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FRCPath Curriculum for Clinical Scientists in Genetics (Higher Specialist Scientific Training)

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FRCPath Curriculum for Clinical Scientists in Genetics (Higher Specialist Scientific Training)

1.1 The Role of the Consultant Clinical Scientist in Genetics

Context

Geneticists examine samples of patients' DNA to identify genetic abnormalities that may be responsible for inherited diseases or conditions, such as cystic fybrosis or cancer. They not only identify abnormal genes but could also predict the likelihood of them being passed on to the next generation. They use chemical examination of cellular DNA to define genetic abnormalities and the majority of your work would revolve around three main categories:

- Prenatal diagnosis examining cells for possible abnormalities in the foetus, usually in families where single gene disorders have been identified by DNA analysis.
- Carrier testing and risk assessment for identifying presymptomatic individuals at risk from single gene disorders.
- Confirmation of diagnosis.

Clinical scientists in genetics deliver a timely, caring and effective diagnostic laboratory and clinical service to patients. Through a programme of Higher Specialist Scientist Training (HSST) reflecting the standards of training undertaken by doctors to train as consultants, selected clinical scientists will bring high-level scientific and clinical leadership as Consultant Clinical Scientists. In conjunction with medical colleagues in genetics, virology and infectious diseases and with other professionals, they will challenge the evidence of existing practice, innovate and introduce new investigations and treatments and build the evidence for change through ethical and appropriate clinical research to influence practice in the workplace and nationally.

Scientific Services and Clinical Care

Consultant Clinical Scientists in genetics are the national experts in their clinical scientific service. While their clinical scientist colleagues deliver today's services, Consultant Clinical Scientists prepare for tomorrow. Whilst Healthcare Science Practitioners and Clinical Scientists are trained to follow current guidelines, Consultant Clinical Scientists will be developing the evidence for new ones and contributing strategically to the national development of genetics.

They will make continuous critical appraisal of the scientific literature, and contribute to it; they will constantly question the evidence for practice with a sharp focus on patient outcomes, ensuring that investigations and rehabilitation are appropriate, timely and delivered with the needs of patients at the forefront. They will be responsible for ensuring that cutting edge science is introduced into genetic scientific practice, and leading developments in a wide range of areas of practice. Throughout, they will be committed to, and experienced in multi-disciplinary team working at the highest level; the various roles within the multi-professional team should collaborate synergistically in a complementary way, based on agreed care pathways that clarify the respective roles of both Clinical Scientists and medical colleagues.

Leadership and Management

Consultant Clinical Scientist in genetics will need to bring strong leadership to their own services and the profession - requiring skills above and beyond simply management. They will give their department's strategic direction, ensuring that this is compatible with the overall direction of the organisation; they will have both the knowledge and authority to develop their service, using vision and their scientific knowledge and expertise to ensure that the potential and rationale for new developments are understood. They will be accountable for service quality, developments and clinical governance, and practised in influencing other colleagues so that excellent science remains at the forefront of clinical practice. In addition they will have a key role in promoting and ensuring quality and consistency of standards across services by promoting networks for quality assurance locally and nationally.

Research, Development, Innovation and Education

Consultant Clinical Scientists in genetics will be clinical scientific leaders and will have the underpinning basic science and research skills to question their own clinical practice, as well as the breadth of cross-disciplinary technical skills to innovate and to effect change. They will be able to evaluate critically the benefits and opportunities offered by new scientific discoveries and technological advances, contextualising them to the clinical arena and the skills to influence their implementation into service for the benefit of patients. Critically, they will have learnt and practised the skills needed to teach the next generation of clinical scientists how to approach learning about science in health in order to optimise outcomes for patients. Consultant Clinical Scientists in genetics will make continuing distinguished contributions to the furtherance of the science and of practice of the specialism, and should be established and known nationally for their contribution, publications and leadership in the profession.

1.2 Overall Description of the HSST Programme

Modernising Scientific Careers (MSC) is a UK programme led by the Chief Scientific Officer (CSO), working in conjunction with the other devolved health administrations and relevant scientific, medical and surgical educational institutions. MSC provides a transparent, standards-driven educational and training framework for more than 45 specialisms in healthcare science.

Higher Specialist Scientist Training (HSST) is a five-year training programme that has been developed to enable a selected cohort of Clinical Scientists to be trained to take on the role of a Consultant Clinical Scientist. During training, Clinical Scientists in HSST and their supervisors will use this HSST curriculum to advance their learning, practice and performance, and monitor their progress by reference to the learning outcomes and competences defined within it. Clinical Scientists in HSST will be encouraged to lead their own learning and to measure their achievement against clear learning objectives. It will help the Clinical Scientist in HSST and their educational supervisor/mentor to maintain a regularly reviewed and updated education plan to ensure that all the outcomes of the curriculum are met. Finally, the curriculum will facilitate regular assessment of the Clinical Scientist's progress and satisfactory completion of training against high-quality standards, providing the means by which the public can be assured that individuals are fit for Consultant Clinical Scientist practice.

It is expected that Clinical Scientists in HSST will train in a multi-professional environment with the opportunity to learn and work with those in other training programmes across the health professions, e.g. medical, nursing, pharmacy and allied health professionals, and with those outwith health, for example those following MBA, leadership, management and finance programmes.

1.3 Curricula Development, Review, Updating and Implementation

HSST curricula were developed during 2012–2015 under the auspices of several of the Medical Royal Colleges (MRCs), following the publication in 2012 of a formal statement of support from the Academy of Medical Royal Colleges (AoMRC) [www.aomrc.org.uk/about-us/news/item/academy-statement.html]. Membership of the MRC curricula development groups included practising senior healthcare scientists nominated by scientific professional bodies and medical representatives from the MRCs, as well as educationalists from the relevant MRC and MSC teams. Consultant-level scientists from the specific scientific specialism provided the major expert input into the development of the scientific curriculum. The public, a range of scientific and medical professional bodies, universities, patients, employers and trainees were also involved. Specifically, review and comments on this curriculum were sought from other MRCs with an interest in the specialism, their related Specialty Advisory Committees (SACs) and specialist societies, healthcare science professional bodies, trainees in healthcare science, patients and the public. Governance and oversight of curricula development was through a dual process involving each relevant MRC and the Health Education England (HEE) educational approval process on behalf of the National Health Service (NHS) and HEE.

Although the curriculum content is derived from current UK clinical, diagnostic and laboratory practice in clinical science, there have been intensive efforts to identify and predict future technological developments, changes in service delivery and future patient requirements in order to ensure that the curricula are as robust and as sustainable as possible. This is in relation both to scientific content and anticipated future scientific developments (e.g. in genomics and precision/personalised

medicine), and is reflective also of the new commissioning system for service and training. There will be regular reviews and updates of the curriculum to ensure that it remains relevant.

Standards of professionalism in healthcare science are set out in *Good Scientific Practice* (GSP; www.academyforhealthcarescience.co.uk/good-scientific-practice/), which describes the principles and values developed for the profession and which are comparable to the standards set by the General Medical Council (GMC) for medicine. This has been developed into a GSP syllabus that is common to all HSST curricula. The five domains of GSP emphasise clinical leadership development, expert scientific and clinical practice, research and innovation, and excellent communication and team working behaviours. For the public, it describes more specifically what can be expected from those who will be CCSs responsible for patient care.

The Academy for Healthcare Science (AHCS) will assess applications from Clinical Scientists applying for recognition of previous training, experience and qualifications ('equivalence to HSST'), based on the professional and scientific contents and standards of behaviour set out in the curricula. Applicants seeking equivalence will be evaluated through AHCS processes against HSST curricula and will need to demonstrate that they have met AHCS requirements for the Certificate of Equivalence in a given area of practice. This will entitle the Clinical Scientist to register on the Higher Specialist Scientist (HSS) Register held by the AHCS.

Implementation of the curriculum will be evaluated and monitored by the National School of Healthcare Science (NSHCS) through continuous feedback from training programmes, educational supervisors, trainers, Clinical Scientists in HSST and patients.

1.4 Curriculum Purpose

The purpose of this HSST curriculum is to define and specify the training programme and outcomes of training to ensure that Clinical Scientists undertaking HSST are fully prepared to provide, lead and innovate scientific services at consultant level in the NHS and in the rest of the UK. It aims to promote excellence through training, assessment and professional development so that Clinical Scientists exiting HSST programmes are fit to practise as Consultant Clinical Scientists.

This HSST curriculum is modular in design. It builds on the Scientist Training Programme (STP) and leads to the Certificate of Completion of Higher Specialist Scientist Training (CCHSST) issued by the NSHCS. Clinical Scientists in HSST will require evidence of satisfactory achievement of the requirements of the GSP professional syllabus, the specialty-specific syllabus and the related assessment programme (including the Innovation in Clinical Sciences [ICS] project), which together form the curriculum for the attainment of the standards of professional and specialism-based knowledge applied to practical, laboratory, clinical, teaching, research activities, as well as innovation. In addition, for those in Physical Science, the Physiological Sciences and Clinical Bioinformatics, the CCHSST will also indicate that the underpinning doctoral programme/award (DClinSci) has been achieved. In the Life Sciences, the CCHSST indicates achievement of the FRCPath and the ICS project (which together meet the learning outcomes of the doctoral programme), although the doctoral award itself is not required. The CCHSST will enable the AHCS to admit the Clinical Scientist to its HSS Register. Once admitted to this Register, Clinical Scientists will be eligible to apply for available Consultant Clinical Scientist posts.

This curriculum also describes the integral teaching, learning programme and assessment programme that are consistent with the both the Health and Care Professions Council's (HCPC) and the GMC's Standards for Curricula and Assessment Systems (April 2010).

1.5 Entry Requirements

Once the Local Education and Training Board (LETB) [or equivalent bodies in the rest of the UK] and training provider (which has been accredited by the NSHCS accreditation process) have agreed the establishment of an HSST post, entry into HSST programmes will be through a national competitive appointment and benchmarking process in England, led by the NSHCS.

Eligibility for appointment into an HSST programme requires the following:

- registration (or eligibility and application to register) as a Clinical Scientist with the HCPC;
- *normally* at least one further year in the workplace to consolidate and enhance skills, learning and experience (including research and education);
- where required, applicants must be eligible to register for doctoral-level study at a higher education institution (HEI);
- individual specialisms may also have specialty-specific requirements, which will be clarified at the time of the appointment process for the HSST post through the job description and person specification.

An individual appointed to an HSST programme may not commence the programme until registration with the HCPC has been completed.

1.6 Routes of Entry

There will be two routes of entry into HSST training. Through the direct entry route, the Clinical Scientist in HSST will be competitively appointed into a formal HSST post, established for the purpose of training a Consultant Clinical Scientist. Alternatively, some Clinical Scientists may enter into HSST with the support of their employers through an in-service training route that does not involve the creation of a new training post *per se*, although the potential appointee will have to meet benchmarking standards for entry into HSST. In both circumstances in England, a training grant will be allocated from the LETB to the provider training unit to support training.

All HSST applicants must participate and be successful in the national appointment process. For direct entry Clinical Scientists this is a competitive process with other applicants for the available training opportunity; for in-service Clinical Scientists, participating in the national selection process ensures benchmarking against the standards for entry into HSST for this specialism. The appointment process will select not only for scientific expertise and talent in all its manifestations, but for abilities in a range of professional areas, including leadership, innovation, personal skills and values.

1.7 Equality and Diversity

The AHCS, HEE, MSC, MRCs and scientific professional bodies are committed to the principle of diversity and equality in employment, membership, academic activities, assessment, examinations and training.

As part of this ethos these groups are committed to inspire and support all those who work, train and provide training in healthcare science to operate in a fair, open and honest manner. The approach taken is a comprehensive one and reflects all areas of diversity, recognising the value of each individual. This means that no one is treated less favourably than another on the grounds of ethnic origin, nationality, age, disability, gender, sexual orientation, race, or religion, in accordance with the Equality Act 2010. This reflects not only the letter but also the spirit of equality legislation, taking into account current equality legislation and good practice.

1.8 The HSST Curriculum

This curriculum sets out the standards of specialism-based knowledge, clinical judgement, technical and professional skills, attitudes and behaviour that must be acquired in order to practise and progress throughout the five-year training programme. The curriculum comprises the following components:

The ***Specialist Scientific Clinical*** syllabus, providing for:

- a broad understanding of the diagnosis and management of patients within the specialism from a clinical and scientific perspective;
- the diagnostic techniques required in the practice of the specialism;

- understanding of the clinical areas detailed in the curriculum;
- knowledge of the specialist areas defined within the curriculum.

The professional generic ***Good* Sci*entific Practice*** (GSP) syllabus, setting out the requirement for the:

- communication skills required for practice in the specialism and the teaching, learning and assessment skills necessary for effective practice;
- acquisition of clinical leadership and management skills needed for the excellent delivery and development of genetics scientific services;
- experience of research, development and innovation projects, and critical evaluation of published work in order to lead scientific, technological and service innovation;
- need for a life-long commitment to adopting a structured approach to continuing personal and professional development (CPPD);
- experience of the practice of clinical governance[1] and quality improvement activity, including audit (specialist and multidisciplinary) through evaluation of practice against the standards of evidence-based medicine;
- consistent demonstration and practice of attitudes, values and behaviours that support those set out in the NHS Constitution.

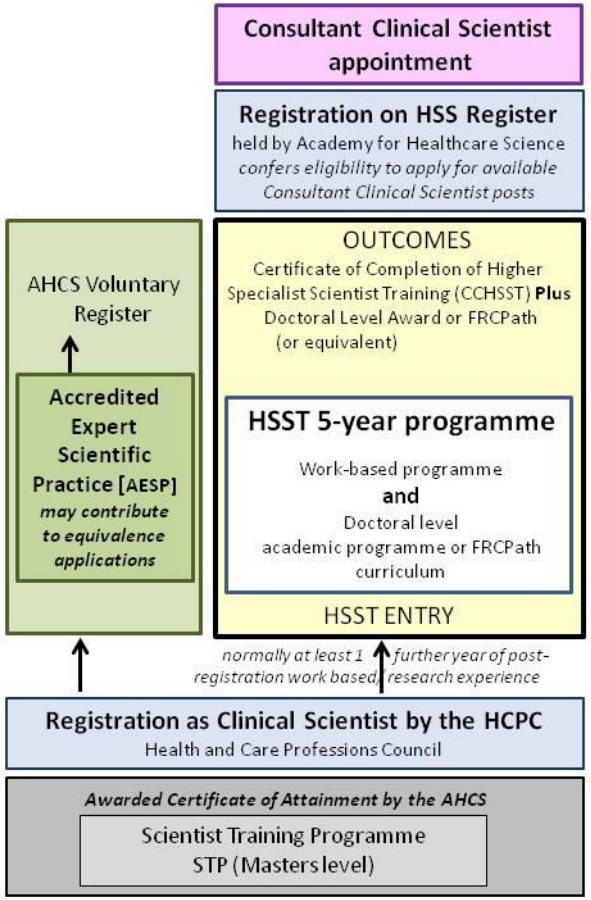
The Relationship of the GSP Syllabus to the Specialist Scientific Clinical Syllabus

The professional knowledge, skills and behaviour of *GSP* are contextualised and evidenced through clinical practice. It is not possible to achieve competence in the specialist scientific and clinical syllabus *unless* these professional skills and behaviours are also evident. Clinical Scientists in HSST must be able to show progress in acquiring GSP competences and the underpinning academic knowledge, demonstrating these behaviours across a range of situations as detailed in the scientific clinical syllabus.

1.9 The Structure and Operation of the HSST Training Programme

The broad structure and description of the HSST programme is shown overleaf.

[1] *A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish. Schellekens W. Clinical governance in a changing NHS.* International Journal of Integrated Care, *vol 6, April to June 2006.*



Higher Specialist Scientist Training (HSST)

Composition of 5-year programme

1. Work-based training

Major component of the 5-year programme; curriculum developed in conjunction with Medical Royal Colleges (MRCs) and scientific professional bodies and overseen by the National School of Heath Care Science (NSHCS)

- training providers accredited through NSHCS
- accredited providers receive training grant through Local Education and Training Board (LETB) for each Clinical Scientist in HSST which includes academic fees
- work-based assessment programme and final assessment process conducted by NSHCS with scientific professional bodies and MRCs
- use of on-line learning and assessment portfolio (OLAT) for documenting and monitoring outcomes by NSCHS

2. Doctoral Level Academic Qualification (DClinSci)

Professional doctorate (PD) awarded by Higher Education Institute (HEI) to underpin/support work-based training (or equivalent evidence of learning) to include:

A. Leadership and professional development (120 credits)
B. Specialist scientific clinical programme (180 credits)
C. Research development and innovation (240 credits)

Note: *The professional doctorate programme is optional for those in the Pathology specialisms) as they will be undertaking the professional qualification of the Fellowship of the Royal College of Pathologists (FRCPath), although the learning outcomes of the PD must be demonstrated.*

Outcomes

- Certificate of Completion of HSST (CCHSST) from NSHCS **and** the Doctoral award or FRCPath (or equivalent) which together lead to
- registration on the Higher Specialist Scientist (HSS) Register held by the Academy for HCS (AHCS). This confers eligibility to apply for available Consultant Clinical Scientist roles.

The implementation and quality management of the HSST programme is the responsibility of the NSHCS, which will ensure through its Themed Boards that Clinical Scientists in HSST are provided with access to an appropriate range of educational experience to complete their training. The appropriate Themed Board in the NSHCS will also monitor and support the overall progress of Clinical Scientists in HSST on a regular basis, throughout the entirety of the programme.

1.10 Modularity of Training and Learning

This curriculum has been developed in a modular format, with each module having defined competences, assessment requirements and learning outcomes. There is a staged approach requiring the satisfactory completion of specified modules within each stage prior to progression to the next, so that Clinical Scientists in HSST may not progress to Stage 2 of training until they have satisfactorily completed Stage 1. They will continue to broaden their experience and understanding of common clinical and scientific problems and their management throughout their training. The underpinning doctoral-level programme will provide the underpinning

academic framework for learning to support workplace practice. The knowledge gained and applied will be supported and assessed on an ongoing basis through quality assured workplace-based assessments and through a structured final assessment programme.

