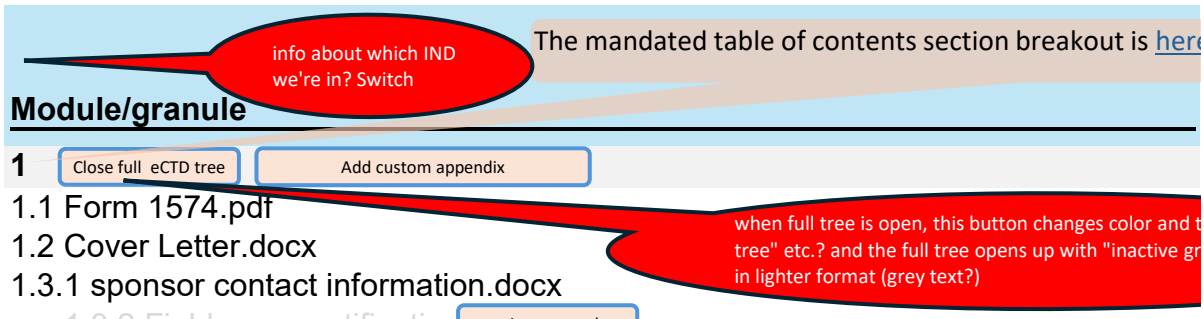

1.1 Form 1574.pdf
1.2 Cover Letter.docx
1.3.1 sponsor contact information.docx
1.3.2 Field copy certification activate granule
1.3.3 Debarment certificatio activate granule
1.3.4 Financial certification and disclos activate granule
1.3.5 Patent and exclusivity activate granule
1.12.1.4 Roadmap of Responses from pre-IND meeting.docx
1.12.13 Request for waiver of in vivo studies.docx
1.12.14 Request for categorical exclusion of environmental assessment.docx
1.14.4.2 Investigational drug labeling.docx
1.20 Introduction and General Investigational Plan.docx
LMN-201 Investigator Brochure V2.0.docx

2 Open full eCTD tree Add custom appendix

2.2 Overview.docx
2.3 Quality Overall Summary.docx
2.4 Nonclinical Overview.docx
2.5 Clinical Overview.docx
2.6.1 Introduction.docx
2.6.2 Pharmacology Written Summary.docx
2.6.3 Pharmacology tabulated summary.docx
2.6.4 Pharmacokinetics written summary.docx
2.6.5 Pharmacokinetics tabulated summary.docx
2.6.6 Toxicology written summary.docx
2.6.7 Toxicology tabulated summary.docx
2.7.1 Summary of current studies.docx

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– other?

3.2.A Open full eCTD tree Add custom appendix

3.2.A.1 Facilities and equipment (Lumen Bioscience).pdf
3.2.A.2 Adventitious agents safety evaluation (LMN-201, capsules, Lumen).pdf
3.2.A.3 Novel Excipients (LMN-201, Lumen).pdf

