

End-point assessment plan for **Medical Statistician** apprenticeship standard

Apprenticeship standard reference number	Apprenticeship standard level	Integrated end-point assessment
ST0892	7	Integrated degree apprenticeship

Contents

Introduction and overview	2
EPA summary table	4
Length of EPA period.....	5
Order of end-point assessment methods	5
Gateway	6
End-point assessment methods.....	7
Reasonable adjustments	14
Re-sits and re-takes.....	15
Roles and responsibilities	17
Internal Quality Assurance (IQA).....	21
Value for money.....	21
Professional body recognition	21
Mapping of knowledge, skills and behaviours (KSBs)	22
Grading Descriptors.....	25

Introduction and overview

This document sets out the requirements for end-point assessment (EPA) for the **Medical statistician** apprenticeship standard. It explains how EPA for this apprenticeship must operate.

This document provides the EPA design requirements for end-point assessment organisations (EPAOs) for this apprenticeship standard. It will also be useful for apprentices undertaking this apprenticeship, their employers and training providers.

EPA must be conducted by an EPAO approved to deliver EPA for this apprenticeship standard. Each employer should select an approved EPAO from the Education & Skills Funding Agency's Register of end-point assessment organisations (RoEPAO).

Full-time apprentices will typically spend **30** months on-programme (before the gateway) working towards this occupational standard. All apprentices must spend a minimum of 12 months on-programme. All apprentices must spend a minimum of 20% of on-programme time undertaking off-the-job training.

Before starting EPA, an apprentice must meet the gateway requirements. For this apprenticeship they are:

- the employer must be content that the apprentice is working at or above the occupational standard
- **Achievement of 120 credits of the MSc integrated degree in Medical Statistics from the on-programme apprenticeship, formally confirmed prior to the gateway progression. (The final 60 credits of the MSc degree will be attributed to the end-point assessment).**
- apprentices must have achieved English and mathematics at Level 2¹.

The EPAO must confirm that all required gateway evidence has been provided and accepted as meeting the gateway requirements. The EPAO is responsible for confirming gateway eligibility. Once this has been confirmed, the EPA period starts.

This EPA should then be completed within an EPA period lasting typically for **6 months**.

¹ For those with an education, health and care plan or a legacy statement, the apprenticeship's English and mathematics minimum requirement is Entry Level 3. British Sign Language (BSL) qualifications are an alternative to English qualifications for those who have BSL as their primary language.

This EPA consists of 2 discrete assessment methods.

It will be possible to achieve the following grades in each end-point assessment method:

Assessment method 1 – Work based project report with presentation and questioning

- fail
- pass
- distinction

Assessment method 2 – Professional interview underpinned by a portfolio of evidence

- fail
- pass
- distinction

Performance in the end-point assessment methods will determine the overall apprenticeship standard grade of:

- fail
- pass
- merit
- distinction

EPA summary table

<p>On-programme (typically 30 months)</p>	<p>Training to develop the knowledge, skills and behaviours (KSBs) of the occupational standard.</p> <p>Training towards mandated qualifications.</p> <p>Training towards English and mathematics Level 2, if required.</p> <p>Compiling a portfolio of evidence.</p>
<p>End-point assessment gateway</p>	<p>The employer must be content that the apprentice is working at or above the level of the occupational standard.</p> <p>Achievement of 120 credits of the MSc integrated degree in Medical Statistics from the on-programme apprenticeship, formally confirmed prior to the gateway progression. (The final 60 credits of the MSc degree will be attributed to the end-point assessment).</p> <p>Apprentices must have achieved English and mathematics at Level 2.</p> <p>The apprentice must agree the subject, title and scope for their EPA project with their employer and EPAO</p> <p>The apprentice must submit a portfolio of evidence to their EPAO, which will underpin the EPA interview</p>
<p>End-point assessment (typically 6 months)</p>	<p>End-point assessment method 1: Work based project report with presentation and questioning, graded:</p> <ul style="list-style-type: none"> • fail • pass • distinction <p>End-point assessment method 2: Professional interview underpinned by a portfolio of evidence, graded:</p> <ul style="list-style-type: none"> • fail • pass • distinction <p>Overall EPA/apprenticeship graded</p> <ul style="list-style-type: none"> • fail • pass • merit • distinction

Length of EPA period

The EPA will be completed within an EPA period lasting typically for **6 months**, starting when the EPAO has confirmed that all Gateway requirements have been met.

