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March 2012 www.pharmatimes.com

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Real-world data and the UK opportunity

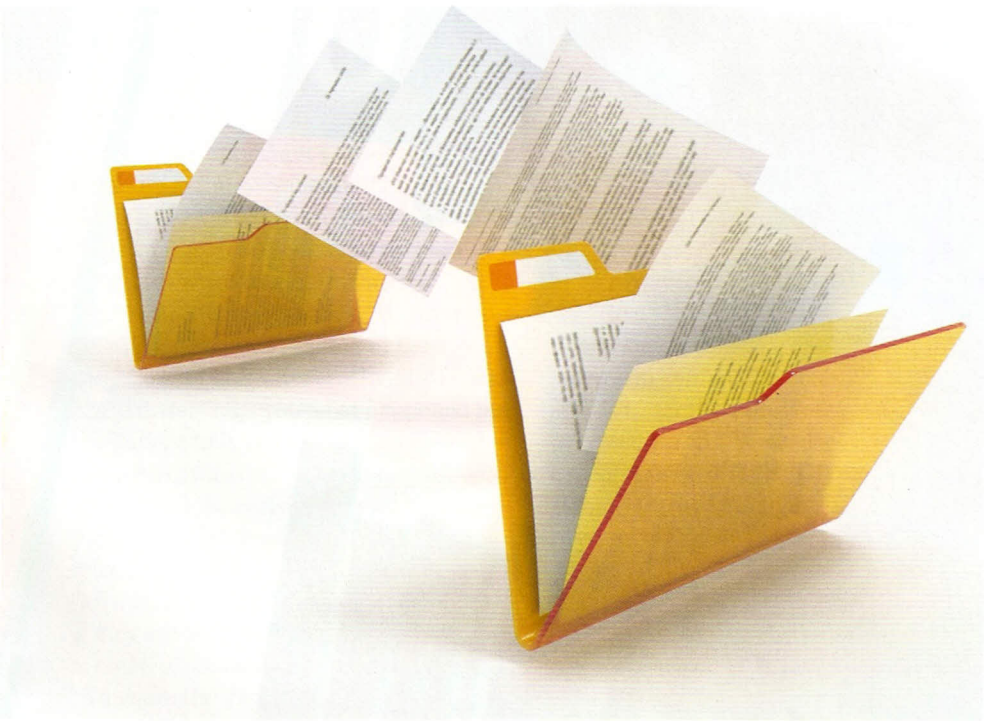
Access to linked data for the 52 million English NHS population, via the CPRD initiative, should not only allow the industry greater ability to demonstrate product value, but could also position the UK as a centre for health outcomes research

Healthcare Writer **Peter Mansell** | Edited by **Jenny Hone/Claire Bowie**

Increasingly, the value of a new medicine is defined not just by clinical trial outcomes, key opinion-leader endorsement, branding or marketing smarts, but by what that medicine actually does once it gets into an uncontrolled patient population. This shift from promise to reality, from efficacy to effectiveness, is driving demand for real-world data both in the pharmaceutical industry and among the health professionals, fund-holders, medicines managers and economists who hold the keys to market access.

Some companies are already gearing up for this environment through partnerships with established data providers in the real-world space, such as AstraZeneca's European collaboration with IMS Health or Sanofi's global tie-up with Medco Health Solutions. But what could aid these efforts enormously is if governments were to capitalise on the shift to electronic patient records by opening up access to vast stores of data on epidemiology, care pathways, resource use, diagnoses, treatments and outcomes captured by healthcare systems such as the NHS.

A white paper issued last September by the Association of the British Pharmaceutical Industry suggested real-world studies are a "unique proposition to encourage the investment, innovation and the use of skills brought by the pharmaceutical industry in the UK". It is an opportunity the present Coalition Government will be keen not to squander when it launches the new Clinical Practice Research Datalink. The plan is that the CPRD should be delivered incrementally over four years from April 2012, with some of the services available to researchers this year.



What really distinguishes the initiative from existing provisions, such as the General Practice Research Datalink, is that the CPRD is not so much the creation of a new reservoir of data as the establishment of productive relationships between previously siloed datasets in primary, secondary and tertiary care, as well as the streamlining of processes through which researchers can access those data. The primary aims of the CPRD, a partnership between the Medicines and Healthcare products Regulatory Agency and the National Institute for Health Research set up to address the specialised needs of the research and life science communities, are to provide access to data and linked data for the 52 million English NHS population, enable primary care trials via an integrated system, and provide a full research service.

