添付資料

B.Risk Indicator の設定について

RI Risk Indicator 項目 項目カウント 1

Category	Sub-Category	Risk Indicator	件数
Data Quality	CRF Completion	Timeliness of data entry	39
Safety	Adverse Events	AE rate	31
Data Quality	Discrepancy Management	Query rate	23
Subject Recruitment and	Subject Discontinuation	Subject discontinuation rate	22
Discontinuation			
Data Quality	Data Trends	Query response time (all	21
		DP)	
Issue Management	Protocol Compliance	Volume of protocol	20
		deviations	
Issue Management	Protocol Compliance	Deviation Outliers	19
Safety	Serious Adverse Events	SAE rate	14
Subject Recruitment and	Screen Failures	Screen fail rate	14
Discontinuation			
Data Quality	Discrepancy Management	Query aging (all DP)	
Subject Recruitment and	Enrollment	Enrollment rate	
Discontinuation			
Investigational Product	Patient Compliance	IP compliance rate	8
Issue Management	Site Compliance	Rate of Data Integrity	8
		Issues	
Data Quality	CRF Completion	Timeliness of data entry	7
		(AEs)	
Issue Management	Protocol Compliance	Subject Visit Timeliness	7
Safety	Lab Data	Trend analysis on lab data	7
Data Quality	Data Trends	Repeated values (freq &	6
		rate)	
Data Quality	Discrepancy Management	Manual query rate	6
Essential Documents	Site Compliance	Submission of safety report	6
		to site and EC/IRB	
Essential Documents	CRA Compliance	Monitoring Visit Report	6
		Approval Compliance	
Issue Management	Protocol Compliance	Major protocol deviation	6
02		-3 F	1

Category	Sub-Category	Risk Indicator	件数
		rate	
Safety	Study Drug Discontinuation	Discontinuation rate	6
Data Quality	CRF Completion	Missing pages	5
Safety	Adverse Events	Rate of discontinuation due	5
		to AE	
Staffing, Facilities and	Site/Staff Turnover	Number of changes in PI,	5
Supplies		sub PI or other (study co-	
		ord)	
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities	4
		delays	
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs	4
		events	
Issue Management	Site Compliance	Site Issue Outlier	4
Safety	Adverse Events	AE causality assessment	4
		distribution per site	
CRA/On-site Workload	CRA Compliance	CRA compliance with	3
		monitoring plan	
CRA/On-site Workload	CRF Review	Volume of SDV (data	3
		points)	
CRA/On-site Workload	CRF Review	Volume of SDV (patient	3
		visits)	_
Data Quality	Patient Compliance	eDiary Compliance	3
Issue Management	Protocol Compliance	Eligibility deviations rate	3
Issue Management	Site Compliance	Number of informed	3
	at a ti	consent issues	
Issue Management	Site Compliance	Rate of Issues	3
Safety	Adverse Events	AE grade distribution per	3
		site	
Safety	Adverse Events	Number of AE's of special	3
G. C.	A.1	interest	2
Safety	Adverse Events	Trend analysis on types of	3
CDA/O : W. 11 1	CD A C 1'	Aes	
CRA/On-site Workload	CRA Compliance	Monitoring report delays	2
Data Quality	CRF Completion	Missing labs	2

Category	Sub-Category	Risk Indicator	件数
Data Quality	CRF Completion	Missing pages (critical	2
		forms)	
Data Quality	CRF Completion	Missing visits	2
Data Quality	CRF Completion	Timeliness of data entry	2
		(SAEs)	
Data Quality	Data Trends	Other (Distribution of	2
		Concomitant Medication	
		and volume by site)	
Data Quality	Discrepancy Management	Number of queries resulting	2
		in data change (critical DP)	
Data Quality	Discrepancy Management	Query rate of those	2
		resulting in a data change	
Essential Documents	CRA Compliance	Investigator Site File	2
		Review compliance	
Safety	Study Drug Discontinuation	Temporary discontinuation	2
Subject Recruitment and	Enrollment	Total Screened	2
Discontinuation			
Data Quality	Data Trends	Efficacy reading post drug	1
		administration	
Data Quality	Data Trends	Other (Change from	
		baseline - Weight)	
Data Quality	Data Trends	Other (Distribution and	1
		Outlier analysis -	
		Demography)	
Data Quality	Data Trends	Other (Distribution of	1
		Medical History terms and	
		volume by Site)	
Data Quality	Data Trends	Other (Number of reference	1
		value)	
Data Quality	Data Trends	Other (PCR - Vital Signs)	1
Data Quality	Data Trends	Other (Variability of	1
		assessment data)	
Data Quality	Data Trends	Outliers of results of lab	1
		exam	

Category	Sub-Category	Risk Indicator	件数
Data Quality	Discrepancy Management	Reissued manual query rate	1
Data Quality	Discrepancy Management	Reissued query count	1
		(critical DP)	
Data Quality	PI Oversight	Frequency of PI EDC	1
		review	
Essential Documents	Study Compliance	Submission of essential	1
		documents to site	
Issue Management	Protocol Compliance	Minor protocol deviation	1
		rate	
Issue Management	Site Compliance	General or site issues -	1
		aging	
Issue Management	Site Compliance	Rate of Human Protection	1
		Issues	
Safety	Adverse Events	Number of patients with	1
		unresolved AEs	
Safety	Adverse Events	Trend analysis on types of	1
		AEs	
Safety	Study Drug Discontinuation	Rate of discontinuation due	1
		to SAE	
Staffing, Facilities and	PI Oversight	PI's presence during	1
Supplies		monitoring visit	
Subject Recruitment and	Enrollment	Other (Increased sampling)	1
Discontinuation			
Subject Recruitment and	Enrollment	Other (Number of Re-	1
Discontinuation		Screening)	
Subject Recruitment and	Subject Discontinuation	Number or rate of subjects	1
Discontinuation		lost to follow up	

RI Risk Indicator 項目 項目カウント 2

Category	Sub-Category	件数
Data Quality	CRF Completion	59
Issue Management	Protocol Compliance	56
Safety	Adverse Events	51
Data Quality	Discrepancy Management	46

Category	Sub-Category	件数
Data Quality	Data Trends	37
Subject Recruitment and Discontinuation	Subject Discontinuation	23
Issue Management	Site Compliance	20
Safety	Serious Adverse Events	14
Subject Recruitment and Discontinuation	Enrollment	14
Subject Recruitment and Discontinuation	Screen Failures	14
CRA/On-site Workload	CRF Review	10
CRA/On-site Workload	CRA Compliance	9
Safety	Study Drug Discontinuation	9
Essential Documents	CRA Compliance	8
Investigational Product	Patient Compliance	8
Safety	Lab Data	7
Essential Documents	Site Compliance	6
Staffing, Facilities and Supplies	Site/Staff Turnover	5
Data Quality	Patient Compliance	3
Data Quality	PI Oversight	1
Essential Documents	Study Compliance	1
Staffing, Facilities and Supplies	PI Oversight	1

RI Risk Indicator 項目 項目カウント 3

Category	件数
Data Quality	146
Safety	81
Issue Management	76
Subject Recruitment and Discontinuation	51
CRA/On-site Workload	19
Essential Documents	15
Investigational Product	8
Staffing, Facilities and Supplies	6

RI Risk Indicator 項目 企業カウント 1

Category	Sub-Category	Risk Indicator	企業 数	%
Data Quality	CRF Completion	Timeliness of data entry	31	96.88

Category	Sub-Category	Risk Indicator	企業数	%
Safety	Adverse Events	AE rate	25	78.13
Data Quality	Discrepancy Management	Query rate	20	62.50
Data Quality	Data Trends	Query response time (all DP)	19	59.38
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	17	53.13
Issue Management	Protocol Compliance	Deviation Outliers	16	50.00
Issue Management	Protocol Compliance	Volume of protocol deviations	16	50.00
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	13	40.63
Safety	Serious Adverse Events	SAE rate	12	37.50
Data Quality	Discrepancy Management	Query aging (all DP)	10	31.25
Investigational Product	Patient Compliance	IP compliance rate	8	25.00
Data Quality	CRF Completion	Timeliness of data entry (AEs)	7	21.88
Issue Management	Protocol Compliance	Subject Visit Timeliness	7	21.88
Issue Management	Site Compliance	Rate of Data Integrity Issues	7	21.88
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	7	21.88
Data Quality	Discrepancy Management	Manual query rate	6	18.75
Safety	Lab Data	Trend analysis on lab	6	18.75
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	5	15.63
Issue Management	Protocol Compliance	Major protocol deviation rate	5	15.63
Safety	Adverse Events	Rate of discontinuation due to AE	5	15.63

Category	Sub-Category	Risk Indicator	企業数	%
Safety	Study Drug	Discontinuation rate	5	15.63
	Discontinuation			
CRA/On-site Workload	CRA Compliance	Monitoring	4	12.50
		visit/activities delays		
Data Quality	Data Trends	Repeated values (freq &	4	12.50
		rate)		
Staffing, Facilities and	Site/Staff Turnover	Number of changes in	4	12.50
Supplies		PI, sub PI or other		
		(study co-ord)		
CRA/On-site Workload	CRA Compliance	CRA compliance with	3	9.38
		monitoring plan		
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs	3	9.38
		events		
CRA/On-site Workload	CRF Review	Volume of SDV (data	3	9.38
		points)		
CRA/On-site Workload	CRF Review	Volume of SDV (patient	3	9.38
		visits)		
Data Quality	CRF Completion	Missing pages	3	9.38
Data Quality	Patient Compliance	eDiary Compliance	3	9.38
Essential Documents	Site Compliance	Submission of safety	3	9.38
		report to site and		
		EC/IRB		
Issue Management	Protocol Compliance	Eligibility deviations	3	9.38
		rate		
Issue Management	Site Compliance	Number of informed	3	9.38
		consent issues		
Issue Management	Site Compliance	Rate of Issues	3	9.38
Safety	Adverse Events	AE causality	3	9.38
		assessment distribution		
		per site		
Safety	Adverse Events	Number of AE's of	3	9.38
		special interest		
Safety	Adverse Events	Trend analysis on types	3	9.38
		of Aes		

Category	Sub-Category	Risk Indicator	企業数	%
Data Quality	CRF Completion	Missing labs	2	6.25
Data Quality	CRF Completion	Missing pages (critical forms)	2	6.25
Data Quality	CDE Completion	<u> </u>	2	6.25
Data Quality	CRF Completion	Missing visits		
Data Quality	CRF Completion	Timeliness of data entry (SAEs)	2	6.25
Data Quality	Data Trends	Other (Distribution of	2	6.25
		Concomitant		
		Medication and volume		
		by site)		
Data Quality	Discrepancy	Number of queries	2	6.25
	Management	resulting in data change		
		(critical DP)		
Data Quality	Discrepancy	Query rate of those	2	6.25
	Management	resulting in a data		
		change		
Essential Documents	CRA Compliance	Investigator Site File	2	6.25
		Review compliance		
Issue Management	Site Compliance	Site Issue Outlier	2	6.25
Safety	Adverse Events	AE grade distribution	2	6.25
		per site		
Safety	Study Drug	Temporary	2	6.25
	Discontinuation	discontinuation		
Subject Recruitment	Enrollment	Total Screened	2	6.25
and Discontinuation				
CRA/On-site Workload	CRA Compliance	Monitoring report	1	3.13
		delays		
Data Quality	Data Trends	Efficacy reading post	1	3.13
		drug administration		
Data Quality	Data Trends	Other (Change from	1	3.13
		baseline - Weight)		
Data Quality	Data Trends	Other (Distribution and	1	3.13
		Outlier analysis -		
		Demography)		

Category	Sub-Category	Risk Indicator	企業数	%
Data Quality	Data Trends	Other (Distribution of	1	3.13
		Medical History terms		
		and volume by Site)		
Data Quality	Data Trends	Other (Number of	1	3.13
		reference value)		
Data Quality	Data Trends	Other (PCR - Vital	1	3.13
		Signs)		
Data Quality	Data Trends	Other (Variability of	1	3.13
		assessment data)		
Data Quality	Data Trends	Outliers of results of lab	1	3.13
		exam		
Data Quality	Discrepancy	Reissued manual query	1	3.13
	Management	rate		
Data Quality	Discrepancy	Reissued query count	1	3.13
	Management	(critical DP)		
Data Quality	PI Oversight	Frequency of PI EDC	1	3.13
		review		
Essential Documents	Study Compliance	Submission of essential	1	3.13
		documents to site		
Issue Management	Protocol Compliance	Minor protocol	1	3.13
		deviation rate		
Issue Management	Site Compliance	General or site issues -	1	3.13
		aging		
Issue Management	Site Compliance	Rate of Human	1	3.13
		Protection Issues		
Safety	Adverse Events	Number of patients with	1	3.13
		unresolved AEs		
Safety	Adverse Events	Trend analysis on types	1	3.13
		of AEs		
Safety	Study Drug	Rate of discontinuation	1	3.13
	Discontinuation	due to SAE		
Staffing, Facilities and	PI Oversight	PI's presence during	1	3.13
Supplies		monitoring visit		
Subject Recruitment	Enrollment	Other (Increased	1	3.13

Category	Sub-Category	Risk Indicator	企業 数	%
and Discontinuation		sampling)		
Subject Recruitment	Enrollment	Other (Number of Re-	1	3.13
and Discontinuation		Screening)		
Subject Recruitment	Subject Discontinuation	Number or rate of	1	3.13
and Discontinuation		subjects lost to follow		
		up		

RI Risk Indicator 項目 企業カウント 2

Category	Sub-Category	企業数	%
Issue Management	Protocol Compliance	32	100.00
Data Quality	CRF Completion	31	96.88
Safety	Adverse Events	29	90.63
Data Quality	Discrepancy Management	27	84.38
Data Quality	Data Trends	21	65.63
Subject Recruitment and	Subject Discontinuation	17	53.13
Discontinuation			
Subject Recruitment and	Screen Failures	13	40.63
Discontinuation			
Issue Management	Site Compliance	12	37.50
Safety	Serious Adverse Events	12	37.50
Investigational Product	Patient Compliance	8	25.00
Safety	Study Drug Discontinuation	8	25.00
Subject Recruitment and	Enrollment	8	25.00
Discontinuation			
CRA/On-site Workload	CRA Compliance	7	21.88
CRA/On-site Workload	CRF Review	7	21.88
Safety	Lab Data	6	18.75
Essential Documents	CRA Compliance	5	15.63
Staffing, Facilities and Supplies	Site/Staff Turnover	4	12.50
Data Quality	Patient Compliance	3	9.38
Essential Documents	Site Compliance	3	9.38
Data Quality	PI Oversight	1	3.13
Essential Documents	Study Compliance	1	3.13

Category	Sub-Category	企業数	%
Staffing, Facilities and Supplies	PI Oversight	1	3.13

RI Risk Indicator 項目 企業カウント 3

Category	企業数	%
Data Quality	32	100.00
Issue Management	32	100.00
Safety	30	93.75
Subject Recruitment and Discontinuation	23	71.88
CRA/On-site Workload	11	34.38
Investigational Product	8	25.00
Essential Documents	7	21.88
Staffing, Facilities and Supplies	5	15.63

RI 当該 Risk Indicator で評価するリスク

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	0	0	0	3
CRA/On-site Workload	CRA Compliance	Monitoring report delays	2	0	0	0
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	1	0	1	3
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	0	4	0	0
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	3	0	0	0
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	2	0	0	1
Data Quality	CRF Completion	Missing labs	2	1	0	1
Data Quality	CRF Completion	Missing pages	5	2	0	0
Data Quality	CRF Completion	Missing pages (critical forms)	1	0	0	1

