August 2017 Proposal to develop a new apprenticeship standard

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Q1. Please confirm that you have read the "How to" guide for Trailblazers on gov.uk (see link here), that you are content that this proposal meets all the criteria for final approval set out within it and that you have discussed the proposal with a relevant Route Relationship Manager within the Institute (Please specify who).

I have read the 'how to' guide for Trailblazers on gov.uk?	Yes
Name of my Relationship Manager	James Corbett

Q2. Name of proposed trailblazer group

Clinical Trials (Sitting under the umbrella of Life Science and Industrial Sciences Trailblazer)

Q3. Are you an existing Trailblazer Group already with approval to develop other standard(s)? If yes or partly, please provide full details.

No

Q4. Name of proposed apprenticeship standard(s).

Clinical Trials Specialist (Level 6)

Q5. Is this a proposed core and options standard? If yes, please give the titles for each of the options.

No

Q6. How many standards are you proposing to develop? Please be aware that commitment from at least 10 employer members for each proposed standard is required.

One - The Clinical Trials Specialist (at Level 6).

Q7. Will there be a requirement for additional new standards to be developed in the future? If so, please provide brief details of what these will be.

No

Q8. Have you submitted a proposal for an apprenticeship standard in this role(s) before? If yes, please give details below including comments from the (pre April 2017) DfE approvals panel or the Institute.

Yes, Clinical Research Specialist and Clinical Research Professional. Following a full day face to face meeting with 21 employer representatives (15 employers) it was unanimously agreed that the former

Q8. Have you submitted a proposal for an apprenticeship standard in this role(s) before? If yes, please give details below including comments from the (pre April 2017) DfE approvals panel or the Institute.

submission of Clinical Research Specialist be renamed as Clinical Trials Specialist and amended to reflect the feedback from the IFA. The feedback expressed concern about overlap with the Regulatory Affairs Specialist Apprenticeship. This component of learning from the Clinical Trials Specialist role has now been removed and the standard focuses on delivery and execution of clinical trials specific to Clinical Operations roles (Clinical Research Associate, Clinical Trials Co-ordinator, Study Co-ordinator and Clinical Project Manager). Regulatory Affairs as a possible landing role has also been removed as this is a specific and distinct career path within industry. An overview of the regulatory environment around Clinical Trials will be needed to support the Clinical Trials Specialist role as we work within a highly controlled, regulatory framework, however this background would be from an education perspective rather than the actual apprenticeship being appropriate for a Regulatory Affairs landing role.

Q9. Please insert details about each proposed standard below.

	Name of occupation	Proposed level of the standard	Proposed as a degree apprenticeship?	Intended to replace/partly replace an existing apprenticeship Framework? [if so please give details]	Do you expect any age restrictions to apply to this standard?	Estimated annual take-up across entire relevant sector(s) (This is separate to the number of apprentices that each individual employer group member will take on)	When do you estimate this apprenticeship would be ready to deliver starts?
1	Clinical Trials Specialist	Level 6	Yes	No	18+	50	Sept 2018
2	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-

Q10. https://www.gov.uk/government/publications/apprenticeship-standards-in-developmentPlease provide any relevant information below regarding potential overlap with other Trailblazer standards published or in development. It is important that you review your proposal against all other apprenticeships published and in development to confirm there is no significant overlap, in overall occupation or in the content of potential skills/knowledge/behaviours. Where there is potential of any overlap, we ask that you contact the existing Trailblazer(s) before submitting a new proposal to discuss whether the existing standards would cover your needs (or email apprenticeship.trailblazers@education.gov.uk). Please then provide below full details of any possible overlap identified, interaction with relevant Trailblazers, and any relevant further detail explaining why this occupational role is sufficiently unique to still justify separate apprenticeship standard. The existing list of standards in development, is here The list of existing published standards and Trailblazer contact details, is here

The Life Sciences and Industrial Sciences group is trailblazing in the most similar and relevant areas to this trailblazer. Since the last submission the Clinical Trials Trailblazer group will now sit under the umbrella of the LS&IS group led by Kate Barclay as a specific task and finish group to ensure that there is no overlap in the roles of the various apprenticeships.

