Clinical Trials Specialist Degree Apprenticeship Level 6:

End-point Assessment Plan

Introduction and Overview

This document sets out the requirements for end-point assessment (EPA) for the Clinical Trials Specialist Degree apprenticeship standard. It is written for end-point assessment organisations who need to know how EPA for this apprenticeship must operate. It will also be of interest to Clinical Trials Specialist apprentices, their employers and training providers.

Full time apprentices will typically spend 54 months on-programme working towards the apprenticeship standard, with a minimum of 20% off-the-job training.

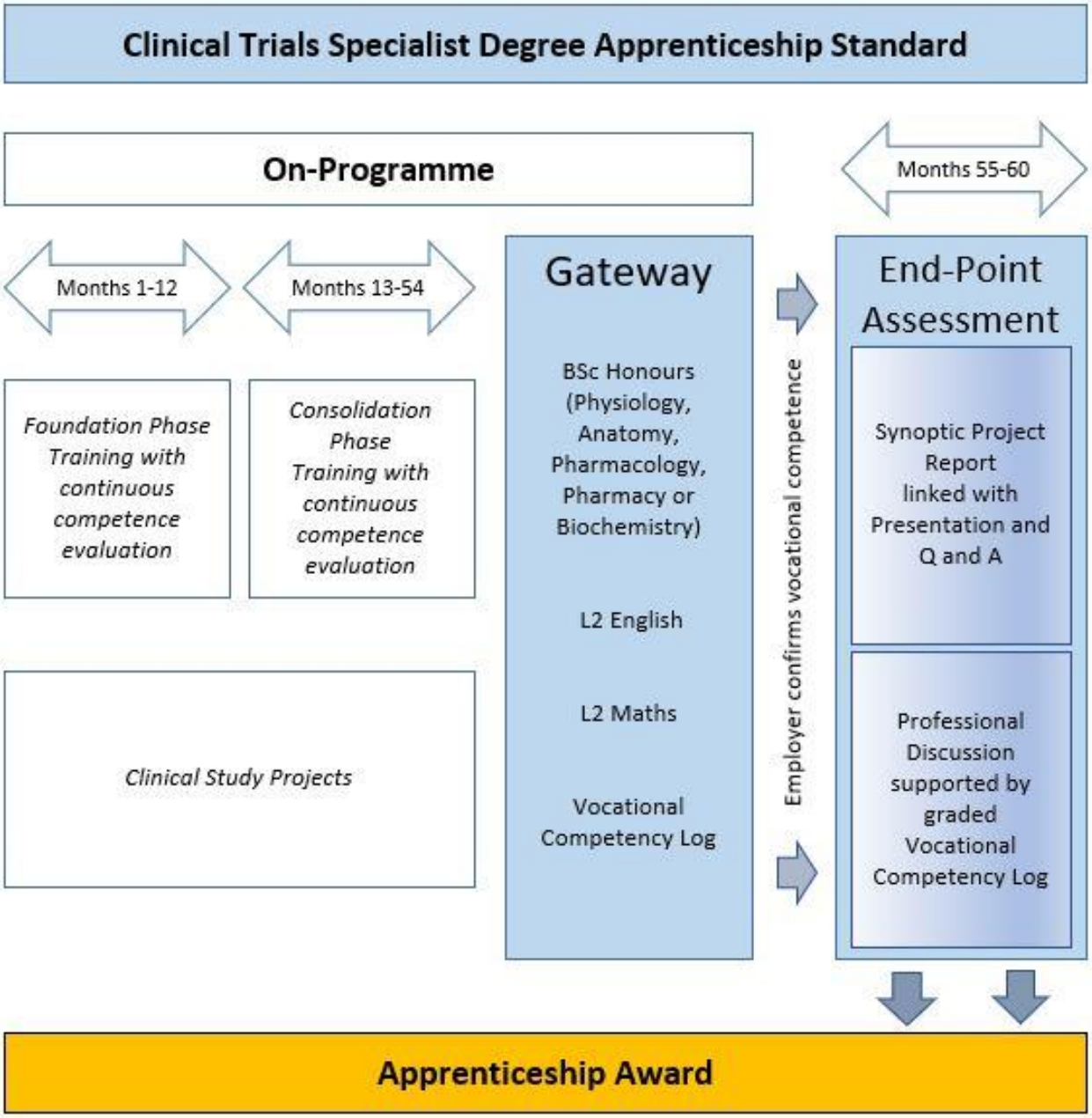
The EPA should only start once the employer deems that the apprentice is consistently working at or above the level set out in the standard, that the pre-requisite gateway requirements for EPA have been met and that they can be evidenced to an end-point assessment organisation (EPAO). As a gateway requirement, apprentices must complete a degree in biological science and complete a Vocational Competency Log. The biological science degree may include, but not limited to; human physiology, anatomy, pharmacology, pharmacy or biochemistry. To complete the apprenticeship, apprentices must have completed and passed both assessment methods as described below and passed the biological science degree. Clinical Trial Specialist apprentices without English and mathematics at Level 2 must achieve level 2 prior to taking their EPA. The EPA must be completed over a maximum total assessment period of 6 months, after the apprentice has met the EPA gateway requirements.