3.2.P Open full eCTD tree Add custom appendix

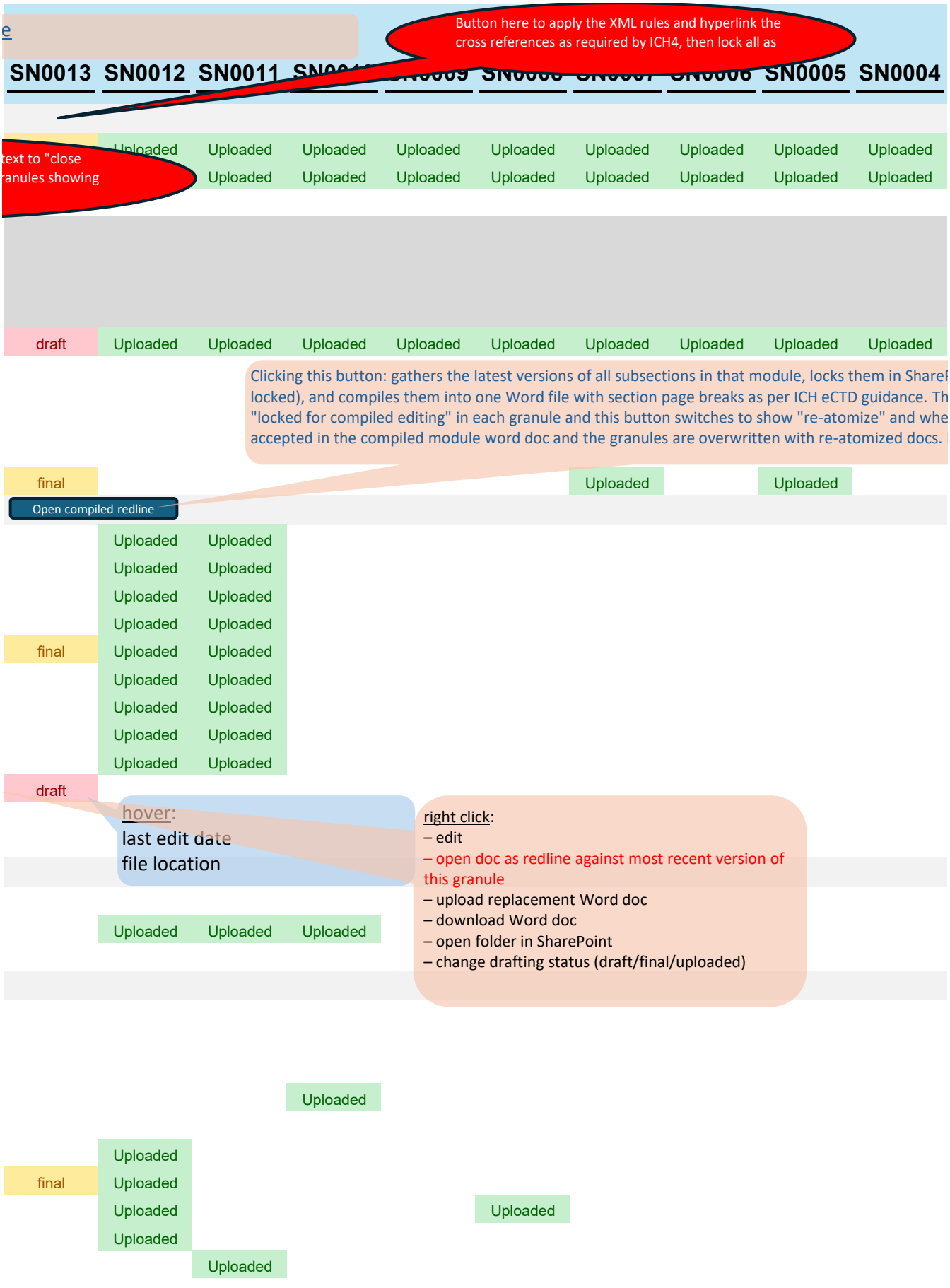
3.2.P.1 Description and composition (LMN-201, capsules).docx
3.2.P.1 Description and composition of the drug product (placebo, capsules).pdf
3.2.P.2 Pharmaceutical development (placebo, capsules).pdf
3.2.P.2.1 Components of the Drug Product.docx
3.2.P.2.2 Drug product (placebo, capsules).pdf
3.2.P.2.2 Drug Product.docx
3.2.P.2.3 Manufacturing process development (placebo, capsules).pdf
3.2.P.2.3 Manufacturing process development.docx
3.2.P.2.4 Container closure system (placebo, capsules).pdf
3.2.P.2.4 Container closure system.docx

3.2.P.2.5 Microbiological attributes (placebo, capsules).pdf
3.2.P.2.5 Microbiological attributes.docx
3.2.P.2.6 Compatibility (placebo, capsules).pdf
3.2.P.2.6 Compatibility.docx
3.2.P.3.1 Manufacturers (placebo, capsules).pdf
3.2.P.3.1 Manufacturers.docx
3.2.P.3.2 Batch formula (placebo, capsules).pdf
3.2.P.3.2 Batch formula.docx
3.2.P.3.3 Description of manufacturing process and process controls (placebo, caps
3.2.P.3.3 Description of manufacturing process and process controls.docx
3.2.P.3.4 Control of critical steps and intermediates (placebo, capsules).pdf
3.2.P.3.4 Control of critical steps and intermediates.docx
3.2.P.3.5 Process validation and or evaluation (placebo, capsules).pdf
3.2.P.3.5 Process validation and or evaluation.docx
3.2.P.4 Control of excipients (LMN-201, capsules).docx
3.2.P.4 Control of excipients (placebo, capsules).pdf
3.2.P.5.1 Specifications (placebo, capsules).pdf
3.2.P.5.1 Specifications 29OCT21.docx
3.2.P.5.1 Specifications.docx
3.2.P.5.2 Analytical procedures (placebo, capsules).pdf
3.2.P.5.2 Analytical procedures.docx
3.2.P.5.3 Validation of analytical procedures (placebo, capsules).pdf
3.2.P.5.3 Validation of analytical procedures.docx
3.2.P.5.4 Batch analyses (placebo, capsules)_26OCT21.docx
3.2.P.5.4 Batch analyses (placebo, capsules).pdf
3.2.P.5.4 Batch analyses.docx
3.2.P.5.5 Characterization of impurities (placebo, capsules).pdf
3.2.P.5.5 Characterization of impurities.docx
3.2.P.5.6 Justification of specifications 29OCT21.docx
3.2.P.5.6 Justification of specifications.docx
3.2.P.6 Reference Standard.docx
3.2.P.6 Reference standards or materials (placebo, capsules).pdf
3.2.P.7 Container closure system (LMN-201, capsules).pdf
3.2.P.7 Container closure system (placebo, capsules).pdf
3.2.P.8.1 Stability summary and conclusion (placebo, capsules).pdf
3.2.P.8.1 Stability summary and conclusion.docx
3.2.P.8.3 Stability data (LMN-201, capsules).docx
3.2.P.8.3 Stability data (placebo, capsules).pdf

