30 September 2021

Clinical Pharmacology Skills Alliance representation to the Spending Review 2021

Investing in an NHS workforce that is 'research ready' and skilled in the development and use of medicines can help the UK to Build Back Better - by supporting delivery of the NHS Long Term Plan, the Life Sciences Vision, the Future of UK Clinical Research Delivery, the triple aim of Integrated Care Systems and helping cement the UK as a science superpower.

The Clinical Pharmacology Skills Alliance (CPSA) is a partnership formed by the Association of the British Pharmaceutical Industry (ABPI), the British Pharmacological Society (BPS), the Faculty of Pharmaceutical Medicine (FPM) and Health Education England (HEE). The purpose of the CPSA is to develop and support a long-term, cross-sector action plan for UK clinical pharmacology. The CPSA is led by an Executive Board, which is co-chaired by Professor Sir Munir Pirmohamed (BPS) and Andrew Foxley (AstraZeneca for ABPI).

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1. Executive summary

1.1. The NHS Long-Term Plan promises a joined-up and personalised approach to patient care, recognising that elderly people have complex needs that will peak in the next decade. It sees the potential of genomic medicine, and the opportunity of a thriving clinical science and innovation base that can deliver transformative treatments. The Life Sciences Vision sees the potential for attracting more commercial research to the UK through supporting NHS research capability – and together with the Future of UK Clinical Research Delivery seeks to ensure that research is embedded across the NHS as a core part of patient care.

1.2. Investing to deliver these strategies will drive better outcomes for patients, a more efficient NHS, better medicines, and economic returns:

- Research active healthcare settings and trusts not only have lower mortality rates and better patient outcomes across their services - staff morale is also higher.
- 6.5% of all hospital admissions are caused by adverse drug reactions, and 237 million medication errors are made in the NHS in England each year. Older patients taking multiple medicines for multiple long-term conditions are at greater risk of medication-related harms. Decreasing adverse drug reactions and prescribing errors improves patient outcomes and results in nearly £6 saved for every £1 invested.
- For every patient recruited onto a commercial clinical trial between 2016/2017 and 2017/2018, the NHS in England earned £9,189 from life sciences companies, and where a trial drug replaced the standard of care treatment, saved £5,813.
- Clinical research activity conducted within the NIHR Clinical Research Network in FY 2016/17-18/19 helped to generate a total of £2.7 billion of gross value added (GVA) and over 47,000 jobs.
- Based on international experience, a £1 increase in government spending on medical research is associated with an increase in private research spending from the pharmaceutical industry of between £0.83 and £1.07.

1.3. Investing in NHS workforce that is 'research ready' and skilled in the development and use of medicines (as part of a strategic approach to workforce planning) will unlock these benefits. Therefore, the Clinical Pharmacology Skills Alliance (CPSA) worked with our partners in NHS England & Improvement (NHSEI), the Department for Health and Social Care (DHSC), and the Office for Life Sciences (OLS) to develop **a future-focused vision for a multi-professional medicines service network embedded in every Integrated Care System (ICS) and across devolved nations.** This network will provide advice, guidance and expertise to enable the NHS workforce and life sciences sector. It will help deliver healthcare and economic priorities through:

- management of multimorbidity and complex polypharmacy
- implementation of pharmacogenomics and precision medicine
- development of NHS capability in clinical research
- collaboration with life sciences to develop transformative treatments and attract commercial research to the UK

In this representation, we ask government **to make critical workforce investments now, to support pharmacy** and **to invest in a 12-month cross-sector task and finish group (£100.5K)** to develop our future-focused workforce vision. HEE and NHSEI have captured the workforce investment required for the current spending review period and funding for the task and finish group:

Critical workforce	Workforce assessment to 2031
Clinical pharmacology (See appendix 2 for workforce strategy)	**£57.5m** to double the number of clinical pharmacologists in the NHS (to 215 consultants and 87 training posts) *Breakdown:* *£27.24m for 57 new StR posts* *£16.02m for 36 clinical fellow posts* *£14.24m for 148 consultant posts*
Pharmacogenomic scientists (See appendix 1, case study 6 for workforce strategy)	**£15,304,000 - £24,493,000** to deliver between 70-105 new clinical scientists trained in pharmacogenomics

In addition, we ask the government to support:

- associated Genomics Programme bids from HEE and NHSEI.
- connected bids from DHSC via the Recovery Resilience and Growth (RRG) programme partners, and as recommended by the new ABPI report "Clinical research in the UK: an opportunity for growth", which will support implementation of the Life Sciences Vision and the Future of Clinical Research Delivery.
- implementation of the Overprescribing Review and associated efforts to drive the safe, effective, and efficient use of medicines - such as initiatives from HEE's e-LfH that aim to improve prescribing education and training.

