Using software to improve data management and output in pharma development

The COVID-19 pandemic has exposed various issues with the software and data processes employed in the pharmaceutical industry and spurred rapid digital transformation at a rate never before seen in the sector. In this article, Jordan Stobaugh, Principal Research Scientist at AbbVie, discusses how software can improve data management and the key points to consider when looking to implement new data technology.

BEING SUCH A highly regulated industry, pharma has tended to be conservative in its application and adoption of new technologies. However, the COVID-19 pandemic has forced digital transformation across a range of sectors, from financial to healthcare, and pharma has been no exception, with some estimating the industry may have undergone more than a decade of transformation in just a year.[1]

However, not all transformation has equal value. In this article, *European Pharmaceutical Review*'s Hannah Balfour discusses with Jordan Stobaugh, Principal Research Scientist, Analytical R&D, Data Strategy & Management at AbbVie, the process of identifying the right piece of software, the factors companies should consider when looking to implement new software technologies and how AbbVie's digital transformation journey has helped increase productivity and output in pharmaceutical development.

Data challenges in pharma development

Stobaugh explained that the majority of data challenges associated with pharma development can be attributed to the fact that so many components must come together to drive the process. According to Stobaugh, the diversity of the field – since pharma development runs the gamut of designing the drug product to developing its manufacturing processes[2] – and the number of professions involved introduces a lot of complexity.

Moreover, once you start to dive into the details of any individual workflow or challenge, the number of technologies needed to address the totality of the problems rises significantly. "Additionally, there are multiple data formats for each analytical technique. So just comparing and contrasting within a technique is difficult, let alone across techniques and then different types of challenges," stated Stobaugh. He continued that, while some issues may be discovery oriented as you break into the development barrier, such as bringing in a drug metabolism and pharmacokinetics (DMPK) group or a pre-clinical safety group, others may be more manufacturing focused, such as in the chemistry, manufacturing and controls (CMC) space. "Each of those presents unique challenges and they each have tremendous data needs in and of themselves."

Another expert working in pharma development at one of the top 20 pharmaceutical companies by revenue in 2020 added that the scale of the data produced during drug development and clinical trials is another massive issue for pharma. "It is not just the data that we are thinking about when developing and understanding our processes, it is also the metadata associated with that data that we need to keep track of. In the past, this has essentially been done manually, with Excel spreadsheets. Handling all of that

data through manual transcription is really one of the biggest challenges my company is facing." They added that this slows down the process of regulatory submissions, since with manual transcription processes data must be repeatedly checked to ensure there are no mistakes. Accordingly, such a process can take several months, requiring two to three people to be focused solely on that task and the consequences for associated failings can be very serious.

How can software help?

Stobaugh explained that while many productivity tools applied in other industries (eg, SharePoint and other collaborative tools) are also used by pharma, because they are not tailored for chemical data, they struggle to support drug development. "Having a set of tools that is specific to the work that we do is incredibly powerful," he said.

He gave the example of Luminata,[3] ACD/Labs' CMC information management system, which allows scientists and engineers to manage and interrogate all of their analytical and process data together in one interface, and was implemented as one part of AbbVie's digital transformation journey in the pharmaceutical development space. Stobaugh said it allows his team to effectively compare data and images by overlaying them, enabling them to interrogate the information more accurately than a typical side-by-side comparison on another platform would allow. "With a side-by-side comparison, you lose a lot of context, but if you can overlay and then zoom in and zoom out, that provides you immense insight into the data and there are many little details that you can pull out, which enable you to plan your next steps accordingly," explained Stobaugh.

He added that these functions, in turn, overcome another key challenge of software used in the CMC space: the need to optimise the insight that can be obtained from the limited datasets available. "Statisticians always want large datasets and sometimes in CMC they are not tremendously big," said Stobaugh. "Instead we gain insight as we repeat things. For instance, as we manufacture using a given process more and more... Gaining insight all along the way is what you are always trying to do; you are always trying to read between the lines of your data. Just being able to make those comparisons effectively is a challenge."

