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 Discontinuation	Subject Discontinuation	Subject discontinuation rate	22
Data Quality	Data Trends	Query response time (all DP)	21
Issue Management	Protocol Compliance	Volume of protocol deviations	20
Issue Management	Protocol Compliance	Deviation Outliers	19
Safety	Serious Adverse Events	SAE rate	14
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	14
Data Quality	Discrepancy Management	Query aging (all DP)	11
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	10
Investigational Product	Patient Compliance	IP compliance rate	8
Issue Management	Site Compliance	Rate of Data Integrity Issues	8
Data Quality	CRF Completion	Timeliness of data entry (AEs)	7
Issue Management	Protocol Compliance	Subject Visit Timeliness	7
Safety	Lab Data	Trend analysis on lab data	7
Data Quality	Data Trends	Repeated values (freq & rate)	6
Data Quality	Discrepancy Management	Manual query rate	6
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	6
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	6
Issue Management	Protocol Compliance	Major protocol deviation	6

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 to AE	5
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	5
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	4
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	4
Issue Management	Site Compliance	Site Issue Outlier	4
Safety	Adverse Events	AE causality assessment distribution per site	4
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	3
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	3
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	3
Data Quality	Patient Compliance	eDiary Compliance	3
Issue Management	Protocol Compliance	Eligibility deviations rate	3
Issue Management	Site Compliance	Number of informed consent issues	3
Issue Management	Site Compliance	Rate of Issues	3
Safety	Adverse Events	AE grade distribution per site	3
Safety	Adverse Events	Number of AE's of special interest	3
Safety	Adverse Events	Trend analysis on types of Aes	3
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 forms)	2
Data Quality	CRF Completion	Missing visits	2
Data Quality	CRF Completion	Timeliness of data entry (SAEs)	2
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	2
Data Quality	Discrepancy Management	Number of queries resulting in data change (critical DP)	2
Data Quality	Discrepancy Management	Query rate of those resulting in a data change	2
Essential Documents	CRA Compliance	Investigator Site File Review compliance	2
Safety	Study Drug Discontinuation	Temporary discontinuation	2
Subject Recruitment and Discontinuation	Enrollment	Total Screened	2
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 and Outlier analysis - Demography)	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	Outliers of results of lab exam	1

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

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

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

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

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

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 Discontinuation	Subject Discontinuation	17	53.13
Subject Recruitment and Discontinuation	Screen Failures	13	40.63
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 Discontinuation	Enrollment	8	25.00
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 Management	Manual query rate	3	0	0	3
Data Quality	Discrepancy Management	Number of queries resulting in data change (critical DP)	1	0	0	1
Data Quality	Discrepancy Management	Query aging (all DP)	8	0	0	4
Data Quality	Discrepancy Management	Query rate	19	1	1	5
Data Quality	Discrepancy Management	Query rate of those resulting in a data change	2	0	0	0
Data Quality	Discrepancy Management	Reissued manual query rate	0	1	0	0
Data Quality	Discrepancy Management	Reissued query count (critical DP)	1	0	0	0
Data Quality	Patient Compliance	eDiary Compliance	3	0	1	0
Data Quality	PI Oversight	Frequency of PI EDC review	0	0	1	0
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	1	3	2	0
Essential Documents	CRA Compliance	Investigator Site File Review compliance	2	1	0	0
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	4	0	0	2
Essential Documents	Study Compliance	Submission of essential documents to site	0	0	0	1
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 data	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 and Discontinuation	Subject Discontinuation	Subject discontinuation rate	14	6	1	8

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

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 entry	Site performance	1
Data Quality	CRF Completion	Timeliness of data entry	データ入力の遅れは、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)	1
Data Quality	CRF Completion	Timeliness of data entry	リソース状況	2
Data Quality	CRF Completion	Timeliness of data entry	施設の入力パフォーマンス	1
Data Quality	CRF Completion	Timeliness of data entry	施設の入力プロセス	1
Data Quality	CRF Completion	Timeliness of data entry	施設パフォーマンスの確認	1
Data Quality	CRF Completion	Timeliness of data entry (AEs)	Data Entry and Collection	1
Data Quality	CRF Completion	Timeliness of data entry (AEs)	施設の入力パフォーマンス	1
Data Quality	Data Trends	Other (Change from baseline - Weight)	安全性	1
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	プロトコルの誤認識や重要な安全性情報を見逃している	1

