General Medical Council

Clinical Pharmacology and Therapeutic (CPT) with General Internal Medicine (GIM)

Specialty Specific Guidance (SSG)

This guidance is to help doctors who are applying for entry onto the Specialist Register via the Portfolio pathway in CPT. The relevant high level learning outcomes for General Internal Medicine will also be demonstrated by meeting all the requirements set out below. You will also need to read the curricula for the specialty and General Internal Medicine (Internal Medicine Stage 2).

An application has been made to change the name of General Internal Medicine to Internal Medicine

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Contents

Introduction

This document is designed to provide helpful information and guidance to enable you to make an application for specialist registration in CPT with General Internal Medicine. This is not a standalone document and should be read in conjunction with the curricula – please see the CPT curriculum on the Joint Royal Colleges of Physicians Training Board (JRCPTB) website for more details. You can contact us and ask for advice before you apply.

It is worth noting that it is sometimes more difficult to make a successful application if you have not worked in the NHS and that applicants with a license to practise in the UK will have already provided some of the evidence below in order to achieve this. Key features of training and practice in the NHS are unlikely to be covered in the same way outside it and the types of evidence may differ. This might include, for example, multidisciplinary team meetings, appraisal, multisource feedback and patient feedback, safety and quality activity especially in clinical audit and quality improvement projects and other areas. You must look at the curriculum and this guidance carefully to make sure that you can demonstrate the knowledge, skills and evidence for entry to the Specialist Register for CPT and General Internal Medicine using an assessment framework of the high level learning outcomes in the curriculum rather than assessing your progress through a programme.

You evidence should focus on summative assessments rather than formative one. If you are or have recently been practising in an environment that is not comparable to practice in the NHS you might find it useful to consolidate your experience elsewhere before applying.

Applicants need to demonstrate that they have achieved the learning outcomes required for all stages of the curriculum.

Curriculum Framework

The curriculum is structured into high-level learning outcomes, known as Capabilities in Practice (CiPs). The CiPs are split into generic, clinical and specialty specific capabilities, as outlined below. To meet the standard you will need to provide evidence that you're working at the level of being entrusted to perform safely and independently for each CiP (described in the curriculum as Level 4 – entrusted to act unsupervised).

Level descriptors for clinical CiPs

Level	Descriptor
Level 1	**Entrusted to observe only:** No provision of clinical care

Level 2	**Entrusted to act with direct supervision**: May provide clinical care, but the supervising physician is physically within the hospital or other site of patient care and is immediately available if required to provide direct bedside supervision
Level 3	**Entrusted to act with indirect supervision**: May provide clinical care when the supervising physician is not physically present within the hospital or other site of patient care, but is available by means of telephone and/or electronic media to provide advice, and can attend at the bedside if required to provide direct supervision
Level 4	**Entrusted to act unsupervised**

The first six CiPs are generic and shared across all physician specialties, covering the universal requirements of Good Medical Practice and the Generic Professional Capabilities (GPC) framework.

The eight clinical CiPs describe the clinical tasks or activities which are essential to the practice of Internal Medicine and the seven specialty CiPs describe the specialty-specific clinical tasks or activities which are essential to the practice of CPT. The CiPs have been mapped to the GPC domains to reflect the professional generic capabilities required to undertake the clinical tasks.

The range of experience needed to achieve the CiPs is outlined in the curriculum – this covers different settings, contexts, clinical problems, conditions and stages of a person's life and illness.

Generic CiPs
1. Able to function successfully within NHS organisational and management systems
2. Able to deal with ethical and legal issues related to clinical practice
3. Communicates effectively and is able to share decision making, while maintaining appropriate situational awareness, professional behaviour and professional judgement
4. Is focussed on patient safety and delivers effective quality improvement in patient care
5. Carries out research and manages data appropriately
6. Acts as a clinical teacher and clinical supervisor

Clinical CiPs
1. Managing an acute unselected take
2. Managing the acute care of patients within a medical specialty service
3. Providing continuity of care to medical inpatients, including management of comorbidities and cognitive impairment
4. Managing patients in an outpatient clinic, ambulatory or community setting, including management of long term conditions
5. Managing medical problems in patients in other specialties and special cases
6. Managing a multi-disciplinary team including effective discharge planning
7. Delivering effective resuscitation and managing the acutely deteriorating patient
8. Managing end of life and applying palliative care skills

Specialty Specific CiPs
1. Performing the clinical assessment, investigation and management of adverse drug reactions, medication errors and overdose at an individual and (where relevant) population level
2. Providing specialist management of patients with complex prescribing needs, including multimorbidity, polypharmacy, adherence issues, and medication intolerance
3. Providing analysis and expert opinion on pharmacokinetic, pharmacodynamic and pharmacogenomic factors to guide therapeutic decisions
4. Providing evidence-based practice and contributing to the evidence base in a therapeutic area of interest
5. Advising on the cost effective, safe and rational use of medicines on a population level
6. Delivering effective education in clinical pharmacology, therapeutics and prescribing to promote safe and effective use of medicines across the whole workforce
7. Providing expertise in the design and delivery of experimental medicine, and other types of clinical pharmacology & therapeutic research, including preclinical and clinical studies

Currency of evidence

Evidence which demonstrates that you have met a curriculum outcome can be drawn from any point in your career. However, there should be corresponding evidence of recent (within the last five years of clinical practice (WTE) to confirm the maintenance of the skill or competency.

Evidence of your recent practice will be given more weight to reflect current capabilities and we suggest that approximately 50% of your evidence for a curriculum outcome is drawn from within the last five years of clinical practice (WTE).

Structured reports

You should nominate a minimum of three referees for the GMC to obtain structured reports from. They should include:

- Current Head of Department or other senior colleague with knowledge of the breadth of your clinical activity. Ideally, they should be an Educational Supervisor with at least 5 years experience themselves or appropriate training experience.
- One Internal medicine referee of consultant level who is able to provide comments based on direct observation. This is especially important if you are relying on your structured reports as evidence of your procedural competencies.
- At least one further report from a colleague working as a consultant in your specialty.

