ACCENTURE AND TOPRA WEBINAR

VIDEO TRANSCRIPT

KULVI CHANA: Welcome everybody to today's webinar, which is all to do with the ISO Identification of Medicinal Products and Readiness or IDMP.

So I would like to take a few second just to introduce myself. My name is Kulvi Chana and I am a Regulatory SME and the IDMP Operations Lead at Accenture, where I've worked with the regulatory affairs function for the past 7 years on a wide variety of projects, both including regulatory strategy, compliance and labeling transformations, front end submission support and activities for new applications, as well as the lifecycle maintenance of products.

Prior to this, I also worked in industry as a regulatory consultant for a number of leading biopharma companies, as well as at the UK affiliate of a top FMCG organization.

I'll now hand you over to Jarryd to introduce himself.

JARRYD CHEN: Thanks, Kulvi. Hi, everyone. My name's Jarryd. I'm a Regulatory Information Management Consultant here at Accenture focused on large scale transformation and implementation of RIM systems. So across your submission planning, your authoring, your managing Health Authority correspondence, registration tracking, labeling and also post-marketing commitments. I'm also focused on regulatory automation opportunities as part of the overall regulatory value chain. And prior to this, prior to Accenture, I worked in regulatory operations at a global pharmaceutical organization.

Back to you, Kulvi.

KULVI CHANA: Thanks, Jarryd. Can we have the next slide please. Just a few quick words on our services and capabilities within the regulatory domain at Accenture. We are a large organization within the life sciences practice and have four operational sites as you can see from the slide shown above.

We have over 200 professionals and we cover a wide portfolio of services as you can see outlined on the right-hand side. And are fully committed to using the depth and breadth of the expertise we have within Accenture in both regulatory operations, technology, strategy and consulting, to deliver and help our clients achieve successful business outcomes.

Next slide please. So as far as the agenda this morning, it's really quite simple, although it's a little deceptive because we have a lot of material to cover. We will be covering the background on context to IDMP, why it came about and the change it brings honing a shift towards a much more data driven function for regulatory.

And then, we'll talk of the four layers that allow you to achieve a successful IDMP adoption where we will cover data supply and governance, technology, processes and last but not least, engagement and change.

Next slide please. So if we're talking about the background to IDMP, for many years, the regulators have sought to find a better way to communicate vital information about medicines

in a unique, but harmonized way in order to simplify the exchange of information between stakeholders and enhance the interoperability of systems.

So it's safe to say, in general, that when regulators go forward, they want regulatory submissions to have more structured data.

The set of five ISO IDMP standards, define the format and have been developed in response to a worldwide demand for internationally harmonized specifications for identifying and describing medicinal products. IDMP provides the basis for the unique identification of medicinal products, which helps Health Authorities worldwide by jurisdiction for a variety of regulatory activities, including development, registrations, lifecycle management, pharmacovigilance and risk management in relation to medicinal products.

In the future, they're also going to be applied to Investigational Medicinal Products or IMPDs, but for now, we're only concentrating on authorized medicines.

The EMA has taken the lead by being the first Health Authority to adopt the ISO IDMP standards and given the very recently updated version 2 of the Implementation Guidance, we can truly say that the timetable and countdown has begun towards IDMP implementation.

So on the right here, you will see the five ISO standards that form the heart of IDMP, which also come complete with technical specifications or TS documents. This is to ensure a common language is used right across all functions from say manufacturing, regulatory, pharmacovigilence and product supply, to ensure a harmonized approach and compliance with controlled vocabularies.

So as you can see, the five ISO standards here on the right, comprise some 200+ cross-functional data elements as far as IDMP is concerned and those will span across these six product categories as shown below, the Medicinal Product, Marketing Authorization, Indication, Pharmaceutical Product, Ingredients and finally, Package Information.

Messaging specifications are also included as an integral part of the IDMP standards. And these will describe and protect the integrity of the interactions for the submission of regulated medicinal products. In the context of a unique product identification. They include acknowledgement of receipt, including the validation of transmitted information. So Health Level 7, or HL7, FHIR message exchange will be used going forward within the IDMP standards and it will specify the content of the data exchanged between healthcare applications and how the exchange is implemented and managed.

So the EMA has published these new data standards that will go into full effect over the next 24 months. New data requirements, new data standards, all of this presents great challenges to regulatory functions, although many groups will, in fact, benefit from these new requirements over time.

The new data requirements are significantly increased compared to today's data requirements or XCVMPD, which is what IDMP implementation will take an iterative approach and it will seek to build upon the experiences gained at the earlier stages to refine and ensure robust processes are in place for submitting your IDMP data.

So if we go to the next slide please. So a critical part of IDMP readiness includes understanding not just of what data is required, but where the data is located.

Now this graphic here illustrates a sample of the IDMP data fields, which can be found in ISO IDMP 11615 and is further discussed at detail in Chapter 2 of the current version 2 of the ISO IDMP guidance.

