

	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-1t-stud/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
206	Element	m4-2-3-4-1-long-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-1t-stud/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
207	Element	m4-2-3-4-1-long-term-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42341-1t-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	<i>Study Report 1</i>
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	<i>Study Report 2</i>
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	<i>Study Report 3</i>
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	

	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	
	Title	<i>Study Report 1</i>
213	Element	m4-2-3-4-3-other-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/study-report-1.pdf
	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/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
215	Element	m4-2-3-4-3-other-studies
	File	m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/study-report-3.pdf
	Comment	
	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)
216	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
	Title	Fertility and early embryonic development
217	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	
	Number	
218	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
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
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
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
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
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
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	

	Number	4.2.3.5.3
	Title	Prenatal and postnatal development, including maternal function
225	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/study-report-1.pdf
	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/study-report-2.pdf
	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/study-report-3.pdf
	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/study-report-1.pdf
	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	

	Number	4.2.3.7.6
	Title	Impurities
258	Element	m4-2-3-7-6-impurities
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp
	Comment	
	Number	
	Title	<i>Study Report 1</i>
259	Element	m4-2-3-7-6-impurities
	File	m4/42-stud-rep/423-tox/4237-other-tox-sind/42376-imp/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
260	Element	m4-2-3-7-6-impurities
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/study-report-2.pdf
	Comment	
	Number	
	Title	<i>Study Report 3</i>
261	Element	m4-2-3-7-6-impurities
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/study-report-3.pdf
	Comment	
	Number	4.2.3.7.7
	Title	Other
262	Element	m4-2-3-7-7-other
	Directory	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other
	Comment	
	Number	
	Title	<i>Study Report 1</i>
263	Element	m4-2-3-7-7-other
	File	m4/42-stud-rep/423-tox/4237-other-tox-sind/42377-other/study-report-1.pdf
	Comment	
	Number	
	Title	<i>Study Report 2</i>
264	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-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	