The EPA period must last for a minimum of one week.

Order of end-point assessment methods

The assessment methods can be delivered in any order.

The result of one assessment method does not need to be known before starting the next.

Gateway

The apprentice should only enter the gateway once the employer is content that the apprentice is working at or above the level of the occupational standard. In making this decision, the employer may take advice from the apprentice's training provider(s), but the decision must ultimately be made solely by the employer.

The EPAO determines when all other gateway requirements have been met, and the EPA period will only commence once the EPAO has confirmed this.

In addition to the employer's confirmation that the apprentice is working at or above the level of the occupational standard, the apprentice must have completed the following gateway requirement prior to starting EPA:

- Achievement of **120** credits of the MSc integrated degree in Medical Statistics from the on-programme apprenticeship, formally confirmed prior to the gateway progression. (The final **60** credits of the MSc degree will be attributed to the end-point assessment).
- achieved English and mathematics at Level 2. For those with an education, health and care plan or a legacy statement, the apprenticeship's English and mathematics minimum requirement is Entry Level 3. British Sign Language (BSL) qualifications are an alternative to English qualifications for those who have BSL as their primary language.

For the work-based project report with presentation the following will be required:

- the employer must be satisfied that the apprentice's on-programme practice is sufficient for the requirements set out in this EPA plan;
- the employer and the apprentice must have set the project scope and title;
- the apprentice must have created the project report proposal (including scope and title)
- at the gateway the EPAO must have approved the project report proposal (including scope and title).

For the professional interview underpinned by a portfolio of evidence, the apprentice will be required to submit:

- a portfolio which they have developed during their on-programme training period i.e. pre-gateway. It must be submitted at the gateway, in electronic form.

Portfolio of evidence requirements:

- apprentices must compile a portfolio of evidence during the on-programme period of the apprenticeship
- it must contain evidence related to the KSBs that will be assessed by the professional interview
- the portfolio of evidence will typically contain 12 discrete pieces of evidence
- evidence must be mapped against the KSBs

- evidence may be used to demonstrate more than one KSB; a qualitative as opposed to quantitative approach is suggested
- evidence sources may include:
 - workplace documentation, for example SAS/R code and output for analyses completed, technical writing such as Protocols, Statistical analysis plans, reports, posters or papers, evidence of sample size calculations and design rationale
 - witness statements
 - annotated photographs

This is not a definitive list; other evidence sources are possible.

- it should not include any methods of reflection or self-assessment
- any employer contributions should focus on direct observation of performance (for example witness statements) rather than opinions
- the evidence provided must be valid and attributable to the apprentice; the portfolio of evidence must contain a statement from the employer and apprentice confirming this
- the portfolio of evidence must be submitted in electronic form to the EPAO at the gateway

The portfolio of evidence is not directly assessed. It underpins the professional interview and therefore should not be marked by the EPAO. EPAOs should review the portfolio of evidence in preparation for the professional interview but are not required to provide feedback after this review of the portfolio.

End-point assessment methods

The apprentice will be assessed against the KSBs assigned to the assessment methods outlined below, as shown in the mapping section of this EPA plan.

End-point assessment method 1: Work-based project report with presentation and questioning

Overview

This assessment method has 2 components.

A project involves the apprentice completing a significant and defined piece of work that has a real business benefit. The project must be undertaken after the apprentice has gone through the gateway.

The project should be designed to ensure that the apprentice's work meets the needs of the business, is relevant to their role and allows the relevant KSBs to be assessed for the EPA. The employer will ensure it has a real business application and the EPAO will ensure it meets the requirements of the EPA, including suitable coverage of the KSBs assigned to this

assessment method as shown in the mapping of assessment methods. The EPAO must refer to the grading descriptors to ensure that projects are pitched appropriately.

This assessment method includes two components:

- a project with an output component - a report
- a presentation and question and answer component to ensure the apprentice is assessed against their evidence.

The rationale for this assessment method is:

- Progressing research in the area of medical statistics as the project is based on real work and can be shared within the organisation and wider statistics community
- Demonstrating report writing skills which is a skill required in their day-to-day work
- People in this occupation are required to deliver presentations and answer questions as part of their role, so the presentation to the assessor replicates this.

The evidence from the project report, presentation and responses to questions will be assessed holistically.

Component 1 – Work-based project report

Delivery

Apprentices will carry out a project and prepare an **electronic written report**.