Each element has been mapped to each of the six product categories we spoke of earlier in the

slide. Together with a color code key which correlates to the functional area where this data is likely to be found. So as you can see, the data is to be found all over and is spread around wide.

With so many functional areas, such as clinical, labeling, PV, manufacturing, etc., now more than ever in readiness for IDMP, it's going to be important that these functions store data using master data management systems and data governance principles to ensure not just the integrity of data, but also a consistent format. One where everyone speaks the same language.

So this is why IDMP represents a really good opportunity for the business to internally align their data and optimize its governance. Clear definition of business process from data source is going to be required, including clear direction as to data ownership and stewardship.

At its best, once it's fully implemented, IDMP will allow people to be able to concentrate in regulatory, particular, on strategy and drug development rather than getting bogged down with inefficiencies, looking for information and trying to find where it is. Now, it will become more accessible and acceptable as a source of truth.

Next slide please. So how far have we come in relation to SPOR Implementation? Well, due to the complexity of the process of ISO IDMP standards, they're being implemented in phases through the SPOR data management services. And as you may recall, it was all the way back in 2016, over five years ago now, when the electronic application form became mandatory for all new marketing authorization applications renewals and variations. And it was approximately a year later, in December 2017, when the EMA launched the OMS and RMS. OMS and RMS projects were rolled out first as the structured substance information and controlled word vocabularies were pharmaceutical dose forms, units of presentation, roots of administration and packaging, etc., are much more challenging to integrate. At that time, industry was encouraged to use OMS and RMS, where OMS managed all the master data from an organizational perspective. So, for example, name and address for the marketing authorization holder, the sponsors, the manufacturers and health authorities and RMS provides for the CVs or Controlled Vocabularies, were list of terms that we describe different product attributes, such as lists of dosage forms, units of measurement, roots of administration.

So the RMS and OMS manage two of the four domains of substance, product, organization and referential master data or SPOR and they lay the data foundations for the subsequent delivery of what will be the SMS for substances or the PMS, the Product Data Management Service.
Now following the relocation of the EMA in 2019, it would then be February 2020 when EMA finally published Implementation Guide version 1, which was a milestone on the SPOR roadmap.

On the 22nd of February, three weeks ago, we had the latest version of that Implementation Guidance and that's version 2, when the first details of the target operating model, TOM, for submitting and updating data as part of the regulatory submission are detailed more fully in Chapter 3.

Users can access information to all these data services for SPOR directly on the SPOR portal. So IDMP represents a fundamental change to the nature of the data that is provided and many companies are using master data management as a strong foundation for well-managed data. MDM skilled people can be great advisors on IDMP as they have similar goal requirements. So before jumping in IDMP, organizations must be able to find their master data information involved in the basic functions of the business. Companies have to ensure that the data is complete and reliable. Then, master data must be enriched with the remaining IDMP data elements and uploaded into IDMP data base accordingly.

Automation of such a process will be a great advantage as an automation tool could potentially be very helpful to cope with such huge amounts of data.

So let's move on now and let's see where we are in terms of the timeline for IDMP.
So where are we at as of today? With the Implementation Guide version 2, having now being published, we can truly say the countdown to IDMP implementation has begun. In the next 12 months from now, for Step 1, the EMA will provide further small updates within this year to the implementation plan after which, in approximately 12 months, the PMS database will go live and be able to receive information and data by FHIR messaging and the EVPRM.
This is because at that stay, user interface is expected to be available, so for both Centrally Authorized Products or CAPs and non-Centrally Authorized Products or non-CAPs at the go live point to the PMS, IDMP submission is still optional for both.

Going forward, approximately for the 12 months though, we'll still be within Step 1, but it will become mandatory for CAPs products, whilst still only remaining operational for non-CAPs products. So when we say non-CAPs products, we mean those products that are registered via MRP, DCP and national procedures.
Now, eventually, even though a timeframe is yet to be determined, when FHIR messaging will finally properly be incorporated into the electronic application form. Then, at that point, it will become Step 2, and IDMP will be mandatory for both CAPs and non-CAPs.

So make no mistake, version is now on the horizon and the impact of marketing authorization holders means decisions are going to need to be made as to how you're going to submit that PMS data set.

So decisions like this and other process and internal considerations we'll deal with a little later in the presentation. For now, I'm going to ask to go to the next slide, where Jarryd will take you through and help you to understand how to manage your data and data readiness for IDMP regarding data supply and governance.

Over to you, Jarryd.

JARRYD CHEN: Thanks, Kulvi. So in this section, I will talk through the four layers to IDMP. The first two main layers of IDMP adoption, so Data Supply and Governance and Technology.

Next slide please. So as previously mentioned, IDMP is focused on the standards that define the format in which a pharmaceutical product information is collected and reported. And so, it makes sense that through these standards, product information will be more reliable and consistent and that it will support the interoperability of this data. And so, it makes sense then to look at IDMP from a data governance and supply perspective.

