

RISK ASSESSMENT FOR MONITORING VISIT PLAN

Trial Code:
Trial Title:
Completed by:
Date (dd/mm/yyyy):

				PREVENTION: Site Initiation Visits			CONTROL: Monitoring Visits					
				PROBABILITY OF ERRORS/ MALPRACTICE/ FRAUDE	Efficacy of on- site visits	Efficacy of remote visits	NEED FOR ON- SITE VISITS	Efficacy of on- site visits	Efficacy of remote visits	NEED FOR ON- SITE VISITS		
CONSIDER THE ELEMENTS HERE BELOW TO ESTIMATE THE RISK OF ERROR/ MALPRACTICE/ FRAUD IN THE SPECIFIC CONTEXT OF THE PRESENT TRIAL AND REPORT FOR EACH ETHICS/QUALITY OBJECTIVE THE APPROPRIATE RISK SCORE IN THE NEXT COLUMN				1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH	1=LOW 2=MEDIUM 3=HIGH		
				Insert value "0" if the risk is not applicable.								
DOES FROM HAVE PREVIOUS EXPERIENCE WITH THE SITES INVOLVED IN THE PRESENT TRIAL?	WERE AUDITS/INSPECTIONS CONDUCTED IN A SIGNIFICANT NUMBER OF INVOLVED SITES?	DO THE TRIAL INVESTIGATORS HAVE CONFLICTS OF INTEREST?									IF SCORE >4 CONSIDER TO INTENSIFY ON-SITE MONITORING	
DOES THE STUDY FORESEE MORE THAN ONE INFORMED CONSENT (E.G., AT DIFFERENT TRIAL STAGES OR FOR ANCILLARY STUDIES)	ARE THERE ANY PARTICULAR ORGANIZATIONAL DIFFICULTIES (E.G., TIGHT TIMELINES BETWEEN INFORMED CONSENT AND TRIAL PROCEDURES START)	DOES THE TRIAL POPULATION INCLUDE VULNERABLE SUBJECTS?										IF SCORE >5 CONSIDER TO INTENSIFY ON-SITE MONITORING
IS THE TRIAL POPULATION RARE?	ARE MOST OF THE INVOLVED SITES REFERENCE CENTRES FOR THE TRIAL DISEASE?	IS THE PLANNED ACCRUAL DURATION LONG?	IS THERE A HIGH RISK OF COMPETING TRIALS THAT COULD START BEFORE ACCRUAL IS COMPLETED?									
ARE CLINICAL TRIAL COORDINATORS AVAILABLE AT THE SITES TO MAINTAIN THE INVESTIGATOR FILES?												
IS THE CRF ELECTRONIC OR PAPER-BASED?	ARE DATA-MANAGERS AVAILABLE AT THE SITES FOR DATA-ENTRY?											
ARE SOURCE DOCUMENTS GENERATED BY MANY DIFFERENT SPECIALISTS BELONGING TO DIFFERENT DEPARTMENTS?	ARE WORKING DOCUMENTS PROVIDED TO THE SITE PERSONNEL TO FACILITATE REPORTING OF TRIAL-SPECIFIC INFORMATION?	IS THE HOSPITAL FILE ELECTRONIC OR PAPER- BASED?	ARE TRIAL COORDINATORS AVAILABLE AT THE SITES CONTRIBUTING TO HOSPITAL FILES' ORGANIZATION, REVIEW AND MAINTENANCE?									
ARE TRIAL COORDINATORS AVAILABLE AT THE SITES CONTRIBUTING TO HOSPITAL FILES' ORGANIZATION, REVIEW AND MAINTENANCE?	DO THE PROTOCOL AND CRF HAVE A HIGH LEVEL OF COMPLEXITY?										IF SCORE >5 CONSIDER TO INTENSIFY ON-SITE MONITORING	