The project may be based on any of the following:

- a specific problem, such as the application of statistical methods to specific disease areas
- a recurring issue, using statistics to analyse data in a better way
- an idea or opportunity, such as a new data type or new experiment or design

The EPAO should sign off the project report proposal (including title and scope) to confirm its suitability at the gateway.

The project starts after the apprentice has gone through the gateway. The duration of the project is **4 months including the writing of the report**.

The employer should ensure the apprentice has sufficient time and the necessary resources, within this period, to plan and undertake the project.

As a minimum, all projects must include:

- an introduction
- the objective or scope of the project (including key performance indicators)

- A review of the methods/literature
- how the outcomes were achieved including any statistical methodology
- a project plan outlining the work to be conducted
- research and findings
- project outcomes
- recommendations, limitations and conclusions

Illustrative project examples are:

- The Spatial Distribution of the Double Burden of Malnutrition in Kenya 2014: A Model-Based Geostatistical Approach
- Bayesian analysis of incomplete data from malaria epidemiological studies investigating pfHRP2/pfHRP3 gene deletions
- Risk factors predicting for Emergency Department revisit or death within 30-day in patients with acute heart failure
- Assessing the dose-response effect of a conditional cash transfer programme on TB cure rate in Brazil
- Multivariate Serological Analysis of Malaria and Chronic Fatigue Syndrome
- Comparing propensity scores for multiple exposure groups
- Combining multiple imputation and non-parametric bootstrapping to analyse skew distrusted cost data
- Meta-analysis for rare events
- Maternal BMI and childhood respiratory health
- Modelling of longitudinal changes in lung function in patients with Systemic Sclerosis and association with development of pulmonary hypertension
- Impact of different timescales on overall survival, and determinants of survival in women with breast cancer
- Adjusted analyses in two cluster randomised trials

The project has a word limit of 12,000. A tolerance of plus or minus 10% is allowed. Appendices, references, diagrams and tables will not be included in this total. The project must map, in an appendix, how it evidences the relevant KSBs for this assessment method.

The project will be conducted as follows:

- The apprentice must be given 4 months to complete and submit the work-based project report following the EPAO's approval of the report scope and title.
- Employers must allow apprentices a minimum of 50 working days of time (within this 4 month period) to do so.

The apprentice should complete their project unaided. When the **report** is submitted, the apprentice and their employer must verify that the submitted project is the apprentice's own work.

The independent assessor will review and assess the project holistically together with the other component of this assessment method.

The independent assessor will make all grading decisions.

Component 2 – Presentation and questioning

Overview

Apprentices will be required to produce, submit and present a presentation to the independent assessor.

A copy of the presentation must be submitted to the EPAO at the same time as the project report; 4 months after the gateway.

The independent assessor must have a minimum of 2 weeks to review the project report and presentation slides in advance of the presentation itself in order to prepare appropriate questions.

The presentation will provide an overview of the apprentice's project and any project outputs. This will be followed by questioning by the independent assessor.

As a minimum, all presentations must include:

- an overview of the project
- the project scope (including key performance indicators)
- summary of actions undertaken by the apprentice
- project outcomes and how these were achieved

Delivery

The presentation will be arranged by the EPAO in consultation with the employer. The apprentice must be given 14 days notice of when the project report and presentation is required to be delivered. It will be presented to an independent assessor on a one-to-one basis, either face-to-face or via online video conferencing. If using an online platform, EPAOs must ensure appropriate measures are in place to prevent misrepresentation and ensure the apprentice is not being aided.

The project report and presentation content must be submitted at least 2 weeks before the presentation to allow the independent assessor sufficient time to review it and prepare appropriate questions.

The presentation and questioning must last for a total of 45 minutes typically including a presentation of 20 minutes and questioning lasting 25 minutes. The independent assessor has the discretion to increase the total time of the presentation and questioning by up to 10% to allow the apprentice to complete their last point. Further time may be granted for apprentices with additional needs, in-line with the EPAO's Reasonable adjustments policy.

The independent assessor will ask a minimum of 8 questions. Questions may be taken from an EPAO question bank or be those generated by the independent assessor. Follow up questions are permitted where clarification is required.

The purpose of the questioning is:

- to verify that the project is the apprentice's own work
- to seek clarification on the report or presentation
- to assess the depth and breadth of knowledge, skills and behaviours
- to assess those KSBs that the apprentice did not have the opportunity to demonstrate during the project, although these should be kept to a minimum

The independent assessor must use the full time available for questioning to allow the apprentice the opportunity to evidence occupational competence at the highest level available, unless the apprentice has already achieved the highest grade available.