Next slide please. So from a data governance perspective, you are looking at the data we already have. So we're assessing our data landscape currently, defining things such as our Control Vocabularies, our data ownership and our data stewardship and also looking at managing some of the current data assets we have, such as our reference data management or master data management of data quality and our data catalogues and I have a slide that will go into this into a little more detail in my next slide.

From a data supply perspective, we're looking at understanding where our data is coming from. So the source identification of our data, the source mapping and profiling, understanding how our data is collected, ensure that there are controls in place to ensure that the data being collected is of quality and if not, then understanding how we can remediate this that data and closing the source gaps as required.
So in my next couple of slides, I will be talking through some of the frameworks that we can use to think about data governance and data supply in relation to compliance to IDMP.

Next slide please. So from a data governance perspective, here we have a framework that considers the four key elements of data governance. So, first, we have data quality. This is your tools, your processes used for profiling, cleansing, standardizing, enriching and monitoring your data, ensuring it aligns to the Implementation Guide version Chapter 2.

From a data catalogue perspective, this is more of a technical asset. So this is about organizing and managing business and technical information where data attributes are structurally stored to help more technical subject matter experts, such as your data stewards or your data professionals, easily search and manage that data. So this would be an inventory of all your IDMP data assets. So structured data, unstructured data, connections between data bases, that will be understood and stored and you have an asset that highlights where they are stored.

Then you have your reference data management. So these are managing your less frequently changing data. So from an IDMP context, this would be your Control Vocabularies would be a referential data. It would be a business rules for data elements that are not part of IDMP, that don't have Controllable Vocabularies, but that you want to standardize and harmonize across the organization.
And finally, you have your master data management. So this ties the three previous points together and it looks at people, process and technology to really define and manage this single source of truth to enable operational efficiency, to enable the reuse of data across various submission types and also, to enable business agility.

Next slide please. So here is initially another framework to look at data supply. So we understand data supply from four key categories that first, you identify your definition and scope. So what data fields are assigned by the EMA? What fields are common with xEVMPD? Which fields may require Controlled Vocabulary?

From a source perspective we're looking at what are the sources of data? Is there an authoritative source that's defined for this data source? Is the source found in structured or unstructured formats? Are there any existing Controlled Vocabularies that may need to be aligned to SPOR vocabularies?

And then, finally, from a quality and accuracy point of view. What is the effort of transformation that is required based on our current data quality? Can we trust the data we currently have? Are we very confident that this is the source of truth? How many hands has received this data before it arrives to us for use for IDMP compliance?

Those are some of the questions that we can start thinking about from a data point of view as we try to achieve IDMP compliance.
Next slide please. So we spoke about the first layer, which is data governance and supply. Now, we will move onto technology and how technology can support in achieving this future state of data governance and managing data supply.

Next slide please. So to achieve data governance and supply in relation to IDMP, where we believe technology can really support this is these five steps shown here on the slide. So first, data mapping and extraction. This is focused on a tool or a technology being able to identify the key sources of IDMP data elements in various system across the organization. As Kulvi previously mentioned, we know that IDMP data will sit not only in regulatory, but across the organization and so, having a tool that's able to pool that together will be very helpful to understand where IDMP data is found and what needs to be aligned.

From a data analysis and mining perspective. So this is a tool that's able to link to SPOR and other industry standards that employs machine learning algorithms to improve over time based on the data they received. So having now mapped and extract that data, now being able to

look at that data and understand what needs to aligned to IDMP. So what needs to be remediated and what needs to be transformed.

And the third step, collecting and maintaining IDMP compliant data. So once that data has been collected and once the target data has been identified and the data that needs to be remediated, now it's identifying what our alignment level is. It's providing the confidence level to allow a user, a regulatory expert, to look at that data and prioritize what they need to focus on.

Step 4 and 5, so these are, we believe, will be able to also support with IDMP compliance from a technology perspective, but will require more definition as the implementation guides get released in the coming year.

From a data cleansing and enrichment. Here, we're focused on the maintenance of data. So Step 1, 2 and 3 will be getting the initial load of data, having the initial submission of IDMP data. And Step 4, will be focused on managing that data, maintaining that data, as new products and new IDMP data come through the tool.

And finally, IDMP submission. So we know that there are various ways to submit IDMP based on Chapter 3 of the version 2 of the Implementation Guide. You can either submit it via your EDT and your working-documents folder or you can submit it via API to the SPOR database. And so, whether you're sending it, the tool will be able to help with the FHIR message creation, focalization that don't have a RIM system and for organizations that do have a RIM system, the tool will be able to help to submit straight to the SPOR database via an API.

So my next couple of slides, I'm going to be talking through, I've given you some screen shots of a tool that we currently have developed that we're working on focused on Step 1, 2 and 3.

So looking at first the data mapping and extraction. First, we have here the ability to profile and classify your data based on IDMP captured in current systems, such as your SAP, your RIM systems, your document management systems. Obviously, the systems listed here is not exhaustive, what's shown on the screen is not exhaustive, but the concept of it is to be able to extract and identify IDMP data in various systems.