Submitting your evidence

Do not submit original documents. You must provide your evidence electronically – it's important that you follow the structure in our user guide when doing so.

You will need to make sure your evidence meets our requirements, this includes:

- Anonymising (redacting) identifiable information
- Verifying your evidence to confirm its authenticity
- Authenticating overseas qualifications
- Translating any documents not in English

It is important that you read and follow our guidance. If your evidence does not meet these requirements, it may not be included in your application.

Please keep in mind when gathering your evidence:

- Triangulated evidence (evidence comprised of three different sources) will make a stronger application
- Evidence of your recent practice (≤within the last 5 years of clinical practise (WTE)) will be given more weight to reflect current capabilities; where some evidence is historical (> than last 5 years of clinical practise (WTE)), the assessors will want to see evidence that the applicant has maintained capabilities in that particular area and the applicant is working at the level of a senior independent clinician.
- Your evidence must be legible

How much evidence to submit

As a general guide, most applications are expected to include around 100 electronically uploaded documents. You must ensure that you follow our guidance on how to present and group your evidence in the online application.

The total number of documents and assessments presented is less important than the quality of the documents, and the breadth of cases covered. This allows the evaluators to form reliable judgements of performance and capabilities.

This guidance on documents to supply is not exhaustive and you may have alternative evidence. You do not necessarily have to supply every type of evidence listed, but you must submit sufficient evidence to address each of the required learning outcomes and the associated capabilities.

Your evidence **must** cover the knowledge, skills and experience to demonstrate the required CiPs in all areas of the curriculum. You should focus on providing **good quality** evidence, rather than quantity.

You should bear in mind the following points:

- Evidence should show that you are able to assess and offer a first opinion in any setting and for any age
- Don't duplicate evidence that is relevant to more than one CiP – you should include one copy and then list it under each relevant CiP (cross referencing)
- Evidence should only be cross referenced where it adds significant support to a CiP
- Evidence should be provided from a variety of clinical settings.

You must ensure you follow our guidance on how to present and group your evidence in the online application

Organising your evidence

Your evidence will need to be organised to reflect the structure of the online application. You should submit your evidence electronically under the correct section of your online application.

You should also submit the evidence requested about your training, qualifications and employment history and your CV in the format set out in the GMC's CV guidance. You will also be asked to nominate referees to provide structured reports.

Your evidence must be mapped to the high level learning outcomes by providing primary evidence for knowledge, skills and experience. If evidence is missing from any of the CiPs, your application may be unsuccessful.

You will not be able to compensate for shortfalls in your evidence of training and experience in a particular area, by providing extra evidence in other areas.

If you have a piece of evidence that is relevant to more than one area, do not include multiple copies in your evidence. Instead, include one copy and list it in your application under each relevant area, stating that the evidence is located elsewhere, and you would like to cross-reference it.

Where we ask in our guidance, please group your evidence together to keep the number of individual electronic uploads manageable. This will need to be done prior to uploading on the GMC application. There are many software solutions widely available that can be used for converting documents/excel sheets/PowerPoint presentations and images to PDFs and combining PDF documents.

Tips for a successful application

In our experience, applications fail because they provide inadequate or poor evidence of current capability covering the knowledge, skills and experience required for practising as an eligible specialist in the United Kingdom. Below are some tips for you to consider when making an application:

- Before submitting an application, you should review the current curriculum in conjunction with this document. A strong application will provide evidence that you hold the knowledge, skills and experience which demonstrate the outcomes set out in the curriculum
- Provide evidence of your **current capability** against the high level learning outcomes of the curriculum. This includes the maintenance of CiPs and key skills all evidence should be clearly linked to the CiPs
- Provide evidence demonstrating medical knowledge and application of this knowledge in practice to the level of completion of Internal Medicine stage 1 training. This can be demonstrated through the generic and clinical CiPs of the curriculum. Applicants will need MRCP (UK) or a comparable assessment of applied knowledge.

- Present your evidence in a clear, logical manner. You should refer to our user guide for advice on how to group, title and upload your evidence
- Ensure your referees can provide detailed support for your key skills across all (or most) areas of the curriculum and understand the requirements for specialist registration in the UK
- Provide evidence of managing a broad range of patients, as seen daily by CPT doctors in the UK
- Provide evidence of your clinical capability across the range of experience, ages and settings
- Ensure your evidence demonstrates you are entrusted to act at an independent level across all of the specialty CiPs

How your evidence can be used to demonstrate key capabilities in different CiPs

You will notice that some of the suggested evidence is listed more than once. This is because these documents are relevant to more than one CiP. For example, MSF can be used to demonstrate competence in most CiPs – therefore, you can use the same MSF to demonstrate the required capability across several CiPs

If you have a document that is relevant to more than one CiP, don't include multiple copies of it. Instead, provide one copy and list it in your application under each relevant CiP, stating that the document is located elsewhere, and you'd like to cross reference it.

Below is a list of evidence that are relevant to most CiPs – it is by no means exhaustive, and you are encouraged to submit a variety of evidence but you should aim to demonstrate knowledge, skills and experience with evidence that is comparable to the examples below.

