

Monitor
Deloitte.

Real World Evidence
Transforming 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 required 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. The formation of life science clusters and biotech incubators is introducing cooperation across the sector and the cross fertilisation of ideas. 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

- E.g. Role of genomics on disease onset and development
- Understand patient behaviour

Manage R&D

- Development asset prioritisation and progression decision-making
- Build R&D collaborations with academia & 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)
- Data collection & analysis



Commercial

Economic Value

- Positioning & economic value analysis (product/class)
- Tracking economic value
- Adverse event monitoring

Precision Targeting

- Market sizing
- Target cohort definition
- Reinforce post-reg market access

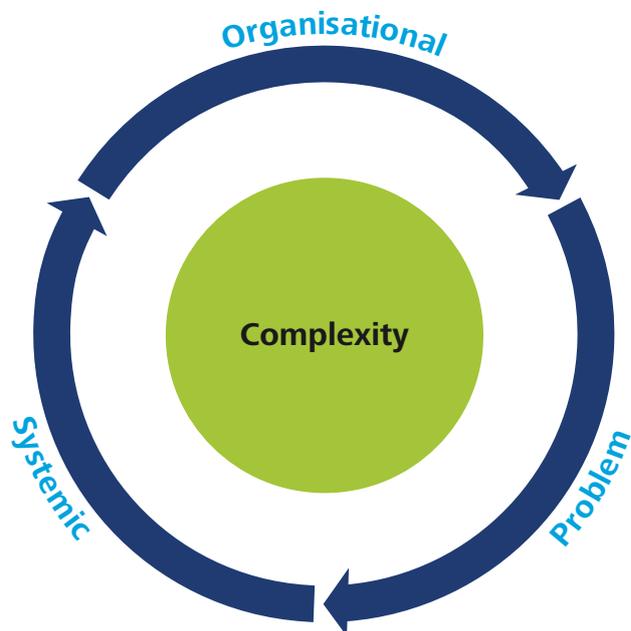
Integrated Solution

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

New Commercial Models (e.g. Value Contracting)

- Contract design
- Contract management

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



Systemic complexity

The value of RWE is strongly linked to the pool of data available for analysis. The broader the sample size, the more reflective the insights of the population as a whole. Detailed, cross-setting datasets are vital in capturing the full complexity of disease state and progression, comorbidity development, healthcare usage, and economic outcomes. However, understandable public concern around the collection and use of patient level information has built a highly complex and rapidly shifting data landscape, with significant national variations. The resulting silos of information are complex to access and manage and often fail to capture key data fields.

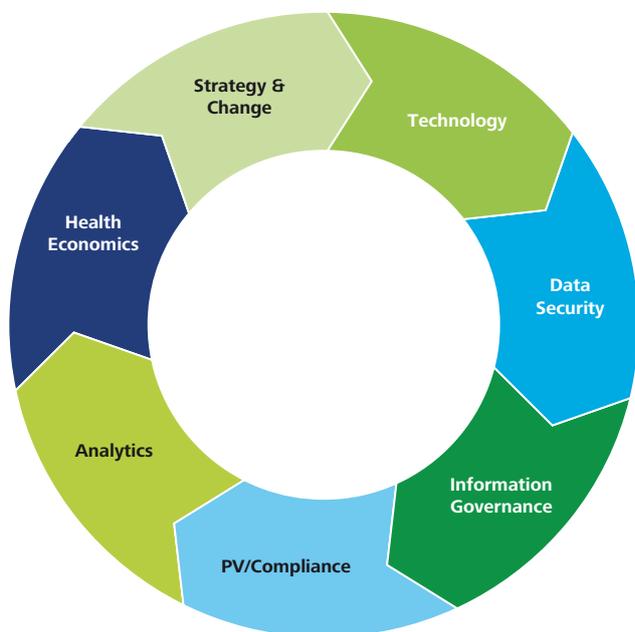
Organisational complexity

At its best, RWE delivers value across all major life science company functions. However, no clear consensus in delivery models has occurred amongst leading pharmaceutical firms as capability is variously located in national companies, in either single function reporting lines or as separate entities. Furthermore, integration of RWE into business as usual processes is poor – for example, few industry players routinely use RWE when prioritising candidate molecules. This failure to fully integrate RWE can constrain the value to isolated high profile projects, or else lead it to fail at attaining its potential altogether.

