Health Products and Food Branch (HPFB)
IT Framework & Investment Plan
FY 11/12 – FY 15/16

Presentation to CAPRA

April 30, 2014

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Canada

Business IT Challenges

- Health Products and Food Regulatory business and other Regulatory Authorities and industry are transforming at high pace and on large scale
- The Government of Canada is asking departments to increase e-business capacity and versatile business-to-business connectivity to foster collaboration and improve service delivery
- Competing with GoC “Enterprise IT” agenda
- The demand for new IT products and for increased performance outpaces current production capacity
- Funding constraints accelerating need to adopt common business processes, common IT platforms and component based re-usable applications

Current approach is Unsustainable, Expensive and Inefficient
HPFB Needs an Approach to Fulfill IT Program Priorities

HPFB at a glance

HPFB Strategic Outcomes

Strategic Outcome 1

Access to safe and effective health products, safe and nutritious food, and information to make healthy choices

Strategic Outcome 2

Recognised as a trusted scientific and regulatory authority for health products and food in Canada and internationally

Strategic Outcome 3

Transparent and efficient health products and food regulatory system contributing to the safety of Canadians

HPFB Operational Objectives

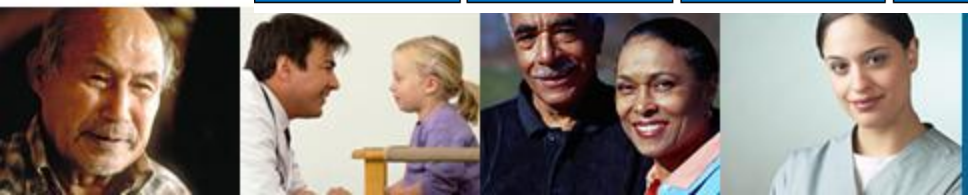
Protects from unsafe products	Minimize risk factors	Promotes and enables healthy choices	Promotes informed decisions	Maximize safety

