National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Bioinformatics Genomics

CBD Scenario

CBD Scenario Title	New assay validation									
CBD Scenario Aim	Demonstrate understanding of the validation process for a new test and the responsibility of the bioinformatics team in ensuring new test is safe to use for the relevant analysis pathway.									
CBD Focus (please provide the codes of the module(s) this scenario addresses)	SBI126 Competency 2 Competency 6 Competency 7		SBI127 Competency 4 Competency 7		SCC110 Competency 6 Competency 20 Competency 22					
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**		**GSP 2**	x	**GSP 3**	x	**GSP 4**	x	**GSP 5**	
CBD Scenario description	The bioinformatics team is developing a new analysis pipeline for a new NGS assay being introduced in the laboratory. You are representing the bioinformatics team in a meeting with Clinical Scientists from genomics to plan the validation. Describe the validation process that should be followed, and any other steps required to ensure the new pipeline is safe for use in a clinical service.									
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	**Pass indicators** some or all of the following points discussed: • Describe validation process (and importance of validation) • Things that could be mentioned: ○ Number of samples ○ Coverage threshold / down sampling experiments ○ Reproducibility ○ Sensitivity, specificity & confidence intervals based on number of samples ○ Comparison against a ‘gold-standard’									

to plan questions in advance including links to trainee's IACC submission.	○ Quality threshold setting ○ Limit of detection • Use of benchmarking samples for validation and continuous validation • Documentation of development and change control, including manuals, user guides and SOPs ○ Mention departmental quality management processes • Training of users both within bioinformatics and within the scientific teams • Discuss requirements and expected output with the scientists to ensure validation plan is fit for purpose **Fail indicators:** • No mention of patient safety • No mention of quality procedures • No mention of validation processes
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	x
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	x
5. Understands and applies associated IT/bioinformatics and other appropriate resources	
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	
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	x
13. Overall ability to perform	x