3.2.S Open full eCTD tree | Add custom appendix

3.2.S.1 General Information (SP1308 SP1312 SP1313 SP1287, Lumen Bioscience)
3.2.S.2.1 Manufacturer.docx
3.2.S.2.2 Description of manufacturing process and process controls.docx
3.2.S.2.3 Control of materials (SP1308 SP1312 SP1313 SP1287, Lumen Bioscience
3.2.S.2.4 Control of critical steps and intermediates.docx
3.2.S.2.5 Process validation and or evaluation.docx
3.2.S.3.1 Elucidation of structure and other characteristics.docx

3.2.S.3.2 Impurities.docx
3.2.S.4.1 Specification.docx
3.2.S.4.2 Analytical procedures.docx
3.2.S.4.4 Batch analyses.docx
3.2.S.4.5 Justification of specification.docx
3.2.S.5 Reference standards or materials (SP1308 SP1312 SP1313 SP1287, Lume
3.2.S.6 Container closure system (SP1308 SP1312 SP1313 SP1287, Lumen Biosci
3.2.S.7.1 Stability summary and conclusions.docx
3.2.S.7.3 Stability data (SP1308 SP1312 SP1313 SP1287, Lumen Bioscience).docx
Appendix 3.2.S.4.2 AM-001 Lysin Turbidity Reduction Assay Rev. 001.pdf
Appendix 3.2.S.4.2 AM-002 Enzyme Linked Immunosorbent Assay Rev. 001.pdf
Appendix 3.2.S.4.2 AM-003 Jess Simple Western Assay Rev.1.pdf
Appendix 3.2.S.4.2 AM-004 BCA Protein Concentration Determination Rev.1.pdf
Appendix 3.2.S.4.4 LMN-201 Product Information_CofA.pdf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locked), and compiles them into one Word file with section page breaks as per ICH eCTD guidance. Th
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v1.2 concepts: roles, access co
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Possible?

how to store and

in templates, ICH "instructions" for each item show in bubble comments—maybe in v1.2 these can be served up in the right-click menu for easy access?

Need a button to create a document that is not in the ICH guidance — common for M3 in particular

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Table 1. Module 2 (paper and eCTD v3.2.2 submissions)

Module 2	2.1	The TOC is only called for in the paper version of the CTD; there is no entry needed for the eCTD	
	2.2		
	2.3 Note 1	Introduction	
		2.3.S Note 2	2.3.S.1
			2.3.S.2
			2.3.S.3
			2.3.S.4
			2.3.S.5
			2.3.S.6
			2.3.S.7
		2.3.P Note 3	2.3.P.1
			2.3.P.2
			2.3.P.3
			2.3.P.4
			2.3.P.5
			2.3.P.6
			2.3.P.7
			2.3.P.8
		2.3.A	2.3.A.1
			2.3.A.2
			2.3.A.3
		2.3.R	
	2.4		
	2.5		
	2.6	2.6.1	
		2.6.2	
		2.6.3	
		2.6.4	
		2.6.5	
		2.6.6	
		2.6.7	
	2.7	2.7.1	
		2.7.2	
		2.7.3 Note 4	
		2.7.4	
		2.7.5	
		2.7.6	

ICH guideline M4 (R4) on common technical document (CTD) for the registration of pharmaceuticals for human use - organisation of CTD
EMA/CPMP/ICH/2887/1999

Feature creep:
— regulatory comments tracker?
  – somehow tag to different underlying granules?
  – track responses over time
  – separately library to track underlying documents
— how about a tracker for assay qualification and validation?
— Multi-jurisdiction tracking
  – different module 1 by country
  – how to track currency of lower modules — GUIDs?
  – possibility to redline consolidated modules against its counterpart currently in e
country?
— AI library of prior INDs and prior FDA comments and published guidance from ICH
— push a button to get AI compliance report?
— table formatting ribbon custom tools in MSFT Word


ffect in another
and FDA etc.