

Achieving Agility: Real Breakthroughs Belong to the Bold

As the old adage goes, if you keep doing the same things it can't come as a surprise when the outcome doesn't improve. Organising data differently offers a way to change that, says AMPLEXOR'S Siniša Belina

It seems counterintuitive that life sciences companies should strive for operational agility and competitive inventiveness, when there are so many regulatory obligations to get past. Red tape is traditionally the enemy of nimbleness, an imposing barrier to innovation; to breaking the mould and doing things differently. It is hard to be responsive to new opportunities when there are so many *is* to be dotted and *ts* to be crossed.

Yet the call to transform and innovate is clearly being heeded. Current merger and acquisition activity¹ is a clear sign that companies are reviewing and honing their portfolios to stay ahead or establish an advantage. In an industry that, by necessity, moves so slowly (inventing and developing new medicinal products is hardly something that can be executed overnight), acquiring attractive product lines or promising start-ups, or merging with businesses that can fill emerging gaps, is organisations' best bet at keeping pace with market change.

For these investments to start paying their way, the process of absorbing those acquired entities needs to be smooth and efficient. Beyond structural and financial considerations, and branding realignment, product data from the merged lines needs to be assimilated.

The vast majority of life sciences organisations are already struggling with huge volumes of data however, which is strewn across their operations, collected and used for a range of different purposes. With each merger or acquisition, this situation is further exacerbated, and data becomes even more unwieldy.

So if companies are to truly capitalise on their new ventures to get ahead of the curve, they need to get all of this data under control.

The challenge for most companies is that there are so many different software tools, each using their own data set, to support a particular function and task. Not only does this singular application limit the return on investment of each software system, it also creates additional work if data needs to be re-used elsewhere – in manual re-entry, in de-duplication/checking it is the most up-to-date version of the 'truth', and in reformatting or data adjustments to meet the current need. Each new process takes time, costs money, and introduces new risk – of human error, for example, or that the information being used may be incomplete or out of date. All of which is likely to lengthen the time to market, and with it the time to market advantage and the time to revenue.

2017 Budget Priorities

In almost every industry that is being digitally transformed or disrupted, it is data that provides the all-important differentiator – the key to new discoveries, insights and opportunities, and the ability to turn these into new services. The ability to collate, consolidate, cross-analyse and readily access and repurpose data is at the heart of some of the most ambitious and successful new business models – from Google and Facebook; to Uber and Airbnb; to IoT apps, including those involved in pre-emptive health monitoring.

If exploiting data strategically was easy though, all businesses would be doing it. Yet information management is highly complex, particularly in life sciences, and bringing multiple sources together in an intelligible form is no mean feat. These might range from structured database files to spreadsheet entries, manual

notes, emails, and PDF scans or attachments. It is hard enough to combine these assets, let alone interrogate them reliably for the insights they might contain.

If this wasn't enough of a challenge, companies' data alignment projects need a clear and specific driver and a robust financial case. The hope was that the regulatory requirements around IDMP would provide that, giving life sciences organisations the strongest reason yet to get their data assets in order. However, repeatedly shifting deadlines² and a lack of specific enough guidance have caused companies to lose momentum with associated projects. Here was a chance to get everyone behind data transformation, and the benefits of a streamlined, consolidated, digital-first approach to product information – a chance to secure budget to put behind the big dream of transforming the way they manage data. Without a hard deadline and fixed terms to meet, however, upper management teams have become distracted, prioritising other more urgent projects instead. Lamentably, as companies take their foot off the pedal with IDMP and associated data transformation initiatives, they risk jeopardising their responsiveness to new opportunities because they will continue to lack the agility required to capitalise on them.

The more pressing compliance issues which are consuming their attention in the meantime include updated EU pharmacovigilance legislation, which has brought about significant changes to electronic reporting requirements for suspected adverse reactions, to support better safety monitoring for medicines and a more efficient system for stakeholders. EMA aims to launch a new EudraVigilance system with enhanced functionalities in November 2017. New requirements include using the ISO/ICH E2B (R3)

data structure (an update from the current R2 format) for individual case safety reports³.

In the US, eCTD (the electronic common technical document standard) continues to be a priority as electronic marketing submissions become the default⁴. eCTD requirements for submissions to CDER and CBER will come into effect on May 5 this year. From that date, new drug applications (NDAs), abbreviated NDAs (ANDAs), biologics licence applications (BLAs), and master files must be submitted using the eCTD format. A year on (from May 5, 2018), commercial investigational new drug applications (INDs) will also need to be submitted in this form. Following those deadlines, submissions that do not use eCTD will not be accepted.

Beyond pharma, other life sciences sub-sectors including medical devices, cosmetics and food supplement manufacturers are also under increased pressure to get their product data in order. Here too now, regulatory bodies are placing more emphasis on electronic submissions and information management processes as part of their efforts to increase safety and improve traceability. As the affected manufacturers start to distance themselves from paper- and spreadsheet-based information management, it makes sense that they look laterally at the wider opportunities this introduces, rather than buying into targeted, single-purpose systems.

