ST0609 - Level 6 Clinical Trials Specialist: End-Point Assessment

Occupational Profile

Working as part of a multi-disciplinary team focusing on the delivery and execution of Phase I-IV clinical trials in humans.

The Clinical Trial Specialist works in Public or Private Clinical Research Organisations, generally in Pharmaceutical or Biotechnology Industries. They are part of a multi-disciplinary team focused on the delivery and execution of Phase I-IV clinical trials in humans. They are mainly office-based but travel to sites (hospitals, pharmacology units and General Practitioners) to conduct monitoring activities. Clinical Trial Specialists work initially with significant oversight as required by external regulations but over time gain increasing autonomy to monitor and deliver clinical trials consistently to the right quality and within budget. Typical job roles may include: Clinical Trials Assistant/Administrator, Clinical Research Associate and Study Coordinator with development to Clinical Project Manager.

The main duties and tasks of a Clinical Trials Specialist are:

- Act as site Monitor on assigned studies. Conduct all stages of site management from set up through to close out, develop recruitment strategies and conduct Source Document Verification (SDV). This process ensures that the record of activity and data at a site are consistent with data collection systems.
- Produce high quality documentation to include site monitoring visit reports, site agreements, risk based monitoring plans, meeting minutes, risk/mitigation and action logs and effective presentations.
- File study documentation to the Trial Master File (TMF) consistent with company SOPs and regulatory guidelines. Maintain all documentation per current quality standards. Participate in TMF and site audits as requested.
- Provide support to Clinical Project Managers e.g. produce reports on data quality, track equipment distribution and return, follow up delayed sample shipments, generate consulting/ confidentiality agreements., liaise with Clinical Research Associates (CRAs) and external contractors.
- Maintain study tracking systems, e.g. eClinical Trial Management Systems (eCTMS), finance and budget management systems, eCase Report Form (eCRF) and trial status reports.

End-Point Assessment

The Clinical Trials Specialist is assessed through two End-Point Assessment (EPA) methods as set out in the assessment plan:

- A Synoptic Project Report based on a Clinical Study Project, linked with a presentation and Question and Answer (Q and A) based on evidence presented in the Synoptic Project Report.
- Professional Discussion underpinned by a Vocational Competency Log.

Apprentices typically spend 54 months on-programme (before Gateway) working towards the occupational standard with a minimum 20% off-the-job training. All Apprentices must spend a minimum of 12 months on programme.

Once the Employer is satisfied that the Apprentice is consistently working at or above the level set out in the standard, and that all Gateway requirements have been met, the Apprentice can proceed to their End-Point Assessment (EPA).

Gateway requirements for End-Point Assessment:

- English and mathematics Level 2 as a minimum (GCSE equivalent grade A-C / 4-9)
- Completed Vocational Competency Log - Apprentices must compile a portfolio of evidence to support the criteria being assessed in the Professional Discussion.
- BSc (Hons) in a biological science (including, for example; physiology, anatomy, pharmacology, pharmacy or biochemistry). Apprentices must complete and pass their degree before Gateway can be confirmed.
- Agreement by the Apprentice's employer and a Marshall Assessment Independent Assessor (IA) of the title and scope of a Synoptic Project Report. The Synoptic Project will focus on a Clinical Study Project, which must be completed prior to the gateway.

The EPA must be completed over a maximum total assessment period of 6 months, after the Apprentice has met the EPA gateway requirements.

Marshall Assessment will provide the following documents which must be used as part of the Gateway process:

- Gateway Declaration – HEI / Training Provider
- Gateway Declaration – Employer
- Gateway Declaration – Apprentice
- 1a Synoptic Project Report Title and Scope

The EPA will usually be completed within 12-14 weeks of Gateway approval (the EPA period), which will begin once the Synoptic Project Report title and scope is agreed by Marshall Assessment and all other Gateway requirements have been met.

A summary of the assessment methods and how Marshall Assessment deliver them has been provided below. Further support can be found in the following documents which will be provided as part of our EPA support and customer / Apprentice engagement pack.

