Health Canada Santé Canada

Canada

# Structured Product Monograph and Drug Health Product Register

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November 16th, 2016

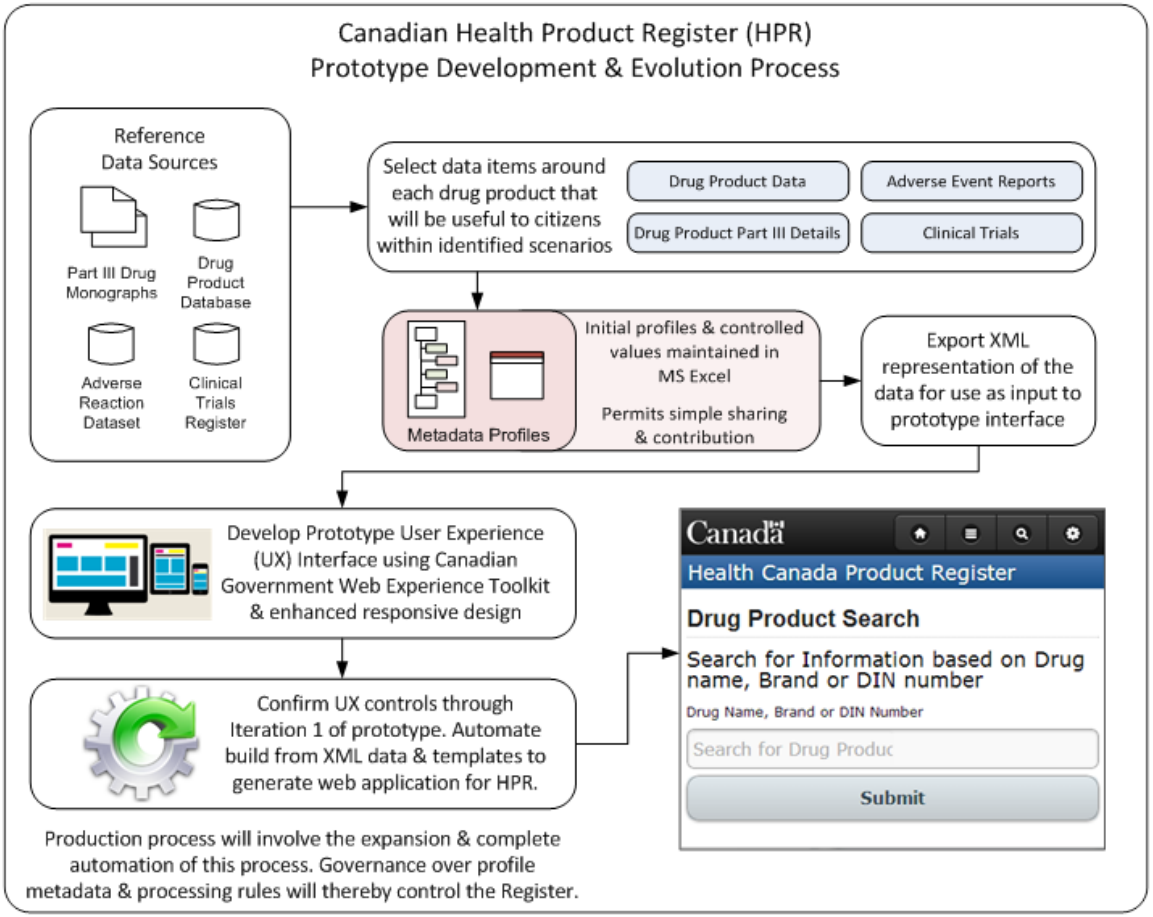
YOUR HEALTH AND SAFETY... OUR PRIORITY.

- DHPR Overview
- Structured Content
- Structured Product Monograph (SPM) Testing Phases
- Technical Walkthrough of IGs
- SPM Web Form Demo

# The Drug and Health Product Register (DHPR)

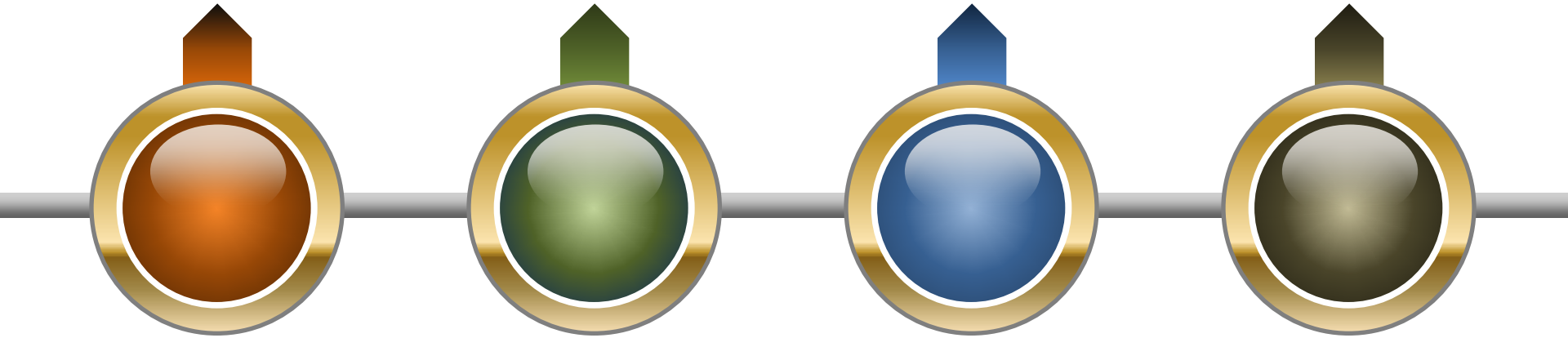
- Web portal designed to give Canadians easy access to consumer-friendly information on a wide range of health products.
- Brings together and organizes health product information drawn from various areas and databases on Health Canada's website and present the information in a consolidated, user-friendly way.
- Mobile friendly so Canadians can access health product information on the go.
- Major milestone under Health Canada's Regulatory Transparency and Openness Framework.
- Demonstrates concrete progress to improve access to timely, useful and relevant regulatory information for Canadians.

