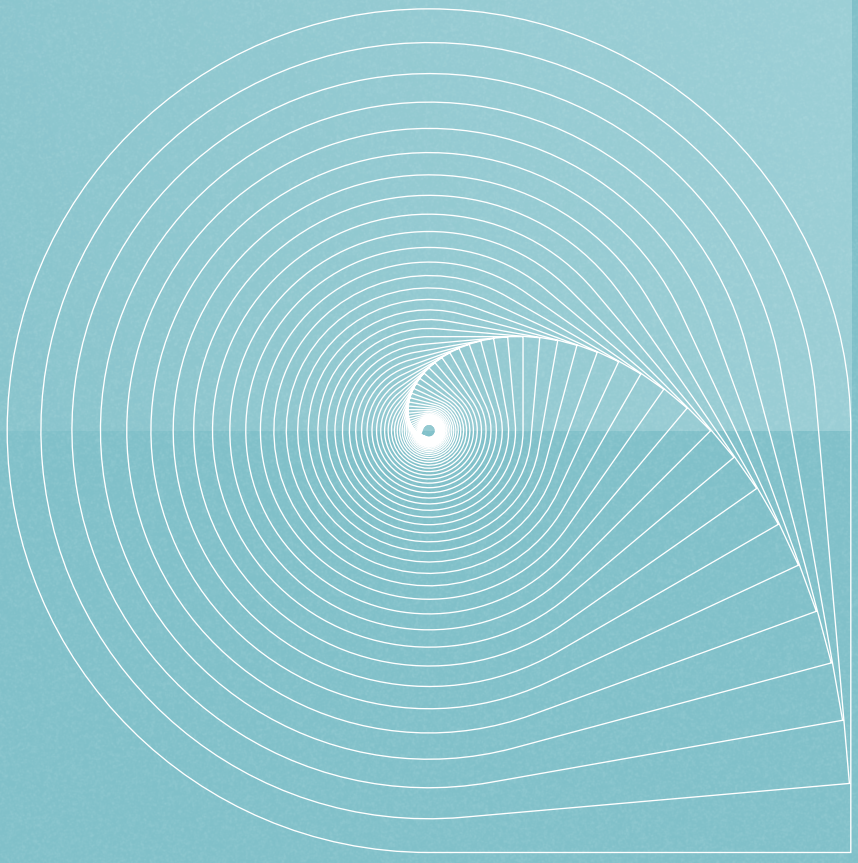
Rx Data News

Vol. 1
Issue 2



DECEMBER 2018

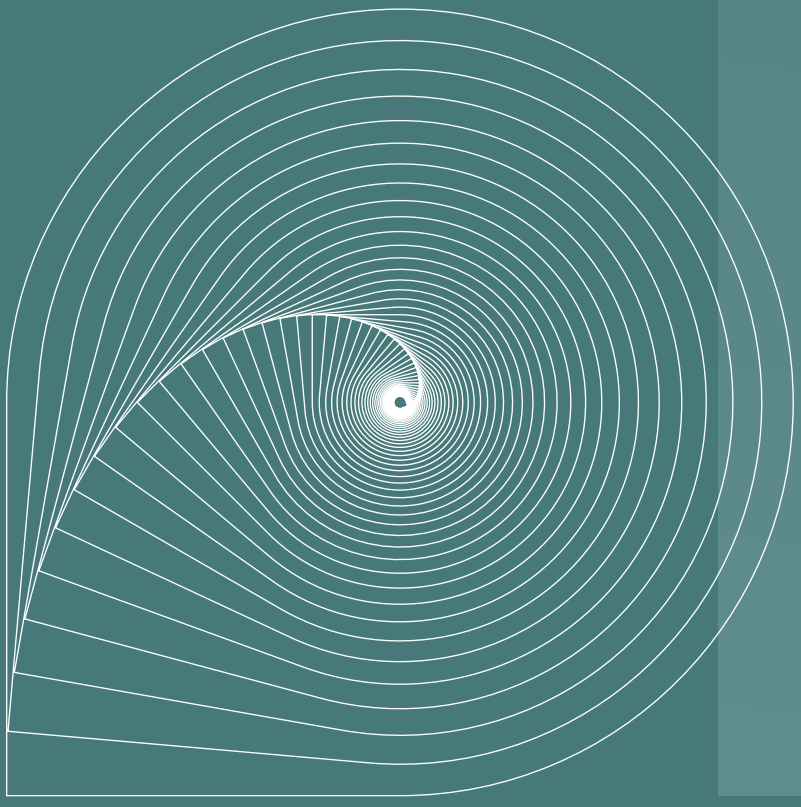
FOUNDER'S MESSAGE

Greetings readers of Rx Data News and welcome to our second issue. We are pleased to be bringing you important information and insights from experts across the biopharmaceutical world on all matters related to data analytics, machine learning and artificial intelligence. In this issue we feature articles on privacy issues, data sharing and data integrity. Our monthly deep focus question is related to the growing importance of real-world evidence in the biopharmaceutical industry. We feature an interview from Floren Robinson Pressman of Accenture on the uses of artificial intelligence on the commercial side of the pharmaceutical business. And finally, Mohammad Ovais, the founder and chief executive officer of qordata offers an excellent analysis of how analytics can improve an organizations compliance program. If you find this unique publication useful, please consider subscribing. You can visit our website at **www.RxDataNews.com**. Thank you.

— Peter Grant Jr., Founder, Rx Data News

MONTHLY DEEP FOCUS:

What are some unique examples of the applications of Real-World Evidence (RWE) in the biopharmaceutical industry?



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News-In-Brief

DECEMBER 2018

Amgen has moved the majority of its cloud infrastructure onto Amazon Web Services (AWS).

Amazon Comprehend Medical will utilize machine learning and natural language processing to improve the delivery of healthcare by mining unstructured electronic health record (EHR) data.

Chinese online healthcare platform Jianke.com has entered into a strategic partnership with Pfizer to establish patient-centric retail, hospital and internet healthcare services in China.

Roche has partnered with Wellthy Therapeutics to offer and AI-based diabetes coaching solution.

Medtronic has announced plans to acquire AI nutrition company Nutrino for its digital diabetes projects.

The UK government has issued a report outlining the establishment by 2019 of five "centers of excellence for digital pathology and imaging". The initiative will cost $65 million and will utilize artificial intelligence.

The technology firm Cambridge Consultants developed a new machine learning tool called Verum, which is designed to make clinical trials more efficient by remotely monitoring patient stress-levels in the hopes of reducing drop-out rates.

California-based NVIDIA has partnered with the Scripps Translational Institute to develop AI-platforms using genomic and digital health sensor data.

The South Korean conglomerate SK Group recently established SK Pharmaceuticals, which announced the creation of an AI-powered drug development and design platform.

Keen Eye, a French artificial intelligence echnology company, is beginning a collaboration with the Clinical Research Organization, Iris Pharma.

Innoplexus, a global artificial intelligence company, has launched a blockchain platform that allows researchers to upload and license unpublished data on the blockchain, increasing the amount of data available for drug research and discovery.

Deep Lens, a digital pathology startup, has released an AI platform designed to enable pathologists to diagnose cancer patients more quickly and accurately.

Precision Therapeutics, a company that applies AI to personalized medicine and drug discovery, and its joint-venture partner GLG Pharma, have acquired rights to technology for the growth of cancer cells for research and testing. The companies have agreed to terms on a non-exclusive license to this technology from a research institution.

TumorGenesis, a subsidiary of Precision, has developed a discovery kit for screening of cancer cell types.

Enable Injection, a drug delivery wearables company, received $50 million in a Series B funding round. Investment was led by Sanofi, with additional funding by the ORI Healthcare Fund, CincyTech, Cincinnati Children's Hospital and others.

Google has hired David Feinberg, the former CEO of Geisinger Health, to help guide its strategic move into the healthcare and life sciences sector.

Oxford-based Exscientia, a drug design company, is attempting to improve its artificial intelligence capabilities through the purchase of Kinetic Discovery, a company that specializes in biophysics.