EPA must be conducted by an organisation approved to offer services against this standard, as selected by the employer, from the Education & Skills Funding Agency's Register of End-Point Assessment Organisations.

The EPA consists of 2 distinct assessment methods:

- A Synoptic Project Report based on a Clinical Study Project.
    - Linked with 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.

The performance of the candidate against the EPA will determine the grade of apprenticeship rewarded: fail, pass, or distinction.



End-point Assessment Gateway

The EPA should only start once the employer is satisfied that the apprentice is consistently performing at or above the level set out in the standard, the pre-requisite gateway requirements for EPA have been met and that they can be evidenced to an EPA organisation. Employers should take advice from their apprentice's training provider(s).

Gateway requirements:

- English and mathematics at Level 2.
- BSc (Hons) in a biological science (including, for example; physiology, anatomy, pharmacology, pharmacy or biochemistry).
- Completed Vocational Competency Log.
- Agreement by the apprentice's employer and an independent assessor of the title and scope of a Synoptic Project Report. The agreed Synoptic Project Report title and scope will mark the start of the apprentice's 26-week (6 months) EPA period. The Synoptic Project Report will focus on a Clinical Study Project, which must be completed prior to the gateway.

Clinical Study Project requirements:

- Reflects the typical duties and responsibilities of a Clinical Trials Specialist, as such the apprentice is expected to be working with increasing independence.
- Includes the apprentice producing and distributing written and non-written content.
- Involves working with internal colleagues (for example data management, patient safety, regulatory, study physician etc), investigators and site staff and external clients and vendors.
- To include use of clinical trial systems (electronic Case Report Form (eCRF), electronic Trial Master File (eTMF), electronic Clinical Trial Management Systems (eCTMS) etc.
- Must be 'real' work completed for the apprentice's employer i.e. simulated projects are not allowed.
- Can be completed as part of and alongside the apprentice's normal work duties/responsibilities.
- Provides the opportunity for the apprentice to demonstrate the knowledge, skills and behaviours (KSBs) being assessed by the Synoptic Project Report (including Presentation and Q and A), as shown in Annex 1.
- 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, to form the basis of the Synoptic Project Report following the EPA gateway.

End-point Assessment Methods, Timescales and Location

The end-point assessment consists of 2 distinct assessment methods:

- Synoptic Project Report based on Clinical Study Project.
    - Linked with presentation and Q and A based on evidence presented in the Synoptic Project Report.
- Professional Discussion review of Vocational Competency Log.

The apprentice will be involved in more than one Clinical Study Project throughout the course of the apprenticeship, as the clinical trial specialist role is a very broad role and spans multiple clinical trials over a 4-year period. Therefore, it is important the project is chosen carefully to form the basis of the Synoptic Project Report and the Presentation Q and A, in order to ensure that all KSBs can be met by both assessment methods. KSBs assessed by each method are provided in Annex 1.

The EPA must be completed over a maximum period of 6 months, after the apprentice has met the EPA gateway requirements. The agreed Synoptic Project Report title and scope will mark the start of the apprentice's 6 month EPA period.

