eCTD Lifecycle - Capture of Industry Issues & Proposals Relating to Policy 0070

FINAL – Webinar 23 Mar 2017

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EMA Policy 70: Current Guidance Review

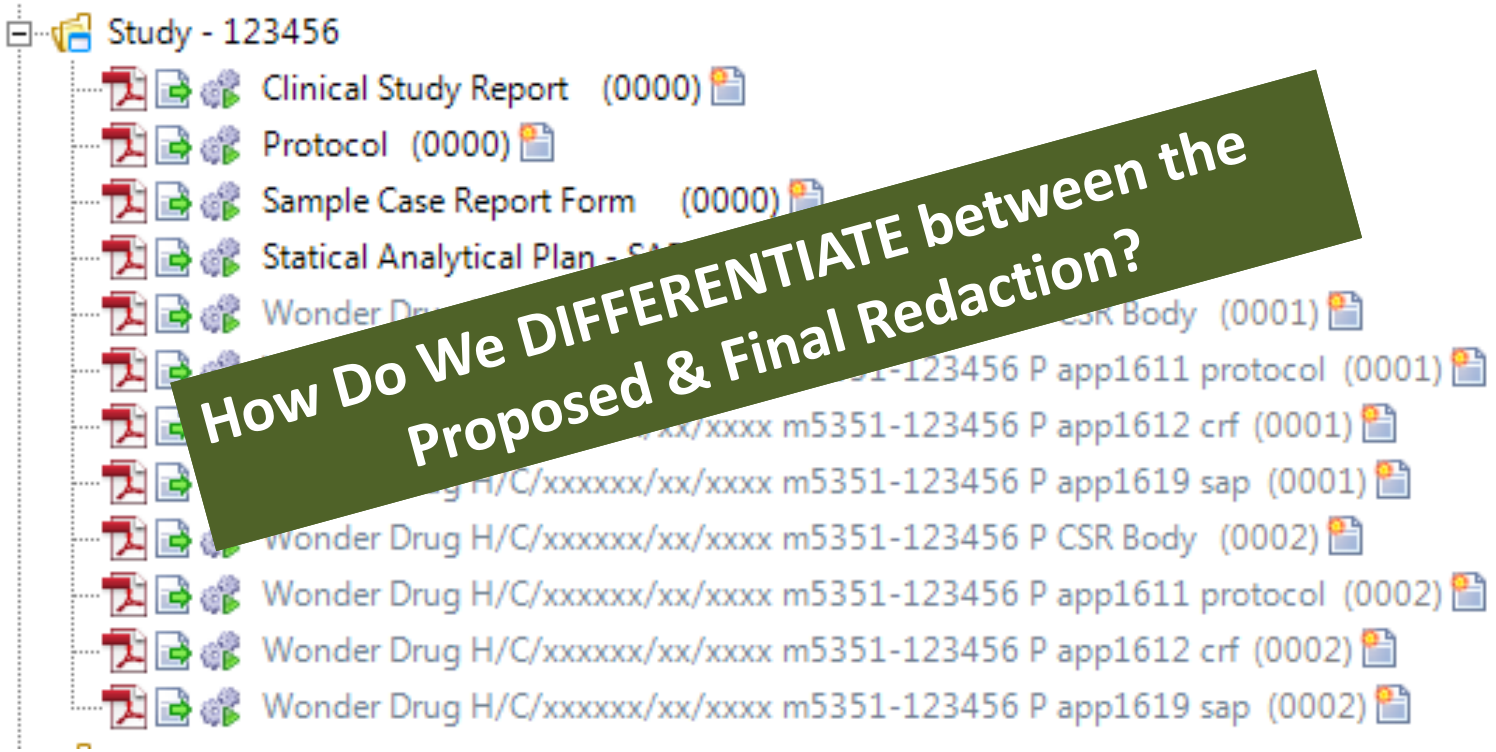
Operational Areas of Concern

- **Leaf Naming conventions:**
  - All eCTD content is ‘new’
  - Redaction proposals and final redactions have exactly the same file names and eCTD Leaf Titles

- **Structural Organisation:**
  - Effective organisation of the Module 5 section of an eCTD in the EU is managed using ‘Node Extensions’, but these are not mentioned in the guidance

What might an eCTD Lifecycle Look like?

eCTD LCM Example Case: Based on current Understanding of the Guidance



How Do We DIFFERENTIATE between the Proposed & Final Redaction?