Those KSBs that the apprentice did not have the opportunity to demonstrate during the project or presentation can instead be covered by questioning, although these should be kept to a minimum.

To deliver the presentation, the apprentice will have access to:

- presentation software
- a copy of the project report and presentation
- notes
- computer

KSBs met and answers to questions, must be recorded by the independent assessor. The independent assessor will make all grading decisions.

Assessment location

The presentation and questioning can take place in a suitable venue selected by the EPAO (e.g. EPAO or employer premises).

The presentation, questioning and answers should take place in a quiet room, free from distractions and influence. Video conferencing can also be used to conduct the presentation and questioning component, but the EPAO must have processes in place to verify the identity of the apprentice and ensure the apprentice is not being aided.

Only the independent assessor will observe the presentation. A representative from the EPAO may be present when necessary for moderation purposes.

Question and resource development

Questions for the question bank must be written by EPAOs, be relevant to the occupation and assess the KSBs mapped to this assessment method. It is recommended that this be done in consultation with employers of this occupation. EPAOs should maintain the security and confidentiality of their questions when consulting employers.

Each EPAO must develop a test specification. They must also develop a question bank of sufficient size to prevent predictability and review it regularly (and at least once a year) to ensure it, and the questions it contain, are fit for purpose.

EPAOs will produce the following material to support this assessment method:

- independent assessor assessment materials which include:
 - training materials
 - administration materials
 - moderation and standardisation materials
 - guidance materials
 - grading guidance
- question bank
- guidance documentation for the independent assessor, apprentice and employer

The independent assessor will assess all components of this assessment method holistically.

End-point assessment method 2: Professional interview underpinned by a portfolio of evidence

Overview

This assessment method has one component.

An interview consists of an independent assessor asking an apprentice a series of questions to assess their competence against the KSBs. The independent assessor's role is restricted to asking set questions, and it is not a two-way discussion. The independent assessor leads this process to obtain information from the apprentice to enable structured assessment decision-making to occur.

The rationale for this assessment method is:

- it allows the apprentice to be assessed against KSBs that do not naturally occur in the project

- it allows for testing of responses where there are a number of potential answers that require discussion
- it replicates the sort of professional interview occupationally competent employees regularly participate in with their manager
- the use of a portfolio allows the apprentice to underpin their responses with evidence

Delivery

The interview must be appropriately structured to draw out the best of the apprentice's competence and cover the KSBs assigned to this assessment method.

The purpose of the questions will be:

- to ensure the apprentice can evidence the KSBs assigned to the assessment method and to provide opportunity for them to show depth and breadth of coverage and, where they are able, to demonstrate the distinction criteria.

The independent assessor will conduct and assess the interview.

The interview must last for 60 minutes. The independent assessor has the discretion to increase the time of the interview by up to 10% to allow the apprentice to complete their last point.

During this assessment method, the independent assessor must refer to the EPAOs question bank. Independent assessors must use the question bank as a source for questioning and are expected to use the portfolio provided by the apprentice at the gateway, and their professional judgement to tailor those questions appropriately. The portfolio will also be used by the apprentice to refer to in order to exemplify a point. Independent assessors are responsible for generating suitable follow-up questions in line with the EPAO's training and standardisation process. The interview will have a minimum of 6 questions.

KSBs met and answers to questions, must be recorded by the independent assessor. The independent assessor will make all grading decisions.

Assessment location

The interview should take place in a quiet room, free from distractions and influence. Video conferencing can also be used to conduct the interview, but the EPAO must have processes in place to verify the identity of the apprentice and ensure the apprentice is not being aided.

The interview can take place in any of the following:

- employer's premises
- a suitable venue selected by the EPAO (for example a training provider's premises)

Question and resource development

Questions for the question bank must be written by EPAOs, be relevant to the occupation and assess the KSBs mapped to this assessment method. It is recommended that this be done in consultation with employers of this occupation. EPAOs should maintain the security and confidentiality of their questions when consulting employers.

Each EPAO must develop a test specification. They must also develop a question bank of sufficient size to prevent predictability and review it regularly (and at least once a year) to ensure it, and the questions it contain, are fit for purpose.

EPAOs must ensure that apprentices have a different set of questions in the case of re-sits/re-takes.