- 1 Synoptic Project Report, Presentation & Questioning Guidance – detailed guidance to help the Apprentice to plan and prepare their Synoptic Project Report and Presentation. The document includes guidance on the grading descriptors that must be met for this assessment, which will also support the Apprentice to prepare for the questioning by the Marshall Independent Assessor (IA). Marshall Assessment have also provided the following documents to support with the delivery of this assessment:

- 1b Synoptic Project Report Declaration. This should be submitted with your completed Project Report.
- 1c Synoptic Project Report & Presentation – Mapping document. This should be completed to demonstrate to the Marshall IA where you feel you have met the required criteria, in your report or in your presentation.

- 2 Professional Discussion Guidance – detailed guidance to help the Apprentice to prepare for their Professional Discussion underpinned by a Vocational Competency Log. Marshall Assessment have also provided the following document for this part of the assessment (this template is not mandatory, however, a Vocational Competency Log which meets the requirements as stipulated in the assessment plan must be submitted):
  - 2a Vocational Competency log - to ensure the Apprentice maps relevant evidence in their log to support the grading descriptors and associated KSBs being assessed in this discussion – this must be submitted at Gateway for review by the assigned Marshall IA ahead of the agreed date of assessment.

Synoptic Project Report, Presentation & Questioning.

Timescale: Total 45 minutes.

20 minutes for the Presentation (plus 10%).

25 minutes for the follow up Questioning (plus 10%).

Takes place in a quiet location, free from distractions with no other personnel present other than those with prior arrangement (Marshall IQA or Technical Expert where requested).

Apprentice will need access to a PC/laptop with a webcam as delivery will be over Microsoft Teams, unless otherwise requested.

Assessments will be recorded for quality and training purposes in line with GDPR and Marshall Assessment Data Protection Policy.

Grading outcomes: Fail, Pass or Distinction.

- Apprentices must produce a Synoptic Project Report during the **post-Gateway**, EPA period. The Project Report must be based on a **clinical study project** carried out in the Employer's workplace as part of the Apprentice's day to day activities whilst on programme (pre-Gateway).
- Apprentices should be allowed 20% of their time post gateway to work on the Synoptic Project Report.
- The Synoptic Project Report will form the basis of a presentation which must be delivered to a Marshall Independent Assessor (IA) and will be followed by Questioning.
- The proposed Synoptic Project Report title and scope (a template has been provided in the resource pack, *1a Synoptic Project Report Title and Scope*) must be submitted by the Apprentice at Gateway for review by Marshall Assessment.
- The scope and definition of the Synoptic Project Report must include a summary of the clinical trial stage and study phase covered by the project, an overview of the clinical trial management systems used and an overview of the tasks and responsibilities undertaken by the Apprentice.
- Work must not begin on the Synoptic Project Report until the title and scope has been agreed by Marshall Assessment, written confirmation will be provided.
- Once the title and scope are confirmed by Marshall Assessment, this will mark the start of the EPA period and the Synoptic Project Report can be written.
- The Project Report must be 6,000 words (+/- 10%), **excluding** tables, figures, references and annexes. There must also be an annex containing a maximum of 10 pieces of evidence relating to the project. The evidence must be attributable to the Apprentice, in part or in full.
- The Clinical Study Project should cover at least one of the key stages of a clinical trial (study start up, study amendment, study maintenance and study interim/final analysis), and should allow the Apprentice to demonstrate knowledge of and experience in the processes and procedures followed (see Synoptic Project guidance document).
- The completed Project Report, prepared presentation and the completed document *1c Synoptic Project Report & Presentation mapping* must be submitted to Marshall Assessment a maximum of **12 weeks** after agreement of the proposed report title, along with the completed Synoptic Project Report Declaration form provided (*1b Project Report Declaration Form* in resource pack).
- Deadline dates for submission of the Synoptic Project Report, presentation and mapping document will be confirmed in writing at the point of acceptance through Gateway (see *1a Synoptic Project Report Title and Scope* in resource pack). Any reports or presentation materials submitted past the stated deadline dates will result in the final grade outcome being capped at a PASS.
- Following the Apprentice's presentation of their Project Report, the IA will ask questions to clarify their understanding of the content of the report and/or presentation, to allow the opportunity for the Apprentice to clarify their understanding of the pass grading criteria, or to demonstrate that they can meet the higher-level distinction criteria.
- Apprentices may refer to their notes, presentation or presentation aides when answering the questions.
- Grading outcomes; FAIL: not all pass criteria met, PASS: all pass criteria met, or DISTINCTION: all pass criteria met and all distinction criteria met.