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

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

Category	Sub-Category	Risk Indicator	その他	件数
Issue Management	Site Compliance	Rate of Data Integrity Issues	施設パフォーマンスやプロトコルの理解	1
Issue Management	Site Compliance	Rate of Issues	Site or monitor responsive	1
Issue Management	Site Compliance	Site Issue Outlier	Poor performing sites	1
Safety	Adverse Events	AE rate	Potential under or over-reporting of AEs	1
Safety	Adverse Events	AE rate	安全性	1
Safety	Adverse Events	AE rate	施設のプロトコールの理解	1
Safety	Adverse Events	Number of AE's of special interest	有害事象数(SAE など)	1
Safety	Adverse Events	Rate of discontinuation due to AE	安全性	1
Safety	Lab Data	Trend analysis on lab data	安全性	2
Safety	Lab Data	Trend analysis on lab data	評価できないサン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	1
Safety	Serious Adverse Events	SAE rate	Potential under or over-reporting of SAEs	1
Safety	Study Drug Discontinuation	Discontinuation rate	投与状況	1
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit	総合評価	1
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other	Operational Risk Control	2

Category	Sub-Category	Risk Indicator	その他	件数
		(study co-ord)		
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	Poor motivation/lack of engagement, fast recruiting sites	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	Operational Risk Control	2
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	計画と実績の乖離	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	進捗把握	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	登録	2
Subject Recruitment and Discontinuation	Enrollment	Total Screened	Operational Risk Control	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	Identify sites with high screen failure rate and reasons	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	Incorrect patients being screened	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	施設は適切な被験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	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	登録	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	Discontinuation	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	Identify sites with high discontinuation (drop out) rate and reasons	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	Poor management of patients within a	1

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

RI 評価する変数 算出方法

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
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	1		1
CRA/On-site Workload	CRA Compliance	Monitoring report delays		2	
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	2	1	
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	3		
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	2	1	
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)		2	1
Data Quality	CRF Completion	Missing labs	2		
Data Quality	CRF Completion	Missing pages	2	1	2
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	26	4	5

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 entry (AEs)	5	1	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 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		

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	Discrepancy Management	Query aging (all DP)	5	3	2
Data Quality	Discrepancy Management	Query rate	7	10	4
Data Quality	Discrepancy Management	Query rate of those resulting in a data change		2	
Data Quality	Discrepancy Management	Reissued query count (critical DP)		1	
Data Quality	Patient Compliance	eDiary Compliance	2		1
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	3		
Essential Documents	CRA Compliance	Investigator Site File Review compliance	2		
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	4		1
Essential Documents	Study Compliance	Submission of essential documents to site		1	
Investigational Product	Patient Compliance	IP compliance rate	2	3	2
Issue Management	Protocol Compliance	Deviation Outliers	2	8	7
Issue Management	Protocol Compliance	Eligibility deviations rate		2	1
Issue Management	Protocol Compliance	Major protocol deviation rate	4	1	
Issue Management	Protocol Compliance	Minor protocol deviation rate		1	
Issue Management	Protocol Compliance	Subject Visit	2	2	1

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
		Timeliness			
Issue Management	Protocol Compliance	Volume of protocol deviations	13	3	4
Issue Management	Site Compliance	Number of informed consent issues	2		
Issue Management	Site Compliance	Rate of Data Integrity Issues	3	4	
Issue Management	Site Compliance	Rate of Human Protection Issues	1		
Issue Management	Site Compliance	Rate of Issues	1		1
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	2		1
Safety	Adverse Events	AE rate	11	11	7
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	2	1	2
Safety	Adverse Events	Trend analysis on types of Aes		1	1
Safety	Adverse Events	Trend analysis on types of AEs		1	
Safety	Lab Data	Trend analysis on lab data	2	1	3
Safety	Serious Adverse	SAE rate	8	3	2

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
	Events				
Safety	Study Drug Discontinuation	Discontinuation rate	1	3	2
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE	1		
Safety	Study Drug Discontinuation	Temporary discontinuation		1	1
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit	1		
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	2		
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	2	3	4
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)	1		
Subject Recruitment and Discontinuation	Enrollment	Total Screened	1		1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	3	6	3
Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up	1		
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	7	9	4

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 Workload	CRA Compliance	CRA compliance with monitoring plan	EDC のオフサイトモニタリングのチ	1