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
Data Quality	CRF Completion	Missing visits	2	0	0	0
Data Quality	CRF Completion	Timeliness of data entry	25	1	1	16
Data Quality	CRF Completion	Timeliness of data entry (AEs)	1	5	0	2
Data Quality	CRF Completion	Timeliness of data entry (SAEs)	1	1	0	0
Data Quality	Data Trends	Efficacy reading post drug administration	1	0	0	0
Data Quality	Data Trends	Other (Change from baseline - Weight)	1	1	0	1
Data Quality	Data Trends	Other (Distribution and Outlier analysis - Demography)	1	1	0	0
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	1	1	0	1
Data Quality	Data Trends	Other (Distribution of Medical History terms and volume by Site)	1	1	0	0
Data Quality	Data Trends	Other (Number of reference value)	1	0	0	0
Data Quality	Data Trends	Other (PCR - Vital Signs)	1	1	0	1
Data Quality	Data Trends	Other (Variability of assessment data)	1	0	0	0
Data Quality	Data Trends	Outliers of results of lab exam	1	0	0	0
Data Quality	Data Trends	Query response time (all DP)	16	1	1	7
Data Quality	Data Trends	Repeated values (freq	4	5	0	1

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
		& rate)				
Data Quality	Discrepancy	Manual query rate	3	0	0	3
	Management					
Data Quality	Discrepancy	Number of queries	1	0	0	1
	Management	resulting in data				
		change (critical DP)				
Data Quality	Discrepancy	Query aging (all DP)	8	0	0	4
	Management					
Data Quality	Discrepancy	Query rate	19	1	1	5
	Management					
Data Quality	Discrepancy	Query rate of those	2	0	0	0
	Management	resulting in a data				
		change				
Data Quality	Discrepancy	Reissued manual query	0	1	0	0
	Management	rate				
Data Quality	Discrepancy	Reissued query count	1	0	0	0
	Management	(critical DP)				
Data Quality	Patient Compliance	eDiary Compliance	3	0	1	0
Data Quality	PI Oversight	Frequency of PI EDC	0	0	1	0
		review				
Essential Documents	Site Compliance	Submission of safety	1	3	2	0
		report to site and				
		EC/IRB				
Essential Documents	CRA Compliance	Investigator Site File	2	1	0	0
		Review compliance				
Essential Documents	CRA Compliance	Monitoring Visit	4	0	0	2
		Report Approval				
		Compliance				
Essential Documents	Study Compliance	Submission of essential	0	0	0	1
		documents to site				
Investigational Product	Patient Compliance	IP compliance rate	7	2	1	1
Issue Management	Protocol Compliance	Deviation Outliers	18	4	3	1

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
Issue Management	Protocol Compliance	Eligibility deviations rate	3	1	0	0
Issue Management	Protocol Compliance	Major protocol deviation rate	5	2	0	1
Issue Management	Protocol Compliance	Minor protocol deviation rate	1	1	0	0
Issue Management	Protocol Compliance	Subject Visit Timeliness	6	1	0	1
Issue Management	Protocol Compliance	Volume of protocol deviations	19	6	0	2
Issue Management	Site Compliance	General or site issues - aging	0	1	0	0
Issue Management	Site Compliance	Number of informed consent issues	1	1	1	0
Issue Management	Site Compliance	Rate of Data Integrity Issues	6	0	0	3
Issue Management	Site Compliance	Rate of Human Protection Issues	1	0	0	0
Issue Management	Site Compliance	Rate of Issues	2	1	0	1
Issue Management	Site Compliance	Site Issue Outlier	3	0	0	1
Safety	Adverse Events	AE causality assessment distribution per site	2	3	0	0
Safety	Adverse Events	AE grade distribution per site	2	1	0	0
Safety	Adverse Events	AE rate	12	25	0	3
Safety	Adverse Events	Number of AE's of special interest	0	3	0	1
Safety	Adverse Events	Number of patients with unresolved AEs	1	1	0	0
Safety	Adverse Events	Rate of discontinuation due to AE	4	4	0	1

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
Safety	Adverse Events	Trend analysis on types of Aes	2	3	0	0
Safety	Adverse Events	Trend analysis on types of AEs	0	1	0	0
Safety	Lab Data	Trend analysis on lab	4	5	0	3
Safety	Serious Adverse Events	SAE rate	3	12	1	1
Safety	Study Drug Discontinuation	Discontinuation rate	4	3	0	1
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE	0	1	0	0
Safety	Study Drug Discontinuation	Temporary discontinuation	2	2	0	0
Staffing, Facilities and Supplies	PI Oversight	PI's presence during monitoring visit	1	0	0	1
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	2	1	3	2
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	5	1	2	7
Subject Recruitment and Discontinuation	Enrollment	Other (Increased sampling)	0	0	0	0
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re- Screening)	1	0	0	0
Subject Recruitment and Discontinuation	Enrollment	Total Screened	1	0	1	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	9	1	1	4
Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up	0	1	0	0

Category	Sub-Category	Risk Indicator	信頼性	安全性	規制要件	その他
Subject Recruitment	Subject	Subject discontinuation	14	6	1	8
and Discontinuation	Discontinuation	rate				

RI 当該 Risk Indicator で評価するリスク その他の記載

Category	Sub-Category	Risk Indicator	その他	件数
CRA/On-site	CRA Compliance	CRA compliance	CRA performance	1
Workload		with monitoring plan		
CRA/On-site	CRA Compliance	CRA compliance	Operational Risk	1
Workload		with monitoring plan	Control	
CRA/On-site	CRA Compliance	CRA compliance	モニターの活動状	1
Workload		with monitoring plan	況	
CRA/On-site	CRA Compliance	Monitoring	Adherance to the	1
Workload		visit/activities delays	SMP	
CRA/On-site	CRA Compliance	Monitoring	Data Entry and	1
Workload		visit/activities delays	Collection	
CRA/On-site	CRA Compliance	Monitoring	Operational Risk	1
Workload		visit/activities delays	Control	
CRA/On-site	CRF Review	Volume of SDV	リソース状況	1
Workload		(patient visits)		
Data Quality	CRF Completion	Missing labs	重要な項目	1
Data Quality	CRF Completion	Missing pages	Poor protocol	1
		(critical forms)	compliance	
Data Quality	CRF Completion	Timeliness of data	CRC のパフォーマ	3
		entry	ンス	
Data Quality	CRF Completion	Timeliness of data	Data Entry and	3
		entry	Collection	
Data Quality	CRF Completion	Timeliness of data	eCOA の回答時間	1
		entry		
Data Quality	CRF Completion	Timeliness of data	Operational Risk	1
		entry	Control	
Data Quality	CRF Completion	Timeliness of data	Risk of site not	1
		entry	entering data and	

Category	Sub-Category	Risk Indicator	その他	件数
			impact on timely	
			safety data, detecting	
			poor data entry	
			habits, lack of site	
			engagement. Driving	
			good scientific	
			practice in line with	
			GCP guidelines.	
Data Quality	CRF Completion	Timeliness of data	Site performance	1
		entry		
Data Quality	CRF Completion	Timeliness of data	データ入力の遅れ	1
		entry	は、施設が試験に	
			必要とされる仕事	
			量を管理できてい	
			ない事を示す。(プ	
			ロセス,リソース	
			等)	
Data Quality	CRF Completion	Timeliness of data	リソース状況	2
		entry		
Data Quality	CRF Completion	Timeliness of data	施設の入力パフォ	1
		entry	ーマンス	
Data Quality	CRF Completion	Timeliness of data	施設の入力プロセ	1
		entry	ス	
Data Quality	CRF Completion	Timeliness of data	施設パフォーマン	1
		entry	スの確認	
Data Quality	CRF Completion	Timeliness of data	Data Entry and	1
		entry (AEs)	Collection	
Data Quality	CRF Completion	Timeliness of data	施設の入力パフォ	1
		entry (AEs)	ーマンス	
Data Quality	Data Trends	Other (Change from	安全性	1
		baseline - Weight)		
Data Quality	Data Trends	Other (Distribution	プロトコルの誤認	1
		of Concomitant	識や重要な安全性	
		Medication and	情報を見逃してい	
		volume by site)	る	
			1	

Category	Sub-Category	Risk Indicator	その他	件数
Data Quality	Data Trends	Other (PCR - Vital	安全性	1
		Signs)		
Data Quality	Data Trends	Query response time	Data Entry and	1
		(all DP)	Collection	
Data Quality	Data Trends	Query response time	Operational Risk	1
		(all DP)	Control	
Data Quality	Data Trends	Query response time	Site/CRA	1
		(all DP)	performance	
Data Quality	Data Trends	Query response time	施設のクエリー対	1
		(all DP)	応プロセス	
Data Quality	Data Trends	Query response time	施設のクエリー対	2
		(all DP)	応パフォーマンス	
Data Quality	Data Trends	Query response time	施設パフォーマン	1
		(all DP)	スの確認	
Data Quality	Data Trends	Repeated values	施設の入力プロセ	1
		(freq & rate)	ス	
Data Quality	Discrepancy	Manual query rate	CRC のパフォーマ	1
	Management		ンス	
Data Quality	Discrepancy	Manual query rate	Data Entry and	1
	Management		Collection	
Data Quality	Discrepancy	Manual query rate	Quality/accuracy of	1
	Management		data entry	
Data Quality	Discrepancy	Number of queries	Data Entry and	1
	Management	resulting in data	Collection	
		change (critical DP)		
Data Quality	Discrepancy	Query aging (all DP)	CRC のパフォーマ	1
	Management		ンス	
Data Quality	Discrepancy	Query aging (all DP)	Data Entry and	1
	Management		Collection	
Data Quality	Discrepancy	Query aging (all DP)	Responsive to	1
	Management		queries, good	
			understanding of the	
			data entry or	
			protocol	
			requirements.	

Category	Sub-Category	Risk Indicator	その他	件数
Data Quality	Discrepancy	Query aging (all DP)	施設のクエリー対	1
	Management		応プロセス	
Data Quality	Discrepancy	Query rate	Operational Risk	1
	Management		Control	
Data Quality	Discrepancy	Query rate	Quality/accuracy of	1
	Management		data entry	
Data Quality	Discrepancy	Query rate	リソース状況	1
	Management			
Data Quality	Discrepancy	Query rate	施設の CRF の理解	1
	Management		度	
Data Quality	Discrepancy	Query rate	施設の理解度	1
	Management			
Essential Documents	CRA Compliance	Monitoring Visit	CRA のパフォーマ	1
		Report Approval	ンス	
		Compliance		
Essential Documents	CRA Compliance	Monitoring Visit	モニターの評価	1
		Report Approval		
		Compliance		
Essential Documents	Study Compliance	Submission of	Adherance to the	1
		essential documents	SMP	
		to site		
Investigational	Patient Compliance	IP compliance rate	投与状況	1
Product				
Issue Management	Protocol Compliance	Deviation Outliers	Poor protocol	1
			compliance	
Issue Management	Protocol Compliance	Major protocol	施設のプロトコル	1
		deviation rate	の理解度	
Issue Management	Protocol Compliance	Subject Visit	投与状況	1
		Timeliness		
Issue Management	Protocol Compliance	Volume of protocol	施設のプロトコー	1
		deviations	ルの理解	
Issue Management	Protocol Compliance	Volume of protocol	施設のプロトコル	1
		deviations	の理解度	
Issue Management	Site Compliance	Rate of Data	Data Entry and	2
		Integrity Issues	Collection	

Category	Sub-Category	Risk Indicator	その他	件数
Issue Management	Site Compliance	Rate of Data	施設パフォーマン	1
		Integrity Issues	スやプロトコルの	
			理解	
Issue Management	Site Compliance	Rate of Issues	Site or monitor	1
			responsive	
Issue Management	Site Compliance	Site Issue Outlier	Poor performing	1
			sites	
Safety	Adverse Events	AE rate	Potential under or	1
			over-reporting of	
			AEs	
Safety	Adverse Events	AE rate	安全性	1
Safety	Adverse Events	AE rate	施設のプロトコー	1
			ルの理解	
Safety	Adverse Events	Number of AE's of	有害事象数(SAE な	1
		special interest	ど)	
Safety	Adverse Events	Rate of	安全性	1
		discontinuation due		
		to AE		
Safety	Lab Data	Trend analysis on lab	安全性	2
		data		
Safety	Lab Data	Trend analysis on lab	評価できないサン	1
		data	プルが通常より多	
			い場合、重要な安	
			全性の情報が失わ	
			れ被験者を危険に	
			さらしている	
Safety	Serious Adverse	SAE rate	Potential under or	1
	Events		over-reporting of	
			SAEs	
Safety	Study Drug	Discontinuation rate	投与状況	1
	Discontinuation			
Staffing, Facilities	PI Oversight	PI's presence during	総合評価	1
and Supplies		monitoring visit		
Staffing, Facilities	Site/Staff Turnover	Number of changes	Operational Risk	2
and Supplies		in PI, sub PI or other	Control	

Category	Sub-Category	Risk Indicator	その他	件数
		(study co-ord)		
Subject Recruitment	Enrollment	Enrollment rate	Poor	1
and Discontinuation			motivation/lack of	
			engagement, fast	
			recruiting sites	
Subject Recruitment	Enrollment	Enrollment rate	Operational Risk	2
and Discontinuation			Control	
Subject Recruitment	Enrollment	Enrollment rate	計画と実績の乖離	1
and Discontinuation				
Subject Recruitment	Enrollment	Enrollment rate	進捗把握	1
and Discontinuation				
Subject Recruitment	Enrollment	Enrollment rate	登録	2
and Discontinuation				
Subject Recruitment	Enrollment	Total Screened	Operational Risk	1
and Discontinuation			Control	
Subject Recruitment	Screen Failures	Screen fail rate	Identify sites with	1
and Discontinuation			high screen failure	
			rate and reasons	
Subject Recruitment	Screen Failures	Screen fail rate	Incorrect patients	1
and Discontinuation			being screened	
Subject Recruitment	Screen Failures	Screen fail rate	施設は適切な被験	1
and Discontinuation			者をターゲットと	
			しているか、選択/	
			除外基準を理解し	
			ているかの確認	
Subject Recruitment	Screen Failures	Screen fail rate	登録	1
and Discontinuation				
Subject Recruitment	Subject	Subject	Discontinuation	1
and Discontinuation	Discontinuation	discontinuation rate		
Subject Recruitment	Subject	Subject	Identify sites with	1
and Discontinuation	Discontinuation	discontinuation rate	high discontinuation	
			(drop out) rate and	
			reasons	
Subject Recruitment	Subject	Subject	Poor management of	1
and Discontinuation	Discontinuation	discontinuation rate	patients within a	

Category	Sub-Category	Risk Indicator	その他	件数
			study	
Subject Recruitment	Subject	Subject	施設、被験者のプ	2
and Discontinuation	Discontinuation	discontinuation rate	ロトコルの理解度	
Subject Recruitment	Subject	Subject	施設のプロトコル	2
and Discontinuation	Discontinuation	discontinuation rate	の理解	
Subject Recruitment	Subject	Subject	評価可能な被験者	1
and Discontinuation	Discontinuation	discontinuation rate	の減少は、有効性	
			や安全性評価の妨	
			げとなる。	

RI 評価する変数 算出方法

	T	1			
Category	Sub-Category	Risk Indicator	1. 件 数· 例	2. 全体に対す	3.1 と2
			数· 日数	る割合	両方
CRA/On-site	CRA Compliance	CRA compliance with	1		1
Workload		monitoring plan			
CRA/On-site	CRA Compliance	Monitoring report		2	
Workload		delays			
CRA/On-site	CRA Compliance	Monitoring	2	1	
Workload		visit/activities delays			
CRA/On-site	CRF Review	Unreported AEs/SAEs	3		
Workload		events			
CRA/On-site	CRF Review	Volume of SDV (data	2	1	
Workload		points)			
CRA/On-site	CRF Review	Volume of SDV		2	1
Workload		(patient visits)			
Data Quality	CRF Completion	Missing labs	2		
Data Quality	CRF Completion	Missing pages	2	1	2
Data Quality	CRF Completion	Missing pages	1	1	
		(critical forms)			
Data Quality	CRF Completion	Missing visits		1	1
Data Quality	CRF Completion	Timeliness of data	26	4	5
		entry			

