Health Canada's
E-Review Project for Therapeutic Products

Perspectives on Regulatory Submissions and Transition to eCTD Format

Presentation to CAPRA
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Presentation Overview

- E-Review @ Health Canada
- Current Situation and Challenges
- Goals and Objectives for Implementation

The E-Review Story

- Canada's 2002 Speech from the Throne established the Canadian Government's priority to:

  "Speed up the regulatory process for drug approvals to ensure that Canadians have faster access to the safe drugs they need, creating a better climate for research on drugs"

- Health Canada developed the Therapeutics Access Strategy (TAS) with the overarching goal to

  "help Canadians maintain and improve their health by ensuring that human drugs and other therapeutic products are safe, of high quality, therapeutically effective, appropriately used and accessible in a timely and cost-effective fashion"

- e-Review is a major component of TAS,
  - 3 yr. development followed by a 2yr. stabilization horizon

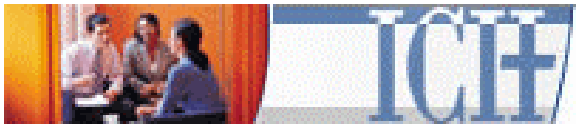
Project Definition

To establish an electronic review (E-Review) system that will offer electronic support to the submission and review of therapeutic products that Health Canada has regulatory authority over, as outlined in the Canadian *Food and Drugs Act.*

E-Review is a Horizontal Initiative

- Health Products and Food Branch (HPFB) is the Canadian regulatory organization responsible for the delivery and implementation of E-Review for therapeutic products
- Within HPFB, the E-Review project will directly impact:
  - Therapeutic Products
  - Biologics and Genetic Therapies
  - Veterinary Drugs
  - Natural Health Products

E-Review Collaborates Internationally



- ICH M2 leading standards development on the eCTD – Canada committed to support

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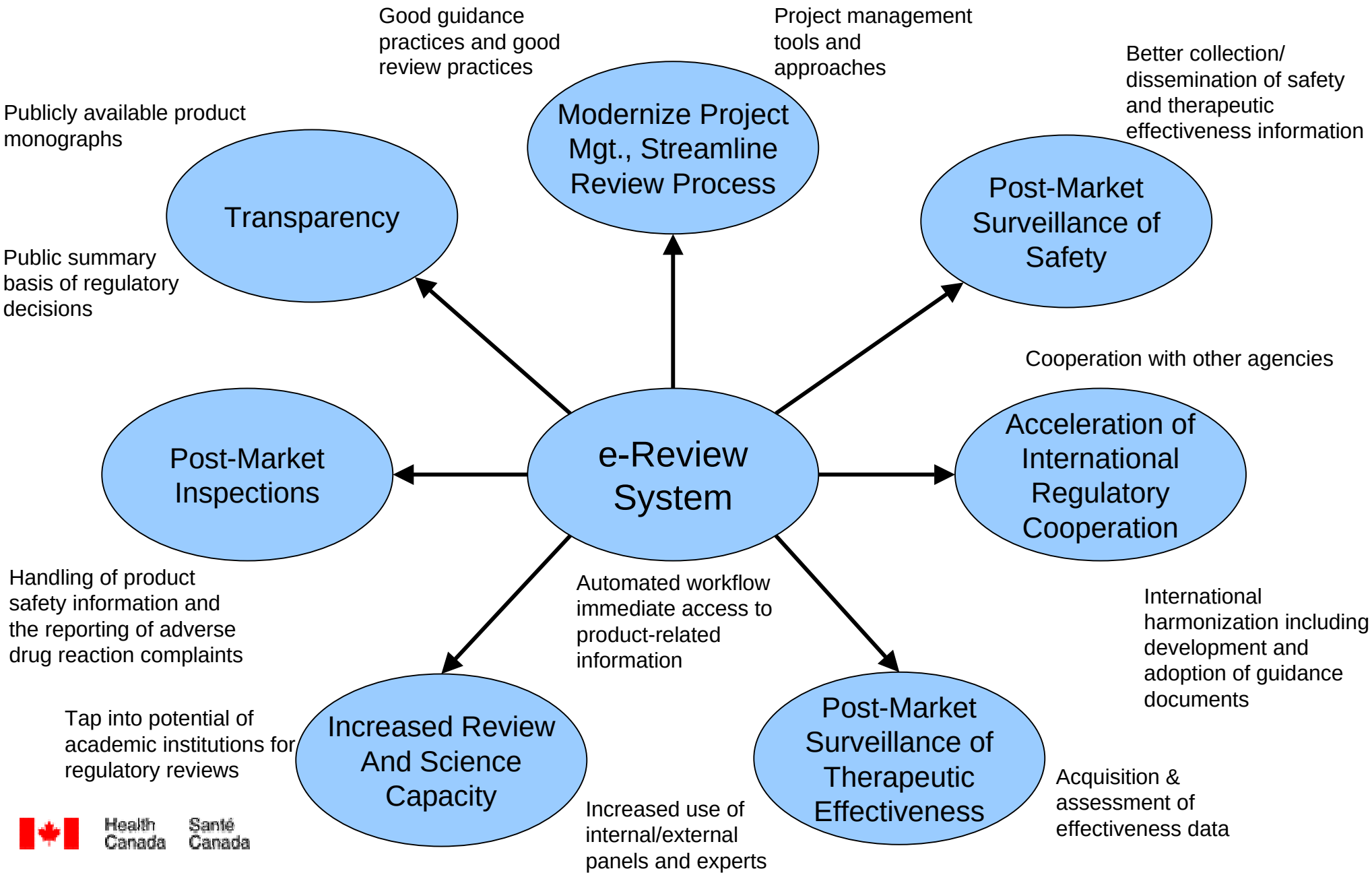
- Health Canada Invited to the EURS meetings
- Strong level of goodwill
- Intent to reciprocate as e-Review progress

