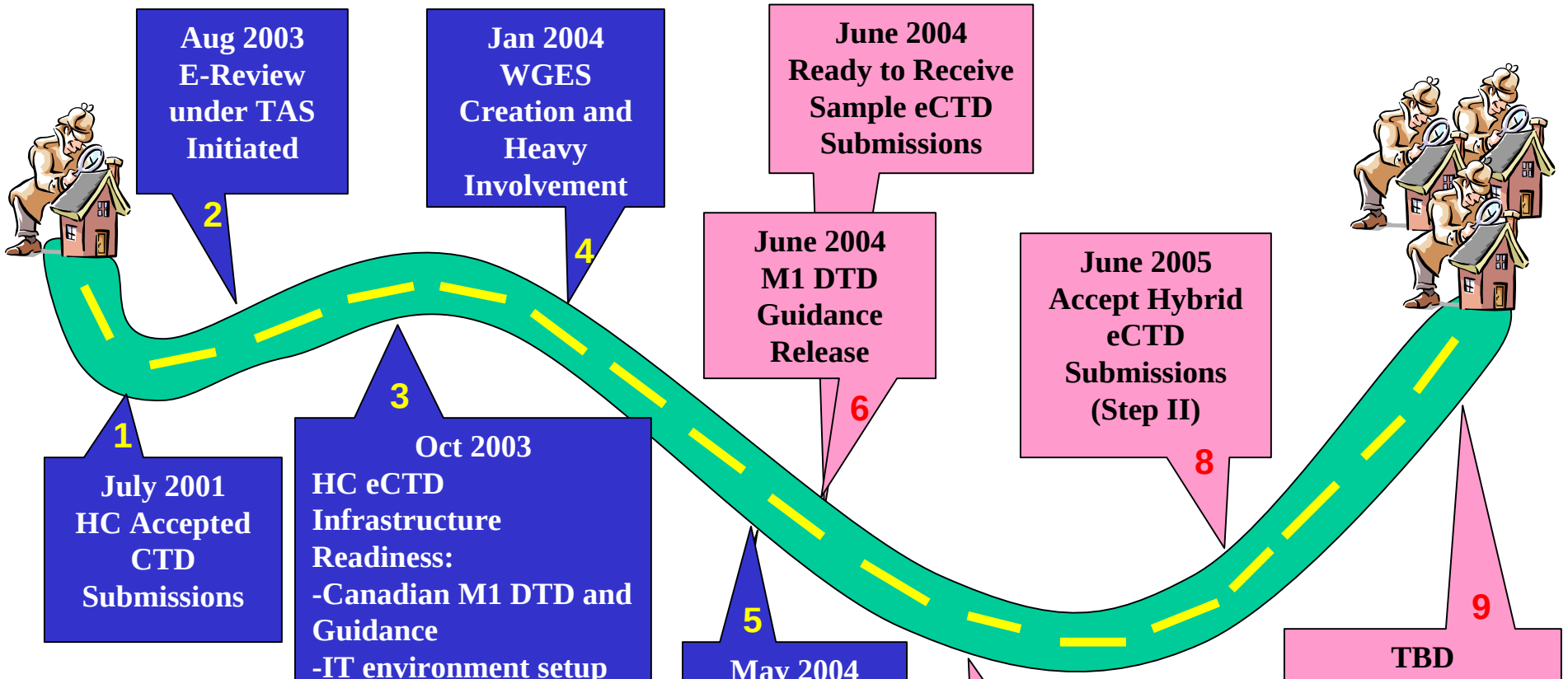
Readiness to Accept eCTD Submissions

CAPRA June 2

Montreal

Lili Hajiesmaili
Office of Information Management and Technology
Health Canada

Health Canada eCTD Roadmap



Past Milestones

Future Milestones

Health Canada Santé Canada

eCTD Submissions During the Pilot Phase

Between Now and Sept 2004

- **Electronic submission (current formats including eCTD) along with the platform – status quo**
- **eCTD submissions on CD's and DVD's will be treated as "sample"**

  Definition: A sample submission is for validation of the technology and processes only. There will be no scientific content review associated with a sample submission. It should have enough data to allow for testing (backbone and some leaf documents)

eCTD Submissions Step I - Sept 2004

- **Health Canada ready to accept eCTD submissions according to the released Guidance**
- **Early notification of upcoming eCTD submission highly desirable**
  - **Technical meetings very beneficial for first time submission of eCTD**
- **Drug sponsors should continue to submit sample eCTD before the real eCTD submission**