# DHPR: Engaging with Citizens to understand their needs




- Seniors and Caregivers
- Patient Safety Groups
- Health Care Professionals
- Industry

# DHPR: Conceptual Framework



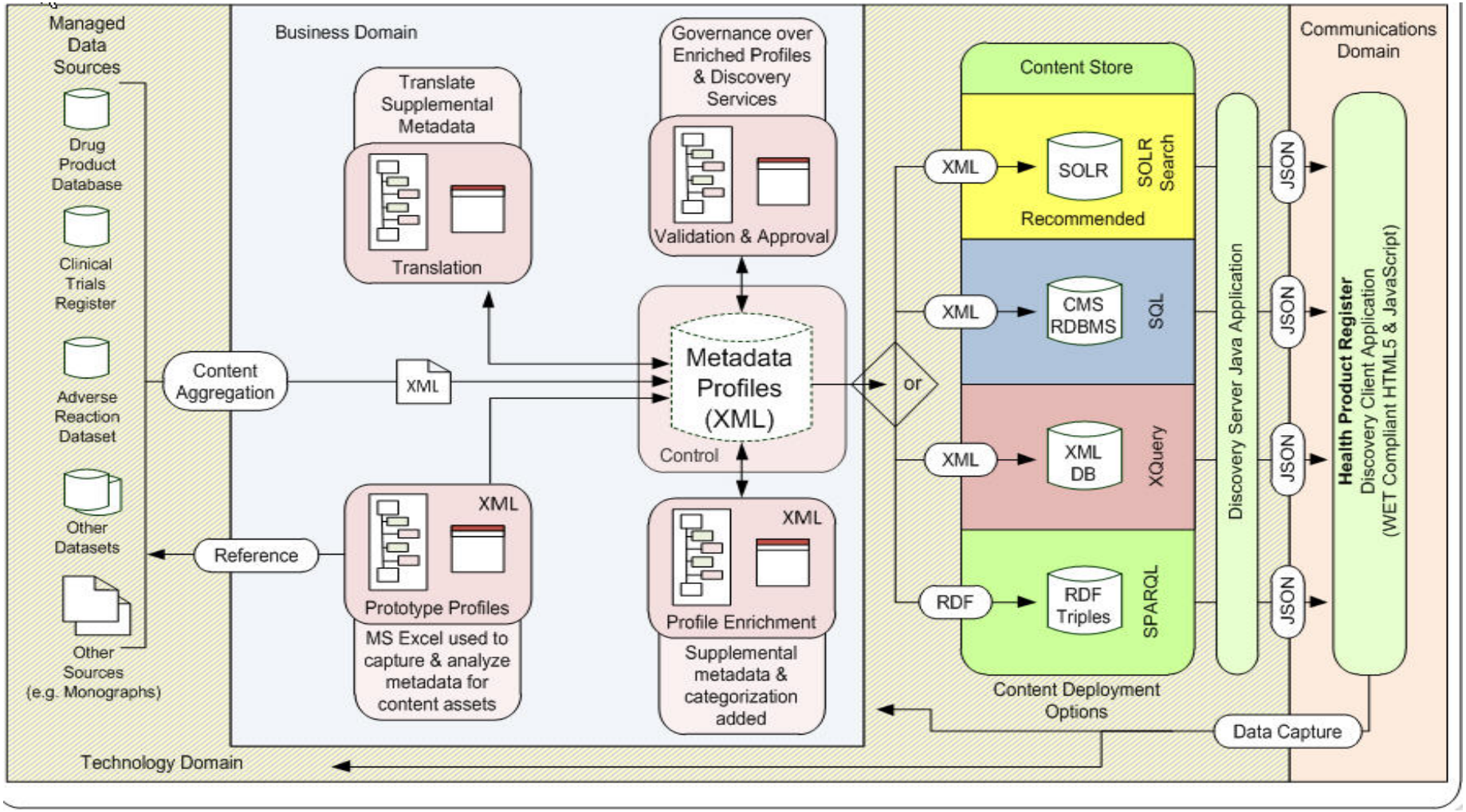

Take any of the existing data sources at Health Canada

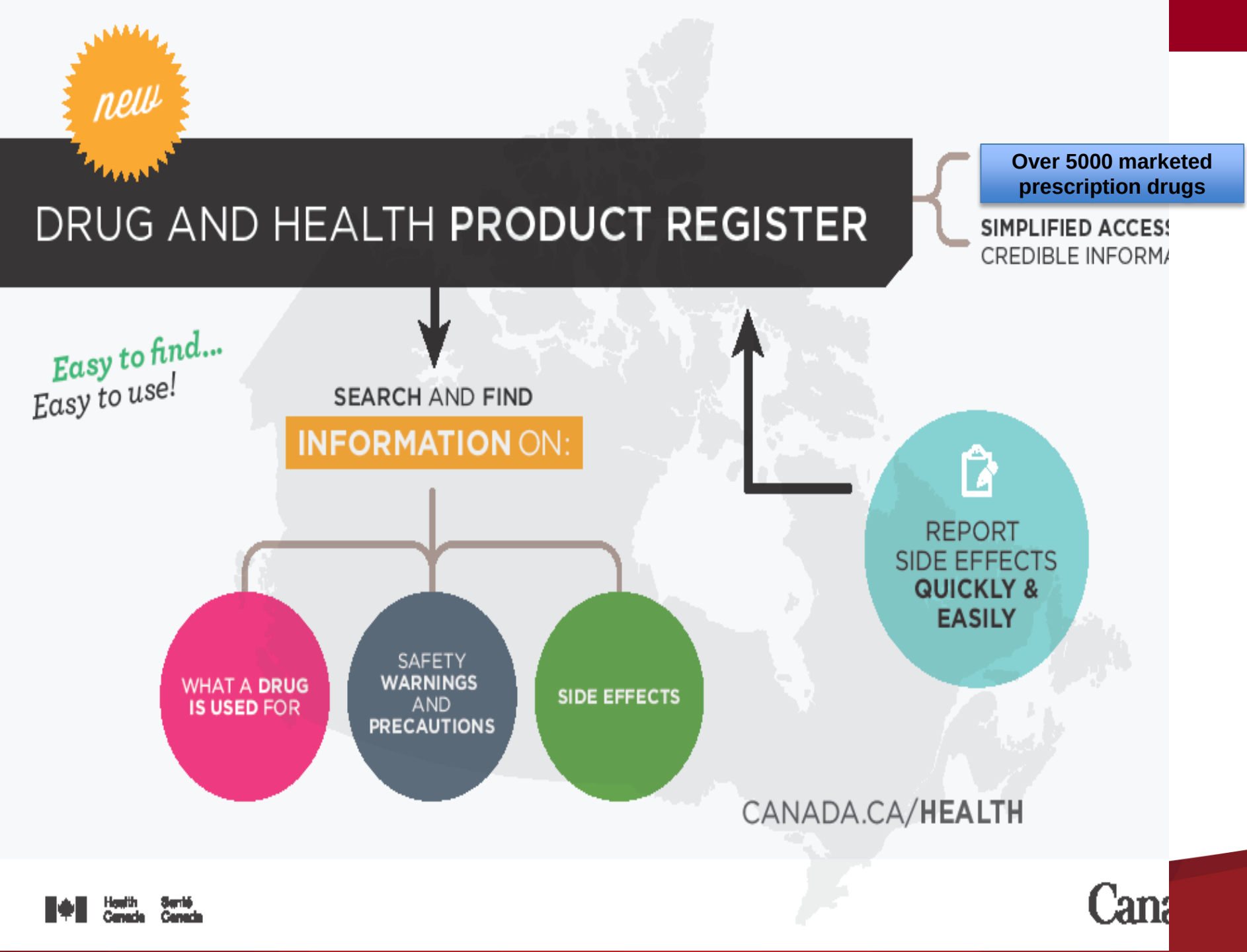
**Profile** the sources by adding metadata that is so rich it serves as stand alone content

**Aggregate** the content into an XML content store with all of the meta content applied

**Leverage** the content to serve the user in a meaningful, easy to access, easy to read way

# DHPR: Open & Extensible Solution Architecture Framework




new
DRUG AND HEALTH PRODUCT REGISTER
Over 5000 marketed prescription drugs
SIMPLIFIED ACCESS
CREDIBLE INFORMA
Easy to find...
Easy to use!
SEARCH AND FIND
INFORMATION ON:
WHAT A DRUG IS USED FOR
SAFETY WARNINGS AND PRECAUTIONS
SIDE EFFECTS
REPORT SIDE EFFECTS QUICKLY & EASILY
CANADA.CA/HEALTH
Health Canada
Santé Canada

# IP450 Roadmap: Drug and Health Product Register (DHPR)

**Completed to date**

- Drug Dataset completion
- Conversion of SSR / SBD / RDS
- Partial integration of SSR / SBD / RDS
- Technical optimization
- Transformation recode / processing
- R1.0 bug fixes / correction
- DHPR search enhancements
- Structured Product Monograph XML Web form (2004 Working Draft)
- Refresh process takeover
- MedEffect decommissioning
- Applied CDN for all HPFB apps