HPFB Management Priorities

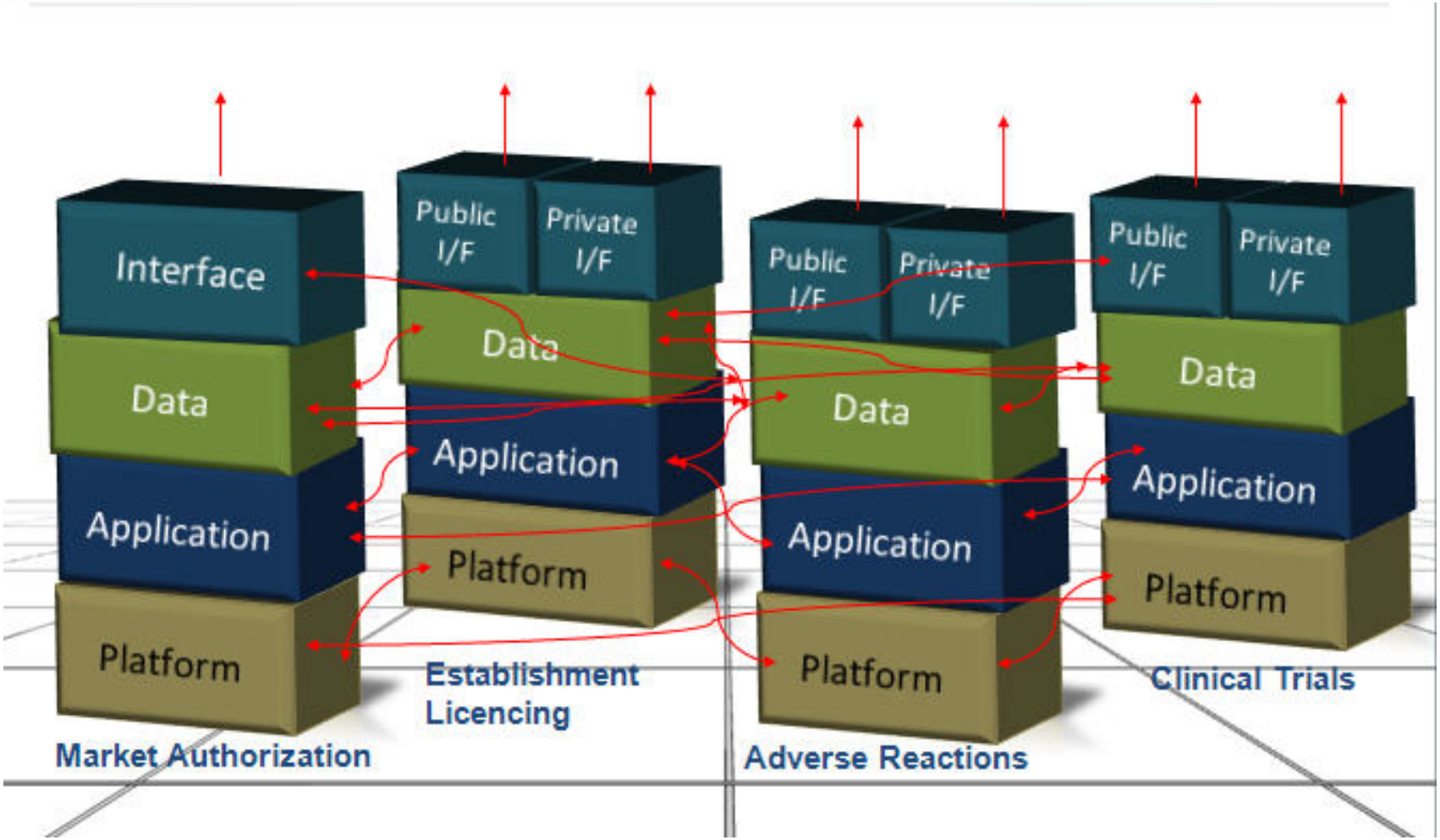
Operational Excellence	People	Regulatory Modernisation
Openness and Transparency	Science	

HPFB Programs and Sub-Programs

PAA 2.1 Health Products Program				PAA 2.2.2 Food Safety and Nutrition	
2.1.1 Pharma	2.1.2 Biologics	2.1.3 Medical Devices	2.1.4 Natural Health Products	2.2.1 Food & Nutrition Safety	2.2.2 Nutrition Policy and Promotion

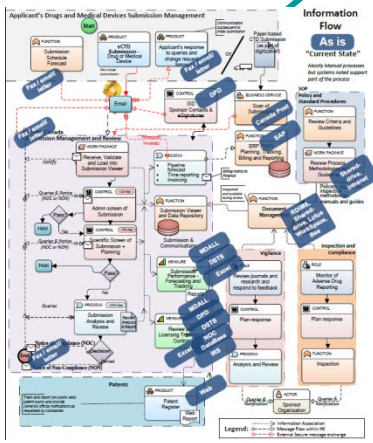


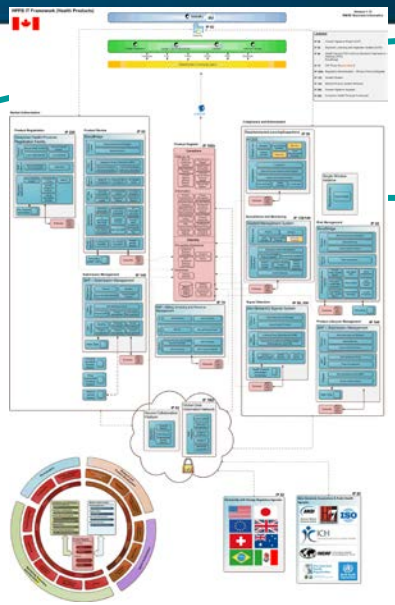
Siloed Approach: Need a better approach to managing regulatory information across to Product Lifecycle