A description of the assessments below, together with template forms, can be found on the JRCPTB website

Evidence / requirement	About	Indicative minimum numbers
Supervised Learning Events (SLEs)		
Acute Care Assessment Tool (ACAT)	These should have been undertaken with a consultant. Each ACAT must include a minimum of 5 cases and should be used for global assessment of an applicant's performance on take, or on presenting new patients on ward rounds, encompassing both individual cases and overall performance (eg prioritisation, working with the team)	GIM: 6 ACATs that indicate that the applicant is performing in an independent manner at Entrustment level 4
Outpatient Care Assessment Tool (OPCAT)	These should have been undertaken with a consultant either during or following a single clinic. There is no minimum number of patients that should be seen, but for a post clinic assessment it would be unusual if the applicant has seen fewer than three patients.	2 OPCATs to level 4 entrustment
Case-based discussion and/ or mini-clinical evaluation exercise (mini-CEX) and/or Project based Discussions (PBDs)	These should have been undertaken with a consultant. CbDs and Mini-CEXs should cover different aspects of the specialty.	GIM: 8 more SLEs, comprised of a mix of CbDs and Mini-CEXs to level 4 entrustment CPT: 14 further SLEs (CBD, Mini-CEX or PBDs) required to demonstrate consultant level capability. Ideally, each CiP should be supported by at least one PBD and one CbD or mini-CEX

Workplace Based Assessments (WPBAs)		
Direct Observation of Procedural Skills (DOPS)	Evidence must be provided for each procedure for which an applicant must be competent to perform unsupervised of procedural/specialist procedures section of this guidance. **For GIM you should provide either:** A structured report concentrating upon the core procedural skills in GIM by a senior colleague – the GMC will request this as part of the application process so you should ensure you nominate at least on GIM doctor who are able to directly comment on your procedural competence OR Provide one summative DOPS for each procedure for which an applicant must be competent to perform unsupervised	
Quality Improvement Project Assessment Tool (QIPAT)	Can be used to demonstrate active involvement in service audit or development projects.	1 QI project with evidence of completion within last 5 years
Patient Survey (PS)	Formal patient feedback is strong evidence as it's an anonymous feedback exercise. It should include approximately 15 patients. The JRCPTB has a template available on their website. A reflective entry reflecting on the survey must be made. If it is not possible to provide a formal patient survey an applicant could provide alternative evidence. However, this must provide equivalent details and breadth of information. Alternative evidence could include: ▪ Thank you letters/cards from patients ▪ Statements from referees ▪ Testimonial letters from colleagues ▪ Feedback from patients/colleagues	1 completed in last 12 months of most recent practice (WTE)

Teaching observation (TO)	At least one should be completed by a consultant in the specialty.	1 completed in last 12 months clinical practice (WTE) or the structured report could include commentary on teaching observation/teaching experience
Multi Source Feedback (MSF)	MSF is a strong piece of evidence as it is an anonymous feedback exercise. Minimum of one in the 12 months clinical practise (WTE) before the application has been submitted – any available from the last 5 years clinical practise (WTE) should also be submitted. MSF should include approximately 12 colleagues, including medical and non-medical sources.	1 completed in last 12 months clinical practice (WTE)
Other evidence		
To be included in the portfolio of evidence	▪ **Appraisal** is good evidence of engaging with systems, processes and mandatory requirements and demonstrates performance (clinical and non-clinical) ▪ **Reflective** diaries/ evidence of self-reflection ▪ **Supervisor report** reports from trainers and supervisors are important evidence to affirm and support capabilities and performance in both clinical and non-clinical activities. JRCPTB provides a Multiple Consultant Report (MCR) template for the purpose of these reports of which there should be 4 in the last 12 months. ▪ **Logbooks** must cover the last 5 years and show the type of procedures you performed and your role in the procedure ▪ **Training events** (courses, study days, meetings) over the last five years ▪ **Evidence of seeing patients** over the last five years covering a range of settings, referral contexts, conditions, stages of illness, ages ▪ **Academic activities**	4 MCRs completed in the last 12 months clinical practise (WTE)

	▪ **Management activities** ▪ **Structured reports**	
Continuing Professional Development (CPD)	CPD represents the acquisition and maintenance of knowledge, skills and key skills. Courses which would provide evidence towards a specific CiP have been listed in the suggested evidence. Examples of evidence could include a personal, reflective diary of learning achievements, in addition to detailed evidence of courses attended.	

Evidence of training, qualifications, and employment

You can see below the evidence you must submit in these general areas. It is useful to submit evidence of your training as background evidence – this allows the evaluators to see your whole career pathway.

Evidence of training and qualifications	
Primary medical qualification (PMQ)	**If you hold full registration with us, you do not need to submit your PMQ** as we saw it when we assessed your application for registration. If you do not hold registration, you will need to have your PMQ independently verified before we can grant you full registration with a licence to practise. You can find out more about primary source verification on our website. You only need to get your PMQ verified by our provider. The rest of your evidence should be verified in line with our guidance.
Specialist medical qualification(s)	Please provide an **authenticated copy** of any overseas specialist medical qualifications you hold. You do not need to authenticate qualifications awarded in the UK. You should provide:

	Evidence of completion of full **MRCP(UK)** or comparable qualification. The MRCP(UK) is comprised of three tests, designed to assess acquisition of the full range of knowledge, skills and behaviour, as well as clinical understanding and execution, as detailed in the UK curriculum for Core Medical/Internal Medicine Training. For further information on the MRCP(UK), click here. If you do not hold the MRCP (UK) or a comparable qualification as above, you can aim to demonstrate the same level of knowledge by providing: A detailed, thorough and succinct cross-referencing mapping exercise, demonstrating how each and every competency in the qualification has been covered in your own qualifications. The evaluators will then determine whether what has been provided is comprehensive enough to demonstrate the same level of knowledge. it will be assessed on a case by case basis and will involve the applicant to produce a portfolio of evidence. There are no qualifications from outside Europe that enable automatic entry to the Specialist Register in any specialty. An evaluation is made based on an applicant's whole career and therefore two applicants with the same qualifications but different training and/or experience may not receive the same decision. If your specialist medical qualification is from outside the UK, please ensure that you provide the following evidence **in addition** to your qualification: ○ Training curriculum or examination syllabus ○ Formal period assessments completed during training (these may be from any point in your career)
Recent specialist training	If you have worked in posts approved for a specialist training programme for a relevant qualification outside the UK in the past five years, please provide an **authenticated copy** of the curriculum or syllabus that was in place when you undertook your training. If a formal curriculum or syllabus (including assessment methods) is not available please provide a letter from the awarding body outlining the content of the training programme or examination. Should you wish to provide further evidence obtained within your UK specialty training, this evidence should have been reviewed and signed off through an ARCP from completed years in training.

