

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

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 ガイドラインに記載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探る場合に、ファイル方式の置換を行うべきである。各試験に対してディレクトリを作成し、試験報告書に関連するファイルはそのディレクトリ内で整理すること。
Number	個々の試験およびファイルには特定の CTID 番号を付与しない。
Title	Study Report 2
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
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
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
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
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-met/study-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-met/study-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-met/study-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
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/532.1-plasma-prot-bind-stud-rep/study-report-3
	Comment	
	Number	5.3.2.2
	Title	Reports of Hepatic Metabolism and Drug Interaction Studies
296	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/532.2-rep-hep-metab-interact-stud
	Comment	
	Number	
	Title	<i>Study Report 1</i>
297	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/532.2-rep-hep-metab-interact-stud/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
298	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/532.2-rep-hep-metab-interact-stud/study-report-2
	Comment	
	Number	
	Title	<i>Study Report 3</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/532.2-rep-hep-metab-interact-stud/study-report-3
	Comment	
	Number	5.3.2.3
	Title	Reports of Studies Using Other Human Biomaterials
300	Element	m5-3-2-3-reports-of-studies-using-other-human-biomaterials
	Directory	m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/532.3-stud-other-human-biomat
	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	<i>Study Report 2</i>
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	<i>Study Report 3</i>
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-to1-stud-rep
	Comment	
	Number	
	Title	<i>Study Report 1</i>
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-to1-stud-rep/study-report-1
	Comment	
	Number	
	Title	<i>Study Report 2</i>
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-to1-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-intrin-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-intrin-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/5333-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/5333-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	
321	Number	5.3.3.5
	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	

	Number	
	Title	<i>Study Report 2</i>
328	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
	Comment	
	Number	
	Title	<i>Study Report 3</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-3
	Comment	
	Number	5.3.4.2
	Title	Patient PD and PK/PD Study Reports
330	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
	Comment	
	Number	
	Title	<i>Study Report 1</i>
331	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
	Comment	
	Number	
	Title	<i>Study Report 2</i>
332	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
	Comment	
	Number	
	Title	<i>Study Report 3</i>
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/study-report-3
	Comment	
	Number	5.3.5
334	Title	Reports of Efficacy and Safety Studies
	Element	m5-3-5-reports-of-efficacy-and-safety-studies