

	Element	m4-2-2-6-pharmacokinetic-drug-interactions
	File	m4/42-stud-rep/422-pk/4226-pk-drug-interact/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
180	Element	m4-2-2-6-pharmacokinetic-drug-interactions
	File	m4/42-stud-rep/422-pk/4226-pk-drug-interact/study-report-3.pdf
	Comment	
	Number	4.2.2.7
	Title	Other Pharmacokinetic Studies
181	Element	m4-2-2-7-other-pharmacokinetic-studies
	Directory	m4/42-stud-rep/422-pk/4227-other-pk-stud
	Comment	
	Number	
	Title	Study Report 1
182	Element	m4-2-2-7-other-pharmacokinetic-studies
	File	m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
183	Element	m4-2-2-7-other-pharmacokinetic-studies
	File	m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
184	Element	m4-2-2-7-other-pharmacokinetic-studies
	File	m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-3.pdf
	Comment	
	Number	4.2.3
	Title	Toxicology
185	Element	m4-2-3-toxicology
	Directory	m4/42-stud-rep/423-tox
	Comment	

	Number	4.2.3.1
	Title	Single-Dose Toxicity (in order by species, by route)
186	Element	m4-2-3-1-single-dose-toxicity
	Directory	m4/42-stud-rep/423-tox/4231-single-dose-tox
	Comment	
	Number	
	Title	<i>Study Report 1</i>
187	Element	m4-2-3-1-single-dose-toxicity
	File	m4/42-stud-rep/423-tox/4231-single-dose-tox/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
188	Element	m4-2-3-1-single-dose-toxicity
	File	m4/42-stud-rep/423-tox/4231-single-dose-tox/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
189	Element	m4-2-3-1-single-dose-toxicity
	File	m4/42-stud-rep/423-tox/4231-single-dose-tox/study-report-3.pdf
	Comment	
	Number	4.2.3.2
	Title	Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)
190	Element	m4-2-3-2-repeat-dose-toxicity
	Directory	m4/42-stud-rep/423-tox/4232-repeat-dose-tox
	Comment	
	Number	
	Title	<i>Study Report 1</i>
191	Element	m4-2-3-2-repeat-dose-toxicity
	File	m4/42-stud-rep/423-tox/4232-repeat-dose-tox/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
192	Element	m4-2-3-2-repeat-dose-toxicity

	File	m4/42-stud-rep/423-tox/4232-repeat-dose-tox/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
193	Element	m4-2-3-2-repeat-dose-toxicity
	File	m4/42-stud-rep/423-tox/4232-repeat-dose-tox/study-report-3.pdf
	Comment	
	Number	4.2.3.3
	Title	Genotoxicity
194	Element	m4-2-3-3-genotoxicity
	Directory	m4/42-stud-rep/423-tox/4233-genotox
	Comment	
	Number	4.2.3.3.1
	Title	In vitro
195	Element	m4-2-3-3-1-in-vitro
	Directory	m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro
	Comment	
	Number	
	Title	<i>Study Report 1</i>
196	Element	m4-2-3-3-1-in-vitro
	File	m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
197	Element	m4-2-3-3-1-in-vitro
	File	m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
198	Element	m4-2-3-3-1-in-vitro
	File	m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/study-report-3.pdf
	Comment	
199	Number	4.2.3.3.2

	Title	In vivo (including supportive toxicokinetics evaluations)
	Element	m4-2-3-3-2-in-vivo
	Directory	m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo
	Comment	
	Number	
	Title	<i>Study Report 1</i>
200	Element	m4-2-3-3-2-in-vivo
	File	m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/ <i>study-report-1.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 2</i>
201	Element	m4-2-3-3-2-in-vivo
	File	m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/ <i>study-report-2.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 3</i>
202	Element	m4-2-3-3-2-in-vivo
	File	m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/ <i>study-report-3.pdf</i>
	Comment	
	Number	4.2.3.4
	Title	Carcinogenicity (including supportive toxicokinetics evaluations)
203	Element	m4-2-3-4-carcinogenicity
	Directory	m4/42-stud-rep/423-tox/4234-carcigen
	Comment	
	Number	4.2.3.4.1
	Title	Long-term studies (in order by species, including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics)
204	Element	m4-2-3-4-1-long-term-studies
	Directory	m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud
	Comment	
	Number	
	Title	<i>Study Report 1</i>
205	Element	m4-2-3-4-1-long-term-studies