	You must provide evidence of formal periodic assessment during your training. This evidence must have been completed at the time the training was undertaken (if it is completed retrospectively less weight will be given to the information provided). If you do not supply formal assessment documents, the curriculum must demonstrate how you were assessed. A detailed letter of verification from an educational supervisor would satisfy this requirement. If areas for development were highlighted, please provide evidence to demonstrate that you have subsequently addressed them.

Evidence of employment in posts and duties (including training posts)	
CV	You must provide an up to date copy of your CV, which includes all the details listed in the guidance on our website.
Employment letters	The information in these letters **must** match your CV. They should confirm the following: • dates you were in post • post title, grade, training • type of employment: permanent, fixed term, or part time (including percentage of whole time equivalent) Usually this will be set out in the letters offering you the post and renewing your contracts. **We do not need to see contracts and terms and conditions of employment**.
Job descriptions	These **must** match the information in your CV. They will usually confirm the following: • your position within the structure of your department • your post title • your clinical and non-clinical commitment • your involvement in teaching or training.

Rotas	You must provide samples of your rotas drawn from (not covering) the last three years of clinical practise (WTE). These should demonstrate your weekly clinical and non-clinical activities. For example, if you worked a 1:8 rota, you should submit eight consecutive weeks' rota to represent that placement.
Departmental/Unit annual caseload statistics	You should provide departmental and unit caseload statistics, activity data, range and scope of work undertaken in a placement from the last three years clinical practise (WTE).
Appraisal	Those working in an NHS or managed environment should submit evidence of annual appraisals or performance reviews. A revalidation or appraisal portfolio would be appropriate (if it is completed retrospectively less weight will be given to the information provided). For non-training posts you should provide evidence of ongoing evaluation of your performance. This may take the format of formal appraisals by the department head or line manager (clinical director, medical director, professor). For those applicants working in independent practice it is recommended that at least one employer. Appraisal is undertaken and summary documentation of this submitted with the application. Where an applicant is not based in the UK alternative forms of appraisal are strongly advised. Alternative evidence may include letters (written at the time) commenting on your performance. In addition, where no formal appraisal or assessment forms are available you must provide information on the method of career review or progression.

Practical Procedures

Below details the practical procedures and the level of competency you will be expected to evidence. You can provide evidence for these procedures using logbooks and DOPS.

Internal Medicine Procedures

Procedure	Level of competence required
Advanced cardiopulmonary resuscitation (CPR)	Leadership of CPR team
Direct current (DC) cardioversion	Competent to perform unsupervised
Temporary cardiac pacing using an external device	Skills lab or satisfactory supervised practice
Central venous cannulation (internal jugular or subclavian)	Skills lab or satisfactory supervised practice
Access to circulation for resuscitation (femoral vein or intraosseous) [a]	Skills lab or satisfactory supervised practice
Pleural aspiration for fluid (diagnostic) [b, c]	Competent to perform unsupervised
Pleural aspiration (pneumothorax) [c]	Competent to perform unsupervised
Intercostal drain for pneumothorax	Skills lab or satisfactory supervised practice
Intercostal drain for effusion [b]	Skills lab or satisfactory supervised practice
Nasogastric (NG) tube	Competent to perform unsupervised
Ascitic tap	Competent to perform unsupervised
Abdominal paracentesis	Skills lab or satisfactory supervised practice

Lumbar puncture	Competent to perform unsupervised

Notes
[a] The requirement is for a minimum of skills lab training or satisfactory supervised practice in one of these two mechanisms for obtaining access to the circulation to allow infusion of fluid in the patient where peripheral venous access cannot be established. [b] Pleural procedures should be undertaken in line with the British Thoracic Society guidelines. These state that thoracic ultrasound guidance is strongly recommended for all pleural procedures for pleural fluid, also that the marking of a site using thoracic ultrasound for subsequent remote aspiration or chest drain insertion is not recommended. Ultrasound guidance should be provided by a -trained thoracic ultrasound practitioner. [c] It can be assumed that a doctor who is capable of performing pleural aspiration of fluid is capable of introducing a needle to decompress a large symptomatic pneumothorax

Generic CiPs

The suggested documentation is given below each CiP and the overall numbers expected are given in the section above. Each piece of evidence can support more than one CiP and you should cross reference

CiP 1: Able to function successfully within NHS organisational and management systems

Key skills:

- Aware of, and adheres to, the GMC professional requirements
- Aware of public health issues including population health, social determinants of health and global health perspectives
- Demonstrates effective clinical leadership
- Demonstrates promotion of an open and transparent culture
- Keeps up to date through learning and teaching
- Demonstrates engagement in career planning
- Demonstrates capabilities in dealing with complexity and uncertainty
- Aware of the role and processes for commissioning
- Aware of the need to use resources wisely

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of taking an active role in governance structures, including service development. This may, for example, include the minutes of meetings for governance and unit management in which the applicant has been involved, MDT meetings, and any documented service development initiatives such as QIPAT.
▪ Evidence of attendance at an NHS / health service management course
▪ CPD evidence including courses in management and business

CiP 2: Able to deal with ethical and legal issues related to clinical practice

Key skills:

- Aware of national legislation and legal responsibilities, including safeguarding vulnerable groups
- Behaves in accordance with ethical and legal requirements
- Demonstrates ability to offer apology or explanation when appropriate
- Demonstrate ability to lead the clinical team in ensuring that ethical and legal factors are considered openly and consistently

