

	このコメントはモジュール4の全試験報告書に適用される。 一般にモジュール4の各試験報告書について、1つのファイルを提供する。しかし、がん原性試験のように大きい試験報告書の場合は、申請者は複数のファイルとして提出することもできる。その場合、報告書の本文を1ファイルとし、付録は1つまたは複数のファイルとする。複数ファイルの方式を採用する場合、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。複数ファイルの方式を採用する場合、試験報告書のレベルにディレクトリを作成し、関連するファイルをそのディレクトリに含めることを推奨する。追加的なグラフファイル、PDF ファイルに直接挿入することにより、ファイル管理を容易にすることも可能である。あるいはグラフファイルは個別に扱ってもよい。 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。
142	Comment Number Title Element File Comment Number Title Element File Comment Number Title Element Directory Comment Number Title Element File Comment Number Title
143	Study Report 2 m4-2-1-1-primary-pharmacodynamics m4/42-stud-rep/421-pharmacol/4211-prim-pd/study-report-2.pdf Study Report 3 m4-2-1-1-primary-pharmacodynamics m4/42-stud-rep/421-pharmacol/4211-prim-pd/study-report-3.pdf 4.2.1.2 Secondary Pharmacodynamics m4-2-1-2-secondary-pharmacodynamics m4/42-stud-rep/421-pharmacol/4212-sec-pd
144	Study Report 1 m4-2-1-2-secondary-pharmacodynamics m4/42-stud-rep/421-pharmacol/4212-sec-pd/study-report-1.pdf
145	Study Report 2
146	Study Report 2

	Element	m4-2-1-2-secondary-pharmacodynamics
	File	m4/42-stud-rep/421-pharmacol/4212-sec-pd/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
147	Element	m4-2-1-2-secondary-pharmacodynamics
	File	m4/42-stud-rep/421-pharmacol/4212-sec-pd/study-report-3.pdf
	Comment	
	Number	4.2.1.3
	Title	Safety Pharmacology
148	Element	m4-2-1-3-safety-pharmacology
	Directory	m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol
	Comment	
	Number	
	Title	Study Report 1
149	Element	m4-2-1-3-safety-pharmacology
	File	m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
150	Element	m4-2-1-3-safety-pharmacology
	File	m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
151	Element	m4-2-1-3-safety-pharmacology
	File	m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-3.pdf
	Comment	
	Number	4.2.1.4
	Title	Pharmacodynamic Drug Interactions
152	Element	m4-2-1-4-pharmacodynamic-drug-interactions
	Directory	m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact
	Comment	

153	Number	
	Title	<i>Study Report 1</i>
	Element	m4-2-1-4-pharmacodynamic-drug-interactions
	File	m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/study-report-1.pdf
	Comment	
154	Number	
	Title	<i>Study Report 2</i>
	Element	m4-2-1-4-pharmacodynamic-drug-interactions
	File	m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/study-report-2.pdf
	Comment	
155	Number	
	Title	<i>Study Report 3</i>
	Element	m4-2-1-4-pharmacodynamic-drug-interactions
	File	m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/study-report-3.pdf
	Comment	
156	Number	4.2.2
	Title	Pharmacokinetics
	Element	m4-2-2-pharmacokinetics
	Directory	m4/42-stud-rep/422-pk
	Comment	
157	Number	4.2.2.1
	Title	Analytical Methods and Validation Reports (if separate reports are available)
	Element	m4-2-2-1-analytical-methods-and-validation-reports
	Directory	m4/42-stud-rep/422-pk/4221-analyt-met-val
	Comment	
158	Number	
	Title	<i>Study Report 1</i>
	Element	m4-2-2-1-analytical-methods-and-validation-reports
	File	m4/42-stud-rep/422-pk/4221-analyt-met-val/study-report-1.pdf
	Comment	
159	Number	
	Title	<i>Study Report 2</i>
	Element	m4-2-2-1-analytical-methods-and-validation-reports