1.11 Doctoral-level Programme

A doctoral-level academic programme underpins HSST. The purpose of this doctoral-level programme is to formalise and *facilitate the learning* of Clinical Scientists in HSST as they:

- systematically acquire and apply a substantial body of scientific and clinical knowledge at the forefront of their specialism and embrace the future scientific and technology advances within the field;
- create and interpret new knowledge through original research and scholarship requiring advanced academic enquiry;
- systematically acquire, develop and apply the qualities and transferable skills necessary for employment as a Consultant Clinical Scientist, requiring the exercise of personal responsibility and taking largely autonomous initiative in complex and unpredictable situations;
- develop the knowledge, skills, experience, behaviours and attitudes required of a clinical leader in an evolving and rapidly developing health and life sciences sector.

Following a full tender and contracting process the doctoral programme will be provided by the Manchester Academy for Healthcare Science Education (MAHSE), a consortium of universities that will deliver the programme through partnership arrangements involving a range of organisations, including specialist professional bodies and/or MRCs. The doctoral programme will have three sections, reflecting the higher-level skills and requirements to support consultant-level practice:

- **Section A: Leadership and Professional Development** aligned to GSP, including leadership, professionalism, innovation, bio enterprise, teaching and learning, quality improvement, bioinformatics, health policy, human resource and business management, and research methods, although these areas are not necessarily exhaustive and others may be identified.
- **Section B: Specialist Scientific Clinical Programme** developed by the MRCs-led curriculum working groups of senior scientists and medical consultants, underpinned by supervised work-based and mentored training. This section will centre on the knowledge and understanding learning outcomes from the specialist scientific clinical syllabus for each HSST specialism, underpinned by supervised work-based and mentored training, reflective practice, experiential learning and a robust assessment system.
- **Section C: Research, Development and Innovation** that aims to improve health and health outcomes and may include scientific and/or clinical outcomes, service transformation, innovation, leadership, policy, education, or educational research.

Since a key purpose of the doctoral programme is to facilitate the opportunities for learning by Clinical Scientists in HSST by providing a structure within which they can obtain underpinning knowledge and learning to support their progression through the programme, it is not necessarily a requirement for the doctoral award itself to be obtained. The doctoral-level programme will be designed in a modular format, and although successful completion of the totality of the programme will lead to the award of a professional doctorate, it is not an essential requirement for all of those undertaking HSST programmes to obtain the doctoral award *per se*.

In the Life Sciences, for example, Clinical Scientists in HSST must obtain the FRCPath, which includes the learning outcomes of the professional doctorate, but not necessarily obtain the award itself. In the Physiological Sciences, Medical Physics and Biomedical Engineering, and Clinical Bioinformatics, all Clinical Scientists in HSST will be expected to participate in the full professional doctorate programme (or potentially show equivalence to aspects of it) and gain the professional doctorate award. It will therefore be necessary for all Clinical Scientists in HSST to demonstrate that they have acquired the knowledge, skills and outcomes of the HSST curriculum to the required doctoral level in all the practice and academic elements of the programme. The doctoral-level award and programme will underpin

and support this, but in itself is not an end point of the HSST programme; nor is the award required for the demonstration of competence and fitness to practise. This will be defined within the HSST assessment strategy and in conjunction with the MRCs and the NSHCS.

Research

Clinical Scientists in all HSST programmes will also be expected to undertake doctoral-level research, usually through the commissioned professional doctorate. Alternatively, research that demonstrates that such a level has been achieved may be offered, e.g. a coherent body of papers that reaches the standard suitable for publication in peer-reviewed journals, which has been undertaken during the HSST programme or during the three years before entry to the HSST programme. Clinical Scientists in HSST will also be encouraged to present and defend their research at national/international scientific conferences.

1.12 Models of Learning

HSST curricula will be delivered through work-based experiential learning and through achievement of the underpinning academic programme and/or its learning outcomes. The environment within the departments must therefore encourage independent self-directed learning and make opportunities for relevant off-the-job education by making provision for attendance at local, national and, where appropriate, international meetings and courses. It is the Clinical Scientist's responsibility, with the support of their educational supervisor and trainers, to seek learning and training opportunities and ensure that they access appropriate experiential learning. The training programme must allow for a significant component of clinical training and experience through service provision. This will normally be in the range of 30–80% of training time, depending on the specialism and the year of training.

It is therefore recognised that a large component of training will occur using an apprenticeship model of learning, under appropriate work-based supervision. Delivery of training must be under the supervision of a scientific or medical consultant and provide appropriate experiential content, including a broad exposure to both scientific and clinical issues. The environment within the department should encourage independent self-directed learning. The NSHCS will be responsible for the quality assurance of the work-based learning environment.

1.13 Learning Experiences

A wide range of teaching/learning opportunities/methods will be used during the programme to support the attainment of the learning outcomes and competences. However, it is part of the Clinical Scientist's professional development to seek out and organise relevant learning opportunities for themselves. In consultation with their educational supervisor, the Clinical Scientist in HSST may wish to consider organising some of the following learning events.

Experiential or opportunistic learning (learning through normal routine work experiences, learning by doing, observing, critical reflection), which will include*:*

- experiential working in the specialism, gaining practical and clinical skills, and observing, assisting and discussing aspects of practice with senior/consultant scientific and medical staff, patients and other members of the multi-professional team;
- task-specific, on-the-job training, working under consultant supervision and reflecting on and discussing experiences;
- observation of diagnostic/clinical/laboratory methods;
- tailored clinical experience, including team and directorate meetings in the specialty;
- attendance and participation at relevant organisational committees to enhance management and leadership skills;
- attending and participating in training provided through equipment and kit manufacturers;
- attending and participating in MDT meetings;
- teaching undergraduates and other health professionals;
- attending and participating in regional, national and international medical or scientific conferences;
- interaction with/attachment to specialist reference laboratories where required;
- completion of a doctoral-level research or innovation project from identification of the research question to dissemination of the output;

- contribution, as the leader or member of a team, to grant applications;
- dissemination of research findings through publications, presentations, etc.;
- attending and participating in medical clinics, including specialty clinics;
- gaining practical diagnostic experience;
- attending and participating in formal postgraduate education/teaching.

Learning approaches, which may include:

- independent self-directed learning;
- e-learning and m-learning (mobile learning);
- learning with peers;
- clinical skills teaching, including simulation;
- advanced library study, journal review;
- work-based experiential learning;
- small group teaching, lectures, tutorials;
- advanced journal clubs, audit meetings, etc.;
- service development projects.

1.14 Completion of Training

Successful completion of the HSST programme results in the award of a CCHSST by the NSHCS. The award will be made to Clinical Scientists in the Physical Sciences and Biomedical Engineering, the Physiological Sciences and Clinical Bioinformatics who complete the requirements of the work-based curriculum through work-based training, the ICS project and the professional doctorate, and who participate in the full training period (or as much as may be required if assessed by the AHCS as having done an equivalent period of training at some other point), including the final annual progression review/assessment, denoting satisfactory completion of the programme. In the Life Sciences, the CCHSST indicates achievement of the FRCPath and the ICS project (which together meet the academic learning outcomes of the doctoral programme), although the doctoral-level award itself is not required. Clinical Scientists in HSST in the Life Sciences may, however, choose to undertake modules from the professional doctoral programme or, indeed, undertake the entire doctoral-level programme and achieve the DClinSci award.

The CCHSST indicates that the Clinical Scientist has achieved the standards set by the AHCS in order to gain entry to their HSS Register, having demonstrated the ability to lead, manage and critically evaluate services and practice, contributing to the team and individually to scientific, technological and service innovation. A Clinical Scientist on the HSS Register will be expected to maintain their professional development in line with GSP. It is anticipated that in due course, as for medical and surgical consultants, Consultant Clinical Scientists will undergo a regular process of revalidation that will be developed and overseen by the AHCS.

1.15 Supervisory Arrangements

Supervision and Feedback

Supervision, support and mentoring for Clinical Scientists in HSST must be available to ensure safe and effective practice for patients and the public, and to support independent learning and high standards of professional conduct. Those undertaking a supervisory, training or mentoring role for Clinical Scientists in HSST programmes must have relevant professional qualifications and experience and have undertaken appropriate and up-to-date training as agreed by the NSHCS. The HEI providing the underpinning doctoral programme will also be expected to have an academic supervisory, support and mentoring scheme in place to support the academic programme.

Clinical Scientists in HSST must be appropriately mentored, supported and supervised by the senior scientific and medical staff on a day-to-day basis, under the direction of a designated educational supervisor. Educational supervision is a fundamental conduit for delivering teaching and training in the NHS. It takes advantage of the experience, knowledge and skills of educational supervisors/trainers and their familiarity with clinical and scientific situations. It ensures regular interactions between an experienced clinician and the Clinical Scientist in a HSST programme. This is the desired link between the past and the future of scientific practice, to guide and steer the learning process of the Clinical Scientist in the programme. Clinical supervision is also vital to ensure patient safety through providing Clinical Scientists in HSST with the support to deliver high-quality services to patients. It is therefore expected that Clinical Scientists in HSST programmes reaching the end of their training will also be able to demonstrate competence in clinical supervision before the award of the CCHSST.

Educational supervision should promote independent learning and reflective practice and support the Clinical Scientist in HSST to produce action plans to address identified learning needs. It will need to ensure that the Clinical Scientist learns specific higher skills and competences, helping them to develop self-sufficiency and self-awareness in the ongoing acquisition of skills and knowledge. At every stage, patient safety must be paramount. Supervision will also require the provision of pastoral care for some Clinical Scientists in HSST. Supervision during training will be undertaken by a range of appropriately trained healthcare professionals within and outwith healthcare science, e.g. consultant or senior medical staff, Clinical Scientists, research scientists, senior biomedical scientists, etc.

The Educational Supervisor

The educational supervisor will be an appropriately skilled senior scientist/clinician under whose direct supervision the Clinical Scientist in HSST is working. This person(s) will be responsible for monitoring, supporting and assessing the Clinical Scientist on a day-to-day basis in their scientific, clinical and professional work, and would usually be expected to take on the role of co-supervisor of the research project as part of the academic supervisory team.

To become an educational supervisor, a senior scientist or medical consultant must have consistently demonstrated an interest in and a commitment to teaching, learning, assessment and training, have appropriate access to teaching resources and be trained in the appropriate delivery of workplace-based assessments and learner-centred feedback in accordance with the MSC HSST assessment strategy. Educational supervisors must undertake appropriate training in educational principles and assessment (e.g. Training the Trainers programme, offered by the NSHCS in England or MRCs). Attainment of formal qualifications such as a postgraduate award in teaching, learning and assessment or an MSc in Medical/Clinical Education is desirable for some members of each supervisory team. Educational supervisors are expected to keep up to date with developments in training, have access to the support and advice of their senior colleagues regarding any issues related to teaching and training, and to keep up to date with their own professional development.

The role of the HSST educational supervisor therefore, with respect to the Clinical Scientist in HSST, includes responsibilities to:

- have overall educational and supervisory responsibility for the Clinical Scientist in HSST in a given post;
- ensure that they are familiar with the curriculum for each year/stage of training;
- ensure that they have appropriate day-to-day supervision appropriate to their stage of training;
- act as a mentor and help with both professional and personal development;
- ensure that they are making the necessary clinical and educational progress;
- ensure that they are aware of the assessment system and process;
- agree a training plan (formal educational contract) to make clear the commitment required to ensure that appropriate training opportunities are available;
- ensure that an induction (where appropriate) has been carried out soon after appointment to the HSST programme;
- discuss the training requirements and progress with other trainers with whom the Clinical Scientist in HSST spends a period of training;
- undertake regular formative/supportive appraisals (at least two per year, approximately every six months) and ensure that both parties agree to the outcome of these sessions and a written record is kept;

- regularly review the evidence submitted to the Online Learning and Assessment Tool (OLAT) so that they are aware of their progress and are encouraged to discuss any issues arising during training, ensuring that records of such discussions are kept;
- keep the NSHCS Professional Lead informed of any educational or pastoral issues that may affect the Clinical Scientist's ability to complete the HSST programme.

The process of gaining competence in supervision must start at an early stage in training, with the Clinical Scientist in HSST supervising more junior trainees, e.g. those undertaking STP. The example provided by the educational supervisor is the most powerful influence on the standards of conduct and practice of a Clinical Scientist in HSST.

Supporting Roles

In addition to the educational supervisor who will have overall educational responsibility for the Clinical Scientist in HSST, there will be other clinical trainers and assessors who will help facilitate the provision of educational opportunities and feedback to the Clinical Scientist as required. They will also be in a position to provide evidence to support the educational supervisor's judgement about a Clinical Scientist's overall performance, competence and capability. Since Clinical Scientists in HSST will learn in a multi-professional environment, assessments will be carried out by a range of members of the team, including those who may not be scientifically or medically qualified. However, all those carrying out assessments must be appropriately qualified in the relevant professional specialism and trained in the methodology of workplace-based assessment, including the delivery of appropriate feedback. This does not apply to multisource feedback (MSF), where those contributing to the feedback will be from a wider pool. Clinical Scientists in HSST and their educational supervisors should look to identify opportunities to incorporate feedback from patients, where possible, in the assessment of competence.

1.16 The Assessment Programme

The assessment programme for HSST is set within the context of the overall assessment strategy for MSC. A summary of the HSST strategy is set out in Table 1, and the detailed assessment programme for Clinical Scientists in HSST is shown in Table 2. Table 1 also shows the methods by which each component is assessed.

The HSST assessment programme is designed to capture evidence of the Clinical Scientist's mastery of the three main components of HSST, reflecting the five domains of GSP.

1. Clinical/scientific skills, and values, behaviours and attitudes relating to professionalism and the delivery of scientific/clinical services (Domains 1 and 3).
2. Scientific content (Domain 2).
3. Contribution to research, innovation and leadership in healthcare science (Domains 4 and 5).

The purpose of the assessment programme is to:

- provide evidence of satisfactory acquisition and application of knowledge, skills, experience and professionalism relevant to practice;
- enable each Clinical Scientist in HSST to demonstrate readiness to progress through the training programme and generate feedback to inform progress and learning needs;
- help to identify Clinical Scientists in HSST who may be in difficulty and who may need additional support;
- provide evidence to inform an annual progression review and the completion of the workplace-based assessment component of HSST;
- gather evidence that would assure the public that the Clinical Scientist in HSST is ready for independent professional practice as a Consultant Clinical Scientist.

Approach and Methods of Assessment

Assessment for HSST is a blend of academic, professional and workplace-based assessments, which together provide evidence of the achievement of learning outcomes, clinical/scientific competence and the progression of the Clinical Scientist in HSST through to completion of training. All assessments are aligned to the curriculum and the domains of GSP. There are two routes through the HSST assessment programme to accommodate different requirements across the sciences: Route 1 is for Clinical Scientists in the Physiological Sciences, Physical Sciences and Biomedical Engineering, and Clinical Bioinformatics, and Route 2 is for Clinical Scientists in the Life Sciences. Table 1 shows that Clinical Scientists following Route 1 will complete assessments relating to the professional doctorate, an assessment of clinical skills, the workplace-based assessment programme and the ICS project. Clinical Scientists following Route 2 will be assessed through the Fellowship Examination of the Royal College of Pathologists (FRCPath), the workplace-based assessment programme (with an option to take selected modules or the entire professional doctorate) and the ICS project.

Aim of the Innovation in Clinical Science Project

The aim of the ICS project is to allow Clinical Scientists in HSST to demonstrate the achievement of the learning outcomes of the ICS set out below by:

1. conceiving an innovation[2] in healthcare science that has the potential to make a positive contribution to service delivery, patient experience, patient outcomes, health economics, or any other aspect of healthcare. The Clinical Scientist's innovation should be at doctoral level and therefore must be original and make a new contribution to knowledge. It must not draw directly from work they may have submitted previously as part of a Master's degree or PhD – although the ICS project may contribute to the HSST professional doctorate or FRCPath dissertation;
2. undertaking a critical review of the literature considering relevant research in order to develop the rationale for the innovation;
3. undertaking a feasibility study, including consultation with stakeholder groups;
4. preparing and planning for implementation;
5. leading implementation and evaluation;
6. drawing realistic and evidence-based conclusions about the potential contribution and feasibility of the innovation.

Learning Outcomes from the ICS Project in the HSST Programme

The ICS project represents one component of the overall assessment strategy for the HSST programme that must be passed in order to receive the Certificate of Completion of Higher Specialist Scientist Training (CCHSST) from the NSHCS. All Clinical Scientists in HSST (including those taking the FRCPath route to completion of HSST) will need to complete the ICS. The project is designed to support the independent learning and demonstration of achievement of the following learning outcomes grouped under three areas, which reflect key components of the GSP syllabus as set out in the HSST curriculum.[3]

Professionalism and Professional Development (Domain 1)

By the end of the ICS project the Clinical Scientist in HSST will be able to demonstrate that they have:

- gained critical insight and professional understanding of the conceptual, ethical, value-based and analytical frameworks that underpin professional practice and their relationship to *Good Scientific Practice;*

[2] Defined as *'An idea, service or product, new to the NHS or applied in a way that is new to the NHS, which significantly improves the quality of health and care wherever it is applied.'* Improvement & Efficiency Directorate, Innovation and Service Improvement (2011, p9). *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS.* Department of Health.

[3] The domains indicated in the table relate to the AHCS's *Good Scientific Practice* document (http://ahcs.flinthosts.co.uk/wordpress/wp-content/uploads/2013/09/AHCS-Good-Scientific-Practice.pdf). Within every HSST curriculum is the detailed GSP syllabus that contextualises GSP to the level and practice of the Clinical Scientist in HSST.

- enhanced their skills and confidence to enable them to operate effectively and creatively within a healthcare science setting and the wider, diverse and changing healthcare environment.

Leadership and Quality Improvement in the Clinical and Scientific Environment (Domains 1, 2 and 5)

By the end of the ICS project the Clinical Scientist in HSST will be able to demonstrate that they have:

- broadened, built and applied their knowledge and skill base so that they are prepared for more senior, leadership roles within healthcare science and the wider healthcare environment where they will have responsibility as a future leader and team member for setting the policy, strategic direction, leadership and quality performance of their service and organisation to provide patient centred, high quality, compassionate patient treatment;
- led a quality improvement programme/s within their clinical environment, using the knowledge, skills and experience of organisational leadership which demonstrate the behaviours and attitudes described in the current frameworks and models of excellent leadership.

Improving Outcomes for Health and Social Care (Domain 4)

By the end of the ICS project the Clinical Scientist in HSST will be able to demonstrate that they have:

- built on and developed the knowledge, skills and experience of research and innovation methodology to demonstrate the high level skills required to undertake doctoral level research.
- the criticality to explain the process, barriers and enablers for publication and implementation of research and innovation findings.

