**Canadian Association of Professionals in Regulatory Affairs/**
**Association canadienne des professionnels en réglementation**

# CAPRA Webinar series 11 December 2014

## Regulatory Information Management and IDMP
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## Qs & As

**You mentioned that much of the data in IDMP overlaps with other regulatory documents (e.g. CPID, PM),.. Are you aware of any discussion among regulators that IDMP might replace other existing equiements?**

Regarding IDMP, No, I am not aware of any plans to remove or diminish existing document or content requirements.

This is one of the reasons for holding this webinar and raising awareness now. Asking questions like this or, better yet, making suggestions in the development stage benefits us all.

**Would you be able to share the presentation and audio about today's presentation?**

Yes, CAPRA will post the slides and the webinar recording. They will be posted in the member's section area only on the web.

**Is one of the objectives of IDMP to facilitate international / concurrent drug submissions?**

Concurrent drug submissions as in concurrent NDS, NDA MAA? No, the IDMP is more about standardizing patient safety and drug identification data. We are closer to concurrent patient safety submissions than concurrent regulatory drug submissions.

That said, I do believe concurrent regulatory submissions will be a strategic outcome. We are closer to that eventuality because co-dependent pieces of the puzzle are coming together over the next three years. A few examples,

- IDMP creates a common means of defining a product.
- Regulated Product Submission, or RPS, is the next major version of eCTD. RPS is like IDMP but for regulatory submissions.
- Standards for structured content already exist and their use will expand: Structured Product Labeling (SPL) would structure and standardize the way product labeling is presented.

- Structured versions of the CPID or QOS are being discussed. There are standards for Clinical, non-clinical and stability data.
- Through the Product Register project Health Canada is structuring product and patient safety information.
- Electronic signatures and electronic approvals.
- A two-way version of the FDA/HC Common eSubmission Gateway is being developed.

**Where can we get a copy of the standard - Can you provide a copy.**

The title of the document I was referring to: *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

A licensed copy of this document can be purchased HERE at the International Organization for Standardization (ISO) webpage:

NB. There are copyright restrictions on sharing.

**Sounds like the IDMP is an international initiative, not just a Health Canada initiative, is that correct?**

Correct. IDMP is an international initiative. Ultimately it will be an ISO standard.

The following organizations play a role in its development: Health Level 7 (HL7); ICH (members and observers); European Committee for Standardization (CEN); and the International Standards Organization (ISO).

**If Health Canada is using this info during inspections, why is it not a collaborative effort with industry so that both can see info?**

IDMP is being developed collaboratively by national and international standards bodies, health authorities and industry associations.

Canadian industry can get involved in its development through Health Canada or through Canadian industry associations.

Regarding inspections, this information is already collected and available to Health Canada. The key difference is its format, availability, accessibility and the ability to manipulate the information (e.g., create reports or meta-analyses).

Regarding our ability to see the information, I do not know the health authorities position on that at this time. Something industry should comment on when the Implementation Guides are released for comment.

**No sound with the exception of static from this webinar. Can it be viewed and listened to at another time.**

We will be posting the slides for members in the member's section area on the web. I am recording the Webinar as well, but not sure how good the recording will come out. Thanks,

**Since IDMP is global, where within the structure of IDMP will inter-country differences between products be captured? (i.e. Health Canada may think they know more than you, but only for a product sold exclusively in Europe!)**

Regarding Inter-country differences in the standard, regional differences will be documented in the implementation guides.

Regarding inter-country differences in the product, these are captured in the standard naturally. For instance, the IDMP structure allows us to identify the overarching product; each physical, chemical, biological or device variant; and the country level market authorization details for each variant.

**The IDMP has overlapping data, would it be possible to submit once at one particular place and then it will be populated at all the other related sections?**

Yes, the standard is meant to work this way.

However, that is just the standard. It is up to the software developers to ensure their applications apply the standard properly. It is also up to industry and health authorities to ensure the developers create applications that apply the standard effectively.

If you are working with any software developers on Regulatory Information applications then help them understand the practical aspects of regulatory affairs. The more they understand our business and the idiosyncrasies of our products the greater the chance that their applications will be effective.

**Are there any pilot projects currently underway?**

None that I am aware of at this time.

As mentioned during the webinar, the EMA chose not to wait for IDMP to be fully operational in 2016. Instead they created their own standard based on a subset of IDMP. This standard is called the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD). It has been mandatory since July 2012. Once IDMP is ready the EMA will roll XEVMPD into IDMP and make it mandatory July 2016.

If you are looking for an example of how IDMP could be used and how it would work I recommend reviewing some of the XEVMPD material: *Overview* or *Training videos* and *presentations*

Some software developers already have applications meant to manage Regulatory Information at the submission lifecycle level or XEVMPD level. Some have applications meant for IDMP level information.

I have attended demos from one developer that was creating an application to track IDMP level product information. At the time they were asking for feedback from their customers (how does this look; how would you manage this type of product; if this scenario occurred how would you like it displayed in the application). This was not a pilot but it was still helpful to have a say in the applications development.

**Will the slide deck be shared?**

Yes please, the slides will be posted in the member's section area only on the web.

**You mentioned that Structured Product Labeling is part of the IT modernizations, are you aware of any timeline for Health Canada?**

No timeline right since this is still at an early stage.

Something to keep an eye on is Health Canada's Product Register project. This is not SPL but it does demonstrate the fact that Health Canada has the ability to transform Word or PDF product monographs into XML. This is a big first step towards an SPL based Product Monograph.