Category	Sub-Category	Risk Indicator	1. 件 数・ 例 数・ 日数	2. 全 体に 対す る割 合	3.1 と2 両方
Data Quality	CRF Completion	Timeliness of data	5	1	1
Data Quality	Data Trends	entry (AEs) Efficacy reading post drug administration	1		
Data Quality	Data Trends	Other (Change from baseline - Weight)			1
Data Quality	Data Trends	Other (Distribution and Outlier analysis - Demography)			1
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	1		
Data Quality	Data Trends	Other (Distribution of Medical History terms and volume by Site)	1		
Data Quality	Data Trends	Other (Number of reference value)			1
Data Quality	Data Trends	Other (PCR - Vital Signs)	1		
Data Quality	Data Trends	Other (Variability of assessment data)	1		
Data Quality	Data Trends	Query response time (all DP)	12	2	4
Data Quality	Data Trends	Repeated values (freq & rate)	1	1	4
Data Quality	Discrepancy Management	Manual query rate	3	3	
Data Quality	Discrepancy Management	Number of queries resulting in data change (critical DP)	2		

			1 /1-	2 ^	
			1. 件	2. 全	
			数•	体に	3. 1
Category	Sub-Category	Risk Indicator	例	対す	と 2
			数•	る割	両方
			日数	合	
Data Quality	Discrepancy	Query aging (all DP)	5	3	2
	Management				
Data Quality	Discrepancy	Query rate	7	10	4
	Management				
Data Quality	Discrepancy	Query rate of those		2	
	Management	resulting in a data			
		change			
Data Quality	Discrepancy	Reissued query count		1	
	Management	(critical DP)			
Data Quality	Patient Compliance	eDiary Compliance	2		1
Essential Documents	Site Compliance	Submission of safety	3		
		report to site and			
		EC/IRB			
Essential Documents	CRA Compliance	Investigator Site File	2		
		Review compliance			
Essential Documents	CRA Compliance	Monitoring Visit	4		1
		Report Approval			
		Compliance			
Essential Documents	Study Compliance	Submission of		1	
		essential documents to			
		site			
Investigational	Patient Compliance	IP compliance rate	2	3	2
Product	1	1			
Issue Management	Protocol Compliance	Deviation Outliers	2	8	7
Issue Management	Protocol Compliance	Eligibility deviations		2	1
	r	rate			
Issue Management	Protocol Compliance	Major protocol	4	1	
	 	deviation rate			
Issue Management	Protocol Compliance	Minor protocol		1	
	r	deviation rate			
Issue Management	Protocol Compliance	Subject Visit	2	2	1
	<u>-</u>	Dubject Visit			_

			1 (14-	2 ^	
			1. 件	2. 全	0.1
~			数•	体に	3. 1
Category	Sub-Category	Risk Indicator	例	対す	と 2
			数•	る割	両方
			日数	合	
		Timeliness			
Issue Management	Protocol Compliance	Volume of protocol	13	3	4
		deviations			
Issue Management	Site Compliance	Number of informed	2		
		consent issues			
Issue Management	Site Compliance	Rate of Data Integrity	3	4	
		Issues			
Issue Management	Site Compliance	Rate of Human	1		
		Protection Issues			
Issue Management	Site Compliance	Rate of Issues	1		1
Issue Management	Site Compliance	Site Issue Outlier	3	1	
Safety	Adverse Events	AE causality	3	1	
		assessment			
		distribution per site			
Safety	Adverse Events	AE grade distribution	2		1
Surety	Traverse Events	per site	_		•
Safety	Adverse Events	AE rate	11	11	7
Safety	Adverse Events	Number of AE's of	3		
2		special interest			
Safety	Adverse Events	Number of patients		1	
Barety	Haverse Events	with unresolved AEs		1	
Safety	Adverse Events	Rate of	2	1	2
Salety	Adverse Events	discontinuation due to	2	1	2
		AE			
Cofety	A dryama Ct-			1	1
Safety	Adverse Events	Trend analysis on		1	1
G. C.	A.I. F	types of Aes			
Safety	Adverse Events	Trend analysis on		1	
		types of AEs			
Safety	Lab Data	Trend analysis on lab	2	1	3
		data			
Safety	Serious Adverse	SAE rate	8	3	2

			1. 件	2. 全	
			数•	体に	3. 1
Category	Sub-Category	Risk Indicator	例	対す	と 2
			数•	る割	両方
			日数	合	
	Events				
Safety	Study Drug	Discontinuation rate	1	3	2
	Discontinuation				
Safety	Study Drug	Rate of	1		
	Discontinuation	discontinuation due to			
		SAE			
Safety	Study Drug	Temporary		1	1
	Discontinuation	discontinuation			
Staffing, Facilities and	PI Oversight	PI's presence during	1		
Supplies		monitoring visit			
Staffing, Facilities and	Site/Staff Turnover	Number of changes in	2		
Supplies		PI, sub PI or other			
		(study co-ord)			
Subject Recruitment	Enrollment	Enrollment rate	2	3	4
and Discontinuation					
Subject Recruitment	Enrollment	Other (Number of Re-	1		
and Discontinuation		Screening)			
Subject Recruitment	Enrollment	Total Screened	1		1
and Discontinuation					
Subject Recruitment	Screen Failures	Screen fail rate	3	6	3
and Discontinuation					
Subject Recruitment	Subject	Number or rate of	1		
and Discontinuation	Discontinuation	subjects lost to follow			
		up			
Subject Recruitment	Subject	Subject	7	9	4
and Discontinuation	Discontinuation	discontinuation rate			

RI 評価する変数 算出方法その他

Category	Sub-Category	Risk Indicator	算出方法_その他	件数
CRA/On-site	CRA Compliance	CRA compliance	EDC のオフサイト	1
Workload		with monitoring plan	モニタリングのチ	

Category	Sub-Category	Risk Indicator	算出方法_その他	件数
			エック件数	
CRA/On-site	CRA Compliance	Monitoring	施設レベルで算出	1
Workload		visit/activities		
		delays		
Data Quality	CRF Completion	Missing labs	施設当たりの件数	1
Data Quality	CRF Completion	Missing pages	施設レベルで算出	1
		(critical forms)		
Data Quality	CRF Completion	Timeliness of data	●日以上	1
		entry		
Data Quality	CRF Completion	Timeliness of data	規定時間以下	1
		entry		
Data Quality	CRF Completion	Timeliness of data	施設ごと、月ごと	1
		entry	に規定の日数超え	
			た件数	
Data Quality	CRF Completion	Timeliness of data	施設レベルで算出	1
		entry		
Data Quality	CRF Completion	Timeliness of data	未入力割合	1
		entry		
Data Quality	CRF Completion	Timeliness of data	●目以上	1
		entry (SAEs)		
Data Quality	Data Trends	Other (Distribution	被験者の観察期間	1
		of Concomitant	(subject week) あ	
		Medication and	たりの併用薬数	
		volume by site)		
Data Quality	Data Trends	Outliers of results of	検査値をピックアップ	1
		lab exam		
Data Quality	Data Trends	Query response time	●日以上	1
		(all DP)		
Data Quality	Data Trends	Query response time	施設ごと、月ごと	1
		(all DP)	に規定の日数超え	
			た件数	
Data Quality	Data Trends	Repeated values	全体からの外れ具	1
		(freq & rate)	合	
Data Quality	Discrepancy	Manual query rate	施設レベルで算出	1
	Management			

Category	Sub-Category	Risk Indicator	算出方法_その他	件数
Data Quality	Discrepancy	Query aging (all	●日以上	1
	Management	DP)		
Data Quality	Discrepancy	Query aging (all	施設レベルで算出	1
	Management	DP)		
Data Quality	Discrepancy	Query aging (all	未解決クエリー数/	1
	Management	DP)	クエリーの発行数	
Data Quality	Discrepancy	Query rate	1000 データごとの	1
	Management		クエリー率	
Data Quality	Discrepancy	Query rate	100 データ当たり	1
	Management		のクエリー数	
Data Quality	Discrepancy	Query rate	施設レベルで算出	1
	Management			
Data Quality	Discrepancy	Query rate	施設当たりの割合	1
	Management			
Data Quality	Discrepancy	Query rate	被験者数	1
	Management			
Essential	Site Compliance	Submission of	●日以上対応なし	2
Documents		safety report to site		
		and EC/IRB		
Essential	CRA Compliance	Monitoring Visit	●日以上	1
Documents		Report Approval		
		Compliance		
Essential	Study Compliance	Submission of	施設レベルで算出	1
Documents		essential documents		
		to site		
Investigational	Patient Compliance	IP compliance rate	設定した閾値を下	1
Product			回る症例の割合	
Issue Management	Protocol	Deviation Outliers	施設レベルで算出	1
	Compliance			
Issue Management	Protocol	Volume of protocol	施設の登録数に偏	1
	Compliance	deviations	りがあるため症例	
			数で調整	
Issue Management	Protocol	Volume of protocol	施設当たりの件数	1
	Compliance	deviations		
Issue Management	Site Compliance	Rate of Issues	施設レベルで算出	1

Category	Sub-Category	Risk Indicator	算出方法_その他	件数
Issue Management	Site Compliance	Site Issue Outlier	施設レベルで算出	1
Safety	Adverse Events	AE rate	施設レベルで算出	1
Safety	Adverse Events	AE rate	施設当たりの有害	1
			事象数/観察日数	
			(人日)	
Safety	Adverse Events	Number of AE's of	規定の有害事象の	1
		special interest	発現数	
Safety	Adverse Events	Trend analysis on	相関関係を図示	1
		types of Aes		
Safety	Lab Data	Trend analysis on	下位、上位の施設	1
		lab data		
Safety	Serious Adverse	SAE rate	観察期間(subject	1
	Events		week) あたりの AE	
			発現数	
Safety	Serious Adverse	SAE rate	施設レベルで算出	1
	Events			
Staffing, Facilities	PI Oversight	PI's presence during	チェックリストを	1
and Supplies		monitoring visit	用いた、モニター	
			の主観による評価	
			(10~20項目)	
Staffing, Facilities	Site/Staff Turnover	Number of changes	●名以上	1
and Supplies		in PI, sub PI or other		
		(study co-ord)		
Subject Recruitment	Enrollment	Enrollment rate	下位、上位の施設	1
and Discontinuation				
Subject Recruitment	Enrollment	Enrollment rate	施設レベルで算出	1
and Discontinuation				
Subject Recruitment	Screen Failures	Screen fail rate	施設レベルで算出	1
and Discontinuation				
Subject Recruitment	Subject	Subject	施設ごとの中止症	1
and Discontinuation	Discontinuation	discontinuation rate	例の件数	
Subject Recruitment	Subject	Subject	施設レベルで算出	1
and Discontinuation	Discontinuation	discontinuation rate		
Subject Recruitment	Subject	Subject	施設当たりの件数	1
and Discontinuation	Discontinuation	discontinuation rate		

RI 評価する変数 評価対象期間

	11 四八1 3人7911日					
Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前 回 価 時 以 期 間	3. 直近(週間	4. 複数の評価期間
CRA/On-site	CRA Compliance	CRA compliance	1	1	1	
Workload		with monitoring				
		plan				
CRA/On-site	CRA Compliance	Monitoring report		2		
Workload		delays				
CRA/On-site	CRA Compliance	Monitoring	3		1	
Workload		visit/activities				
		delays				
CRA/On-site	CRF Review	Unreported	4			
Workload		AEs/SAEs events				
CRA/On-site	CRF Review	Volume of SDV	3			
Workload		(data points)				
CRA/On-site	CRF Review	Volume of SDV	3			
Workload		(patient visits)				
Data Quality	CRF Completion	Missing labs	1	1		
Data Quality	CRF Completion	Missing pages	4	1		
Data Quality	CRF Completion	Missing pages	2			
		(critical forms)				
Data Quality	CRF Completion	Missing visits	2			
Data Quality	CRF Completion	Timeliness of data	23	12	1	2
		entry				
Data Quality	CRF Completion	Timeliness of data	4	3		
		entry (AEs)				
Data Quality	CRF Completion	Timeliness of data	1			

	1	1				
			1.			
			試			4.
			験	2. 前	3.	複
			開	回評	直	数
Catagomy	Cub Catagory	Risk Indicator	始	価時	近	の
Category	Sub-Category	Risk indicator	カュ	以降	()	評
			5	の期	週	価
			全	間	間	期
			期			間
			間			
		entry (SAEs)				
Data Quality	Data Trends	Efficacy reading		1		
		post drug				
		administration				
Data Quality	Data Trends	Other (Change from	1			
		baseline - Weight)				
Data Quality	Data Trends	Other (Distribution	1			
		and Outlier analysis				
		- Demography)				
Data Quality	Data Trends	Other(Distribution	2			
		of Concomitant				
		Medication and				
		volume by site)				
Data Quality	Data Trends	Other(Distribution	1			
		of Medical History				
		terms and volume				
		by Site)				
Data Quality	Data Trends	Other (Number of	1			
		reference value)				
Data Quality	Data Trends	Other (PCR - Vital	1			
		Signs)				
Data Quality	Data Trends	Other (Variability of		1		
		assessment data)				
Data Quality	Data Trends	Query response time	11	8		1
		(all DP)				
Data Quality	Data Trends	Repeated values	4	1		1

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前 評時 降 期 間	3. 直近(週間	4. 複数の評価期間
		(freq & rate)				
Data Quality	Discrepancy	Manual query rate	4	1	1	
	Management					
Data Quality	Discrepancy	Number of queries	2			
	Management	resulting in data				
		change (critical DP)				
Data Quality	Discrepancy	Query aging (all	6	3	1	1
	Management	DP)				
Data Quality	Discrepancy	Query rate	14	5	1	2
	Management					
Data Quality	Discrepancy	Query rate of those	2			
	Management	resulting in a data				
		change				
Data Quality	Discrepancy	Reissued manual	1			
	Management	query rate				
Data Quality	Discrepancy	Reissued query	1			
	Management	count (critical DP)				
Data Quality	Patient Compliance	eDiary Compliance	2			1
Data Quality	PI Oversight	Frequency of PI	1			
		EDC review				
Essential	Site Compliance	Submission of	4	2		
Documents		safety report to site				
		and EC/IRB				
Essential	CRA Compliance	Investigator Site	1	1		
Documents		File Review				
		compliance				

			1.			
			試			4.
			験	2. 前	3.	複
			開	回評	直	数
G.	0.1.0.	D' LT L'	始	価時	近	の
Category	Sub-Category	Risk Indicator	カュ	以降	()	評
			5	の期	週	価
			全	間	間	期
			期			間
			間			
Essential	CRA Compliance	Monitoring Visit	4	1		1
Documents		Report Approval				
		Compliance				
Essential	Study Compliance	Submission of	1			
Documents		essential documents				
		to site				
Investigational	Patient Compliance	IP compliance rate	5	1		1
Product						
Issue Management	Protocol Compliance	Deviation Outliers	8	2	4	4
Issue Management	Protocol Compliance	Eligibility	2		1	
		deviations rate				
Issue Management	Protocol Compliance	Major protocol	3	3		
		deviation rate				
Issue Management	Protocol Compliance	Minor protocol	1			
		deviation rate				
Issue Management	Protocol Compliance	Subject Visit	6			
		Timeliness				
Issue Management	Protocol Compliance	Volume of protocol	10	9	1	
		deviations				
Issue Management	Site Compliance	General or site	1			
		issues - aging				
Issue Management	Site Compliance	Number of informed	3			
-		consent issues				
Issue Management	Site Compliance	Rate of Data	6	1		
		Integrity Issues				
Issue Management	Site Compliance	Rate of Human	1			
)		1	L	ı	l	

