

# Health Products and Food Branch

Your Health and Safety - Our Priority

## Health Canada's Interim In-House eCTD Viewing Tool

February 21, 2006

Mei Ke

Business Integration Office,  
BGTD

CAPRA, Toronto

The logo for e-Review, featuring a stylized orange '@' symbol followed by the word 'Review' in a bold, orange, sans-serif font.

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Canada

Santé  
Canada

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# Background

- Launch of Hybrid Pilot in June 2006
- Ongoing RFP for the long-term eCTD viewing tool
- Interim solution needed until full implementation of long-term tool
- In-house tool created in order to meet basic reviewer needs

# Interim In-house eCTD Viewing Tool (IleVT)

- Interim software designed in-house allowing users to access and view the contents of eCTD submissions quickly and easily



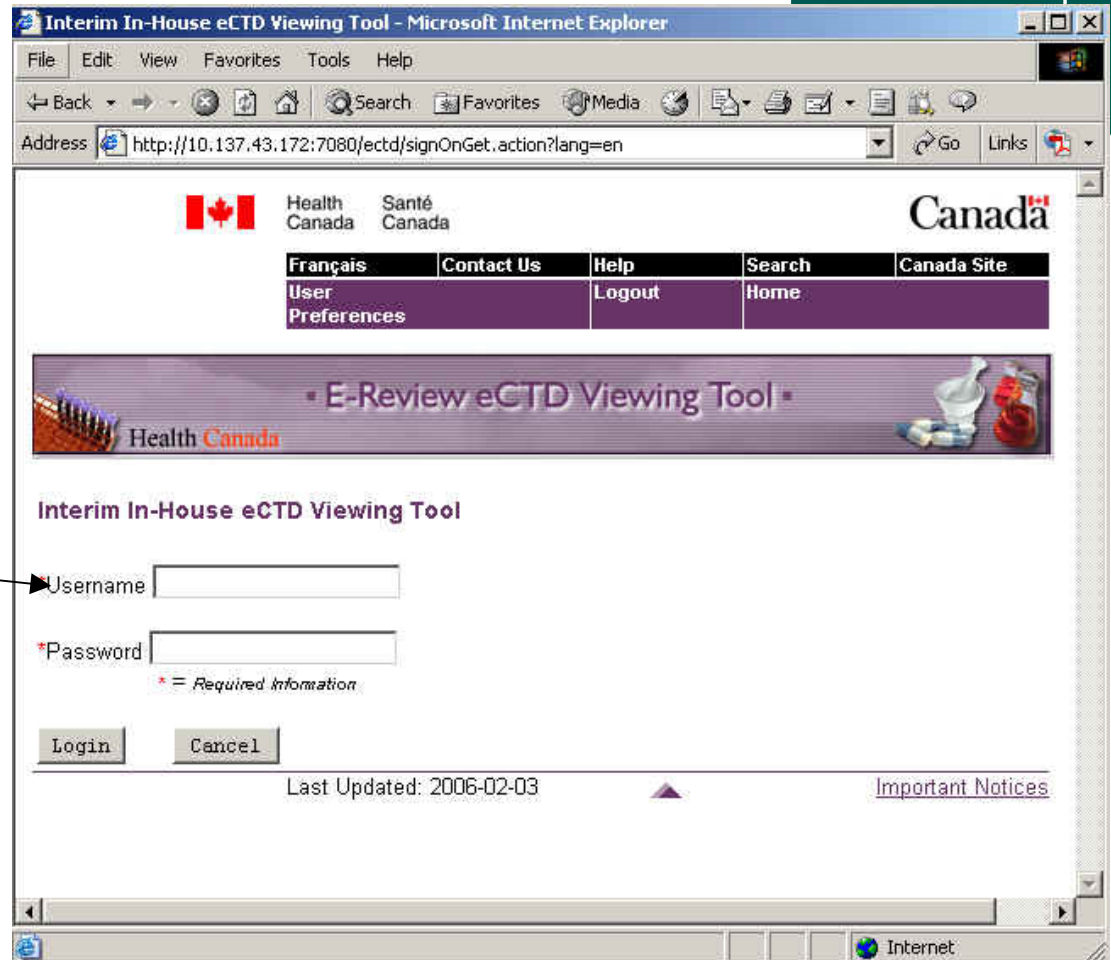
# Overview

- Proof of concept for the IIeVT conducted in the spring of 2005 with very positive reviewer comments
- Very basic functionalities designed for the purpose of viewing the submission (no annotation, basic tracking and workflow)