1.4. There is an unprecedented window of opportunity for alignment across government, the NHS and the life sciences sector - it must be grasped without delay. Through the COVID-19 pandemic, the UK has demonstrated the impact of such collaboration. Now is the time to capitalise on this for the future to help the UK **Build Back Better** by supporting a **strong and innovative NHS** through collaborative, multi-professional working, **delivering growth** and **advancing Global Britain** through making the UK a globally leading hub for life sciences and clinical research that will

cement the UK as a **science superpower**, and **levelling up** through reaching more patients with research and development.

2. Introduction

2.1. The NHS Long-Term Plan promises a joined-up and personalised approach to patient care. As part of this holistic, whole-person centred vision the plan recognises that the NHS must reduce health inequalities and maximise prevention. It recognises that elderly people have complex needs that will peak in the next decade. It sees the potential of genomic medicine, and the opportunity of a thriving clinical science and innovation base that can deliver transformative treatments.

2.2. The Health and Care Bill will embed this vision in legislation in 2022, including putting Integrated Care Systems (ICSs) on a statutory footing to deliver the triple aim of "better health for the whole population, better quality care for all patients and sustainable services for the taxpayer; and merging NHS England and NHS Improvement – formalising the work already done to bring the organisations together."

2.3. The Life Sciences Vision sees the potential for attracting more commercial research to the UK. It will do this through supporting NHS research capability, citing the opportunities for the UK economy and for patients "if Government, the Sector and NHS work together", and aiming to "diagnose, treat, cure and prevent a much wider range of disease than is currently possible" through innovation and technological advances.

2.4. This is all supported by the Future of UK Clinical Research Delivery, which states that the "NHS will be encouraged to put delivery of research at the heart of everything they do, making it an essential and rewarding part of effective patient care" and "to create a research-positive culture in which all health and care staff feel empowered to support and participate in clinical research as part of their job". Building research capability in the NHS will also help attract commercial research. Investing to deliver these strategies will drive better outcomes for patients, a more efficient NHS, better medicines, and economic returns for the UK.

2.5. Investing to deliver these strategies will drive better outcomes for patients, a more efficient NHS, better medicines, and economic returns:

- Research active healthcare settings and trusts not only have lower mortality rates and better patient outcomes across their services - staff morale is also higher.
- 6.5% of all hospital admissions are caused by adverse drug reactions, and 237 million medication errors are made in the NHS in England each year. Older patients taking multiple medicines for multiple long-term conditions are at greater risk of medication-related harms. Decreasing adverse drug reactions and prescribing errors improves patient outcomes and results in nearly £6 saved for every £1 invested.
- For every patient recruited onto a commercial clinical trial between 2016/2017 and 2017/2018, the NHS in England earned £9,189 from life sciences companies, and where a trial drug replaced the standard of care treatment, saved £5,813.
- Clinical research activity conducted within the NIHR Clinical Research Network in FY 2016/17-18/19 helped to generate a total of £2.7 billion of gross value added (GVA) and over 47,000 jobs.

- Based on international experience, a £1 increase in government spending on medical research is associated with an increase in private research spending from the pharmaceutical industry of between £0.83 and £1.07.

2.6. **Investing in an NHS workforce that is 'research ready' and skilled in the development and use of medicines will unlock these benefits.**

2.7. Most clinical pathways involve medicines. They represent the highest area of spend (after workforce) across the NHS, estimated at £20.9 billion per year and growing more than the current annual increase in funding. Reducing the overprescribing of medicines and ensuring the best outcomes and value from them is a strategic priority for the NHS.

