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IT Enabling International Activities

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Presented to GInAS

Friday September 13, 2013



Canada 

IT: Enabling International Activities

Goal: Establish a standards-based business informatics environment for exchange, review, and management of regulatory information.

- *Adoption of international data standards*
 - *Strengthen operation efficiencies through automation, transparency and interoperability with international agencies (e.g unique identifiers, terminologies, messaging standards)*
- *Enable Secure Data Information Sharing*
 - *Establish policy and technical foundation for international data sharing (e.g GMP Inspection Reports, Review Reports)*
- *Enabling the eChannel for electronic submissions*



Relevant International (ICH) Data Standards

- (1) standards setting organization
- (2) standards developing organization
- (3) Planned or Influenced by

Data Standard	SSO ¹	SDO ²	Sponsor	IP Project
<p>eCTD</p> <p>The electronic Common Technical Document (eCTD) is an interface for the pharmaceutical industry to agency transfer of regulatory information (note: eCTD 4 will use a subset of RPS for human drugs only once implemented). IMDRF is currently backing the use of eCTD for eventual use for Medical Devices.</p>	ISO	ICH	ALL	IP62
<p>ICSR</p> <p>Individual Case Study Report (ICSR) is an adverse event report for an individual patient. IMDRF is currently in discussion on how to extend this standard to medical devices similar to FDA.</p>	ISO	ICH	ALL	IP58
<p>MedDRA</p> <p>The Medical Dictionary for Regulatory Activities (MedDRA) is an internationally recognized set of terms used to facilitate the regulation of medical products for humans, including biopharmaceuticals, medical devices and vaccines and is used to enter, retrieve, analyse and present data both before and after a medical product has been authorized for sale.</p>	MSSO	ICH	ALL	IP 58
<p>IDMP (ICH M5)</p> <p>International Identification of Medicinal Product (IDMP) support the regulation of medicines and pharmacovigilance including Individual Case Safety Reports (ICSR). IDMP is one of a group of five standards, which together provide the basis for the unique identification of medicinal products.</p>	ISO	ICH	FDA/EMA	



Other Relevant International Data Standards

Data Standard	SSO ¹	SDO ²	Sponsor	IP Project
<p>RPS The RPS exchange message provides healthcare regulatory authorities a single message specification to manage the entire spectrum of regulated product submission types and encompasses human/vet drugs, foods, NHPs, and medical devices.</p>	ANSI	HL7	FDA	IP62 IP140 ³
<p>Structured Product Information The Structured Product Labelling (SPL) and Structured Product Information Labeling are document markup standards used for exchanging product and medical device labels and facility information.</p>	ANSI	HL7	FDA	n/a
<p>UDI UDI guidance that deals with establishing compatible/inter-operable UDI systems to generate a globally harmonized system.</p>	IMDRF	IMDRF	HC	n/a

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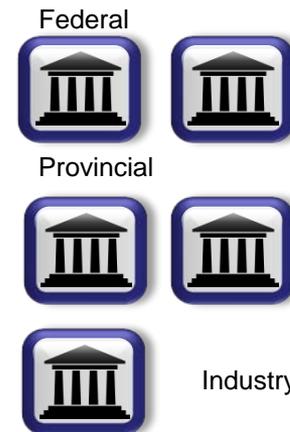
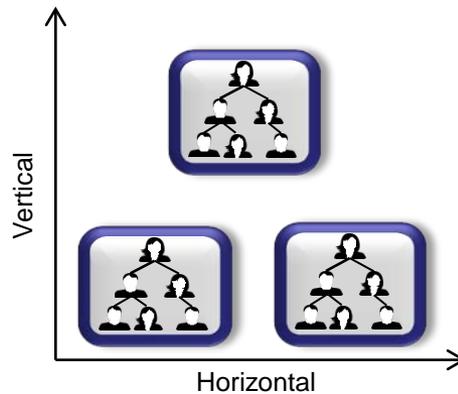
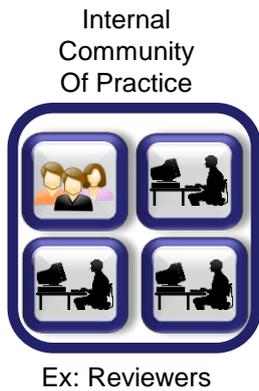
Secure Data & Information Sharing

