

Life Sciences Insights

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A rising interest for patient registries

Traditionally, patient registries have been considered most appropriate for generating hypotheses. However, with increased interest in research and supporting a product through its life-cycle, researchers are now looking at using these data to compare treatment effectiveness in real-world practice.

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EU Directive on cross-border healthcare

At its sitting on February 28th 2011, the Council of Ministers adopted the EU Directive on cross-border healthcare which will allow patients to undergo treatment in another EU Member State and have that treatment reimbursed by their home healthcare provider.

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Social networks and the life sciences industry

Online social networks are everywhere and the life sciences sector is no exception. A report recently published by Deloitte US offers insights about the emerging relationship between social networks and the life sciences industry.

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A rising interest for patient registries

Randomized controlled trials (RCTs) are still the gold standard to demonstrate the efficacy of new treatment options. Their internal validity is admittedly very high. However, their generalisability (also called external validity) is often poor, partly due to restrictions in their target populations.

For decision making purposes it is important to identify the actual effectiveness of new treatment options. Effectiveness is the extent to which planned outcomes, goals, or objectives are achieved as a result of an intervention intended to achieve the desired effect, under real life circumstances. Other study designs are required to measure this effectiveness.

Recently there has been a growing interest within the health economics universe for setting up patient registries in order to obtain real life data.

Unlike randomized clinical trials, which study patients under strict eligibility and treatment protocols, patient registries document the experiences of patients in everyday clinical practice. Observing those patients' responses to treatment can provide important insights into which health care strategies work best in actual practice.

Much of a patient registry's value lies in its ability to address, in one comprehensive program, a variety of objectives, crossing disciplines, to provide important disease and product-specific data, and support a product in the marketplace throughout its life cycle. Registries allow collection of post-approval safety information for regulatory requirements (e.g. safety surveillance) and clinical effectiveness data, and are useful for risk assessment, and evaluation of risk management interventions. They are also an opportunity to prospectively collect and report on important outcomes, such as health-related quality of life (HRQoL), health care resource utilization, and patient satisfaction.

Many patient registries are already in use. One of the best-known registries is the Surveillance Epidemiology and End Results Program, which is managed by the US National Cancer Institute. That registry collects and publishes data on cancer patients, including demographics and information about their tumors, treatment, and follow-up status. For Europe, we may mention the work of Orphanet, which aims to pool information related to patient registries around orphan diseases. In the field of rare diseases, patient registries and databases constitute key instruments to develop clinical research to improve patient care and healthcare planning. They are the only way to pool data in order to achieve a sufficient sample size for epidemiological and/or clinical research.

Of note, the US Department of Health & Human Services' Agency for Healthcare Research and Quality (AHRQ) released a comprehensive handbook which provides guidelines to plan and manage a patient registry.

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Several legal cases by the European Court of Justice had already established EU citizens' entitlement to travel to another member state for medical treatment and have their home country settle the bill. The purpose of this Directive is therefore not to give patients extra rights but, rather, to clarify those existing already and put them into a single piece of legislation. According to the European Commission, cross-border healthcare currently affects only a small proportion of patients in the EU, costing ca. EUR 10bn (i.e. around 1% of national healthcare budgets).

The adoption of the Directive, nonetheless, represents an important milestone on the journey towards enabling patients to receive medical treatment regardless of their country of residence in the EU.

For example, the Directive will offer invaluable opportunities for patients suffering from rare diseases (see Art. 13 of the Directive) to travel abroad and potentially access research centres and the most advanced diagnosis technologies and/or treatments available.

Importantly, the Directive creates a legal basis for future cooperation on health technology assessment across Member States. As such, the Directive formally integrates in EU law the work accomplished by the EUnetHTA collaboration over the past five years. The objectives of the health technology assessment network foreseen by the Directive will be to: support cooperation between national bodies; allow the exchange of information across Member

States on the relative efficacy and on short- and long-term effectiveness of health technologies; and, importantly, avoid duplication of assessments. This last element is key to improve patient access to new health technologies. Transparency and stakeholder involvement are explicitly mentioned by the Directive – which is to be welcome.

Once in force, EU Member States will have 30 months to transpose the Directive into their respective national laws.

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Social networks and the life sciences industry

Because online social networks are new media where the old regulatory rules do not apply, the life sciences industry is currently sitting on the sidelines waiting for more regulatory guidance on how they can engage.

However, part of the hesitation may be because the industry thinks of social networks as marketing, similar to direct-to-consumer advertising – only more targeted. In reality, social networks are promising as tools that let the company collect information from, communicate to, and collaborate with people outside company walls.

In a recent study, Deloitte describes a framework for how social networks are being used today and in the future. It explains how social networks add value beyond marketing but across the commercial and research organization and discusses survey data from industry professionals who are using or plan to use social networks. It also explores the accelerators and barriers to social networking use in the life sciences industry and identifies when it is appropriate to use a social network and for what purpose including whether a company should build it or borrow/buy someone else's. Finally, it examines the right governance and policy measures that should be in place.

The full report can be downloaded [here](#).

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Did you know?

- A small **daily dose of aspirin** (75mg) substantially reduces death rates from a range of common cancers, a recent study suggests. (see The Lancet, Volume 377, Issue 9759, Pages 31 - 41, 1 January 2011)
- The European Commission has launched a public consultation in view of modernising rules on the **transparency of Member States' decisions regarding the pricing and reimbursement** of medicines. Consultation is open till 25 May 2011.

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