Experiences and observations from eCTD submissions to the Slovak Medicine Agency (SUKL)

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Content

- Introduction , background, Setting scene
- eCTD in the system of existing databases, and hardware options , personal
- Outcomes from system – analysis – examples
- Future plans – communication and new option for MAH to follow the process

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Introduction , background, Setting scene

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eCTD system in SK Introduction - background

1. *State Institute for Drug Control in SK uses **local** validation and review tool.*

2. *System was implemented by agency in cooperation with company Balajka M+A, s.r.o., www.sukl.sk, www.ectd.sk*

3. *System was implemented from QI/ 2010*

4. *System known as : eCTD Tracking System.*

5. *Actual version: 1.33 (version reflects previous updates based on requirements)*

6. *Validation criteria actual (used):*
   eCTD – 5.0
   NeeS – 4.0

7. *In 2013 major update of system – system converts NeeS format to eCTD format .*

Main objectives for implementation of eCTD/Nees

- Meet standard requirements for application submitted, harmonisation in EU (ICH for dossiers)
- Content of dossier is available to respective staff across all processes in agency (SIDC) – security access to dossiers
- Accessibility of content of eCTD documentation for complex analyses and assessment
- Both side communication (with PTL and Applicant – „discussion“)
- Optimization of process of receiving registration documentation
- Process of transparency

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Feasibility for implementing system

- Limited No. of Staff – need for optimizing of processes using eCTD
- Establishing effective processes to ensure progress towards the automation of processing, validation and acquisition of data from applications
- Retraining of staff for understanding eCTD, their role for technical and content- of -dossier validation, during life cycle of application and licensed medicine

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Challenges for eCTD system supplier

- Cooperation of validation tool with existing databases systems
- The whole process of validation and acquisition of data from applications must be manageable with a limited number of staff
- Old hardware throughout the agency
- Concept of secure access for Applicants to get information about registration processes
- Implementation data warehouse
- Data capacity increasing

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eCTD in the system of existing databases, and hardware options , personal

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Utility of medicines

Internal systems

(e-Application portal, database of medicinal product)

eCTD- Validation report

MS SQL Server 2008 Web Edition

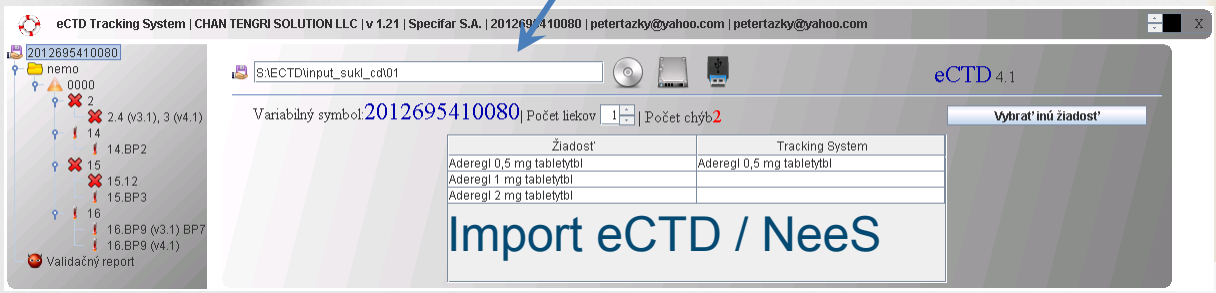
Internet Information Services

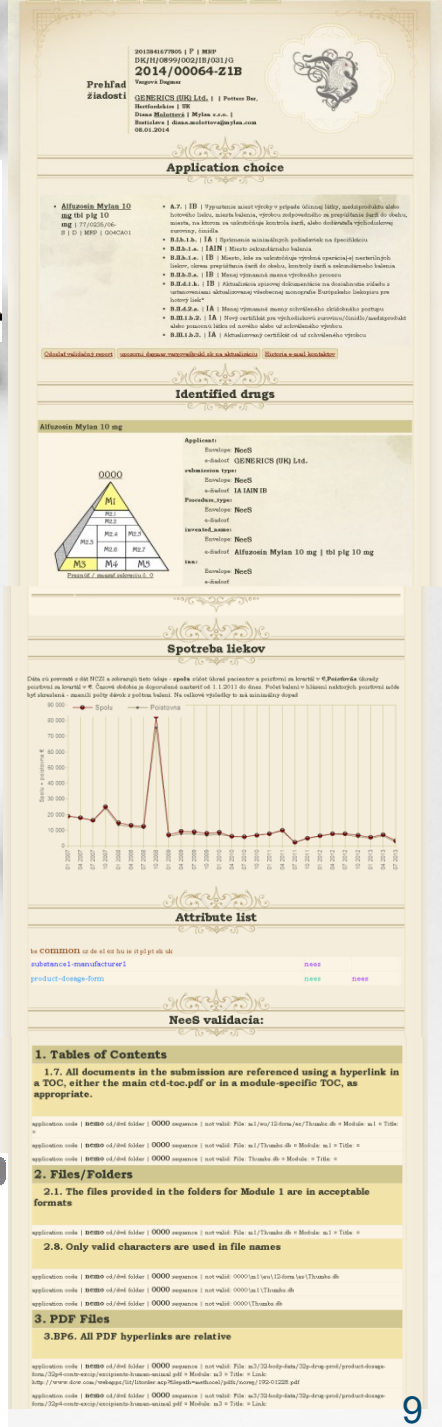
Logi Info Server

eCTD / NeeS validation

Tracking system

NeeS to eCTD





Cooperation with existing systems

RESUME:

Result of technical validation

Technical criteria:

- does not meet the "new EU validation Criteria v 4.1"
- missing the previous sequence /Life Cycle Management validation

Identifikačné údaje (Envelope SK):

eCTD application meets the professional criteria.

VALIDATION REPORT:

Name of a medicinal product, registration number, → imported from internal database SIDC

Application choice:

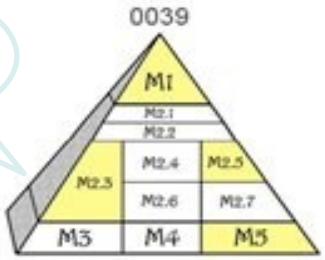
- Metoject 50 mg/ml injekčný roztok sol inj | 44/0659/08-S | R | DCP | L01BA01

Identified drugs:

Data from eCTD

Metoject

Visualisation of sequences

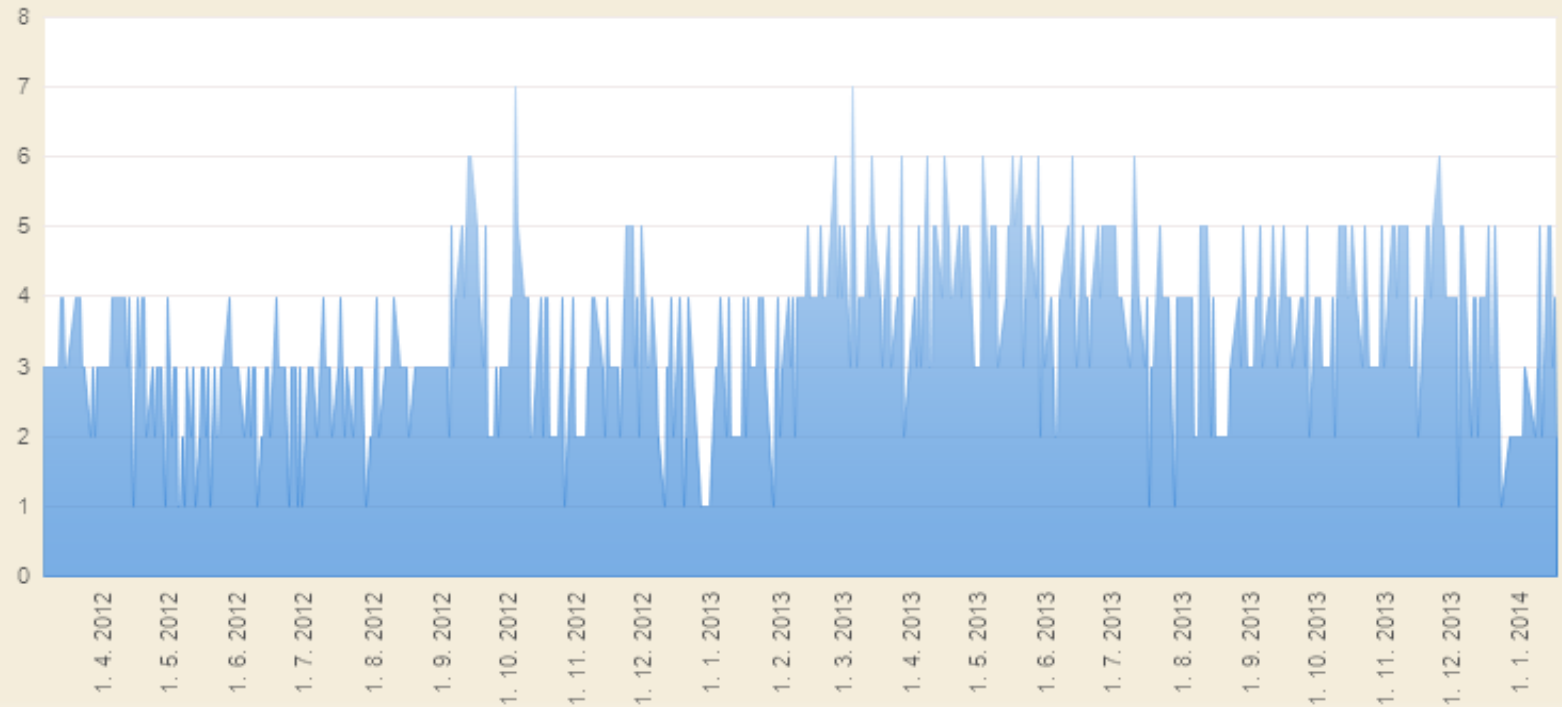


Applicant:
Envelope: medac GmbH
e-žiadosť: medac Gesellschaft für klinische Spezialpräparate m.b.H
submission type:
Envelope: renewal
e-žiadosť:
Procedure_type:
Envelope: decentralised
e-žiadosť: DCP
invented_name:
Envelope: Metoject
e-žiadosť: Metoject 50 mg/ml injekčný roztok | sol inj
inn:
Envelope: Methotrexate
e-žiadosť: Metotrexát
import date: 31.10.2012 01:58
MD5: a90d467b58a23124a03462e77359d148

Data from portal e-Application

The whole process of validation and acquisition of data from applications must be manageable with a limited number of staff

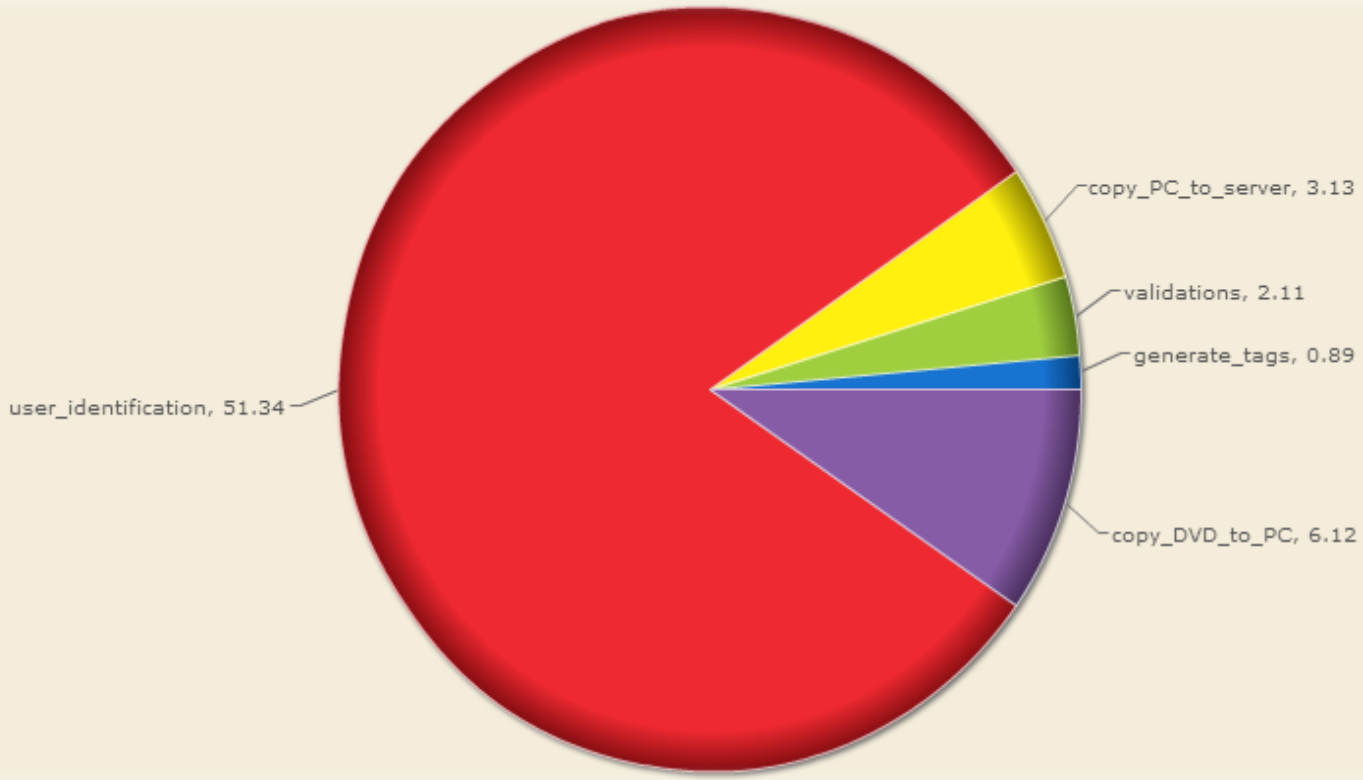
Number of people which upload all eCTD sequences



System has to work in spite „Old hardware“ throughout the agency !

Median time which is necessary for identification of application and drug name .....51 sec.

