The Big Debate

Beyond the data/document distinction:
how to transform life sciences experiences through improved information flow.

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In many industries now, leading companies have realised the ability to handle data and documents interchangeably gives them a new freedom to transform how they operate and the experiences they enable – and even further, to extract data from documents and build documents from data. The key is the ability to do this quickly, reliably and with the lightest touch.

The life sciences industry may have been slower to appreciate the benefits of holistic data/document management, but that is changing rapidly as business pressures and evolving regulatory requirements prompt organisations to overhaul the way they handle information in its various formats.

Here, life sciences data/content management visionaries, **Steve Gens** of **Gens & Associates, Remco Munnik** of **Iperion** and **James Kelleher** of **Generis,** discuss the drivers for digital transformation of data and documents management in life sciences, the practicalities of delivering it, and the opportunities it opens up.

Business and technology journalist, **Sue Tabbitt**, chaired the discussion

About the panellists

Steve Gens is the managing partner of Gens and Associates, a global life sciences consulting firm specialising in strategic planning, RIM program development, industry benchmarking, and organisational performance.

Remco Munnik is Associate Director at Iperion, a globally-operating life sciences consultancy firm which is paving the way to digital healthcare, by supporting standardisation and ensuring the right technology, systems and processes are in place to enable insightful business decision-making and innovation.

James Kelleher is CEO of enterprise information management specialist Generis, whose CARA™ Life Science platform is helping to transform business processes in life sciences and other regulated industries.

Sue Tabbitt: What is driving the change in the way organisations manage their data and documents?

James Kelleher: Well, firstly it makes no sense to treat them separately. The value to a business is in the information, so it isn't logical to store documents in a document or content management system, and then more structured data in a separate database. Documents contain data, and data is used to populate documents, so ideally these assets should be part of the same continuum. It's the way technology evolved that created the restrictions and silos, but they can be overcome now. Today, it's perfectly possible to unify everything on a single platform.

Remco Munnik: All around us, everything is data driven. The days of sending paper correspondence back and forth to rent a car, apply for a loan or pay a bill have gone. We can do it all online, or via our smart phones. Shops and media companies recommend things to us based on data about our preferences. It is curious that in the pharmaceutical industry this concept has not yet been embraced. Certainly, as a patient, I would like to get informed about possible treatments, side effects and availability of products through structured data. It's far more efficient to start with the data and use that as the basis of the actions we take, than rely on static documents – moving information in and out of them for each purpose.

Sue: What value does this more fluid approach to information management offer to life sciences?

Remco: Well, the odd thing is that pharma generates a lot of data, but the industry still relies heavily on documents or PDF files to correspond with the health authorities. And as long as both Regulators and companies are not working in data, they can't easily exchange information so processes remain very time-consuming and can't be optimised.

Steve: I agree that it's the global flow of information that's important in all of this. For life science organisations to become more efficient, they need to rely on the flow of high-quality data between departments to drive analytics and accelerate decision-making. That's a state they want to get to, but it's not as easy as it sounds.

Over the years, we've seen different functions - Manufacturing, Clinical, Finance - progress at a different pace in their management of information. Manufacturing realised the power of platforms and the importance of integrated information in the 1990s. In the 2000s, it was the turn of Clinical operations which were grappling with tonnes of paper, content, study data, safety/PV data and so on. And although we don't often talk about Finance, it has to close its books every month and is very data driven. Although they have masses of documents for tax filing, compliance and so on, Finance teams' flow of information and

the ability to manage both data and documents with a high level of competency is pretty outstanding.

Then we get into Regulatory Affairs and Quality: systems and processes are still too disconnected although this is changing. There's still a lot of manual pushing of information, driven by local spreadsheets and file shares, resulting in struggles to obtain high data quality levels which takes away from a function achieving high operating performance.

Sue: How is that hurting those involved?

