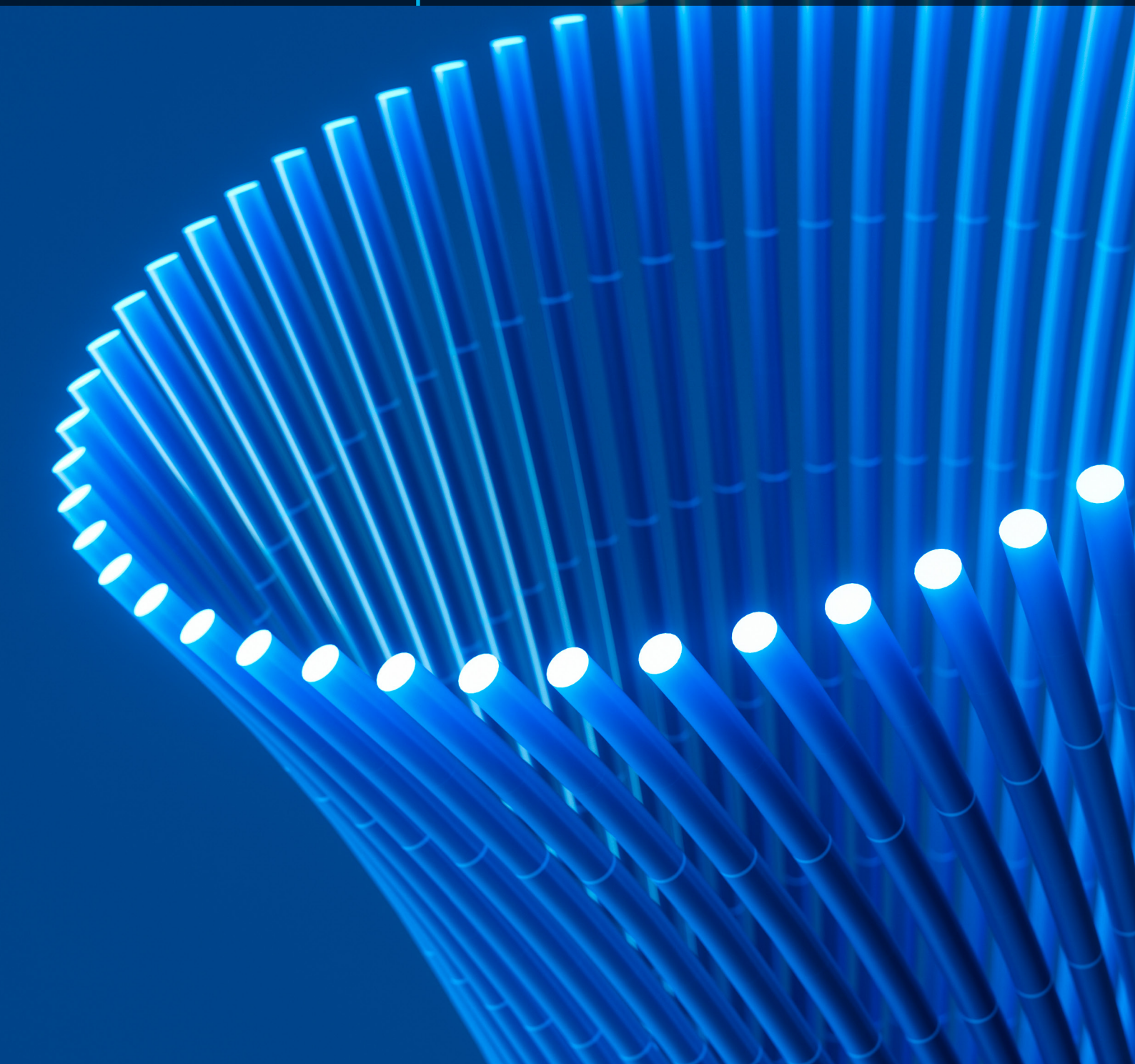
THE BIG DEBATE | **LIVE SERIES**

The future of data & documents and their interrelationship in life sciences

IPERION a Deloitte business | accenture | GENS & ASSOCIATES | Syneos Health | generis



The way that life sciences companies generate, manage and store documents and data is changing irreversibly. It has to, if teams are to be able to think, work and move in more agile and dynamic ways to achieve what they need to – and keep pace with the shifting operating models of industry regulators.