0000 – initial. 0001 – redaction proposals, 0002 – final redactions

Based on current Understanding of the Guidance

Benefits/drawbacks

+ Aligns with current guidance release from EMA

– Difficult to distinguish between ‘Proposed’ & ‘Final’ redacted files
– Increases varied lifecycle options from applicants
– Confusing lifecycle presentation for internal MAH organisations, as well as for the Health Authority assessors reviewing future clinical data

Use of Node Extensions

Purpose/ Outcome: Enhanced file organisation to benefit review

EFPIA Proposal

- Two additional node extensions specifically for Policy 0070 submissions:

  Study xxxx- Redaction proposal

  Study xxxx - Final redaction

  - These node extensions should be named with the same study descriptor prefix as in the original MAA
  - They should preferably be nested within the original study (see next slide)

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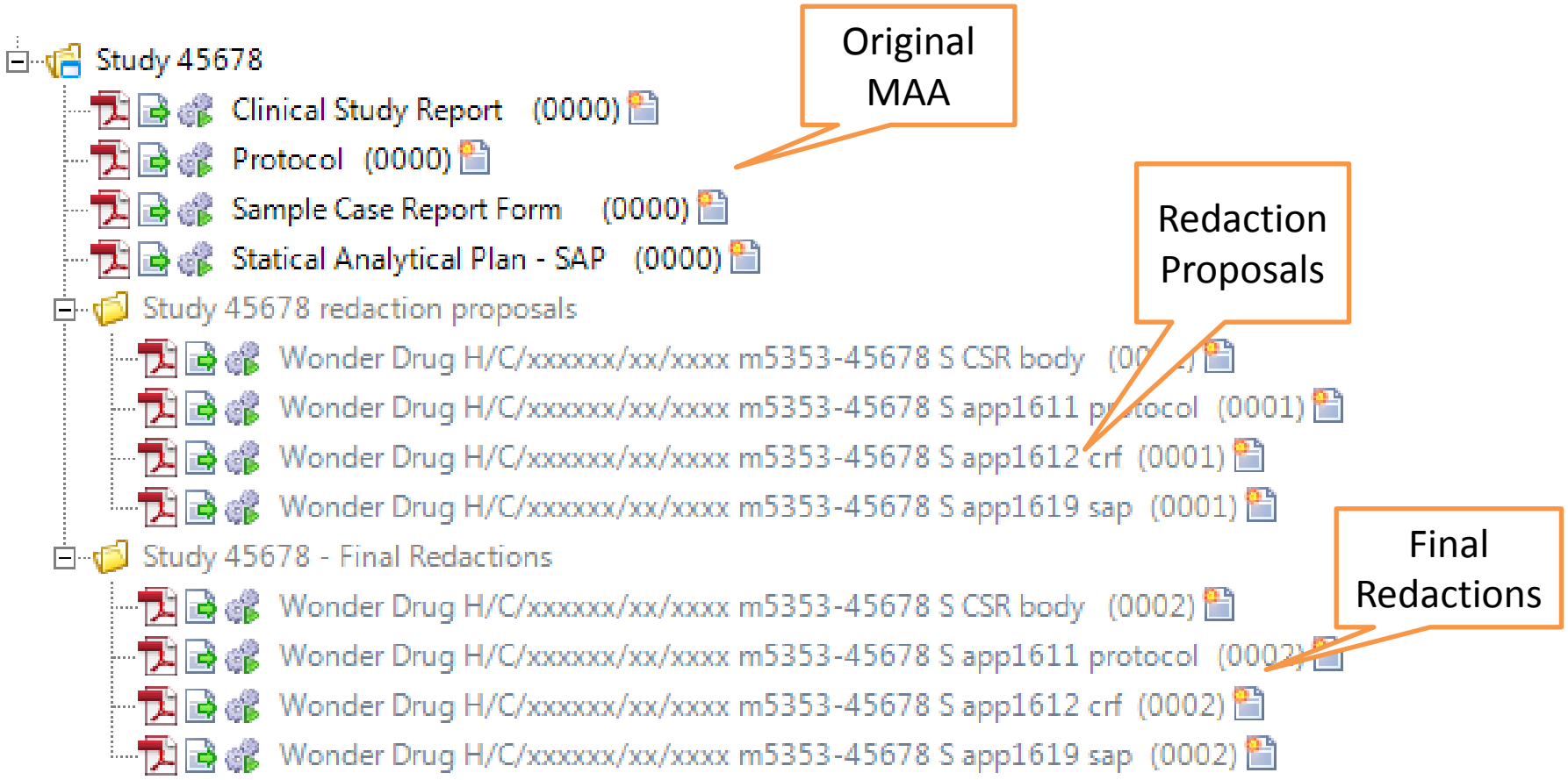
Preferred Option: Node Extensions 'Nested' for Proposed & Final



Node Extensions 'Nested' for Proposed & Final

Benefits/drawbacks

+ Low/zero impact to guidance
+ Proposals and final redactions clearly labelled in the eCTD without changing file names or leaf titles
+ Reduces varied lifecycle options from applicants
+ Improved visibility for internal MAH organisations, as well as for the Health Authority reviewers

- Nested node extensions may display differently in some viewing applications

Proposals

- EFPIA provide example and EMA test preferred option using EURS viewing tool

- Recommend that EMA publish ‘eCTD Lifecycle Best Practice’ for Policy 0070, as part of the current guidance

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Seeking Clarification Management of Redacted Proposals

P70 Redacted Proposals Clarifying use of Eudralink

3.3.2.1.3. Assessment of CCI stage

Following a successful validation, EMA will start the assessment of the justifications submitted by the applicant/MAH. During the assessment EMA will take into account the extent to which the company has followed/adhered to the principles regarding redaction of CCI as described in th guidance (Chapter 4) and as outlined in Annex 3 of Policy 0070. This assessm y to the content of the reasoning/justification behind why particular inform e applicant/MAH. Initially EMA will review the ju re elaborate justifications are needed, the com sted, EMA will clearly indicate the inst /MAH via Eudralink. A ack to EMA via Eudralink within 5-7 c the applicant/MAH fails to submit the requeste justifications irrelevant or insufficient and consequently A maximum of one round of consultation is permitted, which includes idence/exchanges between the applicant/MAH and EMA.