Category	Sub-Category	Risk Indicator Protection Issues	1. 試験開始から全期間	2. 前評時降期間	3. 直近(週間	4. 複数の評価期間
Issue Management	Site Compliance	Rate of Issues	2			1
Issue Management	Site Compliance	Site Issue Outlier	2	2		
Safety	Adverse Events	AE causality assessment distribution per site	3	1		
Safety	Adverse Events	AE grade distribution per site	1	2		
Safety	Adverse Events	AE rate	22	5	1	2
Safety	Adverse Events	Number of AE's of special interest	3			
Safety	Adverse Events	Number of patients with unresolved AEs	1			
Safety	Adverse Events	Rate of discontinuation due to AE	4	1		
Safety	Adverse Events	Trend analysis on types of Aes	3			
Safety	Adverse Events	Trend analysis on types of AEs	1			
Safety	Lab Data	Trend analysis on lab data	4	2		1
Safety	Serious Adverse Events	SAE rate	12	2		
Safety	Study Drug Discontinuation	Discontinuation rate	5	1		

			1.			
			試			4.
			験	2. 前	3.	複
			開	回評	直	数
Cotogory	Sub Catagory	Risk Indicator	始	価時	近	の
Category	Sub-Category	KISK IIIuicatoi	カュ	以降	()	評
			5	の期	週	価
			全	間	間	期
			期			間
			間			
Safety	Study Drug	Rate of	1			
	Discontinuation	discontinuation due				
		to SAE				
Safety	Study Drug	Temporary	2			
	Discontinuation	discontinuation				
Staffing, Facilities	PI Oversight	PI's presence during		1		
and Supplies		monitoring visit				
Staffing, Facilities	Site/Staff Turnover	Number of changes	3	2		
and Supplies		in PI, sub PI or other				
		(study co-ord)				
Subject	Enrollment	Enrollment rate	8			2
Recruitment and						
Discontinuation						
Subject	Enrollment	Other (Increased	1			
Recruitment and		sampling)				
Discontinuation						
Subject	Enrollment	Other (Number of		1		
Recruitment and		Re-Screening)				
Discontinuation						
Subject	Enrollment	Total Screened	1		_	1
Recruitment and						
Discontinuation						
Subject	Screen Failures	Screen fail rate	13		_	
Recruitment and						
Discontinuation						
Subject	Subject	Number or rate of	1			

			1.			
Category			試			4.
			験	2. 前	3.	複
			開	回評	直	数
	Sub Catagory	Risk Indicator	始	価時	近	0
	Sub-Category		カュ	以降	()	評
			5	の期	週	価
			全	間	間	期
			期			間
			間			
Recruitment and	Discontinuation	subjects lost to				
Discontinuation		follow up				
Subject	Subject	Subject	17	4		
Recruitment and	Discontinuation	discontinuation rate				
Discontinuation						

RI リスク評価の閾値 閾値の設定

			1.				
			統	2.			
			計	実		4.	
			的	施	3.	設	
			な	経	1	定	4111.
C.	G 1 C 4	D' 1 T 1' 4	根	験	ک	し	無
Category	Sub-Category	Risk Indicator	拠	を	2	て	口
			を	基	両	٧٧	答
			基	に	方	な	
			に	設		٧٧	
			設	定			
			定				
CRA/On-site	CRA Compliance	CRA compliance		1		2	
Workload		with monitoring					
		plan					
CRA/On-site	CRA Compliance	Monitoring report		2			
Workload		delays					
CRA/On-site	CRA Compliance	Monitoring		2		1	1
Workload		visit/activities					

Category	Sub-Category	Risk Indicator	1. 統計的な根拠を基に設定	2. 実施経験を基に設定	3. 1 と 2 両方	4. 設定していない	無回答
		delays					
CRA/On-site	CRF Review	Unreported		2	1	1	
Workload	CDTD :	AEs/SAEs events					
CRA/On-site	CRF Review	Volume of SDV		3			
Workload	CDTD :	(data points)					
CRA/On-site	CRF Review	Volume of SDV	1	1		1	
Workload	GDT G 1 1	(patient visits)					
Data Quality	CRF Completion	Missing labs		1		1	
Data Quality	CRF Completion	Missing pages		2		3	
Data Quality	CRF Completion	Missing pages (critical forms)		1		1	
Data Quality	CRF Completion	Missing visits	1			1	
Data Quality	CRF Completion	Timeliness of data entry	4	22	3	5	4
Data Quality	CRF Completion	Timeliness of data entry (AEs)		4	2	1	
Data Quality	CRF Completion	Timeliness of data entry (SAEs)		1			
Data Quality	Data Trends	Efficacy reading post drug administration				1	
Data Quality	Data Trends	Other (Change from baseline - Weight)	1				
Data Quality	Data Trends	Other (Distribution				1	

Category	Sub-Category	Risk Indicator	1. 統計的な根拠を基に設定	2. 実施経験を基に設定	3. 1 と 2 両 方	4. 設定していない	無回答
		and Outlier analysis					
D (0 1')	D . T . 1	- Demography)	1			1	
Data Quality	Data Trends	Other (Distribution	1			1	
		of Concomitant					
		Medication and					
Data Ossalitas	Data Tara Is	volume by site)				1	
Data Quality	Data Trends	Other (Distribution				1	
		of Medical History					
		terms and volume					
Data Ossalitas	Data Tara Is	by Site)		1			
Data Quality	Data Trends	Other (Number of		1			
Data Quality	Data Tranda	reference value)	1				
Data Quality	Data Trends	Other (PCR - Vital	1				
Data Quality	Data Trends	Signs)		1			
Data Quality	Data Trends	Other (Variability of		1			
Data Quality	Data Trends	assessment data)	1	9	3	4	3
Data Quanty	Data Helius	Query response time (all DP)	1	9	3	4	3
Data Quality	Data Trends	Repeated values	1	1	1		3
Data Quality	Data Helius	(freq & rate)	1	1	1)
Data Quality	Discrepancy	Manual query rate	1	2	1	1	1
Data Quality	Management	ivianual query rate	1		1	1	1
Data Quality	Discrepancy	Number of queries		1		1	
Data Quality	Management	resulting in data		1		1	
	Management	resulting in uata				<u> </u>	

			1.				
			統	2.			
			計	実		4.	
			的	施	3.	設	
			な	経	1	定	無
Category	Sub-Category	Risk Indicator	根	験	と	し	□
	and Suite golf	11.011 21.010	拠	を	2	て	答
			を	基	両	い	П
			基	に	方	な	
			に	設		い	
			設	定			
			定				
		change (critical DP)					
Data Quality	Discrepancy	Query aging (all		7	1	1	2
	Management	DP)					
Data Quality	Discrepancy	Query rate	4	10	3	4	1
	Management						
Data Quality	Discrepancy	Query rate of those		2			
	Management	resulting in a data					
		change					
Data Quality	Discrepancy	Reissued manual			1		
	Management	query rate					
Data Quality	Discrepancy	Reissued query		1			
	Management	count (critical DP)					
Data Quality	Patient Compliance	eDiary Compliance		1	1	1	
Data Quality	PI Oversight	Frequency of PI			1		
-		EDC review					
Essential	Site Compliance	Submission of		4	1	1	
Documents		safety report to site					
		and EC/IRB					
Essential	CRA Compliance	Investigator Site		2			
Documents		File Review					
		compliance					
Essential	CRA Compliance	Monitoring Visit		4	1	1	
Documents		Report Approval					
		Compliance					
		1	I .	l	l		

		1.				
			2.			
		計	実		4.	
		的	施	3.	設	
		な	経	1	定	無
Sub-Category	Rick Indicator	根	験	と	し	回
Sub-Category	Risk indicator	拠	を	2	て	答
		を	基	両	V	合
		基	に	方	な	
		に	設		い	
		設	定			
		定				
Study Compliance	Submission of				1	
	essential documents					
	to site					
Patient Compliance	IP compliance rate		6	1		
Protocol Compliance	Deviation Outliers	1	7	2	4	4
Protocol Compliance	Eligibility				2	1
	deviations rate					
Protocol Compliance	Major protocol	1	3	2		
	deviation rate					
Protocol Compliance	Minor protocol	1				
	deviation rate					
Protocol Compliance	Subject Visit	1	3	1	1	
	Timeliness					
Protocol Compliance	Volume of protocol	2	14	1	3	
	deviations					
Site Compliance	General or site			1		
	issues - aging					
Site Compliance	Number of		2	1		
	informed consent					
	issues					
Site Compliance	Rate of Data	1	4			2
	Integrity Issues					
Site Compliance	Rate of Human		1			
	Protocol Compliance Protocol Compliance Protocol Compliance Protocol Compliance Protocol Compliance Protocol Compliance Site Compliance Site Compliance	Study Compliance Submission of essential documents to site Patient Compliance Protocol Compliance Protocol Compliance Protocol Compliance Protocol Compliance Protocol Compliance Major protocol deviation rate Protocol Compliance Minor protocol deviation rate Protocol Compliance Subject Visit Timeliness Protocol Compliance Volume of protocol deviations Site Compliance General or site issues - aging Site Compliance Number of informed consent issues Site Compliance Rate of Data Integrity Issues	Sub-Category Risk Indicator 統計的な機模型を基準に設定 Study Compliance Submission of essential documents to site Image: Compliance of essential documents to site Patient Compliance IP compliance rate Image: Compliance of essential documents to site Protocol Compliance Deviation Outliers 1 Protocol Compliance Eligibility deviations rate 1 Protocol Compliance Major protocol deviation rate 1 Protocol Compliance Subject Visit Timeliness 1 Protocol Compliance Volume of protocol deviations 2 Site Compliance General or site issues - aging 1 Site Compliance Number of informed consent issues 1 Site Compliance Rate of Data Integrity Issues 1	Sub-Category Risk Indicator	Sub-Category Risk Indicator 統	Risk Indicator

		1.				
		計	実		4.	
		的	施	3.	設	
		な	経	1	定	無
Sub-Category	Rick Indicator	根	験	と	し	回
Sub-Category	Risk ilidicator	拠	を	2	て	答
		を	基	両	٧٧	合
		基	に	方	な	
		に	設		٧٧	
		設	定			
		定				
	Protection Issues					
Site Compliance	Rate of Issues		1	1	1	
Site Compliance	Site Issue Outlier		3		1	
Adverse Events	AE causality		2		2	
	assessment					
	distribution per site					
Adverse Events	AE grade		1		2	
	distribution per site					
Adverse Events	AE rate	6	9	5	10	
Adverse Events	Number of AE's of		3			
	special interest					
Adverse Events	Number of patients		1			
	with unresolved					
	AEs					
Adverse Events	Rate of		2		3	
	discontinuation due					
	to AE					
Adverse Events	Trend analysis on	1			1	1
	types of Aes					
Adverse Events	Trend analysis on		1			
	types of AEs					
Lab Data	Trend analysis on	3	3	1		
	lab data					
Serious Adverse	SAE rate	4	8		2	
	Adverse Events Lab Data	Protection Issues Site Compliance Rate of Issues Site Compliance Site Issue Outlier Adverse Events AE causality assessment distribution per site Adverse Events AE grade distribution per site Adverse Events AE rate Adverse Events Number of AE's of special interest Adverse Events Number of patients with unresolved AEs Adverse Events Rate of discontinuation due to AE Adverse Events Trend analysis on types of Aes Adverse Events Trend analysis on types of AEs Lab Data Trend analysis on lab data	Sub-Category Risk Indicator 統計的な程標準度 Risk Indicator 根拠を差差にご設定 Example of Protection Issues Protection Issues Site Compliance Rate of Issues Site Compliance Site Issue Outlier Adverse Events AE causality assessment distribution per site Adverse Events AE grade distribution per site Adverse Events Number of AE's of special interest Adverse Events Number of patients with unresolved AEs Adverse Events Rate of discontinuation due to AE Adverse Events Trend analysis on types of Aes Adverse Events Trend analysis on types of AEs Lab Data Trend analysis on lab data	Sub-Category Risk Indicator 統 接 驗 地 を を 基 基 に に 設 設 定 定 Site Compliance Protection Issues 1 Site Compliance Rate of Issues Outlier 3 Adverse Events AE causality assessment distribution per site 2 Adverse Events AE grade distribution per site 1 Adverse Events AE rate 6 9 Adverse Events Number of AE's of special interest 3 Adverse Events Number of patients with unresolved AEs 1 Adverse Events Rate of discontinuation due to AE 2 Adverse Events Trend analysis on types of Aes 1 Adverse Events Trend analysis on types of AEs 1 Lab Data Trend analysis on lab data 3	Sub-Category Risk Indicator 統	Risk Indicator

					ı	l	
			1.				
			統	2.			
			計	実		4.	
			的	施	3.	設	
			な	経	1	定	無
Category	Sub-Category	Risk Indicator	根	験	と	し	回
Cutogory	Sub Category	Risk indicator	拠	を	2	て	答
			を	基	両	い	
			基	に	方	な	
			に	設		い	
			設	定			
			定				
	Events						
Safety	Study Drug	Discontinuation rate		3	1	2	
	Discontinuation						
Safety	Study Drug	Rate of		1			
	Discontinuation	discontinuation due					
		to SAE					
Safety	Study Drug	Temporary		1		1	
	Discontinuation	discontinuation					
Staffing, Facilities	PI Oversight	PI's presence during		1			
and Supplies		monitoring visit					
Staffing, Facilities	Site/Staff Turnover	Number of changes		3	2		
and Supplies		in PI, sub PI or					
		other (study co-ord)					
Subject	Enrollment	Enrollment rate		3	4	3	
Recruitment and							
Discontinuation							
Subject	Enrollment	Other (Increased			1		
Recruitment and		sampling)					
Discontinuation							
Subject	Enrollment	Other (Number of				1	
Recruitment and		Re-Screening)					
Discontinuation							
Subject	Enrollment	Total Screened			2		
Recruitment and							

Category	Sub-Category	Risk Indicator	1. 統計的な根拠を基に設定	2. 実施経験を基に設定	3. 1 と 2 両 方	4. 設定していない	無 回 答
Discontinuation Subject	Screen Failures	Screen fail rate	2	4	1	4	2
Recruitment and							
Discontinuation Subject	Subject	Number or rate of		1			
Recruitment and	Discontinuation	subjects lost to		1			
Discontinuation		follow up					
Subject	Subject	Subject	5	8	3	2	3
Recruitment and	Discontinuation	discontinuation rate					
Discontinuation							

RI リスク評価の閾値 閾値の設定その他

Category	Sub-Category	Risk Indicator	閾値設定_その他	件数
CRA/On-site	CRA Compliance	Monitoring	モニタリング手順	1
Workload		visit/activities delays	書での規定を参考	
			に設定	
CRA/On-site	CRA Compliance	Monitoring	絶対値の閾値は設	1
Workload		visit/activities delays	定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Data Quality	CRF Completion	Missing pages	絶対値の閾値は設	1
		(critical forms)	定していない。統計	

Category	Sub-Category	Risk Indicator	閾値設定_その他	件数
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Data Quality	CRF Completion	Timeliness of data	eCRF入力マニュア	3
		entry	ルでの規定を参考	
			に設定	
Data Quality	CRF Completion	Timeliness of data	絶対値の閾値とあ	1
		entry	わせて、統計処理で	
			算出した各施設の	
			スコアに閾値を設	
			定(施設間比較を目	
			的)。	
Data Quality	Data Trends	Query response time	想定	2
		(all DP)		
Data Quality	Discrepancy	Manual query rate	絶対値の閾値は設	1
	Management		定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Data Quality	Discrepancy	Manual query rate	例えば「±2SD 以上	1
	Management		/以下」のような範	
			囲で設定	
Data Quality	Discrepancy	Query aging (all DP)	絶対値の閾値とあ	1
	Management		わせて、統計処理で	
			算出した各施設の	
			スコアに閾値を設	
			定(施設間比較を目	
			的)。	
Data Quality	Discrepancy	Query aging (all DP)	想定	2
	Management			
Data Quality	Discrepancy	Query rate	実施経験がない場	1
	Management		合は数字に明確な	
			根拠のないまま設	

