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AI IN REGULATORY
VIDEO TRANSCRIPT

PAUL WALSH: Hello, welcome everybody to Artificial Intelligence in Regulatory: Solving Tomorrow's Challenges Today. My name is Paul Walsh and I'm the Analytics and AI Lead for Data and Health at Accenture The Dock, our Global Innovation Center based in Dublin Ireland. But we work close with the clients to explore how AI can add value to their business.

I'm joined today by Kulvi Chana, Regulatory Affairs Manager and Jarryd Chen, Regulatory Information Management Consultant, both from Accenture Life Sciences.

So over to you, Jarryd.

JARRYD CHEN: Thanks, Paul. So just to quickly introduce what the presentation today is about. And essentially, we've identified that the key problem is their regulatory processes in pharma are crucial to the safe and effective development in use of medicine. Life sciences companies continue to face challenges, not just around their current processes, but also in relation to future disruptions, such as the mandatory implementation of IDMP regulation.

In this specific presentation, we explore how artificial intelligence is helping and supporting regulatory teams today and how the technology, such as AI will essentially redefine the future of regulatory.

In terms of some of the challenges that I spoke earlier, I spoke that we've identified, these are just an example of some of them. The list is not exhaustive, but some of these challenges are, for example, when an organization tries to bring a new product to market and they have to manage the complex queries and questions from Health Authorities. All they're trying to keep drug labels, artwork and promotion materials up-to-date and ensure that they're accurate to avoid fines and maintain compliance.

And finally, examples of some challenges with maintaining and adhering to regulations are to submit and maintain IDMP compliant data to ensure industry-wide interoperability and to facilitate the reliable and exchange of medicinal product information.

I will now pass it over to Paul to talk a bit more about how AI is used and the foundation of what it's about. Over to you, Paul.

PAUL WALSH: Great, thanks, Jarryd. So firstly, it's worth highlighting that the development of AI technology significantly different from that of standard software. Traditional software development is concerned with how to code and program's rules, that process data to produce the result.

However, much of AI today is focused on the use of machine learning algorithms that learn from data to automatically produce a program. In fact, the development of AI is more closely aligned to the scientific process of hypothesis generation and experimentation.

So with that in mind, we work very closely with our clients in The Dock using two key phases. Phase 1 is Growth Identification with clients to understand pain points in the problem space. In Phase 2, we rapidly develop working AI based prototypes to demonstrate and validate the value proposition. The photos on the right illustrate this type of co-creation.

So the next slide show how this leads not only to new technology, but new ways of working, providing strategic initiatives to transform regulatory processes and new working practices that provide benefit in terms of patient safety, regulatory compliance, cost and speed to market.

So now, let's take a look at some demos that illustrate these value outcomes.

So in the first example, we'll take a look at Drug Labelling based on work we did for a major pharmaceutical client. After working with our client to identify pain points, we co-created AI solutions that use natural language processing to assist in managing the vast amount of information rather than say effective use of medicines.

Natural language processing is a term that is used to describe a whole family of technologies and algorithms that can be used in applications to ingest and understand human language. In particular, we use natural language processing to automatically extract entities and relationships with drug labels.

An example of it actually here would be a drug name or a drug class. And an example of a relationship would be, for example, a drug interaction. Essentially, we're using NLP to structure unstructured information.

We then take this structured information to build a knowledge base which allows us to reason, recommend and assess the plausibility of information related to drugs.

So let's take a quick look at an example of how we can take drug label information, semantically structure it and then reason over it.

So the text that you see here is an example taken from a publicly available database provided by the National Institute of Standards and Technology in the United States, which they provide to help drive research into the use of AI for processing unstructured clinical information.

For an AI solution automatically reads and processes this text, pulling out relevant drugs and drug classes, highlighted in the next slide in purple, along with drug interactions between those entities highlighted in red.

So the next slide, we see that these entities were relationships. So that means to construct a knowledge graph, which provides us with the ability to reason over drug information. We can now explore this information automatically with queries such as find all ACE inhibitor compounds that interact with Accuretic and related drug classes or any sensible query that we wish to imagine.