	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
206	Element	m4-2-3-4-1-long-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
207	Element	m4-2-3-4-1-long-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-3.pdf
	Comment	
	Number	4.2.3.4.2
	Title	Short- or medium-term studies (including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics)
208	Element	m4-2-3-4-2-short-or-medium-term-studies
	Directory	m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud
	Comment	
	Number	
	Title	Study Report 1
209	Element	m4-2-3-4-2-short-or-medium-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
210	Element	m4-2-3-4-2-short-or-medium-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
211	Element	m4-2-3-4-2-short-or-medium-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-3.pdf
	Comment	

212	Number	4.2.3.4.3
	Title	Other studies
212	Element	m4-2-3-4-3-other-studies
	Directory	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud
	Comment	
	Number	
213	Title	<i>Study Report 1</i>
	Element	m4-2-3-4-3-other-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-1.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 2</i>
214	Element	m4-2-3-4-3-other-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-2.pdf</i>
	Comment	
	Number	
215	Title	<i>Study Report 3</i>
	Element	m4-2-3-4-3-other-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-3.pdf</i>
	Comment	
216	Number	4.2.3.5
	Title	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (if modified study designs are used, the following subheadings should be modified accordingly)
	Element	m4-2-3-5-reproductive-and-developmental-toxicity
	Directory	m4/42-stud-rep/423-tox/4235-repro-dev-tox
	Comment	
	Number	4.2.3.5.1
217	Title	Fertility and early embryonic development
	Element	m4-2-3-5-1-fertility-and-early-embryonic-development
	Directory	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev
	Comment	
218	Number	
	Title	<i>Study Report 1</i>

	Element	m4-2-3-5-1-fertility-and-early-embryonic-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
219	Element	m4-2-3-5-1-fertility-and-early-embryonic-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
220	Element	m4-2-3-5-1-fertility-and-early-embryonic-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-3.pdf
	Comment	
	Number	4.2.3.5.2
	Title	Embryo-fetal development
221	Element	m4-2-3-5-2-embryo-fetal-development
	Directory	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev
	Comment	
	Number	
	Title	Study Report 1
222	Element	m4-2-3-5-2-embryo-fetal-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
223	Element	m4-2-3-5-2-embryo-fetal-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
224	Element	m4-2-3-5-2-embryo-fetal-development
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-3.pdf
	Comment	

225	Number	4.2.3.5.3
	Title	Prenatal and postnatal development, including maternal function
	Element	m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function
	Directory	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev
	Comment	
	Number	
	Title	<i>Study Report 1</i>
226	Element	m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-1.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 2</i>
227	Element	m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-2.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 3</i>
228	Element	m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-3.pdf</i>
	Comment	
	Number	4.2.3.5.4
	Title	Studies in which the offspring (juvenile animals) are dosed and/or further evaluated
229	Element	m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated
	Directory	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv
	Comment	
	Number	
	Title	<i>Study Report 1</i>
230	Element	m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/ <i>study-report-1.pdf</i>
	Comment	
	Number	
	Title	<i>Study Report 2</i>
231	Element	m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated

	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
232	Element	m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated
	File	m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/study-report-3.pdf
	Comment	
	Number	4.2.3.6
	Title	Local Tolerance
233	Element	m4-2-3-6-local-tolerance
	Directory	m4/42-stud-rep/423-tox/4236-loc-tol
	Comment	
	Number	
	Title	Study Report 1
234	Element	m4-2-3-6-local-tolerance
	File	m4/42-stud-rep/423-tox/4236-loc-tol/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
235	Element	m4-2-3-6-local-tolerance
	File	m4/42-stud-rep/423-tox/4236-loc-tol/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
236	Element	m4-2-3-6-local-tolerance
	File	m4/42-stud-rep/423-tox/4236-loc-tol/study-report-3.pdf
	Comment	
	Number	4.2.3.7
	Title	Other Toxicity Studies (if available)
237	Element	m4-2-3-7-other-toxicity-studies
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud
	Comment	
238	Number	4.2.3.7.1