DOES THE DISEASE ON STUDY IMPLY A HIGH NUMBER OF POTENTIALLY SERIOUS CO-MORBIDITIES?	IS THE PROBABILITY THAT PATIENTS ARE ADMITTED IN EMERGENCY TO OTHER HOSPITALS HIGH?	IS SAE REPORTING EASY FROM A LOGISTIC POINT OF VIEW?									IF SCORE >4 CONSIDER TO INTENSIFY ON-SITE MONITORING
DO THE TRIAL SITES HAVE EXTENSIVE EXPERIENCE IN CLINICAL TRIALS?	HAVE THERE BEEN ANY RECENT SIGNIFICANT CHANGES IN THE APPLICABLE REGULATIONS?										IF SCORE >4 CONSIDER TO INTENSIFY ON-SITE MONITORING
IS IT AN EARLY PHASE TRIAL?	ARE FREQUENCY AND COMPLEXITY OF THE SAFETY-RELATED ASSESSMENTS AND PROCEDURES REQUIRED BY PROTOCOL HIGH?	ARE SAFETY-RELATED ASSESSMENTS AND PROCEDURES VERY DIFFERENT FROM THE USUAL CLINICAL PRACTICE?									IF SCORE >5 CONSIDER TO INTENSIFY ON-SITE MONITORING
ARE STUDY ENDPOINTS ASSESSMENTS COMPLEX?	ARE ASSESSMENTS AND PROCEDURES FORESEEN BY PROTOCOL VERY DIFFERENT FROM USUAL CLINICAL PRACTICE?										
DOES THE STUDY TREATMENT INCLUDE MULTIPLE DRUGS? ARE ALL DRUGS ADMINISTERED IN THE SAME WAY AND ON THE SAME DAYS?	ARE STUDY DRUGS SELF-ADMINISTERED BY PATIENTS AT HOME?	IF DRUGS ARE SELF-ADMINISTERED, IS THE TRIAL POPULATION FIT OR ARE PATIENTS OLD/ IN BAD HEALTH CONDITIONS? WILL PATIENTS RECEIVE A DIARY TO RECORD DRUG INTAKE?	DOES THE CRF INCLUDE DETAILED INFORMATION ABOUT STUDY DRUGS DELIVERY, RETURN, BATCH NUMBERS, ETC?								IF SCORE >4 CONSIDER TO INTENSIFY ON-SITE MONITORING
IS THE CRF COMPLEX? IS THE DATA COLLECTION TOOL USER-FRIENDLY?	ARE DATA-MANAGERS AVAILABLE AT THE SITES FOR DATA-ENTRY?	ARE AUTOMATIC WARNINGS GENERATED FOR DATA-ENTRY ERRORS?									
HAVE CRFs AND SAE FORMS A SIMILAR DESIGN?											
IS THE CRF USER-FRIENDLY AND SELF-EXPLANATORY?											
IS THE CRF USER-FRIENDLY AND SELF-EXPLANATORY?	ARE DATA-MANAGERS AVAILABLE AT THE SITES FOR DATA-ENTRY?										

TOTAL SCORE = X TOTAL SCORE = X

< 37 LOW- INTERMEDIATE RISK	Remote Site Initiation Visits	27-35 LOW RISK	At least 1-2 on-site Monitoring Visits per site during the trial, depending on number of patients enrolled and specific issues arisen At least 1 remote Monitoring Visit per site every 6 months while patients are on-treatment Remote Site Closure Visit
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≥ 37 HIGH-VERY HIGH RISK	On-site Site Initiation Visits	36-43 INTERMEDIATE RISK	At least 1 on-site Monitoring Visit per site per year while patients are on-treatment At least 1 remote Monitoring visit per site every 4 months while patients are on-treatment Remote Site Closure Visit
		44-51 HIGH RISK	At least 1 on-site Monitoring Visit per site every 6 months while patients are on-treatment At least 1 remote Monitoring visit per site every 3 months while patients are on-treatment Remote Site Closure Visit
		> 51 VERY HIGH RISK	At least 1 on-site Monitoring Visit per site every 3 months while patients are on-treatment At least 1 remote Monitoring visit per site every 2 months while patients are on-treatment On-site Site Closure Visit