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e-taotlused

Triin Mäesalu
Kvaliteedi hindamise büroo
13.06.2012

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e-taotluste formaadid

- “muu formaat”
- NeeS = **Non-eCTD electronic Submission**
- eCTD = **electronic Common Technical Document**

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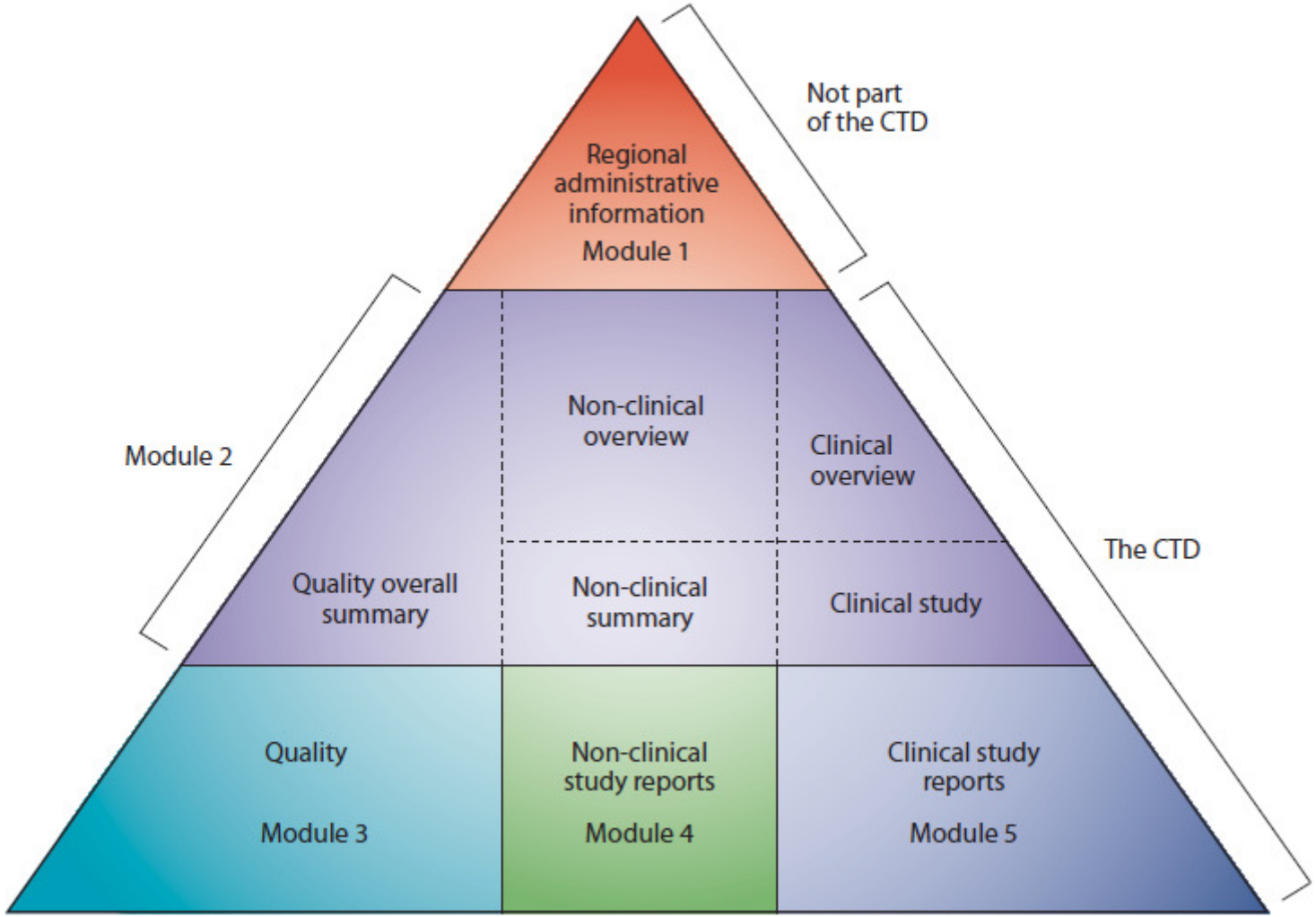
Common Technical Document



