National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Clinical Bioinformatics (Physical Sciences)

CBD Scenario

CBD Scenario Title	Medical Device Determination										
CBD Scenario Aim	For the IACC candidate to demonstrate their understanding of how to assess whether a piece of software is a Medical Device.										
CBD Focus (please provide the codes of the module(s) this scenario addresses)	SBI121, SBI122c1										
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**		**GSP 2**	X	**GSP 3**		**GSP 4**	X	**GSP 5**		
CBD Scenario description	You have been asked to develop a new piece of software for use in your department. Please describe the criteria you would use to assess whether that software will be a Medical Device.										
CBD Scenario model answer/ assessor guidance Detailed guidance that will be available for the assessors. Include guidance on what kinds of behaviours, actions, comments should secure a pass. What should the assessor expect to see? Assessors will be asked to plan questions in advance including links to trainee's IACC submission.	This scenario places the trainee in the position of advising colleagues on whether a piece of software will be a Medical Device. The aim of the scenario is to assess the trainee's understanding of Medical Device classification, in the context of clinical software development. You should: • Seek a description of the requirements for the software. • Establish what (if any) clinical processes the software will form part of. • Confirm the current requirements of the Medical Device regulations; • Define the criteria which would be used to assess whether the software is a Medical Device as discussed in relevant guidance eg MHRA guidance "Guidance: Medical device stand-alone										

	software including apps (including IVDMDs)" eg MEDDEV 2.1/6 "Guidance document Medical Devices - Scope, field of application, definition - Qualification and Classification of stand-alone software." Then, to obtain a pass, you should broadly cover the following themes. **Software Requirements** • Define the clinical purpose and intended use of the software **Medical Device classification criteria** Outline the criteria you need to take into account, e.g. as shown in MEDDEV 2.1/6 Figure 1
Trainee instructions Please include any specific information to be provided to the trainee as part of the CBD scenario	

Criteria being assessed by this CBD scenario

Aspect	Please indicate if this criterion is being assessed
1. Understands the clinical context of the scenario, including priority setting and testing strategies	X
2. Understands scientific principles of scenario	
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	X
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	
5. Understands and applies associated IT/bioinformatics and other appropriate resources	X
6. Is able to interpret and report patient results and provide appropriate clinical advice	
7. Can discuss the significance of patient results within the clinical context of the referral	
8. Understands the ethical, legal and social implications of the scenario	X
9. Is aware of the importance of audit and can use this tool effectively	

10. Output meets accepted laboratory/professional standards	
11. Demonstrates awareness of the limits of responsibility and when to seek advice	
12. Consideration of patient/professionalism	
13. Overall ability to perform	