HPFB IT Framework - Approach for guiding Investment Plan

HPFB Regulatory Program Integration





further expansion

Path of development drives HPFB Investment Planning approach and cost optimisation potential

2011-2012

Initial IT Framework established for Drug Submission Management within IP 62 E-Review 2.0

2012-2013

Level 0 Regulatory Business Reference Model with other regulatory Branches (HPFB, HECSB, PMRA, RAPB)

2013-2014

HPFB IT Framework developed:

- Core Business Process
- Key Business Applications
- Cross Referenced to Investment Plan Projects Distinct Plan f Program and Sub-Program

2015ff

Time

IT Investment Governance

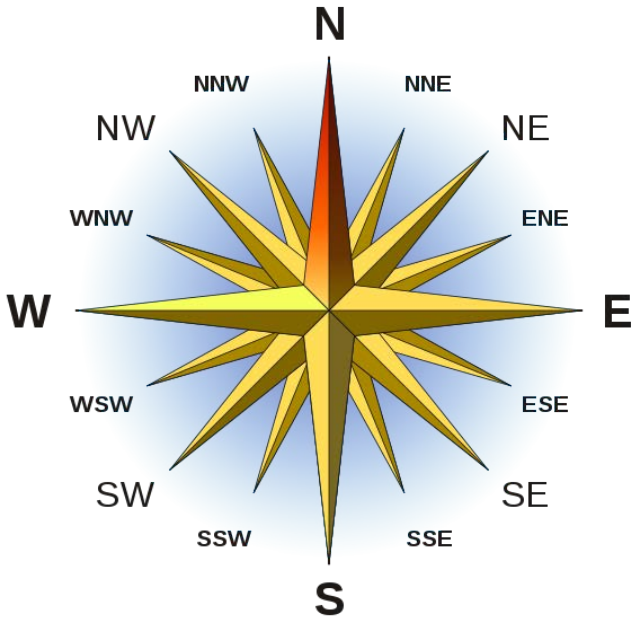
- IT Investment planning processes are aligned with the department's integrated planning, monitoring and performance reporting regime:
  - Annual strategic and operational planning cycle
  - Mid-year and year-end performance reporting
  - Monthly Dashboard

- Funding is released following Gate approval for next stage of work
  - Funding releases are subject to governing body decisions

- Business owner has overall accountability for the project. Partners also contribute and share accountability.

HPFB IT Investment Planning - Guiding Principles

1. HPFB IT Framework to guide a Common Branch approach
2. Investments to support needs of more than a single Directorate
3. Sustain Production
4. Apply Stage-Gate methodology
5. Branch wide capability to support international data standards
6. Mitigate business risks from “end-of-life” systems and “one-off” solutions



HPFB IT Investment Plan Roadmap

	FY 2011-12				FY 2012-13				FY 2013-14				FY 2014-15				FY 2015-16			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
IP 57	NHP Online																			
IP 58	Canada Vigilance Project																			
IP 59	e-Compliance and Enforcement System																			
IP 60	e-Special Access Program (Drugs)																			
IP 62	e-Review																			
IP 64	Food Modernisation																			
IP 74	Cost Recovery Initiative																			
IP 106a					Food Business Systems															
IP 106b									Health Product Register											
IP 139							Incident System													
IP 140							Medical Devices IT Renewal													
IP 200									Canada Vigilance Program Upgrade											
IP 220									Consumer Health Products Framework											
Corporate									Corporate: Lotus Notes Migration											
									Corporate: Aging IT											
									Corporate: Planning for Enterprise Performance											