Problem complexity

At the most fundamental level, dealing with RWE within an organisation requires competencies that span multiple domains which are necessary but not sufficient for success. Organisations must deliver key capability plans that address the current talent gap in order to create high performing RWE organisations.

Competencies necessary for working with Real World Evidence



Why Monitor Deloitte?

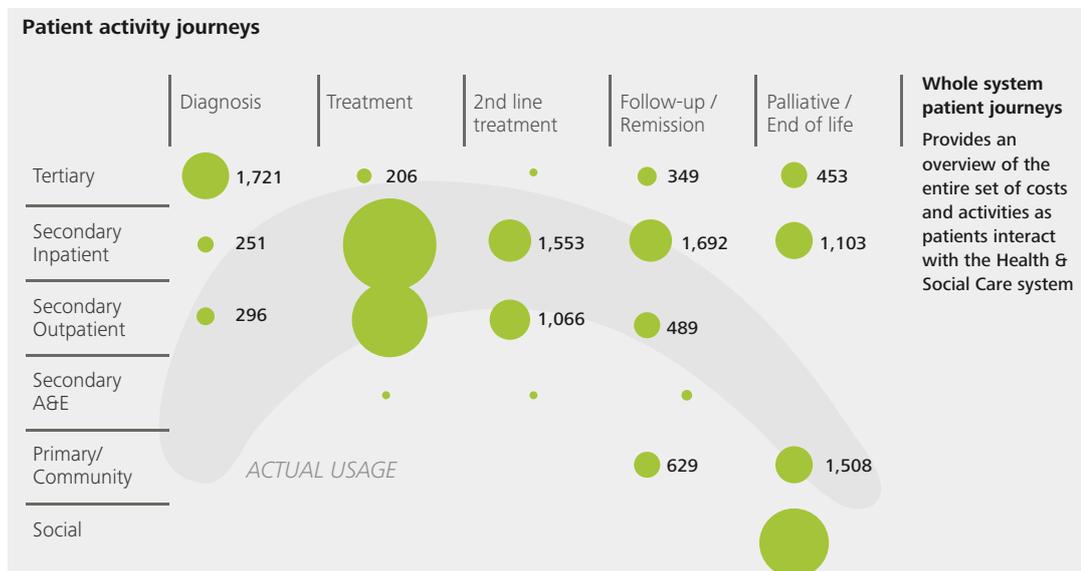
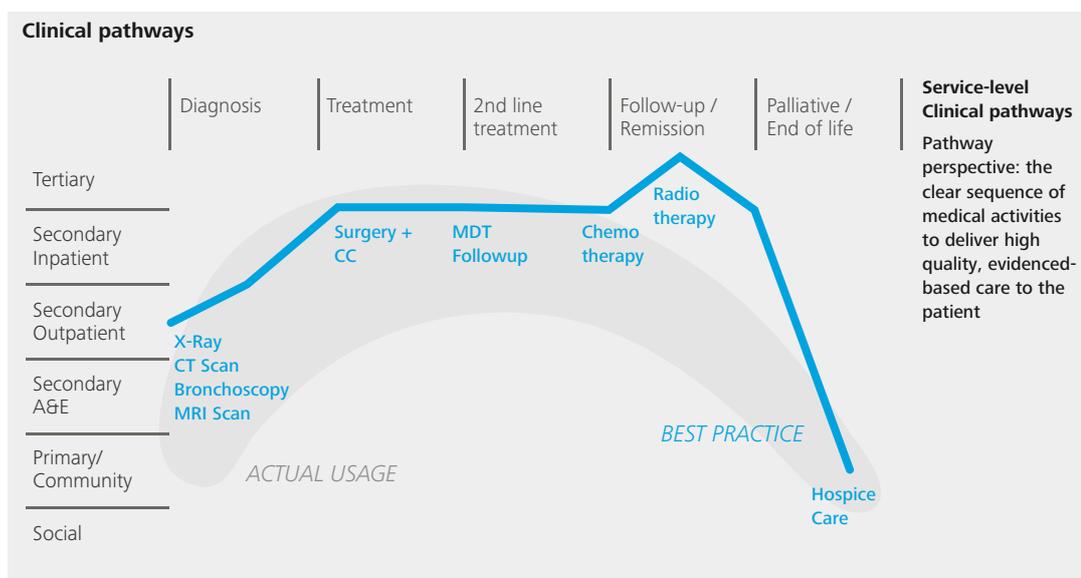
Impact driven