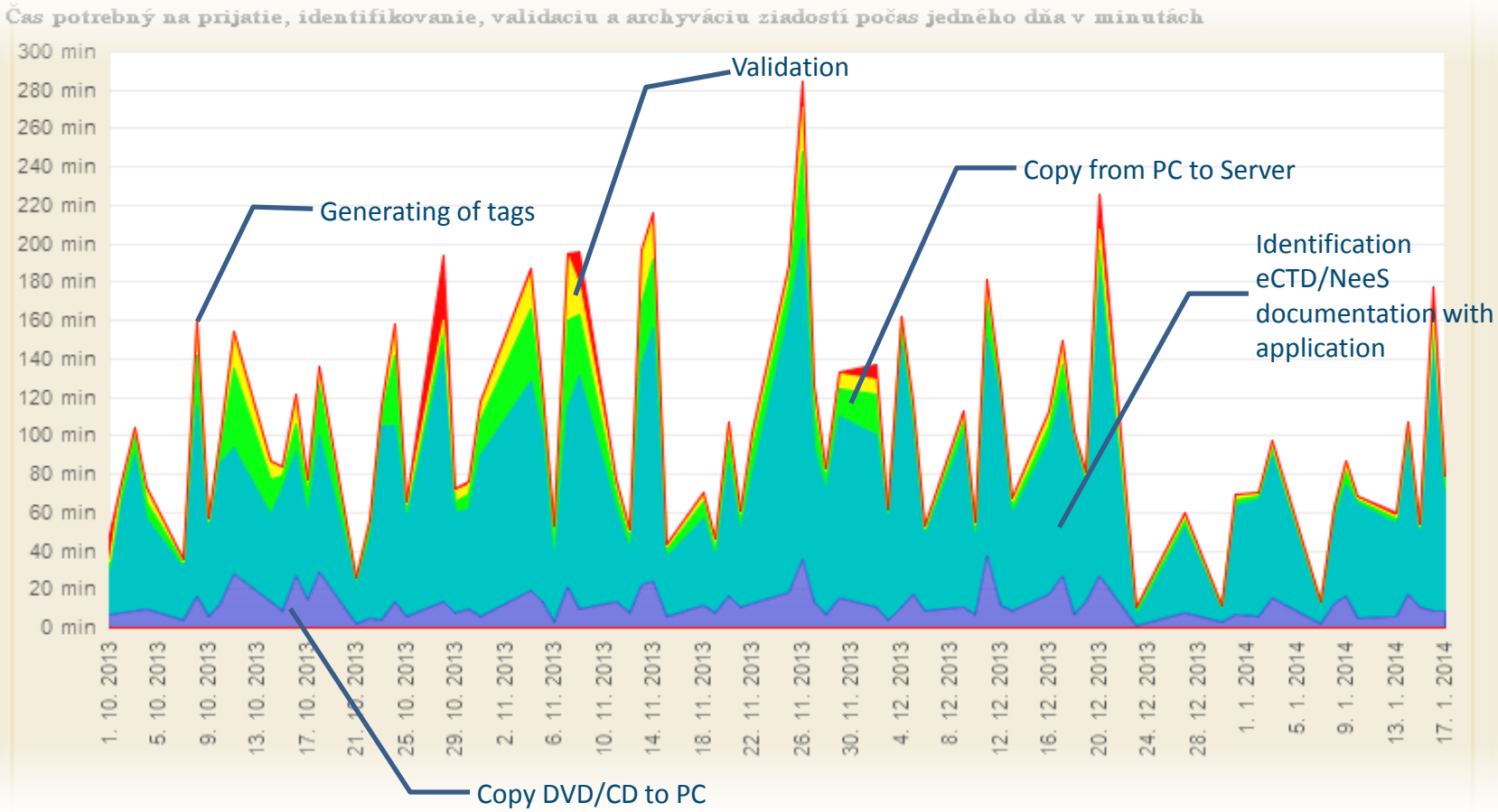
Mechanical processing of application.....12 sec.



Older hardware at the Department of Administrative Support

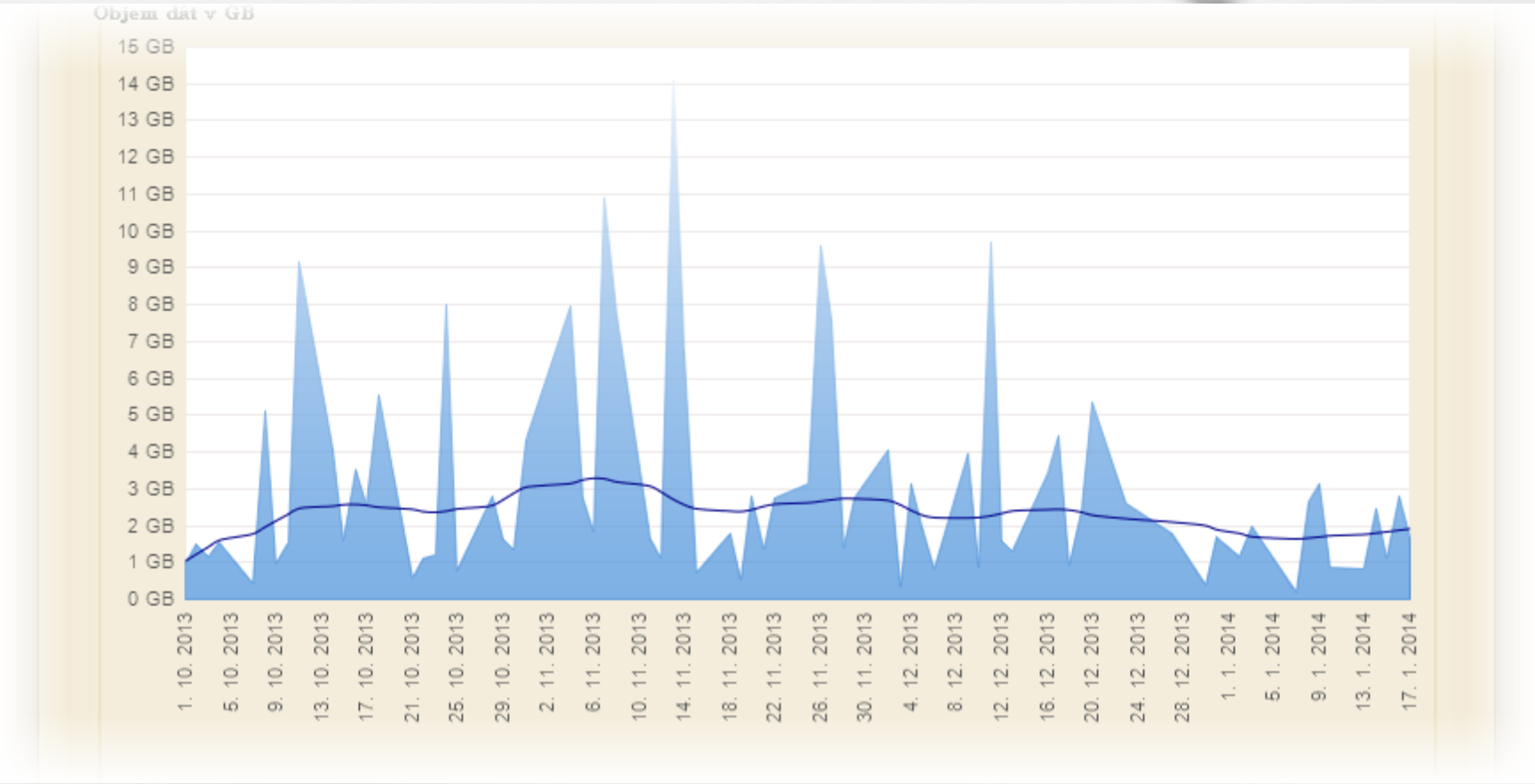
The applications are uploaded in 24hours after receiving documentation.

Sequences are uploaded 2-5 hours per day.