In a bid to improve its real-world evidence generation capabilities and outcomes research offerings to potential biopharma clients, Parexel has adopted Medidata and Shyft Analytics's Platform.

Artificial intelligence-based clinical diagnostics company RenalytixAI raised $29 million to develop and commercialize tests that identify kidney disease at an earlier stage.

Health Catalyst has been adding AI and Life Science experts to their senior leadership team, reflecting their drive toward diversification across markets and the ever increasing importance of artificial intelligence in the field.

C4X Discovery has partnered with AI technology company GTN to advance their shape-based chemistry program and generate novel drug candidates in neurodegeneration.

The CRO Fusion Antibodies and Analytics Engines have partnered to incorporate machine learning and AI into the formers CDRx humanization platform.

Indian pharma company Lupin has developed a chat-bot to dispense medical information.

Featured Interview:

Accenture Interactive

Floren Robinson Pressman
Managing Director, Life Sciences Practice

This month our feature interview is with Floren Robinson Pressman, a Managing Director in the Life Science practice at Accenture. While a great deal of attention has been paid to the uses of artificial intelligence in areas like drug discovery, the technology is also poised to revolutionize the commercial side of the pharmaceutical business. Recently, Accenture has released a report on this very issue. Ms. Pressman was kind enough to break these issues down and go in-depth in this exclusive Rx Data News interview.

Rx Data News: In your recently released report it is noted that while AI has been pursued in the context of R&D for the last decade, the commercial side of the business has been slower in this regard. Why has this been the case and why is this changing now?

Ms. Pressman: Accenture sees three major reasons for the slower uptake:

1. The lion's share of pharma promotional strategy and investment has been focused on the interaction between physician and sales representative. This hasn't lent itself to companies thinking about how to use AI technology to simplify, automate and identify deeper insights.

2. Even as the industry has matured into multi-channel campaign management and digital engagement, it has lagged other industries in terms of the need for true personalization. Still largely believing that the "science sells", many companies struggle to define the ROI for marketing. And because meaningful data is often sparse or hard to come by, the bulk of their investment has not been in cutting-edge commercial capabilities.

3. As the industry further pivots toward patient services, many organizations are underfunded and still struggling to demonstrate ROI on basic service offerings. Investments in more sophisticated service models with embedded AI have largely been limited to experimental/ pilot stage or a single solution for a single brand in a single market. It is changing now, simply because the commercial side has to change and needs to more actively drive innovation and achieve outcomes such as hyper-personalized experiences, new sources of growth, and new levels of efficiency. Overall, AI can take the operational burden out of the system so that the organization can focus on the things that really matter—delivering solutions (products and supporting services) that help patients and providers improve health outcomes in more economically viable ways.

Rx Data News: What are some of the ways that Life Sciences companies can improve commercial operations through utilizing AI?

Ms. Pressman: There are many applications of AI in the commercial space that can significantly accelerate growth, profitability and sustainability. Recognizing when and where AI can be most effective is a vital first step towards applying AI in commercial. Accenture identified four applications:

Most effective applications of AI in the commercial space:

1. Intelligent automation which handles time-intensive/redundant tasks to drive increased profitability.

2. Enhanced judgement which augments human decision-making and can drive growth by improving the quality and efficiently of business intelligence.

3. Enhanced interaction to deliver superior customer experiences through dynamic interactions, personalizations and real-time content.

4. Intelligent products to accelerate growth by creating intelligent / digital therapeutics while unlocking a new kind of value proposition for payers.

Rx Data News: How can AI be used to enhance judgement in marketing operations?

Ms. Pressman: AI will be leveraged to enhance judgement in marketing operations and to augment, but not replace, human judgment most notably in that there can be many complexities to each marketing decision. AI will bring with it new criteria for success: collaboration capabilities, information sharing, experimentation, learning and decision-making effectiveness. Organizations will have to develop training and recruitment strategies for creativity, collaboration, empathy, and judgment skills. Enterprises will have to develop a diverse workforce and team of managers that balance experience with creative and social intelligence — each side complementing the other to support sound collective judgment. An AI system will be able to support decisions through real-time and up-to-date data gathering, forecasting, and trend analysis. AI technology isn't the end but only a means towards effectiveness and efficiency, improved innovative capabilities, and better opportunities.

Rx Data News: Regarding sales operations, how can AI be used to engage physicians?

Ms. Pressman: The same thinking applies in that AI will augment, but not replace human judgement and this becomes even more important when discussing the inter-related role between AI and physicians. Accenture believes that AI does have the promise to impact nearly every aspect of primary care. With AI as a technology that can mimic human thought processes by finding patterns then using what it finds to make decisions, AI for example is capable of screening patients, offering diagnoses, and suggesting optimal treatments as well as triaging patient inquires and processing patient claims. Logically thinking, with AI taking up the role of interpreting data, this could free up more time for higher value activities.

Rx Data News: How can AI help improve patient engagement and what benefits does this bring to life sciences companies?

Ms. Pressman: Accenture believes that AI will enable pharmaceutical companies to provide better experiences and information so that the patient stays on their products and in turn achieve better outcomes The promise of AI will be to improve the patient experience by anticipating patient needs which could include everything from services to content information to help them manage their condition and lifestyle; providing patients with the next-best actions that are personalized to them. AI also has the capacity to offer more convenient care. In fact patients are becoming more welcoming of technology integrated into the healthcare encounter, showing that patient preferences are leaning less toward human interaction and more toward convenient care, according to Accenture's 2018 Consumer Survey on Digital Health.

Rx Data News: Can you provide some concrete examples of life science companies taking advantage of AI in commercial operations today?

Ms. Pressman: Earlier this year Accenture introduced Ella and Ethan, two interactive virtual-assistant bots that use AI to constantly learn and make intelligent recommendations for interactions between life sciences companies, patients, HCPs and caregivers and are designed to deliver a more personalized patient experience and better patient support. By leveraging AI, life sciences companies have the capacity to allow patients to actively participate in their own care, leading to improved care delivery and health outcomes. Two examples that come to mind are Eularis and Boehringer Ingelheim. Eularis, has developed solutions that use AI to increase sales and revenue for pharma companies. These include E-VAI, a cloud-based marketing analytics platform which can learn from the success of marketing campaigns over the past decade and effectively mimic them and apply them to new product. Boehringer Ingelheim, for instance, has launched a website for its animal health business that uses AI to optimize and personalize the experience for vets by learning users' habits though pattern recognition technology. The site can provide personalized search results based on each user's search history and preferences (much like Amazon does in the retail space).

A New Era in Consumer Data Protection: Understanding the Implications of the GDPR and CCPA for the Biopharmaceutical Industry

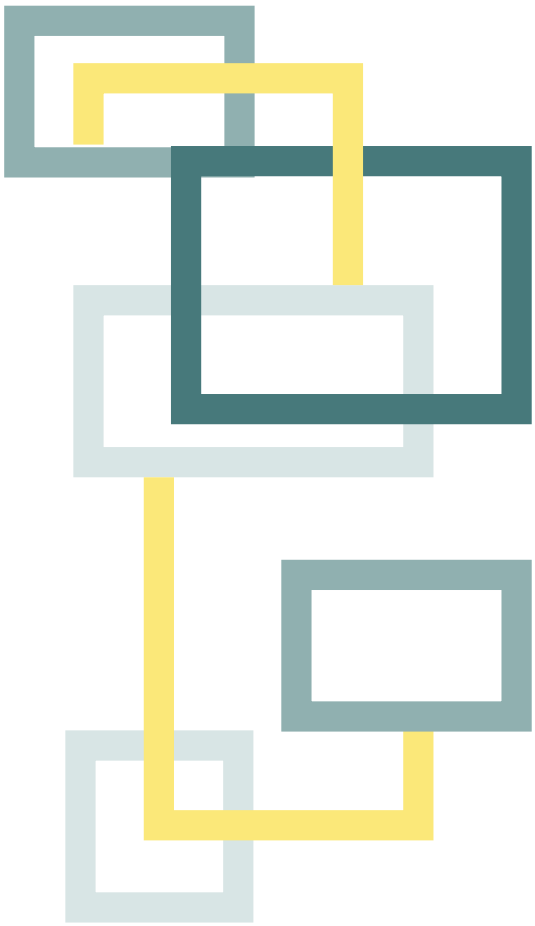
WRITTEN BY: Peter Grant Jr.