He gave the example of comparing development studies to pilot studies and actual manufacturing runs being carried out at the anticipated production scale as one application in late-stage CMC development where these capabilities are key. For instance, he said, being able to move seamlessly between the lab and the plant and easily compare the data from an individual chemist's experiments, carried out prior to scale-up, against what is coming out of a quality control lab in the corresponding run is one of the key capabilities that they needed.

Stobaugh added that the issue of small datasets is being compounded by the industry's drive towards acceleration; such as when developing COVID-19 vaccines or a drug with Breakthrough Therapy Designation, where there may be even fewer opportunities to run the process at scale and therefore scientists must make the most of the data generated during lab and production scale-ups. "The ability to compare your data and scrutinise it very carefully becomes even more important [in these instances], because beyond just a result that may end up on a critical material attributes (CMA), there are tremendous insights and knowledge docked away in the individual files themselves – the raw data. So getting at that is very important to development teams."

Is your business ready to implement new software?

"Fundamentally, as scientists, we like to solve problems and we typically try to find solutions as quickly as we can. What I have »

noticed in the technology space, and we have been guilty of this as well, is perhaps we do not spend long enough understanding what our true business challenges are first and then try to apply technology as rapidly as possible," stated Stobaugh. As part of a team with more than a dozen members, primarily from the process research and development area within development sciences, he spent a lot of time trying to understand what they needed, software wise, for late-stage development, with the key questions being: "what do we need to understand about our compounds, our processes and our scale-up?".

Together, the group compiled a list of requirements for the software they needed that were fundamentally driven by business need. To define these demands, they developed what they deemed 'scientific architecture' where they develop the use cases, identify problems and then seek to uncover potential opportunities. After they defined the scientific architecture, they spent time understanding what the core data elements are; for instance, the basic data elements of a sample, request, formulation or process, and only once these are defined do they begin their search for software solutions.

"By walking through the processes in this way, you cannot jump at a solution that is not the right fit," said Stobaugh. He added that the benefits of investing the time and human resources into these improvements – which can be concerning to management, since time spent on these data initiatives means staff are not working on the drug pipeline – is that it enables you to continue to derive value from current and future use cases, laying a strong foundation for further digital transformation.

Data consistency and nomenclature

He stated that consistency in data processes was an example of one of the challenges identified in their workflows. "Take something as simple as your basic chromatography data system, where data acquisition begins. There are a lot of challenges just in terms of how you name the peaks in a chromatogram. We can all agree a set of principles or rules that govern that, but at the end of the day, those systems tend to not really have much of an enforcement mechanism on the peak name," said Stobaugh. He continued that if you were to name an unidentified peak 'Unknown A', just in that run or synthesis step, the labelling is fairly unambiguous. However, in subsequent steps, this name introduces all kinds of uncertainty.

He added that these inconsistencies are even more problematic when you try to apply a software solution which enables you to compare and contrast across all steps of a process and across various projects. As a result, nomenclature and consistency become critical aspects of data acquisition when looking to implement technologies. For AbbVie, this realisation has since driven them to see how automation could help overcome the shortcomings of some of the basic data acquisition software.

Another consideration when implementing software solutions, highlighted by Stobaugh, was that they are data hungry. "Scientists must have access to the analytical data in order to do what they need to do and provide the insights that you are looking for," he said, continuing that therefore researchers must be willing to take the time to input their data into the system, which can be challenging if faced with manual entry. This is another consideration that is propelling AbbVie's continuing work with ACD/Labs to implement automation of data into Luminata, and thus, reduce the burden of manual data entry on scientsits. Stobaugh explained: "probably the single largest lesson we learned about software is that many of the problems during deployment and change management are not really to do with the technology itself, but how the data is fed in."

Final thoughts

With digital transformation taking place rapidly in the current pandemic environment, it is important that pharma carefully considers its requirements and understands the problems in its current processes when looking to implement new software. Stobaugh explained that while automation and digital transformation may be desirable and, if implemented carefully, highly successful, without proper governance and consideration it is very easy to turn a data lake into a data cesspool.