The assessment methods can be completed in any order, once the synoptic title and scope have been confirmed, allowing the EPAO flexibility in scheduling and cost-effective allocation of resources.

Requirements for each assessment method are detailed below. Annex 1 provides a summary of KSBs and summarises the appropriate means to assess each competency.

Synoptic Project Report Requirements

As apprentices will be working on a wide variety of tasks and have varied responsibilities throughout the Clinical Study Project that they undertake, the employer will provide the title and scope for the Synoptic Project Report to the apprentice prior to the EPA gateway. The EPAO will confirm that the title and scope is appropriate, or will make an alternative suggestion, within 1 week of notification of the title.

The Synoptic Project Report must be 6,000 words +/-10%, excluding tables, figures, references and annexes. The allocated time for this project is 12 weeks, ensuring that it is submitted for grading at least 6 weeks prior to the end of the EPA period. Apprentices should be allowed 20%

of their time to work on the Synoptic Project Report, this could be allocated as a block of time or as a weekly allocation depending upon agreement with the employer.

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.

The Synoptic Project Report content must cover, but not be limited to, the following topics:

- Discussion of the tasks and responsibilities undertaken by the apprentice, and tasks must include monitoring, clinical trial management systems, and data collection/data management and reporting.
- Discussion of risks and mitigations for the study and associated responsibilities.
- Discussion of the study team structure and interactions during the project / tasks
- Records and data handling considerations.
- Discussion of challenges and barriers observed and actions taken - Lessons learned and best practices.

The Synoptic Project Report must include in addition to the 6,000 words 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, as many clinical documentations require input or approval from multiple parties. Evidence must be accompanied by a statement outlining the apprentice's contribution, signed by the apprentice and their employer. Example evidence may include eCTMS reports, TMF inventories and QC reports, and monitoring reports. This list is not definitive and other evidence sources are permissible.

Presentation and Q and A Requirements

EPAOs must ensure that the presentation and questioning elements of the EPA are conducted in suitably controlled environments i.e. the necessary equipment must be available e.g. computer and power-point facilities (if required by the apprentice). It is anticipated that EPAOs will use the apprentice's employer's premises wherever possible to minimise costs. The assessment may be conducted face-to-face or via an online platform e.g. video-conferencing. EPAOs must ensure appropriate methods to prevent misrepresentation are in place should an online option be used. For example, screen share and 360-degree camera function with an administrator/invigilator.

- EPAOs must schedule the presentation and questioning elements, to give an apprentice a minimum of 4-weeks' notice of the time, date and venue. The apprentice must provide the presentation to the EPAO within 2 weeks of the scheduled presentation date.
- The presentation and the questioning elements must take place in the presence of an independent assessor and can include a technical expert as requested by the independent

assessor. The technical expert may be employed by the apprentice's employer but wherever possible they should not have had any direct interaction with the apprentice. The role of the technical expert is to provide a further audience for the apprentice to present to. Prior to the Presentation and Q and A the technical expert will support the independent assessor on the presentation contents only in areas that require further clarification.

- Technical experts must not: ask questions during the presentation, make comments or give input to the grading. This is to mitigate against any potential advantage of an apprentice having someone they know with them during the EPA. Prior to the Presentation and Q and A, the independent assessor must have reviewed the apprentice's presentation and prepared questions for the questioning element. However, the questions may be modified to take into account the content of the oral presentation. Apprentices must give a presentation on a clinical study conducted as part of their Clinical Study Project. The presentation must include the scientific background of the Clinical Study Project (see K7 in Annex1) and a discussion of the clinical study protocol design, including the statistical considerations, and commercial and intellectual property considerations. This presentation and Q and A should be based on the evidence of the project report rather than a different project/ clinical study completed on the programme.

The Presentation, Question and Answer assessment method must take a total of 45 minutes. The presentation component must take 20 minutes (+10% at the discretion of the independent assessor) The Question and Answer element must take 25 minutes (+10% at the discretion of the independent assessor).