Overview of the ICS Project

The innovation may be developed from work that the Clinical Scientist in HSST has submitted as part of the professional doctorate, or FRCPath, or other HSST work, in consultation with their clinical supervisor. It is envisaged that completion of the ICS project will consist of the following stages**.**

Stage 1 *Conception*: identify innovation, literature review, refine innovation and rationale.
Stage 2 *Feasibility*: consultation with stakeholders, financial planning, implementation, plan, analysis of limitations and constraints.
Stage 3 *Pilot testing*: critical analysis and evaluation, reformulation of innovation.
Stage 4 *Assessment*: preparing for the ICS project assessment.

Clinical Scientists in HSST will not pass or fail the ICS project based on the success, or otherwise, of the innovation pilot alone, as it is recognised that innovations may succeed and fail due to factors that are outside the control of the Clinical Scientist. Similarly, it is recognised that Clinical Scientists are operating in a rapidly changing healthcare context and that the rationale for the innovation, or the innovation itself, may be superseded during the course of the project. The chief assessment criteria will therefore relate to the quality of the Clinical Scientist's insight into innovation and leadership in healthcare science, and the appropriateness of the conclusions drawn from their feasibility and pilot studies.

Annual Progression Review

It is a shared responsibility between the Clinical Scientist, their educational supervisor and the NSHCS to monitor and review satisfactory completion of all assessments. At the end of each year there will be a formal progression process that will consist of a meeting between the Clinical Scientist in HSST and their educational supervisor (Annual Progress Review; APR), and a formal meeting of the Annual Progression Review Board (APRB). These two processes will be overseen by the NSHCS and will be the means by which eligibility to progress through the five-year programme will be judged. As a summary of the processes:

- the APR will be conducted by the educational supervisor, using documentation, guidance, criteria and standards that are common across specialisms. The purpose of the APR is to discuss the Clinical Scientist's experiences and perceptions of progress, and to scrutinise evidence of the Clinical Scientist's performance in the workplace to enable the educational supervisor to make a recommendation to the APRB about progression. This may include a recommendation that additional support is required. A progression recommendation will also take into account any issues regarding the completion of HSST in a non-linear way, including consideration of equality and diversity issues.
- an APRB meeting will be convened for each HSST specialism and will involve representation from the NSHCS, the relevant professional body/bodies, Consultant Clinical Scientists and a lay representative. The role of the Board will be to review the recommendations from educational supervisors, the assessment results and any additional feedback from the providers of the professional doctorate (Route 1) or FRCPath (Route 2), the important value judgements made as part of MSF, and to complete a formal scrutiny of the evidence held on the OLAT. The purpose of the APRB is to ensure that the Clinical Scientist in HSST has demonstrated sufficient evidence of achieving the learning outcomes and competences appropriate to the stage of the programme, and to confirm progression to the next year of training. Where the APRB is not able to confirm progression, the NSHCS will, with the guidance of the APRB representatives and the Clinical Scientist's educational supervisor, facilitate the implementation of a remediation and support process or, exceptionally, a HSST exit support strategy (which would require a review of evidence that the remediation and support process had not achieved the outcomes as specified by the APRB).

Table 1: Summary of HSST assessment strategy

Programme component	Route[1]	Assessment components	Assessment tool/s	Administrative responsibility[2]	Component weighting
Mastery of scientific content	**1**	Professional doctorate (PD)	As required by the HEI provider of the PD	HEI	100%; must pass PD or FRCPath to receive the Certificate of Completion for HSST from the NSHCS
	2	FRCPath, with an option to take selected, or all, components of the PD[3]	FRCPath	RCPath	
Mastery of clinical skills, values and behaviours	**1**	Workplace-based assessment (WPBA) Clinical skills assessment	Multiple WPBAs OSFA/OSCSA[4]	Workplace, recorded on OLAT and monitored by NSHCS NSHCS (in collaboration with Medical Royal Colleges [MRCs] & Professional Bodies [PBs])	100%; must have evidence of satisfactory completion of all WPBAs, and gain a 'Pass' in the OSFA/OSCSA or FRCPath to receive Certificate of Completion for HSST from the NSHCS
	2	WPBA FRCPath	Multiple WPBAs FRCPath	Workplace, recorded on OLAT and monitored by NSHCS RCPath	
Contribution to innovation, service improvement, patient safety or quality management in healthcare science	**1**	Innovation in Clinical Science (ICS) project	Short report, plus presentation to multiprofessional panel	NSHCS to administer, in collaboration with MRCs and PBs	100%; must pass component to receive Certificate of Completion for HSST from the NSHCS
	2	Contribution to innovation, service improvement, patient safety, or quality management in healthcare science	Option to (1) complete as part of FRCPath Part 2 (report and presentation to Penultimate Progression Review Board) **or** (2) complete ICS project as for non-Life Sciences[5]	(1) RCPath or (2) NSHCS to administer, in collaboration with MRCs and PBs	

[1] Route 1 is for Clinical Scientists in the Physiological Sciences, Physical Sciences and Biomedical Engineering and Clinical Bioinformatics; Route 2 is for Clinical Scientists in the Life Sciences.
[2] Where assessments are created and delivered by the NSHCS's partners, the School will request access to data about the performance of these assessments, and data on individuals' assessment outcomes.
[3] Clinical Scientists taking the FRCPath route through HSST have the option of completing any of the modules offered as part of the professional doctorate. However, in successfully completing the FRCPath (and the ICS project, which may be part of the FRCPath), the Clinical Scientist has demonstrated that they have achieved the learning outcomes of the professional doctorate.
[4] Work is ongoing to establish whether an OSFA (Objective Structured Final Assessment) or OSCSA (Objective Structured Clinical Skills Assessment) is the best fit to the assessment purpose.

[5] Clinical Scientists in Life Sciences who choose not to undertake the innovation component as part of FRCPath will be required to complete the ICS project, which will require the production of a short report and presentation to a multiprofessional panel.

Table 2: HSST assessment road map for Life Sciences

Stage	Year	Professional Doctorate	FRCPath	Formative assessment	Summative assessment	Annual Progression Review (APR)/Annual Progression Review Board (APRB)	Completion
1	1	OPTIONAL; completion in part or whole to be determined by the CS in consultation with their educational supervisor	Part 1[3]	As available for FRCPath and in workplace	12 DOPS[1]; 1 MSF; FRCPath Part 1	APR, plus APRB[2]	APRB, to include completion of FRCPath Part 1 if completing in Year 1
	2			As available for FRCPath and in workplace	12 DOPS[1]; 1 MSF; FRCPath Part 1	APR, plus APRB[2]	APRB, to include completion of FRCPath Part 1 if completing in Year 2
2	3		Part 2[3]	As available for FRCPath and in workplace	8 OCEs; 4 CBDs[1]	APR, plus APRB[2]	APRB
	4			As available for FRCPath and in workplace, plus local assessment of contribution to innovation, service improvement, patient safety or quality management in healthcare science (to be completed as part of FRCPath Part 2 **or** ICS project for non-Life Sciences)	8 OCEs; 4 CBDs[1]; 1 MSF; Innovation contribution	APR, plus APRB[3]	APRB, including assessment of innovation as part of FRCPath Part 2 or ICS project for non-Life Sciences
	5			As available for FRCPath and in workplace	FRCPath Part 2 exam; 1 MSF	Final Review Board (FRB)[3]	FRB, to include pass FRCPath Part 2
NSHCS awards the Certificate of Completion upon submission of evidence of successful completion of the WPBA programme, the FRCPath, and innovation component (as part of FRCPath or ICS project)							

[1] The number of workplace-based assessments is indicative only; as is the scheduling of DOPS, CBDs and OCEs across Stages 1 and 2. There is no requirement to complete a minimum number of WPBAs, or any requirement to complete certain assessments at particular stages of the programme. Clinical Scientists in HSST should discuss and negotiate with their educational supervisor, as part of the development of the training plan, the type and number of assessments that will be most appropriate to demonstrate achievement of the learning outcomes.

[2] Criteria for progression to be determined in consultation with stakeholders.

[3] Clinical scientists taking FRCPath should aim to take Part 1 during Year 1 or Year 2, and Part 2 during the remaining years.

The Online Learning and Assessment Tool (OLAT)

Every Clinical Scientist in HSST will need to develop and maintain an electronic learning portfolio (e-portfolio) to document and provide evidence of their progress through the training programme. The framework for the e-portfolio will be the OLAT, which is provided by the NSHCS. The OLAT will enable the Clinical Scientist in HSST to record all workplace-based assessments, supervisors' reports, multisource feedback outcomes and reflections on their progress, learning experiences and participation in learning events, such as journal clubs and national and international conferences, etc. The OLAT is also designed to facilitate and encourage ongoing dialogue between the Clinical Scientist in HSST and their supervisor about the Clinical Scientist's personal and professional development at consultant-level practice. Clinical Scientists in HSST will be given access to OLAT upon enrolment.

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GOOD SCIENTIFIC PRACTICE SYLLABUS: A COMMON COMPONENT OF ALL HSST CURRICULA

This syllabus must be followed throughout the whole training period, with engagement at the appropriate level, depending on the stage of training.

The syllabus is divided into five domains. These align with the five domains of Good Scientific Practice:

- Domain 1: Professional Practice
- Domain 2: Scientific Practice
- Domain 3: Clinical Practice
- Domain 4: Research, Development and Innovation
- Domain 5: Clinical Leadership

Each domain contains an overall Learning Objective, which is described by a number of Competence statements. These are presented as:

- Knowledge to be acquired and applied
- Practical skills to be demonstrated
- Attitudes and behaviours to be consistently displayed

Each competence statement is supported by indicative content. Cross referencing of the syllabus to the *Good Scientific Practice* standards is included.

Modernising Scientific Careers: Higher Specialist Scientific Training: Good Scientific Practice Syllabus

Domain 1: Professional Practice

Topic	Professional Practice	GSP Reference
Learning Objective	By the end of the training programme the HSS Trainee will be able to exercise personal responsibility and work largely autonomously taking the initiative in complex and unpredictable situations and performing a range of clinical/practical skills consistent with the roles and responsibilities of a Consultant Clinical Scientist.	
Knowledge	By the end of the training period the HSS Trainee will be able to: 1. Justify the importance of placing the patient at the centre of care and considering services from a user's point of view • Compare and contrast models of promoting patient-centred care and how to ensure that the wishes, beliefs, concerns, expectations and needs of patients are respected. • Critique studies that demonstrate the benefits of patients sharing in decision making on their health. • Defend the rights of patients and carers to treatment without discrimination which includes age; gender; illness; disability; health inequality; cultural and social inequality; diversity. • Critique the evidence base, principles and practice of patient-centred interviewing and examination, including the patient perspective. • Explain and justify why it is important to develop and maintain appropriate patient-professional relationships and evaluate a range of situations which have had a positive and negative impact on those relationships. • Explain and justify why it is important to have a holistic approach to the patient, recognising that there may be social as well as medical aspects to their management. • Summarise local guidelines for responding to complaints from patients and/or carers and evaluate the impact of these systems in promoting patient centre care. • Recognise the importance of gathering and responding to patient derived data. • Summarise local guidelines for responding to unacceptable behaviour by patients, carers or relatives, including harassment, bullying or violence and identify the strengths and weaknesses of these guidelines. • Defend the importance of public engagement in science and its role in health and society. 2. Critically evaluate the important to keeping professional knowledge and skills up to date and work within the limits of personal competence • Create, interpret and construct new knowledge of scientific, clinical and professional developments in area of practice. • Justify the rationale for engaging in continuing professional development and critical reflective practice and evaluate a range of methods for recording learning and developing and evaluating action plans. • Critique the evidence base underpinning continuing professional development with respect to the Consultant Clinical Scientist, the clinical service and the patient. • Recognise the limits of own competence and scope of practice in order to make informed and reasonable decisions.	1.1.1 1.1.9 1.1.10 1.2.1 1.1.3 1.1.4 1.1.5 1.1.7 1.2.5 3.1.5 3.1.17

Topic	Professional Practice	GSP Reference
	• Recognise the limits of competence and scope of practice for those for whom you are responsible and evaluate methods for managing difficult and sometimes unpredictable situations. • Critique methods for evaluating audit and review information on performance of self and those for whom you are responsible.	
	3. Critique the ethical, legal and governance requirements arising from working at the level of Consultant Clinical Scientist across a range of complex situations • Evaluate the principles, guidance and law with respect to medical ethics; patient confidentiality; informed consent; equality and diversity; child protection; use of chaperones. • Justify the role of the Consultant Clinical Scientist in the definition and monitoring of compliance of standards of practice that are ethical and legal often involving complex issues. • Defend the purpose of clinical governance and the requirements of employing organisation. • Evaluate the role of clinical audit in demonstrating compliance with local governance requirements. • Evaluate the effectiveness of the Standards of Proficiency and Standards of Conduct, Performance and Ethics of the Health and Care Professions Council.	1.1.3 1.2.5 3.1.1 3.1.2 3.1.3 3.1.17
	4. Summarise and critique the evidence to support the high levels of probity required when working at the level of Consultant Clinical Scientist as a clinical leader • Evaluate the importance of verifying information in reports and documents, including research • Analyse and justify the Health and Care Professions Council Standards of Conduct Performance and Ethics • Appraise approaches to procedures for identifying and reporting critical incidents. • Appraise approaches to procedures for receiving and responding to complaints. • Summarise the procedures to follow if cautioned, charged with a criminal offence, suspended or have restrictions placed on personal scientific, clinical or professional practice.	1.2.3 1.2.4 1.2.5
	5. Appreciate the importance of personal health and wellbeing in order to ensure that personal performance and judgement is not affected by own health • Responsibilities to the public and how these may be compromised by poor health • Effects of stress on professional performance • Role and availability of occupational health and other support services	1.1.8 1.1.9 1.2.2
	6. Analyse NHS organisation, policy and practice as it affects the provision of healthcare, healthcare science and the patients and populations it serves • Justify the contribution the NHS makes to assuring the health of the nation. • Critically evaluate the structure of the NHS in the relevant jurisdiction of the UK, including Department of Health, Health Boards and Authorities Primary Care Trusts and Hospital Trusts and compare and contrast to alternative models of health delivery in Europe or Internationally. • Evaluate current national and local policy issues as they affect the service provided by Clinical Scientists and the healthcare science workforce.	1.1.3 3.1.3

Topic	Professional Practice	GSP Reference
	• Justify the role of population screening, shared care and self care in diagnosing and managing disease from the perspective of the patient and the healthcare provider. • Identify and explain the finance issues facing providers of healthcare at national and local level in general, especially budgetary management and commissioning and the effect on healthcare provision. • Evaluate the effectiveness of the role of central government health regulatory and quality improvement agencies across the devolved NHS. • Explain and analyse the roles and relationships of Health Education England (and equivalents elsewhere in the UK); Modernising Scientific Careers; Academy for Healthcare Science; National School of Healthcare Science; Council of Healthcare Science in Higher Education, Medical Royal Colleges; specialist societies; postgraduate deans and deaneries and patient organisations in the provision of healthcare science. • Summarise the management structure and key contacts of the employing organisation (including chief executive, medical directors, clinical directors) and evaluate the structure with respect to providing high quality patient care. • Summarise the management structure of and key contacts with relevant major service users and providers and the contribution to the provision of high quality patient care. 7. Discuss theories of teaching and learning to underpin the role of the healthcare scientists in education as a teacher or trainer, according to the best contemporary clinical and educational standards. • Critically review the evidence base and apply knowledge of teaching, learning and assessment within the clinical and scientific work base to design, deliver and evaluate education and training programmes that meet the best clinical and educational standards.	1.4.1 1.4.2
Practical Skills	By the end of the training period HSS Trainees would be expected to apply in practice a range of clinical skills and critically reflect on their performance and will be able to: 1. Critically apply their understanding of professional practice with conduct that places the patient at the centre of care in a manner that promotes patient well-being and self-care through: • Developing and maintaining appropriate patient-professional relationships in practice. • Working with patients and carers in a respectful and non-discriminatory manner. • Taking a clinical history and using the information as part of the clinical decision making process. • Performing a range of clinical examination skills relevant to healthcare science practice. • In the context of patient-centred care giving and receiving feedback sensitively to or from a peer or colleague using an appropriate feedback model. 2. Critically apply their understanding of the role and importance of continuing professional development to ensure that professional knowledge and skills are being kept up to date through: • Maintaining personal records of continuing professional development providing evidence of critical reflection including action planning with respect to clinical practice and professional development in a form suitable for audit by a professional body or regulator and demonstrate continuing fitness to practise. • Recording critical reflective notes justifying how participation in continuing professional development has contributed to	1.1.2 1.1.10 1.1.11 3.1.10 3.1.11 1.1.4 1.1.5 3.1.5

Topic	Professional Practice	GSP Reference
	learning and led to improvements in personal and service performance. • Monitoring own performance by evaluating the outcome of audit and feedback from a range of sources. • Encouraging a culture in which innovation and developments are identified, discussed, evaluated and potentially introduced to improve service delivery. • Encouraging staff and colleagues to recognise learning opportunities in the work place and where necessary supporting them to obtain and use study leave to participate and contribute to additional learning experiences including skills training courses and conferences. 3. Respond to the ethical, legal and governance requirements arising from working at the level of Consultant Clinical Scientist critical applying accrued knowledge and evidence by: • Recognising the factors influencing ethical decision making, including religion, personal and moral beliefs, cultural practices making informed decisions and supporting colleagues. • Justifying the use and sharing of information in accordance with the regulations, encouraging such behaviour in other members of the healthcare team and taking action where breaches of the guidelines make have occurred. • Justifying the use and promotion of strategies to ensure confidentiality is maintained e.g. removal of patient names where appropriate reviewing and analysing published literature and considering the impact of such measures on the clinical service. • Recognising the problems posed by disclosure in the public interest, without consent of the patient • Ensuring patients, relatives and carers are aware of the need for information distribution within members of the immediate healthcare team. • Using appropriate methods of ethical reasoning to justify a decision where complex and conflicting issues are involved. • Perform and evaluate clinical audit to assess compliance with local governance requirements. Take remedial action as required. 4. At all times act in a manner that demonstrates probity in all aspects of professional practice by: • Working in accordance with good scientific practice with conduct that at all times justifies the trust of patients and colleagues and that maintains public trust in healthcare science. • Writing honest and accurate reports and signing documents appropriately. • Applying honesty and accuracy about personal qualifications, experience and position in the scientific community. • Acting honesty with respect to written and verbal information provided to any formal or legal enquiry, including recognition of the limits of scientific knowledge and experience. • Creating and justifying open and non-discriminatory professional working relationships with colleagues and using critical reflection to review personal behaviour and response to challenging issues. • Responding in an open, constructive and timely manner to critical incidents or complaints about own or team performance influencing the response and using critical reflection to review personal behaviour and response to challenging issues. • Taking appropriate action if you suspect you or a colleague may not be fit to practise putting patient safety at the forefront of your practice. • Practising within the Health and Care Professions Council Standards of Conduct, Performance and Ethics.	1.1.11 3.1.1 3.1.2 3.1.17 1.1.8 1.2.2 1.2.3 1.2.4 1.2.5 5.1.3