We have renamed our proposed standard 'Clinical Trials Specialist' and re-worded the scope to clarify the distinction between the other trailblazers in the area of Research and Development, Drug Discovery and Drug Development. For those who work in the industry, the distinction between these career paths is clear and this contributed to the former, less specific, nomenclature, which has now been addressed.

Clinical Trials Specialist – This standard describes specifically the operational aspects of the delivery of a Clinical Trial in humans, from early phase trials in healthy volunteers through to later phase safety and efficacy trials. Practically speaking this includes the acceptable operational standards, process and execution knowledge that you need to be able to conduct and manage a clinical trial with within a given country, ensuring the safety of subjects and the integrity of the data. The roles associated with this include the monitoring and oversight of the trial, through to the project management and administration of the clinical trial by the sponsor. This standard is not looking specifically at the pure research laboratory work required in pre-clinical /discovery drug development roles; however as part of building an apprentice's background and science education to the point which is required for these roles they will need to undertake medical laboratory theory and practicals within their degree programme.

Regulatory Affairs Specialist – This standard will encompass Regulations across the full complement of drug discovery, development and licensing at National level and in other key regions (EMA, Japan and US). This would include regulations/ legislation around conduct of clinical trials but would be limited to an interface between the clinical trials specialist working with the regulatory affairs specialist to ensure appropriate approvals are in place at the beginning of a clinical trials. The roles and responsibilities in this activity are entirely separate within the industry however, the apprentices (given the right level of experience) would sit on the same multifunctional team within a project team for a given drug development. This start up activity interface with the Clinical Trials Specialist role is a very small part of the regulatory role as their role includes a much wider range of expertise i.e. work is often centred around drug licensing, marketing authorisation, labelling and regulations around variations to licensing applications.

Research Scientist – This trailblazer is yet to submit an EOI, however this could be perceived to be an overlap with the Clinical Trials Specialist. This is not the case as this apprenticeship would be looking much more at the scientific (rather than operational) work around Clinical Research. This would include pre-clinical and clinical research.

The reason we would justify that these occupations are sufficiently unique is because you can have a full career in any one of these areas without ever learning the detail of the other apprenticeship areas. From an education point of view you need to have overall knowledge and understanding of the whole drug discovery, development, licensing and marketing space to ensure you understand how your role fits into the overall picture. However this is where the overlap stops as you would not be able to finish one of these apprenticeships and then move into a landing role from another apprenticeship.

Q11. Please provide a full description below of what the occupational role involved (or roles in the case of a proposed core and options standard). The information you provide here is crucial to our assessment of whether the occupational role is suitable for an apprenticeship, so please be as comprehensive as possible, and always refer to the criteria and guidance set out in the "How to" guide for Trailblazers. In particular, the information should include: Main duties and responsibilities - please set out clearly what someone in this occupation will actually be doing; the range of environments/sectors/industries in which someone in this occupation could work; a summary of key competencies/skills etc required for full occupational competence; how the occupational role typically fits within the wider work hierarchy; who would they be working with, and what is the usual relationship between the roles.

The clinical research industry in the UK is worth a total of £2.4 billion currently and supports 45,000 or so jobs, 24,000 in the commercial sector and 21,000 in the non-commercial sector.

Of the 24,000 in the commercial sector we would estimate that between 10-20% of those jobs are for Clinical Research Associates (CRAs) making that somewhere between 2,400 and 4,800 CRAs in the UK. This is one potential landing role of this apprenticeship, but there are also other similar operational roles.