**Release 1.4.1 - Date Nov 24**

- **Sept/Oct** data content refresh
- Knowledge Transfer & Maintenance of DHPR DB

COMMUNICATIONS
Integrate DHPR as part of the service initiation page

TECHNICAL ENGAGEMENT
Technical Spill Over Items/Bugs

STRUCTURED CONTENT
Non-Functional Testing
Technical Implementation Guides Update/Amend
HC Processing of xml files

SUMMARY REPORTS
Inclusion of Medical Devices SBD and RDS
Implement publishing process

2016-04-01 — 2016-07-01 — 2016-10-01 — 2017-01-01 — 2017-03-31

**Version 1.4 Released Aug 22**

- April/May/June/July/Aug data content refresh

COMMUNICATIONS
Creation of External Comms Plan
CPAB Verification / Approval

TECHNICAL ENGAGEMENT
Canada.ca Template – Conversion of DHPR to WET4/Canada.ca

STRUCTURED CONTENT
Design and Development
Initiate Industry and Client Engagement for Testing
SPM Template ready for Use

SUMMARY REPORTS
Configure DB for Regulatory Content
Reg Content in Prod
Revise business processes for DHPR publishing

DHPR CONTENT
Drug Datasets - Extraction and Refresh Process optimization
Drug Datasets - Aggregation / links with AERs and Reg Content
Approved & Discontinued drug data & PM Part III
All Drug Class, Status and Schedule
Licensed Natural Health Products (LNHPD) – Re-Skinned App
Medical Devices (MDALL) – Re-Skinned App

ADVERSE DRUG REACTIONS / PROACTIVE DISCLOSURE
AERs
Phase 1 (AER Process Improvement & View by DHPR product name)
Graphical Summaries

**RELEASE 2.0 Planned for Mar 1/17**

- Nov/Dec/Jan/Feb/Mar data content refresh

COMMUNICATIONS
Implement comprehensive Communication Plan
Web Standards Compliancy Revalidation
Decommission static HC Web pages

TECHNICAL ENGAGEMENT
Knowledge Transfer & Maintenance of DHPR DB

STRUCTURED CONTENT
Functional Testing
Pilot use of XML file to populate DHPR
Development / Testing of remaining 9 Templates

DHPR CONTENT
Minor UI Design Changes
Update DHPR Admin Static HTML content
DHPR usability (UX) validation
Start inclusion of PM Parts I & II
Start publishing full Structured PM Part I, II, III

ADVERSE DRUG REACTIONS
CVP Dataset publication cycle improvements (Quarterly to Monthly)
E2B Compliant (Voluntary AR Form)
Modifications to the Voluntary Side Effects Reporting Form

Innovation Proposal : DHPR Automation

RESTful API CONTENT PUBLICATION
LNHPD, CVP, MDALL, DHPR API Development
API Basic and Advanced Search
API Framework
API usability (UX) validation and External technical feedback – via Hacking Health
Enable all remaining APIs as per Framework

DECOMMISSION ONLINE APPLICATIONS
MDALL
LNHPD

**R3.0 : Analysis and Proposal**

- Health Delivery System Alignment (Open Data)
- IDMP (FDA; Infoway)
- Structured Content Integration with Review & Risk Analytics
- Analysis & Design - Fully Integrated DHPR
- Content Expansion / Integration / Decommissioning of other HPFB Online Applications Development of External Web site (controlled vocabulary, Industry FAQs, Technical guidance [ie: SPL, CESG])
- Future Decommissioning of static and old websites

# What has been delivered recently?

- On August 22nd, 2016, the Drug and Health Product Register (DHPR) 1.4 was released into production.

- **New features of the DHPR include:**
  1. Summary Reports: Regulatory Decision Summaries (RDS), Summary Basis of Decision (SBD) and Safety Summary Review (SSR) are available for drug products, in a structured searchable format
  2. Reported Side Effects:  when there are Adverse reactions reported for a particular drug, these are now linked to the drug information and viewable within the DHPR with graphical illustrations of a break down of side effects (gender, age, seriousness, outcome and source of reports)
  3. Licensed Natural Health Product Database and Medical Device Active Licence Listing have been integrated within the DHPR

DHPR URL: https://hpr-rps.hres.ca/

# Near Term DHPR 2.0 Objectives

- Conceptualization of next phase of the DHPR:
  - Full integration of other datasets like Medical Device and NHP product content while keeping a lens on a common look and feel design.
  - Proposal to incorporate other HC/HPFB published information
  - Enhanced functionality and content to enable the decommissioning of existing public facing applications (DPD Online, CVP Online, LNHPD, AR Reporting, etc.).
  - **Improved Structured, standardised, bilingual PM content received directly from Industry to be utilised as the pristine PM copy for publishing on the DHPR.**

Making drug data available through Open Data and RESTful APIs.