Topic	Professional Practice	GSP Reference
	5. Make appropriate judgements to ensure you limit your work or stop practising if performance or judgement is affected by your health by: • Recognising when personal health takes priority over work pressures, seeking appropriate advice and support and taking appropriate action. • Developing and maintaining appropriate coping mechanisms for a range of potential issues including stress seeking help if appropriate and evaluating the impact of an intervention. 6. Demonstrate professional practice that is consistent with relevant current NHS policy and practice by: • Identifying and evaluating existing and new NHS policy and advice that are relevant to the area of practice and the implications of these for personal and team practice and the impact on patients. • Using a range of communication skills to lead and contribute to discussions and gain agreement in a range of situations, including within the multidisciplinary team and steps that need to be taken to align service delivery with the most recent NHS policy and advice. • Sharing information and advice with peers in order to encourage a consistent approach to the implementation of NHS policy and advice. • Evaluating, documenting and justifying any local decisions that are taken that mean that it is not possible to align service delivery with NHS policy and advice. 7. Contribute to the education and training of colleagues planning, delivering and evaluating teaching on the basis of student and peer feedback and active self reflection • Use a range of teaching methods including lecture based, small group teaching and practical skills teaching appropriate to the learners. • Plan, deliver and evaluate a range of assessments appropriate to learning outcomes in the three domains of learning.	1.1.8 1.1.11 1.1.4 1.3.1 2.1.1 2.1.6 1.4.1 1.4.2
Attitudes and Behaviours	By the end of the training period HSS Trainees would be expected to demonstrate the attitudes and behaviours necessary for the role of a Consultant Clinical Scientist and will be able to: 1. Apply evidence based personal and team professional practice that places the patient at the centre of care • Act in accordance with the principles and practice of patient-centred care, regularly reflecting on personal practice and revising judgments and changing behaviour in the light of new evidence. • Critically assess and evaluate personal and team related performance in the context of evidence based patient care identify areas of good practice and make improvements where necessary. • Seek and critically appraise feedback from patients on own and team performance and adapt practice accordingly. 2. Apply knowledge, experience and deep reflection to identify personal development needs using a range of tools and develop and update action plans to ensure support continuing professional development • Apply the skills of deep reflection to identify personal development needs to transform and maintain up to date practice. • Act as a self-motivated professional scientist being willing to learn from self and others responding positively to constructive and meaningful feedback.	1.1.9 1.1.10 1.1.11 1.1.4 1.1.11 1.3.1 1.3.6

Topic	Professional Practice	GSP Reference
	• Create a culture which values continuing professional development to enable staff under supervision and supports them in recognising their strengths and identifying areas for improvement.	
	3. Display a professional commitment to ethical practice consistently operating within national and local ethical, legal and governance requirements	1.1.11 1.2.1
	• Accept professional ethical standards and encourages informed debate and critical reflection within healthcare teams. • Seek advice of peers, legal bodies and regulators in the event of ethical dilemmas in areas including disclosure and confidentiality. • Respect requests from patients that information should not be shared unless this puts the patient or others at risk of harm. • Share information about patient care with the patient unless they have expressed a wish not to receive such information.	
	4. Apply the principles of *Good Scientific Practice* and the professional standards performing to the highest standards of personal behaviour in all aspects of professional practice	1.1.3 1.1.8 1.1.9 1.1.11 1.2.2
	• Recognise the importance of leading by example in setting high standards of personal behaviour, and in acting with openness, fairness and integrity listening to the views of others. • Accept the requirements for professional regulation. • Promote professional attitudes and values at all times. • Recognise the need to be truthful and to admit and learn from errors. • Accept the requirement to inform the statutory regulator if cautioned, charged with a criminal offence, suspended or have restrictions placed on personal scientific, clinical or professional practice.	
	5. Consistently operate in accordance with relevant current NHS policy and practice	1.1.3 1.3.1
	• Recognise the need to identify and assess the implications of NHS policy and advice for service organisation and delivery of high quality services. • Consult with peers and service users as part of obtaining agreement to align services with NHS policy and advice.	

Domain 2: Scientific Practice

Topic	Scientific Practice	GSP Reference
Learning Objective	By the end of this stage of training HSS Trainees will be able to assess, plan, deliver and evaluate high quality scientific services in a safe and secure working environment.	
Knowledge	By the end of the training period HSS Trainees will be able to:	
	1. Analyse the strengths and weaknesses of current and new scientific investigations and methods used in the diagnosis, monitoring and treatment of clinical disorders relevant to area of practice • Evaluate the scientific basis of investigations and procedures. • Discuss the impact of genomics and personalised medicine on health and healthcare science. • Discuss the impact of clinical bioinformatics on health and healthcare science. • Critique the application of scientific investigations and procedures in protocols and patient pathways. • Summarise the strengths and weaknesses of current service provision both in terms of performance characteristics and clinical application. • Compare alternative approaches and/or improvements to investigations and procedures. • Use scientific principles and reasoning to assess, plan and design new or improved investigations or procedures. • Analyse the role of peer opinion in refining ideas and plans. • Evaluate new and emerging technologies and their potential to improve healthcare and healthcare science.	2.1.1 2.1.3
	2. Critique the application of evidence-based practice to the optimisation of scientific investigations and methods • Summarise and critically review the scientific literature in area of expertise. • Evaluate the principles and practice of evidence-based medicine relevant to area of practice. • Appraise approaches to meta-analyses, systematic reviews, clinical trials, cohort studies and related approaches used in this field. • Critique methods for searching, identifying, ranking and evaluating scientific evidence. • Justify the rationale for the use of methods to evaluate and optimise the performance of scientific investigations. • Defend methods for comparing performance of two or more scientific investigations or procedures. • Appraise relevant statistical measures applied to research publications.	1.1.5 2.1.1
	3. Evaluate and apply information and communication technology to facilitate service delivery and development in relevant areas of healthcare science • Justify the application of information and communication technology in area of practice. • Evaluate the impact and development of bioinformatics on the practice of health care and healthcare science. • Discuss the requirement for data confidentiality, security and protection. • Evaluate the function and operation of the Hospital Information System. • Evaluate and justify the function and operation of linked information systems (e.g. Laboratory Information System) and	2.2.9

Topic	Scientific Practice	GSP Reference
	middleware linking equipment to information systems. • Identify the benefits and barriers with respect to personal computer hardware and software. • Appraise the appropriate use of electronic mail and social networking technology in the context of professional role. • Summarise how electronic literature searching (e.g. PubMed) and storage can be used within the clinical environment. • Access and judge specialist websites and databases relevant to professional role. • Appraise the range of statistical packages relevant to area of expertise, including bioinformatics where appropriate. 4. Justify the principles and practice of quality control, external quality assessment and quality management as applied to relevant areas of healthcare science • Evaluate the purpose and operational requirements of internal quality control and external quality assessment and defend the systems currently in place. • Defend the principles and practice of quality management and, where appropriate, service accreditation. • Critique the required quality standards and monitoring of performance against those standards and the contribution standards make to the provision of a high quality service. 5. Justify the role of audit and the audit cycle and explain how it is used as a tool to facilitate continuous quality improvement • Evaluate the principles and practice of scientific and technical audit including examples of audit improving practice. • Identify aspects of service delivery that should be subjected to regular scientific or technical audit and justify the selection. • Appraise audit reports including recommendations for improvement and the impact on the service when implemented. • Critically review examples of relevant scientific and technical audits performed locally or elsewhere and the impact on service delivery. 6. Summarise and interpret health and safety legislation and guidance for the workplace • Defend the importance of health and safety within the workplace with respect employees, employers, patients and the public. • Appraise current legislation and guidelines relating to health and safety in the workplace including, as appropriate to role, biological specimen handling; COSHH; RIDDOR; radioactivity; fire safety; electrical safety; moving and handling; display screen equipment. • Justify local health and safety guidance. • Justify the principles and practice of infection control including the impact of reducing infection rates on patients. • Critically review procedures involved in risk assessment and risk management and the impact on quality and safety. • Summarise the policy and procedures associated with critical incident reporting and the impact on service improvement and the culture of the organisation.	2.3.1 2.3.2 2.2.2 2.3.4 3.1.17 2.2.6 2.2.7 2.2.8
Practical Skills	By the end of the training period HSS Trainees would be expected to apply in practice a range of clinical skills and critically reflect on their performance and will be able to: **1.** Develop and evaluate investigative strategies/procedures/processes that take account of relevant clinical and scientific evidence and other sources of information • Critically appraise the scientific credentials and validity of existing investigations and procedures.	2.1.1 2.1.3 2.2.2

Topic	Scientific Practice	GSP Reference
	• Critically appraise the way in which scientific investigations and procedures are used in strategies and protocols for the diagnosis, monitoring and treatment of defined clinical disorders. • Work in partnership with peers and service users apply scientific principles and reasoning to plan, develop and assess the scientific validity and clinical effectiveness of new or improved investigations, procedures, strategies or protocols.	
	2. Critique the selection and application in practice of scientific investigations in defined clinical situations using quantitative and/or qualitative methods • Reflect on proficiency in the performance of routine and non-routine scientific and technical procedures used in defined clinical areas of service and develop action plans to improve performance. • Compare own proficiency with experts in the technical validation of data derived from scientific and technical procedures. • Justify the selection and application of scientific and technical procedures to comply with clinical requests and evaluate the efficacy of this n own practice. • Apply the principles and practice of evidence-based medicine to critically appraise the effectiveness of scientific and technical investigations and procedures. • Use and evaluate statistical measures such as likelihood ratio, AUC-ROC, number needed to treat/harm.	2.1.2 2.1.3 2.1.4 2.2.1 2.2.3 2.2.4 2.2.5
	3. Master the use of information and communication technology in relevant areas of healthcare science • Use information and communication technology for all applications in area of practice. • Justify the rationale and conform to requirements for data confidentiality, protection and security. • Use and apply the Hospital Information System; appropriate linked information systems; middleware and instrumentation hardware and software. • Master the use of personal computers and relevant programmes including word processing; databases; PowerPoint; internet and electronic mail; electronic literature searching and storage. • Use relevant statistical packages for data handling including methods for assessing clinical effectiveness and, where appropriate, basic bioinformatics and interpret the results/outcomes.	2.2.9
	4. Set, apply and maintain quality standards and related quality control, assessment and management techniques to assure the validity of scientific and technical investigations adapting and developing systems as required • Critically appraise relevant internal quality control and external quality assessment data and draw conclusions about quality performance. • Present and actively participate in meetings that review quality performance criteria justifying and defending solutions for improvement and adapting and implementing corrective action as required. • Contribute to quality management justifying the definition of standards and monitoring of performance against those standards adapting and developing systems as required. • Prepare and review regular quality management reports including, where appropriate, linkage with service accreditation adapting and developing systems as required.	2.1.6 2.3.1 2.3.2 2.3.3
	5. Perform scientific and technical audit to determine that investigations and methods are fit for purpose justifying and monitoring the	2.2.2

Topic	Scientific Practice	GSP Reference
	impact of recommendations • Perform scientific and technical audit of the performance and effectiveness of scientific investigations and service delivery in accordance with local guidelines. • Identify, critically review and communicate the outcomes of scientific and technical audits performed by others in relevant areas of scientific investigation and service delivery making recommendations for changes and monitoring the impact of those recommendations. • Devise, develop, perform and evaluate scientific and technical audits in own area of expertise reporting the outcomes including learning, modifications and the impact on service delivery resulting from the audit. 6. Promote the importance of health and safety standards in the workplace and identify and justify actions that will improve health and safety and reduce the risk of infection • Perform work place role complying with current legislation and guidelines relating to health and safety in the workplace. • Adhere to local health and safety guidance. • Perform work place role in accordance with the control of infection regulations. • Perform risk assessment and risk management of health and safety in the workplace, make recommendations and monitor the impact of the recommendations. • Comply with requirements for critical incident reporting reflecting on and learning from the occurrence and outcome of critical incidents adapting practice as necessary. • Investigate and respond to reported health and safety incidents in the workplace.	2.3.4 3.1.17 2.2.6 2.2.7 2.2.8
Attitudes and Behaviours	By the end of the training period HSS Trainees would be expected to demonstrate the attitudes and behaviours necessary for the role of a Consultant Clinical Scientist and will be able to: 1. Evaluate current debates in the field and critically appraise scientific developments in area of expertise • Appreciate and utilise a range of approaches to identify, critically review and learn from new and emerging scientific literature in area of expertise. • Make appropriate judgements in order to search and archive scientific literature. • Engage in critical dialogue on the latest scientific developments (e.g. journal clubs). • Development of planning and critical appraisal skills in self and clinical team through peer review, shared exercises and case review. 2. Apply evidence-based scientific practice as a means of improving patient investigation and care where necessary revising judgements and changing behaviour in light of new evidence • Critically evaluate the application of the principles of evidence-based medicine across areas of expertise. • Apply rigorous scientific critiques to the evaluation of data related to clinical practice in the support of clinical decision making and patient management. 3. Evaluate and use information and communication technology to improve service quality and delivery • Use new information and communication technology changing practice and behaviour as appropriate.	 1.1.5 2.1.6 3.1.5 1.1.5 2.1.5 2.1.6 2.2.9

Topic	Scientific Practice	GSP Reference
	• Justify the need to balance data confidentiality, security and protection and the sharing of data with relevant stakeholders including patients to ensure high quality patient-centred care. 4. Listen, influence and lead continuous quality improvement in scientific services • Justify the importance of continuous quality improvement using the available evidence base. • Influence, lead and support staff in the department/organisation to create a culture that recognises the importance of quality and quality improvement in the delivery of scientific services. • Justify the importance of quality control and quality assessment of all investigations and services influencing and shaping the views of others. • Create opportunities for staff to receive training in quality management by justifying the impact of training on service delivery and personal development. 5. Appreciate and utilise audit as a tool to evaluate and optimise scientific services • Defend scientific and technical audit as a valid tool to improve scientific investigation and service delivery. • Identify training needs of self and others and develop training plans to enable audit to proceed. • Communicate outcomes of scientific and technical audits with peers, managers and other interested parties persuading others to implement and/or adapt recommendations in their area of practice. 6. Establish and influence the culture of health and safety in the workplace • Create a culture of health and safety awareness, identification and resolution of issues and modification of systems to enhance health and safety. • Review and report on health and safety issues sharing good practice with individuals, the team and wider organisation. • Identify, justify and create opportunities for staff to receive health and safety and first aid training and monitors the learning and impact of the training on the individual and service.	2.3.2 2.3.3 2.2.2 2.3.4 3.1.17 2.2.6 2.2.7 2.2.8

Domain 3: Clinical Practice

Topic	Clinical Practice	GSP Reference
Learning Objective	By the end of this stage of training, HSS Trainees will be able to assess, plan, deliver, interpret, report and evaluate high quality clinical services that are targeted to meet the needs of individual and groups of patients.	
Knowledge	By the end of the training period HSS Trainees will be able to:	
	1. Analyse the strengths and weaknesses of the procedures required to deliver high quality clinical practice in the investigation and management of patients • Justify the requirement for patient consent for investigation including patients who lack capacity and provide advice to others. • Summarise the requirement to maintain patient confidentiality and respect for patients' privacy involving the patient appropriately and the circumstances when disclosure is allowed. • Justify the rationale of clinical coding and the need for accuracy and use of medical terminology. • Analyse and justify the wider clinical consequences of clinical investigations performed and clinical advice provided. • Relate understanding of setting clinical priorities and time management for patient investigation • Interpret emerging evidence and knowledge that adds to the clinical evidence base underpinning services provided in order to make informed judgements. • Justify the requirements for accurate record keeping and data security. • Summarise the role of standard operating procedures; clinical protocols; clinical guidelines to promote a safe, patient centred environment and underpin high quality scientific services. • Identify common sources of error; identification of risk; critical incident reporting and analyse how this information can be used to improve services and reduce incidents and risk. • Justify the importance of adopting a no blame culture for identification and investigation of error.	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.1.6 3.1.15 3.2.1 3.2.2
	2. Relate understanding of the aetiology of relevant clinical disorders as a means to developing appropriate clinical investigations across the full range of patients accessing the clinical services of personal area of practice • Describe the detailed aetiology of clinical disorders in area of expertise and apply knowledge when selecting investigative strategies. • Analyse the strengths and weaknesses of existing clinical investigations and identify and critically appraise potential strategies to improve or develop new clinical investigations in the best interests of patients.	3.1.5 3.1.6 3.1.7
	3. Discuss and evaluate how the results of clinical investigations may be related to defined disorders and patient management strategies across the full range of patients accessing the clinical services of personal area of practice • Summarise the use of normal limits and describe the levels of uncertainty in the outcome of clinical investigations. • Analyse patterns of data and results obtained from clinical investigations linked to defined clinical disorders. • Evaluate and justify the use of statistics and predictive values in clinical practice recognising potential limitations. • Evaluate the effectiveness of relevant clinical guidelines and patient pathways recognising potential limitations and seeking	3.1.4 3.1.12 3.1.13 3.2.4

