Real-world evidence: the privacy predicament

Implications of data privacy regulations and the management of associated risks
Why data privacy needs to become an inherent part of your real-world evidence framework

Real-world evidence (RWE) allows companies to make more informed and reliable business decisions earlier. The result is: a more agile and commercially valuable life sciences organization able to answer questions that were previously considered beyond their reach. In the life sciences industry, converting real-world data (RWD) into valuable RWE offers great scientific, commercial and societal benefit and opportunity, as has been identified and discussed by many. RWE can materially contribute to more effective clinical trials as well as shorten phase III to accelerate the approval procedures. It also enables organizations to demonstrate health outcomes and support the case for the value of their products to health authorities, payers, health care providers and patients.

The case for accessing and evaluating the plethora of different data sets is clear. However, while the opportunity is large, exploiting the value requires the appropriate governance and analytics capabilities to stay within the acceptable tolerance levels for compliance and reputation risk management. Operating within and up to the board’s stated level of risk appetite is the next challenge. In a rapidly changing regulatory environment, with a diverse set of data sources, contractual mechanisms and data privacy requirements, the capabilities needed to extract the value from the data become strategic in their own right.

This white paper explores the privacy considerations of RWE with the intention of helping the life sciences industry to better understand the data privacy restrictions and legislations that apply. It provides practical guidance to enable organizational management to have the confidence to extract the value while meeting the requirements to effectively manage risk.

Opportunities and challenges of RWE

- Better understanding of diseases and patient population
- More precise evaluation of the value of medicine
- Patient-centric approach, improved personal data management

Risks to consider

- Higher administrative fines
- Adverse publicity, impaired regulatory relationships
- Recruitment and talent management issues: more difficult to attract and retain those who have the required skills and capabilities, including data privacy

“RWD is any data not collected in conventional randomized controlled trials. It includes data from existing secondary sources (e.g., databases of national health services) and the collection of new data, both retrospectively and prospectively.”

“Advances in computing allow us to collect, share, analyze and use large quantities of data routinely at a relatively low cost — as never before. The increased use of new technologies in the health care sector has changed the ways in which patient-level information are collected, stored and used.”

RWD according to the RAND Corporation
RWE aligned with risk management to adequately respond to regulatory trends

Operating within and up to the board’s stated level of risk appetite is a challenge that requires an agile and consistent RWE framework. A thorough understanding of the rapidly changing regulatory environment, contractual mechanisms and data privacy requirements is necessary for a successful interplay of the analytics, hardware and applications framework.

### Data protection regulations
- Protect data against third-party curiosity (including governments)
- Inform about requests of data subjects
- Distinguish and cover privacy and business data
- Mitigate liability for data loss or breach
- Manage declarations to supervisory authorities

### Security standards and certifications
- Encryption
- Description of means for security
- Recovery plan
- Strong authentication
- Legal hold and traceability requirements
- Security and privacy audits

### SLA and licensing
- No liability exclusion on SLA
- Supervision console to show real-time SLA

### Safe and fair contract terms
- Subcontractors known and accepted
- Jurisdiction and court at user’s country
Health outcome conclusions and commercial business cases that leverage RWE rely on capabilities that protect an organization from specific, consequential compliance and reputational risks. Effective capabilities are agile in their response to risks that come from a disparate set of sources:

**Diversity of legislation**

There are numerous significant differences in the ways in which countries regulate their data usage. It is not surprising, therefore, that the sharing of person-level data across borders for international comparisons is rarely reported and there are few examples of data linkages for multi-country comparative studies. A heterogeneous legal landscape demands a careful approach to drafting contractual clauses for transfers of personal data or arrangements that provide insight into personal databases. The rules as well as the consequences of noncompliance vary greatly and impose significant risk.

**Data minimization principle**

The principle of data minimization often collides with the pharmaceutical research objectives, where more data means more precise analysis and results. Storing or collecting data extensively may one day bring some important findings and far-reaching health solutions. The underlying tenet of using RWE is that the data sets are considerably larger. To adhere to the legal requirements, companies must ensure proper accountability standards and demonstrate performance against them, e.g., have sufficient proof available for the case of a “dawn raid” investigation.

