The possibility of conducting safety studies using Nordic registers

The need for safety studies

The benefit-risk profile of a medicine is monitored during its whole life cycle. In the post-marketing setting, safety studies (sometimes referred as phase-IV studies) can be conducted as a complement to routine pharmacovigilance activities, to further investigate the safety profile of a medicine. For instance, safety studies can be carried out to obtain additional information on a safety signal identified during clinical trials or via adverse events reported spontaneously by patients and healthcare professionals. Hence, safety studies are an important method of ensuring patients´ safety and wellbeing.

Imposed safety studies are usually initiated by either the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). It is also worth noting that the EMA and FDA collaborate and usually share information between each other.

Nordic registers offer great opportunities to conduct safety studies

The Nordic registers (for Denmark, Finland, Iceland, Norway, and Sweden), with their large samples, long follow-up and universal coverage, offer unique possibilities for conducting safety studies. As a sign of their strength, the FDA highlighted the strengths of the SWEDEHEART register in their report *Framework for FDA´s Real-World Evidence Program – 2018*. Furthermore, when looking at the ENCePP register, there are to date, more than 150 projects using Swedish and/or Danish data. This shows that the regulatory agencies understand the value of these registers.

In addition, the Nordic registers offer complete follow-up. For every health care contact, a unique Personal Identification Number (PIN) is recorded. By using the PIN, it is possible to follow a patient through and even between different datasets; for instance, it is possible to map a patient´s treatment path and health care visits. Also, given that healthcare is publicly funded and that registers are centralized, it is possible to follow a patient from birth to death. This is often not possible with claims databases. Moreover, the existence of multigenerational linkage, makes it possible to link between generations. The latter may be utilized when analysing the effect between pharmaceutical treatments during pregnancy and malformation.

By combining Nordic registers, it is possible to create a dataset that is tailored for a particular project. Data sources in the Nordics are organized by different datasets. For instance, if one would like to analyse how different pharmaceutical treatments affect the risk of hospital admission, combining data from the patient and prescription registers is a good start. Also, the availability of death certificates enables the analysis of cause-specific

mortality as an endpoint. Furthermore, several quality-of-care registers exist, offering in-depth information about a certain disease area.

A long follow-up is possible when using Nordic registers. Some registers date back to the 1960s. A more recently established register such as the Swedish prescription register, is available from 2005, making a follow-up of 15+ years possible. This is longer than what is possible in many claims databases.

The pool of potential study subjects is large; with a population of more than 27 million individuals in the five Nordic countries, it is possible to analyse rare diseases and look at several subgroups. It is also possible to draw controls to create RCT-like cohorts in a study.

Quantify has extensive experience with Nordic registers

To date, Quantify has more than 200 completed or ongoing Real-World Evidence (RWE) projects, including safety studies in psoriasis and type 2 diabetes. This makes us the number one provider of Nordic RWE studies. Conducting RWE projects often requires a combination of different registers, including but not limited to inpatient, outpatient, prescription data, quality registers, regional registers, and registers for lab data and hospital dispensed drugs. Our extensive practice with data acquisition, combined with our in-house experience with safety studies provides us with the know-how to conduct these studies and communicating the results to the authorities effectively. Based on our teach-record, we are a certified ENCePP member, meaning that we are your reliable partner in safety-studies.

We are experienced in conducting projects involving both a single and several Nordic countries. For some projects, it may be suitable to only use data from one country, such as for large disease areas, where the number of patients in one country is sufficient to conduct a study. For some projects, registers from two or more countries may be needed. For instance, if it concerns a rare disease, the pooling of information from several countries may provide a more substantial sample. In addition, it is possible that the authorities require that the study is conducted in certain countries. Given that Quantify is present with offices in Copenhagen, Oslo, and Stockholm, we have local expertise. Furthermore, with our large network, Quantify can also conduct studies beyond the Nordics.

We would like to discuss your needs with you

Should a project like this be of interest, we encourage our involvement early in the process to advise on what kinds of studies that can and should be conducted. Therefore, please do not hesitate to contact us for consultations. Your contact person is Thomas Fast (PhD and Associate Director), and you can reach him via the following information: thomas.fast@quantifyresearch.com or +46 70 778 99 08