Topic	Clinical Practice	GSP Reference
	alternatives. 4. Evaluate the role of the multidisciplinary clinical team in optimising clinical outcomes for individual and groups of patients • Discuss the role of the multidisciplinary clinical team and evaluate the effectiveness of the team. • Summarise the range of multidisciplinary clinical teams supported by healthcare science and analyse the role of each team. • Justify the operational requirements for individual multidisciplinary clinical teams and evaluate the clinical effectiveness of the team and suggest areas for improvement. 5. Discuss and evaluate the principles and practice of clinical audit as a tool to evaluate the effectiveness of services provided • Principles and practice of clinical audit. • Resources available in local organization to support clinical audit. • Examples of relevant clinical audits performed locally or elsewhere.	1.3.2 1.3.3 3.1.14 3.1.16 2.2.2 3.1.17
Practical Skills	By the end of the training period HSS Trainees would be expected to apply in practice a range of clinical skills and critically reflect on their performance and will be able to: 1. Apply in practice consistent high standards of clinical practice in the investigation and management of patients and critically reflect on your performance • Explain and justify the recommended clinical investigations involving the patient wherever possible. • Explain and justify the procedures for preparing samples for clinical investigation. • Master a range of clinical investigations relevant to area of practice complying with relevant standard operating procedures, clinical protocols and clinical guidelines in accordance with best practice. • Produce and maintain clear, accurate and legible records in accordance with the regulations/guidelines governing patient consent, confidentiality and data security. • Analyse the outcome of clinical investigation and give immediate feedback in accordance with agreed protocol. 2. Plan, develop, perform, evaluate, interpret and report a range of clinical investigations to assist with the diagnosis, monitoring and treatment of patients making informed judgements as necessary • Comply with quality standards in the performance of routine and non-routine clinical investigations in area of practice. • Identify and critique opportunities to develop and/or improve clinical investigations to improve patient experience and/or to add certainty to the outcome following relevant governance procedures and acting on advice and feedback from patients. • Plan, develop and critically evaluate modified or improved clinical investigations producing valid comparative data with existing procedure involving the views of patients or service users. • Discuss outcomes, modifications or improved clinical investigations with patients or service users before agreeing on whether to implement a change in procedure in adhering to governance processes. 3. Provide advice on the clinical significance of the results of investigations including, where appropriate, follow up and further investigation and reflect on the process and justify the advice given • Interpret and report the outcomes of routine and non-routine clinical investigations in the context of the clinical presentation of individual patients justifying the conclusions.	1.1.1 1.1.11 3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.1.6 3.1.7 3.1.8 3.1.10 3.1.11 3.1.15 3.2.1 3.2.2 3.2.3 3.1.12 3.1.13 3.1.14

Topic	Clinical Practice	GSP Reference
	• Provide clear and accurate written and/or verbal clinical advice on the clinical significance of investigations having regard to the importance and urgency for patients and the underpinning evidence base. • Discuss with relevant medical and other healthcare practitioners the follow up, further investigation and/or appropriate treatment of individual patients based on the outcomes of clinical investigations and current best practice/evidence.	3.2.3 3.2.4
	4. Actively participate in multidisciplinary clinical team meetings that review clinical outcomes for individual and groups of patients challenging decisions/recommendations when necessary • Use the evidence base to identify multidisciplinary clinical teams in area of expertise that would benefit from input from a senior Healthcare Scientist and make arrangements for participation to influence the judgements of the team. • Participate in a proactive manner to the conduct of multidisciplinary clinical teams identifying opportunities to prepare and present clinical material and by offering and defending expert opinion and advice. • Contribute to the preparation and adoption of clinical protocols and clinical guidelines and analyse the impact on clinical practice.	1.3.1 1.3.2 3.1.14 3.1.16 3.2.4
	5. Perform systematic clinical audit to critically evaluate the performance and suitability of investigations offered, share the outcome of each audit and where appropriate justify a modification to practice based on the audit findings • Initiate, perform and communicate the outcomes of clinical audits of the effectiveness of routine and non-routine clinical investigations considering national and local audit priorities and in accordance with the governance regulations. • Identify, critically evaluate and communicate the outcomes of clinical audits performed by others in relevant areas of clinical practice and justify a decision to adapt practice as appropriate. • In partnership with service users devise, develop, perform and critically evaluate clinical audits in own area of expertise to identify areas of good practice and areas for improvement. • Analyse and report the outcomes of clinical audits, including learning points and modifications introduced as a result of the clinical audit.	1.1.11 2.2.2 3.1.17
Attitudes and Behaviours	By the end of the training period HSS Trainees would be expected to demonstrate the attitudes and behaviours necessary for the role of a Consultant Clinical Scientist and will be able to:	
	1. Commit to and provide leadership in the provision of high standards of clinical practice taking account of the political, social, technical, economic, organisational and professional environment and act as a positive role model • Perform role to high standards of clinical practice applying knowledge and evidence, making decisions and evaluating the impact of those decisions. • Monitor, evaluate and maintain clinical practice standards. • Share data on clinical practice standards with service users and managers to encourage dialogue and debate.	3.1.1 3.1.2 3.1.3 3.1.14
	2. Evaluate and use new research findings and new technology to plan, develop and deliver improved clinical investigations • Analyse and use research findings and new technology in bringing about quality improvements in clinical investigation. • Use and critically review a range of sources of information to keep up to date with clinical and scientific developments in area of expertise.	3.1.5 3.1.6 3.1.9

Topic	Clinical Practice	GSP Reference
	• Share ideas on improvements to clinical investigations with peers and service users setting out the context for change and evaluating the impact of any resulting change.	
	3. Engage in two-way clinical liaison between those who request and those who provide clinical investigations for individual patients using the skills of team members effectively • Lead and promote a culture of interaction with service users and patients. • Analyse, critically review, generate and revise clinical protocols and guidelines and evaluate how protocols and guidelines contribute to standards of clinical practice. • Train and empower colleagues to participate in two-way clinical liaison. • Initiate and audit of effectiveness of clinical liaison identifying areas for improvement and collaborating with colleagues to bring about change.	1.3.1 3.1.4 3.1.12 3.1.13 3.1.14 3.2.4
	4. Promote the importance of active participation by Clinical Scientists in multidisciplinary clinical team meetings to advise and provide a scientific perspective • Recognise the importance of the multidisciplinary clinical team and takes responsibility for ensuring appropriate and effective decision making processes are in place. • Support and contribute to the development of multidisciplinary clinical team working and work with the team to determine scientific service priorities.	1.3.2 3.1.16
	5. Advocate clinical audit as a tool to evaluate and optimise clinical services and communicate ideas and aspirations • Support the role of clinical audit as a valid tool to improve clinical effectiveness and patient care. • Commit to training of self and others to enable clinical audit to proceed. • Share the outcomes (both positive and negative) of clinical audits with service users and peers having regard to clinical governance consequences.	1.1.11 1.3.6 2.2.2 3.1.17

Domain 4: Research, Development and Innovation

Topic	Research, Development and Innovation	GSP Reference
Learning Objective	By the end of this stage of training, HSS Trainees will be able to generate ideas, assess, plan, conduct, supervise, critically evaluate, interpret and report research and innovation projects, which includes original research, translational research and innovation. and the adoption and diffusion of the findings/output	
Knowledge **Competence**	By the end of the training period HSS Trainees will be able to: 1. Justify the stages of the research and innovation process from conceptualisation to dissemination and if appropriate translation into practice • Describe the stages of the innovation pathway (Invention, Evaluation, Adoption and Diffusion). • Critically evaluate the literature/evidence base to identify the research question or create a new approach, technique, etc. • Evaluate the clinical importance of any proposed research project and recognise its potential impact on patients and carers. • Recognise the priorities and factors affecting research and innovation in the area of study and the practical and financial criteria and constraints affecting research. • Appraise healthcare research and innovation funding policy and strategy. • Evaluate the organisation's research, development and innovation policy and strategy and how this aligns to national policy of the NHS, Higher Education Sector, Research Councils and Charities. • Summarise the organisation's policy with respect to research ethics and regulatory requirements from conception to archive and justify how this protects the researcher, research subjects and the organisation. • Summarise the sources of funding/grants and provision of expert advice on research funding, how to access them and when to use them. • Identify and evaluate sources of information and expert advice. 2. Justify the rationale for research governance and ethical frameworks when undertaking research or innovation as a principal investigator or supervising others • Describe the regulatory requirements including the Research Governance Framework, Ethical Framework, Intellectual Property that must be considered in the area of study. • Conform to the requirements of data protection and confidentiality guidelines. • Identify and evaluate the possible risks associated with the research or innovation project appraising the options in terms of benefits and risks and judging how to manage these. • Recognise the right of pressure groups and others who may oppose the research to present the justification for their views. • Justify the benefits of using project management techniques and tools and how to apply them at strategic level. • Describe the scope, objectives and implications of the specific research programme. • Define the roles and responsibilities of those involved in the research programme and clearly set out the relevant lines of communication and authority for the research programme. • Summarise the monitoring and reporting procedures relevant to the research or innovation project and the importance of these procedures as part of the quality assurance programme.	1.1.5 4.1.1 4.1.2 3.1.7 4.1.3 4.1.4

Topic	Research, Development and Innovation	GSP Reference
	3. Critically appraise the results of a research and development project, draw conclusions in the correct clinical context and where appropriate, use them to plan follow up research and development • Critically appraise the literature review, determine that the conclusions drawn the evidence supports the hypothesis to be tested. • Evaluate the research plan and its ability to confirm or refute the hypothesis, address the ethical issues and the extent to which patients/service users /experts have been involved in the design of the study. • Evaluate criteria/metrics for assessing and grading research data and publications in the Scientific, NHS and HE Sectors. • Summarise and apply the criteria for assessing diagnostic accuracy (e.g. STARD). • Critique methods of capturing and storing data relevant to research programme including the ethical issues relating to access and use of information. • Compare and contrast the range of formats and modes of presentation of data and defend the methods selected. • Apply relevant methods and techniques to analyse results ensuring the integrity of the data • Critically appraise the data analysis strategy including power calculations and apply relevant statistical methods seeking advice from experts when needed and recognising the • Defend personal role and responsibilities in respect of interpretation and analysis of research results and levels of authority in respect of interpretation and analysis of research results	2.1.6 3.1.12 3.1.13 3.1.14 4.1.5 4.1.6 4.1.7
	4. Appraise the ways in which research and development findings can be disseminated amongst the scientific community including peers and other stakeholders in interested parties • Compare and contrast methods of presenting research (written and oral) identify the strengths of each method with respect to the target audience. • Identify and if necessary seek expert advice with respect to potential Intellectual property issues that did not arise in the planning stage and implications for publishing. • Summarise the requirements for publications submitted to scientific, education and similar journals including the current conventions in respect of bibliography and referencing of information, and the implications of open access publishing.	3.1.16 4.1.9 4.1.10
	5. Appraise and justify the process of translating research findings into service in the interests of patient care • Identify the likely impact of research and on innovation in service design, delivery and clinical effectiveness including reverse innovation i.e. stopping doing something that no longer adds value. • With respect to pilot and field studies identify possible risks, evaluate methods and techniques and predict the expected outcomes ensuring compliance with the relevant ethical codes and regulatory requirements. • Identify and evaluate sources of expert advice. • Appraise own role and responsibilities within the testing process and clearly define the levels of authority and decision making within the testing process. • Describe methods of cost-benefit and cost effectiveness analysis and how they can be applied to aid decision making with respect to introducing research findings or innovation into service. • Summarise the relevance of Research Governance Framework to translating research or adopting and diffusion of innovation	4.1.5 4.1.10

Topic	Research, Development and Innovation	GSP Reference
	into practice	
Practical Skills	By the end of the training period HSS Trainees would be expected to apply in practice a range of clinical skills and critically reflect on their performance and will be able to: 1. Create the initial new idea, approach, technique and plan a research and development or innovation project critically evaluating the research proposal and drawing on expert advice where necessary and involving patients and service users • Search for and critically appraise relevant publications in the scientific literature relating ideas to current thinking, knowledge and research. • Identify the potential for innovation in service design and delivery to enhance clinical effectiveness. • Evaluate objectively and critically the feasibility and implications of investigation of the ideas and assessing the potential output, utility and impact of future study. • Identify potential intellectual property (IP) associated with the ideas and the steps to be taken to register IP. • Develop and maintain networks and identify potential collaborators and competition. • Clearly define and prioritise the aims and objectives of the research. • Specify the detailed components and proposed outputs of the research. • Identify methods, tools, techniques and approaches which are capable of achieving the required outcomes. • Establish evaluation criteria and methods. • Identify criteria and issues affecting funding sources at a level of detail sufficient to aid decision making. • Access relevant expert advice regarding sources of funding. • Target appropriate sources of funding for research and innovation. • Incorporate compliance with relevant ethical and regulatory requirements. • Prepare and present the plan to all relevant people, in the appropriate format and by the designated deadline. 2. Conduct and/or supervise a research and development or innovation project • Manage relationships with stakeholders and those involved to maximise effectiveness of the research programme. • Provide clear strategic direction and motivation to those involved in the research programme. • Ensure that all members of the research team understand their role and responsibilities including lines of communication and reporting, and that appropriate training is provided. • Specify clearly the levels of authority and decision making within the research programme. • Ensure availability of, and access to technical and administrative support at the appropriate level of expertise. • Conduct investigations in line with research plan. • Document investigations and results to comply with good research practice and good clinical practice. • Document and report fully any unexpected outcomes of incidents and modify investigation accordingly. • Report any delays or problems experienced to all interested parties, giving full explanation. • Pay proper attention to adverse events arising from investigations and take appropriate action to minimise risks. • Provide clear and timely guidance to deal with contingencies and factors influencing progress of the research programme. • Ensure compliance with Research Governance Framework, including continuous review and quality assurance of the	1.1.4 1.1.5 1.3.1 3.1.7 4.1.1 4.1.2 4.1.3 1.3.1 4.1.3 4.1.4 4.1.5 4.1.8

Topic	Research, Development and Innovation	GSP Reference
	research and development programme and adherence to the data archive process and requirement to provide access to the date for regulatory inspections.	4.1.5
	3. Critically appraise the results of a research and development project, draw conclusions in the correct clinical context, and, where appropriate, use them to plan follow up research and development • Select type and range of data to be collected in line with research plan, including primary and secondary sources. • Ensure that records comply with relevant legal, ethical and organisational requirements. • Ensure that records of research data are complete and accurate. • Assess the research information collected for its validity and reliability. • Select techniques of analysis and evaluation which are valid, reliable and appropriate to the research design and purpose. • Collate, record and analyse information accurately to produce justifiable results. • Verify the analysis using accepted and valid techniques including statistical tests. • Assess the results of research against the original objectives. • Assess the clinical significance and impact of the research. • Investigate reasons where the research has failed to achieve its objectives and provide clear explanation. • Draw conclusions drawn from results and explain the rationale for those conclusions.	4.1.6 4.1.7 4.1.10
	4. Report and communicate research, development or innovation to peers and other interested parties including patients and service users • Report and endeavour to publish all research, including negative findings. • Define the key purpose and objectives of the research programme and match results to these objectives. • Produce findings in format appropriate to purpose, and in line with relevant legal, ethical and organisational requirements. • Record accurately issues of copyright, declaration of interest and intellectual property rights. • Present findings in a format, language and style suitable for the target audience. • Include all relevant bibliographic references in line with current conventions. • Make a clear distinction between the results and the interpretation placed upon them. • Support the presentation with sufficient information to clarify key points. • Support presentation conclusions with reasoned argument and sufficient evidence. • Make recommendations, which are realistic, relevant and clearly defined. • Acknowledge collaborators, contributors and funding sources. • Effectively respond to questions and critical comments. • Observe time limitations for oral presentations and deadlines for written presentations.	4.1.9 4.1.10
	5. Translate research findings or innovation solutions into service and provide examples of where this has been achieved • Realign research findings or innovative approaches to create a service development or change plan • Assess impact of research on innovation in service design and delivery • Complete pilot and field studies in line with plan • Identify and report potential risks associated with the conduct of pilot and field studies	4.1.5 4.1.10

Topic	Research, Development and Innovation	GSP Reference
	• Maintain records of all pilot and field studies in accordance with the plan • Present documentation and provide verbal feedback as required by the plan • Document and report any unexpected outcomes or incidents • Report any delays or problems experienced to authorised personnel with relevant degree of urgency. • Report on cost-benefit analysis of implementation.	
Attitudes and Behaviours	By the end of the training period HSS Trainees would be expected to demonstrate the attitudes and behaviours necessary for the role of a Consultant Clinical Scientist and will be able to: 1. Evaluate current debates and information and identify opportunities for research, development and innovation identifying and solving problems. • Appreciate the impact of current clinical outcomes on patients and carers in research area. • Accept the need to mitigate factors that limit current clinical outcomes and patient experience in research area. • Explore areas of clinical practice where significant improvements could contribute to better clinical outcomes and/or patient experience. • Recognise the opportunities for innovation in service design and/or delivery. • Use examples from the literature and own experience where research, development and innovation has contributed to better clinical outcomes and/or patient experience. 2. Apply rigorous standards to the conduct of research, development and innovation • Adhere to, and accept and work within current research ethics and research governance requirements applicable within organisation raising concerns when necessary. • Promote methods for defining and demonstrating compliance with relevant research ethics and research governance requirements. • Adhere to and accept methods for external assessment of compliance with research ethics and research governance requirements and learn from the process. • Critically reflect on and use examples of problems encountered by others when compliance with research ethics and research governance requirements was inadequate and apply learning to all aspects of research, development and innovation. 3. Commit to and lead collaborative research in the interests of improving clinical outcomes and/or patient experience • Accept and value the knowledge and experience that each research collaborator can bring to the planning, implementation and evaluation of a research project listening to, and evaluating the views of others. • Promote the importance of the multidisciplinary clinical team in setting practice standards and in auditing outcome against those standards. • Identify and promote the benefits to own specialism by being a partner in collaborative research. • Leadership to give examples of good clinical practice deriving from a collaborative approach to research and development. 4. Commit to sharing and disseminating research findings and the outcome and learning from innovation projects with peers • Accept the benefits and constraints of patents and confidentiality in research outcomes and innovation opportunities.	4.1.1 4.1.2 4.1.4 4.1.3 4.1.10 4.1.6

Topic	Research, Development and Innovation	GSP Reference
	• Collaborate with a group of peers with an interest in improving clinical outcomes and/or patient experience in the same area of research to create opportunities for research, development and innovation. • Facilitate peer discussions on the value of current research and the opportunities for new research, be open to challenge and revise views in response to discussion when necessary. • Promote opportunities to present research findings to peers and critically appraise the research findings of others.	4.1.7 4.1.9
	5. Actively seek opportunities to translate research findings and the diffusion and adoption of innovation into clinical practice • Challenge and influence to mitigate current barriers to the translation of research findings or new innovative ways of working into clinical practice across the organisation and, where appropriate, nationally. • Promote opportunities to undertake targeted translational research and innovation encouraging the contribution of the healthcare team. • Identify examples of where the translation of research findings into practice has resulted in improved clinical outcomes and/or patient experience to influence the translation, adoption and diffusion of new findings, negotiating, questioning and challenging where necessary. • Promote the importance of innovation in service design and/or delivery including the contribution of research and innovation in healthcare to business and the UK economy. • Engage service users, patients and the public to promote the positive impact of research and innovation on clinical outcomes and/or patient experience.	4.1.9 4.1.10