Category	Sub-Category	Risk Indicator	閾値設定_その他	件数
			定することもある	
Data Quality	Discrepancy	Query rate	絶対値の閾値は設	1
	Management		定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Essential Documents	Study Compliance	Submission of	絶対値の閾値は設	1
		essential documents	定していない。統計	
		to site	処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Issue Management	Protocol Compliance	Deviation Outliers	実施経験がない場	1
			合は数字に明確な	
			根拠のないまま設	
			定することもある	
Issue Management	Protocol Compliance	Deviation Outliers	絶対値の閾値は設	1
			定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Issue Management	Protocol Compliance	Deviation Outliers	想定	3
Issue Management	Protocol Compliance	Eligibility deviations	想定	1
		rate		
Issue Management	Site Compliance	Rate of Data	例えば「±2SD 以上	2
		Integrity Issues	/以下」のような範	
			囲で設定	
Issue Management	Site Compliance	Rate of Issues	絶対値の閾値とあ	1
			わせて、統計処理で	
			算出した各施設の	
			スコアに閾値を設	
			定(施設間比較を目	
			的)。	

Category	Sub-Category	Risk Indicator	閾値設定_その他	件数
Issue Management	Site Compliance	Site Issue Outlier	絶対値の閾値は設	1
			定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Safety	Adverse Events	AE rate	絶対値の閾値は設	1
			定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Safety	Adverse Events	Trend analysis on	実施経験がない場	1
		types of AEs	合は数字に明確な	
			根拠のないまま設	
			定することもある	
Safety	Serious Adverse	SAE rate	絶対値の閾値は設	1
	Events		定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Subject Recruitment	Enrollment	Enrollment rate	絶対値の閾値は設	1
and Discontinuation			定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Subject Recruitment	Screen Failures	Screen fail rate	Expected rate 🏂	1
and Discontinuation			Protocolに設定され	
			ている場合はそれ	
			を用いる。	
Subject Recruitment	Screen Failures	Screen fail rate	絶対値の閾値は設	1
and Discontinuation			定していない。統計	
			処理で算出した各	

Category	Sub-Category	Risk Indicator	閾値設定_その他	件数
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	
Subject Recruitment	Subject	Subject	Expected rate ガミ	1
and Discontinuation	Discontinuation	discontinuation rate	Protocol に設定され	
			ている場合はそれ	
			を用いる。	
Subject Recruitment	Subject	Subject	プロトコルの症例	1
and Discontinuation	Discontinuation	discontinuation rate	数設計時の想定中	
			止率を参考に設定	
Subject Recruitment	Subject	Subject	絶対値の閾値は設	1
and Discontinuation	Discontinuation	discontinuation rate	定していない。統計	
			処理で算出した各	
			施設のスコアに閾	
			値を設定(施設間比	
			較を目的)。	

RI リスク評価の閾値 試験途中での変更

Category	Sub-Category	Risk Indicator	可	不可	無回答
CRA/On-site Workload	CRA Compliance	CRA compliance with	1		2
		monitoring plan			
CRA/On-site Workload	CRA Compliance	Monitoring report delays	2		
CRA/On-site Workload	CRA Compliance	Monitoring	2	1	1
		visit/activities delays			
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs	3		1
		events			
CRA/On-site Workload	CRF Review	Volume of SDV (data	3		
		points)			
CRA/On-site Workload	CRF Review	Volume of SDV (patient	2	1	
		visits)			
Data Quality	CRF Completion	Missing labs	2		
Data Quality	CRF Completion	Missing pages	5		
Data Quality	CRF Completion	Missing pages (critical		2	

Category	Sub-Category	Risk Indicator	可	不可	無回答
		forms)			
Data Quality	CRF Completion	Missing visits	1		1
Data Quality	CRF Completion	Timeliness of data entry	27	6	5
Data Quality	CRF Completion	Timeliness of data entry	5	1	1
		(AEs)			
Data Quality	CRF Completion	Timeliness of data entry	1		
		(SAEs)			
Data Quality	Data Trends	Efficacy reading post			1
		drug administration			
Data Quality	Data Trends	Other (Change from	1		
		baseline - Weight)			
Data Quality	Data Trends	Other (Distribution and	1		
		Outlier analysis -			
		Demography)			
Data Quality	Data Trends	Other (Distribution of	2		
		Concomitant Medication			
		and volume by site)			
Data Quality	Data Trends	Other (Distribution of	1		
		Medical History terms			
		and volume by Site)			
Data Quality	Data Trends	Other (Number of	1		
		reference value)			
Data Quality	Data Trends	Other (PCR - Vital	1		
		Signs)			
Data Quality	Data Trends	Other (Variability of	1		
		assessment data)			
Data Quality	Data Trends	Query response time (all	12	3	5
		DP)			
Data Quality	Data Trends	Repeated values (freq &	3		3
		rate)			
Data Quality	Discrepancy	Manual query rate	5	1	
	Management				
Data Quality	Discrepancy	Number of queries	2		

Category	Sub-Category	Risk Indicator	可	不可	無回答
	Management	resulting in data change (critical DP)			
Data Quality	Discrepancy Management	Query aging (all DP)	7	4	
Data Quality	Discrepancy Management	Query rate	14	4	4
Data Quality	Discrepancy Management	Query rate of those resulting in a data change	2		
Data Quality	Discrepancy Management	Reissued manual query rate			1
Data Quality	Discrepancy Management	Reissued query count (critical DP)	1		
Data Quality	Patient Compliance	eDiary Compliance	2	1	
Data Quality	PI Oversight	Frequency of PI EDC review			1
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	5		1
Essential Documents	CRA Compliance	Investigator Site File Review compliance	2		
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	6		
Essential Documents	Study Compliance	Submission of essential documents to site		1	
Investigational Product	Patient Compliance	IP compliance rate	7		
Issue Management	Protocol Compliance	Deviation Outliers	9	5	4
Issue Management	Protocol Compliance	Eligibility deviations rate	1	1	1
Issue Management	Protocol Compliance	Major protocol deviation rate	4	1	1
Issue Management	Protocol Compliance	Minor protocol deviation rate		1	
Issue Management	Protocol Compliance	Subject Visit Timeliness	4		2
Issue Management	Protocol Compliance	Volume of protocol	16	3	1

Category	Sub-Category	Risk Indicator	可	不可	無回答
		deviations			
Issue Management	Site Compliance	General or site issues - aging			1
Issue Management	Site Compliance	Number of informed consent issues	2		1
Issue Management	Site Compliance	Rate of Data Integrity Issues	7		
Issue Management	Site Compliance	Rate of Human Protection Issues	1		
Issue Management	Site Compliance	Rate of Issues		1	2
Issue Management	Site Compliance	Site Issue Outlier	3	1	
Safety	Adverse Events	AE causality assessment distribution per site	3	1	
Safety	Adverse Events	AE grade distribution per site	1	2	
Safety	Adverse Events	AE rate	19	7	4
Safety	Adverse Events	Number of AE's of special interest	3		
Safety	Adverse Events	Number of patients with unresolved AEs	1		
Safety	Adverse Events	Rate of discontinuation due to AE	4	1	
Safety	Adverse Events	Trend analysis on types of Aes	1	1	1
Safety	Adverse Events	Trend analysis on types of AEs	1		
Safety	Lab Data	Trend analysis on lab	7		
Safety	Serious Adverse Events	SAE rate	10	3	1
Safety	Study Drug Discontinuation	Discontinuation rate	3	2	1
Safety	Study Drug	Rate of discontinuation	1		

Category	Sub-Category	Risk Indicator	可	不可	無回答
	Discontinuation	due to SAE			
Safety	Study Drug	Temporary	2		
	Discontinuation	discontinuation			
Staffing, Facilities and	PI Oversight	PI's presence during	1		
Supplies		monitoring visit			
Staffing, Facilities and	Site/Staff Turnover	Number of changes in PI,	3		2
Supplies		sub PI or other (study co-			
		ord)			
Subject Recruitment and	Enrollment	Enrollment rate	7	1	2
Discontinuation					
Subject Recruitment and	Enrollment	Other (Increased			1
Discontinuation		sampling)			
Subject Recruitment and	Enrollment	Other (Number of Re-		1	
Discontinuation		Screening)			
Subject Recruitment and	Enrollment	Total Screened	1		1
Discontinuation					
Subject Recruitment and	Screen Failures	Screen fail rate	7	2	4
Discontinuation					
Subject Recruitment and	Subject Discontinuation	Number or rate of	1		
Discontinuation		subjects lost to follow up			
Subject Recruitment and	Subject Discontinuation	Subject discontinuation	18	1	2
Discontinuation		rate			

RI 試験ごとの適用の有無 1.どの試験でも適用、3.試験の相

			全	第I	第	第	第
Category	Sub-Category	Risk Indicator	試	相	II	III	IV
			験	1日	相	相	相
CRA/On-site	CRA Compliance	CRA compliance	3	0	0	0	0
Workload		with monitoring plan					
CRA/On-site	CRA Compliance	Monitoring report	0	0	0	0	0
Workload		delays					
CRA/On-site	CRA Compliance	Monitoring	4	0	0	0	0
Workload		visit/activities delays					

			全	第I	第	第	第
Category	Sub-Category	Risk Indicator	試	相	II	III	IV
			験	IH	相	相	相
CRA/On-site	CRF Review	Unreported	2	0	0	0	0
Workload		AEs/SAEs events					
CRA/On-site	CRF Review	Volume of SDV (data	1	0	0	0	0
Workload		points)					
CRA/On-site	CRF Review	Volume of SDV	1	0	1	1	1
Workload		(patient visits)					
Data Quality	CRF Completion	Missing labs	1	0	1	1	0
Data Quality	CRF Completion	Missing pages	2	0	1	1	1
Data Quality	CRF Completion	Missing pages	2	0	1	1	0
		(critical forms)					
Data Quality	CRF Completion	Missing visits	0	0	1	1	0
Data Quality	CRF Completion	Timeliness of data	20	1	8	10	3
		entry					
Data Quality	CRF Completion	Timeliness of data	4	0	1	2	1
		entry (AEs)					
Data Quality	CRF Completion	Timeliness of data	0	0	0	0	0
		entry (SAEs)					
Data Quality	Data Trends	Efficacy reading post	1	0	0	0	0
		drug administration					
Data Quality	Data Trends	Other (Change from	1	0	1	1	0
		baseline - Weight)					
Data Quality	Data Trends	Other (Distribution	0	0	1	1	1
		and Outlier analysis -					
		Demography)					
Data Quality	Data Trends	Other (Distribution	0	1	2	2	2
		of Concomitant					
		Medication and					
		volume by site)					
Data Quality	Data Trends	Other (Distribution	0	0	1	1	1
		of Medical History					
		terms and volume by					
		Site)					
Data Quality	Data Trends	Other (Number of	1	0	0	0	0

Category	Sub-Category	Risk Indicator	全試験	第I 相	第 II 相	第 III 相	第 IV 相
		reference value)					
Data Quality	Data Trends	Other (PCR - Vital Signs)	1	0	1	1	0
Data Quality	Data Trends	Other (Variability of assessment data)	1	0	0	0	0
Data Quality	Data Trends	Outliers of results of lab exam	1	0	0	0	0
Data Quality	Data Trends	Query response time (all DP)	11	1	5	5	4
Data Quality	Data Trends	Repeated values (freq & rate)	6	0	0	0	0
Data Quality	Discrepancy Management	Manual query rate	2	0	3	3	1
Data Quality	Discrepancy Management	Number of queries resulting in data change (critical DP)	2	0	0	0	0
Data Quality	Discrepancy Management	Query aging (all DP)	4	0	2	2	1
Data Quality	Discrepancy Management	Query rate	12	1	4	5	3
Data Quality	Discrepancy Management	Query rate of those resulting in a data change	0	0	0	0	0
Data Quality	Discrepancy Management	Reissued manual query rate	1	0	0	0	0
Data Quality	Discrepancy Management	Reissued query count (critical DP)	0	0	0	0	0
Data Quality	Patient Compliance	eDiary Compliance	2	0	0	1	0
Data Quality	PI Oversight	Frequency of PI EDC review	1	0	0	0	0
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	4	0	0	0	0

Category	Sub-Category	Risk Indicator	全試験	第I 相	第 II 相	第 III 相	第 IV 相
Essential Documents	CRA Compliance	Investigator Site File Review compliance	1	0	0	0	0
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	4	0	1	1	0
Essential Documents	Study Compliance	Submission of essential documents to site	1	0	0	0	0
Investigational Product	Patient Compliance	IP compliance rate	5	0	1	1	0
Issue Management	Protocol Compliance	Deviation Outliers	9	1	2	2	2
Issue Management	Protocol Compliance	Eligibility deviations rate	0	0	1	1	1
Issue Management	Protocol Compliance	Major protocol deviation rate	3	0	1	1	1
Issue Management	Protocol Compliance	Minor protocol deviation rate	1	0	0	0	0
Issue Management	Protocol Compliance	Subject Visit Timeliness	4	1	2	2	1
Issue Management	Protocol Compliance	Volume of protocol deviations	8	0	5	7	1
Issue Management	Site Compliance	General or site issues - aging	1	0	0	0	0
Issue Management	Site Compliance	Number of informed consent issues	2	0	0	0	0
Issue Management	Site Compliance	Rate of Data Integrity Issues	4	1	1	2	1
Issue Management	Site Compliance	Rate of Human Protection Issues	1	0	0	0	0
Issue Management	Site Compliance	Rate of Issues	3	0	0	0	0
Issue Management	Site Compliance	Site Issue Outlier	1	0	0	0	0
Safety	Adverse Events	AE causality assessment	2	0	0	0	0

Category	Sub-Category	Risk Indicator	全試験	第I 相	第 II 相	第 III 相	第 IV 相
		distribution per site					
Safety	Adverse Events	AE grade distribution per site	1	0	0	0	0
Safety	Adverse Events	AE rate	15	0	6	8	2
Safety	Adverse Events	Number of AE's of special interest	1	0	0	0	0
Safety	Adverse Events	Number of patients with unresolved AEs	0	0	0	0	0
Safety	Adverse Events	Rate of discontinuation due to AE	2	0	2	2	1
Safety	Adverse Events	Trend analysis on types of Aes	3	0	0	0	0
Safety	Adverse Events	Trend analysis on types of AEs	1	0	0	0	0
Safety	Lab Data	Trend analysis on lab	3	1	3	3	1
Safety	Serious Adverse Events	SAE rate	8	1	5	5	2
Safety	Study Drug Discontinuation	Discontinuation rate	4	0	2	3	0
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE	0	0	0	0	0
Safety	Study Drug Discontinuation	Temporary discontinuation	0	0	1	1	1
Staffing, Facilities and Supplies	PI Oversight	PI's presence during monitoring visit	1	0	0	0	0
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	3	0	0	0	0
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	7	0	2	2	0

			全	第I	第	第	第
Category	Sub-Category	Risk Indicator	試	相	II	III	IV
			験	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	相	相	相
Subject Recruitment	Enrollment	Other (Increased	1	0	0	0	0
and Discontinuation		sampling)					
Subject Recruitment	Enrollment	Other (Number of	0	0	0	0	0
and Discontinuation		Re-Screening)					
Subject Recruitment	Enrollment	Total Screened	2	0	0	0	0
and Discontinuation							
Subject Recruitment	Screen Failures	Screen fail rate	6	1	4	4	2
and Discontinuation							
Subject Recruitment	Subject	Number or rate of	0	0	0	0	0
and Discontinuation	Discontinuation	subjects lost to					
		follow up					
Subject Recruitment	Subject	Subject	8	1	9	9	4
and Discontinuation	Discontinuation	discontinuation rate					