Steve: When departments don't have a good flow of information, or sufficiently high data quality, they get caught in verification loops – in other words, verifying the data because they don't have trust or confidence in it. And given the large quantities of information involved, this has a direct impact on productivity in the organisation. From a Regulatory standpoint, we did some benchmarking on this topic five years ago and found that up to 10 per cent of people's time is being spent either verifying information for somebody else, or reaching out to verify information to make decisions or otherwise act on it. That kind of productivity hit is pretty substantial.

The other thing we're seeing, specifically with Regulatory and Commercial organisations, is a big focus on reducing time to market. Historically, the primary focus was first market approvals in the major countries, but getting new products or indications out to secondary markets much faster (i.e. by 3-6 months) is a high priority today. From a business case standpoint, the investment in better data flow and, by extension, optimised global processes becomes largely self-funded.

James: Also, teams can see how long things are taking once they manage all information and content together across a common architecture. That could be the speed of compiling and submitting responses to health authority queries, delivering translated materials to Brazil, or gaining approvals for an order of test tubes. Where companies are still relying on the arduous process of circulating forms or documents for signatures, the scope for process analysis is very limited. Among the benefits we're enabling are new insights into where and how processes might be optimised and accelerated, as well as the ability to report and analyse this at an enterprise management level.

Merck, for instance, is using our CARA platform to manage Safety Data Exchange Agreements, and has brought the generation of submission-ready PSMF Annex PDFs down from three weeks of manual effort to three seconds and a single button click. The same improvements can be applied to many documents, including the Annual Product Quality Review (APQR). That's because the teams involved can automatically pull in correct data from a wide range of sources to create documents. In so doing, they are able to collapse lifecycles and reduce manual rework, not to mention the scope for errors or data inconsistency, as well as re-work.

Remco: The implementation of the new European Pharmacovigilance and Veterinary legislation provide a good example of where companies are gaining from more efficient, data-driven processes. Under EU legislation, a company has to have a named qualified person responsible for Pharmacovigilance. If that person leaves, the company would have to submit a variation to its information - for every product. If there are 20,000 registrations, that 'simple' administration change will take a huge amount of time at both the industry and the regulator side. Time which could be better spent assessing the latest applications for new treatments.

Thanks to Article 57 and XEVMPD, this kind of change becomes a simple data update via a computer and internet gateway. The idea now is to apply the same principle for other straightforward administrative changes (e.g. changes to the name of a company), so that companies are just reporting something once. Currently this kind of admin is easily costing organisations billions of euros in man hours across a period of a few years.

Sue: Why is there a particular urgency today to accelerate this kind of transformation?

Remco: The pandemic has brought to life some of the limitations in information flow for customers including pharmacists, healthcare providers and patients. People are asking, "Which medicines can I take?", "What clinical studies are available?", "When will I get the vaccine?", and "If I have the vaccine and experience any adverse effects, where and how can I report them?". And they're starting to question why this important information isn't readily available to them to search, compare and assess in an accessible, consistent, standardised and user-friendly way.

Part of the issue is that, unlike in other industries, there hasn't been that same competitive imperative to trim administrative processes or create new customer-centric experiences. And, frankly, there has been a lack of leadership from the regulators too – to really drive and align everyone behind a data-first approach.

Sue: Will the implementation of ISO IDMP in the EU help to address that?

Remco: Certainly it provides the language that will make it possible to optimise different systems, for example the delivery and management of electronic patient information, or reporting of product shortages. Without agreed master data (SPOR) in place, it will be hard to benefit from the potential. It doesn't help that many software vendors choose to do the bare minimum – providing individual 'point solutions' designed for submitting dossiers electronically, for example, instead of looking at how they might transform end-to-end processes. I'm not laying the blame at software vendors' door though. Every stakeholder group across life sciences has a responsibility to drive more comprehensive transformation.

Steve: We're seeing regulatory information management leaders take the opportunity to greatly improve the information management layer to better retrieve, connect and consumer information -as opposed to looking at IDMP as a tactical compliance project. The other driving force is the degree of better end-to-end processes, specifically in the change control, variation management and labelling processes. Our latest World-Class RIM study found two-thirds of industry working actively on end-to-end processes. From a software provider standpoint, the progressive players are those that have identified the need for greater data connectivity and cross-functional platforms; they will be the winners.

