



Electronic Submissions in Hungary

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e-Submissions in Hungary



- Historical overview
- Advantages of eCTD
- Authority challenges
 - Digitalizing old paper submissions
 - Launching eCTD tool
- E-Submission requirements in Hungary
 - eCTD
 - non eCTD (NEES)



Historical Overview



- 1996: installation of DAMOS Pharmbridge V.2
 - first electronic MA submissions received
- 1998: PDF-based submissions.
- 1999: html-based submissions
- 2005: testing Reviewer Systems chosen by the EMEA
- January 2006. : NIP decides to use „Eurs is Yours”
- December 2006. : Eurs is Yours wins the EMEA tender for central ECTD repository.



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Historical Overview



2006:

- More than 100 new applications on CD in 2006 (eCTD & non eCTD)

2007-2008:

- NIP (OGYI) is one of the NCAs taking part in the test process of the Central Repository of EiY in a common project with EMEA & vendor.

2007. June - 2008. September:

120 eCTD received for New Applications, more than 80 eCTD based variation loaded to the system



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Historical Overview



OGYI - Popularizing eCTD at conferences:

- April 2007 – 1st hungarian conference on DMS in Pharmaceutical Industry (DMS Labor)
- May 2007 – openeCTD conference at Budapest
- October 2007 – 2nd hungarian conference on DMS in Pharmaceutical Industry (DMS Labor & OGYI)
- December 2007- 8th European Electronic Document Management Confernce (DIA, Prague)
- April 2008 – 3rd hungarian conference on DMS in Pharmaceutical Industry (DMS Labor & OGYI)
- May 2008 - 10th Annual Pharmaceutical Conference (Infotehna, Croatia)
- October 2008 – TOPRA Conference at Budapest
- December 2008- 9th European Electronic Document Management Confernce (DIA, Barcelona)



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Advantages of eCTD



Easier work for assessors:

- **using eTOC and good hyperlinks**
- Possibility of full text search in dossier
- Using copy & paste creating an Assessment Report is easier
- Lifecycle management: seeing the changes immediately at variations



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Advantages of eCTD



Possibility of seeing the whole, complete dossier together at all Departments:

- After pre-assessment (validation) paper dossiers are divided to different sections, only specific parts of the dossiers are given to specific departments (Insp./Med-Biol./Qual.)

Using eCTD tool as a repository:

You can create a **SCIENTIFIC MEMORY** from all eCTDs submitted to your authority!



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Authority challenges

- Digitalizing old paper submissions
- Launching eCTD tool



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Digitalizing old paper submissions



- 30 million pages of paper documentation stored at OGYI Archive (Starting from 1933)
- Different quality of papers
- Partly stored at an external district storage building
- How can you find anything?



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Digitalizing old paper submissions



SOLUTION:

Paper Archive Digitalization Project – I.

Start: November 2006. - November 2007.

25.000.000 pages scanned in 1 year

Paper Archive Digitalization Project – II.

Start: August 2008.

Continuing with the further paper submissions



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Digitalizing old paper submissions



PROCESS:

Selection of documentation by quality

Scanning

1. Creation of scanned TIF file
2. OCR => RTF document created

RTFs are indexed to an Oracle DB



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Digitalizing old paper submissions



RESULT:

DocuSearch application:

- Possibility of full-text search in the full OGYI archive
- Scanned documentation is connected to the database of OGYI
- Search by database attributes
- Image & doc view



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Digitalizing old paper submissions



PLANS:

- Continuing the digitalization of incoming paper documentations
- Creating image-text PDF files from the scanned docs
- Integration of DocuSearch application with eCTD assessing tool
- Possibility of creating eCTD from PDF



Launching eCTD tool



1. Choosing vendor for eCTD Reviewer Tool:
 - Presentations on tools
 - Test installations
 - What kind of IT Infrastructure is needed?
 - Many tools need Oracle as DB Engine
 - Solutions for Offline Reviewing?



Launching eCTD tool

2. Decision on Vendor
3. Installation of software
4. Trainings for users
 - 2 responsible person keep contact with Vendor
 - Making frequent own trainings by pre-trained native language trainer
 - Trainings from Vendor occasionally (Eg. Before bigger version changes)





Actual situation:

- Eurs is Yours is installed already at 70 users

The screenshot displays the 'Eurs is Yours' software interface. The main window shows a document titled 'Annex 6.4 Letter of authorisation for communication on behalf of the applicant / MAH'. The document content is centered and reads:

Annex 6.4
Letter of authorisation for communication on behalf of the applicant/MAH

On the left side, there is a 'Submission-Explorer' pane showing a hierarchical tree structure. The selected item is 'Annex 6.4 Letter of authorisation for communication on behalf of the applicant / MAH'. Below the document viewer, an 'Attributes' pane is visible, containing the following information:

Attributes	
Sequence	0000
Title	Annex 6.4 Letter of authorisation for communication on behalf of the applicant / MAH
Operation	new
Language	
Filename	be-form-annex-6-4-marc-van-bommel.pdf
Checksum	238f30ba24c870978c63a276e78f33bf

The interface also includes a 'Project-Explorer' pane at the top left, a 'Document-Explorer' pane at the bottom left, and a taskbar at the bottom with various application icons and the system clock showing 9:13.



