

Guide for STP Trainees : Clinical Measurement and Development

Learning Outcome Subject	Code	Competency	Examples of evidence	Other competencies which may be demonstrated by this evidence
The Project Life Cycle	DD1-C-1	Devise a plan using an appropriate project management methodology to successfully deliver an innovation and development project controlling the quality, timing and costs of activities.	Devise a Project specification in accordance with local processes.	DD-C-3, DD-C-4
	DD1-C-3	Design a solution to meet the previous point by formulating various options and critically appraising them, taking into account the requirements specification, appropriateness of development tools and sustainability in the proposed operational environment.	Create design description documentation indicating potential options, and justifying why certain options have been considered.	DD-C-7
	DD1-C-2	Work with users to develop a detailed specification of requirements for an innovation and development project.	Create a System/Software requirements for a particular project.	DD-C-5, DD-C-6
	DD1-C-10	Manage a project within the framework of a formal project management methodology.	By familiar and summare your organisations design/development project management framework, as per local quality management systems such as 13485	
	DD1-C-4	Develop and critically evaluate the solution, establishing its appropriateness and limitations, including signal processing, decision support, mathematical modelling and choice of development platform.	Undertake an option appraisal for solutions to a particular design/development project.	DD-C-12
	DD1-C-5	Develop and undertake a validation plan.	Create validation plans to test that the design/product meets all relevant system requirements, ensuring traceability.	DD-C-8
	DD1-C-6	Develop and undertake a verification plan.	Be familiar with the verification plan that shall form part of you rorganisations quality management system.	
	DD1-C-7	Develop user documentation and training.	Create User Manuals, ensuring all user training related mitigations identified within the hazard analysis are considered.	
	DD1-C-8	Develop technical documentation.	Be familiar and summarise the requirements for a full technical file, including software/systems specification, Hazard Analysis, Validation plans and user manuals.	
	DD1-C-9	Follow the requirements of an appropriate development standard (e.g. EN13485, SSADM).	Be familiar with the requirements of the 13485 standard, listing the relevant processes/procedures required to claim compliance.	
	DD1-C-11	Manage security, safety and business risk throughout the development, including the use of ALARP principles.	Follow the requirements within the 14971 standard to assess and mitigate risk.	DRM-C-16, DD1-C-12
	DD1-C-12	Apply risk analysis iteratively to improve and redefine a design.	Follow the requirements within the 14971 standard to assess and mitigate risk.	DRM-C-16, DD1-C-11
	DD1-C-13	Perform end-stage review.	On completion of a project, create project design review which may include indicating aspects of non conformance or issues highlighted during testing.	DD-C-12, DD1-C-4