The data dashboard view provides the visibility on IDMP fields available currently to sources, as I mentioned, but also, data sources, data elements that are not captured in existing systems. So on the right, where it shows subject areas availability, we show what data based on the subject areas of IDMP, so that's your medicinal products, your packaged medicinal product, your ingredients, it shows what data elements are available in systems and what isn't.

And finally, we also have the real time data exchange between systems and tools which enable real time tracking of any change in systems. So, for example, a change that happened in your RIM system, that will reflect in the tool rather than having to have a data steward automatically extract the data and update a different system.

Next slide please. So this slide here just shows that once you've extracted that data, now you need to understand how that data has been extracted. We know that because of the vast data model of IDMP, there are various ways to extract data and can be found in different places. And so, here we focus on three main places to extract data.

First, you have your one-to-one mapping of xEVMPD to IDMP fields. Then also have your rules based approach. These are data elements that already exist in your current systems. Across the organization, but will require some sort of remediation or transformation effort to ensure that they are IDMP compliant rather than through Controlled Vocabularies of business rules.

And finally, you have your artificial intelligence or your machine learning based extraction. So this is where your data is stored in unstructured formats, such as your Model 3 quality documents or your SmPC where extraction is required. And so, the ability to extract data, to form them into structured formats from these documents will be very useful and would save a lot of data, manual data entry work.

So on my next slide, here is an example of the ability of the tool to perform data analysis in mining. So it extracts from data from unstructured sources such as your SmPC, your eAF and your relevant Model 3 documents and can be categorized based on IDMP requirements. Also, to note, that the tool iterates and employs machine learning. So as you feed it more SmPCs, as you feed it more Model 3 documents, the tool learns and iterates and becomes better over time, inherently improving its accuracy.

So looking at the diagram here, we see SmPC section. Section 1, name of the medicinal product and the pharmaceutical form. And on the right, we see that it goes through the tool or the technology layer and it forms a data output. And what this data output shows is, for example, for the name of the medicinal product, it shows how the data output is now IDMP compliant, which is your invented name, your scientific name. And then, from a pharmaceutical form, it's your strength, it's your pharmaceutical dose form, your formulation and your intended use.

So the ability of a tool to support, we've taken that unstructured data source, break it down and turning into a structured source in a tabular format in an IDMP compliant format, which then can be used for a submission.

Next slide please. So finally, we reached a third stage of the tool which is cleaning and enrichment. And here, on the left, we have the review screen which shows the view of the subject, it was previously identified, and whether the algorithm has – whether the tool or the technology layer has confidence in the data that's been extracted.

So, for example, we see that if there are two conflicting data sources or if the tool has low confidence in the data, it's extracted based on historical training data or if there's an unknown value and the tool's able to flag that up to regulatory professional to then look at it and make decisions based on the information that the tool is given them.

In the middle, on the other hand, we have a view of IDMP compliance, by therapeutic area. So highlight specifically the medicinal products for review. So it flags up which medicinal product. In this example here, we're using the product name, which is the product needs to be prioritized and which ones has gaps in the current data set.

And finally, on the right, we have the implementation tracker which demonstrates what benefit we need to focus on and the remediation efforts based on the review initially done. So based on the subject area, the criterias are based on the subject area, availability of data, availability, the confidence, whether there's a conflict, whether it's low or high and provides a proposal to the user on how they should focus their remediation effort.

So that's a huge sea of IDMP data. There's a lot to remediate and a lot to transform and a lot to align to based on these new standards. But where can we focus, where we can have a quick wins and where do we need to focus more of our efforts into. And so, based on this cleansing and enrichment dashboard on this view, the benefits it provides to an organization or to our clients is it identifies alignment, level of target data to IDMP data. It provides confidence level for each transformation to help prioritize QC checking of that – quality checking of their automated output. It enables analytics and to visualize current state and track programs or remediation efforts as shown in the screen on the right.

And finally, it enables robust and specific reporting. So this could help you socialize to

your stakeholders across your organization who's not so much aware of IDMP, but you need to get the message across that where the data needs to be remediated or data needs to be transformed that they currently own.

So next slide please. So now I'll pass it onto Kulvi to talk about how we can be IDMP compliant when we process perspective.

KULVI CHANA: Thanks, Jarryd.

JARRYD CHEN: No worries.

KULVI CHANA: Can I have the next slide please. So as I mentioned earlier on, the timetable has already begun in earnest for IDMP implementation. It's now very much on the horizon and the impact to marketing authorization holders means decisions are going to have to be made as to how that PMS data set will be submitted. So achieving regulatory operational excellence is going to require companies to really look inward and embrace the concepts of a data and insight driven future. Preparation for IDMP, in fact, preparation for several other key industry and regulator led initiatives around the corner, such as EPI or Electronic Product Information, the PSU or Single Assessment or PSUSA, not along too far, for example, in the U.S., we have structured product labeling already in force and, of course, PQ/CMC.