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of ability to assess the mental capacity of patients to make healthcare decisions. Evidence could include: • Reflections on cases where you had to assess a patient's mental capacity
▪ Evidence of involvement in making 'best interests' decisions, such as: • Notes • Letters • Meeting minutes
▪ Awareness of relevant legislation, including mental capacity legislation by completion of an online training course, for example: • eLfH Mental Capacity Act: **https://www.e-lfh.org.uk/programmes/mental-capacity-act/** • CPD Online Mental Capacity Act: **https://cpdonline.co.uk/course/mental-capacity-act/** • SCIE Mental Capacity Act: **https://www.scie.org.uk/e-learning/mca**

CiP 3: Communicates effectively and is able to share decision making, while maintaining appropriate situational awareness, professional behaviour and professional judgement

Key skills:

- Communicates clearly with patients and carers in a variety of settings
- Communicates effectively with clinical and other professional colleagues
- Identifies and manages barriers to communication (e.g. cognitive impairment, speech and hearing problems, capacity issues)
- Demonstrates effective consultation skills including effective verbal and non-verbal interpersonal skills
- Shares decision making by informing the patient, prioritising the patient's goals and wishes, and respecting the patient's beliefs, concerns and expectations
- Shares decision making with children and young people
- Applies management and team working skills appropriately, including influencing, negotiating, re-assessing priorities and effectively managing complex, dynamic situations

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of your ability to analyse a patient's communication difficulties: • Reflective diaries
▪ Feedback from patients, such as a patient survey
▪ Reflective practice entries about patients or families who posed difficulties
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ CPD evidence including courses in simulation (including clinical scenarios and human factors) and communication

CiP 4: Is focused on patient safety and delivers effective quality improvement in patient care

Key skills:

- Makes patient safety a priority in clinical practice
- Raises and escalates concerns where there is an issue with patient safety or quality of care
- Demonstrates commitment to learning from patient safety investigations and complaints
- Shares good practice appropriately
- Contributes to and delivers quality improvement
- Understands basic Human Factors principles and practice at individual, team, organisational and system levels
- Understands the importance of non-technical skills and crisis resource management
- Recognises and works within limit of personal competence
- Avoids organising unnecessary investigations or prescribing poorly evidenced treatments

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Reflective practice entries about patients or families who posed difficulties
▪ Evidence that you have arranged and attended meetings about a patient with Social Services or other non-health organisations. For example: • Meeting minutes, demonstrating your attendance and participation • Invites sent from you demonstrating arranging meetings
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Documented evidence of development of procedures to improve inter-service and inter-agency communication, you will need to demonstrate your involvement in the new procedure and its effectiveness
▪ Evidence of specific quality improvement activity, such as evidence of specific quality improvement activity, such as a QIPAT
▪ Copies of letters you have written to NHS and non-NHS services involved with patients

- CPD evidence including courses in simulation (including clinical scenarios and human factors)

CiP 5: Carries out research and manages data appropriately

Key skills:

- Manages clinical information / data appropriately
- Understands principles of research and academic writing
- Demonstrates ability to carry out critical appraisal of the literature
- Understands the role of evidence in clinical practice and demonstrates shared decision making with patients
- Understands public health epidemiology and global health patterns
- Demonstrates appropriate knowledge of research methods, including qualitative and quantitative approaches in scientific enquiry
- Demonstrates appropriate knowledge of research principles and concepts and the translation of research into practice
- Follows guidelines on ethical conduct in research and consent for research
- Recognises potential of applied informatics, genomics, stratified risk and personalised medicine and seeks advice for patient benefit when appropriate

Suggested documentation:

- Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
- Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
- Evidence of completion of Good Clinical Practice (GCP) training:
  - **www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice**
- Documented evidence of research activity. This may include evidence of:
  - Helping in a project
  - Reviewing research papers / grants
  - Writing and co-authoring research papers
  - Contributing to research projects
- Presentations – either lectures (podium presentations) or poster presentations

▪ Documented evidence of development of procedures to improve quality of care beyond personal practice, e.g. QIPAT or evidence of performing an audit
▪ Publications
▪ CPD evidence including courses in research methodology

CiP 6: Acts as a clinical teacher and clinical supervisor

Key skills:

- Delivers effective teaching and training to medical students, junior doctors and other healthcare professionals
- Delivers effective feedback with action plan
- Able to supervise less experienced trainees in their clinical assessment and management of patients
- Able to supervise less experienced trainees in carrying out appropriate practical procedures
- Able to act as a clinical supervisor to doctors in earlier stages of training

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Completion of relevant Medical Education training course(s)
▪ Teaching Observation (TO) or other observational assessment of teaching
▪ Evidence of organising educational events / programs, with feedback.
▪ CPD evidence including courses in education and teaching

Clinical CiPs

Applicants must demonstrate that they are currently practising at the level of 'entrusted to act independently' in all clinical CiPs. Further detail regarding the descriptors for the key skills in each clinical CiP can be found in the curriculum.

CiP 1: Managing an acute unselected take

Key skills:

- Demonstrates professional behaviour with regard to patients, carers, colleagues and others
- Delivers patient centred care including shared decision making
- Takes a relevant patient history including patient symptoms, concerns, priorities and preferences
- Performs accurate clinical examinations
- Shows appropriate clinical reasoning by analysing physical and psychological findings
- Formulates an appropriate differential diagnosis
- Formulates an appropriate diagnostic and management plan, taking into account patient preferences, and the urgency required
- Explains clinical reasoning behind diagnostic and clinical management decisions to patients/carers/guardians and other colleagues
- Appropriately selects, manages and interprets investigations
- Recognises need to liaise with specialty services and refers where appropriate

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of simulation
▪ Assessment of acute care such as ACATs
▪ Evidence of discussing or reflecting on your professional judgement in a clinical case, such as a CbD
▪ CPD evidence including courses in life support

