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Q&A



Registering results in the real world

A key area of growth in the e-clinical world is the increasing use of patient registries as a tool for monitoring effectiveness and safety, among other measures. We interviewed Dr Richard Gliklich, president and CEO of Outcome Sciences (d/b/a Outcome), to discuss their increasing importance

Q Patient registries are increasingly being used to record the results of medical products, therapies and services. Why are clinical trials not enough and what are the particular strengths of patient registries?

A Although clinical trials provide important data, they focus on selected groups of patients under controlled conditions. Physicians, payers and patients all want evidence of the real-world results of medical products, therapies and services, in larger and more diverse populations, to enable them to judge whether such products and services are safe and effective, and how

disease process and care patterns for abstracts and publications. One of the registries we support has produced more than 300 peer-reviewed publications. Registries are sponsored by organisations including healthcare providers, government organisations and patient advocacy groups, as well as drug and device manufacturers.

Q In what situations are registries particularly effective?

A A drug or device might, for instance, have been proved effective and safe in Caucasian patients aged 21 to 65, but a payer needs to know whether it will be suitable for

people. Here, a safety registry involving the first 10,000 patients can provide the foundation for a wider risk-management programme. A hospital that is introducing new procedures for treating obesity might use a registry to evaluate quality of care, or a biopharmaceutical company looking to bring a new product to market in a specific area, might consult a registry to get information on the natural history of the disease, background safety, the competitive environment, how products are used, and so on. These are just a few examples.

Q So how difficult is it to set up a registry?

A There are definite challenges in setting up registries. Registries are quite different from clinical trials in terms of logistics, sites and site expectations, and, therefore, success demands different expertise and core competencies. It is also critically important to make registries credible, relevant and as easy as possible for the participating physicians. As with other observational studies, an initial planning group is set up to explore purpose, objectives and

feasibility, and this generally includes the key stakeholders, funding sources and domain experts. A governing structure is then put in place to address key questions that arise from design through publications. A data co-ordinating function manages the day-to-day issues of implementation through analysis and a group of sites collects and enters data, and receives reports. The number of sites may range from a handful to thousands and the number of patients currently ranges from less than a hundred in some of our rare disease registries to more than a million in the largest registries. Registries can directly involve hospitals, physician offices, pharmacies and patients.

Q Obviously the technology used to collect and manage data will differ from registry to registry, but what are the key characteristics?

A Since registries are usually established in real-world clinical practices and involve real patients, the technology that supports them needs to be easy to implement and operate in a busy practice or hospital setting. Simple-to-use

“Registries are quite different from clinical trials in terms of logistics, sites and site expectations. Therefore success demands different expertise and core competencies”

quality of care might be improved. Patient registries have therefore become increasingly popular. Sometimes they are required as a condition of approval of a healthcare product; they can also provide a stream of information on

patients over that age or of different ethnicity. A registry can help here. To take another possible scenario, a manufacturer and regulator might be discussing safety data on a product tested in 2,000 patients, which after approval could reach 2 million



interfaces, flexible methods of entering data and good availability and performance are all important. A centralised, real-time database should be set up, to enable sponsors and advisors to monitor the progress of the registry, to review key project and safety metrics and even to see real-time changes in the regional therapeutic area market. This centralised system should be coupled with the ability to dynamically render regional versions of the registry (languages, customised data elements, specialised reports and so on) to different countries and markets. In addition, since only limited if any payments can be made to sites and physicians (to avoid offering any inducement to use the drug or device), the successful registry must deliver additional non-monetary value to its participants. The most efficient way to do this is through the technology itself – by, for instance, generating practice and patient reports.

Q Plans by the US Agency for Healthcare Research and Quality to develop a ‘how to’ guide for the development of patient registries seem to indicate that interest in registries is growing, as well as

highlighting the need for standardisation and consensus.

A Yes, as a result of this effort there will soon be a document, developed by a large working group of experts, that can serve as a reference for others seeking to develop or evaluate patient registries. More information on this project is available at the AHRQ website (www.ahrq.hhs.gov/decide) and a draft will be posted for public commentary this year. It is worth noting that the information focuses on registries for evaluating patient outcomes.

Q What will be the main trends driving the use of registries over the next few years?

A Most important is the recognition that the clinical effectiveness and safety of a drug or device can only be determined in the real world, post-approval. While this might seem obvious, the realisation that measurement and monitoring do not end with approval in fact constitutes a major change. The development of safety and/or effectiveness registries creates the potential for new models for clinical

development – so-called conditional approval periods. These may be a boon for manufacturers facing increasing drug development costs, as well as to the public seeking broader safety information. A second trend is increasing demand by payers and clinicians for evidence that the results of clinical trials are ‘generalisable’ to the populations that they cover. Both payers (for reimbursement) and physicians (for prescribing) will be seeking information that is more customised to the patients they actually treat. Related to this is the growth of personalised medicine. Large registries, potentially coupled to diagnostic tests or genetic databases, will provide the data for increasingly powerful risk models for any number of diseases. Meanwhile biopharmaceutical and device manufacturers are beginning to recognise the competitive advantages offered by patient registries – from the generation of

customised data for more effective reimbursement, to the creation of publications and brand awareness in specific disease areas, to the use of large databases for the recruiting of patients for clinical trials or new risk models.

Physicians and hospitals are striving to improve the quality of care they offer and will be helped to do this by patient registries that are large enough to provide risk-adjusted data at the provider level. At the same time, more medical information is being offered in electronic form and the ability to implement multiple large registries nationally or globally is likely to become widespread. Outcome has been focused on developing and managing global patient registries since our inception in 1998 and we’ve seen accelerating growth in their use every year. I expect even more dramatic growth in this area as the value of registries to all stakeholders becomes more widely appreciated.

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