Domain 5: Clinical Leadership

Topic	Clinical Leadership	GSP Reference
Learning Objective	By the end of this stage of training, HSS Trainees will be able to critically appraise the evidence base underpinning clinical leadership frameworks and operate as a clinical leader involved in the planning, delivery and transformation of health and social care services.	
Knowledge	By the end of the training period HSS Trainees will be able to:	
	1. Evaluate the personal qualities required of a clinical leader and critically reflect on performance to identify his/her own personal qualities, including values, principles and assumptions developing action plans to adapt personal behaviour as necessary • Critically appraise models of leadership including the shared or distributed model for organisations where tasks are more complex and highly interdependent. • Evaluate a range of tools that enable exploration of the ways in which individual behaviours impact on others. • Evaluate a range of feedback models to obtain and respond to feedback from others. • Review and justify the use of a range of tools and techniques for managing stress including occupational health and other support networks. • The importance of best practice, transparency and consistency. • Summarises the professional, legal and ethical codes of the Health and Care Professions Council and other relevant bodies. • Evaluate a range of tools to identify personal preferences and prejudices and those within others, society and cultures.	1.1.2 1.1.3 1.1.5 1.1.6 1.1.7 5.1.1
	2. Evaluate the importance of working with others in teams and networks to deliver and improve services • Discuss the role of team dynamics in the way a group, team or department functions. • Evaluate a range of team structures and the structure, roles and responsibilities of the multidisciplinary teams within the broader health context relevant to the specialism, including other agencies and the impact of different structures on the delivery of care. • Critique a range of techniques and methods that facilitate effective and empathic communication and the evidence base underpinning them • Evaluate a range of models to facilitate conflict resolution • Critically explore a range of leadership styles and approaches and identify the applicability, strengths and weakness of each to different situations and people	1.3.1 1.3.2 1.3.5 5.1.2 5.1.4 5.1.5 5.1.7
	3. Critically evaluate methods by which services may be planned and people and resources managed effectively • Summarise the structure, financing and operation of the NHS and its constituent organisations and compare this to other systems of healthcare. • Ethical and equality aspects relating to management and leadership e.g. approaches to use of resources/rationing; approaches to involving services users in decision making. • Discuss business management principles: priority setting and basic understanding of how to produce a business plan. • Identify the requirements of running a department, unit or practice relevant to the specialism.	5.1.1 5.1.6

Topic	Clinical Leadership	GSP Reference
	• Justify the allocation of funding to scientific services and evaluate how clinical resources to provide high quality care should be allocated considering the financial constraints of the NHS and local organisations. • Summarise the commissioning, funding and contracting arrangements relevant to the specialism including education, training and continuing professional development. • Critique relevant legislation (e.g. Equality and Diversity, Health & Safety, Employment Law) and local Human Resources policies and the impact of these policies on people and the organisation. • Discuss the duties rights and responsibilities of an employer, and of a co-worker. • Justify the role of individual performance review considering its purpose, techniques and processes, including the difference between appraisal, assessment and revalidation. • Compare and contrast methods to measure and manage the performance of the organisation. • Analyse the source of complaints, and review and reflect on how complaints are managed and the learning that is fed back into the organisation to improve the patient and staff experience.	
	4. Critically evaluate how clinical leadership can support the delivery of high quality services and by service improvements and the methods by which it may be achieved delivering high quality services and by developing improvements to service. • Evaluate risk management issues pertinent to the area of practice and wider organisation identifying potential sources of risk and risk management tools, techniques and protocols. • Summarise how healthcare governance influences patient care, research, innovation and educational activities at local regional and national level. • Summarise key government reports on maintaining professional standards and discuss the mechanism for raising issues where you consider that standards are being compromised ('whistleblowing') . • Appraise quality improvement methodologies including a range of methods obtaining feedback from users, staff, patients and the public and explore the impact on patients, services and the organisation. • Discuss the principles and processes of evaluation, audit, research, and development, innovation, clinical guidelines and standard setting in improving quality and identify barriers to the adoption and success of each measure in practice. • Identify a variety of methodologies for developing creative solutions to improving services. • Explore the implications of change on systems and people and methods to minimise the negative effects of change including strategies for motivating people to change, the effect of organisational culture. • Describe project management methodology and how it can be used during change.	1.1.12 2.2.2 2.3.2 2.3.2 2.3.3 2.3.4 3.1.17 5.1.8 5.1.10 5.1.11
	5. Justify the importance of strategic planning in line with the aspirations of the organisation • Summarise the responsibilities of the various Executive Board members and Clinical Directors or leaders. • Summarise the functions and responsibilities of national bodies such as department of Health, Care Quality Commission, NHS Evidence, National Patient Safety Agency, Medicines and Healthcare products Regulatory Agency, Royal Colleges and faculties, specialty organisations, representative bodies, regulatory bodies, educational and training organisations. • Analyse patient outcome reporting systems within the specialism, and the organisation and how these relate to national programmes. • Summarise how research, development and innovation contribute to strategic planning.	1.3.1 1.3.3 5.1.1 5.1.6 5.1.12

Topic	Clinical Leadership	GSP Reference
	• Critically review the decision making for individuals, teams and the organisation and the impact on service delivery and patient care. • Compare and contrast a range of communication strategies and identify the factors that promote effective communication strategies within organisations. • Explore methods of undertaking impact mapping of service change and how this can support the process of change. • Identify barriers to change and how to develop strategies to explore and break down barriers. • Summarise qualitative methods to gather and analyse the experience of users, patients and carers and utilise the data to recognise areas of good practice/planning and help shape the planning process.	
Practical Skills	By the end of the training period HSS Trainees would be expected to apply in practice a range of clinical skills and critically reflect on their performance and will be able to: 1. Demonstrate through personal example his/her own personal qualities, including values, principles and assumptions and critically reflect on personal performance and: • Maintain and routinely practice critical self awareness, including ability to discuss strengths and weaknesses with supervisor, recognising external influences and changing behaviour accordingly. • Show awareness and sensitivity to the way in which cultural and religious beliefs affect approaches and decisions, and to respond effectively. • Recognise the manifestations of stress on self and others and know where and when to look for support. • Balance personal and professional roles and responsibilities, prioritising tasks and having realistic expectations of what can be completed by self and others. • Use a reflective approach to practice with an ability to learn from previous experience. • Use assessment, appraisal, complaints and other feedback to discuss and develop an understanding of own development needs. • Recognise, analyse and know how to deal with unprofessional behaviours in clinical practice taking into account local and national regulations. • Create open and non-discriminatory professional working relationships with colleagues, including awareness of the need to promote equality of opportunity and to prevent bullying and harassment in the workplace. 2. Work with others in teams and networks to deliver and improve services • Work in differing and complementary roles within the different communities of practice within which they work. • Support bringing together different professionals, disciplines, and other agencies, to provide high quality healthcare. • Develop effective working relationships with colleagues and other staff through good communication skills, building rapport and articulating own view. • Communicate effectively in the resolution of conflicts, providing feedback, and identifying and rectifying team dysfunction. • Facilitate, chair and contribute to meetings within the department, the organisation, national societies/professional bodies. • Encourage staff to develop and exercise their own leadership skills. • Enable individuals, groups and agencies to implement plans and decisions.	1.1.12 1.2.3 5.1.1 5.1.2 5.1.3 5.1.4 5.1.12 1.3.4 1.3.5 1.3.6 5.1.1 5.1.2 5.1.3 5.1.4 5.1.10

Topic	Clinical Leadership	GSP Reference
	• Identify and prioritise tasks and responsibilities including to delegate and supervise safely.	
	3. Effectively management of services using critical reflection to evaluate and improve personal performance • Develop and implement protocols and guidelines. • Analyse feedback and comments and integrate them into plans for the service. • Use clinical audit with the purpose of highlighting resources required. • Manage time and resources effectively in terms of delivering services to patients. • Prepare rotas, delegate, organise and lead teams. • Contribute to the recruitment and selection of staff. • Contribute to staff development and training, including mentoring, supervision and appraisal. • Use and adhere to clinical guidelines and protocols, relevant reporting systems and complaints management systems. • Improve services following evaluation/performance management.	1.4.1-1.4.6 5.1.5 5.1.6 5.1.8 5.1.9 5.1.10 5.1.11
	4. Contribute to continuous service improvement developing improvements to service and reflecting on experience to ensure the delivery of high quality services • Report clinical incidents in accordance with reporting procedures. • Assess and analyse situations, services and facilities implementing recommendations in order to minimise risk to patients and the public. • Monitor the quality of equipment and safety of environment relevant to the specialism acting swiftly to resolve issues. • Design and undertake an audit project, present the results and develop an implementation and re-evaluation plan as appropriate to the audit. • Contribute to meetings which cover audit; critical incident reporting; patient outcomes challenges, justifying, influencing as appropriate. • Question and challenge existing practice in order to improve services. • Apply creative thinking approaches (or methodologies or techniques) in order to propose solutions to service issues. • Provide clinical expertise in evolving situations. • Present written and verbal information in a clear, concise way using language appropriate to the audience.	1.1.11 1.4.4 1.4.5 1.4.6 5.1.3 5.1.7 5.1.8
	5. Contribute to and undertake strategic planning in line with the aspirations of the organisation and its impact on service quality and delivery • Discuss the local, national and UK health priorities and how they impact on the delivery of healthcare relevant to the specialism • Identify trends, future options and strategy relevant to the specialism and delivering patient services • Compare and benchmark healthcare services • Use a broad range of scientific and policy publications relating to delivering healthcare services • Prepare for meetings – reading agendas, understanding minutes, action points and background research on agenda items. • Work collegiately and collaboratively with a wide range of people outside the immediate clinical setting.	5.1.1 5.1.12

Topic	Clinical Leadership	GSP Reference
	• Evaluate outcomes and re-assess the solutions through research, audit and quality assurance activities. • Evaluate the wider impact of implementing change in healthcare provision and the potential for opportunity costs.	
Attitudes and Behaviours	By the end of the training period HSS Trainees would be expected to demonstrate the attitudes and behaviours necessary for the role of a Consultant Clinical Scientist and will be able to: 1. Consistently operate within sphere of personal capability and level of authority, managing personal workload and objectives to achieve quality of care. • Adopt a patient focussed approach to decisions that acknowledges the right, values and strengths of patients and the public. • Comply with relevant legislation to recognise and show respect for diversity and differences in others. • Be conscientious, able to manage time and delegate responsibly. • Recognise personal health as an important issue in maintaining personal capability. • Accept responsibility for own actions. • Commit to continuing professional development, which involves seeking training and self-development opportunities, learning from colleagues and accepting constructive criticism. • Accept professional regulation and ensure compliance with relevant standards. • Promote appropriate professional attitudes and values. • Act with probity and be willing to be truthful and admit and learn from errors. 2. Actively seek to encourage and work within a team environment, including multidisciplinary teams • Interact effectively with professionals in other disciplines and agencies • Respect the skills and contributions of colleagues • Recognise good advice and continuously promote value-based non-prejudicial practice. • Use authority appropriately and assertively being willing to follow when necessary. • Use authority sensitively and assertively to resolve conflict and disagreement. • Take full part in multidisciplinary meetings. • Show recognition of a team approach and willingness to consult and work as part of a team • Respect colleagues and other healthcare professionals. 3. Manage resources effectively in the interests of improving patient services promoting equity in healthcare access and delivery • Use public money appropriately and to taking action when resources are not used efficiently or effectively. • Recognise that in addition to patient specific clinical records, clinical staff also have responsibilities for other records (e.g. research). • Supervise the work of less experienced colleagues supporting them to develop. • Use communication skills and inspire confidence and trust. • Respond constructively to the outcome of reviews, assessments or appraisals of performance • Recognise the needs of all staff in the clinical team.	1.1.3 1.1.4 1.1.6 5.1.1 1.3.1 1.3.2 1.3.1 1.3.5 5.1.2 5.1.6 5.1.11

Topic	Clinical Leadership	GSP Reference
	4. Engage in continuous service improvement in the interests of better patient outcomes • Actively seek advice/assistance whenever concerns about patient safety arise. • Take responsibility for clinical governance activities, risk management and audit in order to improve the quality of the service. • Listen to and reflect on the views of users, patients and carers, dealing with complaints in a sensitive and co-operative manner. • Act as an advocate for the service. • Be open minded to new ideas. • Adopt a proactive approach to new technologies and treatments. • Support colleagues to voice ideas. • Be positive about improvement and change. • Strive for continuing improvement in delivering patient care services.	1.1.12 1.2.2 3.1.17 5.1.6 5.1.7 5.1.8 5.1.10 5.1.11
	5. Contribute to articulating the aspirations of the organisation and be willing to align strategic planning with these aspirations to improve service quality and delivery. • Comply with national guidelines that influence healthcare provision. • Articulate ideas and use effective influencing skills. • Identify and reflect on issues and potential solutions before acting. • Appreciate the importance of involving service users, the public and communities in developing health services. • Participate in decision making processes beyond the immediate clinical care setting. • Implement proven improvements in clinical practice and services. • Obtain and analyse the evidence base before declaring effectiveness of changes. • Support the dissemination of good practice.	5.1.10 5.1.11 5.1.12

Specialty-specific genetics curriculum

Stage 1 (12 months)

Introduction

The precise composition of this stage of an individual training programme should take into account past experience (include that gained in the STP programme or equivalent and the aspirations of each trainee and should set out educational objectives against which progress can be assessed. Programmes should identify how specific areas of training not covered by the departments involved will be obtained (e.g. secondment for experience in cancer genetics).

The aim of Stage 1 of the curriculum is to outline the required core knowledge, skills and experience of the scientific, clinical and technical aspects of genetics.

Knowledge gained up to and including Stage 1 will be examined in the FRCPath Part 1 examination.

Stage 1 Module 1: Core genetics and biology

Topic	Stage 1 Module 1 Core genetics and biology	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of core genetics and biology, obtain a working knowledge of the scientific, clinical and technical aspects of genetics and be able to: analyse, synthesise, evaluate and apply knowledge perform a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: an up-to-date knowledge of the general principles of human genetics including: – Mendelian and non-Mendelian genetic inheritance (including the relevant biology) – molecular genetics (including structure, function and organisation of the genome) – molecular cytogenetics (including copy number variation) – cell biology (cell division: mitosis and meiosis) – genetic syndromes and disorders (including acquired disorders).	FRCPath Part 1, WPBA	2
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance of the following technical procedures and laboratory skills: Identification and selection of appropriate starting material – blood – buccal scrapes – foetal tissue from chorion villous biopsy – skin and other biopsy material – formalin fixed paraffin embedded tissues – bone marrow trephine and other related samples – cell culture, including automated techniques – DNA and RNA (including free-fetal). Laboratory techniques – karyotyping (microscopy and semi-automated techniques) – FISH (Fluorescence in situ hybridisation) – polymerase chain reaction (PCR) – southern blotting – QF-PCR and MLPA	WPBA	2

	– microarray technologies and complimentary copy number detection techniques, e.g. q-PCR – nucleic acid sequencing technologies. Systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls and monitoring assay performance – internal quality assurance – external quality assurance. Validity and reliability of test results and their application – understanding of uncertainty of measurement – using systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments – use of computers and appropriate databases.		
Clinical skills	See Stage 1 Module 4		3

Stage 1 Module 2 Laboratory aspects of genetics

Topic	Stage 1 Module 2 Laboratory aspects of genetics	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of the genetics laboratory and its clinical interface, be able to analyse, synthesise, evaluate and apply knowledge perform a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate tests 2. Scientific quality assurance of test procedures 3. Validity and reliability of test results and their application	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: use of the knowledge required for: – diagnosis, prognosis and on-going management of patients who have a particular disorder or disease with a genetic basis or who are pregnant – laboratory techniques potential utility of new technologies in a laboratory, clinical and public health context using appropriate recognised measures, e.g. QALY quality assurance of test procedures and reagents including the use of reference and certified materials where appropriate quality assurance of reference and certified materials where appropriate. clinical utility test results and their application including use and understanding of statistical methodology.	FRCPath Part 1, WPBA	2, 3
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance of the following technical procedures and laboratory skills: identification and selection of appropriate starting material: – blood – buccal scrapes – fetal tissue from chorion villous biopsy – skin and other biopsy material – formalin fixed paraffin embedded tissues – bone marrow trephine and other related samples – cell culture, including automated techniques – DNA and RNA (including free-fetal)	WPBA	2

	laboratory techniques – karyotyping (microscopy and semi-automated techniques) – FISH (Fluorescence in situ hybridisation) – polymerase chain reaction (PCR) – southern blotting – QF-PCR and MLPA – microarray technologies and complimentary copy number detection techniques e.g. q-PCR – nucleic acid sequencing technologies systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls and monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – understanding of uncertainty of measurement – using systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments.		
Clinical skills	See Stage 1 Module 4		3

Stage 1 Module 3 Health and safety in genetics practice

Topic	Stage 1 Module 3 Health and safety in genetics practice	Assessment methods	GSP reference
Learning objectives	By the end of the training period trainees will, with respect to health and safety issues both locally and nationally in order to practise safely in a laboratory, clinical or other settings and advise on safe practice be able to analyse, synthesise, evaluate and apply knowledge perform a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level. Trainees will also be expected to perform risk assessments and develop, refine and evaluate health and safety precautions relating to patient management		
Knowledge 1. Health and safety legislation and guidance 2. ACDP categorisation of biological agents 3. Laboratory safety and containment 4. Transport regulations	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: Health and Safety at Work Act (1974) Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) Control of Substances Hazardous to Health (COSHH) Regulations (2002) Genetically Modified Organisms (Contained Use) Regulations (2001) Management of Health and Safety at Work Regulations (1999) Transport of Infectious Substances (2011) guidance The management, design and operation of microbiological containment laboratories (2001) guidance (HSE) Biological agents: Managing the risks in laboratories and healthcare premises (HSE) Safe disposal of clinical waste (1999) guidance.	FRCPath Part 1, WPBA	1, 2
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance of the following technical procedures and laboratory skills: aseptic technique.	WPBA	2
Clinical skills			

Stage 1 Module 4 Clinical knowledge

Topic	Stage 1 Module 4 Clinical knowledge	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of clinical knowledge, understand the laboratory results and other sources of information required for the diagnosis, management and where appropriate, assignment of reproductive risks for patients and their families for appropriate conditions in order to be able to analyse, synthesise, evaluate and apply knowledge perform a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: genetic syndromes and disorders disease (e.g. cancers) with a defined and recognisable genetic component in the diagnosis and management of patients genetics of pregnancy – screening protocols – copy number changes – targeted testing – genome-wide testing.	FRCPath Part 1, WPBA	3
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance of the following technical procedures and laboratory skills: pedigree construction and analysis.	WPBA	3
Clinical skills	By the end of the training period the trainee will be able to apply clinical knowledge to perform the clinical skills necessary to manage under supervision: counselling skills, attitudes and behaviours.	MSF	3

Stage 1 Module 5 Statistics and bioinformatics

Topic	Stage 1 Module 5 Statistics and bioinformatics	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of statistics and bioinformatics understand the role and use of statistics and bioinformatics in the organisation, assessment and interpretation of data in genetics and be able to analyse, synthesise, evaluate and apply knowledge perform a range **of scientific and** clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: genetic syndromes and disorders disease (e.g. cancers) with a defined and recognisable genetic component in the diagnosis and management of patients genetics of pregnancy – screening protocols – copy number changes – targeted testing – genome-wide testing.	FRCPath Part 1, WPBA	2
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance of the following technical procedures and laboratory skills the use of computers and appropriate databases.	WPBA	2
Clinical skills			

Stage 2 (48 months)

Introduction

This period of training in genetics will consist of consolidation of clinical and laboratory experience started in Stage 1 up to consultant level. The trainee will have a sound theoretical and practical knowledge of genetics practice, but may not have had a great deal of unsupervised experience in applying that knowledge. These stages of training are thus devoted to acquiring self-sufficiency in the specialty. It is meant to be a guide for both the educational supervisor and trainee on the learning topics and themes that should be covered during these stages of training. It is recommended that the educational supervisor, trainer(s) and the trainee plan the training in advance as much as possible.

