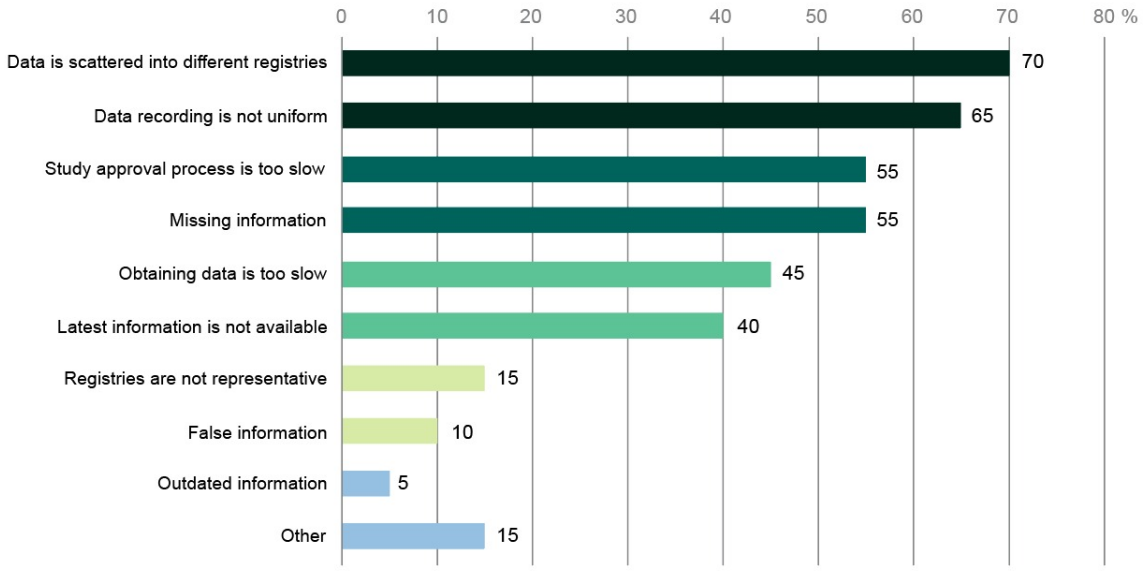


Source: Deloitte analysis

Data Sources

The registries of National Institute of Health and Welfare, Social Insurance Institution, and data of Auria Biobank/Auria Clinical Informatics were the most commonly mentioned sources of registry data. Cooperation with Auria Biobank and Auria Clinical Informatics was especially praised by many participants, and it was suggested that other hospital districts could use Auria as a benchmark. Clinical quality registers are considered essential data sources, but the data content is currently very limited. There should be better access to these registries. In addition, lack of comprehensive and high-quality primary care data is an important limitation for RWD research in Finland. The key limitations with the current data sources according to PIF online survey are illustrated in Figure 2.

Figure 2. Key challenges with current data sources (PIF online survey 2018).



It is important to recognize that RWD is quite difficult to tackle. RWD is collected non-systematically as part of clinical practice and therefore the data tends to be incomplete and riddled with errors. Handling such data properly requires a profound understanding of the data source, expertise in relevant analysis methods, and experience in creating valid study designs. Lack of expertise in these areas might result in false results and wrong conclusions, and may have significant negative implications. Therefore, it is important to build proper methods to ensure sufficient scientific quality in the projects using Finnish registry data.

4 Finnish Research Landscape

Research environment

Finland has several competitive advantages for RWD research:

- A comprehensive public healthcare system, high standards of healthcare, and relatively uniform treatment practices.
- Digitized healthcare records and nationwide registers with extensive health data.
- Personal identity code, which allows individual-level data from different sources to be combined reliably.
- Long traditions in epidemiology and genetics research.
- Advanced legislation in the making on secondary use of health and social data.
- Shared goals for improving data access and data utilization by politicians, authorities, healthcare professionals, and industry.

The areas where development is being sought the most were made clear throughout the interviews: finalizing the act on secondary use of health and social data and establishing a single point of access for the data. This should simplify and harmonize the regulatory procedures and clarify the practices of how to use registry data for research and other purposes. Furthermore, there are major needs for non-scientific use of data and procedures for such use should be made clearer and easier.