So there are many other regions as well, including Australia, Canada, Japan, Russia, Switzerland, all of whom have indicated a very keen interest in IDMP.

So different processes, different standards within a company's organization means there are bound to be impacts on those existing processes. So how do we deal with them? What sort of questions do we have to ask ourselves on the impact on our current processes?

So given the complexity of IDMP, a change of this magnitude generally leads to a change in the business operating models and several IT transformations, highlighting the need for an end-to-end integrated change process involving these crucial steps.

So the sort of questions that you should be asking are whether you understand the regulatory requirements and if you do, have you created the right awareness and cascaded it down throughout the organization?
The impact on business processes, has that been identified? What are those gaps? What are those pinch points or pain points? Where is the data going to come from with submission to PMS?

For example, will you be investing in a software tool? Jarryd's already talked about that in the previous slides and the importance of, for example, a RIM system. Will you be using that? What if you don't have a RIM system? How do you propose to collect and store and maintain your data for IDMP purposes? Looking at your portfolio of products, what are you going to do? Are you going to switch to the new technology for all of them or only part of them?

All of these are really valid questions for organizations to ask and not only that, you then have to identify the remediation plan and actions too. It will become important to identify and create a strategic vision for implementing this change. Analyze whether your people, your data, your systems, your processes, what improvements are necessary? Presenting that business case and define your implementation strategy based on that vision because that is what it will take to ensure that everybody will collaborate and create together the vision of IDMP compliance.

So version 2 of the Implementation Guidance has been published for the first time, the target operating model for the submission of your IDMP data, which we'll take a look at now on the next slide.

So as you can see from this timeline, sorry, it's the previous slide. Thank you. As you can see from this timeline here, this is the same timeline

we presented earlier in the presentation, but now we've populated it essentially with what will need to be submitted as we look towards the IDMP timeline.

So as you can see on the left, we have the situation as it stands right now, which is that you still have to submit for both CAPs and non-CAPs, post approval your EVMPD message that will go at the end, straight to the EMA. But this will change once PMS has gone live and we can see in the next slide, for example, how that will look.

So whilst we're in Step 1 of the target operating model, when considering the CAP products that are on an eCTD format, the initial submission now post-go live of the PMS will be that it has to be included, a FHIR message within your MAA or line extension to generate those pharmaceutical product identifiers.

The FHIR message will be submitted not within the eCTD, but actually within the working-documents folder that goes alongside it and the data will be assessed by the EMA during the procedure. Any discrepancy between that data and the documents will lead to a feedback loop, so there will be data going forward and back until it's fully authorized and accepted.
The closing sequence must contain a FHIR message which is then pushed automatically to the PMS. The closing sequence for maintenance submissions also, for example, variations and renewals must also contain that FHIR message. In the event there is no closing sequence for some other type of variation, say, for example, the Type 1A, the FHIR message is submitted directly to the PMS via the API, post-approval.
So if you go to the next slide. Staying still within Step 1 of the target operating model, we now consider the position for CAPs that are in a non-eCTD format. So, for example, those submissions with like a PIP submission. So for non-eCTD, the FHIR message has to be submitted directly to the PMS via the API, post-approval.

Remember, in Step 1 though, non-Centrally Authorized Products or non-CAPs are still optional. So if a FHIR message is submitted, it won't be assessed during the procedure and it will have to be submitted directly to the PMS via the API, post-approval.

So once the Step 2 has come along and it becomes mandatory for both CAPs and non-CAPs, the situation will become your dossier will be sent with the FHIR message as part of the electronic application form. And that will be assessed by the Competent Authority during the procedure. So really, we're allowing time for Step 2 because we have to ensure that the European Authority have basically brought up the electronic application form to include that FHIR message and that's sometime in the distant future.

So if we go to the next slide, I will now hand back again to Jarryd, who will discuss the change management and engagement part. Over to you, Jarryd.

JARRYD CHEN: Thanks, Kulvi. So in the next couple of slides, I will be speaking to change management and engagement, as we know that there's no point having the technology and the governance and the controls in place and the processes, if we don't get the people to adopt it and to see the vision of IDMP and what is capable of shifting in terms of the paradigm. And so, in my next slide, here this slide essentially just talks about how IDMP is more than just compliance. What we find is that because IDMP spans across the organization, it's no more just about compliance, but it's a fundamental shift in the way a pharmaceutical organization or an organization manages data. And so, while the aim is to be compliance ready and to avoid fines from a Health Authority. There is an opportunity here to increase master data quality and consistency across the organization, across various functions. And by increasing that compliance and that master data quality and the consistency, organizations are then able to look at raising automation as much as possible, enabling operational efficiency and allowing the regulatory function to focus on more strategic

things such as supporting time to market and focusing on managing Health Authority correspondence.