- FDA/HPFB MOU signed November 18th, 2003
- Strong goodwill – free access and evaluation of "EVS" viewer
- Intent to maintain and strengthen interchange of information

E-Review Deliverables

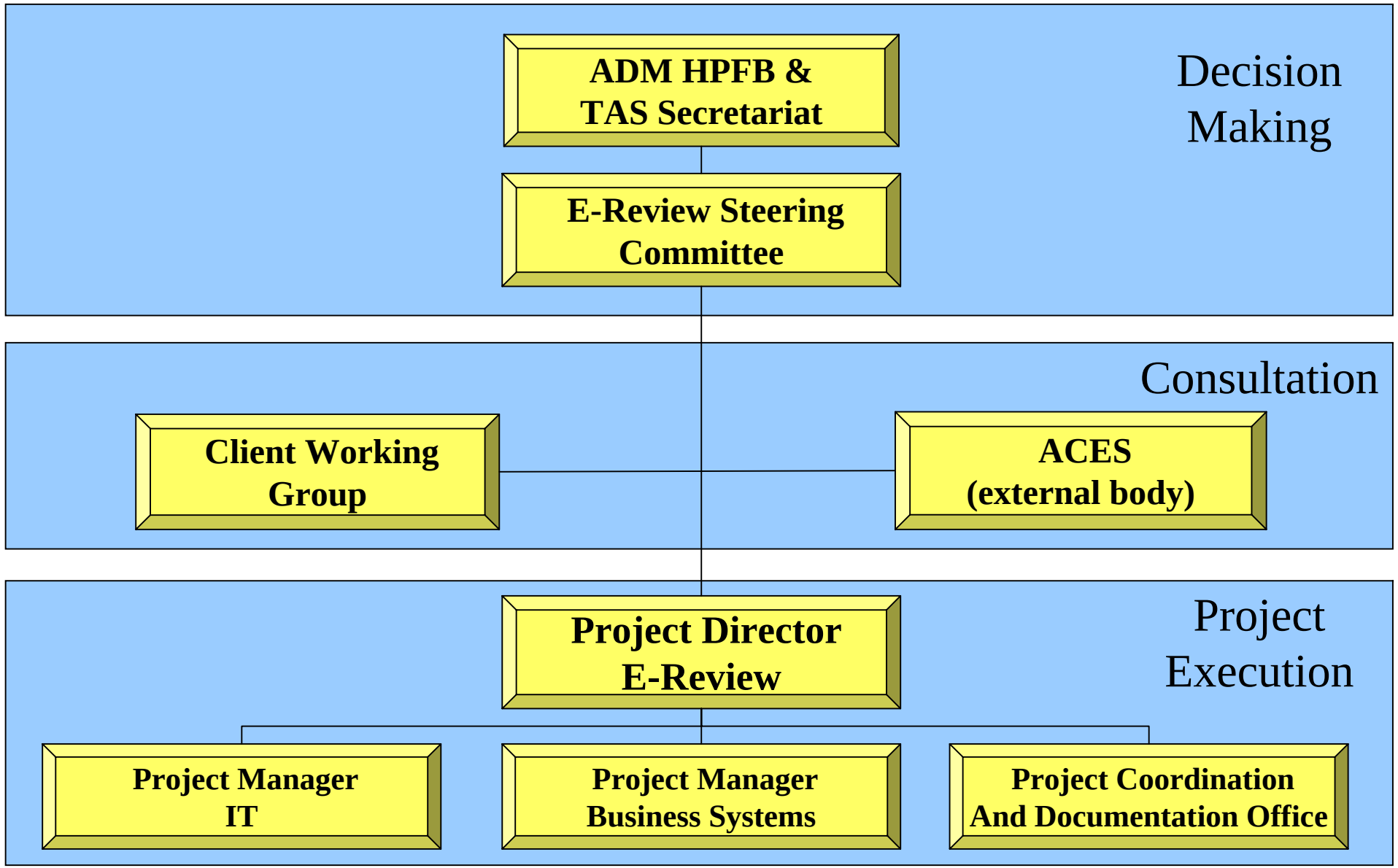
- Decreased approval times for submissions and release to market
- Cost-effective processing of submissions
- Alignment with evolving international standards
- Decreased barrier to entry of more effective and safer products to Canada
- Improved workflow to streamline regulatory system
- Improved performance tracking of regulatory process
- Due consideration of security and privacy issues
- Improved transparency of review process
- Support other Therapeutic Access Strategy (TAS) activities

E-Review impacts many facets of Operations



Health Canada Santé Canada

The E-Review Governance Structure



Advisory Committee on Electronic Submissions (ACES)

- Government, Industry and Public Associations coming together to discuss issues associated with electronic submission in Canada
- Representation:
  - Health Canada - Bayer
  - Aventis - Serono
  - Pfizer - Non-Pres. Drug Manu. Assoc. of Canada
  - Sabex inc. - Can. Generic Pharma Association
  - Apotex - Genpharm
  - McMaster U. - BIOTEC Canada
- Membership is dynamic and changes
- Committee meets quarterly

Working Group on Electronic Submissions (WGES)

- Sub-group of ACES
- Co-operative group discussing and recommending directions for government and private sector
- Contributed to the development of Canadian Guidance for eCTD submissions (available May, 2004)
- Currently working together towards hybrid submissions
- Reports recommendations to ACES

Working Group on Electronic Submissions (WGES)

- Membership is dynamic, aligned to requirements
- Current members:
  - Health Canada - Bayer/BIOTEC
  - Genpharm - Serono
  - Pfizer - Astra Zeneca
  - SFPC Anapharm - Wyeth Consumer Healthcare

The E-Review Phased Approach

Stream 1

Address the immediate implementation and adoption of the most current ICH eCTD version for e-Submissions