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

Category	Sub-Category	Risk Indicator	算出方法_その他	件数
Data Quality	Discrepancy Management	Query aging (all DP)	●日以上	1
Data Quality	Discrepancy Management	Query aging (all DP)	施設レベルで算出	1
Data Quality	Discrepancy Management	Query aging (all DP)	未解決クエリー数/クエリーの発行数	1
Data Quality	Discrepancy Management	Query rate	1000 データごとのクエリー率	1
Data Quality	Discrepancy Management	Query rate	100 データ当たりのクエリー数	1
Data Quality	Discrepancy Management	Query rate	施設レベルで算出	1
Data Quality	Discrepancy Management	Query rate	施設当たりの割合	1
Data Quality	Discrepancy Management	Query rate	被験者数	1
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	●日以上対応なし	2
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	●日以上	1
Essential Documents	Study Compliance	Submission of essential documents to site	施設レベルで算出	1
Investigational Product	Patient Compliance	IP compliance rate	設定した閾値を下回る症例の割合	1
Issue Management	Protocol Compliance	Deviation Outliers	施設レベルで算出	1
Issue Management	Protocol Compliance	Volume of protocol deviations	施設の登録数に偏りがあるため症例数で調整	1
Issue Management	Protocol Compliance	Volume of protocol deviations	施設当たりの件数	1
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	施設当たりの有害事象数/観察日数(人日)	1
Safety	Adverse Events	Number of AE's of special interest	規定の有害事象の発現数	1
Safety	Adverse Events	Trend analysis on types of Aes	相関関係を図示	1
Safety	Lab Data	Trend analysis on lab data	下位、上位の施設	1
Safety	Serious Adverse Events	SAE rate	観察期間（subject week）あたりの AE 発現数	1
Safety	Serious Adverse Events	SAE rate	施設レベルで算出	1
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit	チェックリストを用いた、モニターの主観による評価(10～20 項目)	1
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	●名以上	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	下位、上位の施設	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	施設レベルで算出	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	施設レベルで算出	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	施設ごとの中止症例の件数	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	施設レベルで算出	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	施設当たりの件数	1

RI 評価する変数 評価対象期間

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	1	1	1	
CRA/On-site Workload	CRA Compliance	Monitoring report delays		2		
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	3		1	
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	4			
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	3			
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	3			
Data Quality	CRF Completion	Missing labs	1	1		
Data Quality	CRF Completion	Missing pages	4	1		
Data Quality	CRF Completion	Missing pages (critical forms)	2			
Data Quality	CRF Completion	Missing visits	2			
Data Quality	CRF Completion	Timeliness of data entry	23	12	1	2
Data Quality	CRF Completion	Timeliness of data entry (AEs)	4	3		
Data Quality	CRF Completion	Timeliness of data	1			

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
		entry (SAEs)				
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 and Outlier analysis - Demography)	1			
Data Quality	Data Trends	Other(Distribution of Concomitant Medication and volume by site)	2			
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)	11	8		1
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. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
		(freq & rate)				
Data Quality	Discrepancy Management	Manual query rate	4	1	1	
Data Quality	Discrepancy Management	Number of queries resulting in data change (critical DP)	2			
Data Quality	Discrepancy Management	Query aging (all DP)	6	3	1	1
Data Quality	Discrepancy Management	Query rate	14	5	1	2
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	4	2		
Essential Documents	CRA Compliance	Investigator Site File Review compliance	1	1		

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	4	1		1
Essential Documents	Study Compliance	Submission of essential documents to site	1			
Investigational Product	Patient Compliance	IP compliance rate	5	1		1
Issue Management	Protocol Compliance	Deviation Outliers	8	2	4	4
Issue Management	Protocol Compliance	Eligibility deviations rate	2		1	
Issue Management	Protocol Compliance	Major protocol deviation rate	3	3		
Issue Management	Protocol Compliance	Minor protocol deviation rate	1			
Issue Management	Protocol Compliance	Subject Visit Timeliness	6			
Issue Management	Protocol Compliance	Volume of protocol deviations	10	9	1	
Issue Management	Site Compliance	General or site issues - aging	1			
Issue Management	Site Compliance	Number of informed consent issues	3			
Issue Management	Site Compliance	Rate of Data Integrity Issues	6	1		
Issue Management	Site Compliance	Rate of Human	1			

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近( )週間	4. 複数の評価期間
		Protection Issues				
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		

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE	1			
Safety	Study Drug Discontinuation	Temporary discontinuation	2			
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit		1		
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	3	2		
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	8			2
Subject Recruitment and Discontinuation	Enrollment	Other (Increased sampling)	1			
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)		1		
Subject Recruitment and Discontinuation	Enrollment	Total Screened	1			1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	13			
Subject	Subject	Number or rate of	1			