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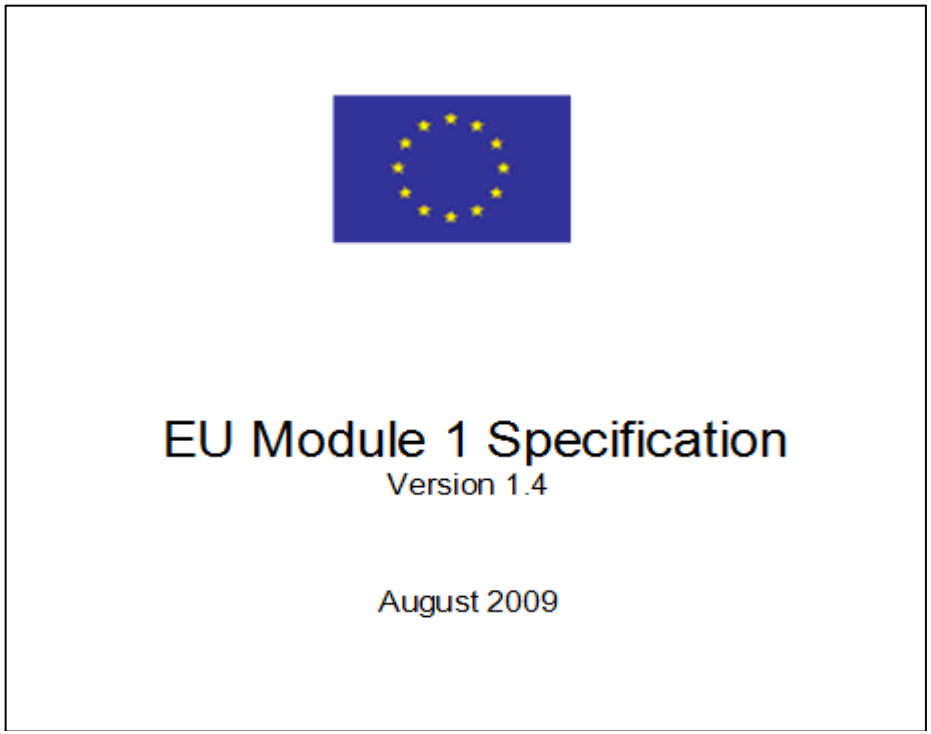
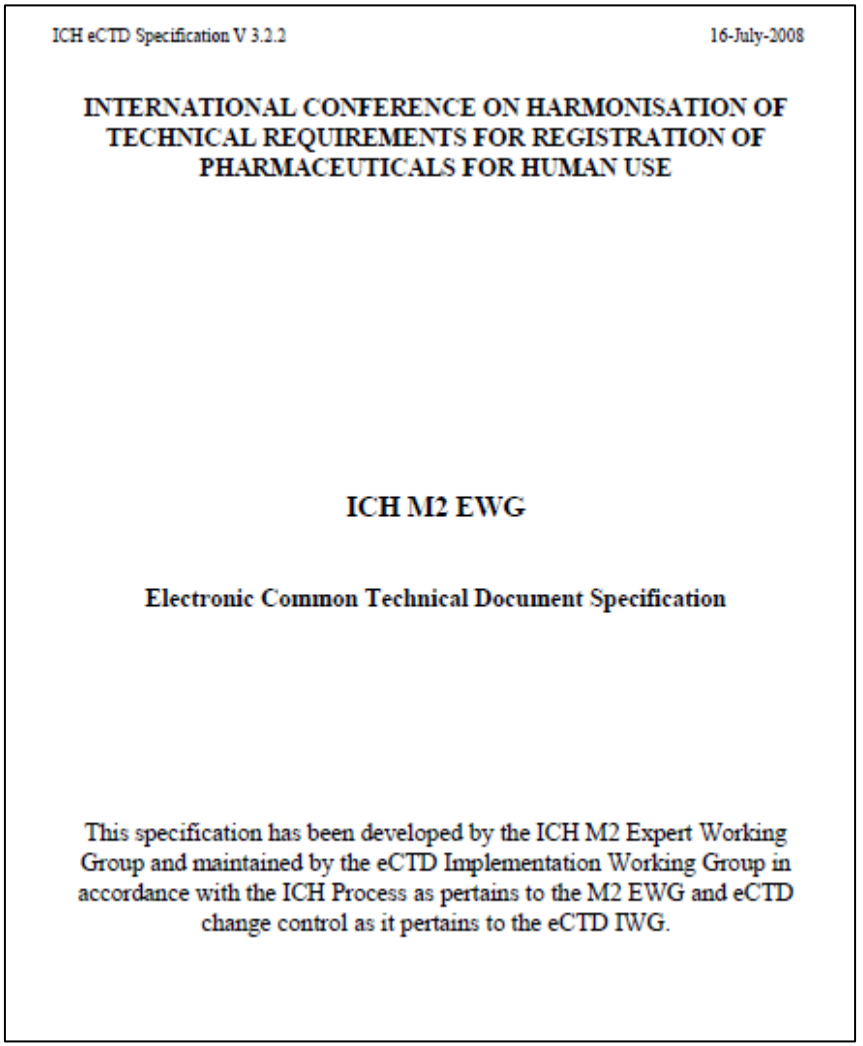
eCTD spetsifikatsioonid