This plays explicitly to the growing importance of real-world data that can elucidate the role of medicines in the wider context of health and social care trends, and underpin partnership with healthcare systems by delivering the

kind of outcomes evidence sought by health technology assessors, budget-holders and the NHS' Quality Innovation Productivity and Prevention programme.

Indeed, the government made this emphasis clear when it issued its Autumn Statement last November. For the first time, it said, services provided by the NHS Information Centre for Health and Social Care would "link datasets from GP and hospital care, providing health service, pharmaceutical industry, academics and other professionals with unequalled information about patient journeys through the care system and the outcomes of different treatments". These services will be used and commissioned by the CPRD.

Certainly, there is industry appetite for the data, in an environment dominated by health technology assessment, the drive for NHS cost efficiency and continuing discussions over value-based pricing in the UK. That said, companies will want to be sure the system can deliver efficiently and cost-effectively on its potential.

Central to the success of the UK's eHealth expansion programme, the ABPI notes, will be "the effectiveness of the proposed Health Research Support Service in facilitating a wide range of research activities undertaken by the life sciences industry in the UK, which include: clinical trial feasibility and recruitment, pharmacovigilance/drug safety monitoring, health outcomes research and stratified medicine". At the same time, the association would want "in-depth discussions with the Health and Social Care Information Centre and CPRD on what they intend to deliver – timelines for supplying requested data, and a realistic competitive pricing model".

For Dean Summerfield, vice president and managing director of Quintiles Consulting in Europe, the main attractions of the CPRD are increased coverage – an almost 10-fold increase in the volume of available NHS data – and the integration of previously disparate datasets.

That integration is an opportunity to "look a little bit more holistically at patients' health and the environment they're in, particularly interactions with their GP, etc, and to understand these interactions in the context of their social environment, so that health authorities and researchers can look at the impact of intervention in the broader sense".

A two-way street

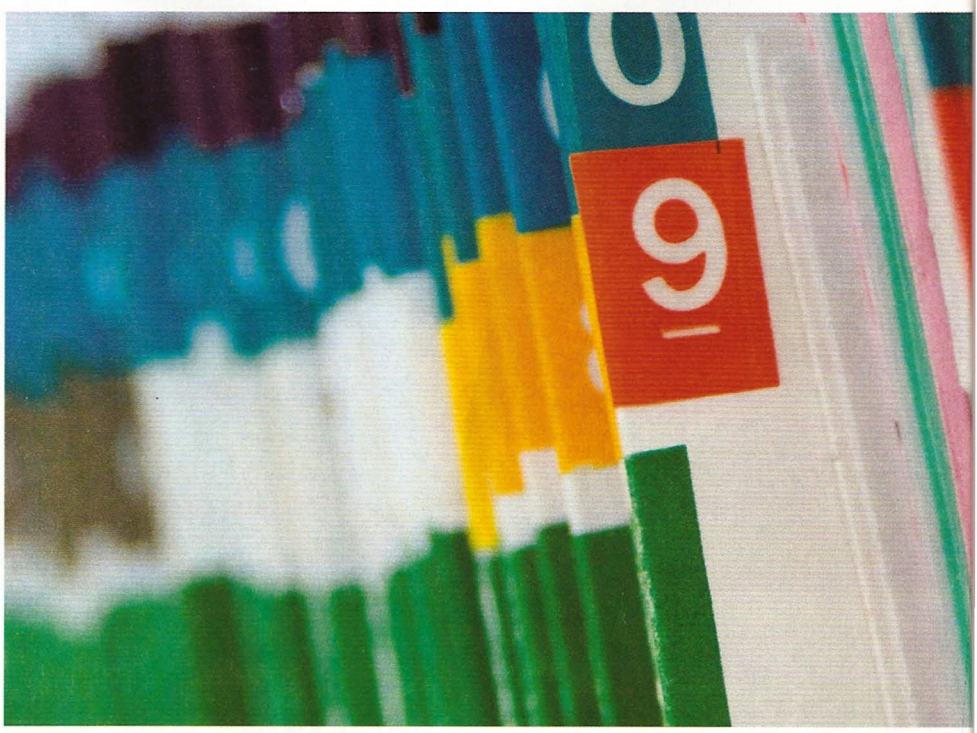
As Chris Kula-Przezwanski, UK partnering director for Quintiles' new digital patient unit, points out, this is a two-way street. "By getting a better dataset on what's happening with the patient, [pharma] can have even more realistic discussions with NHS payers and other stakeholders. For the clinicians, when they're thinking about how to treat the patient, decisions will become more robust... so the outcomes are more efficient from a process, and from a financial, perspective." This is something industry has tried to achieve in the past through initiatives such as GP practice audits, Summerfield adds. But it could only pursue these highly resource-intensive programmes in a handful of practices and the results were "never scaleable".