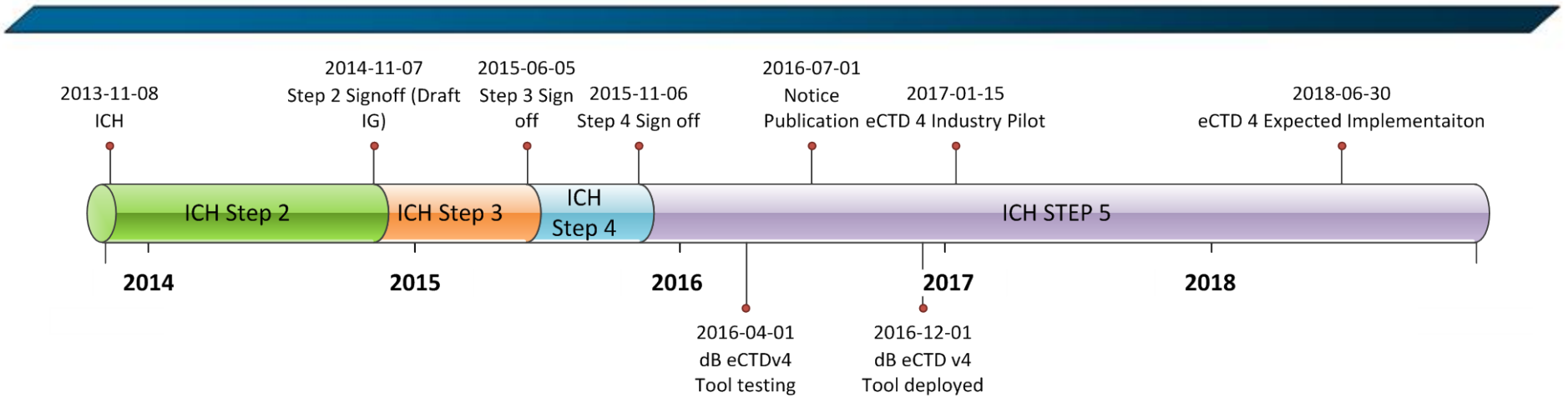
Phase 1: Projects closing in FY13/14

Phase 2: Implementation in FY14/15 and FY 15/16

Phase 3: Project gating not yet started




Looking ahead … eCTD v4



- Started in 2010 preliminary work at Health Level 7 is expected to complete in 2014 allowing for eCTD approval for comment (stage 3) in 2014-15.
- ICH Step 2 Signoff (November 2014)
- ICH Step 3 Comment & Reconciliation (November 2014 – June 2015)
- ICH Step 4 Signoff (November 2015)
- Health Canada relies on docuBridge for submission management of eCTD
- Implementation will need to be incorporated within HPFB IT Investment Plan following Step 4. **Implementation will adopt a phased in approach with industry (including relevant Implementation Guidance)**
- Medical Device (IMDRF) participation in the RPS project

Some Benefits eCTDv4 (RPS)

- The eCTD headings and hierarchy are not changing
  - Think of it as a technology upgrade with some enhancements
- ICH Steering Committee endorsed the decision to develop the next major version of the electronic Common Technical Document (eCTD v4) with Health Level 7 (HL7)
- Core enhancements to eCTD 3.2.2 include
  - Standard (exchange message) that can be used for the submission of any regulated product
  - Message is managed through the use of controlled vocabularies
  - Enhanced Lifecycle Management
  - Cross-reference previously submitted material – File Reuse
  - Enhanced control of dossier
  - Enhanced identification of information contained with a submission
  - Two-way communication
    - The regulatory authority (e.g. HC) can use RPS to send correspondence to the submitter

Industry Engagement

- GERA has been a key forum for HPFB to collaborate with industry to implement standards and electronic initiatives which enable Health Canada and Industry to apply technology in a way that modernizes processes that support regulatory activities.

- HPFB recognizes and embraces the value of involving Industry in our IM/IT Investment Planning process
  - Recent successes: CESG (e.g. CBA, Pilot), eForms, HPFB Electronic Signatures Policy

- We will continue to seek greater opportunities to invite, hear and consider the input of Industry through GERA

Questions?