# IleVT

- Browser- (Microsoft Internet Explorer®), and role-based software
  - Ease of navigation
  - Functionalities assigned based on role of user:
    - processing (SIPD),
    - screening (RPMD & RAD),
    - reviewing (review bureaux/ centres)



# Processing : Registration



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 **E-Review eCTD Viewing Tool** 



- SIPD User**
- eCTD Registration**
  - Create Sponsor
  - eCTD Registration
- Submissions**
  - eCTDs
  - Sample eCTDs
  - Search
- Tracking**
  - Submission Stats
  - Query Submission Stats
  - Submission Log

## Register eCTD by Sponsor

All the sponsors are listed in the following select list.  
The total number of the sponsors is: 1

Create new eCTD:

View existing eCTDs:

Last Updated: 2006-01-31

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# Create a new eCTD entry

**E-Review eCTD Viewing Tool**

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**SIPD User**

**eCTD Registration**

- Create Sponsor
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**Submissions**

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**Tracking**

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**Create eCTD**

Create New eCTD for Sponsor: Demo Company

eCTD Identifier	<input type="text"/>
eCTD Type	submissio ▾
eCTD Directorate	TPD ▾
Brand Name	<input type="text"/>
Medical Ingredient	<input type="text"/>

**Notes**

# View existing eCTD entries



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## Show eCTDs: Demo Company

eCTD ID	Type	Directorate	# of Sequences	Action
e012345	submission	TPD	3 <a href="#">view</a>	<a href="#">Create New Sequence</a>
e111111	submission	BGTD	2 <a href="#">view</a>	<a href="#">Create New Sequence</a>
e123456	submission	TPD	2 <a href="#">view</a>	<a href="#">Create New Sequence</a>

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# Responses & Versions



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- E-Review eCTD Viewing Tool -

- SIPD User*
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### Show eCTD Sequences

Sponsor: **Demo Company**  
 eCTD ID: **e012345**

eCTD Sequence	Control Number	Submission Type	Responses	Versions	Actions
0000	012345	NDS	2 <a href="#">view</a>	3 <a href="#">view</a>	<a href="#">Edit</a> <a href="#">Create New Version</a> <a href="#">Create New Response</a>



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# Registration

# Viewing Response Sequences



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  - Query Submission Stats
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## Show eCTD Sequence Responses

Company Name: **Demo Company**  
eCTD ID by HC: **e012345**  
Sequence Number: **0000**

The response sequences are as follow:

Response	Control Number	Versions	Actions
0001	012345	1 <a href="#">view</a>	<a href="#">Create New Response Version</a>
0002	012345	1 <a href="#">view</a>	<a href="#">Create New Response Version</a>

Last Updated: 2006-02-03

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SIPD User
eCTD Registration:
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■ eCTD Registration
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Show eCTD Sequence Response Versions

Company Name: Demo Company  
 eCTD ID by HC: e012345  
 Parent Sequence Number: 0000  
 The Response Sequence Number: 0001  
 The Response Versions are as follows:

Version: 1  
 Pass IT Validation: true, [Validation Report](#)  
 ICH DTD Version: 3.2, HC DTD Version: 1.0  
 ICH STF Version: 2.0  
 Network Path:  
 Builder Info: , eCTD Viewer Info:  
 Media Type: CD, Media Number: 1, Media Size: 2.0 MB  
 Notes:

Workflow Tracking

Date on Letter	Thu Jan 01 15:08:57 EST 2004
Date to SIPD	Thu Jan 01 15:08:57 EST 2004
Date to DIMT	Thu Jan 01 15:08:57 EST 2004
Date of Validation	Thu Jan 01 15:08:57 EST 2004
Date to Manager	Thu Jan 01 15:08:57 EST 2004
Date back to SIPD	Thu Jan 01 15:08:57 EST 2004
Date to Sponsor	Thu Jan 01 15:08:57 EST 2004

# Viewing Sequence Versions

# Submissions



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Health Canada **E-Review eCTD Viewing Tool**



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## eCTDs

Directorate	Sponsor	eCTD ID	Brand Name	Currently In
BGTD	Demo Company	e111111	Product C	Screen 
TPD	Better Sponsor	e666666	coffee	Review
TPD	DAD_Demo	e111124	Aspirins	Review
TPD	Demo Company	e012345	Product A	Screen 
TPD	Demo Company	e123456	Product B	Screen 

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# Tracking

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Health Canada E-Review eCTD Viewing Tool