Based on this survey, the sources of data also need some improvement:

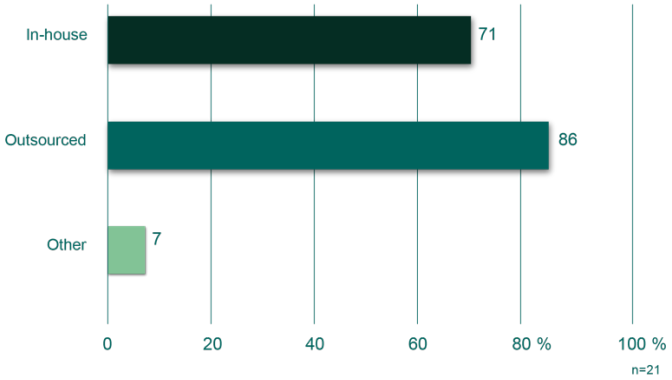
- Data recording needs to be more uniform, systematic and accurate. There should be new tools and incentives to motivate healthcare professionals to do this.
- Data lakes should be available throughout the country and combination of these data should be easy.
- Primary care data should be more comprehensive (broader data content and more complete nationwide coverage).
- Data content in clinical quality registries can be Improved.

- Current efforts for better nationwide data sharing and prompt data delivery by registry holders should be maintained.
- From the research perspective, it would be useful to combine data from the private healthcare sector to other registries as well.
- From the practical perspective, it is important that all the documentation and study permit application forms are also available in English.
- FINBB (the Finnish Biobank Cooperative) should focus on harmonizing the Finnish biobank data and improving data access for the service providers and other data users.

Ecosystem

Typically, the pharmaceutical industry does some in-house RWD research, however they often outsource the work, and this is especially true when the projects are large (Figure 3). According to interviews, there is a good selection of Finnish vendors available for RWD research with slightly different profiles.

Figure 3. Most companies carry out RWD projects both in-house and as outsourced to vendors (PIF online survey 2018).



Many participants highlighted that expanded data use requires increasing numbers of data scientists that have had prior experience with health data. There is increasing competition for such professionals throughout different industries, which may lead to a lack of skilled workers and subsequently present a major obstacle for the growth of healthcare data usage in future.

According to study participants, scientifically oriented healthcare professionals with an interest in RWD research are an essential part of a functional research ecosystem. First, it is important that healthcare professionals understand the value of RWE and are trained and motivated for such research. Second, they need to have sufficient time

and resources for such projects. Therefore, it is important for the industry to find tools and incentives that make collaboration in these projects attractive from the healthcare professional perspective.

Data implementation in healthcare

Many participants highlighted that more training concerning RWD/RWE is required for the healthcare professionals to get the maximum benefit from data. It is also important that hospital management and other healthcare professionals have a good understanding on how RWD is generated and interpreted, and for what it can be used (e.g. in comparison to clinical trials). Industry should have a holistic approach to RWD/RWE and not think just from the industry perspective. Several participants suggested that Sweden could be used as a benchmark in how to effectively implement RWE in healthcare.

Terveystalo is a prime example of a private healthcare provider, which has been active in developing RWE capabilities. Terveystalo has established the first private biobank in Finland and they are implementing RWD as an integral part in their clinical research services and healthcare service development.

Legislation

The Finnish Government has proposed a new act on the secondary use of health and social data. The aim is to ensure flexible and secure use of data by establishing a centralized electronic license service and licensing authority for the secondary use of health and social data. The act on the secondary use of health and social data is considered essential for development of RWE possibilities in Finland. In case new legislation is not effective in the near future, Finland is at risk of losing its first-starter advantage at the forefront of RWD research.

5 Commercial Potential

Based on the analysis by Frost & Sullivan (2018), the global RWE analytics solutions market is expected to grow at ≈16% compound annual growth rate (CAGR) to approximately USD 430 million by 2021 (2). In another analysis, RWE market is projected to reach USD 1.35 billion by 2023, at a CAGR of 14.3% (3). The pharmaceutical and biopharmaceutical companies segment is estimated to be the quickest-growing in the market. High expectations for significant RWE commercial value are also indicated by Roche's acquisition of Flatiron Health for USD 1.90 billion in February 2018 (4).