- Moodulid 2-5: ICH eCTD version 3.2.2
- Moodul 1: M1 EU version 1.4



EU Module 1 Specification
Version 1.4

August 2009



ICH eCTD Specification V 3.2.2 16-July-2008

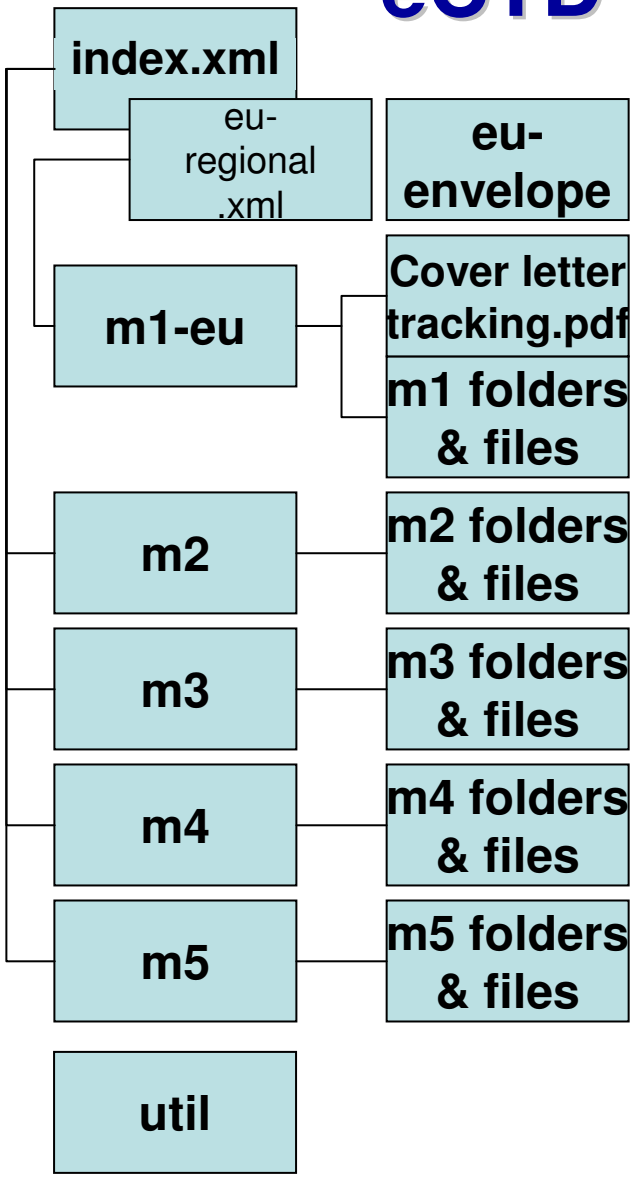
INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH M2 EWG