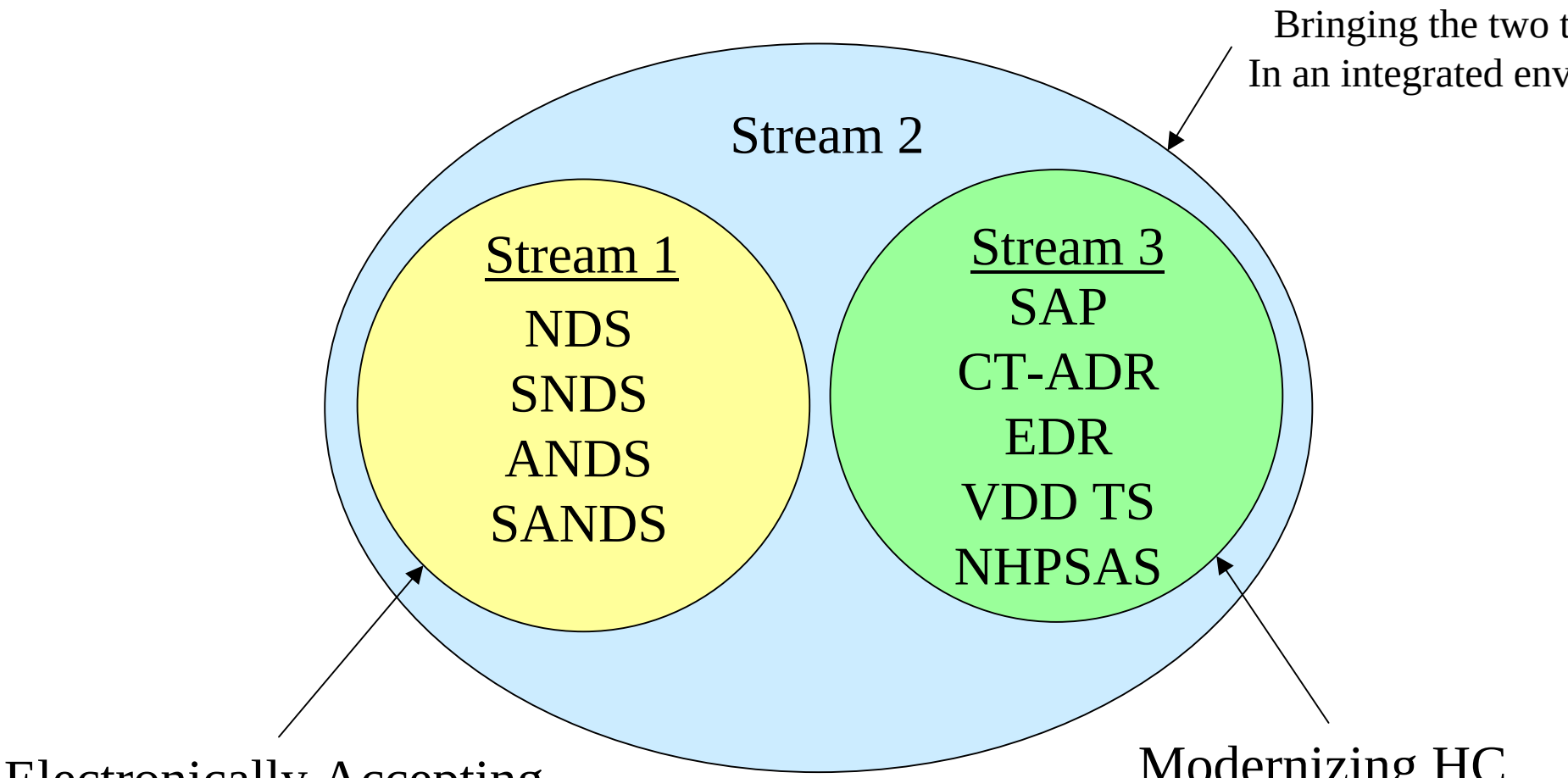
Stream 2

Will be the end-to-end solution that will incorporate ICH guidelines and address specific Canadian business and regulatory needs including document management, workflow and tracking