**Interplay of different players**

The collaboration of numerous players throughout the collection and processing of RWE is indispensable, but again, raises additional risks. The process may include organizationally immature entities which have only recently started to access the market and thus lack privacy-specific knowledge and resources (e.g., they are not aware of the importance of drafting an appropriate privacy policy). When transferring personal data for the purpose of RWE analysis, it is critical that the agreement between the parties includes contractual terms that properly balance the responsibilities of the participants.

**Consent and purpose limitation**

The concept of consent does not always work in the world of the instantly available data, where the data abstracted from patient platforms or social media sites represent the main source. Here, collecting and processing the data may be hindered due to the lack of informed consent. In the world of RWE, the consent procedure should be reconsidered, simplified and made more flexible. E-consent management is one of the possible solutions.
The data privacy regulatory landscape across the globe is changing rapidly

Various Asian countries, specifically the Asia-Pacific Economic Cooperation (APEC) members, have recently adopted the Binding Corporate Rules and Cross-border Privacy Framework. These are the internal rules that define global policy with regard to the international transfers of personal data, within the same corporate group, to entities located in countries that do not provide an adequate level of protection. Some significant changes have been planned for the Safe Harbor Framework, a scheme that companies use to manage data transfers between the US and the EU. Most importantly, there are some crucial improvements expected in the EU where the current draft data protection regulation tends to harmonize and modernize the core rules pertaining to the protection of personal data of individuals within the EU. The current version of the regulation strongly emphasizes the accountability of organizations and establishes the culture of monitoring data processing procedures, minimizing the amount of data processed and installing safeguards to all personal data processing activities. The draft regulation introduces a couple of new requirements and significantly increases fines for noncompliance, up to 5% of an entity’s annual turnover.

In terms of RWE, there are a few regulatory improvements that are up for consideration before the new regulation is adopted. First of all, the consent definition is changing. The draft introduces an explicit consent for all types of data collection and processing, no longer limited to sensitive data as is currently the case. While the concrete consequences of this new requirement are still unclear, there might be a need to reconsider the consent management procedures and impose stricter scrutiny over third parties that transfer the data in house. Second, privacy impact assessments will become a general rule and companies will be required to perform these assessments on a regular basis. This is an important aspect that should be incorporated in all operational initiatives related to RWD, such as patient solution platforms. Finally, and most importantly, the proposed EU regulation restricts the usage of medical data in research purposes; so it is very likely that not all of the data will always be available for further processing.

EU data protection regulation timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>Negotiating the draft proposal</td>
</tr>
<tr>
<td>2015</td>
<td>Adoption</td>
</tr>
<tr>
<td>2017</td>
<td>Full compliance required</td>
</tr>
</tbody>
</table>
Privacy challenges associated with RWE encourage life sciences organizations to become innovative in searching for solutions that deliver compliance as well as effective reputation risk management. Best practices from the public and private sector provide helpful directions for those who are currently implementing an RWE framework.

**E-consent management**

In recent years, it has become clear that the current system of consent does not work as it was supposed to. The information overload and the absence of meaningful choice leads to “consent desensitization.” The academic world calls for a fair transaction consent model where formal requirements for giving and obtaining consent would be relaxed, but still, there would be more room for the reasonable interests of both parties. A concrete answer to academic considerations could be a form of an e-consent: a methodological tool that would equip health care institutions with opt-in consent management solutions. This type of a solution has been recently introduced by a German health care provider.

**The involvement of trusted third parties**

Engaging with third parties that are in charge of collecting consent and making sure that data is anonymized is a common strategy to obtain a consent with ease, and to gain access to observational data. According to a RAND study, reputational effects have a strong impact on physicians’ willingness to share their patients’ data. Involving a trusted party means a pharmaceutical company is excluded from direct communication with a physician which often results in a higher response rate and fewer privacy concerns. A good example of successful cooperation is Genomics England, owned by the UK Department of Health, which provides data on whole genome sequences matched with clinical data, but fully anonymized. This allows organizations to benefit from rich data while minimizing the impact on patients’ privacy.