Cloud Could Prove a Distraction

Many of the more exciting innovation imperatives for life sciences involve dynamic collaboration through secure and strategic data-sharing with complementary service providers across the wider ecosystem or supply chain. This becomes easier once data is managed systematically across an organisation in such a way that supports multiple uses, including those not yet imagined. The point is that companies need to leave themselves open to the wider potential, rather than box themselves into a corner. The less of an IT legacy there is to begin with, the greater the

scope for companies to plan for the bigger picture.

Changes in technology deployment models can help with some of this – cloud models, or centralised data management (which can be achieved virtually, without the need for data to all reside in one place) can make it easier to make data accessible and shareable across geographical locations, for instance, and to keep affiliate/small satellite operations in sync. But companies should not see the cloud as a panacea. Without some hard work and investment at a grass roots level, to get fundamental data in order so that it tells a story that can be relied upon (a consistent ‘truth’), and so that it is sufficiently accessible and intelligible to support decision-making, then whether or not companies harness the cloud to store it, amalgamate it, share it or analyse it will make very little material difference.

In short, there is no avoiding the important groundwork. Without robust, complete, good-quality data that is captured, held, managed and accessed in a consistent and reliable way, any other investments, efforts, systems and processes will be undermined. This is why companies, in their drive to be more agile, need to return to the premise of IDMP and continue to focus on the spirit of the initiative, even while some of the final dictionary-definition detail is still being agreed.

Why IDMP is Still the Best Guide of What to Aim For

The vision of IDMP, and its standardised data formats, is to make the life sciences industry safer, more efficient, and more transparent and traceable. As a programme of change, it has implications for everything from pharmacovigilance and batch recalls to e-prescriptions and product shortages, with expected benefits for everyone concerned. The emphasis on high-quality master data aligns with every organisation's need to more effectively manage all information considered to play a key role in the core operation of a business – data that can and should be re-used for multiple purposes. Although the latest timelines for IDMP compliance stretch into 2019, there

is much that life sciences companies could be doing now to get themselves into a robust, optimised position. In 2017, as firms review and replace older IT systems, they would do well to think laterally about what else they could be enhancing or adding, rather than merely looking for an improved like-for-like capability. What's missing from that current system, and how might that be holding back productivity or performance? What are its limitations, and might there be another, better way of delivering what's needed? Having time on their side before IDMP compliance becomes mandatory buys companies time to get the basics in order – those fundamental aspects of data management that are intrinsic to the ability to adapt, transform, innovate and deliver.

Ideals to work towards include transforming information management from something that's document-based to something that is data-oriented – i.e. from something static and relatively impenetrable to something more dynamic, granular, structured and searchable. A 100-page PDF, for example, would become something more component-based, broken down, stored and recallable as a series of reusable information assets. ‘Data’-based information management makes it easier to observe, analyse and report patterns, and draw conclusions, without the need for someone to manually sift through and compare different content sources.

It would mean companies are able to spot patterns in queries received from the authorities in relation to products or submissions, so that these could be pre-empted and delays avoided. As long as records of previous questions are confined to email trails or scanned letters, those trends will be far harder to identify and prepare for. Any time saved in responding to regulators and navigating the review and decision process increases a company's speed to market, and time to revenue. Quick responses, and getting more marketing applications right first time, could take weeks or even months off the submissions process under a given procedure.

As evident as the efficiency benefits might seem, the scenario painted above is far from the norm. Today, 'good data' scenarios are a rarity, accounting for less than 10 per cent of companies' information management practices. In-house systems are typically proprietary, built internally to bespoke requirements, and a lot of content remains locked in static documents. This reality is a long way from the vision of a centralised, structured master data resource that people with an interest in quality and safety can access readily.

Without an immediate compliance focus, it is somewhat forgivable that organisations have taken their eyes off the prize – after all, it's probably a lot cheaper to get someone to go to the archives and open six months' worth of letters than to invest in a data management project that would address all of this once and for all. But in the context of agility and market responsiveness, the existing and desired scenarios don't bear comparison.

As the industry takes stock of where it needs to be over the next decade, openness needs to play a key role: from openness to new ideas, business models and ways of doing things, to openness in data standards and data sharing. In an article published by World Economic Forum last year, Stephen Caddick, Wellcome Trust's director of innovation, called for greater support for open innovation across life sciences – specifically a commitment to "sharing methodologies, data, hypotheses and outcomes" to enable faster progress¹. But as long as companies remain wedded to legacy systems and processes, and fragmented data sources, it's hard to see how things will move forward.

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Siniša Belina

Senior life sciences consultant at AMPLEXOR Life Sciences. He started his professional career at Pliva (now a member of the TEVA Group), where in addition to his responsibilities in manufacturing, he also engaged in successful EDMS implementation projects. Belina later joined KRKA's Regulatory Affairs Department, and finally moved to AMPLEXOR. He applies his detailed knowledge of pharmaceutical documentation and processes to areas of business process analysis and EDMS optimisation.

Email: sinisa.belina@amplexor.com