EPAOs will produce the following material to support this assessment method:

- independent assessor assessment materials which include:
 - training materials
 - administration materials
 - moderation and standardisation materials
 - guidance materials
 - grading guidance
- question bank
- guidance documentation for the independent assessor, apprentice and employer

Reasonable adjustments

The EPAO must have in place clear and fair arrangements for making reasonable adjustments to the assessment methods for the EPA for this apprenticeship standard. This should include how an apprentice qualifies for reasonable adjustment and what reasonable adjustments will be made. The adjustments must maintain the validity, reliability and integrity of the assessment methods outlined in this EPA plan.

Overall EPA grading

All assessment methods are weighted equally in their contribution to the overall EPA grade

Performance in the EPA will determine the apprenticeship grade of fail, pass, merit or distinction.

Independent assessors must individually grade each assessment method, according to the requirements set out in this end-point assessment plan.

EPAOs must combine the individual assessment method grades to determine the overall EPA grade.

Apprentices who fail one or more assessment method will be awarded an overall EPA 'fail'.

In order to gain an overall EPA 'pass', apprentices must achieve a pass in all the assessment methods.

In order to achieve an overall EPA 'distinction', apprentices must achieve a distinction in both of the assessment methods.

Grades from individual assessment methods should be combined in the following way to determine the grade of the EPA as a whole:

Assessment method 1: Work based project report with presentation and questioning	Assessment method 2: Professional interview underpinned by a portfolio of evidence	Overall grading
Fail	Any grade	Fail
Any grade	Fail	Fail
Pass	Pass	Pass
Pass	Distinction	Merit
Distinction	Pass	Merit
Distinction	Distinction	Distinction

Any grade = fail, pass, or distinction

Re-sits and re-takes

Apprentices who fail one or more assessment method/s will be offered the opportunity to take a re-sit or a re-take at the discretion of the employer. The apprentice's employer will need to agree that either a re-sit or re-take is an appropriate course of action.

If the Work Based Project assessment method is failed, the apprentice is not required to undertake a new project. Instead they should submit an amended project report or presentation.

A re-sit does not require further learning, whereas a re-take does.

Apprentices should have a supportive action plan to prepare for a re-sit or a re-take.

The timescales for a re-sit/re-take is agreed between the employer and EPAO. A re-sit is typically taken within 3 months of the EPA outcome notification. The timescale for a re-take is dependent on how much re-training is required and is typically taken within 4 months of the EPA outcome notification.

All assessment methods must be taken within a 6 month period, otherwise the entire EPA will need to be re-sat/re-taken.

Re-sits and re-takes are not offered to apprentices wishing to move from pass to a higher grade.

Where any assessment method has to be re-sat or re-taken, the apprentice will be able to be awarded fail, pass, merit or distinction as applicable.

Roles and responsibilities

Role	Responsibility
Apprentice	<p>As a minimum, apprentices should:</p> <ul style="list-style-type: none"> • participate in and complete on-programme training to meet the KSBs as outlined in the occupational standard for a minimum of 12 months • undertake 20% off-the-job training as arranged by the employer and EPAO • understand the purpose and importance of EPA • undertake the EPA including meeting all gateway requirements
Employer	<p>As a minimum, employers should:</p> <ul style="list-style-type: none"> • select the EPAO and training provider • work with the training provider (where applicable) to support the apprentice in the workplace and to provide the opportunities for the apprentice to develop the KSBs • arrange and support a minimum of 20% off-the-job training to be undertaken by the apprentice • decide when the apprentice is working at or above the occupational standard and so is ready for EPA • ensure that all supporting evidence required at the gateway is submitted in accordance with this EPA plan • remain independent from the delivery of the EPA • confirm arrangements with the EPAO for the EPA (who, when, where) in a timely manner (including providing access to any employer-specific documentation as required, for example company policies) • ensure that the EPA is scheduled with the EPAO for a date and time which allow appropriate opportunity for the KSBs to be met • ensure the apprentice is well prepared for the EPA • ensure the apprentice is given sufficient time away from regular duties to prepare for and complete all post-gateway elements of the EPA, and that any required supervision during this time (as stated within this EPA plan) is in place

