

Monitor **Deloitte.**

Real World Evidence
Enabling the life sciences
industry to transform
patient care



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“In scarcely an instance have I been able to obtain hospital records fit for any purpose of comparison... if wisely used [hospital records] could tell us more of the relative value of particular operations and modes of treatment.”

Florence Nightingale

Why is Real World Evidence important?

The changing healthcare environment

Healthcare payors and national governments continue to face enormous cost and capacity challenges. Ageing populations are increasingly living with multiple comorbidities due to both improved survival from previously fatal diseases such as cancer, and the impact of modern lifestyles, evident from the prevalence of diabetes and obesity.

Drug prices are on the increase due to both development costs and the increase in personalised treatments meaning R&D investment must be recouped across ever fewer patients. Health Technology Assessment (HTA) agencies and payors are becoming more sophisticated in their demands for evidence which they require for product reimbursement. This is partially in response to continued economic austerity as well as the increased cost of healthcare. Together, these trends are placing unprecedented pressures on life science companies.

However, despite these headwinds, new opportunities are arising. Through heightened focus on patient pathways, and the development of integrated solutions, life science companies are increasingly moving 'beyond the pill' to become solution providers. A renewed focus on measuring and demonstrating value provides opportunities to develop new commercial models, with rewards for those companies that are first to adapt.

The opportunities presented by Real World Evidence

Real World Evidence (RWE) enables companies to respond to these trends. It provides opportunities to discover new molecules, to prioritise asset development and support molecule progression decision making, and to deliver more efficient and insightful trials and boost ROI on R&D investment. RWE also helps to build new commercial models and deliver unique, mutually beneficial partnerships between life science companies and health systems.

Examples of some of the opportunities presented by Real World Evidence



Early Stage R&D

Identify/Demonstrate Unmet Need

- Develop disease understanding
- Explore epidemiology
- Identify patient-reported treatment shortfalls

Explore Root Causes and/or Stratify Disease

- Analyse role of genomics on disease onset and development
- Understand patient behaviour

Manage R&D

- Support progression decision-making and development asset prioritisation
- Build R&D collaborations with academia and providers

Explore Franchise Expansion

- Identify indication expansion opportunities (current Rx)
- Explore business development opportunities



Clinical Trials

Cohort Selection

- Recruit actual trial participants
- Align study protocol to current real world clinical pathways
- Assure study represents real world cohorts and treatment practices

Trial Management

- Facilitate new trial designs (e.g. adaptive trials, pragmatic trials)
- Collect outcome data from new sources



Commercial

Economic Value

- Undertake positioning & economic value analysis (product/class)
- Track economic value
- Monitor adverse events

Precision Targeting

- Improve accuracy of market sizing
- Define target cohort
- Reinforce post-reg market access

Integrated Solution

- Design combined offerings (e.g. Rx + device)
- Design integrated offerings (e.g. Rx + device + pathway change)

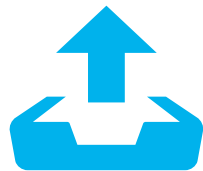
New Commercial Models (e.g. Value Contracting)

- Support contract design and contract management

What are some of the key challenges of working with Real World Evidence?



Data and regulatory issues



- **Data capture** – the quality of data, and in particular the ‘depth’ of clinical markers available, is often more essential than the size of data-sets in ensuring real world evidence programmes can meet strategic imperatives. However, the quality of both current and historic data varies substantially as a function of the roll-out of provider technology systems and as a function of clinical practice. In some healthcare systems, provider (dis-)incentives might also influence coding, thereby introducing unexpected bias. Often a deep understanding of local clinical and healthcare technology practices is necessary to pre-judge the utility of data investments.
- **Data extraction and linkage** – provider systems vary significantly in their capacity and capability to extract data for the use of real world evidence, and also in their interest in participating in data-driven research partnerships. Furthermore, variation in coding standards and patient identifiers across providers can create challenges in both extracting and subsequently linking the data. These factors influence project design choices, particularly around data access models that might be employed. Therefore, the correct choice between transactional models of accessing data and deeper pharma-provider partnerships can determine success at meeting study goals.
- **Data access and regulatory misalignment** – due to a great deal of recent development in the usage of real world evidence, historic regulatory paradigms are becoming obsolete. Without a clear framework, market participants must carefully coordinate their approach amongst different regulators and decision-makers (e.g. those responsible for ethics, patient privacy, and pharmacovigilance). Monitor Deloitte’s experience, particularly in Europe, is that clients often liaise with experts in these domains at provider, regional, and national level due to misalignment. Furthermore, commissioning successful international programmes often requires adherence to very different data privacy legislation in different legal jurisdictions.
- **Regulatory change** – in a number of markets, the public spotlight has shifted to patient privacy. Varying, and often contradictory, perspectives are being communicated by privacy campaigners, providers, researchers and patient advocacy charities as all parties seek to achieve both public confidence in the privacy of their data and to realise the full potential of healthcare data to transform patient outcomes.