Professional Discussion (underpinned by a Vocational Competency Log)

Timescale:
60 minutes (plus 10%)

Takes place in a quiet location, free from distractions with no other personnel present other than those with prior arrangement (Marshall IQA).

Apprentice will need access to a PC/laptop with a webcam as delivery will be over Microsoft Teams, unless otherwise requested.

Session will be recorded for quality and training purposes in line with GDPR and Marshall Assessment Data Protection Policy.

Grading outcomes: Fail, Pass or Distinction.

- The Apprentice must complete a Vocational Competency Log which will underpin the Professional Discussion.
- The Log should contain, as a minimum, a summary of the exact tasks undertaken with relevant dates for each and all aspects of the mapped KSBs and should broadly cover all stages of the clinical trial process. It must be signed by a manager to confirm the completion date for each task.
- A Vocational Competency Log template is provided if required (see *2a Vocational Competency Log* in resource pack). Employers can use their own template, but a completed Log must be submitted at Gateway to underpin this part of the assessment.
- The Apprentice should be prepared for questions, where appropriate, to be based on the evidence provided in the Log.
- The Independent Assessor will ask the Apprentice a minimum 10 open questions. 2 questions on each of the 5 areas outlined for this part of the assessment as below:
    - Compliance with industry regulations, and standard operating procedures
    - Ethical practice and codes of conduct
    - Meeting study targets
    - Stakeholder Management
    - Continuous performance improvement
- 1 question will be competency based and 1 question scenario based (based on the evidence provided in the Vocational Competency Log).
- Professional Discussion will:
    - explore aspects of the work referenced in the Log, including how it was carried out, in more detail.
    - require the Apprentice to draw on their work-based evidence to demonstrate the required KSBs and associated grading descriptors showing the depth of their knowledge and understanding.
- See Appendix I in Professional Discussion guidance for further information on these 5 discussion areas and the related KSBs, including details of, “what needs to be evidenced”, to support preparation for this part of the assessment.
- The Apprentice can have access to their Vocational Competency Log during the discussion.
- Grading outcomes; FAIL: not all pass criteria met, PASS: all pass criteria met, or DISTINCTION: all pass criteria met and all distinction criteria met.

Remote Assessments - any breaks in connectivity will be dealt with in the following way:

- A short break of up to 10 minutes will be acceptable, this must be recorded by the IA and they will confirm the test can continue once connectivity has resumed.
- If there is a break in connectivity once a question has been asked, once resumed, the IA will ask a different question.
- If the break is during a response – the Apprentice will be allowed to continue as long as the break is less than 5 minutes. More than this, a new question will be asked.

Grading outcomes:

The Apprentice must, as a minimum, pass each element to achieve their apprenticeship certificate. If any 1 element is graded a fail, the overall grade result will be a FAIL.

To achieve a distinction, the Apprentice must be awarded a DISTINCTION in both assessment methods.

If the Apprentice fails one or both elements of the EPA, a resit/ retake can be arranged for the failed element(s), however the final grade outcome will be capped at a PASS. Apprentices cannot resit an element to improve their grade.

If an Apprentice fails the Synoptic Project Report element, the same project may be updated and re-submitted within 1 month of the assessment of the Synoptic Project Report by the EPAO.

An individual EPA method re-sit/re-take must be taken within 2 months of the receipt of the grading from the EPAO.

All evidence from the assessments is submitted for Internal Quality Assurance (IQA) before confirmation of the final grade outcome, which will be released to the HEI /Training Provider by Marshall Assessment.

Following confirmation of results from Marshall Assessment, the Apprentice or Training Provider have 15 working days to request a review of the grade. Appeals policy also available at https://www.marshall-assessment.com/our-policies If no request is made, the certificate claim will then be submitted to the Apprenticeship Service (this may take up to 4 weeks to arrive following a claim being made) and will be sent directly to the Employer unless otherwise specified.