> **"By getting a better dataset on what's happening with the patient, [pharma] can have even more realistic discussions with NHS payers and other stakeholders"**

With an integrated electronic system, though, there is the chance to access not just basic information as a precursor for interventional studies but the more holistic data that support quality of life assessments. These are both scaleable and "allow you to look at value in a different way", Summerfield says.

It was clear from the recent Quintiles-sponsored Economist Intelligence Unit report, *The Value Challenge*, that payers are looking at QoL and "almost total patient wellbeing". Until the CPRD or any other system can provide those broader outcomes, then the emphasis will continue to be on interventional studies, Summerfield believes. "The industry desire to have these data to help inform trial design and to help understand the value of products is very strong," he comments. There are transitional initiatives underway to help bridge those gaps, such as the European Commission-supported TRANSFoRm (Translational Research and Patient Safety in Europe) programme. Through TRANSFoRm, a consortium of 15 universities and two private partners (one is Quintiles) is looking to integrate healthcare computer systems across Europe both as a diagnosis aid to GPs and to accelerate the recruitment, management and follow-up of patients for clinical studies.

In the meantime, Summerfield notes, industry is making significant



Expert Opinion

The trajectory of opportunity opened up by the federated services described here, presage improved patient safety through a better understanding of disease, interventions, outcomes and a re-modelled approach to research. This initiative also highlights the need for more medical informatics resources, continuous improvement programmes and horizon scanning.

We must embrace collecting emerging data such as genetic profiles, tend towards real-time data collection where necessary and fully exploit technological advances such as tele-diagnostics and remote monitoring of physiological functions.

Key to the success of our data rich future, however, will be access to the tools and applications that enable reliable and timely analysis.

Steve Mott is Managing Director of DrugLogic UK (www.druglogic.co.uk).

ad hoc investments in post-marketing observational studies, so that it can maintain challenges to drug price reductions by showing "the value story is sustainable".

As things stand, Summerfield points out, companies can only afford to generate these data selectively. If the payer community were to start demanding this evidence "as a matter of course", then the cost burden would become unsustainable. Hence industry's interest in initiatives such as the CPRD, which should enable companies to pull together data on product value more cost-effectively.

Patients tell you why it happened

Another important part of the equation is the actual patient experience, Kula-Przezwanski adds. The more companies can link patient-reported outcomes with datasets such as electronic medical records, "the more we're likely to start moving in the direction" of non-interventional studies. The dataset "tells you what happened but the patient tells you why it happened", Kula-Przezwanski comments.

As Mike Sanvoisin, general manager for IMS UK, Ireland and South Africa, notes, real-world evidence is something "all parts of healthcare" need to master if they are to understand how value is created and sustained for patients. "Gone are the days" when a company could simply run the necessary trials and "monitor how many pills were sold", he warns. In any health technology assessment process there will be claims about improved outcomes that are "never really validated in the real world".

The value of demonstrating those outcomes speaks for itself. In chronic obstructive pulmonary disease, for example, proper management of the condition can head off hospital admissions at "several thousand pounds a go".

Companies need to start using real world evidence in the measuring and monitoring of their business to align with the priorities of the NHS, Sanvoisin emphasises.

Another benefit of the CPRD will be far better targeting of clinical trials, helping to retain research investment in the UK, he adds. At the moment, the UK is "losing out heavily" to other countries on clinical research. Yet the NHS offers a unique cradle-to-grave record, whereas in other markets these data tend to be distributed across a mix of state systems, insurance companies and other private providers.

If handled in the right way, Sanvoisin suggests, the CPRD could position the UK as a centre for health outcomes research alongside its established capabilities in science and technology. A lot of research could be "completed" by integrated data on healthcare trends and patterns, leading to real innovation in healthcare delivery.

But there will need to be appropriate standards across industry if real-world data are genuinely to take off, Sanvoisin cautions. These data will not be as validated as those from clinical trials, which calls for more collaboration between pharma and other organisations such as the CPRD or the NHS Information Centre.

"Real world evidence will change the operation of healthcare within the UK," Sanvoisin comments. "The challenge now is to set the standards by which this information will be used and develop the capabilities within the UK to become a global centre of excellence for this type of work." **PT**

The issues around patient confidentiality, consent and data protection raised by the CPRD will be addressed in a separate feature to be published next month.