Category	Sub-Category	Risk Indicator	1. 試験開始から全期間	2. 前回評価時以降の期間	3. 直近 ( ) 週間	4. 複数の評価期間
Recruitment and Discontinuation	Discontinuation	subjects lost to follow up				
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	17	4		

RI リスク評価の閾値 閾値の設定

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
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan		1		2	
CRA/On-site Workload	CRA Compliance	Monitoring report delays		2			
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities		2		1	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
		delays					
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events		2	1	1	
CRA/On-site Workload	CRF Review	Volume of SDV (data points)		3			
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	1	1		1	
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 - Demography)					
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	1			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)	1	9	3	4	3
Data Quality	Data Trends	Repeated values (freq & rate)	1	1	1		3
Data Quality	Discrepancy Management	Manual query rate	1	2	1	1	1
Data Quality	Discrepancy Management	Number of queries resulting in data		1		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
		change (critical DP)					
Data Quality	Discrepancy Management	Query aging (all DP)		7	1	1	2
Data Quality	Discrepancy Management	Query rate	4	10	3	4	1
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		1	1	1	
Data Quality	PI Oversight	Frequency of PI EDC review			1		
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB		4	1	1	
Essential Documents	CRA Compliance	Investigator Site File Review compliance		2			
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance		4	1	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
Essential Documents	Study Compliance	Submission of essential documents to site				1	
Investigational Product	Patient Compliance	IP compliance rate		6	1		
Issue Management	Protocol Compliance	Deviation Outliers	1	7	2	4	4
Issue Management	Protocol Compliance	Eligibility deviations rate				2	1
Issue Management	Protocol Compliance	Major protocol deviation rate	1	3	2		
Issue Management	Protocol Compliance	Minor protocol deviation rate	1				
Issue Management	Protocol Compliance	Subject Visit Timeliness	1	3	1	1	
Issue Management	Protocol Compliance	Volume of protocol deviations	2	14	1	3	
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	1	4			2
Issue Management	Site Compliance	Rate of Human		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
		Protection Issues					
Issue Management	Site Compliance	Rate of Issues		1	1	1	
Issue Management	Site Compliance	Site Issue Outlier		3		1	
Safety	Adverse Events	AE causality assessment distribution per site		2		2	
Safety	Adverse Events	AE grade distribution per site		1		2	
Safety	Adverse Events	AE rate	6	9	5	10	
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		2		3	
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 data	3	3	1		
Safety	Serious Adverse	SAE rate	4	8		2	

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
	Events						
Safety	Study Drug Discontinuation	Discontinuation rate		3	1	2	
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE		1			
Safety	Study Drug Discontinuation	Temporary discontinuation		1		1	
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit		1			
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)		3	2		
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate		3	4	3	
Subject Recruitment and Discontinuation	Enrollment	Other (Increased sampling)			1		
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)				1	
Subject Recruitment and	Enrollment	Total Screened			2		

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 Recruitment and Discontinuation	Screen Failures	Screen fail rate	2	4	1	4	2
Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up		1			
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	5	8	3	2	3

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 Workload	CRA Compliance	Monitoring visit/activities delays	モニタリング手順書での規定を参考に設定	1
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	絶対値の閾値は設定していない。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)。	1
Data Quality	CRF Completion	Missing pages (critical forms)	絶対値の閾値は設定していない。統計	1

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 entry	eCRF 入力マニュアルでの規定を参考に設定	3
Data Quality	CRF Completion	Timeliness of data entry	絶対値の閾値とあわせて、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)。	1
Data Quality	Data Trends	Query response time (all DP)	想定	2
Data Quality	Discrepancy Management	Manual query rate	絶対値の閾値は設定していない。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)。	1
Data Quality	Discrepancy Management	Manual query rate	例えば「±2SD 以上/以下」のような範囲で設定	1
Data Quality	Discrepancy Management	Query aging (all DP)	絶対値の閾値とあわせて、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)。	1
Data Quality	Discrepancy Management	Query aging (all DP)	想定	2
Data Quality	Discrepancy Management	Query rate	実施経験がない場合は数字に明確な根拠のないまま設	1