SIPD User

**eCTD Registration**

- Create Sponsor
- eCTD Registration

**Submissions**

- eCTDs
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**Tracking**

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**Display eCTD Log**

**eCTD Submission Log**

Compiled by:  
 Compiled Date: 2006-02-03

**Table of Contents**

- [The latest eCTD Numbers summary](#)
- [All the sponsors submitted eCTD](#)
- [Health Canada Staff](#)
- [eCTD Log](#)
- [Each eCTD Submission Sequence Number Log](#)
- [Each eCTD Submission Sequence Number Version And Workflow Log](#)
- [eCTD Data Statics](#)

**1. The latest eCTD Numbers summary**

eCTD	BGTD	TPD	TPD & BGTD
<b>Submission</b>	1	4	5
<b>Sample</b>	0	0	0
<b>Total</b>	1	4	5

- Minimal tracking functions:
  - Number rec'd (samples/eCTDs)
  - Submission Contacts: Sponsor & Health Canada
  - Number of sequences rec'd in each submission
  - Dates rec'd and size
  - Evaluation step

# Screening

Logged in as  
"Screener"



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Health Canada **E-Review eCTD Viewing Tool**



<i>BGTD Screener</i>
<b>Submissions</b>
▪ eCTDs
▪ Search:

## eCTDs

Directorate	Sponsor	eCTD ID	Brand Name	Currently In
BGTD	Demo Company	e111111	Product C	<a href="#">Screen</a> 



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# Screening

To access the sequence, double click on the sequence number



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Health Canada **E-Review eCTD Viewing Tool**

<i>BGTD Screener</i>
<b>Submissions</b>
▪ eCTDs
▪ Search

## eCTD Details

eCTD ID	Sponsor Name	Brand Name
e111111	Demo Company	Product C

Submission Type	Control Number	Submission Sequence	Additional Information
NDS	111111	0000	0001 <a href="#">assign</a>

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In Review

# Reviewing



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Health Canada **E-Review eCTD Viewing Tool**

<i>BGTD Reviewer</i>
<b>Submissions</b>
▪ eCTDs
▪ Search

## eCTDs

Directorate	Sponsor	eCTD ID	Brand Name	Currently In
BGTD	Demo Company	e111111	Product C	<a href="#">Review</a>

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# Processing/Screening/Reviewing

eCTD ID: e111111  
Sequence Number: 0000  
Control Number: 111111

View eCTD M1 - M5

[Expand all](#) [Collapse all](#)

- 1 Administrative Information and Prescribing Information
  - This eCTD Submission Introduction
  - Canadian Module 1
    - 1.2 Application Information
    - 1.3 Product Labelling
    - 1.4 Health Canada Summaries
    - 1.5 Environmental Assessment Statement
- 2 Common Technical Document Summaries
  - 2.2 Introduction
  - 2.3 Quality Overall Summary
  - 2.4 Nonclinical Overview
  - 2.5 Clinical Overview
  - 2.6 Nonclinical Written and Tabulated Summaries
  - 2.7 Clinical Summary
- 3 Quality
- 4 Nonclinical Study Reports
- 5 Clinical Study Reports