The last two points here is the focus on digitizing the R&D function from a strategic perspective and also, to build advanced analytics. So tying back to that strategic asset of the regulatory function, the ability to build predictive analytics capabilities within the company because of that foundational master data management, data quality asset.

So to summarize here, the IDMP initiatives that can be used as a starting point to really drive major strategic initiatives across the R&D functions, increase compliance, expedite digitalization and build predictive analytic capabilities within the R&D function.
Next slide please. So here, we're looking at some of the key things to look at in terms of managing change management and engagement. So first, from a leadership and a stakeholder perspective, understanding the impacted group of stakeholders, understanding who should be informed and who should be involved, aligning the key leaders, the sponsors and engaging them, having champions from a leadership perspective that will support IDMP and speak of the importance of IDMP.

From a communication perspective, ensuring to deliver the right content to the right audience at the right time, really honing in on the business value that it goes beyond just compliance, but also a fundamental shift in the way data is managed in an organization.

Having training and performance support. So developing a role based learning curriculum and having super users within the organization that will really champion IDMP.

And finally, business readiness and measurements. So having pulse checks in place, whether that's through an open forum, whether that's having townhalls, to really understand the readiness and to monitor IDMP adoption throughout the organization and also prepare for a global change network as IDMP moves beyond your Europe and into other regions of the world.

So fundamentally, change strategy and planning can be looked at from three key points. So having a clear understanding of the degree of change across the diverse functional landscape, having stakeholder where there's alignment on program benefits based on the business outputs and based on what is required. And finally, having a detailed framework to guide change activities for program and releases and we see this as implementation guides gets released throughout the year, version 2.1, 2.2, 2.3. Organizations can start informing and training the organization to prepare for IDMP.

So with that, that comes to the end of our presentation. We thank you so much for your time and for listening and we're happy to take any questions that you may have.

Hi, Elizabeth. There's a question here in the chat. Will slides be available after the session? Yes, we will be sending out a shorter version of the slides after the session. And if you have any questions, feel free to contact myself or Kulvi.
KULVI CHANA: So I'll take this question and I just want to also take this opportunity to introduce Pauline Cheema, who is also on the line, available, as part of our panel to answer any questions.

So, Ilene is asking is there any indication that there will be regulatory leniency coming with implementation, for example, to eliminate Type 1A submissions where Admin data is being updated?

So I think as this IDMP is being sort of rolled out, there's going to be lots of time for further guidance to be rolled out. As I mentioned, for the period of from now until the next 12 months, for example, we fully expect there to be further updates in this year, in actual fact, in relation to the current guidance which is only posted three weeks ago. So it's still very, very new and I think this is precisely the sort of thing that we will be

seeing more information on. So I think the short answer to your question is, let's see what comes out in the subsequent gudiances at present, but there's nothing definitive to indicate that. But I think leniency is something that we can all understand it's going to take time to implement these really vast changes to the way we're going to be carrying our regulatory submissions going forward.

So I would say, let's keep eyes peeled on the guidance and, of course, we would be very much looking to that level of detail.

So Stefan, you were asking, can you recommend publications on IDMP implementation?

To be honest with you, from my own personal experience, the only way to really understand IDMP implementation is to read the guidance and from time to time maybe even conjunction with the ISO IDMP standards themselves.
I mean, if we look at the overall IDMP guidance that's being published, obviously, three weeks ago, we have now up to something like 9 chapters and each chapter concentrates on different things. So for the first time, for example, in Chapter 9, or 8, I believe, they've actually produced examples for you to look at, what IDMP would look like and how you would map it. So there's an awful lot of information that has been published and is really needed to be digested. I'm not aware of any other publications, but I think the best thing is always to go to the source. So the actual EMA Implementation Guidance for IDMP, together with the ISO standards is where the detail is, I'm afraid.

So, Jarryd, I think this question is for you from Sara. I'll ask you to take that one.

JARRYD CHEN: Yep, so thanks for the question, Sara. And this question here, when searching for a RIM system, what are the key questions to ask in regards to IDMP readiness? So I guess, the first thing you would look at is its current – the way it actually currently submits or deal with xEVMPD submissions. Do they currently have the ability to create that xEVMPD format? And is there any future roadmap to be able to incorporate the HR7 FHIR submission for in their RIM system?

Some other things to consider is the ability to do it end-to-end. So, for example, from your submission planning, to your submission authoring and then your registration tracking and your labeling, all that data that's currently being used to plan your submission will be required for submission for IDMP data.

And so, being able to understand that if the RIM system has the capability, would be pivotal to be able to extract their data, have the data in the system and then extract it to a HL7 FHIR format for submission to Health Authority. So that will be something key, I would say, to look at.
KULVI CHANA: Okay, so thanks for that, Jarryd. So we also have a question here, I believe, from Rahal. Hope I said that correctly Rahal. What approach do we think is best in engaging leadership and senior stakeholders?