An API Publication Framework, and RESTful API for Summary Reports will be available in the coming weeks while remaining APIs, specifically for DHPR content and controlled vocabulary, will be available between Jan-Mar 2016.

# DHPR Publishing Processes and Challenges

- The current DHPR was developed utilizing agile approaches to quickly and economically achieve and demonstrate the objectives.
- Existing data repositories and manual extraction tools were used where feasible and content was manually selected, cleansed and assembled. Pristine copies of Product Monograph are only available in PDF or Word format and were manually transformed to XML format.
- Current transformation process of PM content to structured format is a manual, labor intensive, non scalable and lengthy process that is highly susceptible to errors that require extensive QA validation by business subject matter experts and correction processes.
- Expansion of content beyond current content (Part III only) is not feasible.

Regulatory Business Processes must take into account downstream use, including Transparency and Openness

# Solution / Strategy to DHPR Challenges

- Introduce structured content as an integral part of the HC business process.
- Receive the bilingual pristine PM (Parts I, II & III) in a structured XML document directly from Industry through the gateway to provide content that is incorporated in to the DHPR and published as required.  This will enhance the publishing volume, quality and currency.
- Introduction of controlled pick lists for some fields (i.e. dosage and route)
- Long-term goal to transition HC review and approval processes to using the MS Word and XML documents.

# Structured Product Monograph Approach

- HC current PM templates are unstructured and no longer suitable in a rapidly modernizing healthcare environment
- HC has developed a standards based Structured Product Monograph Parts I, II & III
- Application that uses e-form approach to generate a valid XML file
- Validation guidance that will enable manual and procedural validation of XML content
- To be utilized by Industry to provide content to HC for efficient input in to DHPR
- Introduction of pick lists and Controlled Vocabulary (CV)

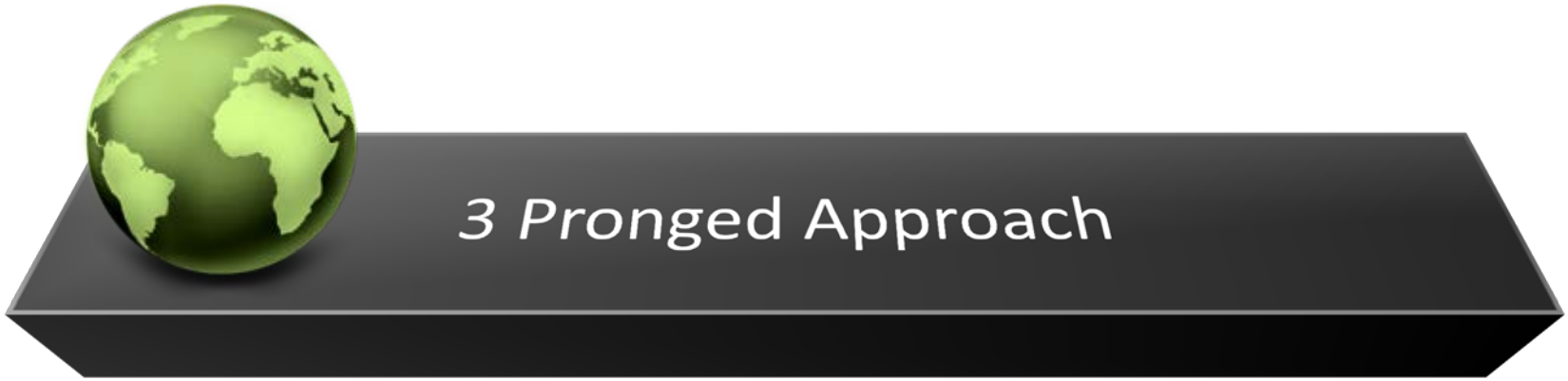
Next steps:  Pilot with industry

# Why Controlled Vocabularies

- Interoperability
  - The ICH is currently focused on implementing data standards which enables interoperability within their Health Care System by using common vocabularies/terms. These standards are known as Health Level 7 (HL 7) standards. These common standards are the basis for interoperability between regulator to regulator, regulatory to industry, and regulator to the Health Care System. In fact, these HL 7 standards are being used by Canada Health Infoway to enable interoperability between provinces and territories.

- Data Quality
  - They reduce the risk of data entry variations. Spelling errors, abbreviations, acronyms are wonderful examples of why free form fields are hard to ensure consistency.

# Leveraging the existing SPL Standard




HC provided application that uses an e-form approach and generates a fully valid XML file.

Tool can be used to validate XML files that have been externally generated.

HC provided schema that enables **fully** validated content creation using schema driven XML authoring tools.

Validation guidance that will enable manual and procedural validation of XML content.

# Structured PM Implementation Plan

- Roadmap Strategy for implementation
  - **Non-Functional Testing** **Oct 2016**
  - **Technical Testing** **Dec 2016 – Mar 2017**
  - **Functional Testing** **Early 2017**

- Introduce pick lists starting with an initial critical mass (1/2 dozen) and evolving to a comprehensive set.
- **Provide Industry with easy to use tool that will enable them to efficiently create and validate structured PMs (parts I, II and III) for submission as pristine PM.**
- The validation tool can also be used for Industry with internal capability to generate XML PMs.
- Develop guidance documentation for Structured PM (e.g. features, requirements, specs, instruction guides) --- see appendix.
- Publish HC's position on XML schema.