Electronic Common Technical Document Specification

This specification has been developed by the ICH M2 Expert Working Group and maintained by the eCTD Implementation Working Group in accordance with the ICH Process as pertains to the M2 EWG and eCTD change control as it pertains to the eCTD IWG.

eCTD



Väljaspool eCTD-d
working documents Word failid

NeeS

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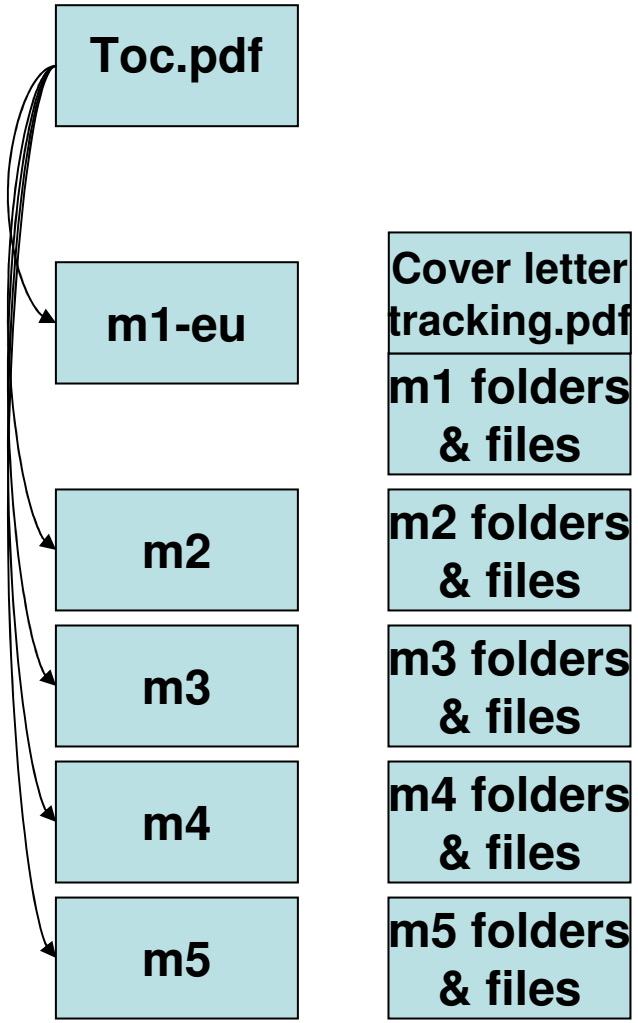