We need to have a highly skilled workforce that is engaged and stable as we are in an internationally competitive market for clinical research and also being looked upon by the regulators to prove that our Clinical Research has been conducted by competent individuals.
A Clinical Trials Specialist Apprenticeship would open up and offer another route to attract the best and most talented resources early into the sector and contribute to the UK developing a skilled and competent workforce thus supporting the UK as an attractive place to conduct clinical research. Our ambition is ultimately (post Brexit) that the UK be positioned as the centre of excellence for conducting clinical trials globally.

Degree: The programme will support the significant demand in the UK for highly talented, technically competent, articulate Clinical Trials Specialists employable in a range of Clinical Research roles including but not limited to: Clinical Trials Assistant, Clinical Research Associate, Study Co-ordinator, project manager.
Apprentices will build their Clinical Research expertise from first principles. They will develop an understanding of the core science units underpinning clinical trials, and through experience and academic study, gain skills to understand the scientific, regulatory, ethical and methodological issues involved in the design, conduct, and analysis and reporting of clinical trials. They will use this background learning to work actively within Clinical Trials Operational roles to deliver the appropriate monitoring, oversight and/or project management of a clinical trial within a sponsor company. Typically this role will sit within a Clinical Trial team within the sponsor company (and / or its CRO partners) working cross functionally with all the relevant departments to ensure the clinical trial is run to the highest of standards, on time and within budget. So for example they may interact with the regulatory affairs specialist to ensure the appropriate regulatory approval is in place before the clinical trials starts. More experienced Clinical Trial Specialists could go on to lead Clinical Trial teams rather than just contribute to the team.

This apprenticeship would be used by employers who are either owners of drugs/devices in development (for example pharmaceutical companies, biotechnology companies, medical device companies) or the service industry to the Pharma to deliver operational work (commonly referred to as CROs – Clinical Research Organisations) and within the NHS and specialist Phase I units where clinical trials are conducted.

Q12. Please provide an overview of the knowledge, skills and behaviours required for these roles.

Knowledge and Skills
1. Broad spectrum understanding of scientific disciplines required to conduct clinical trials, including physiology, pharmacology, biochemistry, genetics and statistics.
2. Comprehensive knowledge of Good Clinical Practice (GCP), ethical and regulatory principles and their application to clinical trials and be able to apply these requirements to ensure patients' rights, safety and wellbeing in clinical trials are not compromised.
3. Ethics –a fundamental understanding of anti-bribery legislation and fair market value,
4. Develop, write and implement effective on-site and remote monitoring, source document verification and recruitment strategies for investigator sites including study and site-level feasibility
5. Be proficient in the use of clinical trial systems including; electronic Trial Management Systems (eCTMS), electronic Case Report Forms (eCRF), Interactive Response Technology (IRT), electronic

Q12. Please provide an overview of the knowledge, skills and behaviours required for these roles.

Patient/Physician Reported Outcomes systems and electronic Trial Master Files (eTMF). Understanding of other systems including eSource, Electronic Medical Records, eConsent, data vizualiation technologies and other technologies within the clinical trial setting.
6. In depth experience of Trial Management File (TMF) and document management requirements with respect to confidentiality and traceability of documentation in a clinical trial.
7. Knowledge of handling, labeling, storage and transport procedures and protocols of bio-samples and investigational product and their application in clinical trials. . Should include appropriate strategies for maintenance of the blind/unblinding and for investigational product accountability.
8. Input into data management documentation, including design of Case Report Forms, Data Management Plans, Data Review Plans, edit checks and User Acceptance Testing Plans.
9. Demonstrate understanding of statistical principles, scientific method and critical evaluation.
10. Project management skills to enable project planning and execution, budget management, scope management, schedule management, risk management, project team management and the use of communication, creative thinking and problem solving to resolve complex issues.
Behaviours
The apprentice must demonstrate the required industry behaviours associated with the clinical research environment including:
• Integrity and reliability - Demonstrate reliability, integrity, and respect for the confidentiality of patients and sponsor information. . Develop an intrinsic ethical stance to all aspects of their day to day activities.
• Time management - Manage time effectively, know how to apply techniques in prioritising work.
• Change management - Able to handle change and understand change management processes.
• Team working, collaboration, influence, and impact on others - Ability to delegate study related duties, in a cross functional team, and influence in order to deliver through others.
• Continuing Professional Development (CPD) - Undertake planning and review of own development needs and undertake CPD.
• Commercial responsibility and business development - Demonstrate a detailed understanding of enterprise issues such as intellectual property and the commercial demands of the business environment.
• Self-management and professionalism - Excellent verbal and written communication skills, with experience in writing extended reports and critiquing others' work. They will have experience of delivering assessed oral presentations and answering questions about their work.
• Manages expectations of senior management, study sponsor, vendors, investigational sites and key opinion leaders utilising appropriate media and interpersonal, communication and assertiveness techniques.
• Critical thinking/analytical skills – able to conceptualise, evaluate and analyse information to develop a plan of action and communicate this effectively to others.