Do the EMA expect to ONLY see 2 sets of redacted studies in the Lifecycle?

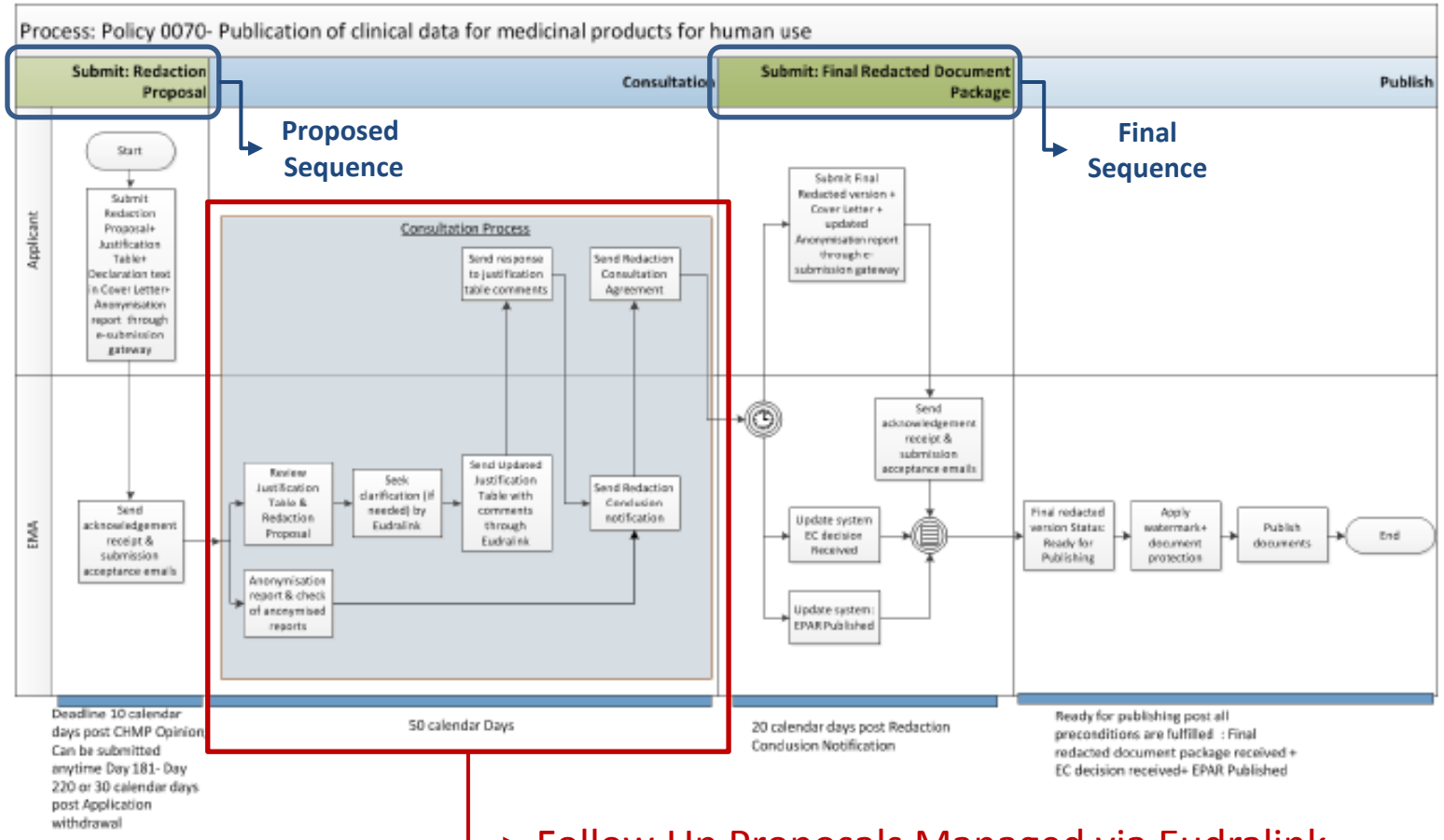
Proposed & FINAL?

At the end of th assessment phase, EMA will inform the applicant/MAH of its conclusion for the entire set of the submitted clinical reports. The outcome of the assessment (rejection, acceptance, or partial rejection of the proposed CCI redactions) will be clearly communicated and documented in the appropriate columns of the justification tables.

The applicant/MAH then carries out the redactions using its redaction tool to create the Final Redacted version of each clinical report.

P70 Operational End to End Workflow

1.9. Workflow for the submission of clinical reports for publication



Follow Up Proposals Managed via Eudralink

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