CiP 2: Managing the acute care of patients within a medical specialty service

Key skills:

- Able to manage patients who have been referred acutely to a specialised medical service as opposed to the acute unselected take (e.g. cardiology and respiratory medicine acute admissions)
- Demonstrates professional behaviour with regard to patients, carers, colleagues and others
- Delivers patient centred care including shared decision making
- Takes a relevant patient history including patient symptoms, concerns, priorities and preferences
- Performs accurate clinical examinations
- Shows appropriate clinical reasoning by analysing physical and psychological findings
- Formulates an appropriate differential diagnosis
- Formulates an appropriate diagnostic and management plan, taking into account patient preferences, and the urgency required
- Explains clinical reasoning behind diagnostic and clinical management decisions to patients/carers/guardians and other colleagues
- Appropriately selects, manages and interprets investigations
- Demonstrates appropriate continuing management of acute medical illness in a medical specialty setting
- Refers patients appropriately to other specialties as required

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Minimum of **one of each** of the below: • Evidence of discussing or reflecting on your professional judgement in a clinical case, such as a CbD • Assessments of acute care such as an ACAT
▪ Evidence of simulation training and assessment
▪ CPD evidence including courses in life support

CiP 3: Providing continuity of care to medical inpatients, including management of comorbidities and cognitive impairment

Key skills:

- Demonstrates professional behaviour with regard to patients, carers, colleagues and others
- Delivers patient centred care including shared decision making
- Demonstrates effective consultation skills
- Formulates an appropriate diagnostic and management plan, taking into account patient preferences, and the urgency required
- Explains clinical reasoning behind diagnostic and clinical management decisions to patients/carers/guardians and other colleagues
- Demonstrates appropriate continuing management of acute medical illness inpatients admitted to hospital on an acute unselected take or selected take
- Recognises need to liaise with specialty services and refers where appropriate
- Appropriately manages comorbidities in medial inpatients (unselected take, selected acute take or specialty admissions)
- Demonstrates awareness of the quality of patient experience

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Assessments of acute care such as ACATs
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Direct observation of procedural skills such as DOPS

CiP 4: Managing patients in an outpatient clinic, ambulatory or community setting (including management of long term conditions)

Key skills:

- Demonstrates professional behaviour with regard to patients, carers, colleagues and others
- Delivers patient centred care including shared decision making
- Demonstrates effective consultation skills
- Formulates an appropriate diagnostic and management plan, taking into account patient preferences
- Explains clinical reasoning behind diagnostic and clinical management decisions to patients/carers/guardians and other colleagues
- Appropriately manages comorbidities in outpatient clinic, ambulatory or community setting
- Demonstrates awareness of the quality of patient experience

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Assessment of care provided in Outpatients eg OPCAT
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from patients such as a Patient Survey
▪ Letters generated at outpatient clinics

CiP 5: Managing medical problems in patients in other specialties and special cases

Key skills:

- Demonstrates effective consultation skills (including when in challenging circumstances)
- Demonstrates management of medical problems in inpatients under the care of other specialties
- Demonstrates appropriate and timely liaison with other medical specialty services when required

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Assessments of acute care such as ACATs
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD

CiP 6: Managing a multi-disciplinary team including effective discharge planning

Key skills:

- Applies management and team working skills appropriately, including influencing, negotiating, continuously re-assessing priorities and effectively managing complex, dynamic situations
- Identifies appropriate discharge plan
- Ensures continuity and coordination of patient care through the appropriate transfer of information demonstrating safe and effective handover
- Effectively estimates length of stay
- Delivers patient centred care including shared decision making
- Recognises the importance of prompt and accurate information sharing with primary care team following hospital discharge

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF). Evidence of leading a Multi-Disciplinary Team.
▪ Assessments of acute care such as ACATs
▪ Discharge summaries, including reason for admission, findings, treatment plan and patient health on discharge

CiP 7: Delivering effective resuscitation and managing the acutely deteriorating patient

Key skills:

- Demonstrates prompt assessment of the acutely deteriorating patient, including those who are shocked or unconscious
- Demonstrates the professional requirements and knowledge of legal processes associated with consent for resuscitation
- Participates effectively in decision making with regard to resuscitation decisions, including decisions not to attempt CPR, and involves patients and their families
- Demonstrates competence in carrying out resuscitation

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Direct observation of procedural skills such as DOPS
▪ Assessments of acute care such as ACATs
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of learning advanced life support techniques such as an ALS certificate
▪ Written reflections on learning and experience
▪ Evidence of simulation
▪ CPD evidence including courses in life support

CiP 8: Managing end of life and applying palliative care skills

Key skills:

- Identifies patients with limited reversibility of their medical condition and determines palliative and end of life care needs
- Identifies the dying patient and develops an individualised care plan, including anticipatory prescribing at end of life
- Demonstrates effective consultation skills in challenging circumstances
- Demonstrates safe and effective use of syringe pumps in the palliative care population
- Able to manage non complex symptom control including pain
- Facilitates referrals to specialist palliative care across all settings
- Demonstrates compassionate professional behaviour and clinical judgement

Suggested documentation:

▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR), end of placement and appraisal reports
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Evidence of regional teaching
▪ Written reflections on learning and experience

Specialty Specific CiPs

Applicants must demonstrate that they are currently practising at the level of 'entrusted to act independently' in all specialty CiPs. Further detail regarding the descriptors for the key skills in each specialty specific CiP can be found in the curriculum.