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 Management	Query rate	絶対値の閾値は設定していない。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）。	1
Essential Documents	Study Compliance	Submission of essential documents to site	絶対値の閾値は設定していない。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）。	1
Issue Management	Protocol Compliance	Deviation Outliers	実施経験がない場合は数字に明確な根拠のないまま設定することもある	1
Issue Management	Protocol Compliance	Deviation Outliers	絶対値の閾値は設定していない。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）。	1
Issue Management	Protocol Compliance	Deviation Outliers	想定	3
Issue Management	Protocol Compliance	Eligibility deviations rate	想定	1
Issue Management	Site Compliance	Rate of Data Integrity Issues	例えば「±2SD 以上/以下」のような範囲で設定	2
Issue Management	Site Compliance	Rate of Issues	絶対値の閾値とあわせて、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）。	1

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）。	1
Safety	Adverse Events	AE rate	絶対値の閾値は設定していない。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）。	1
Safety	Adverse Events	Trend analysis on types of AEs	実施経験がない場合は数字に明確な根拠のないまま設定することもある	1
Safety	Serious Adverse Events	SAE rate	絶対値の閾値は設定していない。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）。	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	絶対値の閾値は設定していない。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）。	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	Expected rate が Protocol に設定されている場合はそれを用いる。	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	絶対値の閾値は設定していない。統計処理で算出した各	1

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 and Discontinuation	Subject Discontinuation	Subject discontinuation rate	Expected rate が Protocol に設定されている場合はそれを用いる。	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	プロトコルの症例数設計時の想定中止率を参考に設定	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	絶対値の閾値は設定していない。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)。	1

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 monitoring plan	1		2
CRA/On-site Workload	CRA Compliance	Monitoring report delays	2		
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	2	1	1
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	3		1
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	3		
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	2	1	
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 (AEs)	5	1	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 and Outlier analysis - Demography)	1		
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	2		
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	3	5
Data Quality	Data Trends	Repeated values (freq & rate)	3		3
Data Quality	Discrepancy Management	Manual query rate	5	1	
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 data	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 Discontinuation	Temporary discontinuation	2		
Staffing, Facilities and Supplies	PI Oversight	PI´s presence during monitoring visit	1		
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	3		2
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	7	1	2
Subject Recruitment and Discontinuation	Enrollment	Other (Increased sampling)			1
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)		1	
Subject Recruitment and Discontinuation	Enrollment	Total Screened	1		1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	7	2	4
Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up	1		
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	18	1	2

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

Category	Sub-Category	Risk Indicator	全試験	第I相	第II相	第III相	第IV相
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	3	0	0	0	0
CRA/On-site Workload	CRA Compliance	Monitoring report delays	0	0	0	0	0
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	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
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	2	0	0	0	0
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	1	0	0	0	0
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	1	0	1	1	1
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 (critical forms)	2	0	1	1	0
Data Quality	CRF Completion	Missing visits	0	0	1	1	0
Data Quality	CRF Completion	Timeliness of data entry	20	1	8	10	3
Data Quality	CRF Completion	Timeliness of data entry (AEs)	4	0	1	2	1
Data Quality	CRF Completion	Timeliness of data entry (SAEs)	0	0	0	0	0
Data Quality	Data Trends	Efficacy reading post drug administration	1	0	0	0	0
Data Quality	Data Trends	Other (Change from baseline - Weight)	1	0	1	1	0
Data Quality	Data Trends	Other (Distribution and Outlier analysis - Demography)	0	0	1	1	1
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	0	1	2	2	2
Data Quality	Data Trends	Other (Distribution of Medical History terms and volume by Site)	0	0	1	1	1
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 data	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

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

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 entry		1	1	1
Data Quality	CRF Completion	Timeliness of data entry (AEs)		1		1
Data Quality	Data Trends	Other (Change from baseline - Weight)	1			
Data Quality	Data Trends	Other (PCR - Vital Signs)	1			
Data Quality	Data Trends	Query response time (all DP)				2
Data Quality	Discrepancy Management	Manual query rate				1
Data Quality	Discrepancy Management	Query rate			1	1
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 deviation rate				1
Issue Management	Protocol Compliance	Subject Visit Timeliness	1			
Issue Management	Protocol Compliance	Volume of protocol deviations		1	1	1
Issue Management	Site Compliance	Rate of Data Integrity Issues			1	
Safety	Adverse Events	AE rate	1		1	2
Safety	Adverse Events	Rate of discontinuation due to AE	1			
Safety	Lab Data	Trend analysis on lab data	2			
Safety	Study Drug Discontinuation	Discontinuation rate	1		1	
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	2			
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	1			
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate				2

RI 試験ごとの適用の有無 4.試験の性質

Category	Sub-Category	Risk Indicator	D	オ	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 (AEs)	1		1
Data Quality	Data Trends	Other (Change from baseline - Weight)	1		
Data Quality	Data Trends	Other (Distribution of Concomitant			1