The Knowledge, Skills and Behaviours required to be met for this Standard are listed in the assessment plan (see link) and also below in this document.

https://www.instituteforapprenticeships.org/media/3760/clinical_trial_specialist_degree.pdf

A detailed guidance pack with assessment criteria (grading descriptors), amplifications, exemplifications, mock material where appropriate and support to prepare for EPA will be provided on registration with Marshall Assessment as the EPAO.

Knowledge, Skills and Behaviours	
Knowledge	
K1:	Good Clinical Practice (GCP), Regulations and Corporate Ethics: Ethical, regulatory and data integrity/privacy principles and their application to human clinical trials, consent and be able to apply these requirements to ensure patients' rights, safety and wellbeing in clinical trials are not compromised.
K2:	Clinical Systems: eSource, Electronic Medical Records, eConsent, data visualisation technologies and other technologies within the clinical trial setting.
K3:	Trial Master File (TMF) and document management requirements with respect to confidentiality and traceability of documentation in a clinical trial.
K4:	Sample Management: Handling, labelling, storage and transport procedures for bio-samples and investigational product (IP). Include appropriate strategies for maintenance of the blind/unblinding and for investigational product accountability
K5:	Statistical principles used in the analysis of clinical trial data: power and sample size, randomisation, odds ratios, confidence intervals, p values, significance, intention-to-treat and per protocol analysis, multiplicity, equivalence and non-inferiority, and futility.
K6:	Drug Development process clinical governance and variability in protocol design in different indications and in different phases of research. Must understand the scientific terminology, method and critical evaluation applied to clinical trial design and interpretation of trial data.
K7:	Scientific Knowledge required to conduct the Clinical Study Project, including physiology, pharmacology, biochemistry, genetics and medical management. Physiology (study of the systems that keep a body alive) which may include renal, hepatic, cardiovascular, gastro-intestinal, endocrine, lymphatic and neurological systems. Pharmacology (the study of the action of drugs) which may include neuro- and renal pharmacology, human metabolism, intracellular metabolism, and intracellular regulation. Biochemistry (chemical and physio-chemical processes and substances which occur within living organisms) and Genetics (the study of genes, genetic variation hereditary), including the role of personalised medicines in healthcare setting.
K8:	Commercial and Business Issues including intellectual property and the commercial demands of the business environment.
Skills	
S1:	Monitor and Source Document Verification and source document review Develop, write and implement centralised and site monitoring plans. Conduct SDV and implement recruitment strategies for clinical trials. Assess suitability of trials at sites based on detailed understanding of protocol requirements and create appropriate feasibility questionnaires at country and site level. Conduct all site monitoring activities: site selection, initiation, maintenance and close out per national and local requirements. Record and report compliance deviations such as Serious Breaches and Product Complaints. Utilise information from clinical systems to oversee accuracy and contemporariness of trial data.
S2:	Clinical Trial Management Systems: Use clinical trial systems including; electronic Clinical Trial Management Systems (eCTMS), electronic Case Report Forms (eCRF), Interactive Response Technology (IRT), electronic Patient/Physician Reported Outcomes systems and electronic Trial Master Files (eTMF). Develop documentation to support set up, programming, maintenance and oversight of these systems to be to be compliant with the protocol and Good Clinical Practice.
S3:	Project Management and Leadership: Generate effective project plans to include management of scope, schedules, and risk. Organise resources, tasks and people. Co-ordinate team activities to meet project requirements and quality processes. Adapt clinical strategy/delivery to be consistent with variations in national, local and Ethics Committee requirements when conducting trials across multiple regions/countries.