RI 試験ごとの適用の有無 2.試験期間

Category	Sub-Category	Risk Indicator	6	24	52	53
Data Quality	CRF Completion	Timeliness of data		1	1	1
		entry				
Data Quality	CRF Completion	Timeliness of data		1		1
		entry (AEs)				
Data Quality	Data Trends	Other (Change from	1			
		baseline - Weight)				
Data Quality	Data Trends	Other (PCR - Vital	1			
		Signs)				
Data Quality	Data Trends	Query response time				2
		(all DP)				
Data Quality	Discrepancy	Manual query rate				1
	Management					
Data Quality	Discrepancy	Query rate			1	1
	Management					
Data Quality	Patient Compliance	eDiary Compliance		1		_
Investigational Product	Patient Compliance	IP compliance rate	1			

Category	Sub-Category	Risk Indicator	6	24	52	53
Issue Management	Protocol Compliance	Major protocol				1
		deviation rate				
Issue Management	Protocol Compliance	Subject Visit	1			
		Timeliness				
Issue Management	Protocol Compliance	Volume of protocol		1	1	1
		deviations				
Issue Management	Site Compliance	Rate of Data Integrity			1	
		Issues				
Safety	Adverse Events	AE rate	1		1	2
Safety	Adverse Events	Rate of discontinuation	1			
		due to AE				
Safety	Lab Data	Trend analysis on lab	2			
		data				
Safety	Study Drug	Discontinuation rate	1		1	
	Discontinuation					
Subject Recruitment	Enrollment	Enrollment rate	2			
and Discontinuation						
Subject Recruitment	Screen Failures	Screen fail rate	1			
and Discontinuation						
Subject Recruitment	Subject	Subject discontinuation				2
and Discontinuation	Discontinuation	rate				

RI 試験ごとの適用の有無 4.試験の性質

Category	Sub-Category	Risk Indicator	D	才	不問
Data Quality	CRF Completion	Missing visits			1
Data Quality	CRF Completion	Timeliness of data entry	2		5
Data Quality	CRF Completion	Timeliness of data entry	1		1
		(AEs)			
Data Quality	Data Trends	Other (Change from	1		
		baseline - Weight)			
Data Quality	Data Trends	Other (Distribution of			1
		Concomitant			

Category			D	才	不問
		Medication and volume			
		by site)			
Data Quality	Data Trends	Other (PCR - Vital	1		
		Signs)			
Data Quality	Data Trends	Query response time (all DP)			3
Data Quality	Discrepancy	Manual query rate			2
	Management				
Data Quality	Discrepancy	Query aging (all DP)			1
	Management				
Data Quality	Discrepancy	Query rate	1		2
	Management				
Data Quality	Patient Compliance	eDiary Compliance	1		
Essential Documents	CRA Compliance	Monitoring Visit Report			1
		Approval Compliance			
Investigational Product	Patient Compliance	IP compliance rate	1		
Issue Management	Protocol Compliance	Deviation Outliers			1
Issue Management	Protocol Compliance	Major protocol			1
		deviation rate			
Issue Management	Protocol Compliance	Subject Visit Timeliness	1		1
Issue Management	Protocol Compliance	Volume of protocol	2		3
		deviations			
Issue Management	Site Compliance	Rate of Data Integrity	1		1
		Issues			
Safety	Adverse Events	AE rate	2		4
Safety	Adverse Events	Rate of discontinuation	1		
		due to AE			
Safety	Lab Data	Trend analysis on lab	2		1
		data			
Safety	Serious Adverse Events	SAE rate			3
Safety	Study Drug	Discontinuation rate	2		
	Discontinuation				

Category	Sub-Category	Risk Indicator	D	才	不問
Subject Recruitment and	Enrollment	Enrollment rate	2		
Discontinuation					
Subject Recruitment and	Screen Failures	Screen fail rate	1		1
Discontinuation					
Subject Recruitment and	Subject Discontinuation	Subject discontinuation			7
Discontinuation		rate			

RI 試験ごとの適用の有無 5.施設数

Category	Sub-Category	Risk Indicator	2	4	10	30
Data Quality	CRF Completion	Missing pages (critical			1	
		forms)				
Data Quality	CRF Completion	Timeliness of data	1	1	2	1
		entry				
Data Quality	CRF Completion	Timeliness of data		1		1
		entry (AEs)				
Data Quality	Data Trends	Other (Change from				1
		baseline - Weight)				
Data Quality	Data Trends	Other (Distribution of	1			
		Concomitant				
		Medication and volume				
		by site)				
Data Quality	Data Trends	Other (PCR - Vital				1
		Signs)				
Data Quality	Data Trends	Query response time	1	2	1	
		(all DP)				
Data Quality	Discrepancy	Manual query rate		1		
	Management					
Data Quality	Discrepancy	Query rate	1	1	2	
	Management					
Data Quality	Patient Compliance	eDiary Compliance				1
Investigational Product	Patient Compliance	IP compliance rate				1
Issue Management	Protocol Compliance	Deviation Outliers	1			

Category	Sub-Category	Risk Indicator	2	4	10	30
Issue Management	Protocol Compliance	Major protocol		1		
		deviation rate				
Issue Management	Protocol Compliance	Subject Visit	1			1
		Timeliness				
Issue Management	Protocol Compliance	Volume of protocol		1	2	1
		deviations				
Issue Management	Site Compliance	Rate of Data Integrity	1		1	
		Issues				
Safety	Adverse Events	AE rate		2	2	1
Safety	Adverse Events	Rate of discontinuation				1
		due to AE				
Safety	Lab Data	Trend analysis on lab	1			2
		data				
Safety	Serious Adverse Events	SAE rate	1		1	
Safety	Study Drug	Discontinuation rate			2	1
	Discontinuation					
Subject Recruitment	Enrollment	Enrollment rate				2
and Discontinuation						
Subject Recruitment	Screen Failures	Screen fail rate	1			1
and Discontinuation						
Subject Recruitment	Subject	Subject discontinuation	1	2		
and Discontinuation	Discontinuation	rate				

RI 試験ごとの適用の有無 6.症例数

Category	Sub-Category	Risk Indicator	21	30	40	100	300
Data Quality	CRF Completion	Missing pages			1		
		(critical forms)					
Data Quality	CRF Completion	Missing visits		1			
Data Quality	CRF Completion	Timeliness of data	1	1	1	1	1
		entry					
Data Quality	CRF Completion	Timeliness of data	1	1			1
		entry (AEs)					
Data Quality	Data Trends	Other (Change from				1	
		baseline - Weight)					

Category	Sub-Category	Risk Indicator	21	30	40	100	300
Data Quality	Data Trends	Other (PCR - Vital				1	
		Signs)					
Data Quality	Data Trends	Query response time	2	1	1		
		(all DP)					
Data Quality	Discrepancy	Manual query rate	1				
	Management						
Data Quality	Discrepancy	Query rate	1	1	1	1	
	Management						
Data Quality	Patient Compliance	eDiary Compliance					1
Investigational	Patient Compliance	IP compliance rate				1	
Product							
Issue Management	Protocol Compliance	Deviation Outliers		1			
Issue Management	Protocol Compliance	Major protocol	1				
		deviation rate					
Issue Management	Protocol Compliance	Subject Visit		1		1	
		Timeliness					
Issue Management	Protocol Compliance	Volume of protocol	1		1	1	1
		deviations					
Issue Management	Site Compliance	Rate of Data Integrity				1	
		Issues					
Safety	Adverse Events	AE rate	2	1	1	2	
Safety	Adverse Events	Rate of				1	
		discontinuation due					
		to AE					
Safety	Lab Data	Trend analysis on lab				2	
		data					
Safety	Serious Adverse	SAE rate		1	1		
	Events						
Safety	Study Drug	Discontinuation rate			1	2	
	Discontinuation						
Subject Recruitment	Enrollment	Enrollment rate				2	
and Discontinuation							
Subject Recruitment	Screen Failures	Screen fail rate		1		1	
and Discontinuation							

Category	Sub-Category	Risk Indicator	21	30	40	100	300
Subject Recruitment	Subject	Subject	2				
and Discontinuation	Discontinuation	discontinuation rate					

RI 試験ごとの適用の有無 7.その他

Category	Sub-Category	Risk Indicator	適用_その他	件数
CRA/On-site	CRA Compliance	Monitoring report	試験ごとに検討	2
Workload		delays		
CRA/On-site	CRF Review	Unreported	試験毎に判断	2
Workload		AEs/SAEs events		
CRA/On-site	CRF Review	Volume of SDV (data	試験ごとに検討	2
Workload		points)		
CRA/On-site	CRF Review	Volume of SDV	試験ごとに検討	1
Workload		(patient visits)		
Data Quality	CRF Completion	Missing pages	基準設定なし	1
Data Quality	CRF Completion	Missing pages	試験ごとに検討	1
Data Quality	CRF Completion	Missing visits	P1 試験は任意、施	1
			設数・症例数は規	
			定なし	
Data Quality	CRF Completion	Timeliness of data	P1 試験は任意、施	3
		entry	設数・症例数は規	
			定なし	
Data Quality	CRF Completion	Timeliness of data	該当するリスク	1
		entry	に応じて	
Data Quality	CRF Completion	Timeliness of data	該当する評価項	1
		entry	目がある場合	
Data Quality	CRF Completion	Timeliness of data	基準設定なし	2
		entry		
Data Quality	CRF Completion	Timeliness of data	試験ごとに検討	3
		entry		
Data Quality	CRF Completion	Timeliness of data	試験毎に判断	2
		entry		
Data Quality	CRF Completion	Timeliness of data	未定	1
		entry		
Data Quality	CRF Completion	Timeliness of data	試験毎に判断	1

Category	Sub-Category	Risk Indicator	適用_その他	件数
		entry (AEs)		
Data Quality	CRF Completion	Timeliness of data	試験毎に判断	1
		entry (SAEs)		
Data Quality	Data Trends	Query response time	該当するリスク	1
		(all DP)	に応じて	
Data Quality	Data Trends	Query response time	試験毎に判断	1
		(all DP)		
Data Quality	Data Trends	Query response time	未定	1
		(all DP)		
Data Quality	Discrepancy	Manual query rate	P1 試験は任意、施	1
	Management		設数・症例数は規	
			定なし	
Data Quality	Discrepancy	Manual query rate	試験毎に判断	1
	Management			
Data Quality	Discrepancy	Query aging (all DP)	P1 試験は任意、施	1
	Management		設数・症例数は規	
			定なし	
Data Quality	Discrepancy	Query aging (all DP)	該当するリスク	1
	Management		に応じて	
Data Quality	Discrepancy	Query aging (all DP)	試験ごとに検討	1
	Management			
Data Quality	Discrepancy	Query aging (all DP)	試験毎に判断	1
	Management			
Data Quality	Discrepancy	Query rate	基準設定なし	2
	Management			
Data Quality	Discrepancy	Query rate	試験ごとに検討	4
	Management			
Data Quality	Discrepancy	Query rate of those	試験ごとに検討	2
	Management	resulting in a data		
		change		
Data Quality	Discrepancy	Reissued query count	試験ごとに検討	1
	Management	(critical DP)		
Data Quality	Patient Compliance	eDiary Compliance	ePRO を使用して	1
			いる場合	
Essential	Site Compliance	Submission of safety	試験毎に判断	2

Category	Sub-Category	Risk Indicator	適用_その他	件数
Documents		report to site and		
		EC/IRB		
Essential	CRA Compliance	Investigator Site File	試験毎に判断	1
Documents		Review compliance		
Essential	CRA Compliance	Monitoring Visit	P1 試験は任意、施	1
Documents		Report Approval	設数・症例数は規	
		Compliance	定なし	
Essential	CRA Compliance	Monitoring Visit	試験毎に判断	1
Documents		Report Approval		
		Compliance		
Investigational	Patient Compliance	IP compliance rate	試験ごとに検討	2
Product				
Issue Management	Protocol	Deviation Outliers	試験ごとに検討	1
	Compliance			
Issue Management	Protocol	Deviation Outliers	未定	1
	Compliance			
Issue Management	Protocol	Eligibility deviations	未定	1
	Compliance	rate		
Issue Management	Protocol	Major protocol	試験毎に判断	2
	Compliance	deviation rate		
Issue Management	Protocol	Volume of protocol	P1 試験は任意、施	2
	Compliance	deviations	設数・症例数は規	
			定なし	
Issue Management	Protocol	Volume of protocol	該当するリスク	1
	Compliance	deviations	に応じて	
Issue Management	Protocol	Volume of protocol	基準設定なし	1
	Compliance	deviations		
Issue Management	Protocol	Volume of protocol	試験ごとに検討	2
	Compliance	deviations		
Issue Management	Protocol	Volume of protocol	試験毎に判断	3
	Compliance	deviations		
Issue Management	Site Compliance	Number of informed	未定	1
		consent issues		
Issue Management	Site Compliance	Rate of Data Integrity	基準設定なし	1
		Issues		

Category	Sub-Category	Risk Indicator	適用_その他	件数
Issue Management	Site Compliance	Rate of Data Integrity	試験毎に判断	1
		Issues		
Issue Management	Site Compliance	Site Issue Outlier	試験毎に判断	3
Safety	Adverse Events	AE causality	該当するリスク	1
		assessment	に応じて	
		distribution per site		
Safety	Adverse Events	AE causality	試験ごとに検討	1
		assessment		
		distribution per site		
Safety	Adverse Events	AE grade distribution	該当するリスク	2
		per site	に応じて	
Safety	Adverse Events	AE rate	P1 試験は任意、施	2
			設数・症例数は規	
			定なし	
Safety	Adverse Events	AE rate	該当するリスク	2
			に応じて	
Safety	Adverse Events	AE rate	基準設定なし	2
Safety	Adverse Events	AE rate	試験ごとに検討	2
Safety	Adverse Events	AE rate	試験毎に判断	1
Safety	Adverse Events	AE rate	未定	1
Safety	Adverse Events	Number of AE's of	該当する評価項	1
		special interest	目がある場合	
Safety	Adverse Events	Number of AE's of	試験ごとに検討	1
		special interest		
Safety	Adverse Events	Number of patients	試験ごとに検討	1
		with unresolved AEs		
Safety	Adverse Events	Rate of	該当するリスク	1
		discontinuation due to	に応じて	
		AE		
Safety	Adverse Events	Rate of	試験ごとに検討	1
		discontinuation due to		
		AE		
Safety	Lab Data	Trend analysis on lab	該当するリスク	1
		data	に応じて	

Category	Sub-Category	Risk Indicator	適用_その他	件数
Safety	Lab Data	Trend analysis on lab	基準設定なし	1
		data		
Safety	Lab Data	Trend analysis on lab	試験毎に判断	1
		data		
Safety	Serious Adverse	SAE rate	P1 試験は任意、施	2
	Events		設数・症例数は規	
			定なし	
Safety	Serious Adverse	SAE rate	試験ごとに検討	1
	Events			
Safety	Serious Adverse	SAE rate	試験毎に判断	1
	Events			
Safety	Study Drug	Discontinuation rate	該当するリスク	1
	Discontinuation		に応じて	
Safety	Study Drug	Rate of	試験ごとに検討	1
	Discontinuation	discontinuation due to		
		SAE		
Safety	Study Drug	Temporary	試験毎に判断	1
	Discontinuation	discontinuation		
Staffing, Facilities	Site/Staff Turnover	Number of changes in	試験ごとに検討	1
and Supplies		PI, sub PI or other		
		(study co-ord)		
Staffing, Facilities	Site/Staff Turnover	Number of changes in	試験毎に判断	1
and Supplies		PI, sub PI or other		
		(study co-ord)		
Subject Recruitment	Enrollment	Enrollment rate	基準設定なし	1
and Discontinuation				
Subject Recruitment	Enrollment	Enrollment rate	試験毎に判断	1
and Discontinuation				
Subject Recruitment	Enrollment	Enrollment rate	未定	1
and Discontinuation				
Subject Recruitment	Enrollment	Other (Number of Re-	該当するリスク	1
and Discontinuation		Screening)	に応じて	
Subject Recruitment	Screen Failures	Screen fail rate	基準設定なし	1
and Discontinuation				
Subject Recruitment	Screen Failures	Screen fail rate	試験ごとに検討	1