Väljaspool NeeS-i
working documents Word failid

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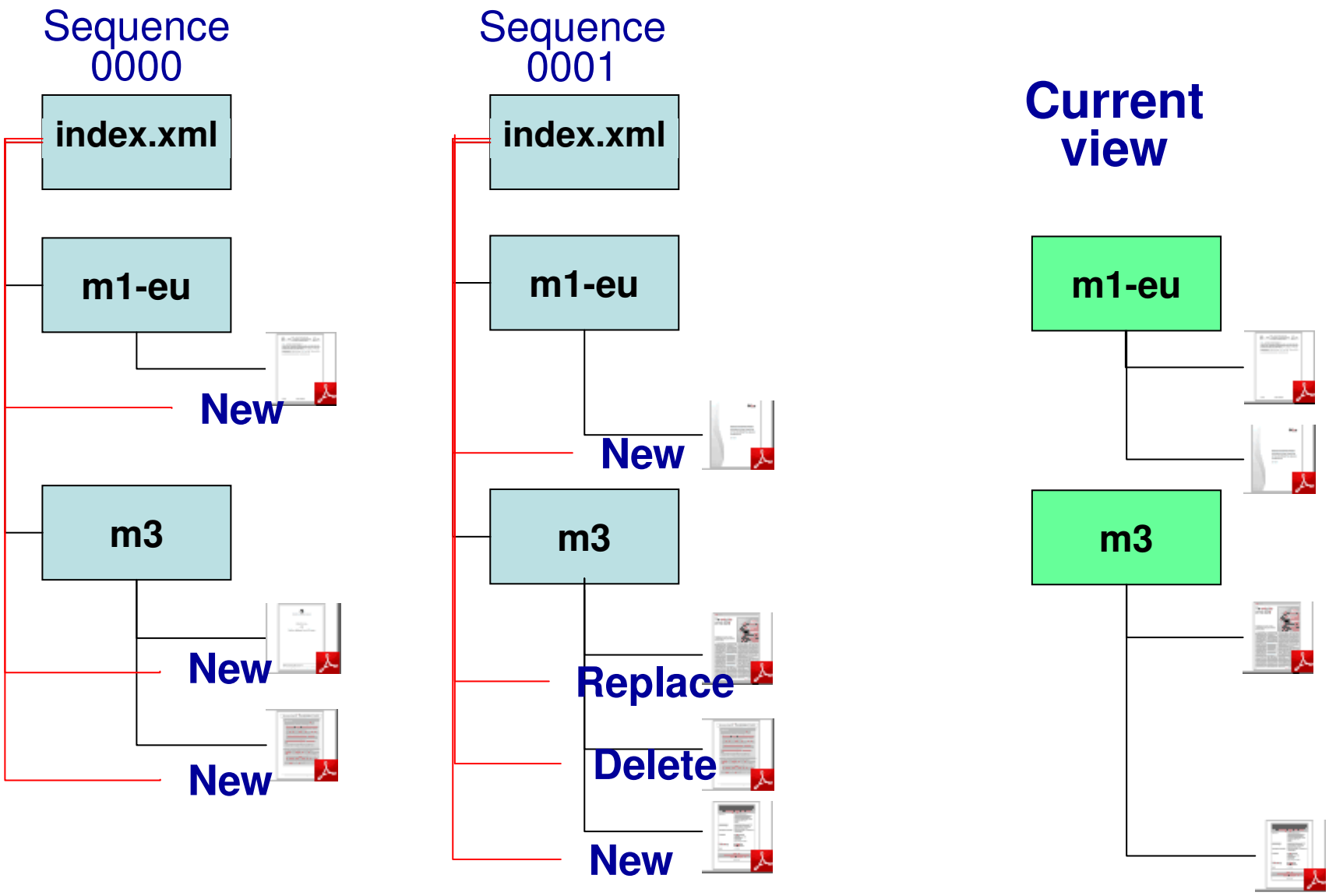
eCTD elutsükkel



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Valideerimiskriteeriumid

- TIGes: The **T**elematics **I**mplementation **G**roup for **e**lectronic **s**ubmission and ICH Implementation
- http://www.ema.europa.eu
- http://esubmission.ema.europa.eu/tiges/tigesdocuments.html
- eCTD v. 3.1 (NB! eCTD v. 4.0 alates 1.12.2012)
- NeeS v. 2.1
- Pass/Fail, Best Practice

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Validaatorid

- eCTD/NeeS
  http://www.extedo.com/support-downloads/eursvalidator-download/
- Meie: EURSvalidator 2.0.00 SP2 Build 11
- eCTD/NeeS
  http://www.lorenz.cc/Downloads.cfm

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Valideerimiskriteeriumid

- eCTD

15.BP2	Files/Folders	The recommended folder structure and folder names in the ICH and EU specifications are used	BP
15.BP3	Files/Folders	The recommended file names from the ICH and EU specifications are used for all files	BP

- NeeS

2.10	Files/folders	For Modules 1-5: The folder structure and names must follow the EU or ICH defined structure and names.	P/F
2.11	Files/folders	For Modules 1-3: The file names must follow the EU or ICH defined names.	P/F
2.BP3	Files/folders	For Modules 4 and 5: The file names should follow the ICH defined names.	BP

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Valideerimiskriteeriumid

eCTD/NeeS

15,6	Files/Folders	Only valid characters are used in file names	P/F	lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)
15,7	Files/Folders	Only valid characters are used in folder	P/F	lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD
2.8	Files/folders	Only valid characters are used in file names	P/F	lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)
2.9	Files/folders	Only valid characters are used in folder names	P/F	lower case characters a-z, digits 0-9 and hyphens are allowed (as documented in the ICH eCTD specification)

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Tehniline valideerimine

Sagedasemad vead (FAIL):