So I think Jarryd and I can both speak to that to some extent. The approach I would suggest is as early as possible. I think one of the things, hopefully, we've – I hope we've impressed upon you is this is going to take a huge collaborative effort from within the organization. The notion that this is sort of a regulatory issue and doesn't involve anybody else is really not the case. Regulatory tends to be where data may end up, but it actually over time elsewhere in the organization, which is why having the buy-in from manufacturing, from PV, from supply, everybody where the data probably often originates, clinical, it's really important that they understand they all have a part to play and that their individual processes are somehow you're going to have to somehow interconnect to be able to work together and help to become ready for IDMP.

It's really about awareness cascading down the information, certainly, definitely sharing the timeline. This is real, this is happening. So that's

really a couple of the pointers I would say in terms of getting the message out. Jarryd, I don't know if you want to add anything?

JARRYD CHEN: Yes, I think the driving factor here is compliance. Its risk being fined and compliance as the driving factor. But beyond that it's having the single source of truth and standardizing IDMP. This opportunity that beyond compliance you're able to really push for the single source of truth or that master data management. We see this shift of the Health Authority, especially the EMA to this data driven paradigm. We see that in the telematic strategy and we see that with the new CTR regulation that's coming for clinical data. And so, there is this focus to have standardized data and harmonized data and the fast organizations react to this, the better in terms of being able to react to future regulations and future change that it will be coming from the EMA or from the Health Authority.

And so, that could be in synergy with the compliance aspect of it. You could also use this shift is coming as the focus, we see other initiatives like structured content authoring or product labeling that's coming and that's really going to change the way regulatory folks deal with data.

And so, that's coming and it's when the organization choose whether they want to be proactive or reactive. And so, driving – using that as a business case would really help the engagement of leadership and senior stakeholders. And, of course, the cost benefits through operational efficiency that could be realized around the organization as we have master data, as we're able to automate a lot of the processes around those little cost benefits add up, which will really drive traction with your senior leadership and engaging them.

KULVI CHANA: Thanks again, Jarryd. It's very important. I mean I think we mentioned in our presentation also, being ready for IDMP is really an investment for the future as a whole. There will be many other regulator-led initiatives like API, except for they're all coming out way. So it's really good, good preparation now.

We have another question from Noreen. Thanks, Noreen, for your question. What is the estimated timing for non-CAPs at this point? Is there anything better than TBD?

I wish I could say, yes, but I can't, I'm afraid. It really is TBD and that's the reason why I mentioned that even though – I mean the guidance was only published three weeks ago. So this is still very, very, very much new and we absolutely expect there to be further minor updates. I mean I don't expect it to be anything really, really major, but later this year, there are expected to be further guidance updates as well to version 2. So it's sort of 2.1 or 2.2. So I think that's really when we'll get closer, but at this stage, this is all the information that's been given out as up until three weeks ago.

The position with regards to non-CAPs is still optional up until not only now, but 12 months from now, approximately. And thereafter, it will be CAPs only which are the first step towards the IDMP data being submitted. So that's about as best as it's going to be at the moment, I think. Jarryd, did you want to add?

JARRYD CHEN: Yeah, I just wanted to add that in the guidance, there are – they do talk about some pre-conditions that are met before non-CAPs will be mandatory. And so, they give four main key points to look out for. So, first, a new version, as Kulvi mentioned, a new version of the Implementation Guide supporting the implementation of non-CAPs. So once that gets released and we know that the clock is ticking in terms of it's coming. Then, we have a structured eAF that is compatible with the IDMP model. So once that is released, that's another key indicator for the mandatory non-CAPs submissions required.

And the, the last two points of having a data governance framework and defining the roles and responsibility, so what's expected of the Health Authority, what's expected of the market

authorization holder. And finally, capabilities to exchange and maintain the medicinal product identifies. So more detail on the technical operating model as we've seen captive three currently, they will provide a more flushed out version of it.

So these are some of the precursors that we could look at, that would start the clock to tick and that way we would know that the non-CAPs at this point would be coming.

KULVI CHANA: Thanks again for that, Jarryd. Thank you. And then, we have a question here from Nickola. Hi, Nicola, thanks for your question. And so, this is a very good question actually. If your new product approved via the Centralized Procedures that you've got a CAP product, before mandatory implementation of IDMP, but a variation is anticipated shortly after mandatory implementation, are there any specific issues, complexities expected?

I don't think the guidance has gone into that level of detail just yet, Nickola. I think that will be forthcoming as this sort of unwraps itself within these next few updates to the guidance. But I would imagine, I think if it's so close to that timeline, there's going to be a sort of period during which these things will be introduced in a very step-wise way. So I don't think there's be any hard and fast rules. I think though that timing, etc., with regards to approvals, etc., we need to think about all of those very carefully. But I think there's nothing hard and fast just yet. So, although, I can't answer your question immediately, I thoroughly anticipate that with the further rollouts of the guidance that are expected, the updates that then will be that level of detail provided.

Jarryd, Pauline, I don't know if you've got anything more to add on that?

JARRYD CHEN: No, nothing for me.