2.8. Over 1.1 billion prescription items are dispensed in the community every year and although medicines have many proven benefits, they can also cause harms. About 90% of drugs only work in 30-50% of patients, 6.5% of all hospital admissions are caused by adverse drug reactions, and 237 million medication errors are made in the NHS in England each year. Decreasing adverse drug reactions and prescribing errors results in nearly £6 saved for every £1 invested, and two-thirds of medicines-related hospital admissions are preventable.

2.9. Precision medicine allows the targeting of drugs to those who will respond favourably, thereby improving the benefit-risk ratio of existing drugs and the development of new drugs. Exposure of primary care patients to pharmacogenomic drugs is common, multiple and increases with age. Genomics is the mainstay of precision medicine at present, and mainstreaming genomics in the NHS could make a major impact on patient outcomes including complex polypharmacy. The new opportunity that pharmacogenomics brings allows for the use of a patient's genetic information to individualise their drug therapy, to select the most ideal medicine and optimise the doses, and support prescribing in primary care. As patients age, they are prescribed more medications and due to physiological changes and other morbidities are more susceptible to adverse events. Pharmacogenomics allows drugs to be selected that will work best or help clinicians to avoid adverse drug reactions in specific patients (e.g., with abacavir), improve tolerability (e.g., with statins), and improve effectiveness (e.g., with clopidogrel). At the same time pharmacogenomics can be used to optimise dosage, preventing over or underdosing e.g., warfarin and 5-fluorouracil.

2.10. The British Pharmacological Society and the Royal College of Physicians established a working party on the implementation of pharmacogenomics in the NHS. It will report soon and recommend that the strategic planning of service delivery models must incorporate workforce planning and development from the outset to ensure there are enough people to deliver the service. This is a principle that should apply across the NHS, and ideally the health and care workforce should be considered as a whole. It will also state that the whole workforce should have access to education and training to support the implementation of pharmacogenomics in the NHS.

2.11. Further, as the population ages, people increasingly have multiple co-existing chronic diseases (multimorbidity), necessitating the use of multiple medicines (polypharmacy) – over 1 million people in the UK take 8 or more medicines per day. An ageing population means that complexity of care and medicines optimisation pose a major challenge for the NHS.

2.12. Professor Sir Munir Pirmohamed, expanded on this when giving oral evidence to the House of Lords Science and Technology Select Committee inquiry on ageing:

> *"Actually, when you have 15 drugs, there are three, four or five-way interactions going on….which compounds the problem and leads to the adverse drug reactions that are common in this age group and often not picked up in routine clinical care.*
>
> *When you have a very complicated patient with seven diseases and on 15 drugs, deciding which one to stop and having that conversation with the patient is quite complicated."*

2.13. The recent Overprescribing Review highlights the need to change prescribing behaviours and culture to obtain the maximum benefit from medicines. This will include deprescribing medicines or choosing alternatives to medicines in the first place, with a key role for enhanced education and training and continued investment in workforce – and importantly, in the context of this representation, better structures to support the workforce. Similarly, a recent review notes that one of the barriers to improving the use of medicines in the NHS is that "assessing the balance between benefit and harm can…be complex, and there is a paucity of good evidence to guide clinicians". Thus, it suggests a systems-wide approach to improving overprescribing and problematic polypharmacy.

2.14. Further, older patients and those with multiple conditions are often excluded from clinical trials and there needs to be a specific focus on research into the issues facing the increasing elderly population. There is also an opportunity to reach other under-served populations. A joined-up approach to inclusive research (e.g., building on NIHR Include) across industry, academia and the NHS would help ensure medicines are developed with and for the patients who need the benefit – helping to reduce health inequalities.