	Title	Antigenicity
	Element	m4-2-3-7-1-antigenicity
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen
	Comment	
	Number	
	Title	<i>Study Report 1</i>
239	Element	m4-2-3-7-1-antigenicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
240	Element	m4-2-3-7-1-antigenicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
241	Element	m4-2-3-7-1-antigenicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/study-report-3.pdf
	Comment	
	Number	4.2.3.7.2
	Title	Immunotoxicity
242	Element	m4-2-3-7-2-immunotoxicity
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox
	Comment	
	Number	
	Title	<i>Study Report 1</i>
243	Element	m4-2-3-7-2-immunotoxicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
244	Element	m4-2-3-7-2-immunotoxicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/study-report-2.pdf

	Comment	
	Number	
	Title	<i>Study Report 3</i>
245	Element	m4-2-3-7-2-immunotoxicity
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/study-report-3.pdf
	Comment	
	Number	4.2.3.7.3
	Title	Mechanistic studies (if not included elsewhere)
246	Element	m4-2-3-7-3-mechanistic-studies
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud
	Comment	
	Number	
	Title	<i>Study Report 1</i>
247	Element	m4-2-3-7-3-mechanistic-studies
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
248	Element	m4-2-3-7-3-mechanistic-studies
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
249	Element	m4-2-3-7-3-mechanistic-studies
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-3.pdf
	Comment	
	Number	4.2.3.7.4
	Title	Dependence
250	Element	m4-2-3-7-4-dependence
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep
	Comment	
	Number	
251	Title	<i>Study Report 1</i>

	Element	m4-2-3-7-4-dependence
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
252	Element	m4-2-3-7-4-dependence
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
253	Element	m4-2-3-7-4-dependence
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-3.pdf
	Comment	
	Number	4.2.3.7.5
	Title	Metabolites
254	Element	m4-2-3-7-5-metabolites
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab
	Comment	
	Number	
	Title	<i>Study Report 1</i>
255	Element	m4-2-3-7-5-metabolites
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
256	Element	m4-2-3-7-5-metabolites
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
257	Element	m4-2-3-7-5-metabolites
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-3.pdf
	Comment	

258	Number	4.2.3.7.6
	Title	Impurities
259	Element	m4-2-3-7-6-impurities
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp
260	Comment	
	Number	
261	Title	Study Report 1
	Element	m4-2-3-7-6-impurities
262	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/study-report-1.pdf
	Comment	
263	Number	
	Title	Study Report 2
264	Element	m4-2-3-7-6-impurities
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/study-report-2.pdf
265	Comment	
	Number	
266	Title	Study Report 3
	Element	m4-2-3-7-6-impurities
267	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/study-report-3.pdf
	Comment	
268	Number	4.2.3.7.7
	Title	Other
269	Element	m4-2-3-7-7-other
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other
270	Comment	
	Number	
271	Title	Study Report 1
	Element	m4-2-3-7-7-other
272	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/study-report-1.pdf
	Comment	
273	Number	
	Title	Study Report 2
274	Element	m4-2-3-7-7-other
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/study-report-1.pdf
275	Comment	
	Number	
276	Title	Study Report 2
	Element	m4-2-3-7-7-other

	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
265	Element	m4-2-3-7-1-other
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/study-report-3.pdf
	Comment	
	Number	4.3
	Title	Literature References
266	Element	m4-3-literature-references
	Directory	m4/43-lit-ref
	Comment	通常、参考文献の写しは、個別のファイル（例えば、各参考文献ごと）として提出されるべきである。
	Number	
	Title	Reference 1
267	Element	m4-3-literature-references
	File	m4/43-lit-ref/reference-1.pdf
	Comment	
	Number	
	Title	Reference 2
268	Element	m4-3-literature-references
	File	m4/43-lit-ref/reference-2.pdf
	Comment	
	Number	
	Title	Reference 3
269	Element	m4-3-literature-references
	File	m4/43-lit-ref/reference-3.pdf
	Comment	