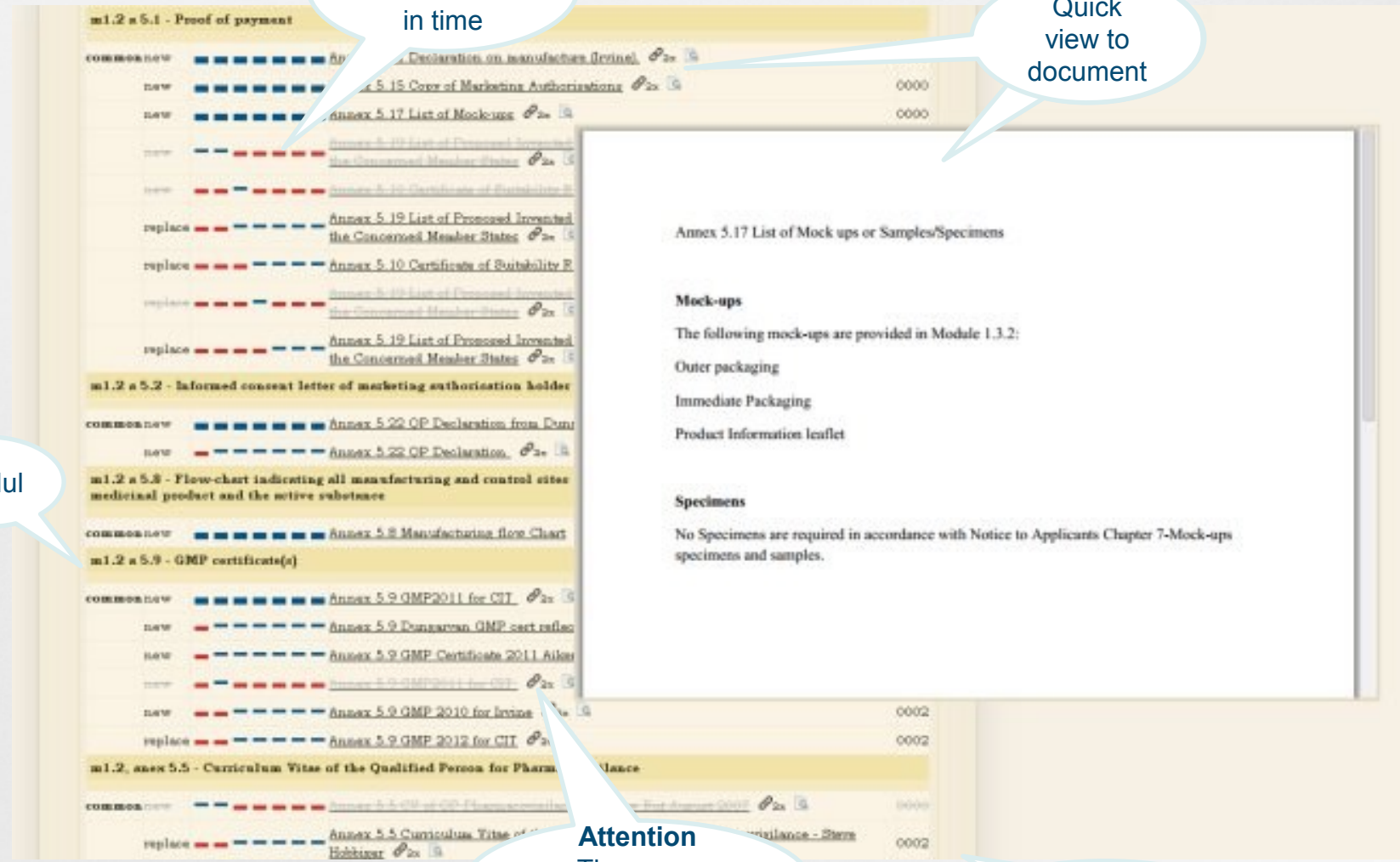


Data capacity

Champion for capacity data imported (at 14.11.2013 -14GB) - 220 minutes for complex processing.



Content of dossier available to respective staff across all processes in agency (SIDC)



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Outcomes from system – analysis – examples

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Available ad hoc analysis from System

- What are the formats of registration documentation (eCTD, Nees, paper,...)?
- How many percent of applications are in eCTD format?
- Improving of quality of eCTD applications in timeframe (after trainings for applicants,...)?
- What are the most frequent errors in the eCTD dossiers based on validation protocol?
- Applicants with top number of applications?
- How many percent of applications met with validation criteria?
- How many applications have valid Life Cycle Management?
- Which companies have stopped to notify changes in status of documents? (each next change in document is marked as new)

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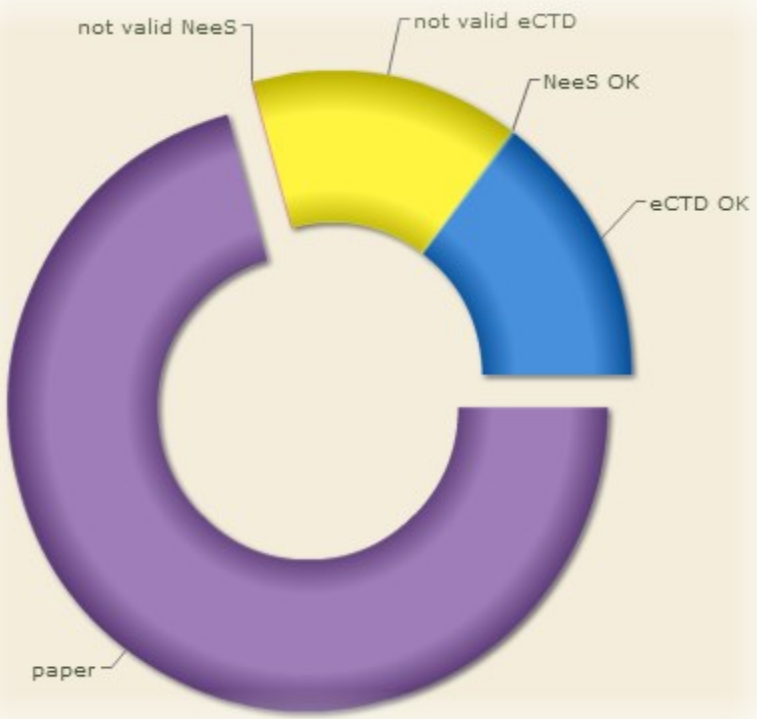
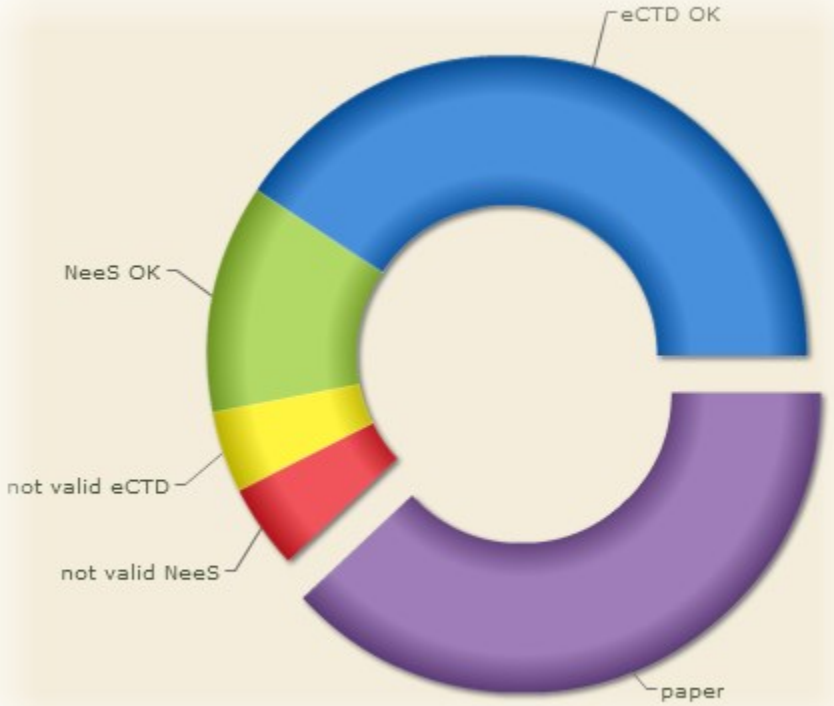
What are the formats of registration documentation submitted