MAY 25TH, 2018

The EU's GDPR came into effect, changing the data regulatory environment for biopharmaceutical companies the world over by offering strict guidance on integrity, use and procurement of personal data.

JUNE 28TH, 2018

The California State Legislature passed, and Governor Jerry Brown signed, the California Consumer Protection Act (CCPA) into law, which also has important implications for Biopharma companies operating in North America.



2018 has been a watershed year when it comes to the regulation of consumer data privacy in the biopharmaceutical industry. On May 25th, the European Union's General Data Regulation (GDPR) officially took effect. Little more than a month later, on June 28th, the California State Legislature passed, and Governor Jerry Brown signed into law, the California Consumer Protection Act (CCPA). Both have significant implications for biopharma companies and mark a new era in consumer privacy.

The GDPR transforms EU law as it relates to data protection and privacy for individuals. It was passed into law on April 14th, 2016 and organizations across the business spectrum were given two years to prepare for its official implementation. While the law primarily focuses on data protection for individuals in the EU and European Economic Area, it also contains provisions on the export of personal data outside of these regions. As a result, every organization that does business in the EU is impacted by the law.

The GDPR provides strict guidance on the integrity, use and procurement of personal data. The implications for biopharma companies are manifold, as personal data infuses a wide variety of areas in which they practice. Clinical research is primarily concerned with highly-sensitive personal data. Beyond this, post-marketing activities, advertising, patient outreach, safety reporting and numerous other areas which biopharma companies operate deal with personal data and will be profoundly impacted by the new regulatory environment.

"Personal data is crucial to the pharmaceutical industry's research and development of drugs and therapies," said Kimberly Gold, a partner at the Law firm Reed-Smith. "The pharmaceutical industry also uses personal data for the purposes of marketing to healthcare provider customers and patients, collecting and reporting of adverse events, and recruiting and managing personnel".

"GDPR compliance is not simply a legal problem or an IT project, but an enterprise-wide issue requiring a robust and comprehensive approach," says Ashley Slavik, the Senior Counsel and Global Data Protection Officer at Veeva. "This understanding requires setting the tone from the top, executive buy-in, and resources."

Pharmaceutical companies need to develop internal policies and procedures for GDPR compliance that can be operationalized and complied with. Gold emphasizes that it is not enough to develop a set of GDPR policies and procedures – but rather they must be suitable for the organization's culture and structure – as well as easily understood by employees.

Personnel with exposure to personal data must also be trained on GDPR compliance – this is a key aspect of ensuring that an organization meets GDPR requirements.

Recently a movement in the industry to partner with organizations that can provide de-identified or anonymized data for use in research and development has emerged. This anonymized information is typically not considered personal data and therefore is not subject to data protection laws like the GDPR.

Even as these partnerships proliferate, the use of consumer data covered by GDPR regulations is inescapable. One of the key distinctions that has been emphasized by GDPR regulations is the difference between a data controller and a data processor.

"With the previous EU Data Protection Directive of 1995, legal responsibility rested primarily on the data controller, but the GDPR stipulates shared responsibility between the controller and the processor," says Slavik. "Under the GDPR, the controller determines the purpose and means of processing personal data, while the processor is responsible for processing personal data on behalf of the controller in accordance with its instructions".

The GDPR provides strict guidance on the integrity, use and procurement of personal data. The implications for biopharma companies are manifold, as personal data infuses a wide variety of areas in which they practice. Clinical research is primarily concerned with highly sensitive personal data. Beyond this, post-marketing activities, advertising, patient outreach, safety reporting and numerous other areas which biopharma companies operate deal with personal data and will be profoundly impacted by the new regulatory environment.

Processors, Slavik continues, now must maintain records of personal data and processing activity, and they have liability for data breaches. Controllers must ensure contracts with processors include all of the cooperation obligations. Most companies may act as both a processor (if they provide a service) and a controller (for their employee and customer data for example).

"It is crucial to understand the definitions and the corresponding obligations in order to properly assess your organization's ultimate responsibilities and develop your compliance roadmap," said Slavik.

In addition to these changes, the GDPR stipulates a clearer but more stringent definition of consent. Where consent is relied upon as grounds for processing personal data, it must be clear that the data subject understood and freely agreed to provide such consent. Under Article 4 of the GDPR, consent must be a "freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her."

"Consent under the GDPR," said Gold, "requires a positive opt-in; pre-checked boxes are not sufficient. Consent language also needs to be kept separate from and cannot be buried under other terms and conditions. In addition, Article 7 of the GDPR requires that data subjects be able to withdraw their consent at any time – and that it is as easy to withdraw consent as it is to give consent.

With the GDPR in full effect, more and more companies have established the role of a Data Protection Officer (DPO). Specifically, the GDPR states that a company acting as a data controller or a processor shall designate a DPO in any case where the core activities consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale, or processing special categories of data on a large scale. Additionally, it is both a business imperative and common sense to have a single point of contact to oversee privacy.

"Any biopharma working with personal data would be well served to have a DPO," says Slavik. "The DPO must be qualified with an expert knowledge of data protection law and practices and have the ability to fulfill the following tasks using a risk based approach: 1) inform, advise, and monitor compliance with the requirements of the GDPR through policies (such as a Data Protection Impact Assessment (DPIA)), procedures, training, and audits and 2) act as the point of contact for supervisory authorities and data subjects."

The GDPR also stipulates, Slavik continues, that there must be a contract in writing between the controller and processor which clearly sets out the subject matter of the processing and its duration, as well as the nature and purposes of processing, the types of personal data, any particularly special categories of data, and the obligations and rights of both parties. Failure to have a suitable data processing agreement (DPA) in place is a breach of the law under the GDPR.

"Before entering into a DPA," says Gold, "It is important for data controllers to perform due diligence on data processors to ensure that they can meet all of the requirements of the GDPR. The types and sensitivity of the data, as well as the processing activities, will also have bearing on the negotiation of DPA terms on both the data controller and data processor sides."

While these new regulations may seem complex and onerous, there may in fact be a silver lining for companies that successfully comply with the GDPR. Positive outcomes, Slavik points out, include raising awareness to the importance of data protection and developing a critical mass of people dedicated to the GDPR. An organization can create a network of privacy champions made up of individuals in leadership roles whose jobs demand deeper understanding and knowledge of data protection, or who demonstrate strong understanding of the regulations.

These people become the points of contact for their teams – and integral to turning GDPR compliance from a potential add-on to an employee's day job to something second-nature across the organization. Having people who really understand the impact and implications of the GDPR means you can identify and address potential risks across the business earlier – which enables you to be much more proactive in terms of GDPR compliance.

"While it can be costly and cumbersome for an organization to comply with the GDPR," says Gold, "It is crucial to ensure compliance in order to avoid regulatory investigations, penalties, and lawsuits. From a practical perspective, the GDPR demands accountability and can serve to create a culture of data protection and compliance.

Further, now that new GDPR-like privacy laws such as the California Consumer Privacy Act (and any new privacy law that may come down at the federal level) are soon coming into effect, a GDPR-compliant organization will have an easier time complying, as they can often apply their existing programs to the new requirements."

With the passage of the California Consumer Protection Act (CCPA), biopharmaceutical companies have another set of regulations to take into consideration.

"The top consideration for a pharmaceutical company in approaching the CCPA is how to allocate limited resources toward the CCPA while also addressing the increasing variety of privacy and security regulations worldwide," said Chris Nelson, the Vice President of Marketing Automation and Data Management at Intouch Solutions. "If not carefully planned, resources spent on specific requirements in the CCPA may take away from other compliance efforts, including compliance with the GDPR, which may result in an overall greater risk to the company."