Case example 1

Good Clinical Practice (GCP) is an established and successful standard used by governments and international regulators to develop regulations for clinical trials using human subjects. It covers aspects of monitoring, reporting and archiving clinical trials and incorporates both practical and ethical guidelines. These provide confidence to all stakeholders including clinical trial subjects, academics, patients, physicians, payors and regulators in the conduct and outcome of clinical trials. ‘Good Evidence Practice’ could be an analogous framework for conducting real world evidence studies and should address much of the current regulatory uncertainty. As a key industry stakeholder, Monitor Deloitte is playing a leading role in consultations on this topic.

Capabilities and internal ownership

- **Where to apply RWE** – life sciences companies face clear choices on how selectively or broadly to invest in RWE capabilities and on what basis to undertake any prioritisation. Different models are emerging of geographic prioritisation, and of targeting RWE investments against specific therapeutic areas. Whilst some companies are seeking to build international datasets to maximise the reach of real world evidence, others are prioritising geographies with favourable data availability or where RWE is more acceptable to payors and HTAs.
- **Ownership of RWE** – different models are also emerging of where RWE sits within life science companies. One dilemma is whether to centralise capability in the hope of developing scale and facilitating oversight or whether country franchises should play a larger role given their enhanced understanding of local market access conditions and health systems. Different organisational options also determine how well capabilities can be shared across the product life cycle. A clear understanding of desired use is therefore vital when designing RWE organisations.
- **Payor relationship** – life science companies can and are proactively cooperating with payors and regulators, through pioneering adaptive trials for example, or through seeking to negotiate new value-based reimbursement contracts. Of course, such decisions are based both on pre-existing payor relationships and payor interest and on risk appetite.
- **Pacing** – life sciences companies have some choice in the speed at which they develop their RWE capabilities. Successful decisions are not only based on a real-time understanding of how quickly RWE is transforming the industry but also on an assessment of whether leadership in this field is achievable or even desirable.



Case example 2

Monitor Deloitte supported a leading pharmaceutical client to revitalise its approach to Real World Evidence. After providing a present-state diagnostic and updated market analysis, the team challenged the client to build a perspective on:

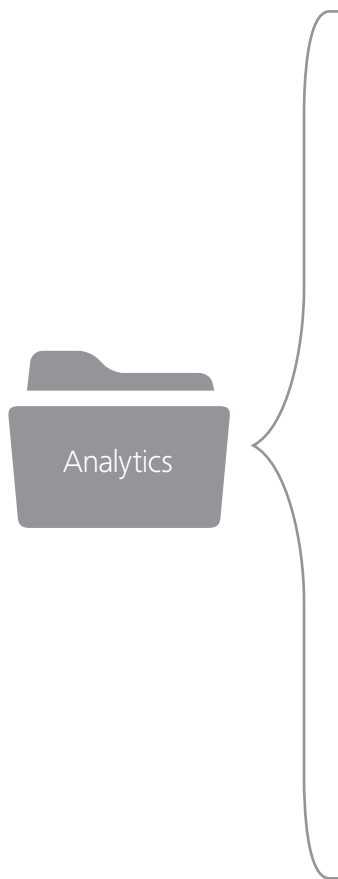
Strategic vision – what should the role of RWE be in our organisation, and where do we want to be in five years?