2011



2013



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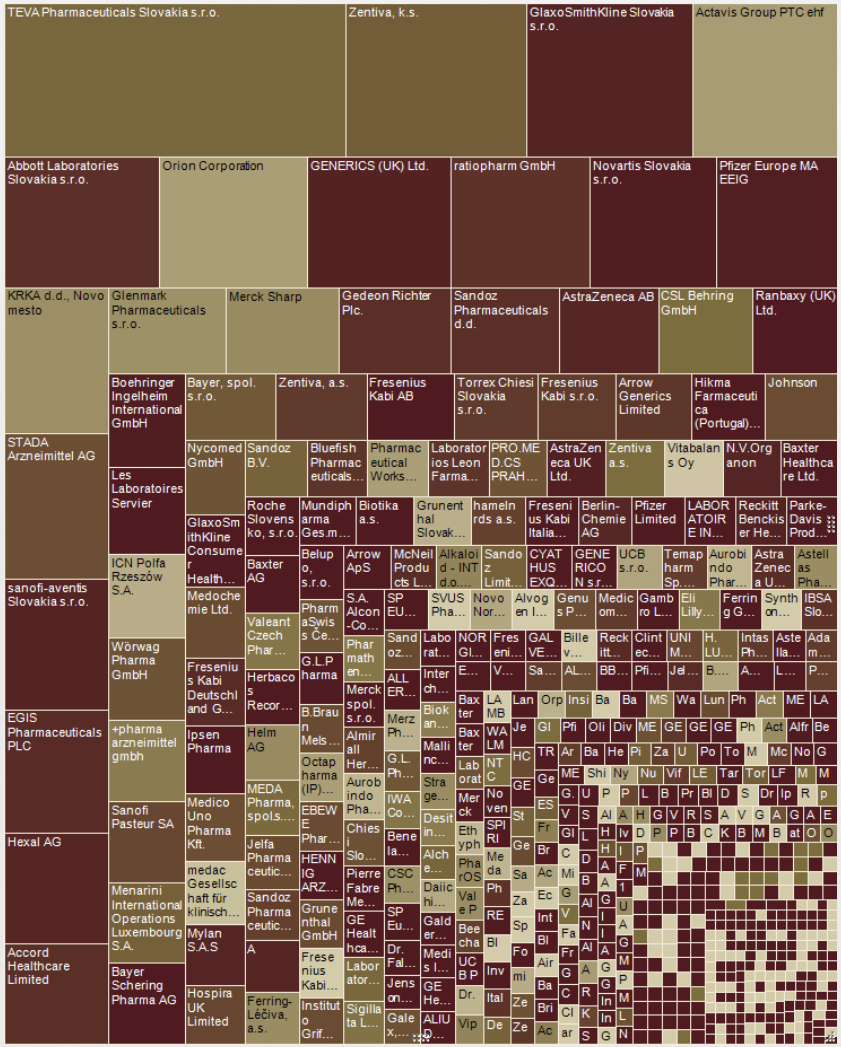
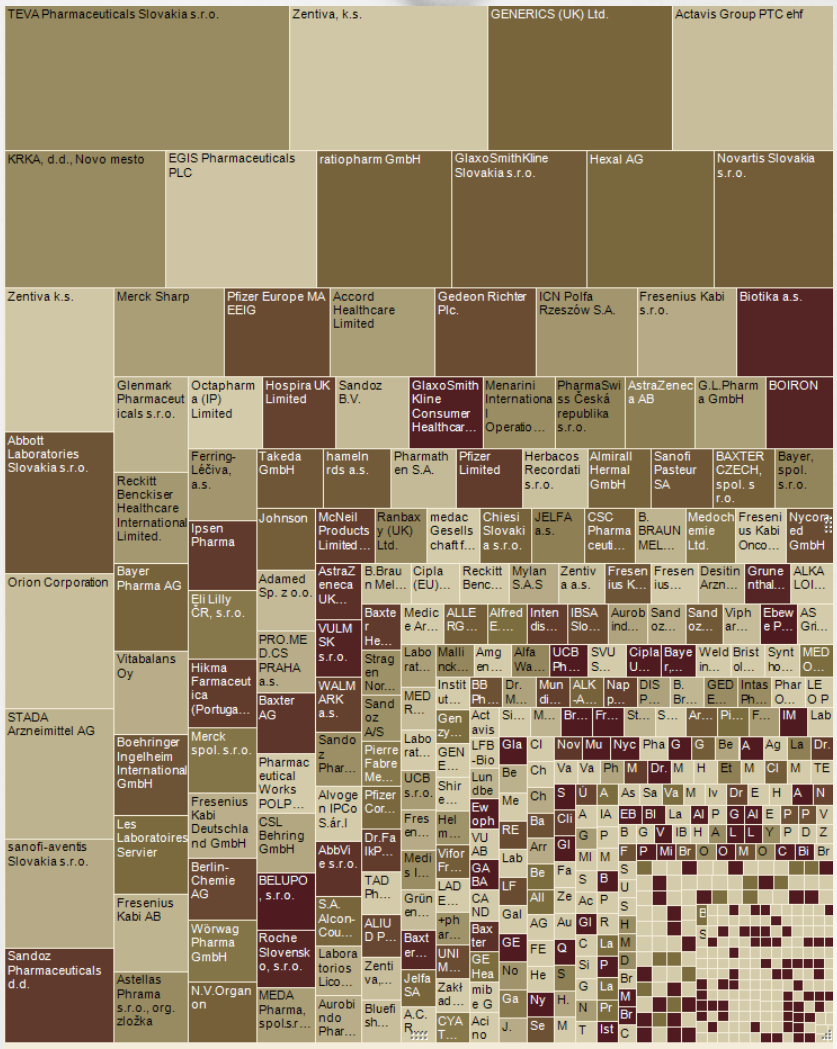
Number of total submissions vs eCTD format - by MAH