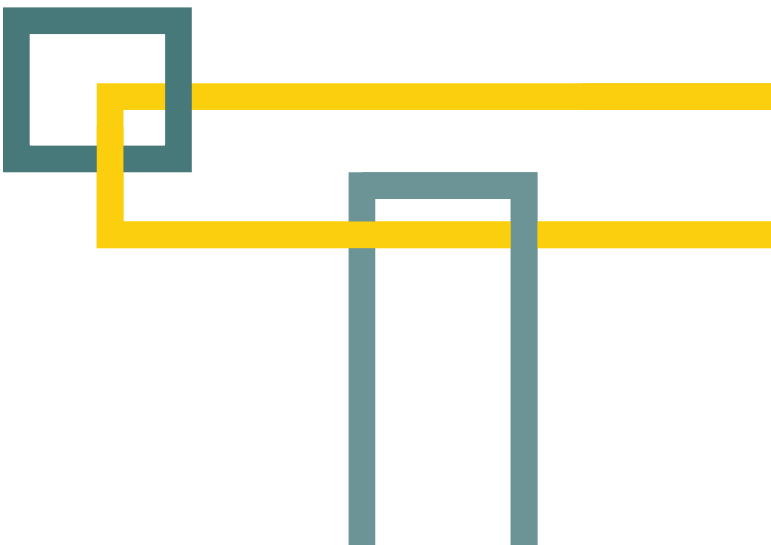
The CCPA, Nelson explains, has been described as California's version of the GDPR. The two laws share significant similarities: both apply to a broad range of "personal information" (rather than being limited, for example, to health information, like HIPAA); both encourage transparency in privacy practices, especially relating to any disclosure of personal information to third parties; and both provide individuals with certain rights to access, amend, or erase personal information, or to opt out of certain processing of personal information. However, there also exist key differences. Here are three examples:

- The CCPA applies to "consumers" who are California residents only and does not apply to employee personal information;
- The CCPA has certain thresholds that a business must qualify in order for the regulation to apply. The GDPR has no such thresholds; and
- The CCPA does not require a "basis for processing," which means that, unlike the GDPR, the CCPA does not impose a consent requirement (opt-in) for the processing of personal information (with an exception for the sale of personal information of a minor).

"We recommend viewing CCPA compliance in the context of an overall privacy and information security strategy," said Nelson."Identify key areas of overlap between the CCPA, the GDPR, and other privacy requirements, and prepare policies and procedures that meet the "highest common denominator."

Although other states are not making as much news as California did with the CCPA, Nelson continues, we continue to see new legislation and regulations impacting privacy. For example, Ohio recently passed Senate Bill 220, which incentivizes compliance with internationally recognized cybersecurity standards by providing a safe harbor from tort litigation for a company that complies with such standards.

Don't forget to keep an eye out for developments in federal law. With some high-profile incidents recently (most notably, Cambridge Analytica), Congress has started to focus on the issue of privacy. Legislation has been proposed that would apply CCPA- and GDPR-like standards at a federal level, but it is too early to tell how much momentum such laws will have in this current political environment.



MONTHLY DEEP FOCUS:

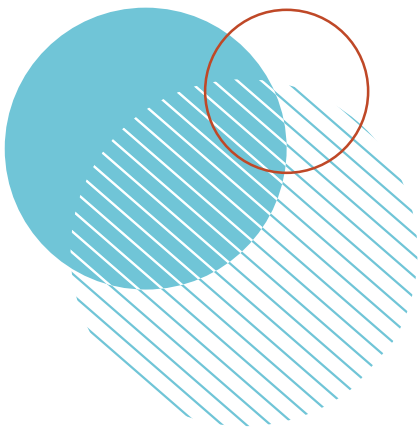
What are some unique examples of the applications of Real-World Evidence (RWE) in the biopharmaceutical industry?

Shailja Dixit
MD, MS, MPH
Founder and President ApexBio
Fellow Health Innovation Technology Lab, NYC

Over the past decades, with increased usage of Electronic Health Records (EHR), adoption of wearable devices computers along with electronic health insurance data across the global patient population have enabled us to capture vast volume and variety of data very fast. It is not necessarily a problem of data scarcity but a problem of plenty!

The real-world data powered by "right" tools & analytics has potential to impact every aspect of drug development and launch. Today it is a well-recognized fact that drug development has become very expensive as well as time consuming. Yet, often, the desired outcomes are still not achieved.

Often patients, providers, and payers lack answers to fundamental questions like: "What treatment is best for me or my patient?", "How do patients treated in the 'real world' perform on this therapy?", and "What is the differential value of this therapy relative to other treatment options?"



The evidence gap persists despite a richness of available data, novel analytic methods, and inexpensive computing and genomic sequencing power. The insights generated from data collected during routine clinical practice i.e. Real-World Data (RWD)—provides a platform which can close the gap from bench (clinical research) to bedside (clinical practice).

Figure 1 outlines the time and percentage of expenditure on each phase of drug development.

Early Discovery & Pre-Clinical Research: By leveraging RWD powered by "right" analytics tools that leverage life-sciences knowledge, we can reveal connections and relationships among genes, drugs, diseases, and other entities. RWE analyses can identify biomarkers of therapeutic response and resistance to optimize a drug development strategy. For example, clinico-genomic database with tumor sequencing information from large patient dataset can help identify and characterize genomic profiles of patients with rapid progression or otherwise poor prognosis. Researchers can generate new hypotheses backed with evidence-based predictions. This approach can cut down risk in some elements of early discovery by focusing on identification of high-responding patient cohorts.

Leveraging Geo-Mapping as a Valuable Tool to Recruit and Design Phase II and III Trials: A few key challenges that impact cost as well as timing of the trials are: ensuring that trial design especially patient population is reflective of real world, identifying 'right" patients for recruitment in trials, and identifying site locations. RWE can help answer these question and geo-tag patients. In certain conditions, especially in oncology, it may not be possible to have a control arm or a control arm can be difficult to recruit – prolonging the trial. Historic Real-World Data can be leveraged to create or simulate a control arm that may reduce trial size (that is, required number of patients), duration, and cost.

Drugs for conditions with high unmet need: Today FDA's Breakthrough Therapy Designation Pathway allows stakeholders to get many essential drugs to patients faster. In these situations, RWE provides an alternative means of satisfying regulatory requirement that is faster, cheaper, and more representative of real-world populations. This is a major win-win for patients and pharmaceutical manufacturers!

RWE has seen a widespread use in early understanding of positioning, pricing, and market size. In a crowded space where many drugs exist for an indication, it's important for companies to identify in

Fig. 1

Problem

Drug Research/ Discovery	Development/ Pre Clinical	Clinical Trials	FDA Review	Phase IV Studies
Basic research	Laboratory and animal testing	Patient testing	1 Drug approved	
10,000 compounds screened	250 compounds tested	5 compounds tested		
5 years	**1.5 years**	**6 years**	**6 months - 2 years**	**3+ years**
27% of R&D spend		**54%** of R&D spend	**5%** of R&D spend	**14%** of R&D spend

Solution

Preclinical/ Phase I	Phase II	Phase III	Market	Phase IV
PK/PD driven drug development	Curate and standardize biomarker data for clinical trial participants	Better trial design Targeted point recruitment Precicely target highest levels of unmet need	Medication adherence Engage payors much earlier in R&D Combine health, social and behavioral patient data	Combine RWE with FDA adverse event reporting system Include social media for signal validation Conduct studies with RWE cohorts

what population sub-set the drug works best and what is the differential value.

Indication expansion is an important part of lifecycle management and has tangible benefits for patients. Label expansion is often very important for ensuring clinical guidelines, inclusion, and treatment coverage. Recently, the FDA launched Friends of Cancer Research's efforts program to identify older products needing updates in labels specifically for generic therapies where labels no longer fully reflect how a therapy is used in practice. Although the pilot was terminated due to complexities related to execution, if used with right framework RWE has potential to provide evidence required for such initiatives.

As healthcare landscape becomes more complex coupled with ever escalating cost of care, RWE has potential to provide valuable insights and bring efficiencies that are much needed by all the stakeholders: be it pharmaceutical companies, patients, providers, or payers. There is a need to democratize the data and tools so that the RWE is readily available to small and mid-sized companies. With advancement of machine learning and Artificial Intelligence, we will see wider adoption and usage of real-world data (RWD).