**Integral approach for RWE platforms**

The purpose of the RWE platform is to establish a solid governance structure for the data analysis as well as to provide a secure and legally allowed research environment. One of the world’s leading pharmaceutical organizations believes this is the right way to reverse the growing data asymmetry and skepticism between the payers and pharmaceutical companies.
Implications for life sciences companies: risks and opportunities

<table>
<thead>
<tr>
<th>Risk</th>
<th>Impact</th>
<th>Likelihood</th>
<th>How to mitigate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Data privacy risks depend on the activities to which they relate, on the nature of personal data that is collected, the specific type of personal data (i.e., sensitive personal data, data via social networks) collected, what the data is used for, who it is shared with, how long it is retained and what the security arrangements are</td>
<td>• Risk of administrative fines</td>
<td>Initial stage</td>
<td>• Think carefully about consent, what the business intends to do with the data that is provided directly or indirectly by patients, how the data will be used or shared, how long it will be kept</td>
</tr>
<tr>
<td>• The type of supplier that an entity engages to collect its RWE, including patient data, is a risk in itself. The potential exists for these suppliers to have relatively immature capabilities, with perhaps little experience or track record of data privacy, contrary to the type of suppliers that have traditionally been used to process patient identifiable data</td>
<td>• Data breaches leading to strong reputational damage</td>
<td>Later stage</td>
<td>• Provide for appropriate resource to manage the material and train personnel on their obligations</td>
</tr>
<tr>
<td></td>
<td>• Risk of being held responsible due to misconduct of the chosen supplier</td>
<td></td>
<td>• Perform due diligence and/or proper review or implementation of data privacy contract clauses with the suppliers</td>
</tr>
<tr>
<td></td>
<td>• Risk of court actions (as the competitors’ counter-reaction), distrust from patients and other customers</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Deference and delay of in-market activity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data privacy capabilities protect the right of access to future data, and mitigate the risk of significant fines and penalties.

Effective and trusted data privacy capabilities reduce both cost and lead time for decision-making.

The business case is therefore clear — agile data privacy capabilities are a necessary and strategic asset in the life sciences market that leverages RWE.
### Topics to consider when you establish your RWE capabilities

<table>
<thead>
<tr>
<th>Processes</th>
<th>People</th>
<th>Technology</th>
<th>Regulatory insight and governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Have you implemented the right controls to sufficiently manage the regulatory challenges that RWE presents?</td>
<td>- How do you raise awareness and educate your employees on privacy associated with RWE?</td>
<td>- How do you manage application control and IT security to comply with information security requirements?</td>
<td>- Do you update your procedures and policies to reflect the current status of the relevant regulations that have implications for RWE?</td>
</tr>
<tr>
<td>- Can you and do you demonstrate your compliance by adhering to the information security standards (e.g., ISO)?</td>
<td>- Do you provide training and clear guidance to avoid penalties?</td>
<td></td>
<td>- Are you in control of all the cross-border movement of data within your organization?</td>
</tr>
</tbody>
</table>
RWE and data privacy in practice

RWE as a source of adverse events

RWE can be a valuable source of (spontaneous) adverse event reports. Obtaining adverse event reports directly from the patient has a number of advantages for pharmacovigilance. Among others, it allows for the identification of different types of events from those reported by health care providers, it helps to address under-reporting and, when provided with enough detail, it can lead to useful information regarding the impact on the patient and the causality of the event. Currently, however, the options that patients have for reporting adverse events are often inconvenient and time consuming. Therefore, smartphones can play an important role in making patient reporting faster and more convenient. For example, a mobile app can allow patients to directly report their adverse events anytime, anywhere. An app also allows you to request the right information from the patient, ensuring that the report will be complete and contain sufficient detail.

Data privacy implications and considerations

- What data is required? It is important to predetermine what kind of data is necessary for a complete and informative adverse event report, so that the principle of data minimization can be complied with.
- Under which legislation should the report be processed? A German patient report sent during a vacation in the US should still enter the German system.
- Can the data easily be anonymized and centralized for further use after processing?
- Does the patient understand and consent to everything that will happen with their data? Articulating the intended purpose of the data and ways in which it will be processed or shared in a transparent and understandable way is essential when obtaining consent.
- When collaborating with third parties to create an app, know who the data controller and the data processor are. Understanding the roles and responsibilities of each party and enforcing compliance is of critical importance.
- Can an adverse event report get lost in transit over the internet, e.g., due to a bad connection?
- What kind of data remains on the device after reporting?