Category	Sub-Category	Risk Indicator	適用_その他	件数
and Discontinuation				
Subject Recruitment	Screen Failures	Screen fail rate	試験毎に判断	1
and Discontinuation				
Subject Recruitment	Subject	Number or rate of	試験ごとに検討	1
and Discontinuation	Discontinuation	subjects lost to follow		
		up		
Subject Recruitment	Subject	Subject	A-5 設問で CM 実	1
and Discontinuation	Discontinuation	discontinuation rate	施と判断した試	
			験では,基本的に	
			設定。以下全て同	
			じ。	
Subject Recruitment	Subject	Subject	P1 試験は任意、施	4
and Discontinuation	Discontinuation	discontinuation rate	設数・症例数は規	
			定なし	
Subject Recruitment	Subject	Subject	基準設定なし	1
and Discontinuation	Discontinuation	discontinuation rate		
Subject Recruitment	Subject	Subject	試験ごとに検討	1
and Discontinuation	Discontinuation	discontinuation rate		
Subject Recruitment	Subject	Subject	試験毎に判断	1
and Discontinuation	Discontinuation	discontinuation rate		
Subject Recruitment	Subject	Subject	未定	1
and Discontinuation	Discontinuation	discontinuation rate		

RI 設定して有用でなかった RI 項目

				項目は	
C-4	Carla Cata a a sur	D:-1- I., 4:4	回答い	有用	非有用
Category	Sub-Category	Risk Indicator	いえ数	か?回	率(%)
				答数	
Subject	Screen Failures	Screen fail rate	3	9	33.3
Recruitment and					
Discontinuation					
Data Quality	Discrepancy	Query rate	2	17	11.8
	Management				
Safety	Adverse Events	AE rate	2	20	10.0
Subject	Subject	Subject	2	10	20.0

Category	Sub-Category	Risk Indicator	回答いいえ数	項目は 有用 か?回 答数	非有用 率(%)
Recruitment and	Discontinuation	discontinuation rate			
Discontinuation					
CRA/On-site	CRA Compliance	Monitoring	1	3	33.3
Workload		visit/activities			
		delays			
Data Quality	CRF Completion	Timeliness of data	1	25	4.0
		entry			
Data Quality	Data Trends	Query response	1	14	7.1
		time (all DP)			
Data Quality	Discrepancy	Reissued manual	1	1	100.0
	Management	query rate			
Essential	Site Compliance	Submission of	1	4	25.0
Documents		safety report to site			
		and EC/IRB			
Essential	Study Compliance	Submission of	1	1	100.0
Documents		essential documents			
		to site			
Issue Management	Protocol	Deviation Outliers	1	14	7.1
	Compliance				
Issue Management	Site Compliance	Number of	1	3	33.3
		informed consent			
		issues			
Safety	Adverse Events	Trend analysis on	1	2	50.0
		types of Aes			
Subject	Enrollment	Other (Number of	1	1	100.0
Recruitment and		Re-Screening)			
Discontinuation					

C.Fraud Detection について

Fraud Detection 項目

接験者間のデータの分布を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。	Fraud Detection 項目	具体的手法	企業数
Correlation 変数間の相関を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 CRF データの繰り返された値(頻度と割合) 試験共通指標(目安)として設定しているが、実際に指標として設定した試験はない。 1 EDC で入力された値の最後がりが多い 1 Event dates 土曜日、日曜日の来院頻度を分析し、試験全体の傾向と異なる施設を検出する。 1 Initial value Screening/baseline のデータ分布を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Mean 平均値を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Missing 未報告データの割合を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Propagate value 繰り返しデータパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Proportion カテゴリカルデータを対象に、データの比率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Reporting rate AE, 併用薬など、Event が発生すると報告されるデータに関して、その報告率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Sequences outliers 外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。 1 Transition Pre と Post のデータの変化のパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータ分布を施設レベルで分析し、試験者内のデータを対していて分析し、対験者内のデータの変化のがあるを検出する。	Between-patient	被験者間のデータの分布を施設レベルで分析し、試	1
向と異なる施設を検出する。		験全体の傾向と異なる施設を検出する。	
CRF データの繰り返された値(頻度と割合) 試験共通指標(目安)として設定しているが、実際に指標として設定した試験はない。 1 EDC で入力された値の最後が 0 が多い 土曜日、日曜日の来院頻度を分析し、試験全体の傾向と異なる施設を検出する。 1 Event dates 土曜日、日曜日の来院頻度を分析し、試験全体の傾向と異なる施設を検出する。 1 Initial value Screening/baseline のデータ分布を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Mean 平均値を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Missing 未報告データの割合を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Propagate value 繰り返しデータパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Proportion カテゴリカルデータを対象に、データの比率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Reporting rate AE, 併用薬など、Event が発生すると報告されるデータに関して、その報告率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Sequences outliers 外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。 1 Transition Pre と Post のデータの変化のパターンを施設レベルで分析し、試験ならのデータ分布を施設レベルで分析し、試験ならのデータ分布を施設レベルで分析し、試験ならのデータ分布を施設レベルで分析し、試験ならので分析し、対験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験なら施設を検出する。 1	Correlation	変数間の相関を施設レベルで分析し、試験全体の傾	1
Table Ta		向と異なる施設を検出する。	
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Proportion カテゴリカルデータを対象に、データの比率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Reporting rate AE, 併用薬など、Event が発生すると報告されるデータに関して、その報告率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Sequences outliers 外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。(Fraud よりも Miss conduct の可能性が高い) 1 Transition Pre と Post のデータの変化のパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 全体の傾向と異なる施設を検出する。 1	Propagate value	繰り返しデータパターンを施設レベルで分析し、試	1
レベルで分析し、試験全体の傾向と異なる施設を検出する。 Reporting rate AE, 併用薬など、Event が発生すると報告されるデータに関して、その報告率を施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Sequences outliers 外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。(Fraud よりも Miss conduct の可能性が高い) 1 Transition Pre と Post のデータの変化のパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 全体の傾向と異なる施設を検出する。		験全体の傾向と異なる施設を検出する。	
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ータに関して、その報告率を施設レベルで分析し、試験全体の傾向と異な。 Sequences outliers 外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。(Fraud よりも Miss conduct の可能性が高い) Transition Pre と Post のデータの変化のパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 1全体の傾向と異なる施設を検出する。		出する。	
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Sequences outliers外れ値を施設レベル分析し、試験全体の傾向と異なる施設を検出する。(Fraud よりも Miss conduct の可能性が高い)1TransitionPre と Post のデータの変化のパターンを施設レベルで分析し、試験全体の傾向と異なる施設を検出する。1Within-patient被験者内のデータ分布を施設レベルで分析し、試験 11全体の傾向と異なる施設を検出する。1		ータに関して、その報告率を施設レベルで分析し、	
Transition Pre と Post のデータの変化のパターンを施設レベル 1 で分析し、試験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 1 全体の傾向と異なる施設を検出する。		試験全体の傾向と異なる施設を検出する。	
Transition Pre と Post のデータの変化のパターンを施設レベル 1 で分析し、試験全体の傾向と異なる施設を検出する。 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 1 全体の傾向と異なる施設を検出する。	Sequences outliers	外れ値を施設レベル分析し、試験全体の傾向と異な	1
Transition Pre と Post のデータの変化のパターンを施設レベル で分析し、試験全体の傾向と異なる施設を検出する。 1 Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 全体の傾向と異なる施設を検出する。 1		る施設を検出する。(Fraud よりも Miss conduct の可	
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る。被験者内のデータ分布を施設レベルで分析し、試験 全体の傾向と異なる施設を検出する。1	Transition	Pre と Post のデータの変化のパターンを施設レベル	1
Within-patient 被験者内のデータ分布を施設レベルで分析し、試験 1 全体の傾向と異なる施設を検出する。		で分析し、試験全体の傾向と異なる施設を検出す	
全体の傾向と異なる施設を検出する。		る。	
	Within-patient	被験者内のデータ分布を施設レベルで分析し、試験	1
バイタルサイン 最終桁数の分布を調査 1		全体の傾向と異なる施設を検出する。	
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	バイタルサイン	最終桁数の分布を調査	1

Fraud Detection 項目	具体的手法	企業数
バイタルサイン	同一施設内で同じ組み合わせの入力(体重、脈拍、血	1
	圧)	
バイタルサイン	同一症例内で連続した同値の入力	1
脈拍	倍数(3、4倍)を調査	1

Risk Indicator 項目名(文献) Category, Sub-Category, Risk Indicator ごとの集計

Category	Sub-Category	Risk Indicator	件数
Data Quality	Discrepancy Management	Query rate	5
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	4
Data Quality	Discrepancy Management	Query count (critical DP)	4
Safety	Adverse Events	AE rate	4
Data Quality	CRF Completion	Timeliness of data entry	3
Issue Management	Site Compliance	Number of informed consent issues	3
Issue Management	Site Compliance	Site Issue Outlier	3
Safety	Serious Adverse Events	SAE rate	3
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	3
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	3
Data Quality	Data Trends	Query response time (all DP)	2
Data Quality	Discrepancy Management	Query aging (all DP)	2
Issue Management	Protocol Compliance	Volume of protocol deviations	2
Issue Management	Site Compliance	Rate of Data Integrity Issues	2
Safety	Study Drug Discontinuation	Discontinuation rate	2
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	2
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	1
CRA/On-site Workload	CRA Compliance	Monitoring report delays	1
Data Quality	Adverse Events	AE Errors	1
Data Quality	CRF Completion	Missing pages (critical forms)	1
Data Quality	CRF Completion	Timeliness of data entry	1

Category	Sub-Category	Risk Indicator	件数
Data Quality	CRF Completion	Timeliness of data entry	1
		(SAEs)	
Data Quality	Data Trends	Other(atypical pattern in	1
		electronic patient diaries	
		completion)	
Data Quality	Data Trends	Other(body temperature)	1
Data Quality	Data Trends	Other(data tampering to	1
		meet the eligibility criteria)	
Data Quality	Data Trends	Other(fraud in patient	1
		diaries completion)	
Data Quality	Data Trends	Other(psychometric	1
		properties of the scale)	
Data Quality	Data Trends	Other(QT interval)	1
Data Quality	Data Trends	Other(scoring that appears	1
		non-random)	
Data Quality	Discrepancy Management	Reissued manual query rate	1
Data Quality	Protocol Compliance	Other(inappropriate	1
		handling of blood samples)	
Issue Management	Protocol Compliance	Deviation Outliers	1
Issue Management	Protocol Compliance	Eligibility deviations rate	1
Issue Management	Protocol Compliance	Major protocol deviation	1
		rate	
Issue Management	Protocol Compliance	Rate of Subjects with	1
		Procedures Not Done	
Issue Management	Site Compliance	Issue resolution time	1
Issue Management	Site Compliance	Other(General concern)	1
Staffing, Facilities and	Site/Staff Turnover	Number of changes in PI,	1
Supplies		sub PI or other (study co-	
		ord)	
Staffing, Facilities and	Site/Staff Turnover	Number of non-PI site staff	1
Supplies		turnovers	
Subject Recruitment and	Subject Discontinuation	Number or rate of subjects	1
Discontinuation		lost to follow up	

Risk Indicator 項目名(文献) Category, Sub-Category ごとの集計

Category	Sub-Category	件数
Data Quality	Discrepancy Management	12
Issue Management	Site Compliance	10
Data Quality	Data Trends	9
CRA/On-site Workload	CRA Compliance	6
Data Quality	CRF Completion	6
Issue Management	Protocol Compliance	6
Safety	Adverse Events	4
Subject Recruitment and Discontinuation	Subject Discontinuation	4
Safety	Serious Adverse Events	3
Subject Recruitment and Discontinuation	Enrollment	3
Safety	Study Drug Discontinuation	2
Staffing, Facilities and Supplies	Site/Staff Turnover	2
Subject Recruitment and Discontinuation	Screen Failures	2
Data Quality	Adverse Events	1
Data Quality	Protocol Compliance	1

Risk Indicator 項目名(文献) Category ごとの集計

Category	件数
Data Quality	29
Issue Management	16
Safety	9
Subject Recruitment and Discontinuation	9
CRA/On-site Workload	6
Staffing, Facilities and Supplies	2

Risk Indicator 項目名(文献) Category, Sub-Category, Risk Indicator ごとの 文献数カウント

Category	Sub-Category	Risk Indicator	文献数	%
Data Quality	Discrepancy	Query rate	4	50.00
	Management			
Data Quality	CRF Completion	Timeliness of data entry	3	37.50
Issue Management	Site Compliance	Number of informed	3	37.50

Category	Sub-Category	Risk Indicator	文献数	%
		consent issues		
Safety	Adverse Events	AE rate	3	37.50
Subject Recruitment and	Enrollment	Enrollment rate	3	37.50
Discontinuation				
Subject Recruitment and	Subject Discontinuation	Subject discontinuation	3	37.50
Discontinuation		rate		
Data Quality	Data Trends	Query response time (all DP)	2	25.00
Data Quality	Discrepancy	Query aging (all DP)	2	25.00
	Management			
Issue Management	Protocol Compliance	Volume of protocol	2	25.00
		deviations		
Issue Management	Site Compliance	Site Issue Outlier	2	25.00
Safety	Serious Adverse Events	SAE rate	2	25.00
Safety	Study Drug	Discontinuation rate	2	25.00
	Discontinuation			
Subject Recruitment and	Screen Failures	Screen fail rate	2	25.00
Discontinuation				
CRA/On-site Workload	CRA Compliance	CRA compliance with	1	12.50
		monitoring plan		
CRA/On-site Workload	CRA Compliance	Monitoring report delays	1	12.50
CRA/On-site Workload	CRA Compliance	Monitoring	1	12.50
		visit/activities delays		
Data Quality	Adverse Events	AE Errors	1	12.50
Data Quality	CRF Completion	Missing pages (critical	1	12.50
		forms)		
Data Quality	CRF Completion	Timeliness of data entry	1	12.50
		(AEs)		
Data Quality	CRF Completion	Timeliness of data entry	1	12.50
		(SAEs)		
Data Quality	Data Trends	Other(atypical pattern in	1	12.50
		electronic patient diaries		
		completion)		
Data Quality	Data Trends	Other(body temperature)	1	12.50

Category	Sub-Category	Risk Indicator	文献数	%
Data Quality	Data Trends	Other(data tampering to	1	12.50
		meet the eligibility		
		criteria)		
Data Quality	Data Trends	Other(fraud in patient	1	12.50
		diaries completion)		
Data Quality	Data Trends	Other(psychometric	1	12.50
		properties of the scale)		
Data Quality	Data Trends	Other(QT interval)	1	12.50
Data Quality	Data Trends	Other(scoring that	1	12.50
		appears non-random)		
Data Quality	Discrepancy	Query count (critical	1	12.50
	Management	DP)		
Data Quality	Discrepancy	Reissued manual query	1	12.50
	Management	rate		
Data Quality	Protocol Compliance	Other(inappropriate	1	12.50
		handling of blood		
		samples)		
Issue Management	Protocol Compliance	Deviation Outliers	1	12.50
Issue Management	Protocol Compliance	Eligibility deviations	1	12.50
		rate		
Issue Management	Protocol Compliance	Major protocol deviation	1	12.50
		rate		
Issue Management	Protocol Compliance	Rate of Subjects with	1	12.50
		Procedures Not Done		
Issue Management	Site Compliance	Issue resolution time	1	12.50
Issue Management	Site Compliance	Other(General concern)	1	12.50
Issue Management	Site Compliance	Rate of Data Integrity	1	12.50
		Issues		
Staffing, Facilities and	Site/Staff Turnover	Number of changes in	1	12.50
Supplies		PI, sub PI or other (study		
		co-ord)		
Staffing, Facilities and	Site/Staff Turnover	Number of non-PI site	1	12.50
Supplies		staff turnovers		
Subject Recruitment and	Subject Discontinuation	Number or rate of	1	12.50