But what does this future look like, what is the wider potential, and how can companies redesign their information/content management processes without substantial upheaval, complexity and cost – given that their starting point for document and data management is likely to be less than ideal.

With the EU's implementation of the ISO IDMP standards for managing and submitting regulated product data now within grasp, the timescales for improving data completeness, quality and governance, converging data/content management, and adjusting operating models, are growing tighter. But, as our expert panellists continue to advise their clients – this move to a more coordinated and streamlined approach to document and data management really shouldn't be a compliance-led transformation.

This leap that companies are making now brings with it all sorts of efficiency, quality and risk reduction benefits across life sciences businesses. More important still, it will help to transform product traceability and transparency across the entire health ecosystem, and empower patients in new ways to play a more proactive role in their own healthcare, though enhanced product knowledge/ improved information access.

With this in mind, Generis invited four industry experts to discuss the process of data/document transformation and the specific ways these two information formats will co-exist and interoperate in future.

The panel

James Kelleher
CEO, Generis - moderator

Remco Munnik
Director at Iperion, a Deloitte company

Peter Brandstetter
Senior Manager for Technology Consulting, Accenture

Steve Gens
Managing Partner, Gens & Associates

Caroline Masterman-Smith
Senior Engagement Manager, Syneos Health

Below are the highlights of their discussion, along with some practical tips they distilled for life sciences organisations keen to accelerate their data/document process innovation. The debate session was very interactive, featuring questions from the life sciences industry attendees and poll questions used to gauge current levels of engagement with the shift towards greater data/document interchangeability.

The coming together of documents & data

The panellists agreed that the world around us is becoming more data-driven, so it's a logical development that the life sciences industry is moving this way to track and manage product information, and to exchange this with regulators.

ISO IDMP, now being progressed in the EU, applies a data standard allowing a single medicine or product to be uniquely identified, traced and queried in detail. Alongside this is the coming requirement to submit regulatory information in data form in parallel to document provision (the next step to data becoming the primary means of interaction with information).

To take full advantage, driving new efficiencies into internal information management and related processes, companies need to start aligning their need to set up new processes and new technology, with the need to amalgamate the data currently residing in documents and that stored in structured databases, to ensure there are no anomalies between the different formats, and that they can work with feedback from the regulator in data form. Ultimately, the shift is to a situation in which data becomes the master source of intelligence, and documents – where they have to exist – are a secondary manifestation and in support of that data. This was the very strong view of Remco Munnik from Iperion-Deloitte, which was echoed by the other panellists.

Data ownership

As data becomes the definitive central source of product intelligence, the quality, completeness, governance and maintenance of that data becomes paramount. But this introduces the question of who owns, and is responsible for that data and its integrity over time.

During the online chat with participants during the debate, a member of audience noted the importance of defining what data is, in depth. Data models– which organise the elements of data and standardise how they relate to one another, and to the properties of external entities - can help with this.

Gens & Associates, which has been tracking regulatory information management trends for over a decade, sees these issues coming to the fore as companies become more ambitious and holistic in their data organisation plans – recognising the increased value of a data-centric rather than document-dependent operating environment. In this context, Steve Gens has observed an increasing preoccupation with improving data quality, so that as a definitive source of product truth evolves, teams can depend on the reliability and accuracy of that data, which in turns boost productivity.

Data connectivity and exchange becomes important here, too – supporting diverse use cases spinning off from the same master data source: not just structured data submissions to regulators, but also cross-functional processes – spanning Regulatory, Quality, Manufacturing, Clinical operations etc - for streamlining activities such as global labelling management and content change control/variation management says Gens.

In a cross-functional context, though, matters of data quality/ownership and governance become particularly important. While everyone is trusting in the source data, this assumes that someone is overseeing that data's integrity and ongoing maintenance, so that all the strands of activity flowing from it do not fray.