New UK Collaborative Uses AI to Predict Missing Data Points in Compound Data

WRITTEN BY: Frederick Dawson

A new UK collaboration focuses on taking sparse data – data where a significant amount of points are missing from the complete sets – or "noisy" data – data where a significant amount of variables could contribute to issues and changes in results – and making predictive models that fill in missing points with degrees of certainty and without having to undergo costly experimentation.

A new UK collaborative start-up is looking to use AI to predict missing data points in compound data. The collaboration is between Intellegens, a process modeling company spun out of Cambridge University, Optibrium, a provider of software solutions to the pharmaceutical industry, and the UK Medicines Discovery Catapult, a non-profit created by the UK government to support the creation of businesses in targeted sectors such as medicine.

Together the three entities have created a technology that will be able to predict missing values in sparse data sets to provide better direction in drug discovery and cut down on the amount of costly testing companies need to undertake. This has led to the collaboration being awarded £1m in funding from the UK government.

"There's a lot of hype about AI in drug discovery and it's building to a crescendo at the moment," says Matt Segall, chief executive officer and company director of Optibrium. "We've been looking at what tech will make a real difference. Lots of people are doing the same old things in the same old processes with shiny new toys. And there are also lots of same old toys being rebadged as new." Each member in the collaboration brings an essential tool to the project.

Intellegens developed the actual software used in making the predictions. Optibrium has experience in drug discovery and has developed a software setup called StarDrop that helps with the complete process for analysis and visualization of data.

And the Medicines Discovery Catapult organizes the collaboration while also undertaking database facilitation, benchmarking and access.

Intellegens originally developed its software in the material sciences field. It thought there could be other applications for it and wondered if drug discovery would be a candidate. After discussions with Optibrium, it was found to be a near perfect match.

The model focuses on taking sparse data – data where a significant amount of points are missing from the complete sets – or "noisy" data – data where a significant amount of variables could contribute to issues and changes in results – and making predictive models that fill in missing points with degrees of certainty and without having to undergo costly experimentation.

"The work translates beautifully to biology," says

Segall. "It's very noisy in biology. You can do the same test five times and get five different results. It's also very sparse. A big pharmaceutical company may have some data on a couple million compounds – all of which can have thousands of assays run on them such as different physical chemical properties or solubility. But for all of those different experimental data points, they'll only have measured only a handful per compound."

No compound will have had all assays run on it. And no assay will have been run on all compounds. Meanwhile biological experiments can produce different results from something as simple as how cells are handled, he adds.

The companies hope the new development can go some way towards solving this without involving significant amounts of expensive testing of compounds. A proof of concept study for the collaboration's system has been undertaken on an industry database. Results were favorable and have been submitted for peer review in the Journal of Chemical Information and Modeling.

Optibrium will be responsible for commercializing the technology once fully proven and developed. But that is still some degree of time away, according to Segall.

It is about a two year development program before fully going out to market, though there is a web app that customers in pharma as well as other verticals are paying to access, adds Gareth Conduit, chief technology officer and co-founder of Intellegens.

The full idea is that a company would be able to take its proprietary information on what happens to proteins when a certain drug is injected and combine that with other data such as publicly available sets to train a model and predict missing values.

This then means a company avoids having to conduct an experiment to check that particular process. "It can predict what value it would be," says Conduit. "You can also say: 'We want to activate this protein and deactivate that one. What would do that?' And the modeling should be able to propose a brand new chemical that could satisfy those targets."

Further uses in commercial situations could be for double-checking information. The model could go in and predict all values in a data set then compare that to what has been identified in a set. Those values the furthest away from what is in the sheet could point to potentially incorrect values – for example numbers that have been mistyped or lost in transcription – both common enough occurrences in drug discovery, he adds.

And the model could be used to identify which assay pairs could be of interest for further experiments. "You can say: 'There are ones in which if we perform one additional experiment here, it would give us a lot of information about that local chemical space to really help us extrapolate into that new domain and understand what is going on,'" says Conduit. "We can do experiment design to recommend what is most important to do to gain the most additional information out of each of the experiments the clients perform."

Overall the collaboration has a commercial advantage over others working in similar areas when it comes to data sets with sparse points. "That's where the company has the competitive edge," Conduit adds.

The Medicines Discovery Catapult recognized this. As part of its mandate it provides capabilities that small companies would otherwise be unable to access due to prohibitive costs and effort, according to John Overington, chief informatics officer at the Medicines Discovery Catapult.

In the case of Intellegens and Optibrium, the Catapult provides access to large databases and puts them in a format capable of being used for machine learning. "[We're] good at finding data and putting it in a form that feeds machine learning right away," he says. "For a company to do that in-house is a huge overhead. It would require a librarian type organization or mindset. Leveraging outside help is a good way to do that instead."

In the field of drug discovery there is not easy table of data for assays and compounds. The information may exist but it will be published as part of an in-depth study. Medicines Discovery Catapult has found a way to draw this data out and model it in a way machine learning algorithms can process.

"There are not these nice tables of data you can extract and put into a database. They tend to be published as one compound studied in-depth in a specific journal in that field. It's very hard to extract that data from the literature to understand and model it."

Medicines Discovery Catapult is only a couple months into the two year period of the £1m grant. During that time it will work with the companies before moving on to help other partners. By that point Optibrium and Intellegens shall have hopefully proven that their model is significantly more accurate than anything else out there. If it proves to be more than 10% more accurate than current models, it could create a quantum effect on productivity, Overington says.

"In olden days, which turns out to be the 1990s, people used to make compounds and then test them and that make and test cycle was very expensive. But it turns out that for a lot of tasks you're interested in something like solubility. So because solubility is a common feature, there's a lot of data out there for it. So people began to investigate predictive models that replace the experiment in many cases," he adds.

"The field has gone quite a long way in the development of predictive models but there's a limit to how accurate they are and they need to be more accurate to have a quantum effect [which is hopefully what Optibrium and Intellegens have done]."

MONTHLY DEEP FOCUS:

What are some unique examples of the applications of Real-World Evidence (RWE) in the biopharmaceutical industry?

Nancy A. Dreyer
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Real-world (RW) evidence is gaining attention from regulators, payers, and health care providers looking for new ways to understand the safety and effectiveness of medical treatments.

Interest in RW evidence has grown, in part, due to the trend toward precision medicine and the rapid growth in specialty drugs. Experts have estimated that roughly half the money spent in 2020 for the pharmacy benefits will be for specialty drugs that will be prescribed for fewer than two percent of patients.[1] Unlike blockbuster drugs, which serve large markets and use traditional evidence generation through classical randomized clinical trials (RCT), it is unrealistic to expect to satisfy stakeholders' evidence needs with RCT for each patient subgroup and setting of interest for these specialty drugs. This is especially true when you consider the median cost of a phase 3 trial was roughly $21.4 million in 2016.[2]

Interest has also been stimulated by the notice in March 2016 from the FDA that it would include the use of RW evidence in regulatory decision making within the context of the Prescription Drug User Fee Act (PDUFA) VI for 2018-22, followed by passage of the 21st Century Cures Act. These actions sent a clear signal to the biopharma community that the FDA is willing to consider applications that use RW data within the proper context and situations. This clear indication of interest has generated several new use cases for RWE in biopharma applications, including the following examples:

Real-world data comparators for single arm trials: Recognizing the importance of niche markets, we are starting to see successful submission of single arm trials supplemented with comparator information derived from contemporary RW data. Consider the recent approval of Avelumab as a treatment for metastatic Merkel cell carcinoma. EMD Serono offered up contemporary data on overall response and duration of response from registry and electronic medical record data. These RW benchmarks highlighted the dramatic improvement offered by the drug and helped to secure product approvals in the USA, the EU, and Japan.[3] That said, this strategy works best when a group of strong responders can be identified and studied since regulators are more likely to be persuaded in situations where a product shows a marked improvement – generally 30% or better – no small hurdle. Smaller effect sizes, although important, may be masked by various types of bias present in non-interventional research.