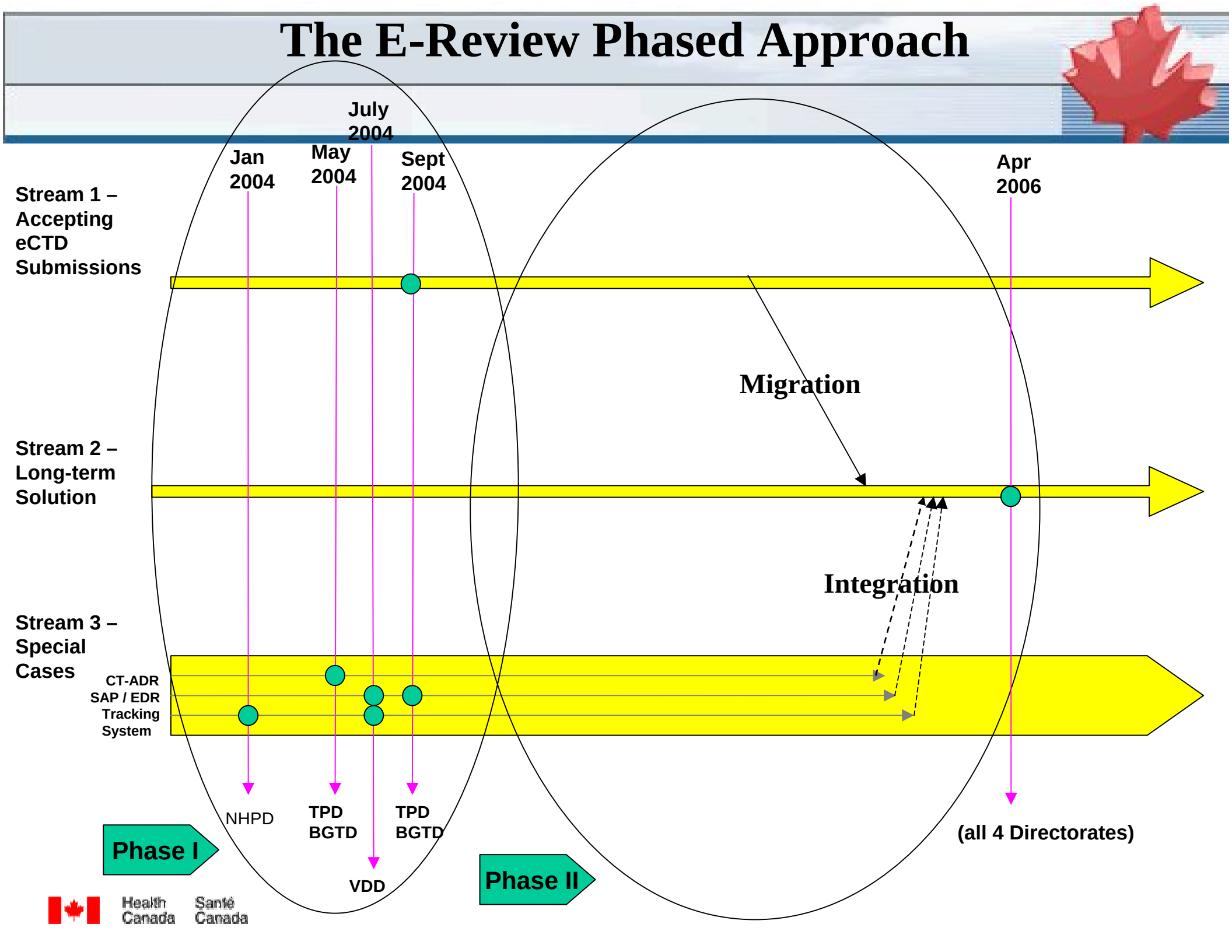
Stream 3

Addresses some pressing business issues, some that are in development in ICH, (e.g. ADR)

E-Review Stream Alignment



The E-Review Phased Approach



Communications

- Communications is a key success factor for E-Review
  - Internal
  - External
- Communications plan developed to uphold Health Canada's commitment to stakeholder engagement
  - Tailored to the needs of each audience
  - Structured to ensure that all involved are aware of the project and understand the outcomes
- The Strategic Communication Plan is essential for clarity of message and inclusion of the stakeholders