Where to play – how do we prioritise therapeutic areas, geographies, and value sources when developing our capabilities?

How to win – what delivery model(s) should we use in order to achieve these goals?

Capabilities – what capabilities must we develop and how do we redesign our organisation accordingly?

This resulted in significant re-alignment of strategic alliances, a renewed focus on linking RWE to the company's value drivers and an embedded RWE model at the core of business decision-making.



Analytics

- **Adoption of new analytical techniques** – Real World Data offers greatly enhanced sample sizes and the opportunity to glean richer insights than available from Randomised Clinical Trial [RCT] data. However, the cost of these benefits is a new analytical challenge – new confounding factors and sources of bias. The additional opportunity to explore a wide number of possible associations means many statisticians are increasingly cautious in the interpretation of p-values. Therefore, RWE practitioners need to continuously build their statistical arsenal. Similarly, unstructured data offers deeper and more novel insights to those companies that can deploy tools such as natural language processing.
- **Ways of working** – the richness of Real World Data supports the development of far richer methodologies than the simple statistical testing of the past, thereby raising the prospect of developing intellectual property through codification of this analysis itself. Furthermore, it provides for more iterative and exploratory studies, rendering a linear research sign-off process inefficient to maintain.
- **Analytical risk** – RCTs' time to implement lent itself to much scrutiny ahead of data analysis. An era of RWE, however, can democratise analytics within the institution. Whilst broadening the analytical stakeholder group provides advantages, risk controls have to remain in place. Internal risk frameworks have to be adapted to ensure, for example, pharmacovigilance reporting is completed and poorly thought-out analysis avoided.
- **Communicating new techniques** – in an era of new approaches and ways of working, communication is important internally – to front-line sales and marketing personnel – and externally – to HTAs, payors, regulators, and providers. Visualisation tools provide promise, but only in so far as they are deployed to convey tailored and specific messages aimed at driving change.

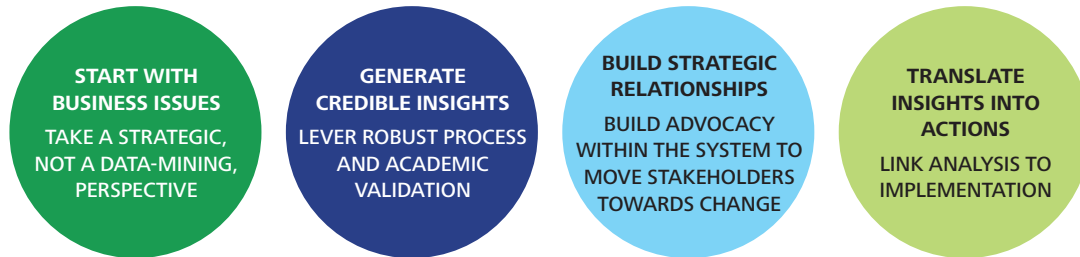
Case example 3

Historic analytical approaches in UK cancer have focused on understanding the impact of point interventions, often in isolation of the variability brought about by social factors and comorbidities in the real world. RWE provides a new opportunity to build a more holistic view of the patient, though with lower control over confounding factors. Monitor Deloitte, in conjunction with NCIN and Macmillan Cancer Support, has been developing the 'Routes from Diagnosis' methodology – a new approach to explore and quantify patient journeys following a cancer diagnosis. This has created new insight into the interaction of socio-economic factors and healthcare; identified new opportunities for pre-empting and managing comorbidities; and supported prioritisation of healthcare change.

Why Monitor Deloitte?