In Finland, the RWE market is currently very small. According to results from the online survey, the estimated total investments for RWD research by participating companies were only EUR 1.60 million in 2017. The average cost of an individual study was estimated to be EUR 38 thousand, which means that the projects were generally small. Based on interviews, there is wide variation in costs but local projects with budget exceeding EUR 100 thousand are rare. A modest increase in total investment was estimated for the next 2 years. On the other hand, most companies estimated that the number of RWE projects will increase either significantly (33%) or to some extent (43%) if the act on secondary use of health and social data becomes effective (Figure 4). Altogether, 24% of the companies participating the online survey estimated that after two years, they will carry out ≥10 RWE projects annually (Figure 5).

Figure 4. Effect of the act on the secondary use of health and social data on the number of RWD projects (PIF online survey 2018).

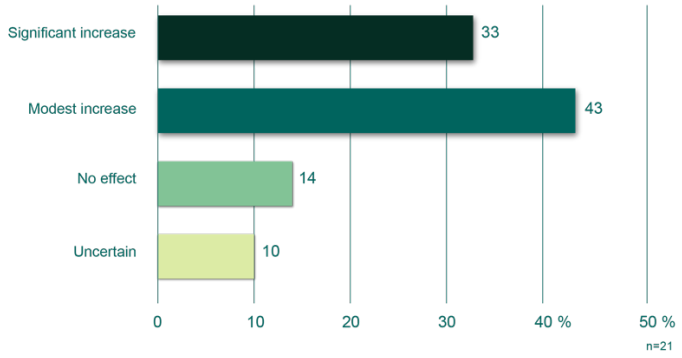
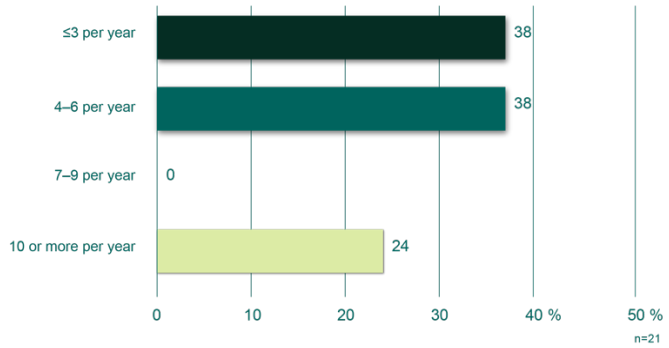


Figure 5. Estimated number of RWD research projects in 2020 (PIF online survey 2018).



Succeeding in the global marketplace

RWE's commercial potential in Finland can be fulfilled only by attracting global investments. Finland has many advantages for RWD research, but there are many other countries with advanced capabilities and significant investments for this area as well. Most interviewees highlighted that finalizing the act on the secondary use of health and social data, establishing a single point of access for the data, and improving quality and usability of the data are highly important for succeeding in the global marketplace.

However, high-quality registries and smooth processes are not a guarantee for global success. One of the key questions is whether the results generated in the Finnish population can be generalized to the other markets and whether authorities around the globe, such as the FDA, consider Finnish RWE valid for their regulatory processes. For some study settings, Finland might also have too small a population to obtain a sufficient number of patients, especially if nationwide data is not available. This issue is likely becoming more relevant as the pharmaceutical industry focuses more on rare diseases and rare disease subpopulations. Therefore, Finland should focus on appropriate project types, which would offer a competitive advantage over larger markets. The "testbed" approach, as presented by Sitra, was supported by many survey participants. Furthermore, the FinnGen project (www.finngen.fi) was considered to be an excellent case example, which is successfully built upon unique Finnish core competencies.

There is also a need to better understand the global operations of the pharmaceutical industry. Each company has a strictly defined RWE strategy and, from a global perspective, there are a wealth of high-quality registries and scientifically high-level

project proposals available. Therefore, the projects need to be tightly aligned with the company's global strategies to succeed in a highly competitive environment.

Nordic perspective

There were mixed opinions about Nordic collaboration. In some organizations, there is a clear emphasis for a Nordic approach in RWE projects. Collaborating with other Nordic countries might increase the total number of projects, help to obtain sufficient study populations, and increase interest from the global perspective. Also, the Baltic countries, especially Estonia, have strong capabilities in this area and could join Nordic countries in some projects.