Debate poll question 1: How does your company view improvement to document and data management?

Of the votes cast, the largest proportion of event attendees suggested document and data management improvements were already in hand – as part of Regulatory Information Management (RIM) improvements; a digitisation initiative; or a Continuous Improvement Programme. By contrast, no one suggested they were already where they needed to be.

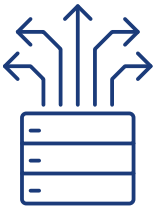
A specific improvement project	**10.50%**
Falls under our Continuous Improvement Programme	**15.80%**
Is part of our Digitisation Initiative	**26.30%**
Is part of our RIM Modernisation Program	**31.60%**
Good question, I'm not sure	**15.80%**
We're already great at this, no improvement necessary	**0.00%**

Where to focus data quality efforts

It's already well established that life sciences organisations need to invest in improving data quality so that they are ready to comply fully with EU IDMP once this becomes mandatory within the next couple of years. But where specifically should companies be focusing this activity?

In the discussion, Iperion's Remco Munnik noted that matters of data quality needed to be resolved before multiple processes started to connect into that data. With departmental systems previously having held their own versions of relevant information in their respective silo systems, each addressing a single use case, an important first undertaking is to understand where all the original contributing data sources exist and what needs to happen to them to clean up that data, verify its current integrity, and make it more consistent across its different manifestations (synchronising or de-duplicating as teams work towards a common single source). Even within a single department, the content in current RIM and eCTD publishing systems can be inconsistent in its reference to vital information, such as substances, dosage forms and so on. As the vision expands, and teams start to look at how they might link regulatory data to ERP systems, eliminating any anomalies and arriving at core data that everyone can rely on becomes paramount, so that errors and risk do not multiply.

EMA's IDMP helps here, setting down the precise, prescribed ways that substance, products, organisation and referential data should be formatted, making it possible to work towards a definitive trusted and compliant data set, from which all processes and use cases begin.



Process considerations

Caroline Masterman-Smith of multinational CRO Syneos Health noted the process-related barriers that pharma organisations need to overcome to make data work optimally for them, as they start to adopt integrated solutions that handle both data and documents.

Concurring that data rather than documents will serve as glue that fits regulatory into the wide enterprise in future, she says life sciences companies need to consider the context of particular submissions, because it won't always be obvious which data elements are required.

In her company's dealings with clients, on calculating their IDMP readiness assessments, governance matters soon rear their head, she said. ***"In a lot of cases we're looking at regulatory processes and defining pain points that fall within several categories: things like manual handoffs and rework, but a large part of it all comes back to that duplicate data entry occurring, multiple QC loops, and the lack of end-to-end metrics."***

Much of this can be addressed by defining better processes/reviewing operating models and how they can best fit the organisation, she noted. ***"We're seeing some companies move towards centrally-managed data entry and governance, and some moving away from this – so that everyone is accountable for their own data at source."***

There are pros and cons to both approaches, she noted. ***"Having everyone accountable for their own data can reduce data entry efforts, or transfer of data through forms, and so on."***

But it also puts additional pressure on governance and consistency of that data across countries and products, around the organisation and around the globe, she added.

"All of this leads back to making sure the processes to manage and gather data and documents are well defined, and that the technology used or implemented actually makes that process easier for everyone."

But things are improving. Looking back over his company's research in recent years, Steve Gens has seen the time lost to data verification loops, to verifying and ensuring trust in data, has reduced as companies have worked hard to streamline their processes.

"There's no such thing as perfect, but my sense is that the work here has at least been cut in half," he said.

Technology factors

Looking at progress from a technology perspective, Accenture's Peter Brandstetter considered how companies can maintain a robust central source of master data when they may be outsourcing data-based work to multiple vendors across their various different departments.

Noting that the focus on a data-driven journey has existed for at least a couple of years now, he said many of the tools companies need to consolidate and clean up their data are already well established and well within reach, citing 'big data' analytics tools, and the use of AI to extract information from unstructured data, among the example.