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

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

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 forms)			1	
Data Quality	CRF Completion	Timeliness of data entry	1	1	2	1
Data Quality	CRF Completion	Timeliness of data entry (AEs)		1		1
Data Quality	Data Trends	Other (Change from baseline - Weight)				1
Data Quality	Data Trends	Other (Distribution of Concomitant Medication and volume by site)	1			
Data Quality	Data Trends	Other (PCR - Vital Signs)				1
Data Quality	Data Trends	Query response time (all DP)	1	2	1	
Data Quality	Discrepancy Management	Manual query rate		1		
Data Quality	Discrepancy Management	Query rate	1	1	2	
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 deviation rate		1		
Issue Management	Protocol Compliance	Subject Visit Timeliness	1			1
Issue Management	Protocol Compliance	Volume of protocol deviations		1	2	1
Issue Management	Site Compliance	Rate of Data Integrity Issues	1		1	
Safety	Adverse Events	AE rate		2	2	1
Safety	Adverse Events	Rate of discontinuation due to AE				1
Safety	Lab Data	Trend analysis on lab data	1			2
Safety	Serious Adverse Events	SAE rate	1		1	
Safety	Study Drug Discontinuation	Discontinuation rate			2	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate				2
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	1			1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	1	2		

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 (critical forms)			1		
Data Quality	CRF Completion	Missing visits		1			
Data Quality	CRF Completion	Timeliness of data entry	1	1	1	1	1
Data Quality	CRF Completion	Timeliness of data entry (AEs)	1	1			1
Data Quality	Data Trends	Other (Change from baseline - Weight)				1	

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

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

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 Workload	CRA Compliance	Monitoring report delays	試験ごとに検討	2
CRA/On-site Workload	CRF Review	Unreported AEs/SAEs events	試験毎に判断	2
CRA/On-site Workload	CRF Review	Volume of SDV (data points)	試験ごとに検討	2
CRA/On-site Workload	CRF Review	Volume of SDV (patient visits)	試験ごとに検討	1
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､施設数・症例数は規定なし	1
Data Quality	CRF Completion	Timeliness of data entry	P1 試験は任意､施設数・症例数は規定なし	3
Data Quality	CRF Completion	Timeliness of data entry	該当するリスクに応じて	1
Data Quality	CRF Completion	Timeliness of data entry	該当する評価項目がある場合	1
Data Quality	CRF Completion	Timeliness of data entry	基準設定なし	2
Data Quality	CRF Completion	Timeliness of data entry	試験ごとに検討	3
Data Quality	CRF Completion	Timeliness of data entry	試験毎に判断	2
Data Quality	CRF Completion	Timeliness of data entry	未定	1
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 entry (SAEs)	試験毎に判断	1
Data Quality	Data Trends	Query response time (all DP)	該当するリスクに応じて	1
Data Quality	Data Trends	Query response time (all DP)	試験毎に判断	1
Data Quality	Data Trends	Query response time (all DP)	未定	1
Data Quality	Discrepancy Management	Manual query rate	P1 試験は任意､施設数・症例数は規定なし	1
Data Quality	Discrepancy Management	Manual query rate	試験毎に判断	1
Data Quality	Discrepancy Management	Query aging (all DP)	P1 試験は任意､施設数・症例数は規定なし	1
Data Quality	Discrepancy Management	Query aging (all DP)	該当するリスクに応じて	1
Data Quality	Discrepancy Management	Query aging (all DP)	試験ごとに検討	1
Data Quality	Discrepancy Management	Query aging (all DP)	試験毎に判断	1
Data Quality	Discrepancy Management	Query rate	基準設定なし	2
Data Quality	Discrepancy Management	Query rate	試験ごとに検討	4
Data Quality	Discrepancy Management	Query rate of those resulting in a data change	試験ごとに検討	2
Data Quality	Discrepancy Management	Reissued query count (critical DP)	試験ごとに検討	1
Data Quality	Patient Compliance	eDiary Compliance	ePRO を使用している場合	1
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 Documents	CRA Compliance	Investigator Site File Review compliance	試験毎に判断	1
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	P1 試験は任意、施設数・症例数は規定なし	1
Essential Documents	CRA Compliance	Monitoring Visit Report Approval Compliance	試験毎に判断	1
Investigational Product	Patient Compliance	IP compliance rate	試験ごとに検討	2
Issue Management	Protocol Compliance	Deviation Outliers	試験ごとに検討	1
Issue Management	Protocol Compliance	Deviation Outliers	未定	1
Issue Management	Protocol Compliance	Eligibility deviations rate	未定	1
Issue Management	Protocol Compliance	Major protocol deviation rate	試験毎に判断	2
Issue Management	Protocol Compliance	Volume of protocol deviations	P1 試験は任意、施設数・症例数は規定なし	2
Issue Management	Protocol Compliance	Volume of protocol deviations	該当するリスクに応じて	1
Issue Management	Protocol Compliance	Volume of protocol deviations	基準設定なし	1
Issue Management	Protocol Compliance	Volume of protocol deviations	試験ごとに検討	2
Issue Management	Protocol Compliance	Volume of protocol deviations	試験毎に判断	3
Issue Management	Site Compliance	Number of informed consent issues	未定	1
Issue Management	Site Compliance	Rate of Data Integrity Issues	基準設定なし	1