2.15. Recent work by the Academy of Medical Sciences on enhancing the NHS-academia interface and work on research in the NHS by the Royal College of Physicians and Cancer Research UK (CRUK) all recommend investing in the research capacity and capability of the NHS workforce on the basis that patients treated in research-active healthcare settings have better outcomes and receive better care. Engaging in research improves job satisfaction amongst health workers, boosts staff morale and can reduce burnout: 57% of doctors surveyed by the Royal College of Physicians (RCP) said they would like to be more involved in research and 67% of those surveyed said having dedicated time for research would make them more likely to apply for a role. Care Quality Commission analysis also shows that staff working in NHS sites with higher clinical research activity levels are more likely to recommend their own organisation. A cross-sector evidence submission to Health and Care Bill Public Bill Committee calls for a strengthened mandate for research delivery in the NHS. This should mandate that Integrated Care Systems ensure that NHS organisations for which they are responsible conduct and resource clinical research, recognising that a properly trained and confident workforce is fundamental to this.

2.16. The establishment of Integrated Care Systems is an opportunity to reimagine the traditional, siloed research and care paradigm (which focuses on one target, one disease and one treatment) in favour of a multi-professional, collaborative systems-approach to the development and use of medicines in the NHS. **Our vision seeks to achieve this through establishing a medicines service network in every Integrated Care System, and across devolved nations.**

2.17. There is an unprecedented window of opportunity for alignment across government, the NHS and the life sciences sector - it must be grasped without delay. Through the COVID-19 pandemic, the UK has demonstrated the impact of such collaboration. Now is the time to capitalise on this for the future to help the UK **Build Back Better** by supporting a **strong and innovative NHS** through collaborative, multi-professional working, **delivering growth** and **advancing Global Britain** through making the UK a globally leading hub for life sciences and clinical research that will cement the UK as a **science superpower**, and **levelling up** through reaching more patients with research and development.

3. Our vision: a medicines service network to enable the NHS workforce and the life sciences sector.

3.1. We envisage the medicines-service network to be a multi-professional collaboration, comprised of a core medicines service, and specialist medicines services. See appendix 1 for supplementary case studies that have informed the development of this vision.

3.2. *Who is part of the medicines service network, and how will they work?*
The core medicines service will comprise pharmacy leaders/specialists and clinical pharmacologists. This core service will partner with specialist services comprised of experts including clinical geneticists, genomic scientists, and researchers to tackle specific health care needs. Together, they will use their complementary skills to collaborate on cross-cutting priorities (**multimorbidity and complex polypharmacy**, **pharmacogenomic and precision medicine** and **clinical research and development**) using defined networks and pathways in an Integrated Care System. They will provide advice, guidance, clinics, and education and training across primary and secondary care to collectively support the wider workforce (e.g., doctors, pharmacists, nurses, other specialist services, patients and carers) to deliver better patient outcomes, increase research capacity and capability, protect precious NHS resources and facilitate connectivity with the life sciences sector. Our ambition is that this approach will encourage collaboration and build confidence and skills across all Integrated Care Systems. This model has been developed based on knowledge of current innovative practice, national investments and strategy, and the skills we know that healthcare professionals and scientists can contribute (see appendix 1).

Medicines service network:	**Supporting the wider workforce to enable the ICS:**
Core medicines service • Pharmacy leaders/specialists • Clinical pharmacology **Specialist medicines services** • Genomics • Clinical Research	**Community** (e.g., care homes, community pharmacy, patients)
	Primary care (e.g., primary care networks)
	Secondary care (e.g., acute, specialist and mental health trusts, testing laboratories)
	Research, innovation & Education networks (e.g., Clinical Research Networks, Clinical Research Facilities, Academic Health Sciences Networks, Academic researchers and clinician scientists, Higher Education Institutes)

Table 1. A medicines service network can act as enabler, supporting the wider workforce across an Integrated Care System. *A medicines service network creates a collaborative environment for knowledge generation and research. Core medicines services – clinical pharmacology service working in partnership with pharmacy leaders & specialists in strategic pharmacy networks. Specialist medicines services – experts in genomics and clinical research will collaborate with the core medicines service to relevant expert support. The overall medicines service network will be visible and accessible to the wider workforce (doctors, pharmacists, nurses, other specialist services, patients and carers) in a structured way across the ICS.*