# Non-Functional Testing

- The non-functional testing of the SPM will provide HPFB with early feedback on the usability, design, and functionality of the form, as well as the technical requirements of the XML form and the structured PM authoring tool.
- Focus on the 2004 PM Template as it captures the most iterations of PMs currently being used by Industry.
- It will also include non-functional end-to-end testing for eCTD submissions.

# Technical Testing

- Technical testing will be done to validate the technical instruction guides and ensure a valid SPL XML can be generated by industry using both the HC tool and vendor developed tool.

- HC will publish our XML schema, XSLT and CSS, which will allow vendors to build or use a XML editor to generate a valid HC xml document.

# Functional Testing

- Act as a working pilot to confirm both the SPM form content and process proceed as expected, as well as uploading of the PM to the DHPR.
- Based on outcomes of Non-functional testing.
- The functional testing is expected to run for four to five months, depending on whether sufficient submissions have been received **(30 submissions).**
- During the functional testing pristine PMs will be uploaded into the DHPR production site.

# Group on Electronic Regulatory Activities (GERA)

- An innovative third-party model that is co-chaired by Industry and HPFB. It is secretarially managed by Industry.
- Multi-lateral partnership that focusses on advancing technical initiatives related to our electronic regulatory environment.
- In order to ensure success of technical initiatives, industry's early engagement in the development process is essential.
- "Pre"-consultation activities (Proof of Concept and Industry Pilot) will be managed via the GERA .
- GERA website will be platform to share information, Q&As, and collect industry feedback on the SPM Proof of Concept amongst other key technical activities like Regulatory Enrollment Process (REP).
- Links to the GERA website may be created from the Health Canada website to ensure openness and transparency with all interested industry stakeholders.

https://collaboration.hres.ca/

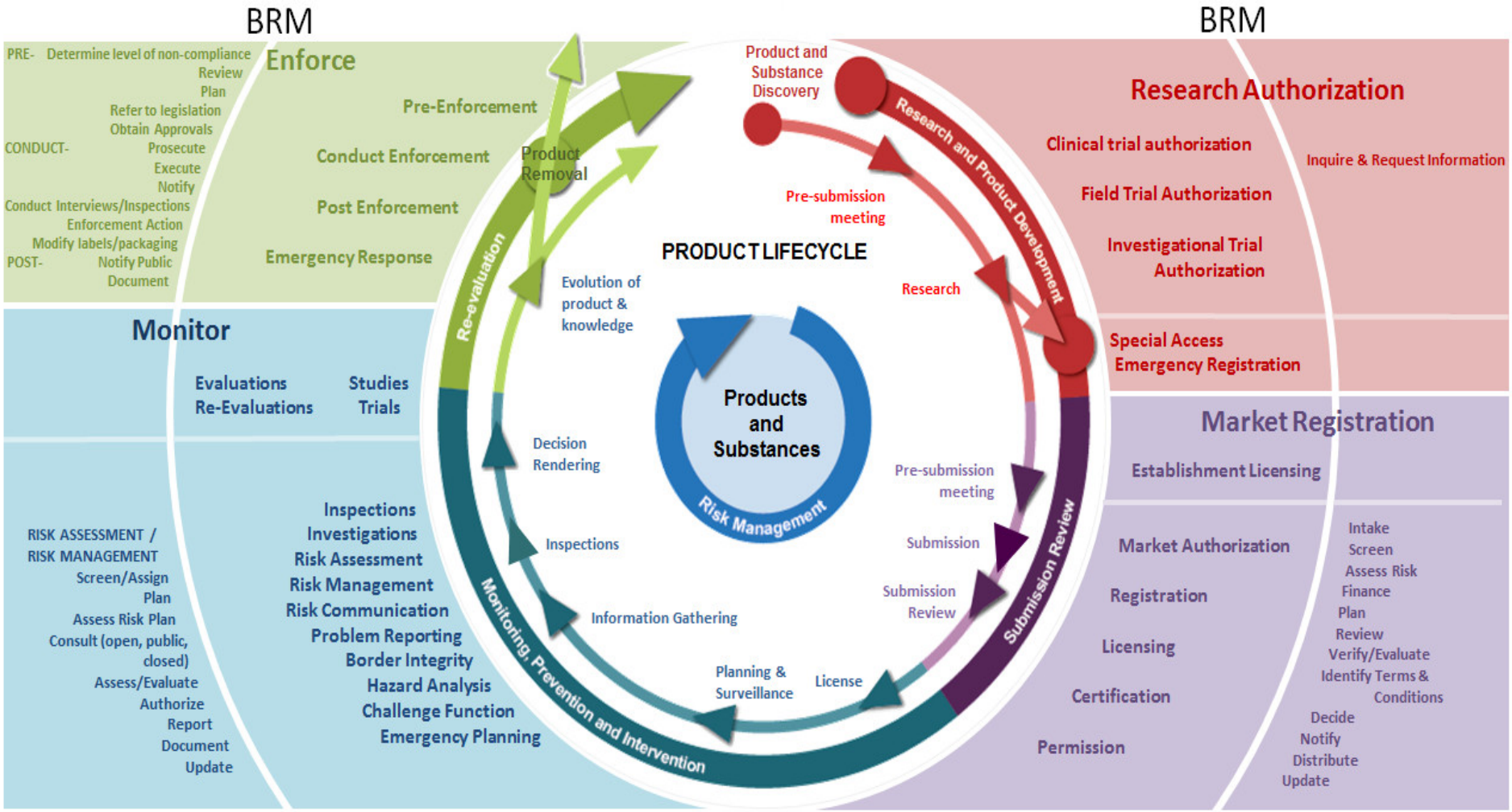
- Discussion and Technical Walkthrough of IGs (see Appendix)
- SPM Web Form Demo (http://iis-rep.hres.ca/)