Directorate

Branch

GoC

International



Legislative and Policy Perspective

informs

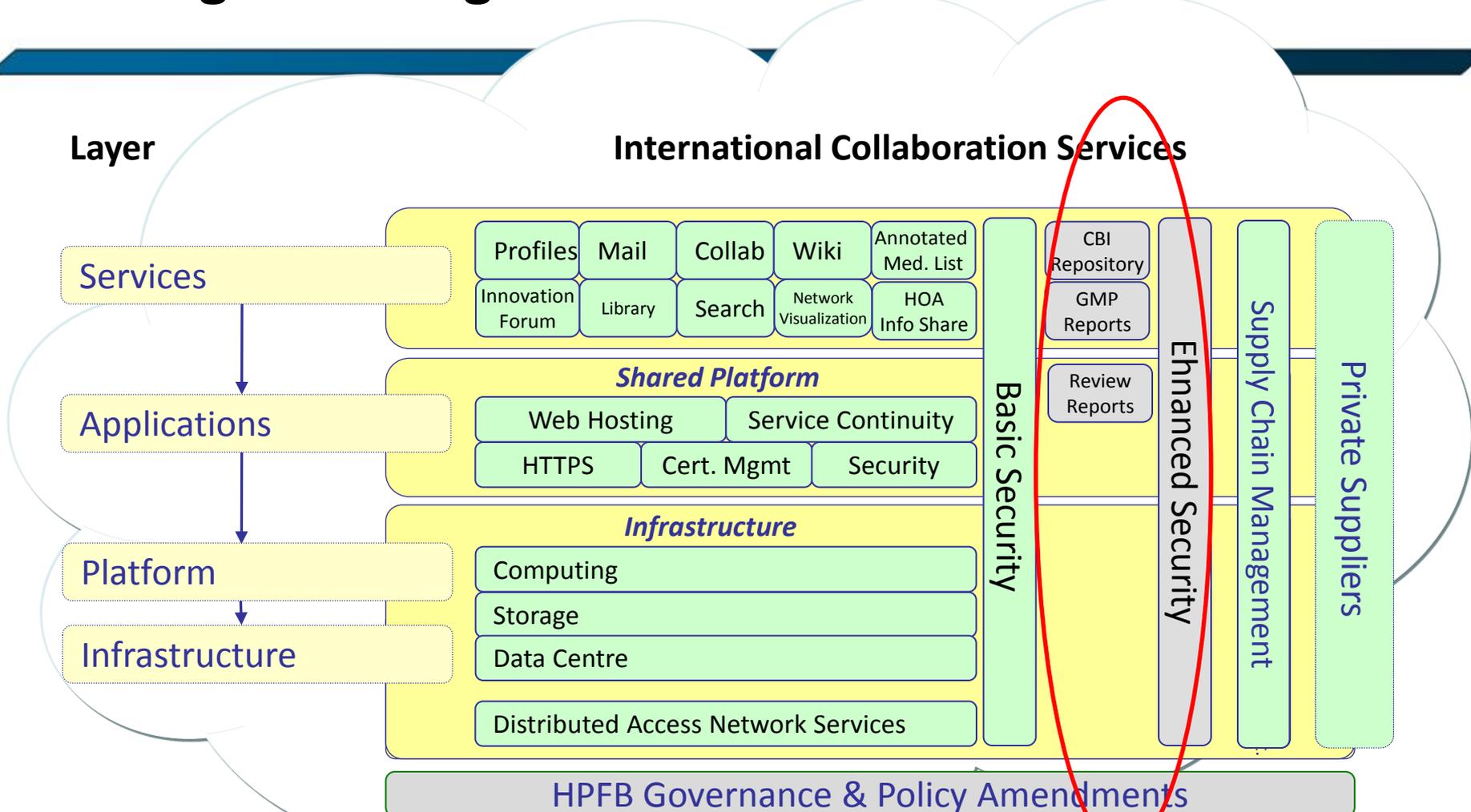
Organizational & Managerial Perspective

informs

Technological Perspective



Leverage Existing Collaboration Platform



Phases

1

PAHO Services

2

Secure Services



Secure Data and Information Sharing

- Phased approach
 - Near-term
 - Join existing secure collaboration platform with select partner(s)
 - Example: SwissMedic secure Sharepoint platform, TGA
 - Confirm acceptability with Departmental Security Officer (e.g. TRA)
 - Create/maintain an “application inventory” of IT tools/platforms used to support international regulatory activities.
 - Longer-term
 - Work with Pan American Health Organization (PAHO)
 - Define business and technical requirements
 - Build secure document exchange solution with broader international community