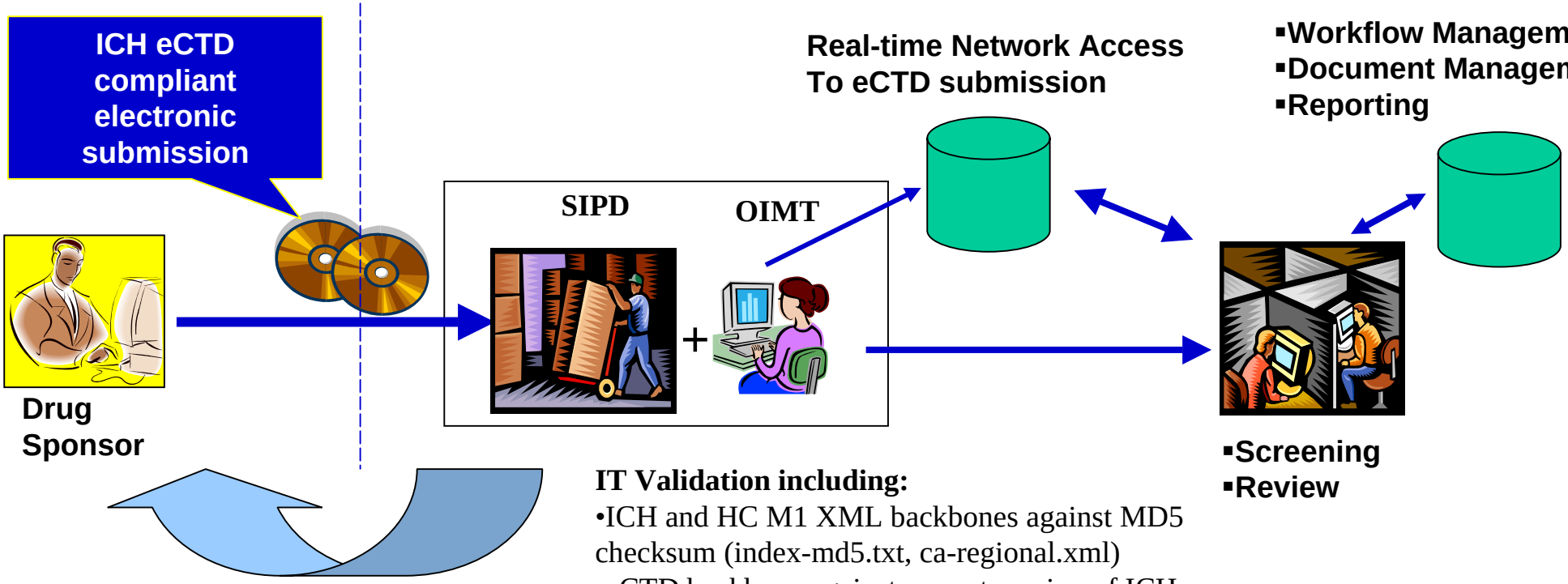
eCTD Submissions Step II - June 2005

- **Hybrid submission (Modules 1 and 2 paper and electronic, Modules 3 to 5 electronic only)**
- **Pre-submission meetings status quo**
- **Early notification of upcoming eCTD submission highly desirable**
  - **Technical meetings very beneficial for first time submission of eCTD**
- **Possible scenario: Complete hybrid submission (paper and electronic arrive simultaneously)**
- **Print on-demand by Drug Sponsors as required**

eCTD Submissions Step III - TBD

- **Full eCTD submission (no paper)**
- **All submission types**
- **Pre-submission meetings status quo**
- **Early notification of upcoming eCTD submission highly desirable**
  - **Technical meetings very beneficial for first time submission of eCTD**
- **Possible scenario: Complete eCTD**

IT Validation Process



IT Validation including:

- ICH and HC M1 XML backbones against MD5 checksum (index-md5.txt, ca-regional.xml)
- eCTD backbone against correct version of ICH DTD and Spec
- Canadian Module 1 XML backbone against HC M1 DTD and Spec
- Folder structure
- Leaf documents referenced in backbone exist in the eCTD submission, and vice versa
- Leaf document's MD5 checksum
- Leaf elements' modified file exists in previous submissions

Progress To-Date

- **Training requirements**
  - Survey to assess level of skill among internal users
  - Training on Adobe, MS-Word, eCTD, eCTD viewing tools, new SOPs and processes (new IT component)
- **Security requirements**
  - Completed Threat Risk Assessment and Privacy Impact Analysis
  - Studying implementation of ESTRI standards in the current HC IT environment while investigating Gov. of Canada security policies and mechanisms
- **eCTD Viewing tools**
  - Multiple tools in place
  - Plan to expand the QA lab to allow for evaluation of more COTS

Challenges

- **Step I** (E-Review Phase I)
  - **Encouraging Drug Sponsors to submit eCTD in addition to paper submission**
  - **Handling change management: people, processes, and technology**
- **Step II** (E-Review Phase II)
  - **Life cycle management at both submission and product levels ?**
  - **Appropriate electronic document management to support hybrid submissions (secure, reliable, always available)**
  - **Handling change management: people, processes, and technology**
- **Step III** (E-Review Phase II)
  - **Regulatory amendment**

Questions ?