- Apprentices can use presentation aides i.e. power-point, video clips, flip chart, work products, notes.
- EPAOs must ensure any reasonable presentational requirements are in place e.g. power-point facilities; apprentices must make any requirement requests at least 2 weeks prior to the scheduled date for the presentation and questioning.
- EPAOs must produce a question bank of sufficient size to prevent predictability and review them regularly (and at least once a year) to ensure they, and the specifications they contain, are fit for purpose. Independent assessors should also be able to devise their own questions based around the Presentation content that they have reviewed. The independent assessor should use their judgment to select appropriate questions from both the EPAO question bank and those they have devised themselves.
- At the end of the presentation, the independent assessor must ask the apprentice their prepared questions (a minimum of 9 open questions) which should be taken from the question bank; follow up questions are allowed to seek clarification.
- Questioning must be completed during an additional 25-minute period (+10% at the discretion of the independent assessor).

- Questions must seek to assess KSBs (as detailed in Annex 1 for this EPA method) that were not evidenced through the presentation and/or to ensure depth of understanding in order to assess performance against the distinction criteria.
- Apprentices may refer to their notes, presentation or presentation aides when answering the questions.
- The presentation and questioning audio should be recorded electronically.
- Independent assessors must assess the presentation and questioning using the grading criteria in Annex 1.

Professional Discussion supported by a Vocational Competency Log Requirements

The Vocational Competency Log is designed by each individual company in order to record activities and tasks undertaken by the apprentice during the apprenticeship period prior to the EPA gateway. The log ensures that the apprentice has experienced and documented all the required KSBs that are mapped to this assessment method. The log underpins the Professional Discussion, and should contain, at 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 plus include a signature of line or functional management to demonstrate the completion date for each task.

EPAOs must ensure that the Professional Discussion is conducted in a suitably controlled environment. i.e. quiet room away from workplace, free from distraction and possible outside influences.

It is anticipated that EPAOs will use the apprentice's employer premises wherever possible to minimise costs. The assessment may be conducted face-to-face or via an online platform e.g. video-conferencing. EPAOs must ensure appropriate methods to prevent misrepresentation are in place should an online option be used. For example, screen-share and 360-degree camera function with an administrator/invigilator.

Other Requirements:

- The duration of the Professional discussion should be 60 minutes (+10% at the discretion of the independent assessor)
- The Vocational Competency Log should underpin the Professional Discussion. Note that the Vocational Competency Log must not be graded or directly assessed. These may be in a format defined by the apprentice's workplace but must meet the minimum criteria as detailed above.
- The Apprentice may refer to the Vocational Competency Log during the Professional Discussion.
- The EPA Organisation will create a bank of questions designed to assess the KSBs addressed by the Professional Discussion EPA method. Questions will be asked from this question bank and, as described above, the EPAO must produce a question bank of

sufficient size to prevent predictability and review them regularly (and at least once a year) to ensure they, and the specifications they contain, are fit for purpose. There will also be the opportunity for the independent assessor to ask follow-up questions.

- The independent assessor must ask the apprentice a minimum 9 open questions from the agreed question bank.
- Questions will be 50% competency based and 50% scenario based.

Apprenticeship Grading

Independent assessors must individually grade each assessment method either fail, pass or distinction, according to the requirements set out in this plan. Restrictions on grading apply where apprentices re-sit/re-take an assessment method – see re-sit/re-take section below. An independent assessor and/or EPAO must combine the grades of all the assessment methods to determine the overall EPA grade.

- To achieve an overall EPA pass, apprentices must achieve a pass in both assessment methods.
- To achieve an overall EPA distinction, apprentices must achieve a distinction in both assessment methods (Synoptic Project Report/ Presentation and Q and A, and Professional Discussion).
- A fail in either assessment will result in a fail overall.

Pass means the apprentice has demonstrated the KSB in the standard. Distinction criteria must represent additional depth/breadth of understanding of the KSBs (defined in Annex 2).

Where more than one independent assessor is involved, the independent assessor responsible for the assessment method completed last will be responsible for combining the grades to provide the overall grade. The EPAO will finalise the grading decisions.

Independent assessors' decisions must be subject to moderation by the EPAO – see internal quality assurance section below. Decisions must not be confirmed until after moderation.