PAULINE CHEEMA: Yeah, so I think this is a question of watch this space. Again, as to these questions which are going to straddle the two sort of stages between which you don't have to provide your FHIR messaging and then you do, what happens? I think there will be a gentle period, I'm sure, that will allow you to transition.

KULVI CHANA: Okay, so thank you for that. Going over to a question now from Anna. Thanks, Anna. How does this link in with UDOMed where there are medical device elements?

I don't have the answer to that actually, I'm afraid. That's something that I'm not sure about, but it's a very good question and I can certainly come back to you offline about that. But I'm not entirely sure.

I don't know, Jarryd, you've got anything else to add? I think that's something that we would have to look into. Anna, good question though.

JARRYD CHEN: Yeah, we can get back to you, Anna. We can look into that and get back to you.

KULVI CHANA: Okay, thank you for that, Anna. And then, over to Sherika. Hi, Sherika. Is there any further technologies apart from those mentioned in the presentation considered in the future whilst collecting IDMP data and submission?

Jarryd, over to you on that one?

JARRYD CHEN: Yeah, thanks for the question, Sherika. That is a good question. So because the landscape is so new, because the real operating model for IDMP has only been released a couple of weeks ago in terms of how we're going to exchange this data, how we're going to send the data to the Health Authority, the current technology landscape is very – is not as mature as we would like. And so, where we look at it from a technology landscape, we're looking at it from the extraction of their data, the remediation of their data and the ability to write to that database.

As of now, based on the latest guidance, this is the end-to-end process of achieving IDMP

compliance. There may be an element of it of ensuring the maintenance and the constant remediation of that data. But we feel that the main two key technologies that will support the whole IDMP process is artificial intelligence and natural language processing.

Artificial intelligence in the way where it's able to identify, assess current data and remediate it and map it and support the regulatory professionals to fix that data, to ensure that it's IDMP compliance or align that data to Control Vocabulary to the IDMP compliant. And then, natural language processing, the ability to extract data from unstructured sources, to go through all your Model 3 quality documents and extract the valuable data. Those are the two key technologies we see that really show support IDMP in the future.

And based on that, tools and variations of the technology could be built. But the fundamentals underlying technology would be those two. And so, for now, I don't foresee any other SPOR technologies that would be able to support this.

KULVI CHANA: Thank you, Jarryd. Hope that helps, Sherika. And I think that probably was the last question that we have time for today. Oh, we got something else just coming in. Okay, I'll try to squeeze this one in, it's quite a long one.

Again, from Rahal. Hi. With respect to the change management, how do you envision stakeholder communication collaboration would be best approached? I am thinking, for example, some organizations have the quality team that champion this, but with respect to IDMP, who should be the ideal driver for the change management, regulator or a different functional group?

That's a really good question. I think – go, Jarryd, go for it.

JARRYD CHEN: No, you can go, Kulvi.

KULVI CHANA: Well, I was going to say, I don't think it is – as we said earlier, it's no one person's responsibility unfortunately. In fact, the responsibility is really for everyone, but there has to be somebody to drive it. And I would have thought really, as a regulatory person myself, it's something of extreme importance to me. But as Jarryd will tell you, with somebody with technology background as he's got, that's equally as much for him. So I think when it comes to regulations, you know, regulatory are out there and they would be aware and they would know about it. But it's really important to gather some traction so that you approach this in a way that it doesn't look like just a regulatory initiative because I think that's the hardest thing often is to get that engagement from the other stakeholders.

So from a regulatory perspective, as I would take, I would be the one to pick this up and absolutely run with it and sort of bring that wakeup call to everybody else within the organization as to how crucially important this IDMP is.

Jarryd, over to you.

JARRYD CHEN: Yeah, and I would agree with that. The driver should be for regulatory because IDMP is a regulation. But what we've seen with big organizations is what they do is they have a taskforce, an internal taskforce consisting of members from different parts of the organization that meet at a specific cadence or meets weekly or biweekly to discuss how it impacts the existing processes and have their representatives there.

And so, while the owner and the driver is regulatory, you're right, there's going to be, as Kulvi mentioned, there's going to be other stakeholders that will be impacted and they will need to be involved. And so, what we frequently see is a taskforce, an internal taskforce that manages the impact of IDMP across the organization.

And then, Stefan, his question is can you please repeat the two technologies again? So they are artificial intelligence, machine learning. So

artificial intelligence and machine learning that can be used there synonymous. And then, you have natural language processing. So the ability to extract data from unstructured formats. So those are the two key technologies that both drive and will support the adoption of IDMP.

KULVI CHANA: I think that was the last question. So thank you so much.

SPEAKER: And I just wanted to thank you and all the speakers to deliver such an engaging and interesting presentation and all the MDs for joining in and asking so many interesting questions. As was mentioned during the presentation, it will be shared later on today by email, but if you have any further questions, please contact me or, indeed, Kulvi or Jarryd directly.

So thank you once again and hopefully, see you another time.