Category	Sub-Category	Risk Indicator	文献数	%
Discontinuation		subjects lost to follow up		

Risk Indicator 項目名(文献) Category, Sub-Category ごとの 文献数カウント

Category	Sub-Category	文献数	%
Data Quality	Data Trends	5	62.50
Data Quality	Discrepancy Management	4	50.00
Issue Management	Site Compliance	4	50.00
Data Quality	CRF Completion	3	37.50
Issue Management	Protocol Compliance	3	37.50
Safety	Adverse Events	3	37.50
Subject Recruitment	Enrollment	3	37.50
and Discontinuation			
Subject Recruitment	Subject Discontinuation	3	37.50
and Discontinuation			
Safety	Serious Adverse Events	2	25.00
Safety	Study Drug Discontinuation	2	25.00
Subject Recruitment	Screen Failures	2	25.00
and Discontinuation			
CRA/On-site	CRA Compliance	1	12.50
Workload			
Data Quality	Adverse Events	1	12.50
Data Quality	Protocol Compliance	1	12.50
Staffing, Facilities and	Site/Staff Turnover	1	12.50
Supplies			

Risk Indicator 項目名(文献) Category ごとの 文献数カウント

Category	文献数	%
Data Quality	7	87.50
Issue Management	5	62.50
Safety	5	62.50
Subject Recruitment and Discontinuation	4	50.00
CRA/On-site Workload	1	12.50
Staffing, Facilities and Supplies	1	12.50

文献 RI リスト

文献中の Risk	文献中の Risk TransCelerate-I		イング情報				
Indicator 項目名	Category	Sub-Category	Risk Indicator	閾値	補足	Reference	
Data entry delay	Data Quality	CRF Completion	Timeliness of data entry				
Rate of queries	Data Quality	Discrepancy Management	Query rate		We developed a data- driven risk assessment system to rank 133 investigator sites comprising 3442 subjects and identify those sites that pose a potential risk to the integrity of data collected in implantable cardiac device clinical trials. This included identification of specific risk factors and a weighted scoring	driven risk assessment system to rank 133	
Open query duration	Data Quality	Discrepancy Management	Query aging (all DP)				
Rate of re- opened queries	Data Quality	Discrepancy Management	Reissued manual query rate				
Rate of noncompliance	Issue Management	Site Compliance	Site Issue Outlier	-		[1]	
Unavailability of critical data	Data Quality	CRF Completion	Missing pages (critical forms)				
Rate of subject follow-up	Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up			This included identification of specific risk factors and	
noncompliance	Issue Management	Site Compliance	Site Issue Outlier		mechanism.		
Corrective actions pending	Issue Management	Site Compliance	Issue resolution time				

Severe noncompliance incidence	Issue Management	Protocol Compliance	Major protocol deviation rate
Informed consent violations	Issue Management	Site Compliance	Number of informed consent issues
Subject attrition	Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate
Site personnel replacement	Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)
Site personnel	Staffing, Facilities and	Site/Staff	Number of non-PI
attrition	Supplies	Turnover	site staff turnovers
Adverse event over-reporting	Safety	Adverse Events	AE rate
Adverse event under-reporting	Safety	Adverse Events	AE rate
Adverse event reporting delay	Data Quality	CRF Completion	Timeliness of data entry (AEs)
Unmonitored case report forms	CRA/On-site Workload	CRA Compliance	Monitoring report delays

Recent on-site monitor	CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays			
assessment	CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays			
Historical on-	CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays			
monitor assessment	CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays			
Frequency of on-site monitor visits	CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan			
General concern	Issue Management	Site Compliance	Other(General concern)	-	Subjective assessment of site performance and/or objective concerns not covered by triggers.	[2]
Overall CRF return rate	Issue Management	Site Compliance	Rate of Data Integrity Issues	Eg. <80% of expected CRFs	-	[2]

				received + >20 CRFs		
Return rate, specific CRF Return rate, Patient consent	Issue Management Issue Management	Site Compliance Site	Rate of Data Integrity Issues Number of informed	As above, for specific CRF As above, for	-	
form	issue Management	Compliance	consent issues	specific CRF		
Data query rate (overall)	Data Quality	Discrepancy Management	Query rate	Eg. >5% of data items missing or under query	-	
Data query rate (specific question)	Data Quality	Discrepancy Management	Query rate	As above, for specific CRF		
Data query resolution time	Data Quality	Data Trends	Query response time (all DP)	Eg. >50% of missing or queried data items outstanding for >3 months	-	

SAE rate (high)	Safety	Serious Adverse Events	SAE rate	Eg. number SAEs/person years on study > threshold (based on average for trial)	-	
SAE rate (low)	Safety	Serious Adverse Events	SAE rate	Eg. number SAEs/person years on Study < threshold (based on average for trial)	-	
Protocol deviation (treatment)	Issue Management	Protocol Compliance	Volume of protocol deviations	Eg. treatment administered when clinical	-	

Protocol deviation (eligibility)	Issue Management	Protocol Compliance	Eligibility deviations rate	tests out of range Eg. date of investigation out of range	-	-
Protocol deviation (procedure)	Issue Management	Protocol Compliance	Rate of Subjects with Procedures Not Done	Eg. failure to perform blood test when mandated	-	
Protocol deviation (withdrawal rate)	Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	Eg. >20% of patients at site recorded as completely withdrawn from trial	-	

High recruitment	Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	>30 patients (Trial 1); >10% patients (trial 2 –never met)	For exploratory prognostic analyses, a high recruitment trigger was defined retrospectively for all trials as a site ranked in the top 10% of sites ordered by recruitment.	
Missing informed consent	Issue Management	Site Compliance	Number of informed consent issues	【Low risk】 No instances of a missing informed consent 【Moderate risk】 — 【High risk】 At least one instance of a missing informed consent	-	[3]

Randomized per week active	Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	[Low risk] ≤5 % more than median value of all sites [Moderate risk] >5 and ≤15 % more than median value of all sites [High risk] >15 % more than median value of all sites	
Percent screen fail of total patients	Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	【Low risk】 ≤5 % more or less than median value of all sites 【Moderate risk】>5 and	

			1	1	 ٦
				≤15 % more	
				or less than	
				median value	
				of all sites	
				【High	
				risk】>15 %	
				more or less	
				than median	
				value of all	
				sites	
				[Low risk]	
				≤5 % more	
				than median	
				value of all	
				sites	
CDE .		CDE		[Moderate	
CRF entry	Data Quality	CRF	Timeliness of data	risk] >5 and	
response time		Completion	entry	≤15 % more	
				than median	
				value of all	
				sites	
				【High	
				risk] >15 %	

			more than median value of all sites
Queries per patient week Data Quality	Discrepancy Management	Query rate	【Low risk】 ≤5 % more or less than median value of all sites 【Moderate risk】>5 and ≤15 % more or less than median value of all sites with at least 2 queries per patient week 【High risk】>15 % more or less than median value of all

				sites with at least 2 queries per patient week	
Query response time	Data Quality	Data Trends	Query response time (all DP)	【Low risk】 ≤5 % more than median value of all sites 【Moderate risk】>5 and ≤15 % more than median value of all sites 【High risk】>15 % more than median value of all sites	

SAE per patient week	Safety	Serious Adverse Events	SAE rate	[Low risk] ≤5 % more or less than median value of all sites [Moderate risk] >5 and ≤15 % more or less than median value of all sites [High risk] >15 % more or less than median	
AE per patient week	Safety	Adverse Events	AE rate	【Low risk】 ≤5 % more or less than median value of all sites 【Moderate	

	1	1	T	T	$\overline{}$
				risk] >5 and	
				≤15 % more	
				or less than	
				median value	
				of all sites	
				【High	
				risk】>15 %	
				more or less	
				than median	
				value of all	
				sites	
				【Low risk】	
				≤15 % more	
				or less than	
				median value	
Percent				of all sites	
discontinued of	Subject Recruitment	Subject	Subject	[Moderate	
randomized	and Discontinuation	Discontinuation	discontinuation rate	risk] >15	
patient				and ≤30 %	
				more or less	
				than median	
				value of all	
				sites with an	

				observed percentage of at least 3 [High risk] >30 % more or less than median value of all sites with an observed percentage of at least 3		
misreporting of adverse events due to lack of training	Data Quality	Adverse Events	AE Errors	-	Atypically few adverse events recorded in Center A, with an atypically high proportion of serious adverse events in that center	[4]
data tampering to meet the eligibility criteria	Data Quality	Data Trends	Other(data tampering to meet the eligibility criteria)		Atypical distribution of a psychiatric score observed in all centers of Country B; the score value at the	

				eligibility visit determines patient eligibility
non-compliance to the protocol related to sloppiness	Issue Management	Site Compliance	Site Issue Outlier	Atypical propagation of respiratory rate, systolic blood pressure and diastolic blood pressure in Center C: more than 95 % of the observed values for those variables are duplicates of the values observed at the previous visit
inappropriate handling of blood samples	Data Quality	Protocol Compliance	Other(inappropriate handling of blood samples)	Atypically high within- patient variability for several laboratory results in Center D
fraud in patient diaries completion	Data Quality	Data Trends	Other(fraud in patient diaries completion)	Electronic patient diaries completed in a very concentrated period of time (only seconds or few minutes apart) in Center E

atypical pattern in electronic patient diaries completion	Data Quality	Data Trends	Other(atypical pattern in electronic patient diaries completion)		Time of completion of electronic patient diaries abnormally concentrated around the same evening time in Center F	
body temperature	Data Quality	Data Trends	Other(body temperature)	-	Histogram of mean temperatures (in degrees Celsius) in the 218 centers of a multinational clinical trial with two groups	[5]
QT interval	Data Quality	Data Trends	Other(QT interval)		Boxplot of QT interval durations (in ms) in centers 511 and 815 compared with the other centers	
early discontinuation	Safety	Study Drug Discontinuation	Discontinuation rate	A funnel plot with risk thresholds based on 95%(moderat e limits) and 99.7%(severe limits)	-	[6]

				confidence intervals.		
Queries per 100 fields	Data Quality	Discrepancy Management	Query rate			
Primary endpoint queries	Data Quality	Discrepancy Management	Query count (critical DP)			
Critical field queries	Data Quality	Discrepancy Management	Query count (critical DP)			
Time to query resolution	Data Quality	Discrepancy Management	Query aging (all DP)		This article provides a framework to assist	
Time from patient visit to CRF entry	Data Quality	CRF Completion	Timeliness of data entry	-	biopharmaceutical companies in selecting and	[7]
Protocol deviations	Issue Management	Protocol Compliance	Volume of protocol deviations		implementing a risk-based monitoring approach or selecting a service provider.	
Protocol deviation under/over reporting	Issue Management	Protocol Compliance	Deviation Outliers		selecting a service provider.	
Adverse events under/over reporting (by	Safety	Adverse Events	AE rate			

comparison with study median)						
Serious adverse event queries	Data Quality	Discrepancy Management	Query count (critical DP)			
Adverse event queries	Data Quality	Discrepancy Management	Query count (critical DP)			
Time to serious adverse event reporting	Data Quality	CRF Completion	Timeliness of data entry (SAEs)			
Enrollment rate	Subject Recruitment and Discontinuation	Enrollment	Enrollment rate			
Screenfail rate	Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate			
Discontinue rate	Safety	Study Drug Discontinuation	Discontinuation rate			
psychometric properties of the scale	Data Quality	Data Trends	Other(psychometric properties of the scale)	-	the expected relationship between items of a scale (intra-scale item consistency) and the expected relationship between items and total	[8]

				scores on different scales (inter-scale consistency)	
scoring that appears non-random	Data Quality	Data Trends	Other(scoring that appears non-random)	score patterns, for example, a majority of items are scored the same; variability, for example, a majority of item scores do not change from prior visit; unexpected change, for example, scores that are significantly different from the mean change from the prior visit, or a dramatic increase or decrease from the prior visit, and so forth.	[8]

D その他

D-2 QTI	を設定されている場合は以下に具体例を回答ください
有効性	・有効性評価不能症例/投与例の割合(被験者による中止、追跡不能、抗癌剤
	の場合は未検査で腫瘍評価ができない等)
	・主要評価データの欠測割合・件数
安全性	・有害事象発現率
	・DLT 評価可能症例から除外された症例数
中止、脱	・中止割合
落	・有害事象による中止
	・有害事象以外の理由による中止
	・同意撤回した被験者の割合・件数
	・治験薬を早期中止した被験者の割合・件数
逸脱	・逸脱件数
	・重要な選択除外基準を満たしていない被験者の割合
	・重大な逸脱をおこした症例の割合
その他	・主解析に必要な最小限の症例数を基準として適宜マージンを設定
	・追跡不能例の割合・件数・有害事象の報告遅れの割合・件数
	・適切な投与が行われていない被験者の割合(治験薬が全く投与されていな
	い、割付けられた治療群の治験薬を服薬しない重大な併用禁止薬違反など)
	・臨床検査値の基準値を基準にo%の Threshold を設定

D-3 CM を実	施するうえで参考にしているサイトや論文があれば教えてください。(自		
由記載)			
文献	A Statistical Approach to Risk-Based Monitoring (Buyse)		
	Strategies for dealing with fraud in clinical trials (Jay Herson)		
	Central site monitoring Results from a test of accuracy in identifying trials		
	and sites failing Food and Drug Administration inspection (Anne S Lindblad)		
	など		
FDA	A Risk-Based Approach to Monitoring of Clinical Investigations Questions		
	and Answers		
	Oversight of Clinical Investigations — A Risk-Based Approach to		
	Monitoring		
TransCelerate	Initiatives: Risk Based Monitoring		
	RBM Information Materials Modules: Risk-Based Monitoring Methodology		
	Position Paper: Risk Based Monitoring Methodology		
	Risk Assessment and Categorization Tool (RACT) Template		
	Risk Indicator Library		
	RISK-BASED QUALITY MANAGMENT:QUALITY TOLERANCE		
	LIMITS AND RISK REPORTING		
製薬協資料	・「リスクに基づくモニタリング(RBM)の導入上の課題と留意点」		
	・「臨床試験における QMS の実装に向けた実践的な取り組み~ケースス		
	タディを用いた品質管理ツールの現場での活用事例~」		
	・その他製薬協成果物 など		
その他	System vendor のトレーニング資料、DIA や学会資料 など		

D-4 CM を検	討・実施するうえで気になる点、困っている点などあれば教えてください。
(自由記載)	
CM 全般	・CMの実施可否の判定基準
	・CM の対象とする試験の規模
	・解析ソフトが無く Statistical monitoring が実施できていない
	・試験横断的な評価ができていない
	・CM 結果のモニターへの連絡・コミュニケーション方法(CM からのク
	エリーに対してどの程度までモニターがアクションするのか、KRI レビュ
	ー結果の原因分析・回答作成に CRA に多くのリソースがかかる)
	・シグナルレビューの効率(ノイズデータが多く処理に負荷がかかる)
	・各 Observation に対する Action と対応結果のマネジメント
	・CM からのクエリー・CRA からの回答のパターン化に陥りがち。問題の
	原因を精査し、施設の体制を整えるところまで介入が必要
KRI •	・KRIの設定基準・絞り込み
Threshold	・Threshold の適切な設定方法 (妥当性、試験規模に応じた設定の判断が難
	しい)
	・KRIごとの目的の明確化が必要である
	・KRI は多く設定しない方が良い(10 個以下程度)
	・KRI は経時的な変化を確認する必要がある
社内対応	・社内リソースが十分でないこと(リソースが不十分で KRI のレビュー
	が十分できないなど)
	・保管しておくべき成果物
	・社内的な一般化
その他	・CRO に委託する場合の業務範囲
	・QTLs の設定
	・CSR への記載方法
	・Risk の数
	・試験途中の見直し方法
	• 他社動向
	・品質とコストのバランス
	・まだ効果が見えない

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