Using real-world outcomes in pragmatic randomized trials: Pragmatic clinical trials use randomization to assign treatment, generally comparing a new therapy to other treatments that a patient and doctor might realistically use. The outcomes are then evaluated that actually present within typical practice settings, instead of using surrogate markers that are typically relied on as part of the traditional RCT approach. Randomization is such a familiar tool that these studies automatically gain more credibility than a simple non-interventional study, or supplementation of a single arm trial with RWD.

Nonetheless, after randomization, pragmatic trials are very much like non-interventional studies since clinicians observe patients as they present for care and conduct tests and measurements that are generally consistent with customary medical practice. These studies are generally conducted using approved products, without masking the product identity, and use less source-data verification than classical RCT. Thus they are substantially less expensive than classical randomized clinical trials and more interesting to diverse stakeholders than comparisons of active treatments to placebos.

Although challenging to compare a new product to active comparators, we are seeing some traction by regulators. One of the most exciting recent examples is the Paliperidone Palmitate Research in Demonstrating Effectiveness (PRIDE) study of treatments for patients with schizophrenia, which was used successful to secure a label expansion.[4]

Interest in RW evidence has grown, in part, due to the trend toward precision medicine and the rapid growth in specialty drugs. Experts have estimated that roughly half the money spent in 2020 for the pharmacy benefits will be for specialty drugs that will be prescribed for fewer than two percent of patients.

The PRIDE study compared treatment of a monthly injection with palmitate injection to daily oral antipsychotics in schizophrenics who were recruited from nontraditional locations such as homeless shelters and jail-release programs, and who had been incarcerated at least once during the prior two years. They were offered a choice of oral anti-psychotics or flexible dosing with a monthly injection. Those willing to participate under those conditions were then randomized and followed for 15 months. The study showed that patients using the injection had substantially lower rates of treatment failure, suicide attempts, and re-institutionalization.[5]

Direct-to-patient studies: In direct-to-patient studies, patients provide data relevant to their treatment experience, including the impact of their condition on their day-to-day life, whether they adhere to treatments and why, etc. These studies tell us what is most important to patients.

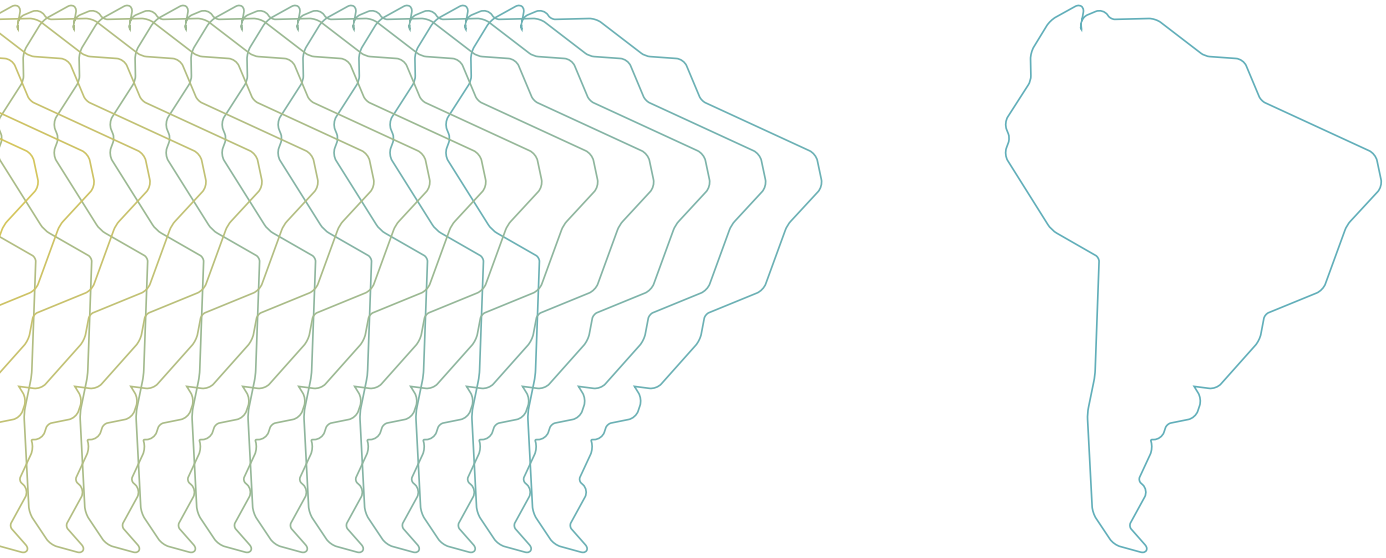
In the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium (PROTECT) study, pregnant women across Europe shared their medication use during pregnancy, and reported details about prescription and over-the-counter medications they took during pregnancy, use of recreational drugs as well as homeopathic medications, and the eventual outcomes of their pregnancies.[6]

The study showed that women correctly reported most prescription medications. In contrast to data that could be obtained through pharmacy prescription databases, this study also showed that roughly 25% of these women reported taking non-prescription medications, many of which were not recorded in their electronic health records.[7]

While they were less accurate in reporting the medical details of possible adverse pregnancy outcomes, the study has led to a new model for this type of research where long-term follow-up can be accomplished through direct contact with treated patients, and medical events of special interest can be confirmed by additional follow-up with their medical care providers. This model points to the positive potential of driving budget toward follow-up activities and selective follow-up, while minimizing routine study-driven doctor visits for mostly healthy patients, resulting in study savings of 50% or more.

The future of real-world evidence

These examples show new uses of RWE to generate information that can be used to guide treatment and pharmacy benefit decisions, as well as new applications of interest to regulators in support of faster approval of medicines to treat serious and unmet needs, both in rare diseases as well as for niche oncologic indications. These approaches offer huge potential for new, cheaper, and quicker insights. However, this is a new territory, particularly for regulators. Since there is no formal guidance yet, biopharma companies should consult with regulators to keep abreast of what evidence they find reliable, as well as if and when any validation or other supporting evidence will be needed.



The Benefits of Data Sharing Yet to be Fully Appreciated by South American Pharmaceutical Industry

WRITTEN BY: Frederick Dawson

New Startups are emerging in Brazil and across South America that are dedicated to healthcare data collection.

The South American Pharmaceutical industry has yet to fully embrace data sharing practices.

Issues of data sharing are demonstrated by a new AI-driven healthcare package being developed in Brazil. The company behind the plan told Rx Data News that no South American pharmaceutical company has shown any interest, at this time, in collaborating or purchasing any data produced.

UIBI, a robotic device and app designed to aid children with chronic diseases, collects information on completing courses of medication as well as other health-related choices for a variety of long-term diseases.

But Bruna Paese, the managing director behind it, said that she had not been able to get South American pharmaceutical companies to agree to do anything with the data collected. The set represents significantly more than simple information on whether a patient has taken their entire course of medicine, she says. It includes a unique combination of environmental, biological and personal readings.

"It's more than just data collected. It can provide background environmental data and how decisions relate with biologic past. It can provide a powerful knowledge solution – more than just taking a pill and seeing if a prescription is being followed – but a gathering of important and interesting data that no one else has access to," she adds.

This can include weekly accurate measurements of data points such as temperature, heart rate and oxygen levels.

IUBI can also play a role in the ongoing opioid addiction crisis. Practitioners have traditionally found it difficult to assess pain levels for children using traditional scales. IUBI can take more constant measurements of this and add in qualitative information to develop a fuller picture, Paese says.

Altogether the data could help both insurance and pharma companies to produce better results at lower costs. Nonetheless no companies have expressed an interest in partnering with it. Part of that is down to scale admits Paese. The project is a start-up with an ambition of only placing around 1,000 pre-orders for units before distribution starts in May 2019.

Overall that is a very small basis for a sample population. But it is also a small target population too. IUBI is designed specifically to work with children that have health issues that require a course of treatment longer than three months – with the exception of diabetes, which would require a separate set of parameters to work.

Issues such as cancer and HIV however would be ideal candidates for IUBI trials. And the company could provide useful information to a pharmaceutical firm working in those areas. But there has not been a response.