Specialty CiP 1: Performing the clinical assessment, investigation and management of adverse drug reactions, medication errors and overdose at an individual and (where relevant) population level

Key skills:

- Able to define the factors that determine the benefit to harm balance in therapeutic interventions
- Able to define, identify, classify, investigate and manage adverse drug reactions appropriately
- Able to explain the role of pharmacovigilance including post Market Authorisation surveillance and reporting systems such as the Yellow Card system of the Medicines and Healthcare products Regulatory Agency (MHRA).
- Able to describe how adverse event signals are evaluated and the actions that medicines regulators may take.
- Reports adverse drug reactions appropriately through the yellow card system
- Works effectively with pharmacy to promote policy and good practice to avoid drug errors, including involvement in safety and governance processes that reach across primary and secondary care e.g., safety incident review panels and medicine optimisation committees
- Able to define, identify, classifies, investigate and manage common drug overdoses and poisoning appropriately (including decontamination and risk to staff and others and the use of common antidotes).
- Able to describe the role of the National Poisons Information Service and accesses information by telephone or via TOXBASE to support the management of drug overdose
- Demonstrates initial assessment and management of suicide risk, mental capacity and mental health status in poisoned patients, including effective interaction and multidisciplinary working with liaison psychiatry services. Shows practical expertise in the use of the Mental Capacity Act (MCA), Mental Health Act (MHA) and Deprivation of Liberty Safeguards (DOLS).
- Shows preparedness for chemical incidents, including terrorism, by describing examples of hazardous substances and explaining how local Trust major incident plans and Public Health England guidance prepare healthcare systems to deal with such incidents

Suggested documentation:

▪ Assessments of acute care such as ACATs
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Reflective practice
▪ Project based discussions (PBD), audits, quality improvement activity (QIPAT) if appropriate
▪ Managerial contribution to governance in medicine
▪ Teaching in relevant topics
▪ End of placement reports

Specialty CiP 2: Providing specialist management of patients with complex prescribing needs, including multimorbidity, polypharmacy, adherence issues, and medication intolerance

Key skills:

- Can formulate a comprehensive assessment of patients with complex prescribing needs, including characterisation of patient, carer and clinician priorities, assessment of adherence, medication intolerances and treatment burden (for example using a Clinical Pharmacology Structured review)
- Effectively communicates complex prescribing issues and proposed management choices to patients, their carers and healthcare providers, including in primary care. Signposts patients to reliable resources to support decision making

- Works in partnership with patients to construct a medicines optimisation plan to address complex prescribing needs. Uses an evidence-based and guideline informed approach, medicine optimisation tools, and shared decision making to align evidence with patient priorities
- Summarises options and strategies available to deal with polypharmacy, poor adherence or medication intolerance, using evidence-based approach.
- Able to describe General Medical Council and national guidance on prescription of off-label or unlicensed medicines. Provides appropriate additional information to patients when prescribing unlicensed drugs and to healthcare practitioners when advising on this practice

Suggested documentation:

▪ Assessments of acute care such as ACATs
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Project based discussions (PBD), audits, quality improvement activity (QIPAT) if appropriate
▪ Teaching in relevant topics
▪ End of placement reports

Specialty CiP 3: Providing analysis and expert opinion on pharmacokinetic, pharmacodynamic and pharmacogenomic factors to guide therapeutic decisions

Key skills:

- Able to state the underlying determinants of drug kinetics (including absorption, distribution, metabolism and elimination) and applies these principles to therapeutic decisions, including choosing and adjusting dose regimens
- Uses knowledge of mechanisms of action and pharmacokinetics of therapeutic drugs to;
    - select the correct drug, dose, route of administration and duration of treatment most appropriate to the individual and to groups of patients.
    - predict likely effects, both beneficial or adverse, of introducing novel drugs, including the effect of deviation from normal dose or dosing regimens
    - predict the effects of combinations of drugs and uses this to guide therapeutic decisions
- Able to explain basic pharmacokinetic concepts such as the area under a plasma drug concentration-time curve (AUC), clearance, volume of distribution and half-life, and applies these principles to therapeutic decisions. This should include choosing and adjusting dose regimens.
- Advises on indication for, optimum timing of, and type of drug concentration, analyses and interprets the relationship between blood concentration and drug effects
- Able to make therapeutic decisions that consider individual variation including genetic, age- and gender- related (including pregnancy and lactation), co-existing renal, hepatic and other disease, and drug interaction (both beneficial and adverse)
- Orders pharmacogenomic tests and interprets the results appropriately.
- Uses national guidelines to personalise medication regimens for patients

Suggested documentation:

▪ Assessments of acute care such as ACATs
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Reflective practice
▪ Project based discussions (PBD), audits, quality improvement activity (QIPAT) if appropriate
▪ Teaching in relevant topics

▪ End of placement reports

Specialty CiP 4: Providing evidence-based practice and contributing to the evidence base in a therapeutic area of interest

Key skills:

For a chosen area of therapeutics, to be able to:

- Use the best available evidence to clinically assess and manage patients with the relevant presentations and conditions
- Systematically collect, synthesise and apply information from the scientific literature to develop therapeutic protocols, guidelines and care pathways in conjunction with clinicians in the specialist area
- Deliver audit and quality improvement projects related to the therapeutics used or proposed
- Contribute to the evidence base for that area through design, delivery, analysis and dissemination of clinical research and trials
- Share expertise with the multiprofessional team in the relevant specialist area through contribution to MDT meetings, delivering teaching and training sessions
- Works with patients in the selected therapeutic area to promote shared decision making, the patient voice and inclusivity in relation to research and quality improvement projects.

