

RISK ASSESSMENT FOR MONITORING VISIT PLAN

Trial Code:

Trial Title:

Completed by:

Date (dd/mm/yyyy):

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				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
				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

<p>≥ 37 HIGH-VERY HIGH RISK</p>	<p>On-site Site Initiation Visits</p>	<p>36-43 INTERMEDIATE RISK</p>	<p>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</p>
		<p>44-51 HIGH RISK</p>	<p>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</p>
		<p>> 51 VERY HIGH RISK</p>	<p>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</p>