	<ul style="list-style-type: none"> • where the apprentice is assessed in the workplace, ensure that the apprentice has access to the resources used on a daily basis • pass the certificate to the apprentice
EPAO	<p>As a minimum, EPAOs should:</p> <ul style="list-style-type: none"> • conform to the requirements of this EPA plan and deliver its requirements in a timely manner • conform to the requirements of the Register of End-Point Assessment Organisations (RoEPAO) • conform to the requirements of the external quality assurance provider (EQAP) for this apprenticeship standard • understand the occupational standard • make all necessary contractual arrangements, including agreeing the price of the EPA • develop and produce assessment materials including specifications and marking materials (for example mark schemes, practice materials, training material) • appoint suitably qualified and competent independent assessors • appoint administrators (and invigilators where required) to administer the EPA as appropriate • provide training for independent assessors in terms of good assessment practice, operating the assessment tools and grading • provide adequate information, advice and guidance documentation to enable apprentices, employers and training providers to prepare for the EPA • arrange for the EPA to take place, in consultation with the employer • where the apprentice is not assessed in the workplace, ensure that the apprentice has access to the required resources and liaise with the employer to agree this if necessary • develop and provide appropriate assessment recording documentation to ensure a clear and auditable process is in place for providing assessment decisions and feedback to all relevant stakeholders • have no direct connection with the apprentice, their employer or training provider. In all instances, including when the EPAO is the training provider (i.e. HEI), there must be no conflict of interest

	<ul style="list-style-type: none"> • have policies and procedures for internal quality assurance (IQA), and maintain records of regular and robust IQA activity and moderation for external quality assurance (EQA) purposes • deliver induction training for independent assessors, and for invigilators and/or markers (where used) • undertake standardisation activity on this apprenticeship standard for all independent assessors before they conduct an EPA for the first time, if the EPA is updated and periodically as appropriate (a minimum of annually) • manage invigilation of apprentices in order to maintain security of the assessment in line with the EPAO's malpractice policy • verify the identity of the apprentice being assessed • use language in the development and delivery of the EPA that is appropriate to the level of the occupational standard • provide details of the independent assessor's name and contact details to the employer • have and apply appropriately an EPA appeals process • request certification via the Apprenticeship Service upon successful achievement of the EPA
Independent assessor	<p>As a minimum, independent assessors should:</p> <ul style="list-style-type: none"> • have the competence to assess the apprentice at this level and hold any required qualifications and experience in line with the requirements of the independent assessor as detailed in the IQA section of this EPA plan • understand the occupational standard and the requirements of this EPA • have, maintain and be able to evidence up-to-date knowledge and expertise of the subject matter • deliver the end-point assessment in-line with the EPA plan • comply with the IQA requirements of the EPAO • have no direct connection or conflict of interest with the apprentice, their employer or training provider; in all instances, including when the EPAO is the training provider (i.e. HEI) • attend induction training • attend standardisation events when they begin working for the EPAO, before they conduct an EPA for the first time and a minimum of annually on this apprenticeship standard

	<ul style="list-style-type: none"> • assess each assessment method, as determined by the EPA plan, and without extending the EPA unnecessarily • assess against the KSBs assigned to each assessment method, as shown in the mapping of assessment methods and as determined by the EPAO, and without extending the EPA unnecessarily • make all grading decisions • record and report all assessment outcome decisions, for each apprentice, following instructions and using assessment recording documentation provided by the EPAO, in a timely manner • use language in the development and delivery of the EPA that is appropriate to the level of the occupational standard • mark open (constructed) test answers accurately according to the EPAO's mark scheme and procedures
Training provider	<p>As a minimum, training providers should:</p> <ul style="list-style-type: none"> • work with the employer and support the apprentice during the off-the-job training to provide the opportunities to develop the knowledge, skills and behaviours as listed in the occupational standard • conduct training covering any knowledge, skill or behaviour requirement agreed as part of the Commitment Statement (often known as the Individual Learning Plan). • monitor the apprentice's progress during any training provider led on-programme learning • advise the employer, upon request, on the apprentice's readiness for EPA • remain independent from delivery of the EPA. Where the training provider is the EPA (i.e. a HEI) there must be procedures in place to mitigate against any conflict of interest

Internal Quality Assurance (IQA)

Internal quality assurance refers to the strategies, policies and procedures that EPAOs must have in place to ensure valid, consistent and reliable end-point assessment decisions. EPAOs for this EPA must adhere to all requirements within the Roles and Responsibilities section and:

- have effective and rigorous quality assurance systems and procedures that ensure fair, reliable and consistent assessment across employers, places, times and independent assessors
- appoint independent assessors who have recent relevant experience of the occupation/sector gained in the last 5 years or significant experience of the occupation/sector
- appoint independent assessors who are competent to deliver the end-point assessment
- operate induction training for independent assessors, markers and invigilators
- provide training for independent assessors in terms of good assessment practice, operating the assessment tools and grading
- where appropriate:
 - provide ongoing training for markers
 - provide ongoing training for invigilators
- undertake standardisation activity on this apprenticeship standard for all independent assessors:
 - before they conduct an EPA for the first time
 - if the EPA is updated
 - periodically as appropriate (a minimum of annually)
- conduct effective moderation of assessment decisions and grades
- conduct appeals where required, according to the EPAO's appeals procedure, reviewing and making final decisions on assessment decisions and grades

Value for money

Affordability of the EPA will be aided by using at least some of the following practices:

- Use of technology – for example video conferencing where applicable
- Location – for example use of employer premises or training provider premises
- Making maximum use of each typical 7.5 hour working day
- Observation of naturally occurring evidence in the workplace

Professional body recognition

Professional body recognition is not relevant to this occupational apprenticeship.

Mapping of knowledge, skills and behaviours (KSBs)

Assessment method 1: Work-based project report with presentation and questioning

Knowledge
K1: Statistical knowledge of methods that enable effective analysis of data in research studies
K2: Project management techniques and strategies (meeting timelines, managing timelines and contingency planning).
K4: Strategic approaches to risk and compliance in relation to study design and data collection and interpretation.
K5: Communication and influencing techniques and strategies, both written and oral (including presenting).
K12: Methods to safely store and handle data in line with national and international data protection and cyber security regulations.

Skills
S2: Select and perform the appropriate statistical technique relevant to the given data set and objective.
S3: Use statistical software (SAS® and R or other appropriate software) to perform the required statistical methods.
S4: Use statistical software (SAS® and R or other appropriate software) to create appropriate graphical and tabular representations of the data to aid interpretation (for example: summary tables, individual data listings, histograms, boxplots, scatter plots, line charts, bar charts, frequency tables).
S5: Assess and interpret the results of data analysis and communicate these to peers in written and verbal discussion (for example: written medical statistical reports and oral presentations).
S6: Adapt communication technique when communicating statistical concepts to different audiences including people from a non-scientific background.
S7: Critique technical documents affecting projects they are working on, written by other professionals (for example: medical writers, study directors, project managers, medical consultants).

S9: Identify issues that can affect projects, finding solutions that meet the commercial demands of the business environment.
S10: Lead projects to completion within agreed and defined timescales and project parameters.
S12: Search and critically appraise scientific literature, including literature on new and emerging methods and techniques relevant to medical statistics.
S13: Evaluate new statistical methodologies relevant to medical statistics.
S16: Collaborate with other professionals to deliver mutually agreed outcomes.

Assessment method 2: Professional interview underpinned by a portfolio of evidence

Knowledge
K3: Statistical knowledge that enables effective research study design (for example: The drug development process; Study design - parallel group, cross-over, adaptive, placebo controlled, active comparator, open label; Methods allied to different trial objectives – superiority, non-inferiority and equivalence; Randomisation and blinding; Methods for data presentation; Estimands; Missing data strategies; Multiple testing and alpha control methods; Simulation; Sample size and power calculations; Complex innovative designs (CID)).
K6: Leadership and management techniques and strategies, including coaching and mentoring techniques.
K7: The structure and function of a multidisciplinary team and the role of the Medical Statistician within it, and how to achieve effective partnership working.
K8: Learning and development strategies, to enable personal and professional development, including giving and receiving feedback and critical reflection.
K9: The importance of continuing personal and professional development and the role of critical reflection in maintaining fitness to practice.
K10: Key regulatory authorities and documentation relevant to the study they are working on (for example: International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use Guidelines; European Medicines Evaluation Agency (EMA); Pharmaceutical and Medical Devices Agency (PMDA); Food and Drug Administration (FDA); The National Institute for Health and Care Excellence (NICE); Medicines and Healthcare products Regulatory Agency (MHRA); Therapeutic area specific

guidance; Good Clinical Practice (GCP); Good Laboratory Practice (GLP); Good Manufacturing Practice (GMP)).
K11: Ethics in clinical and non-clinical research.
K13: Health economics methods (including cost benefit analysis and cost effectiveness models).