Use should be made of the College's training portfolio for recording progress in training. It is a modular curriculum, consisting of core and optional components. **All higher specialist trainees must complete the core components**. The optional components are designed to provide the trainee with options to choose from if they have completed the mandatory requirements of the curriculum prior to the award of FRCPath and that best reflect their needs and aspirations. In many instances, the optional component may need to be arranged anything up to a year before the anticipated start date.

No time limit has been set for any of the components because it is envisaged that many of the components may be running concurrently, e.g. dealing with management issues and contributing to the clinical service.

It is expected that training will be delivered as an appropriately supervised apprenticeship and therefore 50–80% of training would normally take the form of training while contributing to delivery of the service. There should be readily available consultant or equivalent support to consult with if necessary. The trainee should continue to be well supervised. The trainee should have a broad exposure to appropriate curriculum content.

As for the Stage 1 curriculum, the knowledge, skills, attitudes and behaviours are given for each module (if relevant).

Experience gained by the provision of independent practice should continue for a period of training sufficient to enable the trainee to give independent advice in relation to the practice of this specialty (see section above, 'Development of independent practice').

Key components

The key components of Stage 2 are designed to equip the trainee with competencies required for the acquisition of FRCPath by examination in genetics and to allow practice of genetics at consultant level. They consist of the following:

1 Developing independent professional practice – Stage 2 Module 1
2. Specialty-specific genetics practice – Stage 2 Module 2
3. Leadership and management – Stage 2 Module 3
4. Training and education – Stage 2 Module 4
5. Understanding research and development in genetics – Stage 2 Module 5.

In-course assignments (in development for genetics) will be an integral part of the FRCPath genetics examination. The assignment for each of the components must be completed and assessed to be satisfactory before the trainee will be permitted to sit for the FRCPath Part 2 examination. It is the responsibility of the educational

supervisor to ensure that the trainee's assignment(s) meet the guidelines for the FRCPath examination for genetics, before they are submitted to the College for assessment. The assignments and the responsibility of the trainee and their educational supervisor are listed at the end of each of the essential components.

Optional components (in development for genetics)

These components are designed to complement the essential modules undertaken by the trainee in Stage 2. They allow trainees to develop a specialist interest and are suitable for those trainees who have achieved core components quickly. The time at which these optional components are taken depends on the progress of trainee through the core components. They may be undertaken at any stage of the training. These optional modules are designed to build upon the core competencies already acquired by the trainee as a result of undergoing the training outlined in the core components.

Trainees should select modules which best suit their training requirements and career aspirations. As these are optional, only guidance on the aims and objectives of each module can be given. Optional components may also be designed by the trainee. These need to be written in conjunction with the educational supervisor and should be submitted to the Chair of the SAC for approval. As time goes on, extra optional components may be added.

Responsibilities of the trainer or educational supervisor

- Confirm that the trainee is already a member of appropriate learned societies, e.g. Association of Clinical Genetic Science (ACGS), British Society for Genetic Medicine (BSGM).
- Encourage/facilitate attendance at local/national/international meetings.
- Help trainee organise time and information regarding relevant courses.
- Approve attendance at meetings/courses so that funding of study leave can be applied for from the relevant quarters.
- Supervision and encouragement of acquisition of portfolio evidence of competence and completion of the written assignments.

In-course assessment

Write one review article of up to 3000 words (format as per *Reviews in Nature Genetics Reviews*). Candidates are encouraged to devise their own suitable topics, in consultation with their educational supervisors:

Stage 2 Module 1 Developing independent practice module

Objective

Throughout their training, trainees are given increasing responsibility and independence appropriate for their demonstrated level of competence and professional development, as judged by their clinical and educational supervisors. The purpose of this stage of training is to take such graded responsibility further, to enable the transition to the independent practice required of an FRCPath holder.

Demonstration of the skills required for independent practice is a requirement of the curriculum, and the relevant competencies must be assessed and achieved prior to completion of the training programme.

Currently, the most appropriate context in which to train for and achieve the competencies for independent practice is out-of-hours working, in an 'on-call' setting. However, there may be practical alternatives to this training context. If a training programme does not offer the opportunity to develop and demonstrate these skills through out-of-hours working, there must be alternative arrangements agreed by the relevant individual overseeing training.

Since the trainee will have reduced supervision during this form of training, to ensure patient safety and to optimise the benefits of this training, the following criteria must be met before it starts:

- the trainee must have been assessed by clinical and educational supervisors to be capable of safe practice with reduced supervision in relevant areas of the curriculum. They must therefore be in full compliance with the educational processes of the Annual Progression Review, i.e. ready to start more independent practice.
- before starting this training, the trainee must have a formal induction to ensure that they are familiar with the aspects of the work to be performed. This induction must be relevant to the time at which the work is to be performed, and for the organisations for which it is to be performed. It will include relevant local policies.
- the supervisor must ensure that the trainee understands the professional obligations of this form of practice, including availability and confidentiality.
- the trainee must have demonstrated to clinical and educational supervisors through previous directly supervised practice, competence in managing common clinical and laboratory problems of the kind likely to be encountered in the genetics service, relevant to the setting in which the trainee will undertake this form of practice.
- arrangements for 'handover' of clinical responsibility during this form of practice must be explicit.

Arrangements for cover by clinical supervisor

The ultimate responsibility for the quality of patient care and the quality of training lies with the supervisor. However, the trainee will be expected to exercise professional judgement in recognising the limits of their capabilities and in involving senior colleagues in complex or challenging issues/decisions. The arrangements for obtaining such help and advice, at any time during this training period, must be formal and explicit. Although the purpose of this training is to enable independent working, the trainee must not be discouraged from asking for help from a clinical supervisor during this period at any time.

After a period of independent practice, the trainee must be debriefed by the clinical supervisor. The purpose of this debrief is to ensure that patients are being managed safely, and that prompt feedback is provided on the trainee's performance against the relevance competencies for this form of training (see below) and other competencies in the curriculum. The debriefing session may take the form of 'handover' to colleagues.

Competencies to be demonstrated

Topic	Stage 2 Module 1 Development of independent professional practice	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of development of independent professional practice, be able to prioritise tasks and work independently and be able to • analyse, synthesise, evaluate and apply knowledge • perform, adapt and master a range of technical and clinical skills and procedures. Demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge Independent practice and working out of hours	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice with respect to • increasing familiarity with laboratory and clinical aspects of genetics • know what must be dealt with urgently and what may be dealt with less urgently.	FRCPath Part 2	1, 2, 3
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: recognise and work within own limitations in knowledge • liaise and communicate with a wide range of healthcare workers involved in in relevant patient care • communicate effectively in person and by telephone • refer to more experienced colleagues as appropriate • provide continuity of care • prioritise work according to urgency • deal with difficult situations independently • recognise and analyse the overall effects of competing pressures on healthcare resources, e.g. availability of laboratory tests, availability of beds • collect, analyse and interpret information from a variety of sources • make safe decisions when clinical, laboratory or epidemiological information is incomplete or evolving • work with clinical and laboratory colleagues under pressure	FRCPath Part 2, WPBA, MSF	1, 2, 3
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of developing independent practice to perform, adapt and master the clinical skills necessary to: • demonstrate increasing familiarity with laboratory and clinical aspects of geentics • demonstrate knowledge of what must be dealt with urgently and what may be dealt with less urgently.	FRCPath Part 2, WPBA	1, 2, 3

Stage 2 Module 2 Specialty-specific genetics practice

Stage 2 Module 2a Prenatal screening and diagnosis of genetic conditions

Stage 2 Module 2b Biology of pregnancy

N.B. The table below covers both modules 2a and 2b

Topic	Stage 2 Module 2a Prenatal screening and diagnosis of genetic conditions Stage 2 Module 2b Biology of pregnancy	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of prenatal screening and diagnosis of genetic conditions (biology of pregnancy), understand the rationale of genetics screening and testing for prenatal screening and diagnosis, and the biology of pregnancy to support the timing and choice of tests and the interpretation of results be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate screening protocols 2.Selection and validation of appropriate tests 3.Scientific basis of the genetics of prenatal testing 4. Selection and use of appropriate samples 5. Timeliness of tests 6. Scientific quality assurance of test procedures 7. Validity and reliability of	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: selection and validation of appropriate screening procedures and protocols in pregnancy (to identify cohorts for genetic testing) – clinical procedures – relevant (family) history – physical procedures – ultrasound anomalies – pre-implantation diagnosis of genetic disorders: ○ chromosomal anomalies ○ single gene disorders ○ whole genome testing – biochemical procedures – screening protocols and their application – awareness of national guidelines related to prenatal testing biology of pregnancy – fertilisation – embryogenesis	FRCPath Part 2, WPBA	2, 3

test results and their application 8. Costs of tests	– placental structure and function selection and validation of appropriate genetic tests including their basis – invasive o cytogenetic analysis o molecular analysis for common trisomies o molecular analysis of single gene disorders – non-invasive o fetal sexing o rhesus status o trisomies o single gene disorders scientific basis of the background to tissues used for prenatal tests – understanding of amniotic fluid, chorionic villous biopsy and free fetal DNA selection and use of appropriate samples – sample types – sample masses or volumes – storage/transit life – pre-processing of samples prior to genetic analysis understanding of the timeliness of tests in the context of pregnancy scientific quality assurance of test procedures – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application – internal quality assurance – external quality assurance – value of user feedback and interaction costs of tests.		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: detection and identification of free-fetal DNA (ffDNA), cells or tissue and maternal cell contamination laboratory techniques relevant to the test repertoire – chromosome analysis – microarrays – nucleic acid technologies to include fragment analysis and sequencing systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls and monitoring assay performance	WPBA	2

	– internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments.		
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of biology of pregnancy to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered ethical issues raised by prenatal testing genetic tests required to investigate the risk to a pregnancy as a result of: – a particular family history – a prior finding from a screening protocol or test interpretation of results and any further follow-up testing.	WPBA	3

Stage 2 Module 2c Paediatric genetics including dysmorphology (excluding cancer)

Topic	Stage 2 Module 2c Paediatric genetics including dysmorphology (excluding cancer)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of paediatric genetics including dysmorphology (excluding cancer), understand the rationale of genetics screening and testing in paediatric medicine and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: selection criteria for genetic testing in paediatric medicine – clinical signs ○ syndromic ○ anatomical ○ behavioural – recognised patient care/testing pathways selection and availability of appropriate genetic tests in paediatric medicine – general paediatrics ○ whole genome ○ gene panel ○ single gene – dysmorphology ○ whole genome ○ gene panel ○ single gene – disorders of sexual differentiation ○ whole genome ○ gene panel ○ single gene selection and use of appropriate samples – sample types – sample volumes – storage/transit life understanding of the timeliness of tests in the context of paediatric medicine scientific quality assurance of test procedures	FRCPath Part 2, WPBA	2, 3

	– test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application – internal quality assurance – external quality assurance – value of user feedback and interaction.		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: detection and identification of fetal ffDNA, cells or tissue and maternal cell contamination laboratory techniques relevant to the test repertoire – whole genome – gene panel – single gene systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls – monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of paediatric genetics including dysmorphology to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered genetic tests required to investigate the risk to a pregnancy as a result of: – a particular family history – a prior finding from a screening protocol or test.	WPBA	3

Stage 2 Module 2d Cardiac genetics

Topic	Stage 2 Module 2d Cardiac genetics	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of cardiac genetics, understand the rationale of genetics screening and testing for cardiology and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: selection criteria for targeted genetic screening in inherited cardiac conditions – clinical features – results of other pathology testing – family history – care pathways selection and validation of appropriate genetic tests including their basis – whole genome or exome (DNA sequencing) – gene panel (DNA sequencing) – single gene (DNA sequencing) – targeted tests (FISH, PCR fragment analysis, DNA sequencing, MLPA) selection and use of appropriate samples – sample types – sample volumes – transportation/storage issues timeliness of tests in the context of cardiology/sudden adult death scientific quality assurance of test procedures – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application – document control/process records – audit – value of user feedback and interaction costs of tests (equipment, consumables and associated staffing costs).	FRCPath Part 2, WPBA	2, 3
Technical skills and	By the end of the training period the trainee will be able to demonstrate a critical	WPBA	2

procedures	understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the test repertoire – whole genome (DNA sequencing) – gene panel (DNA sequencing) – single gene (DNA sequencing) – targeted tests (FISH, DNA sequencing, MLPA) systems for ensuring the quality of test procedures and reagents – use of appropriate internal controls and monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems/laboratory database to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments – use of bioinformatics resources to assess pathogenicity – calculation of recurrence risks – calculation of risks to relatives.		
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of cardiac genetics to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered ethical issues raised by testing in inherited cardiac conditions (for example predictive testing) best practice guidelines and disease-specific databases in interpretation and reporting of results genetic tests required to investigate the risk to a patient as a result of: – a particular family history – a particular clinical phenotype interpretation of results and any further follow-up testing.	WPBA	3

Stage 2 Module 2e Neurological genetics

Topic	Stage 2 Module 2e Neurological genetics	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of neurological genetics, understand the rationale of genetics screening and testing for neurology (neurological /neuromuscular disorders) excluding cancer and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge of 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: selection criteria for neurogenetic testing: – clinical features – results of other pathology testing (neurological function, immunoanalysis, biochemical tests) – family history – care pathways selection and validation of appropriate genetic tests including their basis: – whole genome sequencing/exome sequencing/mitochondrial genome sequencing – sequencing gene panel (e.g. LGMD) – sequencing single gene (e.g. *DMD*) – targeted tests (sequencing, MLPA, PCR fragment analysis, Southern blotting) – linkage analysis using microsatellite markers selection and use of appropriate samples: – sample types – sample volumes – transportation/storage issues understanding of the timeliness of tests in the context of neurological/neuromuscular disorders scientific quality assurance of test procedures: – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application: – document control/process records	FRCPath Part 2, WPBA	2, 3

	– audit – value of user feedback and interaction costs of tests (equipment, consumables and associated staffing costs).		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the test repertoire – whole nuclear/mitochondrial genome (DNA sequencing) – gene panel (DNA sequencing) – single gene (DNA sequencing) – targeted tests (DNA sequencing, MLPA, PCR fragment analysis for trinucleotide expansions, southern blotting) – linkage analysis using microsatellite markers systems for ensuring the quality of test procedures and reagents – use of appropriate internal controls and monitoring assay performance – internal quality assurance – external quality assurance Validity and reliability of test results and their application – using available IT systems/laboratory database to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments – use of bioinformatics resources to assess pathogenicity – calculation of recurrence risks – calculation of risks to relatives.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of neurological genetics to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered ethical issues raised by testing in neurogenetic conditions (for example presymptomatic testing in Huntington disease) best practice guidelines and disease-specific databases in interpretation and reporting of results genetic tests required to investigate the risk to a patient as a result of: – a particular family history – a particular clinical phenotype interpretation of results and any further follow-up testing.	WPBA	3

Stage 2 Module 2f Endocrinological genetics (including infertility and disorders of sexual differentiation [DSD])

Topic	Stage 2 Module 2f Endocrinological genetics (including DSD)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of endocrinological genetics, understand the rationale of genetics screening and testing for endocrinology (including infertility and disorders of sexual differentiation excluding cancer) and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests 8. Normal sexual development 9. Steroidogenesis pathway and other aspects of	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: the selection criteria for testing in postnatal medicine re endocrinology – clinical signs ○ adults, e.g. cancers (MEN, FTC, phaeochromocytomas, MODY, Turners ○ paediatric, e.g. DSDs (inc CAH, delayed puberty), short stature (SHOX, Turners), growth hormone deficiency, septo-optic dysplasias (hypothalamus/pituitary malfunction) – biochemical, imaging and other investigations – recognised patient care/testing pathways – complex diseases – e.g. diabetes – no testing the selection and availability of appropriate genetic tests in endocrinology – Endocrinology/DSD ○ whole genome/cytogenetics ○ gene panel (e.g.CAH) ○ single gene (e.g. WT1, AR gene) – Fertility ○ whole genome/cytogenetics ○ gene panel (e.g. Kallman) ○ single gene (e.g. CF, FrX x POF, DM, AZF delns) the selection and use of appropriate samples – sample types – sample volumes – storage/transit life the timeliness of tests in the context of endocrinology scientific quality assurance of test procedures – test validation – quality control measures	FRCPath Part 2, WPBA	2, 3

endocrine organs and pathways 10. Theories of genetic contribution to complex disease	– internal/external quality assurance validity and reliability of test results and their application – internal quality assurance – external quality assurance – value of user feedback and interaction.		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the test repertoire – whole genome – gene panel – single gene systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls – monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments o database o software to assess pathogenicity o recurrence risks o risks to relatives.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of endocrinological genetics to perform, adapt and master the clinical skills necessary to manage the biological and clinical context in which tests are offered socio-economic context in which tests are offered genetic tests required to investigate the patient as a result of: – phenotype – biochemical and other test results.	WPBA	3