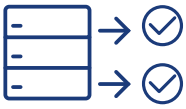
He believes any barriers are more to do with a certain mind-set that still pervades life sciences: a preference for continuing in the same way teams have always worked, relying heavily on static documents as the main means of collating and storing information.

From point solutions to multi-purpose platforms

With all of the talk about cross-functional process transformation and data exchange, the debate moved on to discuss how companies approaches to end-to-end RIM have evolved. Steve Gens noted that between his company's international surveys in 2016 and 2021, much has changed. ***"We project in two or three years that 60 per cent of industry will have taken a consolidated platform approach to organising and repurposing regulatory information and specially regulated product data for multiple use cases, with a view to system and process simplification,"*** he said.

Even the remaining 40 per cent are looking to use fewer providers, with an emphasis on greater inter-system connectivity – enabled by consistent use of agreed data standards. Some of that structure was introduced with eCTD, but IDMP SPOR brings further structure to product data at a more granular level.

"We have a lot more companies investing in 'master data management': we see that very clearly in our benchmark data," Steve noted, adding that there has been a realisation that this is an involved task, with no shortcuts.

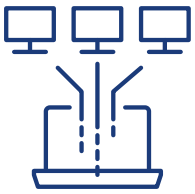


Is IDMP the only way?

The panel then considered whether, if an organisation already had a well-defined set of data standards in place, how it might persuade senior management of the business case for implementing IDMP terminology.

Caroline at Syneos Health noted the inevitability of IDMP for regulatory compliance, and the importance of starting from the right footing – but that delivering the correct process is more critical still. ***"Even if the standards keep changing, if you've got this solid processes in place to help build from that, it will really help - making sure, across the board, that data is correct,"*** she said.

For instance, a company might have a strong custom-built tool for managing XEVMPD, but lack processes for content review, for checking that output reflected the most current source of truth – an omission which could risk compromising the promised efficiency benefits of the system.



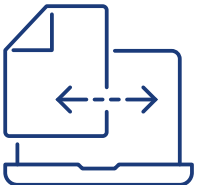
Securing business buy-in

The panel agreed that data-driven/IDMP-led transformations are a foundational investment, making it harder to directly map projects to business benefits – beyond 'better application of information'.

Accenture's Peter Brandstetter noted that the bigger benefits will extend beyond IDMP and regulatory compliance, and as teams are able to call on reusable master data across the whole product lifecycle, from early research until a product retires.

Remco Munnik at Iperion agreed that EMA's application of IDMP is not the be-all-and-end-all for resolving data issues and transforming life sciences processes.

"The most important is that trying to tie the data together with the process, which is what we've been working towards with EMA and other stakeholders. The aim is to get to a target operating model, to one set of data, that supports a range of downstream processes. In all of this, it's important to make sure that, if there are changes made in one location that there's dialogue and agreement that this is what will be taken forward for the next submission for the next step, and so on. Essentially, it's about ensuring alignment right across the board."



Quick wins

Finally, answers to the debate's second poll question (see box) suggested a strong sense of data-driven process possibility. With documents still playing a prominent part in regulatory submissions, debate host James Kelleher of Generis wondered what quick wins companies might aim for, in using a concerted approach to data/document management – to help sell the business benefits to senior stakeholders.

The panel discussed the scope of structured content authoring, taking a more data-driven and granular approach to the fragments making up documents – with the potential to remove up to 80 per cent of the manual work involved in managing content variations across application forms, cover letters, eCTD sequences etc.

The imperative now is to pin down these extended business use cases which will help drive through next stages of data-driven process transformation linked to, but not exclusively dependent on IDMP, compliance.

Debate poll question 2: What percent of regulatory submissions do you believe can or should be managed via data only?

Of the votes cast here, more than 55 per cent expected that over half of submissions activity could or should be managed using data only in future:

0% - 25%	**14.30%**
26% - 50%	**28.60%**
51% - 75%	**42.90%**
76% - 100%	**14.30%**

Get in touch to find out more:

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