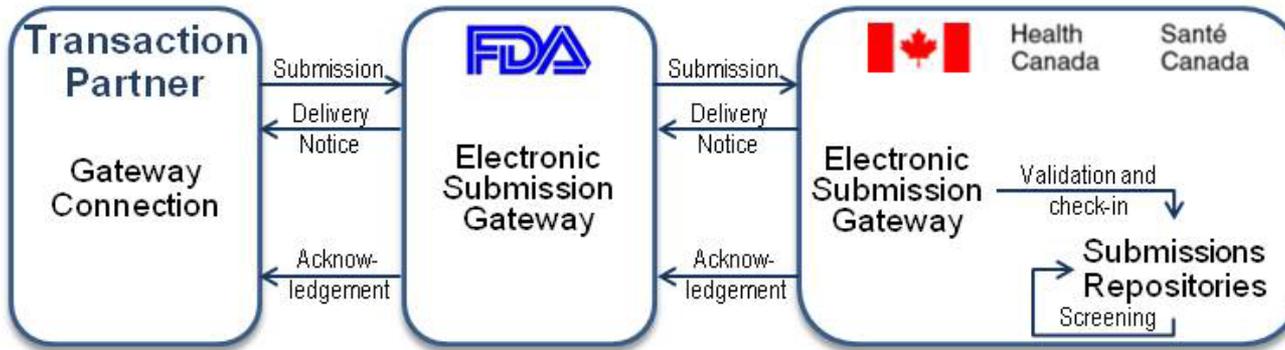
Enabling e-Channel - ESG

Goal:

Test and Implement the Health Canada/FDA Common Electronic Submissions Gateway

2013-14 Scope:

- Industry test of Health Canada environment
- Provision and installation of infrastructure of HC environment at FDA
- HC to FDA web linkages, Bilingual service presentation
- Joint FDA-HC Industry Pilot



Data Standards Development and Adoption

NIH/NCATS

ISO/ICH/HL7



1

Standard Development

2

Implementation and Adoption

3

Hosting & Development Platform

Participating RA's: US FDA, EMA, Swiss Medic, HC, MEB



Goal

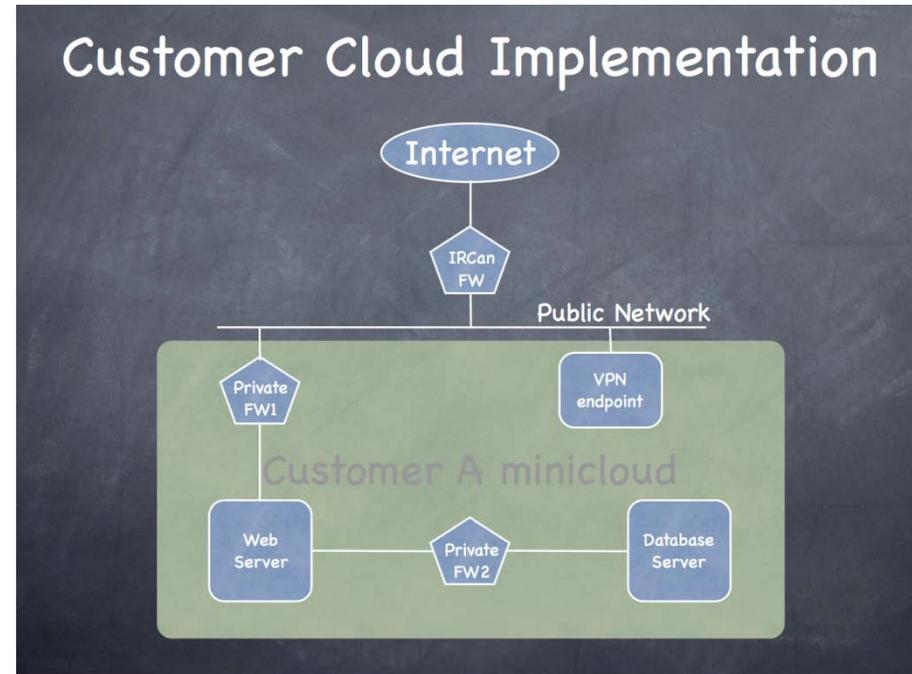


- Health Canada can directly contribute to this global effort by providing the environment for collaborative development within the Intellectual Resources Canada (IRCAn) domain within our current operating agreement.
- IRCAn is a business framework and set of online services that simplify the distributed management of many sorts of digital works, including those for which participants require highly structured management, such as technical texts, computer programs, and data sets.
- IRCAn's framework and set of services accommodate a wide spectrum of business models for joint and collective authorship. Each work is managed autonomously by its community of authors by whatever arrangements they make.
- The [Economic Drivers](#) for this environment are to augment benefits, reduce costs and manage risk through knowledge-sharing and inter-organizational learning.
- HC has deployed various open source internal tools on the IRCAn platform in support of its mandate and intend to leverage this platform to deploy other experimental work/projects



IRCan: GInAS Project Hosting

- Global Ingredient Archival System (GINAS) project is hosted on the IRCan Platform
- Managed autonomously
- Project supported by robust suite of operational systems with information security capability up to “Protected B”, and availability of 99.8% plus failover options across deployed nodes.



Questions