2011

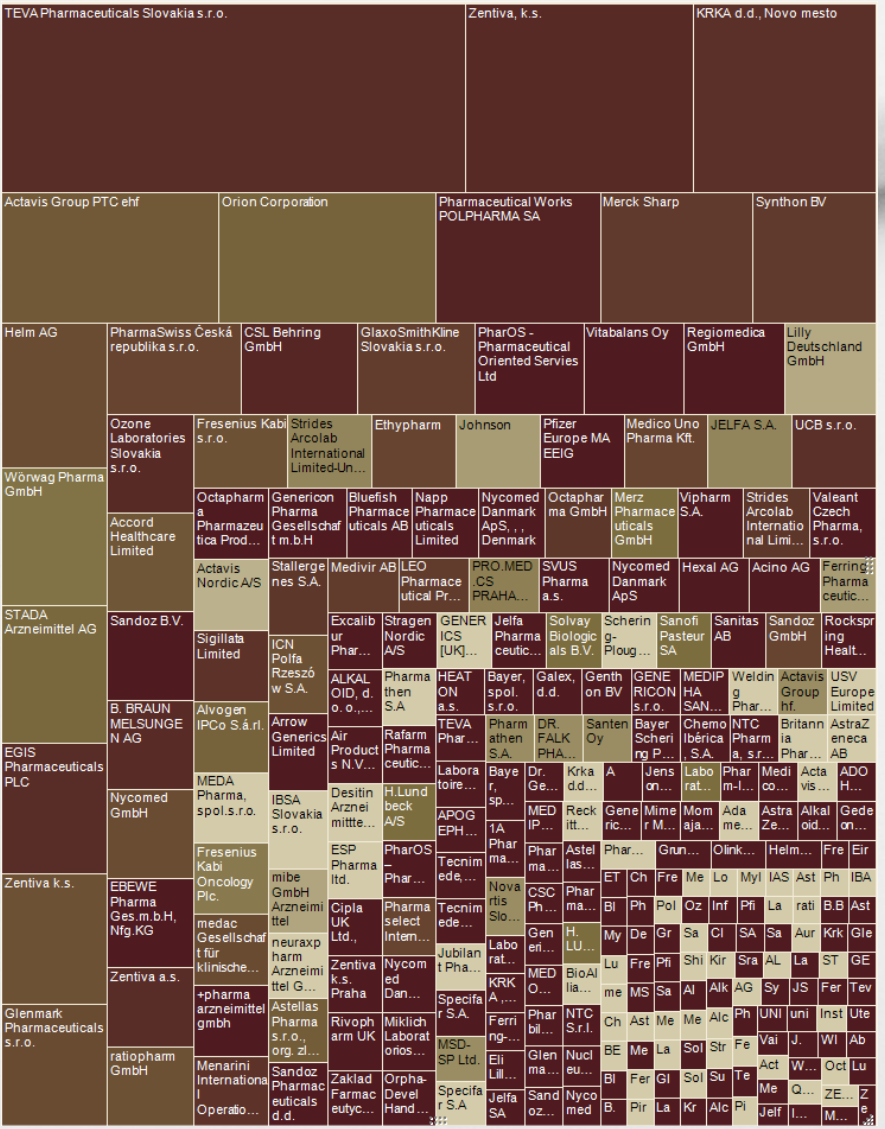


2013

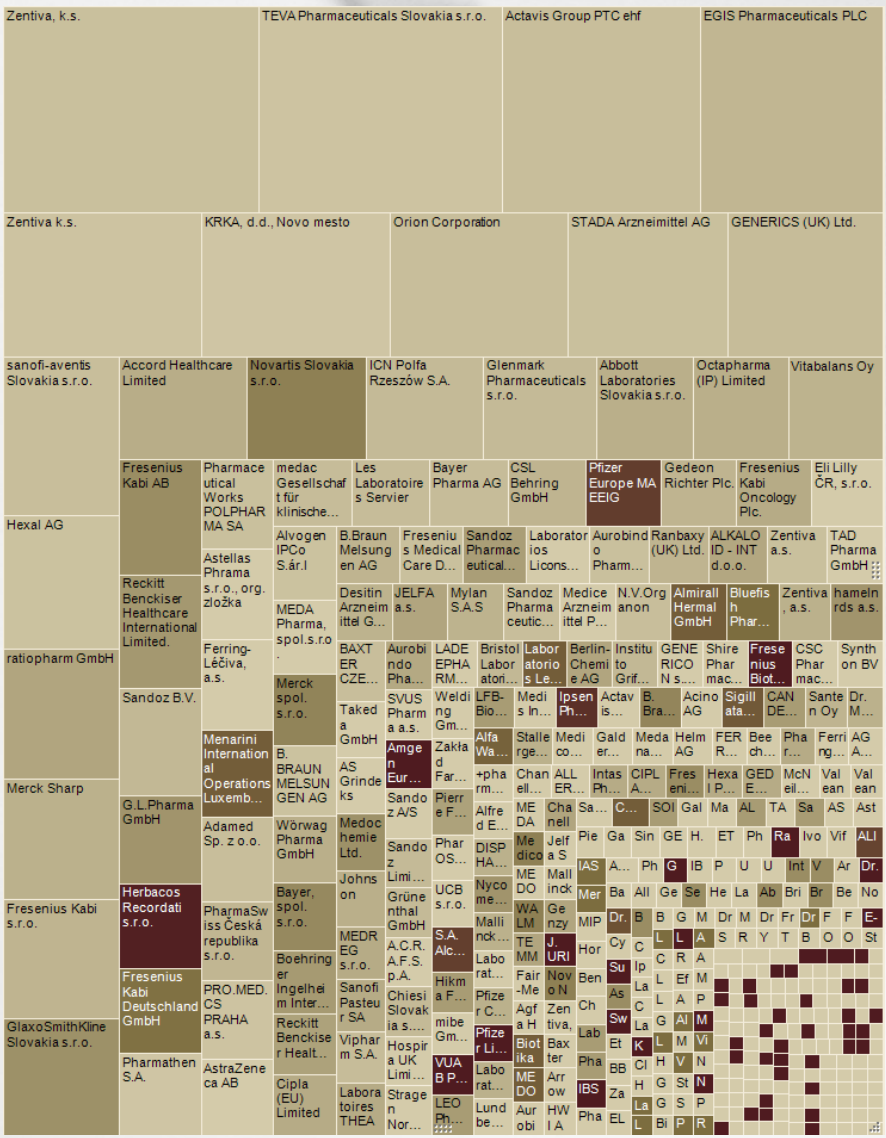


Number of eCTD dossiers vs number of valid eCTD by MAH

2010



2013



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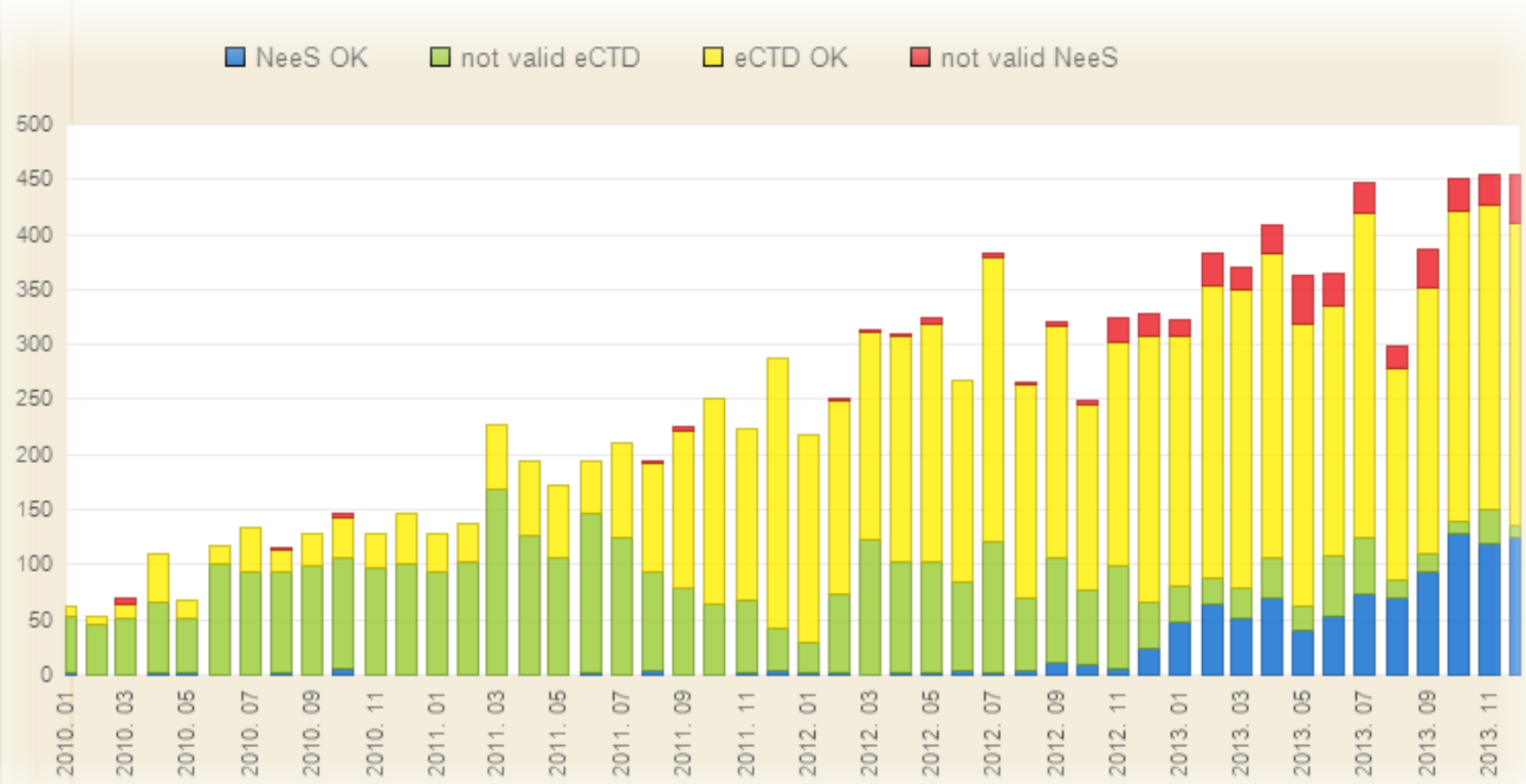
Improving of quality of eCTD/NeeS applications in timeframe