Stream 1 – Accepting eCTD Submissions

- Finding a flexible solution to accepting various submission file formats
- Legal policy issues in accepting electronic signatures
- Security of submission and evaluation of Canadian Government and ICH ESTRI security requirements and standards
- Migration plan that is acceptable to industry and development of guidance
- Development of viewing tool for Canadian eCTD

Stream 1 Progress

- Draft eCTD guidance published to Health Canada website – May 2004 (subject to 60 day consultation and Q&A)
- Canadian module 1 DTD (ver. 1.0) published to Health Canada website - May 2004
  - Corresponding draft guidance to be released June 2004
- Date for acceptance of eCTD submissions (with paper co-submission) – Sept 2004
- Evaluation of software from various companies installed to evaluate the ability to view the Canadian eCTD

Stream 1 - the Canadian eCTD

- Health Canada HC-SC-3011 form is the key document containing the tombstone data for tracking submissions
- Finalize the Canadian eCTD by releasing the Canadian module 1 DTD and the guidance document
- Initial implementation will revolve around paper and electronic co-submission. Considerations: legal, security, integrity and user readiness
- Efforts underway to explore modifications to regulations for acceptance of electronic signatures
- Submission types to be initially supported: NDS, SNDS, ANDS, SANDS
- Pre-submission meetings will be held to guide companies through the eCTD submission process

Stream 1 - Health Canada's eCTD Challenges

- Legal and security/privacy concerns must be clarified and addressed
- Viewer must be in-place with user interface in both official languages
  - Business Processes and SOP's for accepting eCTDs. Centralized electronic document room?
- Defining protocol for working the first few submissions through the system to ensure proper workflow
- To satisfy GoC reporting requirements, will baseline current performance and measure improvements

Stream 1 - The Legal Challenges

- Current legislation does not allow submissions in an all electronic format, however:
- Recently determined that Health Canada can move to accept a hybrid solution – targeting hybrid submission acceptance for June 1st, 2005
- Concurrently, Health Canada regulatory amendment process to allow electronic signatures has been initiated
- Final component is secure electronic 2-way communications. Health Canada is investigating possible solutions including use of the Government Secure Channel while also considering ICH ESTRI standards

Stream 3 – Addressing Immediate Needs

- Implementation to support the 24 hr. turn-around-time required for Special Access Program/ Emergency Drug Release
- Implementation of a tracking tool to provide process management
- Implementation of a tool for clinical trial adverse drug reaction monitoring
- Integration of business processes of common business processes across the Branch
- Implementation of solutions that are compatible and able to integrate with the future Stream 2 ICH-based end-to-end solution