Suggested documentation:

▪ Managerial contribution to governance in medicine
▪ Project based discussions (PBD), audits, quality improvement activity (QIPAT) if appropriate
▪ End of placement reports
▪ Teaching in relevant topics
▪ Logbook showing number and type of patients seen
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD or an assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX for selected area of disease
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR) for selected area of disease

▪ Feedback from patients, such as a patient survey, complaints or compliments received
▪ Attendance at relevant course/conference
▪ Reflective practice
▪ Guidelines, protocols, evidence summaries produced
▪ Evidence of specific quality improvement activity, such as a QIPAT
▪ Academic output e.g., protocols, trial delivery, papers, conference presentations

Specialty CiP 5: Advising on the cost effective, safe and rational use of medicines on a population level

Key skills:

- Able to define pharmacoepidemiology and describes the main types of pharmacoepidemiology studies (including case-control and cohort studies), data sources and repositories.
- Systematically collects, synthesises, appraises and applies information from a wide range of, sometimes conflicting, sources in relation to the efficacy, clinical effectiveness, safety and cost of medicines and therapeutics to advise on medicines use at population level (eg local, regional (integrated care system), national).
- Participates in decision making processes of multiprofessional committees making decisions about medicines (e.g., formulary, optimisation, management), including reviewing and presenting submissions. Contributes to discussions, respecting the views of others.
- Makes an objective assessment of cost effectiveness, safety and rational use of medicines in clinical use e.g., by audit, systematic review, retrospective research, and quality improvement projects
- Considers the factors that affect drug utilisation including social class, ethnicity, nationality, economic status, co- morbidity, age and gender (including pregnancy and lactation) when advising on medicines use at population level.
- Considers the factors that affect professional and public perception of drugs and their use in treating and preventing disease, including effects of advertising, marketing and media on medicines utilisation when advising on medicines use at population level.
- Applies understanding of the structure and function of medicines regulation in the UK and internationally, including the requirements for Marketing Authorisation of a new medicine, to inform advice on optimal medicines use at the population and individual level

- Contributes to the development of prescribing policies, formularies and guidelines and clinical decision support systems related to medicines, including recognition of drugs likely to be high risk or high cost in routine use and suggests strategies to manage this. Examples may include gene therapies, cell therapies and devices.
- Able to describe how NICE and SIGN select and make evidence based clinical guidance and technology appraisals about new medicines. Analyses the cost effectiveness of medicines using and interpreting standard health economic models and discussing their strengths and limitations

Suggested documentation:

▪ Participation in committees making decisions about medicines
▪ Project based discussions about committee work, guidelines etc
▪ Performance report from an Educational Supervisor such as an Educational Supervisor's Report
▪ Attendance at relevant course/conference
▪ Reflective practice
▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Evidence of specific quality improvement activity, such as a QIPAT
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ End of placement reports
▪ Teaching in relevant topics
▪ Research output e.g., protocols, trial delivery, papers, conference presentations
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)

Specialty CiP 6: Delivering effective education in clinical pharmacology, therapeutics and prescribing to promote safe and effective use of medicines across the whole workforce

Key skills:

- Develops and delivers effective education and training in clinical pharmacology, therapeutics and prescribing for undergraduate students and postgraduate practitioners to promote safe and effective use of medicines across the whole healthcare workforce
    - Develops and delivers training and competency assessment in prescribing for medical and non-medical prescribers
    - Develops and delivers effective training to multiple staff groups who are not prescribers focusing on the safe and effective use of medicines
- Supports national initiatives around safe and effective use of medicines
- Contributes to public education about drugs and their utilisation.
- Develops assessment materials relevant to clinical pharmacology, therapeutics and prescribing education in undergraduate or postgraduate arenas (e.g. question writing for the prescribing safety assessment (PSA), medical schools or membership of the Royal College of Physicians MRCP(UK))

Suggested documentation:

▪ Project based discussions e.g. around teaching delivered or materials developed
▪ Teaching observations
▪ Teaching evaluation data
▪ Teaching diary
▪ Submissions of PSA/MRCP assessment material and peer review
▪ Reflective practice
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)

- Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)

Specialty CiP 7: Providing expertise in the design and delivery of experimental medicine, and other types of clinical pharmacology & therapeutic research, including preclinical and clinical studies

Key skills:

- Able to describe the phase of clinical trials, including for each phase appropriate clinical trial design, selection of participants, dosing strategy and outcome measures
    - Able to describe the design and interprets the results of early phase studies to determine the pharmacokinetic and pharmacogenetic parameters that inform the design and conduct of later phase studies
    - Explains what is meant by parallel, crossover, platform, basket, umbrella, adaptive trial designs, when they are used, their advantages and limitations.
- Able to describe the national structure for clinical trial delivery in the NHS including the roles of the National Institute for Health Research NIHR), Medicines and Healthcare products Regulatory Authority (MHRA), Health Research Authority (HRA), National Research Ethics Committee, Comprehensive Research Network and Clinical Research Facilities
- Explains the purpose of guidelines produced by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and acquires and maintains certification in Good Clinical Practice (GCP)
- States the regulatory, legal and ethics requirements for clinical trial approval, trial registration and reporting in the UK
- Able to describe the process by which pre-clinical drug discovery and development data are generated and is able to synthesise and analyse pre-clinical data to describe, in summary, a safe first-trial-in-human study including starting dose and dose escalation, biomarker selection and monitoring schedule
- Contributes to clinical study design and delivery including critical review of protocols, study set up, meeting regulatory requirements and maintaining documentation, participant recruitment and consent, monitoring, safety reporting, biomarker and patient-centric outcomes strategy and trial close out.
- Demonstrates research leadership e.g., by one or more of; acting as a trial co-principal investigator or sub-investigator, medical monitor or study sponsor physician, membership of research management or governance committees, membership of research ethics committee.

Suggested documentation:

▪ Evidence of a case-based discussion with a consultant to assess professional judgement, such as a CbD
▪ Reports from consultants who have worked with you, such as the Multiple Consultant Report (MCR)
▪ Assessment of observed clinical skills, attitudes and behaviours, such as a Mini-CEX
▪ Feedback from a variety of clinical and non-clinical colleagues who have worked with you, such as the Multisource Feedback (MSF)
▪ Reflective practice
▪ Project based discussions (PBD), audits, quality improvement activity (QIPAT) if appropriate
▪ Managerial contribution to research delivery
▪ GCP certificate
▪ End of placement reports
▪ Teaching in relevant topics
▪ Safety monitoring