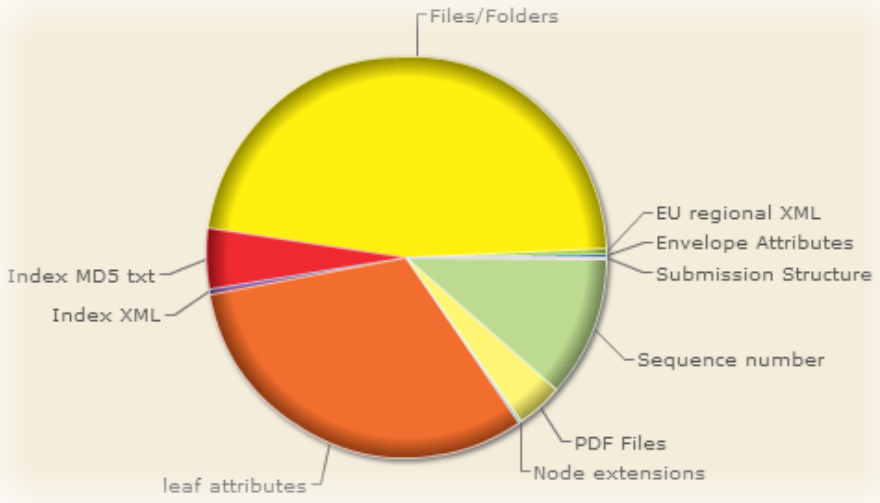
We have arranged two seminars in 2011, which have contributed to the increase of the quality and quantity of eCTD applications.

We started with uploading NeeS format in 2013. This format is automatically converted to eCTD .

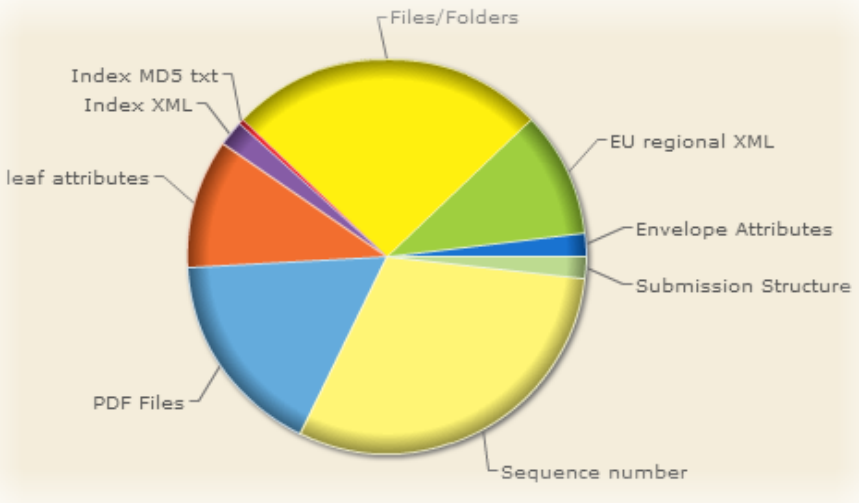


The most frequent errors in the eCTD dossiers based on validation protocol

2010



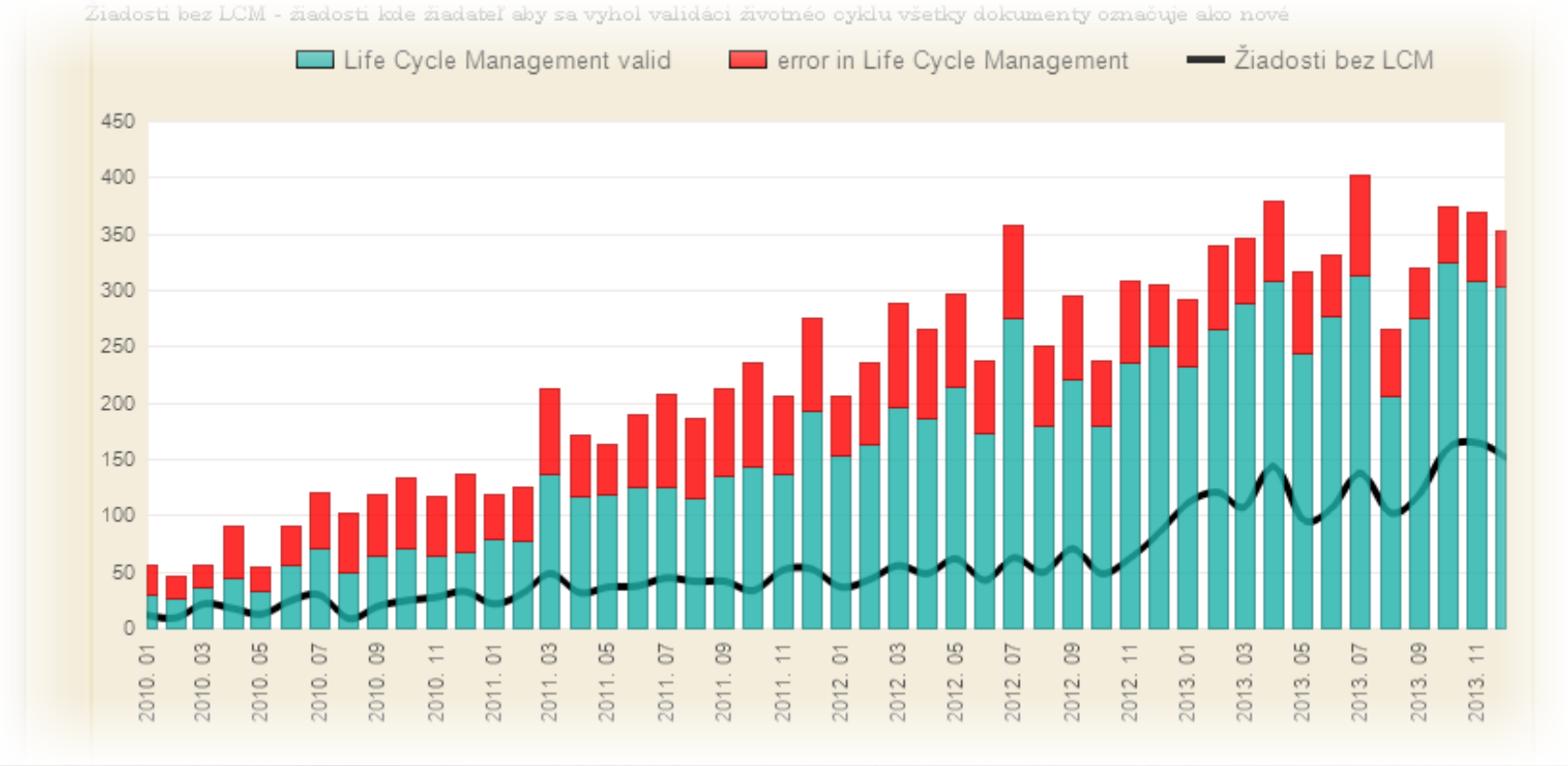
2013



POZOR – opakovane predložiť to isté číslo sekvencie ku žiadosti je možné len v prípade opravy technickej chyby, alebo poškodeného CD/DVD

Number of valid/invalid Life Cycle Management

Applicants have ceased with marking of validity of documents. Often are all documents marked as new, what complicates work with them.