3.3. *What will a medicines service network deliver?*

A medicines service network will support decision-making on the safe, effective, and cost-effective use of medicines in complex care settings, using genomic information and linked health data to inform care. It will help the NHS incorporate clinical research and life sciences into everyday practice, leading and supporting the development of new medicines and treatments for the patients who need the benefit. It will provide and enhance education and training for the wider NHS workforce, in both formal and informal settings helping to create an environment for training, lifelong learning, knowledge-sharing and collaboration. Overall, a medicines service network will help the wider NHS workforce to be skilled in the use of medicines (particularly in complex care settings), and to be 'research-ready', meaning healthcare professionals will be supported to be familiar with and confident to engage in clinical research. It will support:

Tackling multimorbidity and complex polypharmacy

The medicines service network will:

- Improve the safe, effective, and cost-effective use of medicines e.g., in complex polypharmacy, by decreasing adverse drug reactions and prescribing errors, and improved prevention and management of drug-drug interactions.
- Reduce medicines wastage and contain costs
- Support education and training, so the NHS workforce is skilled in the use of medicines.

Implementation of pharmacogenomic and precision medicine

To help ensure that the right patient receives the right medicine, the medicines service network will:

- Lead implementation of pharmacogenomics to reduce harms and improve efficacy.
- Provide education and training via the Pharmacy, Healthcare Science and Medical Education programmes in HEE and the Clinical Pharmacology Service, in order to develop and upskill the wider workforce and the consultant scientists of the future.
- Develop strategies to stratify by disease, genomics, and other biomarkers, embedding this into trials and clinical practice to guide treatments to specific populations.
- Support functional genomics to improve the identification of potential drug targets.

Increased capacity and capability in clinical research & life sciences

The development of new medicines and treatments is essential to address unmet clinical need, bringing benefit for both society and the UK economy. The medicines service network will:

- Advise on trial methodology and regulatory requirements, including hybrid and adaptive designs, digital and decentralised trials, master protocols and efficient platform trials.
- Deliver and support more innovative early phase trials.
- Lead use of electronic health record data, gaining insights via state-of-the-art analytics.
- Support the wider NHS workforce – providing training and advice to build confidence and support healthcare professionals in reaching more patients with research and development, including those in under-served populations and areas.
- Clinical pharmacologists will have a leading role in supporting this development and helping pharmacists to become significant contributors to the research agenda.

4. What do we need to make this happen?

4.1. We need to secure the immediate, critical workforce investments that will lay the foundation for this work. Specifically, we are seeking funding for our clinical pharmacology workforce strategy via HEE and NHSEI spending review bids, and pharmacogenomic scientists via NHSEI spending review bid.

4.2. We also need a joined-up, thoughtful approach to workforce planning, and to explore how the model we have presented could be scaled across the NHS. To our knowledge, this vision is the first time that addressing complex polypharmacy, implementation of pharmacogenomics and precision medicine, and increasing capability for clinical research has been framed holistically with a collaborative approach. However, this is still at a formative stage, and we are seeking funding for a 12-month task and finish group to develop it via the NHSEI Genomics Programme bid.

4.3. We have built significant cross-sector support to:

- Expand the core project team (BPS, HEE, NHSEI) to include relevant leads from DHSC, OLS, MHRA, NICE, NIHR Academy, the Association of the British Pharmaceutical Industry (ABPI), the Faculty of Pharmaceutical Medicine, the Academy of Medical Sciences and representatives from relevant healthcare professions/sciences and organisations and the devolved nations to build cross-sector consensus on the model and associated workforce planning.
- Perform a skills assessment and workforce mapping exercise against this model.
- To refine and define ways of working across parts of the medicines service network, and with the wider workforce.
- To develop a full workforce strategy for each profession identified as part of the medicines service network (similar to that outlined in appendix 2 for clinical pharmacology) and associated education and training plan.
- To evaluate and quantify the benefit of the medicines service network
- To have a robust implementation plan for the workforce strategy with clear deliverables.

5. Our proposal

5.1. The CPSA has worked in partnership with NHS England & Improvement (NHSEI), the Department for Health and Social Care (DHSC), and the Office for Life Sciences (OLS) and Life Sciences Industrial Strategy Implementation Board (LSIS IB) to develop a vision for **a multi-professional medicines-service network embedded in every Integrated Care System (ICS) and across devolved nations**. This will **enable** the wider NHS workforce – encouraging collaboration and synergy within the NHS (and with academia and industry) - to support the delivery of government and sector priorities.