On the other hand, some of the participants were strongly suggesting that the focus should be on developing the competitive advantages of Finland instead of broader Nordic approach. They thought that this is a better way to attract investments for Finland and to ensure that Finland has a wider role in projects than just being a data source. There are also some scientific and practical issues that should be considered in Nordic collaboration, such as different healthcare practices between countries and difficulty in combining individual-level data across the borders due to privacy considerations.

6 Communication

For many pharmaceutical companies, the “big five” countries, UK, Germany, Spain, France, and Italy, have a dominant position in RWD research in Europe. According to this survey, however, the Nordic area is generally considered a strong cluster of RWD research. Also, Finnish RWE capabilities are well-known in some companies, but there is a lack of awareness in others.

The following activities were suggested to increase the global awareness of Finnish RWE capabilities:

- Active promotion by Finnish colleagues with their international counterparts.
- Production of carefully designed slide decks about the possibilities for RWD research in Finland.
- Case examples of successful projects with Finnish data.
- Specifically, use the FinnGen-project as a showcase of the research possibilities in Finland.
- Increase the visibility of Finland in relevant congresses, such as ISPOR and HIMSS.
- Finnish delegate visits to corporate headquarters, using the recent Team Finland visit to Basel as an example.

The pharmaceutical industry should also have even more active communication with healthcare professionals and the general public within Finland. This communication should increase the awareness of the importance of health data for medical research and improvement of patient care, as well as provide accurate information about data privacy. It is also important that communication sets realistic expectations for the commercial potential of this type of research.

7 Visions for the Future

The importance of RWE will increase significantly in the future and there will be both new sources of data and much wider applications for its use. Currently, the emergence of value-based healthcare and personalized medicine are the driving forces for the RWE adoption. In the future, RWD will transform drug discovery and clinical trials, and it is expected that authorities will increase use of such data in evaluation of marketing authorization applications. It is also expected, that RWD will be used as an integral part of healthcare. New sources of RWD, such as mobile applications, smart phones, smart watches, next-generation medical devices, and various sensors producing a constant flow of health data, have already started to emerge. According to the interviews, machine learning and artificial intelligence (AI) solutions are already in scope of most pharmaceutical companies, although there are a limited number of practical applications available so far. Finally, it is expected that there will be significant new players in the field coming from outside pharmaceutical industry, such as technology giants Google and Amazon.

Although the market for RWE research is still small in Finland, it holds promise for significant commercial value in the future. RWE has the potential to transform activities throughout a product lifecycle, from pre-clinical to clinical development and during the post-marketing phase. The commercial implications are not limited only to potential investments in Finland, but also involve more cost-effective drug development processes, new pricing models, and better targeted, thus more valuable, treatments.

Much of the RWE's promise depends on how it will help to manage and develop healthcare practices. RWE activities also offer physicians and other healthcare professionals new opportunities to engage in research projects, which leads to significantly increased academic output and improved medical expertise. Increased RWE activity helps Finland to stay at the forefront of medical research and maintain a high quality of healthcare.

Finland has a good starting point for building a globally competitive ecosystem for RWE. However, much work needs to be done to be successful in the highly competitive market place. Based on this survey, the most important steps needed are:

- Finalize the legislative act on the secondary use of health and social data and other related legislation, such as updated biobank act.

- Ensure sufficient interest and expertise among healthcare professionals, as well as time and resources within healthcare organizations.
- Make sure that there are a sufficient number of data scientists with expertise in health data analytics.
- Improve data sources: functional data lakes of primary and secondary data, as well as high-quality clinical quality registries, are essential.
- Generate better understanding of the global operations and strategies of pharmaceutical industry.
- Actively promote internationally the possibilities of RWD research in Finland.

8 References

1. Getting real with real-world evidence. Deloitte 2017.

2. Growth Insights – Real World Evidence Analytics Solutions Market. Frost & Sullivan 2018.

3. Real World Evidence Solutions Market worth 1.35 billion USD by 2023. Markets and Markets 2018.

4. https://www.roche.com/media/releases/med-cor-2018-02-15.htm