Stage 2 Module 2g Dermatological genetics (excluding cancer)

Topic	Stage 2 Module 2g Dermatological genetics (excluding cancer)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of dermatological genetics, understand the rationale of genetics screening and testing for dermatology excluding cancer and be able to analyse, synthesise, evaluate and apply knowledge perform, adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge Selection and validation of appropriate screening protocols Selection and validation of appropriate tests Selection and use of appropriate samples Timeliness of tests Scientific quality assurance of test procedures Validity and reliability of test results and their application Costs of tests Complex disorders 9. Pathology of the skin	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: selection criteria for genetic testing in postnatal medicine referred from dermatology – clinical signs: o adult: TS, cancers (Muir-Torre, melanomas) o paediatric: de-, hypo-pigmentation (IP, TS, etc.); patchy pigmented skin lesions (inc cafe-au-lait spots), e.g. IP, McCune-Albright, NF1, Carney complex; unusual hair, teeth, nails and skin (e.g. in ectodermal dysplasias, icthyosis, etc.); DNA repair defects (Bloom syndrome, Xeroderma pigmentosum, etc.) – recognised patient care/testing pathways selection and availability of appropriate genetic tests in dermatology – whole genome – gene panel – single gene selection and use of appropriate samples – sample types – sample volumes – storage/transit life timeliness of tests in the context of dermatology scientific quality assurance of test procedures – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application – internal quality assurance – external quality assurance – value of user feedback and interaction.	FRCPath Part 2, WPBA	2, 3

Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the test repertoire – whole genome – gene panel – single gene systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls – monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of dermatological genetics to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered genetic tests required to investigate the patient as a result of: – a particular family history – phenotype.	WPBA	3

Stage 2 Module 2h Clinical genetics

Topic	Stage 2 Module 2h Clinical genetics	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of clinical genetics, understand the rationale of genetics screening and testing for clinical genetics and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge of 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: selection criteria for clinical genetic testing: referrals from clinical genetics cover a wide spectrum, potentially including any genetic condition where laboratory testing can aid in diagnosis, in determining carrier status, in establishing recurrence risks, and in predictive, presymptomatic or prenatal testing. selection and validation of appropriate genetic tests including their basis (any test from the cytogenetic/molecular genetic repertoire may be relevant depending on the referral) – genomic tests (conventional chromosomal analysis, aCGH, whole genome or exome sequencing) – sequencing of gene panels or single genes – targeted tests (FISH, MLPA, sequencing, PCR fragment analysis, Southern blotting) selection and use of appropriate samples – sample types – sample volumes – transportation/storage issues the timeliness of tests in the context of the specific test requested, including prenatal and presymptomatic testing scientific quality assurance of test procedures – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application – document control/process records – audit – value of user feedback and interaction costs of tests (equipment, consumables and associated staffing costs).	FRCPath Part 2, WPBA	2, 3

Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the entire test repertoire – genomic tests – sequencing of gene panels or single genes – targeted tests systems for ensuring the quality of test procedures and reagents – use of appropriate internal controls and monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems/laboratory database to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments – use of bioinformatics resources to assess pathogenicity – calculation of recurrence risks – calculation of risks to relatives.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of clinical genetics to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered ethical issues raised by testing across the entire spectrum of genetic tests best practice guidelines and disease-specific databases in interpretation and reporting of results genetic tests required to investigate the risk to a patient as a result of: – a particular family history – a particular clinical phenotype – advise on the interpretation of results and any further follow-up testing	WPBA, MSF	3

Stage 2 Module 2i Genetics of cancer medicine (constitutional)

Topic	Stage 2 Module 2i Genetics of cancer medicine (constitutional)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of genetics of cancer medicine (constitutional), understand the rationale of genetics screening and testing for oncology and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests 8. Current scientific theories of cancer development 9. Pathways of cell cycle control, etc.	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: identifying selection criteria for genetic testing in cancer medicine – general population screening (e.g. bowel, breast) versus selection for inherited cancer – diagnostic investigations for cancer (e.g. MRI, US, PET, histopathology) – calculation of risks of inherited cancer ○ family based ○ age at onset ○ types of tumour – national guidelines identifying selection and availability of appropriate genetic tests in cancer medicine – tumour screening (e.g. MSI, IHC) – mutation screening ○ scanning methods ○ sequencing (whole genome, gene panel, single gene, ethnic specific mutations) – predictive testing for mutation in family or ethnic group – genes involved in selection of cancers (+phenotypes) ○ colorectal (e.g. HNPCC, FAP, MUTYH) ○ breast/ovarian (BRCAs) ○ endocrine (MEN1,2) ○ Li Fraumeni - TP53 ○ CNS (VHL, NF1/2) ○ pancreatic ○ gastric (E-cadherin, etc.) ○ renal (VHL, translocation) identifying selection and use of appropriate samples	FRCPath Part 2, WPBA	2, 3

	– sample types
	  o tumour
	  o blood
	– sample preparation
	  o tumour
	– sample volumes
	– storage/transit life
	understanding of the timeliness of tests in the context of cancer medicine
	– mutation detection
	  o standard
	  o urgent (surgery, treatment)
	– predictive testing
	scientific quality assurance of test procedures
	– test validation
	– quality control measures
	– internal/external quality assurance
	validity and reliability of test results and their application
	– basis/theory of assigning pathogenicity to variants
	– internal quality assurance
	– external quality assurance
	– value of user feedback and interaction.		

Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills:
	tumour screening (e.g. MSI testing with microsatellites)
	laboratory techniques relevant to the test repertoire
	– whole genome
	– gene panel
	– single gene
	systems for ensuring the quality assurance of test procedures and reagents
	– use of appropriate internal controls
	– monitoring assay performance
	– internal quality assurance
	– external quality assurance
	validity and reliability of test results and their application
	– using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments
	  o database
	  o software to assess pathogenicity
	  o cancer risks in mutation carriers
		WPBA	2

	○ risks to relatives.		
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of genetics of cancer medicine (constitutional) to perform, adapt and master the clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered genetic tests required to investigate a cancer referral as a result of: – family history – tumour/other characteristics.	WPBA	3

Stage 2 Module 2j Genetics of cancer medicine (acquired) (excluding leukaemia and lymphoma)

Topic	Stage 2 Module 2j Genetics of cancer medicine (acquired) (excluding leukaemia and lymphoma)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of genetics of cancer medicine (acquired), understand the rationale of genetics screening and testing for oncology (acquired) and be able to analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge of 1. Selection and validation of appropriate screening protocols 2. Selection and validation of appropriate tests 3. Selection and use of appropriate samples 4. Timeliness of tests 5. Scientific quality assurance of test procedures 6. Validity and reliability of test results and their application 7. Costs of tests 8. Current scientific theories of cancer development 9. Pathways of cell cycle control, etc. 10. Significance of different pathways of cancer development (i.e. of	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: identify selection criteria for genetic testing in cancer medicine – general population screening (e.g. bowel, breast) v selection for inherited cancer – diagnostic investigations for cancer (e.g. MRI, US, PET, histopathology) – current knowledge mutations in specific tumour types v prognosis and treatment regimes – national guidelines identify selection and availability of appropriate genetic tests in cancer medicine – FISH/IHC testing (e.g. to detect ALK translocations in non-small cell lung cancer) – microarray testing (e.g. MIP arrays) – molecular testing: mutation detection and LOH ▪ testing methods (MALDI-TOF, pyro, sequencing, NGS, RT-PCR) sensitivity, cost, specimen requirements: Liaison x pathology re. tumour content, activating mutations v TS loss – genes and mutations important in different cancer types ○ EGFR, ALK x non small cell lung cancer ○ BRAF x melanoma ○ KRAS/BRAF/MSI x colorectal cancer ○ CRUK listed genes (e.g..: KIT, PTEN, TMPRSS-ERG, TP53) identify selection and use of appropriate samples – sample types ○ tumour – primary, metastases ○ cell free DNA in blood – sample preparation ○ tumour	FRCPath Part 2, WPBA	2, 3

mutations in different genes) to cancer treatment and prognosis	– sample volumes – storage/transit life understand of the timeliness of tests in the context of cancer medicine scientific quality assurance of test procedures – test validation – quality control measures – internal/external quality assurance validity and reliability of test results and their application basis/theory of assigning pathogenicity to variants – internal quality assurance – external quality assurance – value of user feedback and interaction.		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: laboratory techniques relevant to the test repertoire, e.g.: – pyrosequencing – FISH – LOH – RT-PCR – sequencing: Sanger and NGS systems for ensuring the quality assurance of test procedures and reagents – use of appropriate internal controls – monitoring assay performance – internal quality assurance – external quality assurance validity and reliability of test results and their application – using available IT systems to produce timely, accurate and relevant laboratory reports with appropriate interpretative comments o database o software to assess pathogenicity o significance for treatment options o significance for prognosis o further testing recommended.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of genetics of cancer medicine (acquired) to perform, adapt and master clinical skills necessary to manage the: biological and clinical context in which tests are offered socio-economic context in which tests are offered molecular/cytogenetic tests required to investigate a cancer referral as a result of:	WPBA	3

	– one family history – tumour/other characteristics.		

Stage 2 Module 2k Genetics of haematological malignancies (leukaemia and lymphoma)

Topic	Stage 2 Module 2k Genetics of haematological malignancies (leukaemia and lymphoma)	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of genetics of haematological malignancies (leukaemia and lymphoma), understand the rationale of genetics screening and testing for cancer medicine and be able to: analyse, synthesise, evaluate and apply knowledge perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level. (* acquired haematological disorders to include: acute leukaemia, chronic leukaemia, multiple myeloma and other plasma cell dyscrasis, Hodgkins and non-Hodgkin's lymphoma, myelodysplastic disorders, MPN.)		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to the: pathogenesis and diagnosis of acquired haematological disorders. classification, staging systems and prognostic factors and any implications for therapy use of trial protocols. principles and limitations of autologous and allogenic haematopoietic stem cell transplantation in management of disease. underlying principles of available cytogenetic and molecular genetics tests.	FRCPath Part 2, WPBA	2, 3
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: selection and use of appropriate sample and preparation types including minimal sample requirements and storage/transit life sample preparation cytogenetic chromosome analysis FISH using single/panel probe sets molecular -PCR, RT-PCR, sequencing.	WPBA	2
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of genetics of haematological malignancies (leukaemia and lymphoma), to perform, adapt and master the clinical skills necessary to manage the: appropriate cytogenetic and/or molecular genetic laboratory investigations to establish diagnosis appropriate investigations in monitoring/staging of disease. test results and writing of interpretative clinical reports	WPBA, MSF	3

	management plan in the setting of MDT test results with other healthcare professionals and patient/family. timeliness of tests in the context of presentation and test results.		

Stage 2 Module 3 Training, Education, Leadership and Management
Stage 2 Module 3a Leadership and management

Topic	Stage 2 Module 3a Leadership and management	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, with respect to the management, communication and leadership skills to run a laboratory and deliver a high-quality clinical service be able to analyse, synthesise, evaluate and apply knowledge perform, adapt and master a range of skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: good laboratory management – concepts of good laboratory practice – process of management and being managed – budgetary control and planning • describing the criteria and process for laboratory accreditation – describe and explain quality system management and accreditation (UKAS, ISO) – describe and explain test validation and verification and related quality assurance processes how the appraisal process works the process of clinical audit the importance of clinical governance and delivery of high-quality standards in genetics – concepts of clinical risk management and procedures designed to minimise risks – importance of patient consent to use data or specimens for ethically approved research or teaching the current organisation of NHS and allied organisations – the healthcare structures the role of the Care Quality Commission (CQC) – the roles of 'arm's length bodies' involved in health protection including the Public Health England,(PHE) Food Standards Agency (FSA), MHRA and NICE laboratory data entry and retrieval and surveillance systems the Data Protection Act the requirements for patient confidentiality and the Caldicott principles current: – employment law – staff appointment procedures – related issues including equality and diversity legislation – European working time directive requirements – career progression	FRCPath Part 2, WPBA	1, 2, 3, 5

	– remuneration scales and banding of laboratory scientific staff the need to comply with HCPCs standards of conduct, performance and ethics.		
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following skills to: demonstrate awareness of organisation and structure of a genetics laboratory including: – staffing and financial issues – planning – implementation of policies and rotas implement these criteria use constructive listening, mentoring, and appraisal skills use personal appraisal constructively audit and evaluate: – personal and departmental activities – existing and new tests, techniques or clinical services present information utilising presentations and public speaking skills organise teaching search electronic databases and use the internet as a learning and communication resource – databases, word processing and statistics programmes – undertake searches – apply the principles of confidentiality and their implementation in terms of clinical practice – understand data protection, patient confidentiality and information governance.	WPBA	1, 2, 3, 5
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of leadership and management to perform, adapt and master the clinical skills necessary to manage the appropriate laboratory diagnostic repertoire and research and innovation programmes to maintain a cutting edge diagnostic service.	WPBA	3, 4

Stage 2 Module 3b Training and education

Topic	Stage 2 Module 3b Training and education	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of Training and Education, be able to critically evaluate the key theories of teaching and learning that underpin the role of the consultant clinical scientist in training and education as a teacher or trainer, according to the best contemporary clinical and educational standards. Students will acquire an understanding of the theoretical basis of learning, teaching and assessment and the practical application of these skills.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: a range of teaching, learning and assessment methods including a critical analysis of the underpinning evidence base a range of different supervision and mentoring styles from the perspective of the learner and the teacher the background knowledge of different healthcare groups at different stages of their career development and the need to establish what the learner already knows and teach accordingly the curricula and training and assessment guidelines relating to colleagues being closely supervised a good knowledge of the clinical context before teaching or training others.	FRCPath Part 2, WPBA	1
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to teaching, learning and assessment: in order to: plan, prepare, deliver and evaluate a PowerPoint presentation identify relevant background information, perform literature searches as necessary and critically evaluate the material in preparation for teaching sessions plan, prepare, deliver, evaluate and critically reflect on clinical and technical skills teaching sessions empathise with other trainees and be able to deal effectively with those who need additional support.	WPBA	1
Clinical skills	By the end of the training period the trainee will be able to apply knowledge of training and education appropriate to the teaching, learning or assessment situation with respect to: a range of evaluation techniques to improve teaching performance a range of feedback models to give effective feedback the variety of question types appropriate to the stage of learning and purpose good interpersonal and communication skills for example describing, explaining and instructing.	WPBA	1, 3

Stage 2 Module 3c Research, development and innovation

All HSS Trainees to undertake doctoral level research that either (i) meets the research requirements of the doctoral level training programme or (ii) results in a coherent body of papers that reaches the standard suitable for publication in peer reviewed journals, undertaken during the HSST programme *or in the immediate 3 years prior to HSST*. They will also be expected to present and defend their research at national /international scientific conferences.

Topic	Stage 2 Module 3c Research, development and innovation	Assessment methods	GSP reference
Learning objective	By the end of the training period trainees will, in respect of Research, Development and Innovation, be able to analyse, synthesise, evaluate and apply knowledge perform, adapt and master a range of scientific and clinical skills and procedures perform adapt and master a range of scientific and clinical skills and procedures understand the technical principles and processes underpinning these skills demonstrate the attitudes and behaviours necessary for professional practice as a consultant clinical scientist dealing with the complexities, uncertainties and tensions of professional practice at this level.		
Knowledge	By the end of the training period the trainee will be able to demonstrate the ability to analyse, evaluate and synthesise relevant knowledge and its application to their professional practice in relation to: the steps to be taken in planning a research, development or innovation project research governance and the steps to be taken to conduct and supervise a valid research, development or innovation project the regulatory requirements including the research governance framework, ethical framework, intellectual property that must be considered in the area of study critical appraisal of the results of a research and development project, drawing conclusions in the correct clinical context, where appropriate, using them to plan follow-up research and development activities range of ways in which research and development findings can be reported and communicated to peers and other interested parties steps required to translate successful research findings into service in the interests of patient care.	FRCPath Part 2, WPBA	1, 3, 4
Technical skills and procedures	By the end of the training period the trainee will be able to demonstrate a critical understanding of current relevant research, theory and knowledge and its application to the performance, adaptation and mastery of the following technical procedures and laboratory skills: plan a research and development project conduct and/or supervise a valid research and development project critically appraise the results of a research and development project, draw conclusions in the correct clinical context, and, where appropriate, use them to plan follow-up research and development use of a variety of ways in which research and development findings has been reported and communicated to peers and other interested parties translate successful research findings into service and provide examples of where this has been achieved.	WPBA	1, 3, 4
Clinical skills			

Appendix 1 Acronyms and abbreviations

ACGS	Association of Clinical Genetic Science
AHCS	Academy for Healthcare Science
AHSN	Academic Health Science Network
AoMRC	Academy of Medical Royal Colleges
BSGM	British Society of Genetic Medicine
CbD	Case-based discussion
CCHST	Certificate of Completion of Higher Scientist Training
COSHH	Control of Substances Hazardous to Health
CPPD	Continuing personal and professional development
CQC	Care Quality Commission
CSO	Chief Scientific Officer
DH	Department of Health
DOPS	Directly observed practical skills
FRB	Final Review Board
FRCPath	Fellowship of The Royal College of Pathologists
GCP	Good Clinical Practice
GMC	General Medical Council
GSP	Good Scientific Practice
HCPC	Health Care Professions Council
HCS	Healthcare Science
HEE	Health Education England
HEI	Higher Education Institution
HSS	Higher Specialist Scientist
HSST	Higher Specialist Scientist Training
ICS	Innovation in Clinical Sciences
IT	Information technology
LETBs	Local Education and Training Boards
MAHSE	Manchester Academy for Healthcare Science Education
MDT	Multi-Disciplinary Team
MHRA	Medicines and Healthcare products Regulatory Agency
MSC	Modernising Scientific Careers
MSF	Multi-source feedback
NHS	National Health Service
NHSSTN	National Higher Specialist Scientific Training Number
NICE	National Institute for Health and Clinical Excellence
NSHCS	National School of Healthcare Science
OCE	Observed clinical event
OLAT	On-line Learning and Assessment Tool

OSCSA	Objective Structured Clinical Skills Assessment
OSFA	Objective Structured Final Assessment
PD	Professional Doctorate
PSA	Professional Standards Authority
SAC	Specialist Advisory Committee
STARD	Standards for Reporting of Diagnostic Accuracy
STI	Sexually transmitted infection
STP	Scientist Training Programme
WPBA	Work-placed based assessment