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

Category	Sub-Category	Risk Indicator	適用_その他	件数
Safety	Lab Data	Trend analysis on lab data	基準設定なし	1
Safety	Lab Data	Trend analysis on lab data	試験毎に判断	1
Safety	Serious Adverse Events	SAE rate	P1 試験は任意､施設数・症例数は規定なし	2
Safety	Serious Adverse Events	SAE rate	試験ごとに検討	1
Safety	Serious Adverse Events	SAE rate	試験毎に判断	1
Safety	Study Drug Discontinuation	Discontinuation rate	該当するリスクに応じて	1
Safety	Study Drug Discontinuation	Rate of discontinuation due to SAE	試験ごとに検討	1
Safety	Study Drug Discontinuation	Temporary discontinuation	試験毎に判断	1
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	試験ごとに検討	1
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	試験毎に判断	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	基準設定なし	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	試験毎に判断	1
Subject Recruitment and Discontinuation	Enrollment	Enrollment rate	未定	1
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)	該当するリスクに応じて	1
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	基準設定なし	1
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 and Discontinuation	Screen Failures	Screen fail rate	試験毎に判断	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Number or rate of subjects lost to follow up	試験ごとに検討	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	A-5 設問で CM 実施と判断した試験では，基本的に設定。以下全て同じ。	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	P1 試験は任意､施設数・症例数は規定なし	4
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	基準設定なし	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	試験ごとに検討	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	試験毎に判断	1
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	未定	1

RI 設定して有用でなかった RI 項目

Category	Sub-Category	Risk Indicator	回答いいえ数	項目は有用か？回答数	非有用率(%)
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	3	9	33.3
Data Quality	Discrepancy Management	Query rate	2	17	11.8
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	discontinuation rate			
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	1	3	33.3
Data Quality	CRF Completion	Timeliness of data entry	1	25	4.0
Data Quality	Data Trends	Query response time (all DP)	1	14	7.1
Data Quality	Discrepancy Management	Reissued manual query rate	1	1	100.0
Essential Documents	Site Compliance	Submission of safety report to site and EC/IRB	1	4	25.0
Essential Documents	Study Compliance	Submission of essential documents to site	1	1	100.0
Issue Management	Protocol Compliance	Deviation Outliers	1	14	7.1
Issue Management	Site Compliance	Number of informed consent issues	1	3	33.3
Safety	Adverse Events	Trend analysis on types of Aes	1	2	50.0
Subject Recruitment and Discontinuation	Enrollment	Other (Number of Re-Screening)	1	1	100.0

C.Fraud Detection について

Fraud Detection 項目

Fraud Detection 項目	具体的手法	企業数
Between-patient	被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。	1
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 0 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。(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
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、血圧)	1
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 (AEs)	1