RWE in market access

In conjunction with data from randomized control trials (RCTs), RWE can be a valuable source of information that is used to enrich and support efficacy, safety and health economic claims related to launch or in-market drugs. Its use as evidence in marketing application authorization submissions and discussions with health authorities as well as in pricing and reimbursement (P&R) agreements with payers, is becoming increasingly more common. Complementing RCT evidence for launch drug HTAs, conditional or outcomes-based P&R agreements are the most common use of RWE in market access. The data can be sourced from registry data sources, electronic medical records, pharmacy and medical claims data sources as well as social media and mobile devices to name but a few. The secondary use of this data has a number of data privacy implications and considerations that will need to be addressed given the legislation that has been introduced.
Implementing a data privacy approach within an RWE framework, which can effectively respond to the regulatory challenges, can be a daunting task. However, regardless of current capability levels, there are easily identifiable actions to raise performance to the next level.

At EY, we help our clients to achieve their ambition, providing advisory, regulatory and legal input to:

- Interpret the data privacy requirements and their legal implications as the requirements are finalized
- Identify, evaluate and prioritize enhancements to RWE governance processes, IT systems, assets and capabilities, to support streamlined adoption of data privacy requirements
- Anticipate and adapt to future needs and changes to data privacy regulations beyond today’s requirements
- Provide a risk-based approach to guide the implementation program, and a framework for helping to ensure ongoing steady state compliance
- Embed pragmatic change management and program management that take into account the complexity of the landscape and the affected stakeholder groups

We draw from a wide range of capabilities and geographies to build the best team to support your needs.
The authors would like to acknowledge the invaluable contributions of Helena Ursic, Walraaf Borkent, Mark Hammond, Thaddeus Wolfram, Peter Curle, Jamie Burrows and Fabian Schmidt.

Contacts

Glen Giovannetti
Global Life Sciences Leader
glen.giovannetti@ey.com
+1 617 374 6218

Patrick Flochel
Global Pharmaceutical Leader
patrick.flochel@ch.ey.com
+41 58 286 4148

Kim Ramko
Global Life Sciences Advisory Leader
kim.ramko@ey.com
+1 615 516 7546

Virginie Lefebvre-Dutilleul
Attorney at Law, Legal Practice Leader for Life Sciences,
Ernst & Young Société d’Avocats
virginie.lefebvre-dutilleul@ey-avocats.com
+33 1 55 61 10 62

Chris Moore
EMEIA Life Sciences Advisory Leader
cmoore2@uk.ey.com
+44 7768 390 097

Authors

Fiona Gadd
UKI Advisory Life Sciences Risk Leader
fgadd@uk.ey.com
+44 7500 823727

Joanna Taylor
EMEIA Advisory Centre, Life Sciences
joanna.taylor@ch.ey.com
+41 58 289 82 08

Nora Boukadid
EMEIA Data Privacy Lead
nora.boukadid@nl.ey.com
+31 88 40 73 082
About EY
EY is a global leader in assurance, tax, transaction and advisory services. The insights and quality services we deliver help build trust and confidence in the capital markets and in economies the world over. We develop outstanding leaders who team to deliver on our promises to all of our stakeholders. In so doing, we play a critical role in building a better working world for our people, for our clients and for our communities.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit ey.com.

How EY’s Global Life Sciences Sector can help your business
Life sciences companies – from emerging start-ups to multinational enterprises – face new challenges in a rapidly changing health care ecosystem. Payers and regulators are increasing scrutiny and accelerating the transition to value and outcomes. Big data and patient-empowering technologies are driving new approaches and enabling transparency and consumerism. Players from other sectors are entering health care, making collaborations increasingly complex. These trends challenge every aspect of the life sciences business model, from R&D to marketing. Our Global Life Sciences Sector brings together a worldwide network – more than 7,000 sector-focused assurance, tax, transaction and advisory professionals – to anticipate trends, identify their implications and develop points of view on responding to critical issues. We can help you navigate your way forward and achieve success in the new ecosystem.

For more timely insights on the key business issues affecting life sciences companies, please go to ey.com/VitalSigns. You can also visit ey.com/lifesciences or email global.lifesciences@ey.com for more information on our services. To connect with us on Twitter, follow @EY_LifeSciences.

© 2015 EYGM Limited.
All Rights Reserved.

EYG no. FN0248

BMC Agency
BACS 1002537
ED None

In line with EY’s commitment to minimize its impact on the environment, this document has been printed on paper with a high recycled content.

This material has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax or other professional advice. Please refer to your advisors for specific advice.

ey.com