	Number	5
	Title	Clinical Study Reports
270	Element	m5-clinical-study-reports
	Directory	m5
	Comment	
	Number	5.2
	Title	Tabular Listing of all Clinical Studies
271	Element	m5-2-tabular-listing-of-all-clinical-studies
	Directory	m5/52-tab-list
	Comment	
	Number	5.2
	Title	Tabular Listing of all Clinical Studies
272	Element	m5-2-tabular-listing-of-all-clinical-studies
	File	m5/52-tab-list/tabular-listing.pdf
	Comment	
	Number	5.3
	Title	Clinical Study Reports
273	Element	m5-3-clinical-study-reports
	Directory	m5/53-clin-stud-rep
	Comment	
	Number	5.3.1
	Title	Reports of Biopharmaceutic Studies
274	Element	m5-3-1-reports-of-biopharmaceutic-studies
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud
	Comment	
	Number	5.3.1.1
	Title	Bioavailability (BA) Study Reports
275	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep
	Comment	
	Number	
276	Title	Study Report 1

	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/study-report-1
	Comment	このコメントはモジュール5の全試験報告書に適用される。 申請者は試験報告書を複数ファイル(概要、本文及び適切な付録)として提供すること。付録は、ICH E3 ガイドラインに記述された臨床試験報告書の内容と様式に従って構成すること。複数のファイル方式を採る場合に、ライフサイクルのあらゆる時点において、関連情報に変更があった際には、ファイル一式の置換を行うべきである。各試験に於いてデータトリを作成し、試験報告書に関連するファイルはそのデータトリ内で整理すること。 個々の試験およびファイルには特定のCTD番号を付与しない。
	Number	
	Title	Study Report 2
277	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/study-report-2
	Comment	
	Number	
	Title	Study Report 3
278	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/study-report-3
	Comment	
	Number	5.3.1.2
	Title	Comparative BA and Bioequivalence (BE) Study Reports
279	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep
	Comment	
	Number	
	Title	Study Report 1
280	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep/study-report-1
	Comment	
	Number	
	Title	Study Report 2
281	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep/study-report-2

	Comment	
	Number	
	Title	<i>Study Report 3</i>
282	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep/study-report-3
	Comment	
	Number	5.3.1.3
	Title	In vitro – In vivo Correlation Study Reports
283	Element	m5-3-1-3-in-vitro-in-vivo-correlation-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
284	Element	m5-3-1-3-in-vitro-in-vivo-correlation-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
285	Element	m5-3-1-3-in-vitro-in-vivo-correlation-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
286	Element	m5-3-1-3-in-vitro-in-vivo-correlation-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-3
	Comment	
	Number	5.3.1.4
	Title	Reports of Bioanalytical and Analytical Methods for Human Studies
287	Element	m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-met
	Comment	
	Number	
288	Title	<i>Study Report 1</i>

	Element	m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-metstudy-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
289	Element	m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-metstudy-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
290	Element	m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-metstudy-report-3
	Comment	
	Number	5.3.2
	Title	Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials
291	Element	m5-3-2-reports-of-studies-pertinent-to-pharmacokinetics-using-human-biomaterials
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat
	Comment	
	Number	5.3.2.1
	Title	Plasma Protein Binding Study Reports
292	Element	m5-3-2-1-plasma-protein-binding-study-reports
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
293	Element	m5-3-2-1-plasma-protein-binding-study-reports
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
294	Element	m5-3-2-1-plasma-protein-binding-study-reports
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/study-report-2
	Comment	

295	Number	
	Title	<i>Study Report 3</i>
	Element	m5-3-2-1-plasma-protein-binding-study-reports
296	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/study-report-3
	Comment	
	Number	5.3.2.2
297	Title	Reports of Hepatic Metabolism and Drug Interaction Studies
	Element	m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud
298	Comment	
	Number	
	Title	<i>Study Report 1</i>
299	Element	m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud/study-report-1
	Comment	
300	Number	
	Title	<i>Study Report 2</i>
	Element	m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies
301	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat
	Comment	
	Number	5.3.2.3
301	Title	Reports of Studies Using Other Human Biomaterials
	Element	m5-3-2-3-reports-of-studies-using-other-human-biomaterials
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat
301	Comment	
	Number	
	Title	<i>Study Report 1</i>
301	Element	m5-3-2-3-reports-of-studies-using-other-human-biomaterials