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

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 Management	Query rate	4	50.00
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 Discontinuation	Enrollment	Enrollment rate	3	37.50
Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	3	37.50
Data Quality	Data Trends	Query response time (all DP)	2	25.00
Data Quality	Discrepancy Management	Query aging (all DP)	2	25.00
Issue Management	Protocol Compliance	Volume of protocol deviations	2	25.00
Issue Management	Site Compliance	Site Issue Outlier	2	25.00
Safety	Serious Adverse Events	SAE rate	2	25.00
Safety	Study Drug Discontinuation	Discontinuation rate	2	25.00
Subject Recruitment and Discontinuation	Screen Failures	Screen fail rate	2	25.00
CRA/On-site Workload	CRA Compliance	CRA compliance with monitoring plan	1	12.50
CRA/On-site Workload	CRA Compliance	Monitoring report delays	1	12.50
CRA/On-site Workload	CRA Compliance	Monitoring visit/activities delays	1	12.50
Data Quality	Adverse Events	AE Errors	1	12.50
Data Quality	CRF Completion	Missing pages (critical forms)	1	12.50
Data Quality	CRF Completion	Timeliness of data entry (AEs)	1	12.50
Data Quality	CRF Completion	Timeliness of data entry (SAEs)	1	12.50
Data Quality	Data Trends	Other(atypical pattern in electronic patient diaries completion)	1	12.50
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 meet the eligibility criteria)	1	12.50
Data Quality	Data Trends	Other(fraud in patient diaries completion)	1	12.50
Data Quality	Data Trends	Other(psychometric properties of the scale)	1	12.50
Data Quality	Data Trends	Other(QT interval)	1	12.50
Data Quality	Data Trends	Other(scoring that appears non-random)	1	12.50
Data Quality	Discrepancy Management	Query count (critical DP)	1	12.50
Data Quality	Discrepancy Management	Reissued manual query rate	1	12.50
Data Quality	Protocol Compliance	Other(inappropriate handling of blood samples)	1	12.50
Issue Management	Protocol Compliance	Deviation Outliers	1	12.50
Issue Management	Protocol Compliance	Eligibility deviations rate	1	12.50
Issue Management	Protocol Compliance	Major protocol deviation rate	1	12.50
Issue Management	Protocol Compliance	Rate of Subjects with Procedures Not Done	1	12.50
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 Issues	1	12.50
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of changes in PI, sub PI or other (study co-ord)	1	12.50
Staffing, Facilities and Supplies	Site/Staff Turnover	Number of non-PI site staff turnovers	1	12.50
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 and Discontinuation	Enrollment	3	37.50
Subject Recruitment and Discontinuation	Subject Discontinuation	3	37.50
Safety	Serious Adverse Events	2	25.00
Safety	Study Drug Discontinuation	2	25.00
Subject Recruitment and Discontinuation	Screen Failures	2	25.00
CRA/On-site Workload	CRA Compliance	1	12.50
Data Quality	Adverse Events	1	12.50
Data Quality	Protocol Compliance	1	12.50
Staffing, Facilities and Supplies	Site/Staff Turnover	1	12.50

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 Indicator 項目名	TransCelerate-RI-Library コーディング情報			閾値	補足	Reference
	Category	Sub-Category	Risk Indicator			
Data entry delay	Data Quality	CRF Completion	Timeliness of data entry	-	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 mechanism.	[1]
Rate of queries	Data Quality	Discrepancy Management	Query rate			
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			
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			
noncompliance	Issue Management	Site Compliance	Site Issue Outlier			
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 attrition	Staffing, Facilities and Supplies	Site/Staff Turnover	Number of non-PI 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-site	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	-	

				received + >20 CRFs outstanding		
Return rate, specific CRF	Issue Management	Site Compliance	Rate of Data Integrity Issues	As above, for specific CRF	-	
Return rate, Patient consent form	Issue Management	Site Compliance	Number of informed consent issues	As above, for 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	-	

				tests out of range		
Protocol deviation (eligibility)	Issue Management	Protocol Compliance	Eligibility deviations rate	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		

				≤15 % more or less than median value of all sites 【High risk】>15 % more or less than median value of all sites		
CRF entry response time	Data Quality	CRF Completion	Timeliness of data entry	【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		
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 value of all sites		
AE per patient week	Safety	Adverse Events	AE 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 value of all sites		
Percent discontinued of randomized patient	Subject Recruitment and Discontinuation	Subject Discontinuation	Subject discontinuation rate	【Low risk】≤15 % more or less than median value of all sites 【Moderate risk】>15 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%(moderate limits) and 99.7%(severe limits)	-	[6]

				confidence intervals.		
Queries per 100 fields	Data Quality	Discrepancy Management	Query rate	-	This article provides a framework to assist biopharmaceutical companies in selecting and implementing a risk-based monitoring approach or selecting a service provider.	[7]
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)			
Time from patient visit to CRF entry	Data Quality	CRF Completion	Timeliness of data entry			
Protocol deviations	Issue Management	Protocol Compliance	Volume of protocol deviations			
Protocol deviation under/over reporting	Issue Management	Protocol Compliance	Deviation Outliers			
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　QTL 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、脱落	・中止割合 ・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○%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・ Threshold	・KRI の設定基準・絞り込み ・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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