Q13. How will the apprenticeship allow the individual to develop transferable skills to perform the role in a business of any size or relevant sector?

The purpose of the apprenticeship is to build suitable knowledge and skill set to allow further job and career opportunities within the Clinical Research arena. The proposal would be that apprentice rotates within their employer to ensure they gain the breadth of understanding of Clinical Trials operational roles and therefore pursue a range of operational roles thereafter. These could be transferred with more experience into professional scientific / research / clinical development roles within pharmaceutical, biotechnology, NHS, private and public sectors roles.

Q14. Will the occupation require rigorous and substantial training of at least 12 months prior to the end-point assessment to achieve full competence, with off-the-job training accounting for at least 20% of the apprenticeship? Please provide detail of what this will include.

Yes. The proposal would be that the apprenticeship off the job training would include a significant proportion of scientific education, in addition to specific training around skills and behaviours (for example communication with impact) but that the remainder of the skills and knowledge would be obtained whilst working with the employers.

Q15. What will the duration of the apprenticeship be?

The typical duration will be a maximum of 5 years, this includes modules to achieve a BSc (Hons) degree (360 credits at level 4-6) or equivalent (detailed within the assessment plan), with work assignments designed by the employer and academic providers from a range of sources.

Q18. Please provide details below of any professional body recognition of this standard. This should include information on what this will be.

As an industry there is currently no professional body recognition routinely utilised for this occupation by employers. There are a number of commercial organisations and non-profit organisations offering differing options in this area that could in the future be considered a professional registration / professional body recognition. As a trailblazer group we are continuing to explore all of these options to determine support for associating these options with the Clinical Trials Specialist Standard. For now however it can be considered that there is no professional body recognition of this standard.

Q19. We are committed to ensuring that the standard we design provides sufficiently transferable skills to enable a successful apprentice to perform this role in an employer of any size and in any relevant sector. We are collectively representative of our sector(s) and are willing to work with other employers who come forward with an interest in this occupation and with colleagues from other sectors where our standards are closely related. We will develop the apprenticeship standard and assessment plan in line with the latest edition of the Institute's "How to" Guide for Trailblazers, will aim to complete this process within a year and are committed to working with relevant sector organisations to promote the use of the resulting standard once it is ready for delivery.

Agreed

Q21. I am happy for my organisation to be publicly named as the lead employer and the companies listed above are happy to be named as working together to deliver this is the standard is approved for development

Name of lead organisation

Q22. Name and email address of contact we can use publicly on the gov.uk website (and Institute website when ready) as a contact point for any enquiries relating to the Trailblazer. (By filling out this box you consent to the publication of these details. If you wish to opt out please leave this box blank)

Name of public contact

Email address

Q24. Do you have a copy of the draft standard? If so, please include it with your submission.

- File: Clinical Trials Specialist Version 5 Final 15 August 2017CLEAN.docx