Advanced Information and Communication Technology Skills	DD2-C-1	Discuss and agree the operation of major ICT hardware, software and networking components.	Create a report on the provision of hardware and network for new software running on new hardware, discuss and agree with Hospital IT or other stakeholders as appropriate, e.g., medical application, medical device firewall, etc.; Review local network standard and relate to medical device requirement of ISO 80001-1 (network component only).	
	DD2-C-2	Undertake implementation of at least one standard server-based operating system, including security management and routine housekeeping tasks.	Install an Operating System (Windows/linux) on a system (hardware/Virtual Machine) following local centre guidelines (network, antivirus, security) and configure for system management, e.g., backup, regular tasks (task schedule/cron) and/or services/daemons.	DD2-C-4
	DD2-C-3	Apply relevant safety standards and guidance for the use of computers in clinical practice, including electrical safety.	Assist in the routine provision and maintenance of clinical workstations. Review local practices for provision of such computers and relate these to the appropriate Medical Devices legislation, ISO80001, IEC60601 and other relevant standards.	
	DD2-C-4	Develop and maintain protective measures for ICT systems, including disaster measures, antivirus protection, maintenance, updating, firewalls and virtual servers/networks.	Configure a computer system (hardware/Virtual Machine) following local centre guidelines relating to network, firewall, antivirus and security; and configure for system management, e.g., backup and regular monitoring and maintenance tasks	DD2-C-2
	DD2-C-5	Critically appraise the ICT standards adopted by the NHS, including Digital Imaging and Communications in Medicine (DICOM) and Health Level 7 International (HL7).	Review DICOM conformance statement for one piece of clinical software or clinical computer system and relate this to DICOM standard; create a report on processes in use for anonymisation and pseudonimisation of DICOM data, and relate this to the DICOM standard; Review support for HL7 in medical applications in department/centre and consider safety improvement that might be achieved; Review local network standards and relate to medical device requirement of ISO 80001-1	
	DD2-C-6	Plan and carry out the implementation of ICT components in a controlled fashion, taking into account the impact on existing facilities and clinical service.	Undertake a project for an upgrade to existing clinical software or provision of a new installation of software on workstation or server, including a risk assessment and review of any changes required in support and peripheral services, such as backup and archiving.	DD2-C-3
Clinical Measurement	DD3-C-1	Obtain specific clinical measurements from patients under supervision.	Measurements may come from such areas as respiratory, audiology, cardiology, neurophysiology, urology, audiology, ophthalmology, GI physiology.	
	DD3-C-2	Interpret data and advise on the use of specific measurements (particularly in terms of accuracy, reproducibility, bias, specificity and sensitivity).	Use statistics as appropriate to interpret measurements and advise on the clinical significance of the results.	DD3-C-11
	DD3-C-3	Critically appraise procedures, applications and strategies and advise on their modification in the light of developing knowledge.	Review scientific literature, critically compare measurement systems, assess guidance documents and protocols between different centres.	DD3-C-6; DD3-C-5; DD3-C-7; DD3-C-11
	DD3-C-4	Write a report on the outcome of the clinical measurement.	Use a report to demonstrate understanding of the clinical significance of the measurement and communicate this to patient/professional appropriately.	DD3-C-2; DD3-C-11
	DD3-C-6	Identify problems, determine their nature and devise a strategy for solving them.	Undertake calibration procedures. Complete quality assurance measurements. Document and present data describing a problem and recommend/implement action.	DD3-C-5; DD3-C-7; DD3-C-8; DD3-C-9
	DD3-C-5	Implement effective corrective actions when performance deteriorates.	Monitor QA results and take action when results are out of tolerance.	DD3-C-3
	DD3-C-7	Solve a problem through application of specialist knowledge and experience.	Identify artefacts on a measurement and be able to take action to remove or advise on the impact on the measurement.	DD3-C-9; DD3-C-10; DD3-C-11
	DD3-C-8	Discuss and agree with co-workers, and the patient where appropriate, the steps being taken to resolve a problem.	Describe reaction to when unexpected issues/difficulties are encountered and reflect upon how these could be avoided or how student would deal with them in the future.	DD3-C-8; DD3-C-10; DD3-C-11

DD3-C-9	Advise on health and safety issues relevant to the investigation.	Perform risk assessment for a procedure or particular case.	DD3-C-7; DD3-C-11
DD3-C-10	Take appropriate action in the case of incidents and accidents	Undertake root cause analysis. Knowledge or experience of incident reporting using hospital systems e.g. DATIX	DD3-C-9
DD3-C-11	Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues.	Write a report from a clinical measurement. Participate in an MDT review meeting. Present measurement data at research meetings, workshops, study days etc	DD3-C-2; DD3-C-3; DD3-C-4; DD3-C-6; DD3-C-8

DOPS

	DOPS	Examples of evidence	Competencies which may share evidence with this DOPS
The Project Lifecycle	Direct observed practical skill	Observe student create hardware software to fulfil a medical device design specification	
	Produce user documentation and training	Observe student ceate user training material in relation to a newly developed medical device.	DD1-C-7
	Produce technical documentation	Observe student create documents for a technical file, such as a design specification, validation/verification plan and hazard analysis	DD1-C-8
	Review an ongoing project and identify the lifecycle of the project and ways of taking it forward	Observe the student use project methodology to review a current project and understand the steps required to progress the project by developing an appropriate project plan.	DD1-C-1, DD1-C-10
	Undertake vigilance and end of life procedures	Observe the student consider post market survelliance procedures for the device and how feedback will be recorded, prioritised and actioned	
	Develop a specification of requirements	Observe the student develop a safety and functional specification.	DD1-C-2
	Design a solution to respond to a specification of requirements	Observe student create a design that meets the original specification, and documents design in design description document.	CC1-C-3, DD1-C-4
	Develop a formal project management plan for a project lifecycle	Observe the student use project methodology to review a current project and understand the steps required to progress the project by developing an appropriate project plan.	DD1-C-1, DD1-C-10
	Undertake a risk analysis of a project	Observe Student create a risk management file for a product design in accordance with ISO 14971.	DD1-C-12
	Produce an implementation plan to manage the risks of medical device	Observe the student plan impementation of a newly developed device including consideration of user training, configurations and access levels, aswell as commisioning procedures.	
	Apply lifecycle process to a project and undertake validation	Observe the student undertake validation in accordance with the pre-created validation plan.	
	Undertake a risk analysis to support the improvement and redefinition of a design	Observe the student undertake a risk assessment in relation to a medical device design/modification	DD1-C-11, DD1-C-12
	Install a system and applications software on a void PC	Install Windows onto a PC, going through the full update cycle of both the Operating System and Anti-Virus.	CMICT-C-12, DD2-C-2, DD2-C-4
	Undertake a range of system administration tasks on a clinical system	Purge log files, review backups, manage user accounts, manage access controls to shared resources.	
	Set up or modify a local area network	Connect a medical device to the local network, following policy and procedure. Refer to ISO 80001-1.	