So the next slide, we have a video of this process in action which shows the AI automatically annotating drug entities. So here, we see the entities highlighted in green automatically by the AI.

On the next slide, we show a 3D representation of this vast knowledge graph, which is created from the newly structured information. This graph represents a machine learning model and has been trained on thousands of validated drug labels. This system is useful for flagging inconsistencies with drug labels and recommending additional interacting drugs that should be further considered for the labelling.

So where managed to the phase where AI is assumed to validate these results in alignment to the continuing to improve and learn.

So next, we look at the case of promotional materials, which is used to ensure that information appearing in marketing material is accurate. And the challenge here is to streamline the approval process by using AI and automation to flag inconsistencies in materials and reduce the number of review cycles in order to get materials to market.

So the next slide, we see this in action. Here, the system checks the promotional material against drug safety information, highlighting any inconsistencies. PDFs uploaded by marketing material, job agents for this automatic review and any discrepancies are flagged and highlighted in red, whereas, text that is aligned to the drug label is highlighted in green.

And in the next slide then, you'll see how you can check the material against brand guidelines. Fonts and font colors that are outside brand guidelines are detected

automatically and job agents can further annotate any inconsistencies for further action or any exceptions.

We can see how computer vision is used to detect logos. Here, the logo is detected as being in the correct position, however, the system has detected that there are issues in relation to its position on the material and also the amount of clear space around it.

Okay, the next slide then, we also examine text for eligibility and this includes, white space around the text, leading, which is space between lines and tracking, which is the space between letters. There are certain guidelines to ensure that this text is legible. We also highlight any inconsistencies here and we also check material in terms of color against the brand guidelines.

So let's move onto another use case in the next slide where we look at Semantic search. Here, we're handling response to queries or TQs related to chemistry manufacturing control for new drug applications.

Once a new drug application is submitted, regulators can query the chemistry manufacturing controls related to that drug. So to solve this, we developed a Semantic search engine which uses the techniques that we spoke previously to pass and organize the thousands of documents related to the MDA, including lab notebooks, tables and figures.

So here, we use our – which is to answer question related to virus detection and clearance manufacturing. So the Semantic search engine pulls out all written documents and figures relevant to that drug application to answer the response to the regulators.

Now, I hand you over to Jarryd, who will discuss further uses of AI in compliance.

JARRYD CHEN: Thanks, Paul. So in terms of this concept, unlike the other three concepts. This is more of a theoretical use case which is based on a tool we're currently developing which works on AI for compliance.

And so, Health Authorities are focused on creating a more data driven paradigm in the regulatory space. And we see this with the XEVMPD regulation where organizations had to collect medicinal product data and submit them to the Health Authority. Building on this, the Health Authority has released a new regulation called IDMP, which focuses – which is very similar to XEVMPD and is built on XEVMPD, but has a larger scope and has a more specific focus on data standards.

At Accenture, we believe that the pathway to IDMP compliance is strong master data management and governance and powered by technologies such as artificial intelligence and natural language processing.

Specifically, we believe that these tools can allow our clients in a regulatory space to focus on more strategic things such as planning a submission and responding through HA queries rather than manually extracting data and managing data.

And so, here on the screen, we have our five steps to achieve strong data, master data management and governance for IDMP compliance. Before I talk through these five steps, it is noted that we are currently developing a tool to support our clients within the first three steps.

In terms of Steps 4 and 5, these are still in the process of built and will be built in parallel as the Implementation Guide for IDMP version 2 gets released at the end of Q1 2021.

And so, talking through the first three steps from a data analysis and mining perspective. Our solution helps clients to understand their data through analyzing their data in their current systems in the context of IDMP requirements. And so, it profiles that data based on the IDMP model.

From a mapping and extraction point of view, it maps the data collected as part of XEVMPD and maps them to the IDMP data model. For data that is not available in the systems because they are unstructured in documents, natural language processing can extract the data and make it into a structured format that is machine readable.