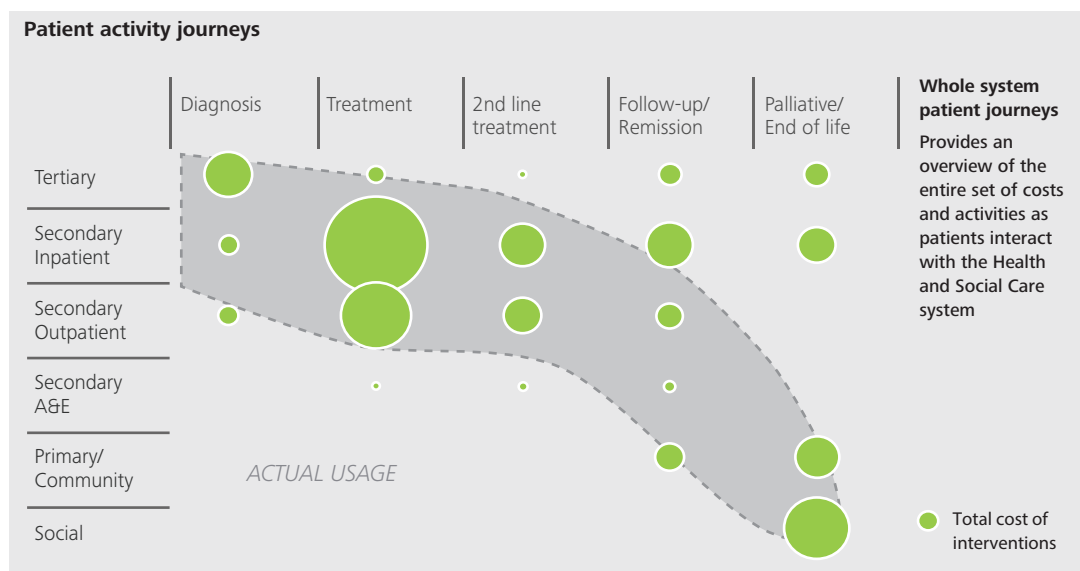
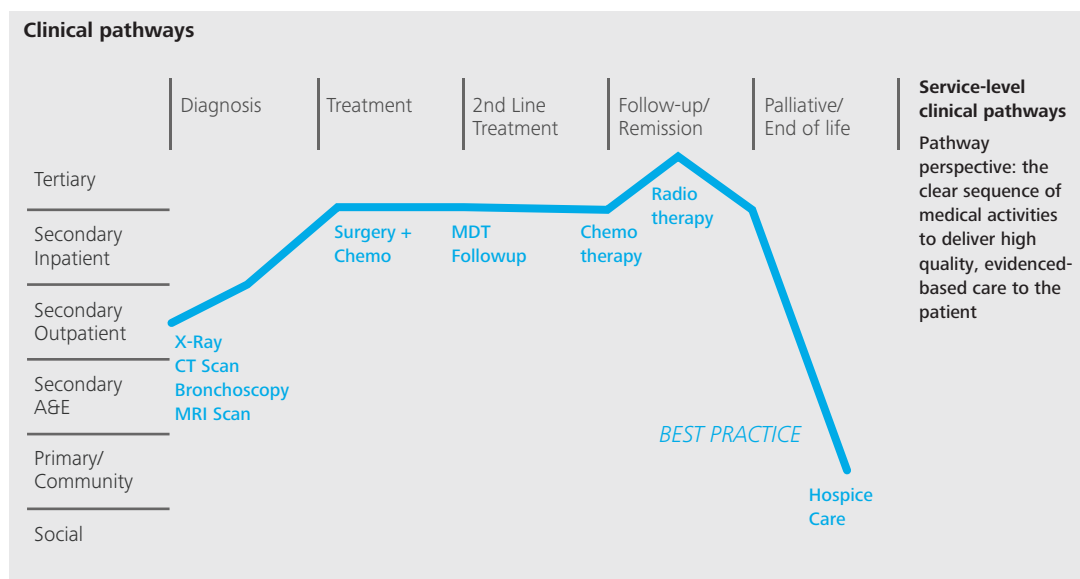
Impact driven

Monitor Deloitte's global leadership in strategy consulting helps to ensure their approach is led by business issues which can then leverage real world data to turn evidence into impact:



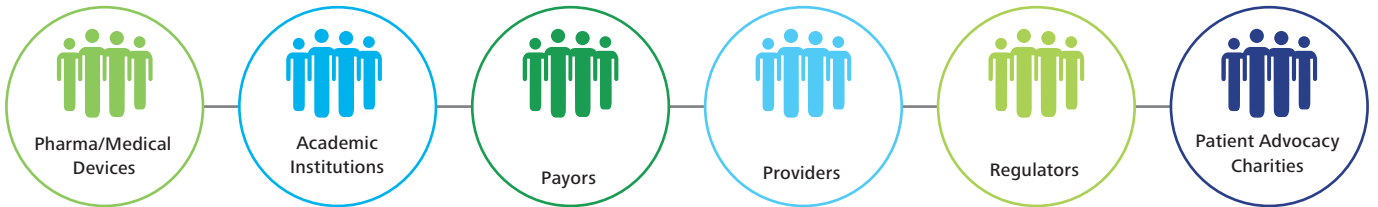
Pathway focussed

Central to Monitor Deloitte's approach is the understanding of actual patient service use, across all care settings and along the entire treatment pathway:



Experience across the healthcare setting

Monitor Deloitte works with all participants in the healthcare market and understands their data requirements, value drivers, and perspectives:



Breadth of capabilities

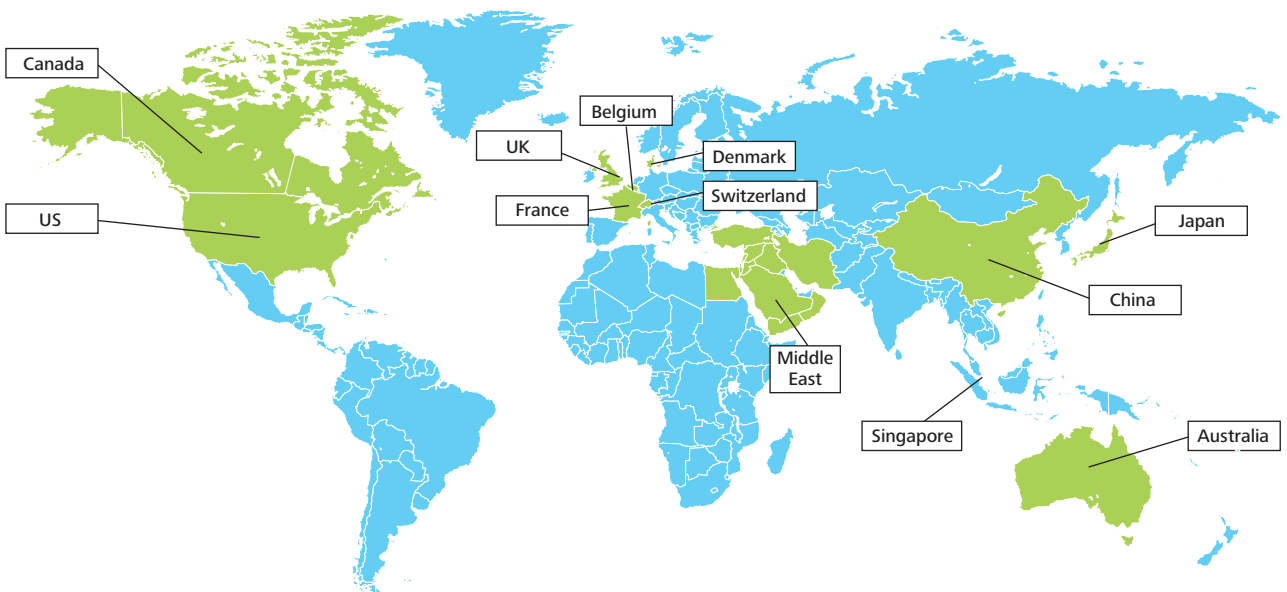
The team deploys the full range of Deloitte’s capabilities to support clients at every step of the data lifecycle:



International experience

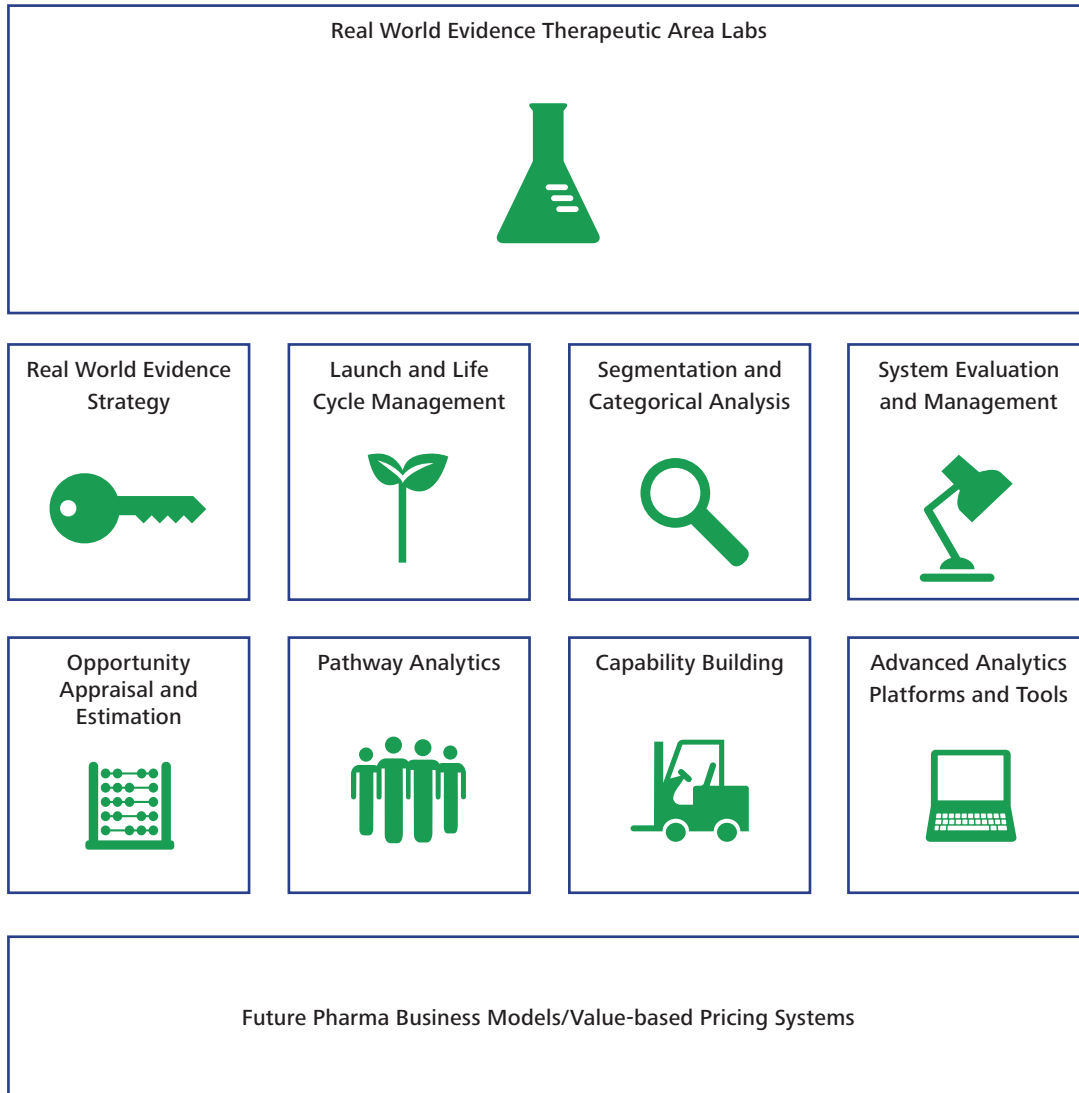
Monitor Deloitte’s international healthcare analytics footprint, as optimised by the acquisition of Recombinant Data Corp and formation of ConvergeHealth in the US territory, allows the team to bring global insight and capability to client needs.

Monitor Deloitte’s current healthcare analytics footprint



How can Monitor Deloitte support Real World Evidence activities?

The team has developed a range of bespoke services for clients that balance strategy and implementation.



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Acknowledgements: We would like to acknowledge the significant contribution received from Marine Serres, and Ozgur Odemis

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Designed and produced by The Creative Studio at Deloitte, London. 44465A