Advance ICT Skills		Programme a void PC to produce and report clinical measurement or other laboratory data	Create an interface to a medical device in order to extract information from it. Store this in a database of your design.	CMICT-C-13
		Develop a prototype web-based application for clinical applications	Create a web interface to an existing (non-web) SQL database in order to allow remote reporting (e.g. allow wards to view their equipment and the current repair status).	CMICT-C-13
		Analyse, summarise and present complex data using computer software	Data mine a patient database (comprised of more than one table) for information. Present findings to an audience using presentaiton software.	
		Comply with the information governance and operational management requirements for clinical systems	Undertake the local IG training course.	
		Identify the ICT infrastructure requirements for a diagnostic service, including networking, data storage and interconnectivity	Audit an ICT-dependent service (e.g. Nuclear Medicine).	DD2-C-3, DD2-C-5
		Develop a software application to support a clinical service	Use ImageJ (or similar) to create a program for MRI QA which replaces several manual steps/procedures.	CMICT-C-13
		Design a system to analyse quality control results	Extract PPM information from the local equipment management database and report on key performance indicators as held in the local QMS.	
		Develop and maintain protective measures for ICT systems	Undertake an audit of the current disaster recovery plans for a system, including business continuity. Propose amendments. Install Windows onto a PC, going through the full update cycle of both the OS and AV.	CMICT-C-12, DD2-C-2, DD2-C-4
		Implement ICT components in a controlled environment	Undertake a hardware upgrade of a PC, e.g. the addition of RAM or the replacement of a video capture card.	CMICT-C-12
		Undertake a range of routine house keeping tasks associated with standard server based operating systems	Purge log files, review backups, manage user accounts, manage access controls to shared resources.	
		Undertake a governance review of an ICT system	Audit an ICT system according to the local policies and procedures held in the QMS.	
Clinical Measurement		Develop new clinical measurement solution and present to assessor	Modify measurement protocols for a complicated case or sply novel measurement methods	DD3-C-3; DD3-C-6; DD3-C-7; DD3-C-8; DD3-C-11
		Report on a novel or complex clinical measurement	Write a report from a noval case.	DD3-C-2; DD3-C-4; DD3-C-11
		Implement a clinical measurement solution	Observe the student addressing a problem with a measurement or developing an innovation	DD3-C-5; DD3-C-7; DD3-C-10
		Select the appropriate equipment and its use in clinical measurement for 12-lead ECG, polysomnography, ERG or equivalent	Observe the student showing reasoning for the appropriate choice of equipment	DD3-C-2; DD3-C-3
		Identify and implement effective corrective actions when performance deteriorates	Observe student taking corrective action such as recalibration when equipment is deteriorating	DD3-C-5; DD3-C-6; DD3-C-7
		Identify problems, determine their nature and devise a strategy for solving them	Observe student taking appropriate action in response to a measurement error/artefact or equipment problem	DD3-C-6; DD3-C-7; DD3-C-8; DD3-C-9; DD3-C-10