And finally, from a data cleansing and enrichment perspective, for data that is not aligned to IDMP or not aligned to its controllable vocabulary or in consistent in any shape or form. The tool's able to flag that up and provide prioritization and more focused remediation efforts.

Looking to the next slide and taking a deeper dive into data analysis and mining. We see here a screen shot of the dashboard of what the tool does when it helps our clients.

It provides a way to identify which systems the data is captured in or stored in and it provides that profiling based on subject areas availability.

So these are the subject areas found in the Implementation Guide version 1 and what the tool does is it helps our clients profile their data based on that data model. It also enables real time data exchange. So our clients are able to access the data when they need to and have transparency and visibility of the most up-to-date latest version of their data.

I'll now pass it onto Kulvi to talk through the data mapping and extraction and to talk a little bit about the dashboard for cleansing and enrichment. Over to you, Kulvi.

KULVI CHANA: Thank you, Jarryd. So, yeah, as you can see here, data mapping and extraction represents that second point on our process map for IDMP readiness. And as this graphic shows, we use a scenario where, for example, the SmPC, on the left, is used as the source for our data input.

Now, building upon what we already know from XEVMPD, we're looking to extract the data and categorize it now based on the much more detailed requirements of IDMP standards.

And what we've heard from our clients is that having a cloud-based solution, like this, allows for it to sit much more comfortably on top of or alongside existing RIM systems that clients have and this allows for a much easier flow and migration of the data using not just one, but several different approaches. So not just a direct one-to-one data migration, but a migration based also on controlled vocabularies, a dictionary based and/or additional business rules that can be customized to the client's requirements.

So the extraction, as well as these methods, will also depend upon machine learning which will allow the tool to continue to improve over time as more data is ingested and provided.

So looking at the SmPC, on the left, we can see that that information that's typically presented under Sections 1, name of the medicinal product and say Section 3, pharmaceutical form, using the tool, we're now able to be fully map that data and produce data output reports that clearly show that same data, only now expressed in conformance with IDMP standards.

So from just medicinal product name, we now have in accordance with IDMP the invented name, the scientific name, strength, pharmaceutical dose form, formulation, intended use, target populate and etc., etc.

And then if we go to the next slide, please. On this slide, the graphic clearly shows that having sourced and mapped that relevant data, this slide now shows a few snapshots of the views that are available in our tool for clients to check the integrity of the analytics.

So each screen here represents a different view, so that the alignment levels can be checked directly against the IDMP standards for accuracy and completeness. Clients will be able to produce metrics or generate different summary reports to show the confidence level and accuracy of the data and the integrity of the transformation.

So what is the overall result? Well, what we've achieved here for our clients is a clear path of action and a prioritization plan to ensure a high level conformance with IDMP standards as well as any remediation steps that are going to be necessary to reach the required levels for IDMP readiness.

Now the European Commission, European Union, EU Network Data Board and EU ISO IDMP Taskforce has already endorsed a phased implementation of these ISO IDMP standards. And the idea behind that was to allow lessons learned during each phase to be applied and implemented in subsequent phases, processes and, indeed, systems to mature over time.

Now the first phase of SPOR management systems implementation and remember, SPOR stands for Substance Product Organization and Referential, was published around this time a year ago and focused on first delivering the referentials management system and organization management systems, which lay the data foundations for the subsequent delivery of what will be product and substance management systems.

The EMA is developing version 2 or the EU IG v2, which will provide the basis for medicinal product data exchange in the EU and is currently anticipated, as Jarryd mentioned already, to be published next month. This represents that next really important round in IDMP compliance and we're really excited to continue to develop our solution as we wait eagerly for the next release of the IDMP implementation Guidance hopefully next month.

Back over to you, Jarryd.

JARRYD CHEN: Thank you very much for your time and thank you for listening. We hope you found today's presentation useful as we talk about the case for AI and its use in the context of regulatory from a CMC perspective, from a labelling perspective and from even a regulatory and compliance perspective. With that being said, please feel free to reach out if you have any questions or any queries regarding the things we have discussed today. Our details here are on the screen and we hope to hear from you. Thank you.