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:

Start with business issues	Leverage Real World Data to address specific, well defined issues
Generate credible insights	Construct robust processes to generate credible insights
Build strategic relationships	Build advocacy within the system to move stakeholders towards change
Translate insights into actions	Translate insights into actions to capture the value of Real World Data

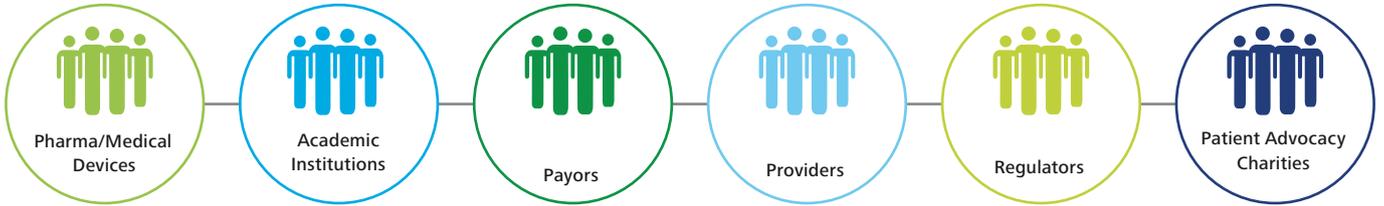
Pathway focussed

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 and perspectives:



Breadth of capabilities

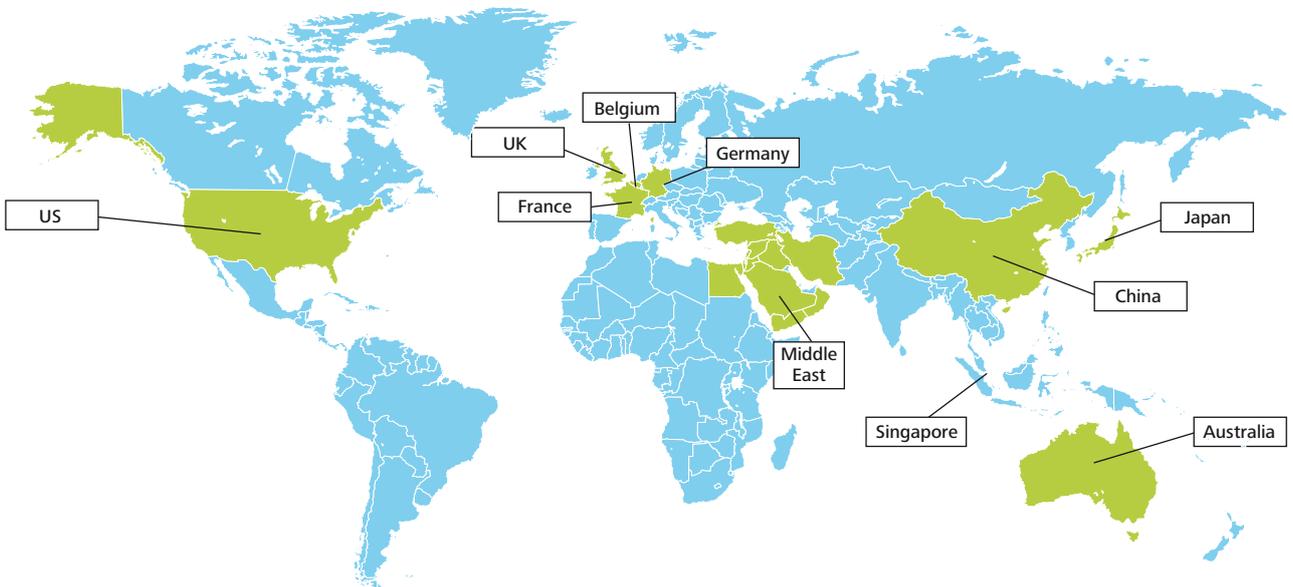
The team deploys the full range of Deloitte’s capabilities to support clients at every step of the data lifecycle:



International experience

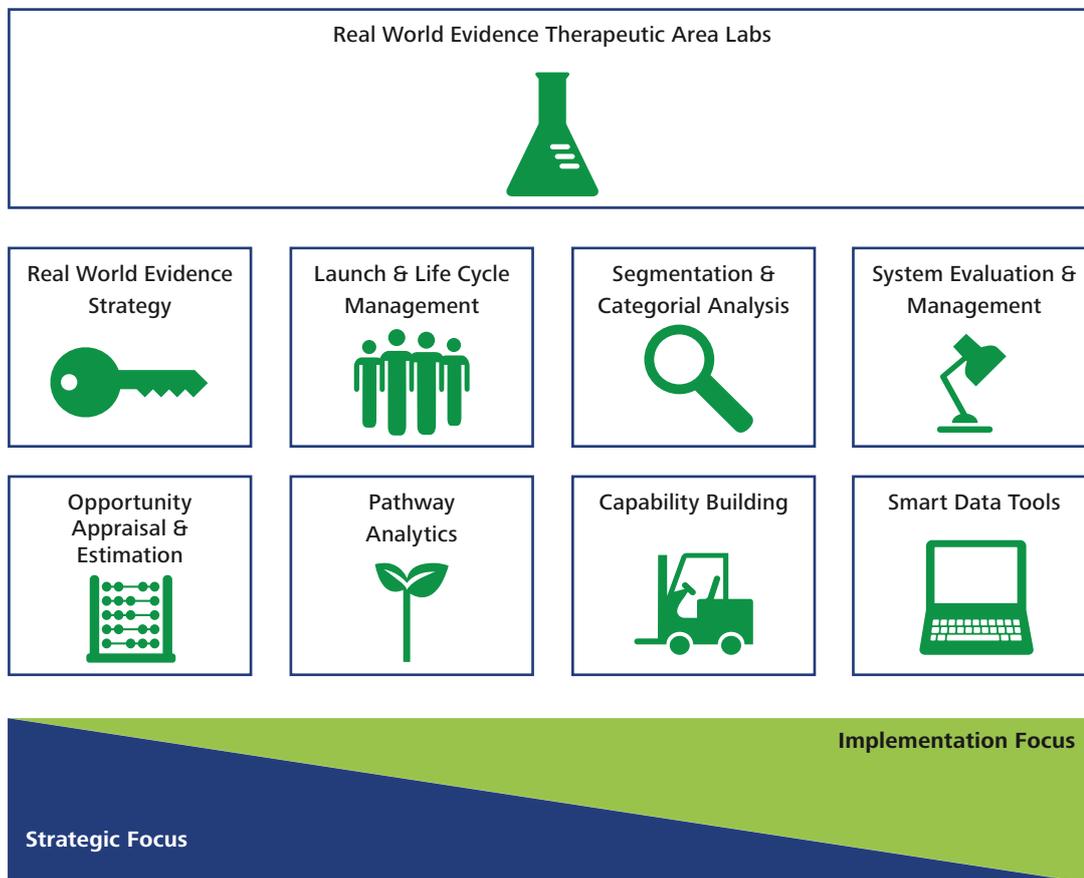
Monitor Deloitte’s international healthcare analytics footprint, as optimised by the acquisition of Recombinant Data Corp and formation of ConvergeHealth in the US territory, allows the team to bring global insight and capability to client needs.

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.



Case examples

Therapeutic Area Lab

Diabetes. Monitor Deloitte built a major RWE alliance between a pharmaco and a local health economy in a major European city. They developed a platform to integrate data across primary, secondary and community care – capturing 60,000 pseudonymised longitudinal care records. Deploying advanced analytics, they identified opportunities to improve care whilst maintaining economic sustainability. Monitor Deloitte then supported the creation of a new world-class diabetes strategy where their findings were presented at the American Diabetes Association and appeared in the Wall Street Journal.

Pathway Analytics

Cancer. Monitor Deloitte has enjoyed a long running partnership with Macmillan Cancer Support and National Cancer Intelligent Network (NCIN). Through the 'Routes from Diagnosis' programme, they have built the most detailed evidence driven map of UK cancer survivorship yet – demonstrating post diagnosis pathways and national variations. These insights have supported health service improvement to tackle high cancer mortality across a major local health economy. Their findings were presented at NCIN Conference and were covered by the BBC and the Guardian newspaper.

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