As well as size, utilizing start-ups as suppliers plays a part in the reason why – and that is a factor that comes into play in more sectors than just pharmaceuticals. A major barrier to growth for start-ups across all sectors is agreeing supply deals with larger firms that have established procurement routines.

And, Paese adds, South American pharmaceutical companies she has talked to have also been satisfied with their own generated data – uninterested in partnering with outside organizations to find new sources and new uses for those sources. "They say they don't want to just track patients – it's not a big deal for them now," she says. "Their attitude is they have their own data – why buy others?"

But the collection of further end-user data could provide new insights that lead to improvements in efficiency or cuts in cost. The entire premise behind IUBI is to cut down on the number of children that do not follow processes required by treatment. The company estimates that 55% of children do not suitably follow, or completely abandon, prescribed courses of treatment.

Paese says that health care workers report communication with patients to be the greatest problem following discharge. IUBI, an AI driven app and robotic assistant, helps to combat this through a number of means including gamification.

The general premise is that the child teaches the robotic assistant, which questions the activities performed by the user and offers suggestions. This can involve a variety of tasks ranging from taking medication to looking for healthy snacks using an augmented reality feature.

If an action is fulfilled in the right period, it gains points and the system evolves. If the child experiences low interaction with the app, parents receive notifications and suggestions about how to help the child complete the activity.

Other problems, such as collection of data on health from a child are addressed in a different way. For example, to gather information on temperature, heart-rate and oxygen children are told they must hug their IUBI once a week to "charge" it.

"Each user has a customized experience, that is, the game changes according to the needs of the child and the parents. This is unique in the world and allows us to go beyond a tool to educate. We help the patient to become healthier and to be protagonist of the treatment itself," Paese says.

IUBI is undergoing a crowd-funding campaign on the site Indiegogo.

MONTHLY DEEP FOCUS:

What are some unique examples of the applications of Real-World Evidence (RWE) in the biopharmaceutical industry?

Leela Barham
Independent Policy Expert and Health Economist
Leela Barham Econonic Consulting, Ltd

There's a buzz around real-world evidence (RWE) – the evidence that comes from analyzing real-world data (RWD). RWD can be based on a host of types of data. It can be data held in electronic medical records and lab reports, billing data, or data generated entirely outside of the health care system – such as patients contributing their experiences in online forums or social media. Whilst not everyone agrees on a definition of RWE, a key distinction is that it is based on data that is not from a randomized study, such as a randomized clinical trial.

The buzz is being generated because of the myriad potential ways that RWE can be used. This includes informing the whole pathway of a biopharmaceutical: from R&D through to safety monitoring, as well as being helpful to secure commercial success, according to McKinsey analysis.

With so many options for generating RWE available, it's not so much a question of unique applications but rather, what are the best applications of RWE? According to companies surveyed by Deloitte in 2017, is the biggest opportunity to leverage RWE is in market access.

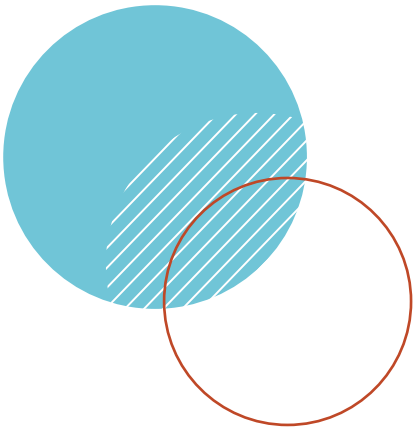
In the UK – credited as a major country in RWE – there are precedents of using RWE to help companies achieve the much sought after approval from the National Institute for Health and Care Excellence (NICE). They include using data from the Systemic Anti-Cancer Therapy (SACT) database in the appraisal of Osimertinib in the treatment of locally advanced or metastatic EGFR T790M mutation positive non-small cell lung cancer. SACT is a dataset on the use of systemic-anti-cancer therapies, including outcomes. Other RWE came from a Type IV amucopolysacharidosis disease registry used in a submission for Elosulfase alfa. In these examples, RWE has helped achieve temporary reimbursement.

NICE is not alone in drawing on RWD. Other HTA agencies in Europe draw on it too. In the US, there's been discussion of the potential for RWE to inform coverage decisions from the Institute for Clinical and Economic Review (ICER); in no small way shaped by the UK perspective too, reflecting collaboration from the UK-based Office for Health Economics (OHE).

RWE can go beyond meeting the needs of HTA agencies and support a more flexible approach to pricing and reimbursement. RWE can help explore when a biopharmaceutical works – and from a payer perspective, equally important – when it doesn't.

Price can flex in response to RWE – most likely down, not up in today's cash-strapped systems. In the USA, such deals are referred to as Value-Based Contracts (VBCs) or Outcome-Based Contracts (OBCs). An example includes the US not-for-profit Harvard Pilgrim Health Care striking a deal with Novartis for Entresto (sacubitril/valsartan) in heart failure. Under the deal, hospitalisations will drive just how much Novartis gets paid. That's RWE, in an OBC, in action.

RWE may be accepted by some payers, yet there is still a way to go to convince all payers that RWE is a credible source of data. It's a fair point too. After all there are studies as highlighted by Parexel that have found that using RWE can deliver results that are more favourable in terms of cost-effectiveness than drawing on randomized controlled trial (RCT) data. It's just that RCTs can't answer all the questions that payers' want answered. RWE can step in to help fill those gaps and shape commercial deals. It's this potential that may see RWE become routine, and most definitely not unique.



Real-World Evidence Case Study:

GSK's Salford Lung Study

Leela Barham

Ground breaking new GlaxoSmithKline study uses real-world evidence to come to novel conclusions.

Real-world evidence (RWE) – essentially evidence generated from any data collected outside of a randomized controlled trial (RCT) – is something that stakeholders want, because everyone wants to know whether a biopharmaceutical really works when it's used 'in the wild'. Health Technology Assessment (HTA) agencies and payers are particularly interested in not only whether a drug is effective and not just efficacious, but also in whether the drug offers value for money in their patients, many of whom may differ from those studied in a an RCT. What can be learned from the world's first pragmatic clinical trial?

GlaxoSmithKline's UK-based Salford Lung Study (SLS) is a world first; it's the first time that a phase III pragmatic clinical trial has been run. RWE is at the very heart of the study to explore the benefits of Relvar Ellipta (fluticasone furoate/vilanterol in a dry-power inhaler) in both Chronic Obstructive Pulmonary Disease (COPD) and asthma.

The study built an extensive database covering a host of information drawing on electronic health records from across the National Health Service (NHS), from primary to secondary care. Collaborators included NorthWest EHealth (NWEH), the University of Manchester, Salford Royal NHS Foundation Trust, Salford Clinical Commissioning Group's General Practitioners and community pharmacists. That's just those who formally collaborated in the study; GSK also sought the views of the UK regulator, as well as the UK's Health Technology Assessment (HTA) agency, the National Institute for Health and Care Excellence (NICE).Plus patients used apps to help collected patient experience data too.

The database covers more than 6,000 patients, capturing how often they went to see their GP, went to hospital for an outpatient appointment or needed emergency care as well as prescriptions over a year. The database probably qualifies for the moniker 'big data'. By March 2016, it included over 55,000 patient visits and 235 mil-

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lion rows of data. That is what £80 million can buy you.

With the SLS starting in 2012, top-line results emerged in May of 2016. They revealed that Relvar Ellipta reduced severe COPD exacerbations compared to standard care. That is even more impressive against the backdrop of failure on this trial metric in a 2015 trial. They also showed that costs were higher for patients on Relvar Ellipta because they saw their GP more often than patients on standard care.

A year later in May 2017, top line results came out for asthma finding that asthma was controlled in 71 per cent of patients on Relvar Ellipta compared to 56% of those on standard care as measured by the Asthma Controlled Test. Secondary endpoints also showed patients on Relvar Ellipta had higher quality of life and a greater fall in work impairment but there were no differences in use of health care.