- Pdf versioon 1.3
- Failide/kaustade nimetused valed
- *Tracking table* puudub (MRP/DC)
- Index.xml viidatud dokument puudub
- NeeS: ctd-toc.pdf, mX-toc.pdf puuduvad
- Turvaseadistused
- Faili suurus üle 100 MB
- Tühjad kaustad

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Taotluse esitamine

- Moodul 1-5 elektrooniliselt, ainult taotluse vorm (tagasivõtmise kiri) originaalallkirjaga/digiallkirjastatult
- 1 CD/DVD
  - formaat (eCTD/NeeS)
  - Taotleja nimi
  - Ravimi nimi
  - Toimeaine nimi
  - MRP/DC number
  - eCTD/NeeS järjekorra (sequence) number
  - Taotluse liik (esmane, muutus, uuendamine)
- Eudralink (80 MB, zip)
- E-mail (zip)
  mrp@ravimiamet.ee,documentation@ravimiamet.ee

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Taotluse esitamine

- Eelistatult ühine eCTD/NeeS sama ravimi eri tugevuste, ravimvormide kohta (nt. EE/H/0162/001-004/DC)
- CMDh eCTD juhend http://www.hma.eu/277.html
- PDF täistekstiliselt otsitav: TIGes eCTD juhend v. 2.0, Annex 2
- Word failid (eestikeelsed infod) e-CTD/NeeS väliselt "working documents"
- Sisulise valideerimise vastused ja MRP/DC vastused esialgu pdf failid e-mailiga, hiljem eCTD.
- Esitada ainult muudetud dokumentatsiooni osad.
- Sama numbriga eCTD järgnevus ainult tehniliste vigade parandamisel, sisuline muutus → järgmine number.

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Formaadi muutus

- Paber → NeeS → eCTD
- Muutuse/ML uuendamise, ML laienduse taotluse esitamisel (mitte hindamisprotsessi ajal!)
- eCTD ~~→~~ NeeS ~~→~~ paber
- Kinnitus kaaskirjas http://www.hma.eu/219.html
- eCTD (re)start: baseline submission 0000

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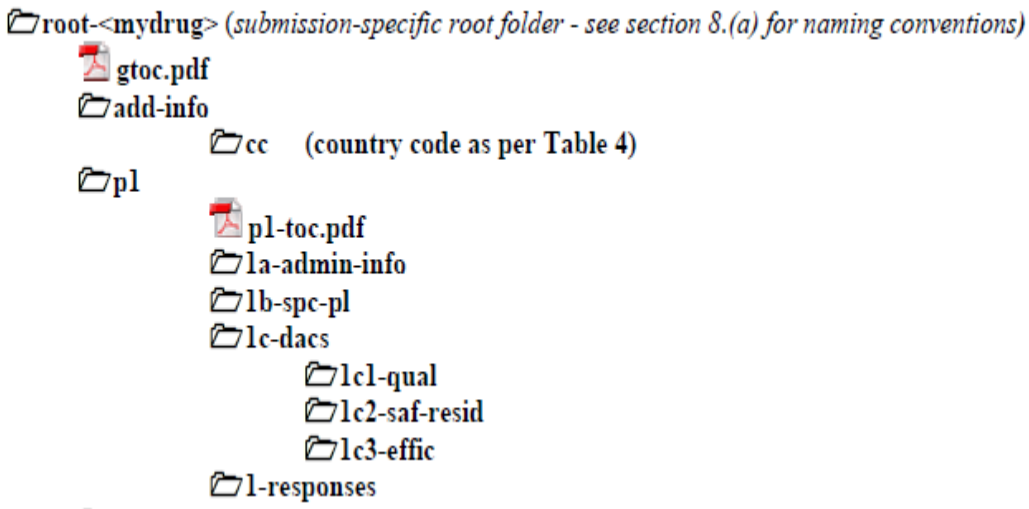
VNeeS

- NTA Volume 6B
- VET eSubmission
- VNeeS validation checklist
- Validaator: VNeeS Checker
- VNeeS põhikaust “root-mydrug”



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Muutuste e-taotlused

- Grupeeritud muutus ühe ML kohta: üks eCTD järgnevus, kaaskirjas ja taotluse vormis muutused loetletud.
- Mitu samal ajal esitatavat paralleelset muutust ühe ML kohta: soovitavalt samal CD/DVD-l, eraldi eCTD järgnevustes.
- Grupeeritud/WS muutus mitme ravimi kohta: eraldi eCTD järgnevustes, eraldi põhikaustades, sama CD/DVD. Sama kaaskiri ja taotluse vorm igas järgnevuses.

