TEST MATRIX BROK®- and GCP-WMO - EXAMS DATE OF VALIDITY 1-3-2022

BROK					GCP-WMO				
Attainmentlevel		Delineation	Taxonomy	No. of questions	Attainmentlevel		Delineation	Taxonomy	No. of questions
1. General research					**1. General research**				
1.1	The candidate can state which legislation (national and international) is applicable to a specified study.	WMO WGBO AVG ICH-GCP MDR ECTR ISO 14155	T	1	1.1	The candidate can state which legislation (national and international) is applicable to a specified study.	WMO WGBO AVG ICH-GCP ECTR ISO 14155	T	2
1.2	The candidate is familiar with the Medical Research Involving Human Subjects Act (WMO), can distinguish between research that is subject to the WMO and that which is not, and can estimate whether it is subject to the WMO based on the design of the study.		T	2	1.2	The candidate is familiar with the Medical Research Involving Human Subjects Act (WMO), can distinguish between research that is subject to the WMO and that which is not, and can estimate whether it is subject to the WMO based on the design of the study.		T	1
1.3	The candidate is familiar with the ICH-GCP guidelines and knows when they apply to a specified study.		T	6	1.3	The candidate is familiar with the ICH-GCP guidelines and knows when they apply to a specified study.		T	4
1.4	The candidate is familiar with the MDR and knows when it applies to a specified study.		T	1					
1.5	The candidate can state the type of research involved in a specified study.	Pharmaceutical research Medical devices research Surgical techniques Nutritional supplements	T	1					
1.6	The candidate can name the types of agreements /contracts for medical-scientific research and knows when they apply and why.	Processor agreement Confidentiality agreement Contracts with other sites Contracts with laboratories Contracts with sponsors and investigator CTA's Publication rights agreements Intellectual property/patent Cover of legal risks	T	1	1.6	The candidate can name the types of agreements /contracts for medical-scientific research and knows when they apply and why.	Processor agreement Confidentiality agreement Contracts with other sites Contracts with laboratories Contracts with sponsors and investigator CTA's Publication rights agreements Intellectual property/patent Cover of legal risks	T	2
1.7	The candidate can name the types of insurance for medical-scientific research and knows when they apply and why.	Study subject insurance(s) Liability insurance(s) Product liability insurance(s) Cover of legal risks	T	1	1.7	The candidate can name the types of insurance for medical-scientific research and knows when they apply and why.	Study subject insurance(s) Liability insurance(s) Product liability insurance(s) Cover of legal risks	T	1
1.8	The candidate can describe the method and procedure for assessing research.		K	3	1.8	The candidate can describe the method and procedure for assessing research.		K	2
1.9	The candidate can define additional testing and the necessary documentation based on the study design.		T	1	1.9	The candidate can define additional testing and the necessary documentation based on the study design.		T	1
1.10	The candidate can specify when an amendment/substantial amendment is necessary and the required documentation for submission.		K	1	1.10	The candidate can specify when an amendment/substantial amendment is necessary and the required documentation for submission.		K	1
1.11	The candidate can describe the characteristics of a researcher with integrity (according to the VSNU code of conduct) and knows the risks of being out of integrity.		K	1					
1.12	The candidate can name the different aspects of quality management systems.		K	1					
1.13	The candidate can specify the aim and various degrees of risk classification		K	1					
1.14	The candidate can describe the purpose of a Data Safety Monitoring Board (DSMB) and knows what its work involves.		K	1	1.14	The candidate can describe the purpose of a Data Safety Monitoring Board (DSMB) and knows what its work involves.		K	1
1.15	The candidate can describe the aspects of financing medical-scientific research.		K	1					
1.16	The candidate can specify inclusion and exclusion criteria (the requirements and purpose).		K	1	1.16	The candidate can specify inclusion and exclusion criteria (the requirements and purpose).		K	1
1.17	The candidate can specify the most important aspects of research methodology.	Blinding Parallel Inclusion and exclusion Monitoring DSMB (S)AE Stratification	K	1	1.17	The candidate can specify the most important aspects of research methodology.	Blinding Parallel Inclusion and exclusion Monitoring DSMB (S)AE Stratification	K	2
1.18	The candidate is familiar with the process backgrounds of randomisation and (de-)blinding and what to do in case of deviations.		T	1	1.18	The candidate is familiar with the process backgrounds of randomisation and (de-)blinding and what to do in case of deviations.		T	2
2. Legislation, procedures and reports					**2. Legislation, procedures and reports**				
2.1	The candidate knows about (Serious) Adverse Events and can apply this knowledge to a specific situation.	Criteria Reporting procedure(s) Mandatory report(s)	T	3	2.1	The candidate knows about (Serious) Adverse Events and can apply this knowledge to a specific situation.	Criteria Reporting procedure(s) Mandatory report(s)	T	3