Sue: Once pharma companies have identified that this is the path they want to take, what kind of plan do they need to get from where they are now to this desired new state?

Steve: Interestingly, when I look back across our survey data from 2014 onwards, there is no correlation between our study top performers and any one software provider or system strategy. So it's not a case of 'invest in this software and you're good to go'. The highest achievers are the ones doing the organisational work (data quality governance and continuous improvement) along with achieving mature and consistent processes. The frontrunners have data quality sustainability programmes, a data governance structure, and new roles like data stewards, data scientists and even Chief Data Officers.

If I had to boil all of this down to three steps companies need to take it would be these. Whether the goals are function-specific or cross-functional, organisations need a strong, modern technology foundation to underpin transactional systems (ERP, safety/PV, registration document management and so on). In parallel with technology investments, having very high data quality standards and effective cross-functional data governance is critical. With the right foundations in place and reliable data to work with, companies can start taking advantage of robotics/ automation, AI and so on, and accelerate their business benefits.

Sue: If companies feel they are lacking in data science expertise, will we see increasing use of managed services?

Steve: Organisations might want to bring in advisors to help guide their strategy, improvement journey and/or five-year investment plan, how to deliver it, and how to choose the right software provider. When we conduct our next major RIM survey in early 2022, we'll know more about whether companies are starting to look to managed data services. We do see some companies bringing outside firms that specialise in maintaining high data quality, but is that temporary or long term? At this point we don't know, but we're tracking it.

Sue: Has the pandemic crystallised the importance of a more fluid approach to managing data or information and documents?

Steve: Well, we know the 13 companies we've identified as having achieved or being well on their way towards World-Class RIM have fared better than their peers. The vast majority of these leaders (92 per cent) have thought through their information flow and process optimisation, and have truly global systems.

When we conducted our COVID-19 regulatory impact study in September/October last year, we found these companies had an easier time with transitioning to remote work because that had standard global systems and processes in place, and as long as team members had an internet connection, they could continue to contribute effectively.

Sue: How important is the cloud in enabling all of this?

Steve: I think the cloud plus a SaaS [software-as-a-service] delivery model gives companies earlier access to the latest capabilities. And, during the pandemic, it's allowed people to be a lot more mobile/virtual, so I think adoption will further accelerate coming out of COVID-19.

Sue: Going back to what Remco was saying earlier about new real-world experiences that could be enabled by a better flow of data between functions, and greater standardisation of information between organisations and different countries, what do you think will drive that kind of innovation? Are initiatives like ISO IDMP enough?

Remco: It's certainly a great start, but more needs to be done and even IDMP initiatives are fragmented. EMA, for example, is setting up an EU-wide database but following Brexit the UK isn't part of it, so we're still seeing silos - even within geographical Europe. The only way to really get global transformation of customer experiences would be if there was a global cloud system run by a body like the World Health Organization where everyone registers their data. But I don't think that's very likely in the short term.

It might take a disruptor (Google, Amazon, etc) to step in before we see serious transformation from a consumer perspective. And, actually, every industry needs a disruptor to force change. It might be the only way to really change the pharma mind-set away from its entrenched conservatism. The hope is that it will just take one innovative leader to step out and do something new, and then others will follow.

Steve: Yes, if you look at how Amazon works – it delivers experiences, and doesn't just focus on data or documents: in three clicks, you get to what you want to buy. To achieve that kind of scenario in life sciences, it's a matter of overcoming disjointed systems and being able to trust the information sources. Once you simplify and standardise, the information will flow much more readily, enabling new experiences.

I think we're well on the way to this kind of scenario, with some of the newer platform capabilities that are coming through. The companies offering the once-popular best-of-breed niche solutions are seeing their market share drop off a cliff in most RIM capabilities now.

Our market reports suggest that by 2023-24, 60 percent of the Regulatory market will be using cross-functional platforms and the remainder will have a simplified, but connected best of breed.