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Launching eCTD tool



Helping the work of assessors:

- New LCD screens
- Special needs:
 - Paralell submissions with the same content
 - Copying annotations from one submission to another

New development was asked from vendor to solve the problem!

No time for waiting for the „Vendor’s Wishlist”
-> custom development was finished in 45 days for OGYI



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Launching eCTD tool



Next steps:

- Creating SOPs for the work with electronic reviewing tool!
- Assessment report creating?
 - Using reviewer tool annotations
 - Using copy & paste in MS Word
- Connecting Reviewer Tool with Workflow Engine



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IT Challenges



- Choosing database for the tool
- Installing the environment
- Size of repository?
 - How many TB will be needed?
 - Creating backup of repository?
 - UDO Jukebox / Storage Device:
 - » New OGYI storage has a capacity of 4 TB, and can be extended to more then 20 TBs!
- Adobe Acrobat Professional for all Reviewers
- Buying new screens



IT Challenges



- Trainings for IT Helpdesk!
 - IT Helpdesk must be able to help reviewers having questions about the tool
- External Reviewers
 - Connecting to EiY Repository from Outside – Firewall / Security
 - Synchronization at the Agency for offline use

PLAN:

- Connecting Reviewer Tool with Workflow Engine



e-Submission requirements



- eCTD requirements
- Non eCTD requirements



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eCTD requirements



From 2006 the National Institute of Pharmacy (OGYI) in Hungary is able to accept full electronic, eCTD applications, without any printed sections of the dossier!



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eCTD requirements



Validation criteria of new application (OGYI – website)

- „submission of electronic format (eCTD) is also possible – if so, please submit 4 copies of Application Form and the certificates in paper form, the CD should contain the remaining parts in hyperlinked version”



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eCTD requirements



Requirement:

- Printed Accompanying Letter
- 2 CD copies

Suggestion:

- Module 1, 2 and 3 text-based or image-text PDF

- Usable formats in eCTD:

- PDF
- MS Word
- XML backbone



What kind of PDF to use?

- **PDF Formatted Text and Graphics**

- in case of having the original text doc
- Full text search without OCR mistakes, Smaller file size

- **PDF Image + Text**

- starting from paper or image files:
- Scanning +OCR

- **PDF Image** (not preferred)

- Much bigger file size, Not searchable
- Acceptable only at special cases:
E.g.: GMP Certificates or other AF annexes

Non-eCTD applications



PROPOSAL:

- use NEES, according to HMA Best Practice Guide, 2008 Aprile
- CTD folder structure & naming convention, without XML

OBLIGATORY:

- Hyperlinks & eTOC
- Not just scanned pictures!
- Can not contain special executable files



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THANK YOU!

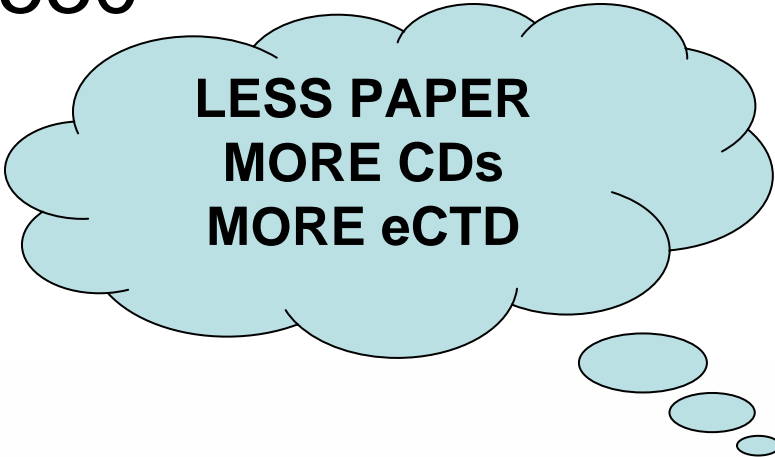


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LESS PAPER
MORE CDs
MORE eCTD

A light blue thought bubble with a black outline, containing the text "LESS PAPER MORE CDs MORE eCTD". The bubble has three smaller circles leading to it from the bottom right.

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