# Appendix-Technical/Operational Guidance to be updated

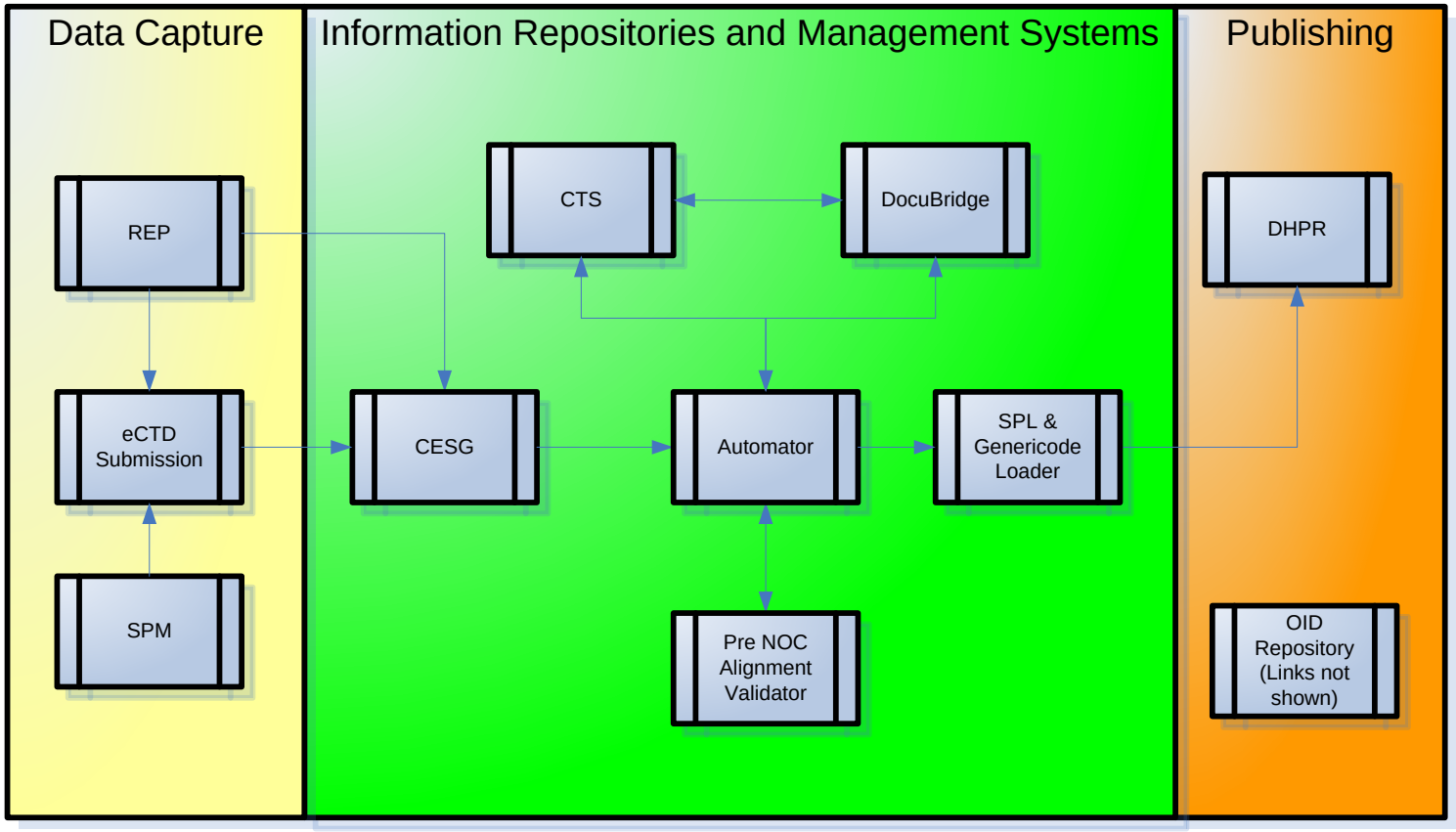
- [UPDATE] Preparation of Drug Regulatory Activities in the eCTD Format.
- [UPDATE] Product Monograph Guidance Document
- [UPDATE] Preparation of Drug Regulatory Activities in the “Non-eCTD Electronic-Only”
- [AMEND] Validation rules for regulatory transactions submitted to Health Canada in the electronic Common Technical Document (eCTD) - eValidator
- [NEW] Notice to Industry
- [NEW] Technical Guidance Document for SPL Documents - This document provides the technical guidance on how to create HC compliant SPL documents, it does not detail the specific rules for a document type rather it covers SPL documents in general.
- [NEW] HC Guidance for Pristine Structured PM Documents - This document provides the specific technical guidance on how to create HC compliant Pristine PM SPL documents.
- [NEW] Technical Guidance Document for SPL related Controlled Vocabularies - This document provides the technical guidance on all SPL related control vocabularies.
- [NEW] XML Schema and Reference