OCEs

		OCEs	Examples of evidence	Competencies which may share evidence with this OCE
The Project Lifecycle		Present technical information for both technical and non-technical users	Observe student present project status at local or national seminar/conference.	
		Review a completed project, understand the clinical and scientific background, and explain to colleagues the development lifecycle, suggesting alternatives and/or improvements	Observe student write a project proposal including options for designs including drawbacks and benefits of each one, concluding a preferred option with rationale.	DD1-C-4
		Present information about a project to a range of users and purposes including providing information, training and general reference	Observe student develop training documentation in relation to the developed product	DD1-C-7
		Advise colleagues on health and safety issues relevant to a development project or a medical device	Observe student undertake a formal risk assessment in relation to design	DD1-C-11
		Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues	Observe student present newly developed device as per specification to clinical teams for feedback.	
		Obtain a patient history from a normal volunteer or typical patient referred to your service and present the findings to a colleague or peer	Observe Student review patient notes and suggest conclusions and opinions on test regimes to follow.	
Advance ICT Skills		Discuss with clinical team and agree the operation of major ICT hardware, software and networking components	Observe student present on a networked software system including underlying hardware used in a clinical environment for discussion and feedback.	DD2-C-1, DD2-C-6
		Explain complex software to clinical colleagues	Observe student present a review of complex software used in a clinical environment.	
		Explain key factors affecting security management factors influencing data integrity to a clinical team	Observe student training/presenting to clinical team on 'best practice' related to data integrity.	DD2-C-3, DD2-C-4, DD2-C-5
		Advise on health and safety issues relevant to the investigation	Observe student discuss a self-developed risk assessment with relevant clinical team.	DD2-C-6
		Contribute at a professional level to clinical teams and communicate scientific material	Observe student present at local or other meeting on scientific software.	
		Describe to clinical colleagues the potential influences, advantages, disadvantages of implementation on data management	Observe student present at local or other meeting on data access and management of software used in a clinical environment.	DD2-C-3, DD2-C-4, DD2-C-5

Clinical Measurement		Record complex electrophysiology data such as 12-lead ECG, polysomnography, ERG, and present numerically and graphically the main findings	Obtain electrophysiological measurements and select appropriate methods of reporting.	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11
		Obtain specific clinical measurements from patients	Student leads a clinical measurement assessment.	DD3-C-1
		Conduct pressure and flow measurement such as respiratory, blood flow, urodynamics, etc and present numerically and graphically the main findings to clinical colleagues	Observe a student undertaking a measurement and presenting the results	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11
		Conduct a gait analysis and present numerically and graphically the main findings to clinical colleagues	Observe a student undertaking a gait analysis and presenting the results	DD3-C-1; DD3-C-2; DD3-C-4; DD3-C-11
		Take patient consent for the procedure	Observe student discussing the measurement with a patient and recording informed consent. Student understands the process of informed consent.	
		Explain to the patient the procedure and next steps	Observe the student explaining a measurement procedure to a patient. Review/develop patient information literature.	DD3-C-2; DD3-C-3; DD3-C-4; DD3-C-6; DD3-C-8; DD3-C-11
		Advise on health and safety issues relevant to the investigation	Observe student discussing a health and safety issue such as a risk assessment	DD3-C-8; DD3-C-9; DD3-C-10; DD3-C-11
		Contribute at a professional level to clinical teams and communicate scientific material effectively to professional colleagues	Observe student taking part in an MDT meeting or presenting scientific material at a local or national conference/seminar	
		Discuss and agree with co-workers, and patient where appropriate, the steps being taken to resolve a problem	Observe student explaining the reasoning behind how a problem has been dealt with	

CBD

	CBD Example	Examples of evidence	Competencies which may share evidence with this CBD
CMICT1	Setup and evaluate a new piece of measurement equipment and make recommendations for its use.	Development of local guidance, protocol, demonstrate compliance with manufactures reported specifications.	DD3-C-2, DD3-C-3, DD3-C-4, DD3-C-7, DD3-C-11
CMICT2	Obtain exploratory measurements using either a new measurement technique or an existing technique but in a new application	Written report, abstract, presentation at meeting/conference.	DD3-C-2, DD3-C-3, DD3-C-4, DD3-C-6, DD3-C-7, DD3-C-11
CMICT3	Critically compare two or more measurement systems/methods intended to evaluate the same physiological parameter.	Critical comparison. Recommendations	DD3-C-2, DD3-C-3, DD3-C-4