	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat/study-report-1
	Comment	
	Number	
	Title	Study Report 2
302	Element	m5-3-2-3-reports-of-studies-using-other-human-biomaterials
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat/study-report-2
	Comment	
	Number	
	Title	Study Report 3
303	Element	m5-3-2-3-reports-of-studies-using-other-human-biomaterials
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat/study-report-3
	Comment	
	Number	5.3.3
	Title	Reports of Human Pharmacokinetic (PK) Studies
304	Element	m5-3-3-reports-of-human-pharmacokinetics-pk-studies
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud
	Comment	
	Number	5.3.3.1
	Title	Healthy Subject PK and Initial Tolerability Study Reports
305	Element	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-to-stud-rep
	Comment	
	Number	
	Title	Study Report 1
306	Element	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-to-stud-rep/study-report-1
	Comment	
	Number	
	Title	Study Report 2
307	Element	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-to-stud-rep/study-report-2
	Comment	
308	Number	

	Title	<i>Study Report 3</i>
	Element	m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-tol-stud-rep/study-report-3
	Comment	
	Number	5.3.3.2
	Title	Patient PK and Initial Tolerability Study Reports
309	Element	m5-3-3-2-patient-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
310	Element	m5-3-3-2-patient-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
311	Element	m5-3-3-2-patient-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
312	Element	m5-3-3-2-patient-pk-and-initial-tolerability-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/study-report-3
	Comment	
	Number	5.3.3.3
	Title	Intrinsic Factor PK Study Reports
313	Element	m5-3-3-3-intrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intin-factor-pk-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
314	Element	m5-3-3-3-intrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intin-factor-pk-stud-rep/study-report-1

	Comment	
	Number	
	Title	<i>Study Report 2</i>
315	Element	m5-3-3-3-intrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/53333-intrin-factor-pk-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
316	Element	m5-3-3-3-intrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/53333-intrin-factor-pk-stud-rep/study-report-3
	Comment	
	Number	5.3.3.4
	Title	Extrinsic Factor PK Study Reports
317	Element	m5-3-3-4-extrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
318	Element	m5-3-3-4-extrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
319	Element	m5-3-3-4-extrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
320	Element	m5-3-3-4-extrinsic-factor-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-3
	Comment	
	Number	5.3.3.5
321	Title	Population PK Study Reports

	Element	m5-3-3-5-population-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
322	Element	m5-3-3-5-population-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
323	Element	m5-3-3-5-population-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
324	Element	m5-3-3-5-population-pk-study-reports
	Directory	m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/study-report-3
	Comment	
	Number	5.3.4
	Title	Reports of Human Pharmacodynamic (PD) Studies
325	Element	m5-3-4-reports-of-human-pharmacodynamics-pd-studies
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud
	Comment	
	Number	5.3.4.1
	Title	Healthy Subject PD and PK/PD Study Reports
326	Element	m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
327	Element	m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/study-report-1
	Comment	

328	Number	
	Title	<i>Study Report 2</i>
329	Element	m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/study-report-2
330	Number	
	Title	<i>Study Report 3</i>
331	Element	m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/study-report-3
332	Number	5.3.4.2
	Title	Patient PD and PK/PD Study Reports
333	Element	m5-3-4-2-patient-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep
334	Number	
	Title	<i>Study Report 1</i>
335	Element	m5-3-4-2-patient-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/study-report-1
336	Number	
	Title	<i>Study Report 2</i>
337	Element	m5-3-4-2-patient-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/study-report-2
338	Number	
	Title	<i>Study Report 3</i>
339	Element	m5-3-4-2-patient-pd-and-pk-pd-study-reports
	Directory	m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/study-report-3
340	Number	5.3.5
	Title	Reports of Efficacy and Safety Studies
341	Element	m5-3-5-reports-of-efficacy-and-safety-studies
	Directory	