**Double-clicking folders will open the subfolders...**

# Processing/Screening/Reviewing

**Clicking on the file will launch the document in a new window in its native application...**

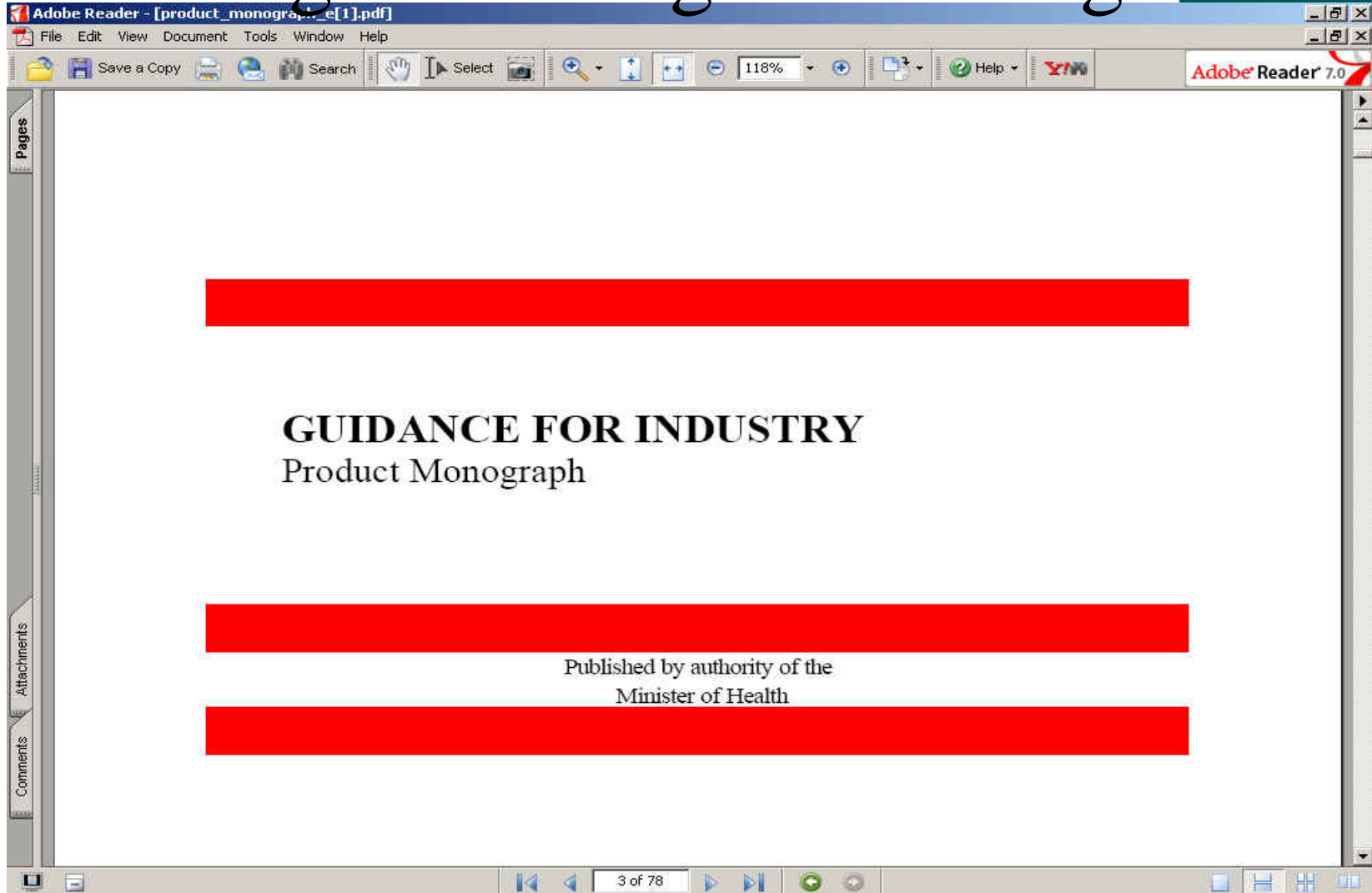
eCTD ID: e012345  
Sequence Number: 0000  
Control Number: 012345

View eCTD M1 - M5

[Expand all](#) [Collapse all](#)

- 1 Administrative Information and Prescribing Information
  - 2 This eCTD Submission Introduction
  - Canadian Module 1
    - 1.0 Cover Letter [new]
    - 1.2 Application Information
    - 1.3 Product Labelling
      - 1.3.1 Product Monograph
        - 1.3.1 Annotated Product Monograph [new]
        - 1.3.1 Annotated Product Monograph [new]
        - 1.3.1 Non-Annotated Product Monograph [new]
        - 1.3.1 Non-Annotated Product Monograph [new]
      - 1.3.2 Draft of All Inner and Outer Labels
      - 1.3.3 Non Canadian Package Inserts
    - 1.4 Health Canada Summaries
    - 1.5 Environmental Assessment Statement
- 2 Common Technical Document Summaries
- 3 Quality
- 4 Nonclinical Study Reports
- 5 Clinical Study Reports

# Processing/Screening/Reviewing



# Next Steps

- End of Feb 06 : Launch of IieVT Pilot
  - Proof of concept and test sustainability and operational support on a limited number of staff
  - Provide training and support for staff
- April 06 : QA on further development/develop training materials
- May 06 : Application Implementation
  - Migrate data to production environment
  - Preparation for roll out – production
  - Provide training for staff
- June 06 : Hybrid Implementation for IieVT
- In the meantime, continue with RFP process to determine long-term solution

Questions?

# Thank You

Mei Ke

(613) 946-0697

Mei\_Ke@hc-sc.gc.ca

E-Review Project Lead, BGTD

Business Integration Office