	File	m4/42-stud-rep/422-pk/4221-analyt-met-val/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
160	Element	m4-2-2-1-analytical-methods-and-validation-reports
	File	m4/42-stud-rep/422-pk/4221-analyt-met-val/study-report-3.pdf
	Comment	
	Number	4.2.2.2
	Title	Absorption
161	Element	m4-2-2-2-absorption
	Directory	m4/42-stud-rep/422-pk/4222-absorp
	Comment	
	Number	
	Title	Study Report 1
162	Element	m4-2-2-2-absorption
	File	m4/42-stud-rep/422-pk/4222-absorp/study-report-1.pdf
	Comment	
	Number	
	Title	Study Report 2
163	Element	m4-2-2-2-absorption
	File	m4/42-stud-rep/422-pk/4222-absorp/study-report-2.pdf
	Comment	
	Number	
	Title	Study Report 3
164	Element	m4-2-2-2-absorption
	File	m4/42-stud-rep/422-pk/4222-absorp/study-report-3.pdf
	Comment	
	Number	4.2.2.3
	Title	Distribution
165	Element	m4-2-2-3-distribution
	Directory	m4/42-stud-rep/422-pk/4223-distrib
	Comment	
166	Number	

	Title	<i>Study Report 1</i>
	Element	m4-2-2-3-distribution
	File	<u>m4/42-stud-rep/422-pk/4223-distrib/study-report-1.pdf</u>
	Comment	
	Number	
167	Title	<i>Study Report 2</i>
	Element	m4-2-2-3-distribution
	File	<u>m4/42-stud-rep/422-pk/4223-distrib/study-report-2.pdf</u>
	Comment	
	Number	
168	Title	<i>Study Report 3</i>
	Element	m4-2-2-3-distribution
	File	<u>m4/42-stud-rep/422-pk/4223-distrib/study-report-3.pdf</u>
	Comment	
	Number	4.2.2.4
169	Title	Metabolism
	Element	m4-2-2-4-metabolism
	Directory	m4/42-stud-rep/422-pk/4224-metab
	Comment	
	Number	
170	Title	<i>Study Report 1</i>
	Element	m4-2-2-4-metabolism
	File	<u>m4/42-stud-rep/422-pk/4224-metab/study-report-1.pdf</u>
	Comment	
	Number	
171	Title	<i>Study Report 2</i>
	Element	m4-2-2-4-metabolism
	File	<u>m4/42-stud-rep/422-pk/4224-metab/study-report-2.pdf</u>
	Comment	
	Number	
172	Title	<i>Study Report 3</i>
	Element	m4-2-2-4-metabolism
	File	<u>m4/42-stud-rep/422-pk/4224-metab/study-report-3.pdf</u>

	Comment	
	Number	4.2.2.5
	Title	Excretion
173	Element	m4-2-2-5-excretion
	Directory	m4/42-stud-rep/422-pk/4225-excr
	Comment	
	Number	
	Title	<i>Study Report 1</i>
174	Element	m4-2-2-5-excretion
	File	m4/42-stud-rep/422-pk/4225-excr/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
175	Element	m4-2-2-5-excretion
	File	m4/42-stud-rep/422-pk/4225-excr/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
176	Element	m4-2-2-5-excretion
	File	m4/42-stud-rep/422-pk/4225-excr/study-report-3.pdf
	Comment	
	Number	
	Title	4.2.2.6
177	Title	Pharmacokinetic Drug Interactions (nonclinical)
	Element	m4-2-2-6-pharmacokinetic-drug-interactions
	Directory	m4/42-stud-rep/422-pk/4226-pk-drug-interact
	Comment	
	Number	
	Title	<i>Study Report 1</i>
178	Element	m4-2-2-6-pharmacokinetic-drug-interactions
	File	m4/42-stud-rep/422-pk/4226-pk-drug-interact/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
179		

	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	Study Report 3
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	Study Report 1
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	Study Report 2
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	Study Report 3
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/study-report-1.pdf
	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/study-report-2.pdf
	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/study-report-3.pdf
	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	
205	Title	<i>Study Report 1</i>
	Element	m4-2-3-4-1-long-term-studies