Life Cycle Management valid – Medicinal product with min. two sequences and Life Cycle Management is valid
Error in Life Cycle Management – Sequence or document in sequence is missing or deleted
Applications without LCM – All documents in sequences are marked as **new**

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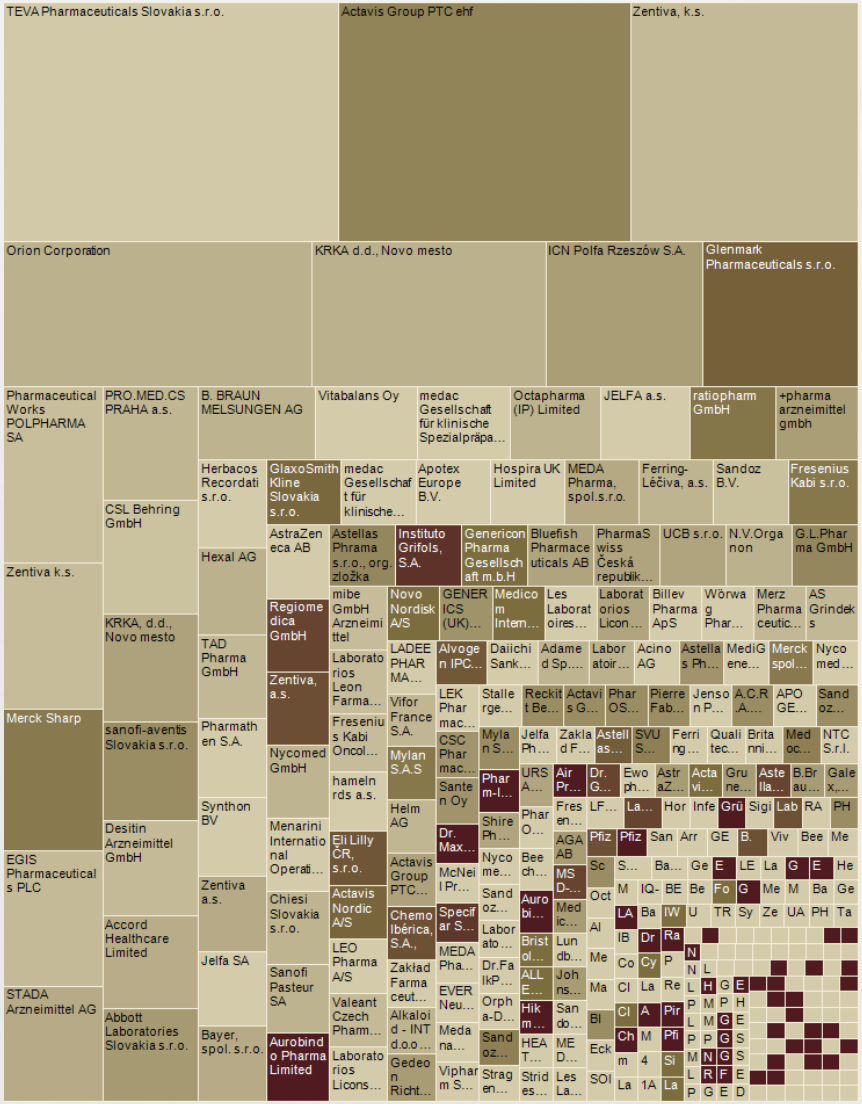
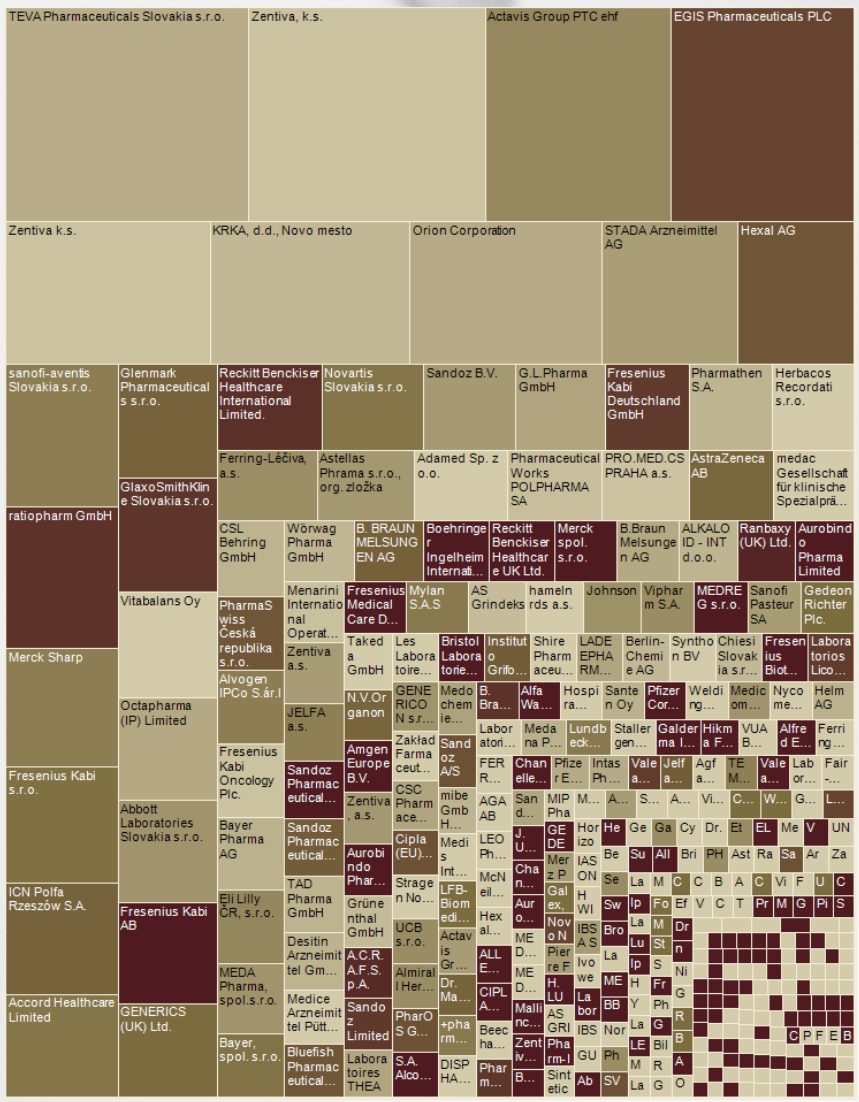
Number of valid eCTD vs invalid Life Cycle Management

2012



2013



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Future plans – communication and new option for MAH to follow the process

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FUTURE PLANS:

FUTURE PLAN

Transparency of processes - communication PTL vs Applicant - discusion
Objective: to follow procedure from MAH

Applicant can communicate with coordinator as now or could utilize new offered options:

- To see comments of coordinator in eCTD documentation
- To upload own comment to eCTD documentation
- To upload new working document to eCTD documentation
- To monitor status of application
- To monitor if the application waits for answer/feedback from applicant
- To monitor dates
- To see the valid version of document in dossier

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Ďakujem!

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Najčastejšie nedostatky s ktorými sa stretávame

- CD/DVD neobsahuje žiadne súbory
- súbory na CD/DVD sú vo formáte ZIP, RAR
- nie je dodržaná štruktúra zložky, ktorá obsahuje dokumentáciu
- pri oboch formátoch (NeeS, eCTD) pomocné súbory a dokumentácia v jednotlivých moduloch nie sú uložené v spoločnej zložke s názvom sekvencie
- názov zložky je nesprávny (nesprávne 0001 - 20mg)
- pri dokumentácii vo formáte NeeS chýba na CD/DVD súbor ctd-toc.pdf
- na CD/DVD sa nachádzajú aj sekvencie, ktoré už boli použité v predchádzajúcich podaniach (predkladať iba aktuálne sekvencie k danej žiadosti)
- pri dokumentácii vo formáte eCTD sú poškodené súbory XML (uvedenému problému sa dá predísť znížením rýchlosti pri napálení CD/DVD)
- CD/DVD sú predkladané na ŠÚKL bez povinného označenia a bez ochranného obalu