2.2	The candidate can name the procedures and rules for processing, storing and sending research material (labelling, encrypting, etc.).		K	1	2.2	The candidate can name the procedures and rules for processing, storing and sending research material (labelling, encrypting, etc.).		K	1
2.3	The candidate can describe the procedure for reporting the termination (incl. premature) of the study.		K	1	2.3	The candidate can describe the procedure for reporting the termination (incl. premature) of the study.		K	1
2.4	The candidate can name the procedures for archiving research data.		K	1	2.4	The candidate can name the procedures for archiving research data.		K	1
2.5	The candidate can describe the procedures for collecting research data (Trial Master File/ Investigator Site File).		K	1	2.5	The candidate can describe the procedures for collecting research data (Trial Master File/ Investigator Site File).		K	1
2.6	The candidate understands the purpose and conditions of a Standard Operating Procedure (SOP) .		K	1	2.6	The candidate understands the purpose and conditions of a Standard Operating Procedure (SOP) .		K	2
2.7	The candidate can name the procedures for implementing changes in (digital) essential documents.		K	1	2.7	The candidate can name the procedures for implementing changes in (digital) essential documents.		K	1
2.8	The candidate knows what product accountability involves and is familiar with the procedures.		K	1	2.8	The candidate knows what product accountability involves and is familiar with the procedures.		K	1
2.9	The candidate is familiar with the terms IMPD, IMDD and IB and knows when these documents must be used.		T	1	2.9	The candidate is familiar with the terms IMPD, IMDD and IB and knows when these documents must be used.		T	1
3. Data(management)					**3. Data(management)**				
3.1	The candidate knows what data management is.		K	1	3.1	The candidate knows what data management is.		K	1
3.2	The candidate knows what a Data Management Plan (DMP) is and when to apply one.		T	1	3.2	The candidate knows what a Data Management Plan (DMP) is and when to apply one.		T	1
3.3	The candidate understands the purpose of an (electronic) Case Report Form (CRF).		K	1	3.3	The candidate understands the purpose of an (electronic) Case Report Form (CRF).		K	1
3.4	The candidate can describe the conditions of data management to comply with the FAIR principle.		K	1					
3.5	The candidate can name the roles and responsibilities in data management.	Importing rights Data management rights Sign off rights Approval rights Amendment rights	K	1	3.5	The candidate can name the roles and responsibilities in data management.	Importing rights Data management rights Sign off rights Approval rights Amendment rights	K	1
3.6	The candidate knows the requirements for a valid data management system (audit trail, etc.)		K	1					
4. Parties involved and their responsibilities					**4. Parties involved and their responsibilities**				
4.1	The candidate can describe the tasks, roles and responsibilities of the research support departments (clinical chemistry, laboratory, etc.)		K	1	4.1	The candidate can describe the tasks, roles and responsibilities of the research support departments (clinical chemistry, laboratory, etc.)		K	1
4.2	The candidate can describe the tasks and responsibilities of the pharmacy.		K	1	4.2	The candidate can describe the tasks and responsibilities of the pharmacy.		K	2
4.3	The candidate can name the roles of agencies (national and international) for medical-scientific research and knows when they are involved.	CCMO IGJ FDA EMA METC	K	1	4.3	The candidate can name the roles of agencies (national and international) for medical-scientific research and knows when they are involved.	CCMO METC RA	K	2
4.4	The candidate can describe the different responsibilities of the sponsor and the investigator		K	2	4.4	The candidate can describe the different responsibilities of the sponsor and the investigator		K	2
4.5	The candidate can describe the rights and obligations of the parties involved in research that is subject to the WMO and research that is not subject to it.		K	1					
5. Study subjects					**5. Study subjects**				
5.1	The candidate can describe the necessity for quality monitoring and quality assurance in research (for study subjects and for the quality of the study).		K	1	5.1	The candidate can describe the necessity for quality monitoring and quality assurance in research (for study subjects and for the quality of the study).		K	1
5.2	The candidate can specify the elements rules applying to the Patient Information Form (PIF)/Informed Consent (IC).		K	1	5.2	The candidate can specify the elements rules applying to the Patient Information Form (PIF)/Informed Consent (IC).		K	2
5.3	The candidate can specify why, when and which participants must be informed again and possibly sign a new Informed Consent in a particular research situation.		T	1	5.3	The candidate can specify why, when and which participants must be informed again and possibly sign a new Informed Consent in a particular research situation.		T	2
5.4	The candidate can specify which aspects are important regarding the process of obtaining Informed Consent in a particular research situation.		T	2	5.4	The candidate can specify which aspects are important regarding the process of obtaining Informed Consent in a particular research situation.		T	2
6. Auditing, Monitoring and Inspection					**6. Auditing, Monitoring and Inspection**				
6.1	The candidate knows the difference between monitoring and auditing.		K	1	6.1	The candidate knows the difference between monitoring and auditing.		K	1
6.2	The candidate can name the purpose of monitoring, auditing and inspection and is familiar with the legal context.		K	1	6.2	The candidate can name the purpose of monitoring, auditing and inspection and is familiar with the legal context.		K	1
6.3	The candidate can describe the aspects of monitoring and auditing.		K	1					
6.4	The candidate is familiar with the procedures for monitoring and auditing and following up findings during the study.		T	1	6.4	The candidate is familiar with the procedures for monitoring and auditing and following up findings during the study.		T	1

6.5	The candidate can specify the link between risk classification, monitoring and DSMB.		K	1	6.5	The candidate can specify the link between risk classification and monitoring.		K	1
6.6	The candidate can describe the responsibilities of the parties concerned with monitoring and auditing and knows when they apply.		T	1	6.6	The candidate can describe the responsibilities of the parties concerned with monitoring and auditing and knows when they apply.		T	1
				60					55