S4:	Data Collection and Reporting: Input into the development of data management documentation, including design of Case Report Forms, Data Management Plans, Data Review Plans, edit checks and User Acceptance Testing Plans.
S5:	Communication Skills: Write extended reports and critique others' work across a range of documentation, e.g. protocols, consent forms and clinical study reports. Deliver oral presentations and answer questions about their work and/or the work of their team. Utilise interpersonal skills, communication and assertiveness to persuade and motivate.
S6:	Critical Thinking: Conceptualise, evaluate and analyse information to solve problems.
Behaviours	
B1:	Integrity and Reliability: Respect for the confidentiality of patients and sponsor information. An intrinsic ethical stance to all aspects of day to day activities. Reputation of trust internally and externally.
B2:	Flexibility and Adaptability: Responsiveness to change, adjusting to different conditions, technologies, situations and environments.
B3:	Team Working: Collaboration, influence, and respect for others and an understanding of the importance of team diversity and impact on others
B4:	Management of Expectations: of senior management, study sponsor, vendors, investigational sites and key opinion leaders, knowing when to escalate issues.
B5:	"Patients First" Attitude: Accountability for self and others to ensure that actions are in the best interest of patients in accordance with GCP.
B6:	Planning, Prioritisation and Organisation: Effective time management, knows how to apply techniques to prioritise work and delegate study related duties.
B7:	Continuing Professional Development (CPD): Accountability of own and others development needs, undertaking CPD. Curiosity of science and proactively develops knowledge to ensure that scientific and business decisions are based on strong science.

Synoptic Project Report – Grading criteria				
KSB	**Assessment element**	**Fail**	**Pass**	**Distinction**
S3	Project scope & definition	Defines boundary poorly, and lack of clarity on project scope.	Defines project scope and boundaries clearly.	Allows predicted and unforeseen outcomes to be realised.
S3	Project Management	Demonstrates poor project planning and management.	Considers resources clearly in project plan. Evidence of systematic evaluation of project progress and risk assessment.	Shows effective management of project risk and mitigating actions. Exercises extended troubleshooting and risk mitigation strategies.
S3. B3	Teamwork	Provides no examples of contributing to teamwork and interacting effectively including taking account of the impact of work on others.	Provides two examples of building working relationships within a team and interacting effectively, including taking account of the impact of work on others. Understanding	Provides two examples of leading a team to achieve project objectives.

			the roles within a cross functional study team.	
B3	Use of personal/ professional skills	Demonstrates no use of personal/ professional skills and good working practices within the context of the work based project activity.	Utilises personal/ professional skills and good working practices in overall approach and evidence presented in the competency log for the project and within the context of the work-based project activity. Demonstrates understanding of the need to collaborate and in the benefits of diverse teams in Professional Discussion. Overall approach indicates ability to treat others with respect.	Seeks to influence others to use personal/professional skills and good working practices within the context of the work-based project activity. Demonstrates ability to initiate productive collaboration with colleagues, in addition to both commanding respect and respecting others. Approach indicates understanding the importance of diversity in a team.
S1, S4, K3	Record keeping and data integrity	Explains good practice in record keeping and data integrity poorly. Does not demonstrate understanding of rules pertaining to traceability & confidentiality and data privacy e.g. ALCOA CCEA.	Explains good practice in record keeping and data integrity. Shows understanding and use of rules pertaining to traceability & confidentiality and data privacy, and how these pertain to incidences of serious breaches. Supports explanation with example from own practice.	Explains how good practice in record keeping and data integrity impacts on the wider business. Supports explanation with example of impact on the business and displays ability to create a mitigation strategy for any deviations and breaches.
S6	Creative thinking & problem solving	Explains own use of problem solving techniques such as root cause analysis poorly.	Explains own use of problem solving techniques such as root cause analysis, to challenge assumptions, innovate, make new proposals and build on existing ideas. Supports explanation with example from own practice.	Explains how problem solving techniques such as root cause analysis impacts on the wider business. Supports explanation with example of impact on the business.
K2, S2	Technical expertise – clinical systems	Explains key clinical systems used and their purpose and importance poorly.	Explains key clinical systems used as part of synoptic project report and the importance of those, supporting explanation with	Explains how clinical systems integrate / interact to support the business and business reporting. Articulates how systems and