	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud
	Comment	
	Number	5.3.5
	Title	Reports of Efficacy and Safety Studies - Indication Name
	Element	m5-3-5-reports-of-eficacy-and-safety-studies
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1
335	Comment	<p>フォルダ名には申請する適応症 (例えば「asthma」、適切であれば略す) を必ず含める。複数の適応症 (例えば、喘息および偏頭痛) を申請する場合には、1番目の適応症のフォルダ名は「asthma」、2番目の適応症のフォルダ名は「migraine」とする。XML バックボーン内の適応症の属性値はフォルダ名に使用するものと一貫性を保つべきであるが、違うものである場合、XML 属性値は「Non-Small Cell Lung Cancer」という適応症の属性値があった場合、その文書のフォルダ名に「NSCLC」と表記してもよい (例えば、summcineff-nsclc.pdf)。現在これらの属性について標準的な用語の一覧は存在せず、申請者はこれらの属性の値が申請ライブラリの間に容易に変更されることのないよう、慎重に表記を選ぶべきである。現在これを達成する唯一の方法は、不適切な属性値を持ったリソース要素をすべて削除し、これらのフォルダ名の変更した属性値を持つ新しいリソース要素を提供することである。申請者はこれらの属性値を変更する前に、変更が適切かどうか、またその対応方法について地域の規制当局に相談すること。</p>
	Number	5.3.5.1
	Title	Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication
336	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5351-stud-rep-cont
	Comment	
	Number	
	Title	Study Report 1
337	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5351-stud-rep-cont/study-report-1
	Comment	
	Number	
	Title	Study Report 2
338	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5351-stud-rep-cont/study-report-2
	Comment	
	Number	
	Title	Study Report 3
339	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication

	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5351-stud-rep-contr/study-report-3
	Comment	
	Number	5.3.5.2
340	Title	Study Reports of Uncontrolled Clinical Studies
	Element	m5-3-5-2-study-reports-of-uncontrolled-clinical-studies
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5352-stud-rep-uncontr
	Comment	
	Number	
	Title	Study Report 1
341	Element	m5-3-5-2-study-reports-of-uncontrolled-clinical-studies
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5352-stud-rep-uncontr/study-report-1
	Comment	
	Number	
	Title	Study Report 2
342	Element	m5-3-5-2-study-reports-of-uncontrolled-clinical-studies
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5352-stud-rep-uncontr/study-report-2
	Comment	
	Number	
	Title	Study Report 3
343	Element	m5-3-5-2-study-reports-of-uncontrolled-clinical-studies
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5352-stud-rep-uncontr/study-report-3
	Comment	
	Number	5.3.5.3
	Title	Reports of Analyses of Data from More than One Study
344	Element	m5-3-5-3-reports-of-analyses-of-data-from-more-than-one-study
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5353-rep-analys-data-more-one-stud
	Comment	
	Number	
	Title	Study Report 1
345	Element	m5-3-5-3-reports-of-analyses-of-data-from-more-than-one-study
	Directory	m5/53-clin-stud-rep/535-rep-efic-safety-stud/indication-1/5353-rep-analys-data-more-one-stud/study-report-1
	Comment	
346	Number	

	Title	<i>Study Report 2</i>
	Element	m5-3-5-3-reports-of-analyses-of-data-from-more-than-one-study
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5353-rep-analys-data-more-one-stud/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
347	Element	m5-3-5-3-reports-of-analyses-of-data-from-more-than-one-study
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5353-rep-analys-data-more-one-stud/study-report-3
	Comment	
	Number	5.3.5.4
	Title	Other Study Reports
348	Element	m5-3-5-4-other-study-reports
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5354-other-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
349	Element	m5-3-5-4-other-study-reports
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5354-other-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
350	Element	m5-3-5-4-other-study-reports
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5354-other-stud-rep/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</i>
351	Element	m5-3-5-4-other-study-reports
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/indication-1/5354-other-stud-rep/study-report-3
	Comment	
	Number	5.3.6
	Title	Reports of Postmarketing Experience
352	Element	m5-3-6-reports-of-postmarketing-experience
	Directory	m5/53-clin-stud-rep/536-postmark-exp