Re-sit and re-take information

Apprentices who fail one or more EPA methods will be offered the opportunity to take a resit/retake. A re-sit does not require further learning, whereas a re-take does.

The apprentice's employer will need to agree that a re-sit/re-take is an appropriate course of action. Apprentices should have a supportive action plan to prepare for the re-sit/re-take. This should be generated as a collaboration between employer and EPAO.

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

The maximum grade awarded to a re-sit/re-take will be pass, unless the EPAO identifies exceptional circumstances accounting for the original fail.

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.
If the apprentice fails the Professional Discussion, then this must be re-schedules and different questions must be asked.

EPAOs must ensure that apprentices answer different questions when taking a re-sit/re-take.

End-point Assessment Organisations

Employers must choose an independent EPAO approved to deliver the EPA for this apprenticeship from the Education & Skills Funding Agency's (ESFAs) Register of End Point Assessment Organisations (RoEPAO).

Requirements for Independent Assessors, Invigilators and Markers (as applicable) EPAOs must appoint:

- Administrators/invigilators and markers to administer/invigilate the Synoptic Project Report with Presentation, Q and A, and Professional Discussion.
- Independent assessors to mark and grade the Synoptic Project Report with Presentation and Q and A, and Professional Discussion.
- Quality assurance staff to undertake moderation of EPA:
    - Internal moderation by EPAO
    - External quality assurance by EQA Provider.
- Technical experts to support aspects of the End-point Assessment. Technical experts may be needed to provide the independent assessor with assistance or clarification regarding Synoptic Project Report content or Presentation and Q and A content, where

the independent assessor requires more up to date expertise on a particular clinical trial / clinical operations topic. The technical expert will only be permitted to be part of the EPA at the EPAO's request. The technical expert will not ask questions or make comments unless asked for clarification by the independent assessor. The technical expert will not be able to contribute to the grading decisions.

Technical Experts must meet the following requirements:

- Currently active professional in a Clinical Operations role in the industry (pharma, biotech or contract research organisation) with more than 5 years of experience, or if retired they must have worked within the industry in a clinical operations role in the last 5 years.
- Proven experience in clinical research in a range of phases (I-IV) of research in a variety of therapeutic indications.
- Wherever possible they should have had no direct interaction with the apprentice previously.
- Undertake a minimum of 1 days' EPAO standardisation training per year on this Standard.

Independent Assessors must meet the following requirements:

- Be independent of the apprentice, their employer and training provider(s) i.e. there must be no conflict of interest.
- Hold or be working towards an assessor qualification e.g. A1 and have had training from their EPAO in terms of good assessment practice, operating the assessment tools and grading.
- Experience within healthcare/ drug development with a broad understanding of Clinical Operations
- Undertake a minimum of 1-days' EPAO standardisation training per year on this Standard.

Quality assurance staff must hold or be working towards quality assurance qualifications. They must be independent of the apprentice, their employer and training provider i.e. there must be no conflict of interest.

Internal Quality Assurance

Internal quality assurance refers to the requirements that EPA organisation must have in place to ensure consistent (reliable) and accurate (valid) assessment decisions. EPA organisations for this EPA must undertake the following:

- Appoint independent assessors that meet the requirements as detailed in this plan – see above.
- Appoint Technical Experts that meet the requirements as detailed in this plan – see above.
- Provide training for independent assessors in terms of good assessment practice, operating the assessment tools and grading, prior to their delivery.
- Provide training for Technical Experts so that they can support the independent assessor appropriately during the Presentation, Questioning and Answer method, prior to their delivery.
- Have quality assurance systems and procedures that support fair, reliable and consistent assessment across organisation and over time.
- Operate regular standardisation events which ensure that both independent assessors and. Operate moderation of assessment activity and decisions, through examination of documentation and observation of activity. Assessment Tools and Materials.