			examples form own experience.	technology may change in the future.
S1, S4, K3, K4, S6	Presentation of evidence	Presents insufficient evidence to justify successful completion of the project.	Indicates clearly with evidence that the project scope and definition were met, and specifically how sample management and blinding was maintained. Explanation given of what went well, and any lessons learnt as a result of the project.	Indicates with evidence that the project expectations were exceeded, and how unsuccessful sample management/ blinding would impact the business
S5	Presentation and Communication	Presents ineffectively and cannot communicate the project during presentation and Q and A. Overall approach to presentation and Q and A does not demonstrate understanding of content.	Presents confidently and articulately. Able to respond to technical questioning with ability to respect opinion of others. Overall approach to presentation and Q and A demonstrates understanding of content.	Provides additional insights and depth of knowledge through answers to technical questions. Demonstrates understanding beyond content delivered, may include potential future developments in a study design and can communicate ambiguity and scenario plan complex possible situations.
K5, K6, K7, K8	Technical Expertise – study design	Presents inappropriate content and / or conclusions. Unable to explain and present logical progression of ideas based on data presented through to conclusions. Inability to discuss the commercial impacts of clinical trials.	Reasons content and conclusions based on experience and appropriate data/information analysis. Can explain how study design impacts on the commercial side of the business. Explains statistical principles relevant to analysis referred to in presentation. Can eloquently detail the drug development process with specific terminology. Is comfortable linking content of presentation to its scientific origin (i.e. how the drug of a trial affects an individual's	Provides recommendation for immediate next steps for the clinical study justified with reference to conclusions. Can explain the wider impact of clinical trials and intellectual property and the impact on the commercial organisation. Refers to scientific background of presentation content without receiving a prompt to do so. Details commercial impacts of the intellectual property described. Ability to critically evaluate drug development is

			physiology). Approach indicates awareness of business issues related to project.	demonstrated. Can provide clear background about statistics used in analysis of clinical trial data.
K7	Scientific Knowledge	Demonstrates scientific understanding unclearly. Inaccuracies in content presented and major inaccuracies in answers during Q and A.	Demonstrates clear scientific understanding during presentation and able to answer the Q and A competently and without major inaccuracies.	Relates scientific knowledge in the Clinical Study Report to areas outside of the study, indicating that their scientific knowledge is broader than that of one specific project.

Professional Discussion Grading Criteria				
KSB	**Assessment element**	**Fail**	**Pass**	**Distinction**
K1, B1, B5,	Compliance with industry regulations, and standard operating procedures (SOP)	Explains unsuccessfully (or cannot explain) relevance of key regulatory guidelines on their own role and does not understand such guidelines.	Understands and explain the importance of key regulatory guidelines relative to their own role. Supports explanation with examples from own practice and can describe impact on the business of failure to comply with these guidelines.	Articulates future developments in the regulatory environment or process changes within the organisation and their impact on the business.
B1, B5	Ethical practice and codes of conduct	Explains their organisation's and their industries' ethical practices and codes of conduct unsuccessfully or unclearly.	Explains their organisation's and their industries' ethical practices and codes of conduct. Provides example from own practice of compliance with organisation's ethical practices and codes of conduct.	Explains the impact of non-compliance with organisational ethical practices on the business.
B6	Meeting study targets	Explains how complying with defined company procedures and legislative requirements impacts on setting and meeting study	Explains how complying with defined company procedures and legislative requirements impacts on setting and meeting study targets. Supports explanation	Explains how changes in the industry impact and shift targets.

		targets unsuccessfully or unclearly.	with example from own practice.	
B4, B6	Stakeholder Management	Communicates within project poorly, or has difficulty conveying meaning to others.	Utilises tools effectively to define stakeholders internal & external to the project. Manages all stakeholder's expectations and use of judgement to influence project direction. Clearly uses interpersonal skills	Demonstrates how stakeholder management affected the outcome of the project and the impact on the business.
B7, B2	Continuous performance improvement	Explains processes used to lead continuous improvement and own use of change management principles unsuccessfully.	Explains processes used to lead continuous improvement and own use of change management principles. Supports explanation with example of leading continuous improvement from own practice.	Supports explanation with example of continuous improvement with impact on the business. Displays understanding of implications of changing conditions/technologies / situations and environments on the business. Demonstrates accountability of own and others development needs.