Skills
S1: Interpret, apply and comply with legislation, statutory frameworks, professional codes of practice and guidance, including quality control.
S8: Provide statistical input into the preparation of technical documents (for example: study protocols, statistical analysis plans (including specifying the format and structure of planned regulatory required analysis outputs), study reports, regulatory submissions and grant applications).
S11: Work within limits of personal and professional competence, justifying and taking responsibility for own actions and seeking advice when required.
S14: Facilitate learning and provide feedback to others as appropriate.
S15: Critically review own practice and identify areas for personal and professional development.
S17: Contribute to the wider statistical community (including their own organisation), through sharing knowledge, such as peer review, authorship and co-authorship of papers for publication or presentation at conference.

Behaviours
B1: Be open, honest, compassionate, act with integrity at all times, observe duty of candour and maintain confidentiality.
B2: Be respectful, non-judgemental and engage with people in an inclusive and non-discriminatory manner.
B3: Maintain good character as outlined in professional Code of Conduct and refrain from activities which would bring the profession or organisation into disrepute.
B4: Be adaptable and able to respond professionally to all feedback.
B5: Be prepared to challenge and/or report inappropriate behaviours and practices, using established procedures.
B6: Take a proactive approach to own personal wellbeing, and that of others, reporting concerns as appropriate.

Grading Descriptors

End-point assessment method 1: Work-based project report with presentation and questioning

Fail: Fails to meet all of the pass criteria. Distinction: meets all of the distinction criteria and all of the distinction criteria

Theme	KSBs	Pass (the apprentice must meet all of the pass criteria)	Distinction (must meet all of the pass criteria and all of the distinction criteria)
Statistical techniques	K1, S2	Selects, performs and justifies their choice of statistical technique appropriate to the given data set and objective.	Critically evaluates a highly statistically advanced method applicable to the project objective, demonstrating application of the method in a novel area, or application of an existing advanced method in a novel area (K1)
Data storage and programming methods	K12, S3, S4	Analyses data using statistical software (or other appropriate software) to perform statistical methods and create graphical and tabular representations of the data. Explains the protocols for data storage and the implications of failing to store data in line with regulation.	Justifies the statistical methods and graphical and tabular representations selected and explains how they aid interpretation. (S4)
Literature review	S7, S12, S13	Appraises scientific literature, including technical documents, literature on new and emerging methods and techniques relevant to medical statistics and evaluates and explains the impact on the project and professional practice.	
Communication and collaboration	K5, S5, S6 S16	Analyses and presents data and research findings using language and materials appropriate for a peer	

		audience, both in writing and orally in an inclusive and non-discriminatory manner. Observes duty of candour and maintains confidentiality when doing so.	
Project management	K2, K4, S9, S10	Plans for effective project management, taking account of potential issues that can affect project outcomes and puts in place measures to mitigate risk. Monitors project progress against set milestones and targets, ensuring project outcomes and outputs are completed to meet set KPIs.	Justifies solutions selected and critically evaluates the wider impact of those choices.

End-point assessment method 2: Professional interview underpinned by a portfolio of evidence

Fail: Fails to meet all of the pass criteria. Distinction: meets all of the distinction criteria

Theme	KSBs	Pass (the apprentice must meet all of the pass criteria)	Distinction (must meet all of the pass criteria and all of the distinction criteria)
Regulation and compliance, including detection of fraud	K10, K11, S1, B3, B5	Evaluates how they have complied with and applied the relevant legislation, frameworks, codes of practice and guidance to their role. Explains the importance and methods to detect data fraud and provides an example of how they would challenge the data and report suspected inappropriate behaviours or practice	
Professional competence	S11, B1, B2	Evaluates how they effectively worked within the limits of personal and professional competence, engaging with others in an engaging and non-discriminatory way. Explains how they review own practice and identifies areas for professional development.	
Statistical input to design and medical research	K3, S8, K13, S17	Evaluates their statistical and strategic input to study design, data collection and technical documents, justifying their decisions. Explains with examples the importance of health economics. Evaluates how they have contributed within their company sharing statistical knowledge	Evaluates how they have contributed to the wider statistical community external to their own company (S17)
Partnership working	K7	Evaluates how they have built effective and sustainable partnership working with different stakeholder groups.	Critically analyses the factors that contribute to the success or failure of effective partnership working. (K7)
Leadership and management	K6, S14	Evaluates their use of leadership and management techniques and strategies to support the development of others	

CPD	K8, K9, S15, B4, B6	Evaluates own practice and the role of CPD in improving their own performance	Critically evaluates at least one example of their CPD activity and explains how this has or could impact their professional practice or the wider organisation. (K9)
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