Moreover, success requires imaginative people with an enthusiasm for the project and sufficient time to work on data initiatives, Stobaugh said, because these efforts must be driven from within the scientific community. "Through our digital transformation effort we have seen that the most critical assets in data initiatives are the human resources that are placed on these programmes."

Hannah Balfour

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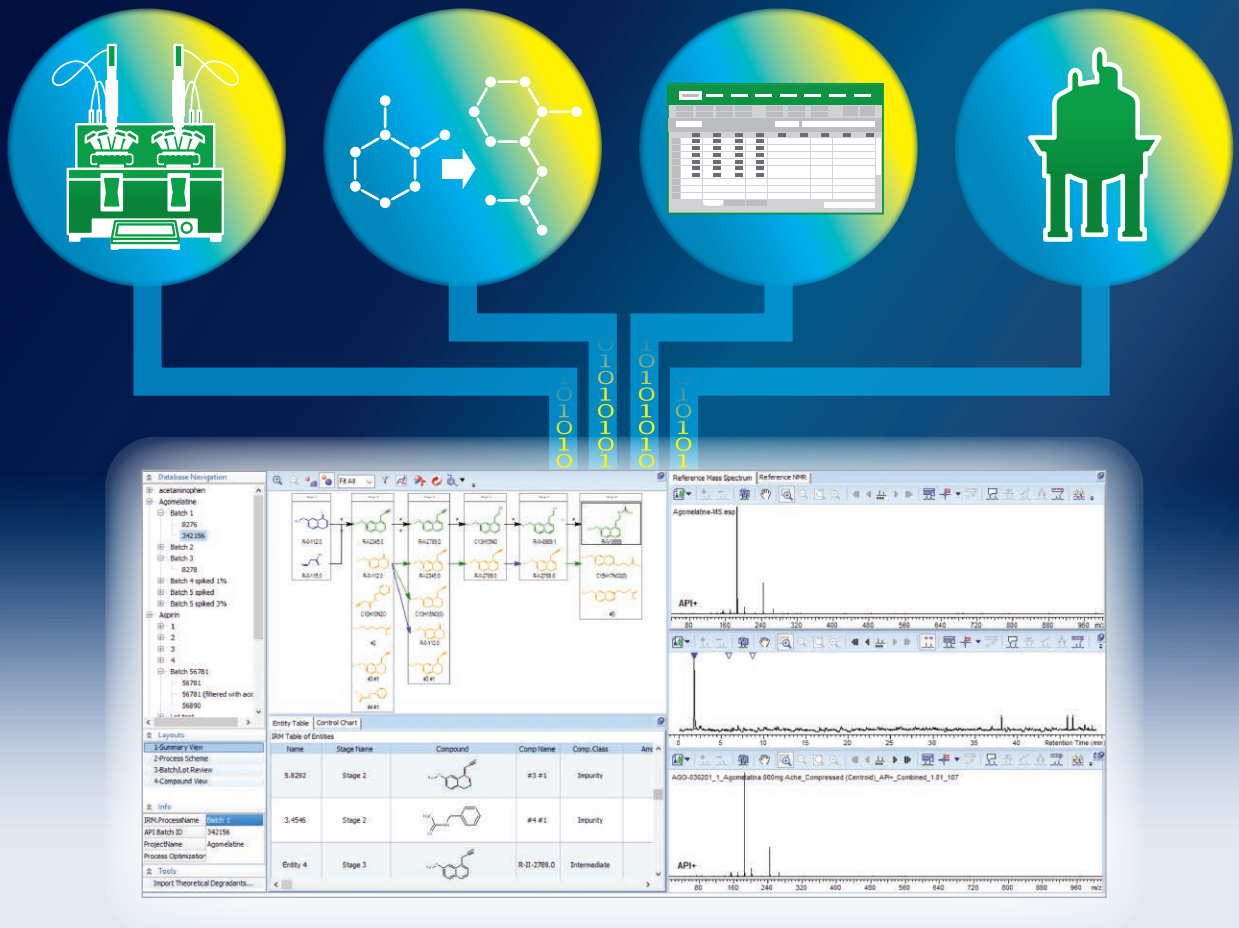

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