	Comment	
	Number	5.3.7
	Title	Case Report Forms and Individual Patient Listings
353	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl
	Comment	
	Number	
	Title	Study 1
354	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl/study-1
	Comment	
	Number	
	Title	Document/Dataset 1
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
355	File	m5/53-clin-stud-rep/537-crf-ipl/study-1/filename-1.pdf
	Comment	付録 2 に従ってファイルの名前はファイルを記述するものとし、拡張子は適切なものであること。データセットの提出が受理されるかどうかについては、地域ガイドラインを参照すること。
	Number	
	Title	Document/Dataset 2
356	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-1/filename-2.pdf
	Comment	
	Number	
	Title	Document/Dataset 3
357	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-1/filename-3.pdf
	Comment	
	Number	
	Title	Study 2
358	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl/study-2
	Comment	要素を定義する。
359	Number	

	Title	Document/Dataset 1
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-2/filename-1.pdf
	Comment	
	Number	
360	Title	Document/Dataset 2
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-2/filename-2.pdf
	Comment	
	Number	
361	Title	Document/Dataset 3
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-2/filename-3.pdf
	Comment	
	Number	
	Title	Study 3
362	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl/study-3
	Comment	要素を定義する。
	Number	
363	Title	Document/Dataset 1
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-3/filename-1.pdf
	Comment	
	Number	
	Title	Document/Dataset 2
364	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-3/filename-2.pdf
	Comment	
	Number	
	Title	Document/Dataset 3
365	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/study-3/filename-3.pdf

	Comment	
	Number	5.4
	Title	Literature References
366	Element	m5-4-literature-references
	Directory	m5/54-lit-ref
	Comment	通常、参考文献のコピーは個々のファイル (すなわち文献ごとに1ファイル) として提出する。
	Number	
	Title	Reference 1
367	Element	m5-4-literature-references
	File	m5/54-lit-ref/reference-1.pdf
	Comment	
	Number	
	Title	Reference 2
368	Element	m5-4-literature-references
	File	m5/54-lit-ref/reference-2.pdf
	Comment	
	Number	
	Title	Reference 3
369	Element	m5-4-literature-references
	File	m5/54-lit-ref/reference-3.pdf
	Comment	

370	Number	
	Title	
370	Element	
	Directory	util
	Comment	ユーティリティライ
371	Number	
	Title	
371	Element	
	Directory	util/dtd
	Comment	DTD/スキーマー申請する地域以外の地域 DTD/スキーマーを含める必要はない。 372-379 行のファイル名は単なる例である。最新のファイル名やバージョンについては地域ガイドンスを参照すること。
	Number	
372	Element	
	File	util/dtd/loh-ecid-n.did
	Comment	インスタンズに対する DTD-eCTD 申請を作成するために使用したバージョンを含めること。「n」は特定のバージョンを示す (例えば、3-2)。
	Number	
373	Title	
	Element	
373	File	util/dtd/eur-regional-n.dtd
	Comment	EU 固有の文書に対する DTD。「n」は特定のバージョンを示す (例えば、1-1)。
	Number	
	Title	
374	Element	
	File	util/dtd/jp-regional-n.xsd
	Comment	日本固有の文書に対するスキーマ。「n」は特定のバージョンを示す (例えば、1-0)。
	Number	
375	Title	
	Element	
375	File	util/dtd/us-regional-n.dtd
	Comment	US 固有の文書に対する DTD。「n」は特定のバージョンを示す (例えば、1-0)。

	Number	
	Title	
	Element	
376	File	util/dtd/xx-regional-n.dtd
	Comment	xx に固有な文書に対する DTD。ここで、xx は ISO-3166-1 の 2 文字の国コード。[n] は特定のバージョンを示す (例えば、1-0)。
	Number	
	Title	
	Element	
377	Directory	util/style
	Comment	スタイルシートに対するディレクトリ - ICH および地域のスタイルシート
	Number	
	Title	
	Element	
378	File	util/style/ectd-n.xsl
	Comment	申請書作成時に申請者が基準として使用した eCTD スタイルシートのバージョンを含める。[n] は特定のバージョンを示す (例えば、1-0)。