** Last 4 technical documents are in draft mode but can be shared*

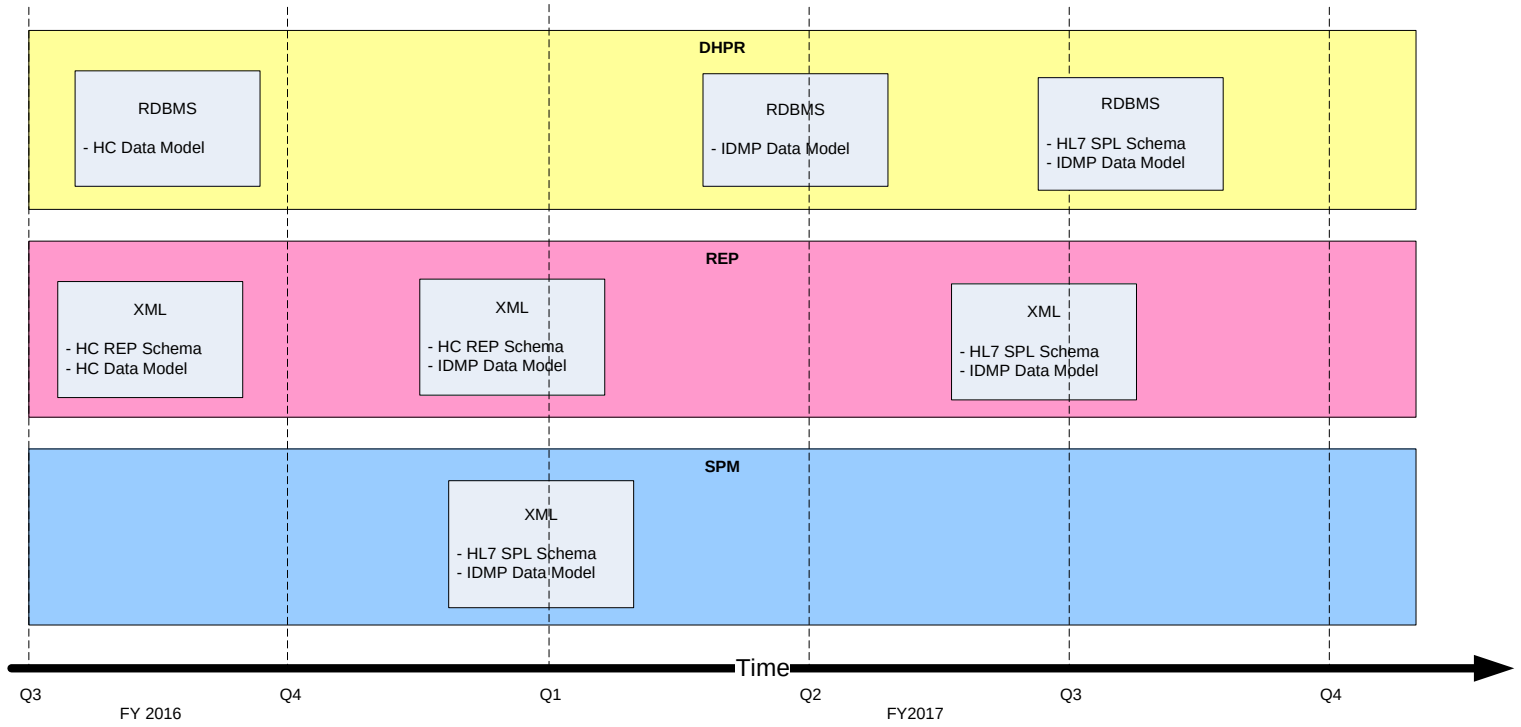
# Health Canada Business Reference Model



# Long Term – System View



# Format View


DHPR
RDBMS
- HC Data Model
RDBMS
- IDMP Data Model
RDBMS
- HL7 SPL Schema
- IDMP Data Model
REP
XML
- HC REP Schema
- HC Data Model
XML
- HC REP Schema
- IDMP Data Model
XML
- HL7 SPL Schema
- IDMP Data Model
SPM
XML
- HL7 SPL Schema
- IDMP Data Model
Time
Q3
FY 2016
Q4
Q1
Q2
FY2017
Q3
Q4

# Progression of Structured Information in eSubmissions