Searching for the results of the SLS generates the type of hits you'd expect: media reports on the clinical results plus academic articles and more than a few white papers and position pieces on the potential for RWE, citing the SLS as an example. There is little, even as time has gone on, to help understand whether the SLS has delivered on the ambition to give stakeholders – particularly UK HTA agencies and payers – the evidence that they want. For example, NICE doesn't appear to have updated its 2014 evidence summary on Relvar Ellipta in asthma, nor its 2013 evidence summary on Relvar Ellipta in COPD.

Relvar Ellipta is paid for by Clinical Commissioning Groups (CCGs) – responsible for planning and delivering primary care in the English NHS - who each have their own local decision-making processes to inform their formularies. Timelines for review of many formulary decisions don't always coincide with when new evidence comes out.

With Relvar Ellipta, many formulary decisions were made in 2014 soon after Relvar Ellipta was given its marketing authorization from the European Medicines Agency in November 2013. Some of those formulary decisions will have gone through one round of review, but before the results of the SLS were available. Formulary positions haven't necessarily yet – formally at least – referenced the SLS. GSK has naturally stepped in to provide COPD formulary guidance – published in October 2017 – that includes the SLS.

The absence of formal referencing the SLS in documents like NICE's evidence summaries and formularies isn't however an indication that the SLS hasn't had an impact (there is always the absence of evidence doesn't mean evidence of absence argument). Relvar Ellipta was already included in many formularies. There is variation though; could the SLS could help get on to those formularies where it isn't already there? Plus it may be the case that the results from the SLS have given prescribers reassurance.

It's also possible that with the SLS being a world first, there is the potential for precedents to be set. Stakeholders like HTA agencies and payers are likely to want to reflect more on the role and weight to place on RWE as part of the suite of evidence they draw on to make decisions about what, when, and how to reimburse. There is, as with much in the economics of pharmaceuticals, a need to consider context and there isn't likely to be a one size fits all view on what RWE is useful along with the how and when it should be used. That explains the plethora of initiatives to tackle just those issues including the Innovative Medicines Initiative (IMI) GetReal project.

Nor are there any hints how the SLS has contributed to uptake of Relvar Ellipta in the UK in what is a crowded class. What is there is the assertion, coming from some in the NHS, that the adoption of approaches like the SLS can help assure and accelerate getting to market. Of course, there will be a host of other drivers too; not least of which is the cost of Relvar Ellipta and competitors.

Further afield there are hints on how to make the most of the SLS with payer audiences. Laura Vallegjo-Aparicio, working in market access at GSK in Spain, along with others, has used the SLS data to inform a cost-consequence analysis of using Ellipta in COPD in the Spanish NHS, published in June 2018. The headline is the potential to achieve savings because of the reduced rate of exacerbations seen in the SLS compared to usual care.

It's too soon to know how RWE can really be useful in helping achieve market access but there is at least much potential to explore.

COMPLIANCE CORNER

Giving Your Compliance Program An Edge With Spend Analytics

Compliance programs have evolved - but so have their risks

Mohammad Ovais
Founder and Chief Executive Officer
qordata

With changes in the CMS Open Payments system, it's easier for medical drug and device manufacturers to submit their spend data. But is ease of submission the same as ease of mind? Studies suggest that although CCOs have more confidence in their compliance programs than they did when the Sunshine Payments Act was first rolled out, their apprehensions about risks surrounding pharmaceutical spend have not gone away. The risks compliance professionals remain most apprehensive of,include:

1. Kickbacks
2. On-Label/Off-Label Promotion
3. Foreign Corrupt Practices/Poor International Distributor Due Diligence

Roughly over a third (35.78%) listed kickbacks as the biggest risk to the industry, followed by on-label/off-label promotion (11.93%) and then FCPA violation (11.09%). On average, at least two Big Pharma companies have been making front-page news for violating the anti-kickback statute since 2015. Many more feature elsewhere every month.

The issue isn't the prevalence of compliance risks, or lack of knowledge about them. Indeed, even applicable manufacturers in the small and mid-sized segment have clear guidelines that educate their teams about potential compliance incidents.

Rather, the real problem points the other way: There is too much information. Since 2013, each applicable manufacturer has on average, submitted payments data worth $24.21 million via 6,805 records.

Year	Applicable Manufacturer	Average Value ($million)	Average Records
2013	1,428	3.03	3,228.29
2014	1,627	4.93	7,400.12
2015	1,609	5.23	7,719.08
2016	1,600	5.51	7,750.00
2017	1,525	5.51	7,567.21
TOTAL	7,789	24.21	6,805.75

Given the ultra-competitive, highly-regulated environment of the industry, the consolidation of data is a very real challenge. In other words – on any given day, a compliance professional will never be short of work.

Year	Applicable Manufacturer	Payment Value ($ Billion)	No. of Records (Million)
2013	1,428	4.33	4.61
2014	1,627	8.02	12.04
2015	1,609	8.42	12.42
2016	1,600	8.81	12.4
2017	1,525	8.4	11.54
TOTAL	7,789	37.98	53.01

When spend data is compiled manually, or even through systems (i.e. expense management), ERP data, hard copy receipts and sales logs that separately collect data, the probability of error is real. In our work at qordata, we've uncovered incidents of the same physician's name being recorded in two different ways by sales reps, the same drug being identified differently, depending on the state it's being distributed in, and so on. It's not hard to imagine how these oversights feed into the risks mentioned above. We don't expect incidence volume to decrease anytime soon.

Can analytics in the compliance process solve these problems?

Compelling evidence says yes.

Our work with some of the world's largest pharmaceutical brands confirms that using spend data analytics in compliance reduces both operational and reporting cost by 50%, while improving accuracy by 70%. Compliance programs using spend analytics experience operational accuracy by 80% compared to those that do not.

Getting the most out of data analytics

Like output from any other BI solution, pharma spend analytics start by offering data visibility. The benefits of data visualization are manifold. They allow decision-makers to not only spot problematic data entries, but also to instantly assess their magnitude and direction.

In other words, pharma-compliance professionals get instant answers to:

▼ How big is the risk?

▼ How controllable?

▼ Who can mitigate it?

Risks often materialize in the form of outliers—any data that fails to fit in within an acceptable range. Some compliance officers incorrectly assume that only very large anomalies ('macro payments') are problematic. But even small payments hint at big problems. In the past, our team uncovered incorrect entries precisely by following micropayments in Consulting Fees. These entries are easily fixed— provided they are detected in time.

Number Of Transactions By Threshold In Consulting Fee

Year	≤ $1.00	≤ $10.00	< $25.00
2013	662	2,694	2,959
2014	4,901	557	6,555
2015	237	169	4,987
2016	24	188	692
TOTAL	5,824	3,608	15,193

Unsurprisingly, we find that erroneous entries—such as missing or redundant data is often the byproduct of data "entered in a hurry". Marketing and sales professionals are reportedly the worst at adhering to compliance processes. When asked to name the "department that most frequently has difficulties adhering to healthcare compliance laws and regulations", 60.78% named sales and 17.64% named marketing: the only answers to get double-digit responses.

For those managing several health-care practitioner (HCP) relationships at a time, it is not unusual to enter spend data incorrectly — for instance, by abbreviating or misspelling first names, assigning spend to the wrong category (Nature of Payments), or failing to enter the correct drug ID. It's easier to gain support for internal changes when the Governance, Risk and Compliance (GRC) function knows where the erroneous entries are coming from, and their impact on the overall spend report.

Mastering data is a prerequisite to producing analytics. When a solution does the data cleaning, sorting and categorization on their behalf, users can effortlessly isolate values that distort the overall spend picture. Interactive dashboards help with drill-up and drill-down analyses, and provide all the quantitative support needed in investigations. In ride-alongs, for instance, compliance professionals can use analytics to zone in on a specific sales rep instead of combing the data to find out what went wrong, when, and with which HCP.

In my interactions with GRC professionals, I'm surprised by how many worry about the "unknown unknowns" in their physician spend data. And that, in my opinion, is where they can get the maximum mileage outof their spend data analytics. A pie chart describing R&D spend for the year, for instance, can tell you more about questionable spend with HCOs than scrutinizing several spreadsheets of annual data.

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Monthly Deep Focus: Nancy A. Dreyer, MPH, PhD

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