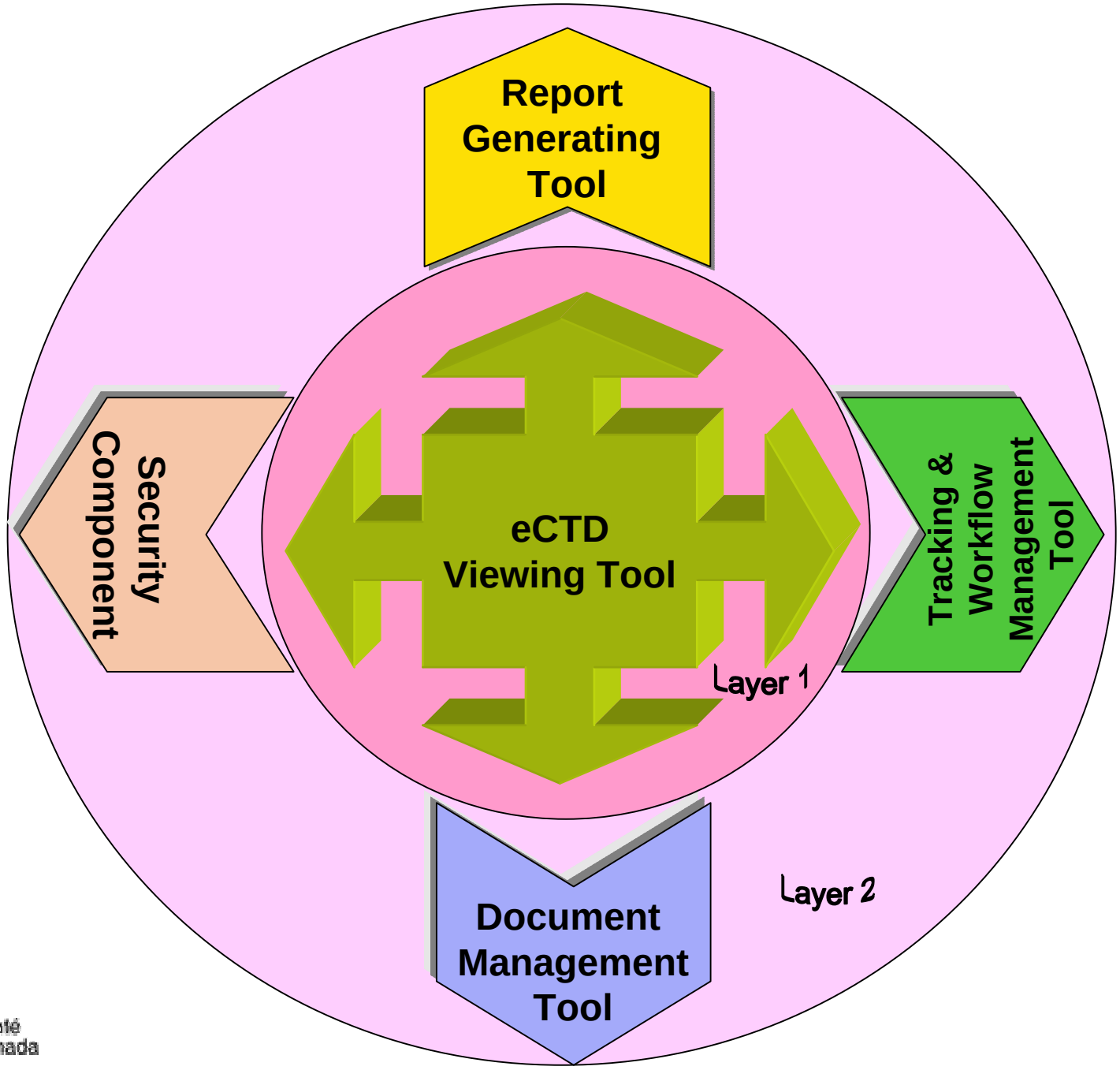
Stream 2 – Long Term Solution

- Integrates viewing capabilities realized in stream 1 and Health Canada support applications enhancements in stream 3
- Adds full submission lifecycle tracking, analysis and reporting
- Based on Common Off the Shelf (COTS) solutions

Stream 2 – Approach

- A complete study of all systems and sub-systems involved
- Initial approach was the preparation of an all inclusive RFP that would lead to a complete solution contract, including all sub-systems in 2004-2005
- A Request for Information (RFI) was posted in January of 2004, inviting responses from private industry
- Responses identified no single “solution”. Typically Common Off The Shelf (COTS) solutions engineered for eCTD viewing or Management Information System capabilities
- Decision to split focus into 2 layers of functionality

Stream 2 - Solution Components



Stream 2 Approach

- Focus of RFP will be on layer 1 functionality
- Identify layer 2 requirements while developing the RFP
- Include the integration standards and requirements in the RFP
- Complete procurement of the viewing tool in 2004-2005
- Implement viewing tool in 2005-2006 while resolving process-related issues (e.g. “hybrid” submissions)
- Implement sub-systems in layer 2 in 2005-2007

E-Review Summary

+ Globally Aligned
+ International Collaboration
+ Internal Departmental Collaboration
+ Industry Collaboration
+ Common tools based on international standards
+ Iterative “build on success” approach

= Formula for Success!

"We are entering one of the most important decades in our history. A decade where we will seize the opportunities before us."

2004 Speech from the Throne

Questions?