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Muutuste e-taotlused

- WS muutus mitme ravimi kohta eri formaadis (eCTD/NeeS): eraldi kaustades, sama CD/DVD.
- Tagasi lükatud/ võetud eCTD taotlus: parandav järgnevus (*consolidation sequence*). Kaaskiri ja *tracking table* jäetakse alles!

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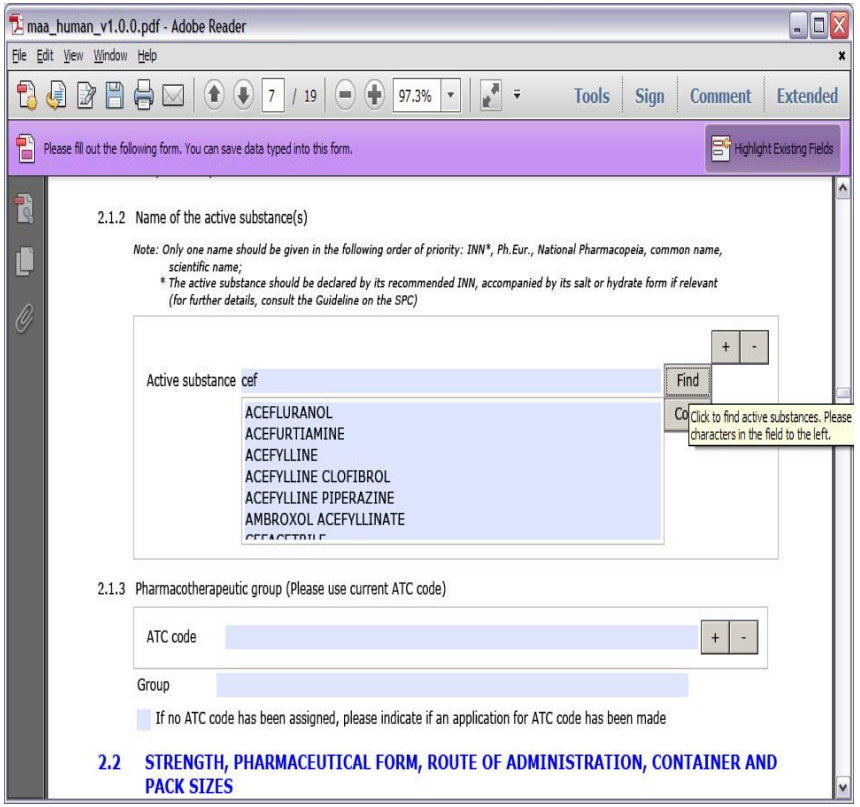
E-taotluse vorm

- Avaldatud: http://esubmission.emea.europa.eu/eaf/index.html
- XML/PDF
- EUTCT (European Union Telematics Controlled Terms), vabad tekstiväljad
- “Validate form” nupp



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RMS tehniline valideerimine

- CMDh juhend: Technical validation of eCTD submissions for new MAAs in DCP
- Pilootfaas alates 1.03.2012: eCTD formaadis esmased DC taotlused
- Taotlejatele vabatahtlik, kõik Euroopa ravimiametid osalevad
- Kaaskirjas märge: “Pilot for RMS technical validation is used”

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CESP

- Common European Submission Platform: http://cesp.hma.eu/
- Lihtne lahendus (sFTP client/Web)
- MRP, DC, riiklikud taotlused
- Inimravimid, veterinaarravimid
- Kõik elektroonilised formaadid
- Extended POC: Veebruar 2012
- 17 ravimiametit, ~170 kasutajat
- CESP + CD
- CD/ kaaskiri: “cesp_submission_99”
- Piloot: September 2012

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Tänan kuulamast!

Küsimused:
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