EPAOs must produce assessment tools and supporting materials for the EPA that follow best assessment practice, as follows:

- Sample questions (question bank) for Synoptic Project Report, Presentation and Q and A and Professional Discussion. The EPAO must produce a question bank of sufficient size to prevent predictability and review them regularly (and at least once a year) to ensure they, and the specifications they contain, are fit for purpose.
- Documentation for recording assessment evidence and decisions.
- Guidance for independent assessors on conducting the EPA.
- Guidance for apprentices, their employers and training providers on the EPA.

Affordability:

The following factors should ensure the EPA is affordable:

- Allowing the assessments to be performed in any order.
- Ensuring efficiency of assessment e.g. performing assessments on multiple candidates on the same date(s) where possible.
- Using real work projects rather than simulations.
- Carrying out assessments in employer premises.

Annex 1 – Knowledge, Skills and Behaviours to be assessed by each assessment method

Knowledge - The Clinical Trials Specialist will have knowledge of the following:		Assessment
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.	**Professional Discussion**
K2	**Clinical Systems:** eSource, Electronic Medical Records, eConsent, data visualisation technologies and other technologies within the clinical trial setting.	**Synoptic Project Report (including Presentation Q&A)**
K3	**Trial Master File (TMF)** and document management requirements with respect to confidentiality and traceability of documentation in a clinical trial.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**

K8	**Commercial and Business Issues** including intellectual property and the commercial demands of the business environment.	**Synoptic Project Report (including Presentation Q&A)**

Skill - A Clinical Trials Specialist can:		
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**
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.	**Synoptic Project Report (including Presentation Q&A)**

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.	**Synoptic Project Report (including Presentation Q&A)**
S6	**Critical Thinking:** Conceptualise, evaluate and analyse information to solve problems.	**Synoptic Project Report (including Presentation Q&A)**

Behaviour - A Clinical Trials Specialist demonstrates:		
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.	**Professional Discussion**
B2	**Flexibility and Adaptability:** Responsiveness to change, adjusting to different conditions, technologies, situations and environments.	**Professional Discussion**
B3	**Team Working:** Collaboration, influence, and respect for others and an understanding of the importance of team diversity and impact on others.	**Synoptic Project Report (including Presentation Q&A)**
B4	**Management of Expectations:** of senior management, study sponsor, vendors, investigational sites and key opinion leaders, knowing when to escalate issues.	**Professional Discussion**
B5	**"Patients First" Attitude:** Accountability for self and others to ensure that actions are in the best interest of patients in accordance with GCP.	**Professional Discussion**
B6	**Planning, Prioritisation and Organisation:** Effective time management, knows how to apply techniques to prioritise work and delegate study related duties.	**Professional Discussion**
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.	**Professional Discussion**

Annex 2 – Grading Criteria

Synoptic Project Report

KSB	Assessment element	Fail	Pass	Distinction Meets the pass criteria and:
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 the roles within a cross functional study team.	Provides two examples of leading a team to achieve project objectives.

B3	Use of personal/ professional skills	Demonstrates no use of personal/professional skills and good working practices within the context of the workbased 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 examples form own experience.	Explains how clinical systems integrate / interact to support the business and business reporting. Articulates how systems and 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 physiology). Approach	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

			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.

Synoptic Project Report with Presentation Q and A Grading

Fail = fails to meet pass grade criteria for the Synoptic Project Report with Presentation and Q and A.

Pass = achieves the pass grade criteria for every descriptor within the grading table for the Synoptic Project Report with Presentation and Q and A.

Distinction = achieves all the pass grade criteria and in addition achieves the distinction grade criteria for every descriptor within the grading table for the Synoptic Project Report with Presentation and Q and A.

Professional Discussion

KSB	Assessment element	Fail	Pass	Distinction Meets the pass criteria and:
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 targets unsuccessfully or unclearly.	Explains how complying with defined company procedures and legislative requirements impacts on setting and meeting study targets. Supports explanation with example from own practice.	Explains how changes in the industry impact and shift targets.

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.

Professional Discussion Grading Criteria

Fail = fails to meet pass grade criteria for the Professional Discussion

Pass = achieves the pass grade criteria for every descriptor within the grading table for the Professional Discussion

Distinction = achieves all the pass grade criteria and in addition achieves the distinction grade criteria for ever descriptor within the grading table for the Professional Discussion.