5.2. The network will comprise a core medicines service (pharmacy leaders/specialists and clinical pharmacologists), which will partner with specialist medicines services (experts including clinical geneticists, genomic scientists, and researchers, *see appendix 1*). The medicines service network will provide advice, guidance, clinics, and education and training across the ICS to collectively support the wider workforce (e.g., doctors, pharmacists, nurses, other specialist services, patients and carers) to deliver better patient outcomes, protect precious NHS resources, and to drive collaboration, learning and research. Please see section 4 for more details.

5.3. This collaboration is reflected in spending review representations from our partners across the NHS and life sciences. We ask government to fund spending review bids

and support initiatives directly associated with this vision (see 2.4), and strongly support associated bids from our partners that seek to improve patient access to clinical research and investment in the UK scientific and healthcare workforce of the future.

5.4. We ask government to **(a) make critical workforce investments now**, and in parallel **(b) invest in a 12-month, cross-sector task and finish group to develop this vision**:

a) Make critical workforce investments now

Workforce	Workforce assessment to 2031
Clinical pharmacology (See appendix 2 for workforce strategy)	**£57.5m** to double the number of clinical pharmacologists in the NHS (to 215 consultants and 87 training posts) *Breakdown:* *£27.24m for 57 new StR posts* *£16.02m for 36 clinical fellow posts* *£14.24m for 148 consultant posts*
Pharmacogenomic scientists (See appendix 1, case study 6 for workforce strategy)	**£15,304,000 - £24,493,000** to deliver between 70-105 new clinical scientists trained in pharmacogenomics

*HEE and NHSEI have captured the workforce investment required for the current spending review period.

b) Investment in a cross-sector 12-month task and finish group.
Fund £100.5K via the NHSEI Genomics Programme bid for a cross-sector task and finish group reporting into the Diagnostics Board to develop our vision over 12 months to develop a clearly defined and quantified proposal:

- Programme lead (band 8a): £53,219
- Administrative role (band 5): £27,780
- Oncosts @ 24% £19,439.76
- **Total: £100,438.76**

7. List of appendices (see following pages)

Appendix 1
Supplementary case studies illustrating the building blocks of the workforce model:

- Case study 1: outline of the healthcare professionals that make up the medicines service network *(pages 1 – 3)*
- Case study 2: building on national pharmacy strategy *(page 4)*
- Case study 3: building on the SW London pilot clinical pharmacology service *(pages 5-7)*
- Case study 4 – blueprint for how a clinical pharmacology service could enhance drug discovery and development capability in an ICS *(page 8)*
- Case study 5: how clinical pharmacology embedded research in primary care during COVID-19 *(page 9-10)*
- Case study 6: the scientific workforce in the medicines-service network *(page 11-12)*

Appendix 2
Clinical pharmacology workforce strategy.

APPENDIX 1

Supplementary case studies illustrating the building blocks of the workforce model:

***Case study 1: outline of the healthcare professionals that make up the* medicines service network**

The table below is an illustrative workforce map setting out the key healthcare professionals. It will be refined as part of the medicines service network strategy.

Health care professional	**Who are they, and what is their role in the medicines service network?**
Core medicines service	
Clinical Pharmacologist	Clinical pharmacologists are expert generalists, using knowledge of how medicines work and affect the body to provide integrated assessment and care, including for complex polypharmacy. They are research leaders who investigate the mechanism(s) of action of potential therapeutics, translating these into clinical use through the design and delivery of innovative trials. They are precision medicine leaders, supporting stratification of trials and implementation of pharmacogenomics in the NHS. They are regulatory and policy leaders, ensuring safety, effectiveness, quality and value through regulatory evaluation, pharmacovigilance and health technology assessment. They are education leaders, supporting the NHS workforce to be skilled in the use of medicines and to engage in research. Clinical pharmacologists are experts in the development and use of medicines; applying clinical pharmacology principles at all stages of therapeutics' research, development and use can help establish not just whether a drug will work but crucially, whether it will be safe. Role in the medicines-service network: • Providing a clinical pharmacology service across the ICS in partnership with pharmacy, and connectivity with the life sciences industry. • Providing education and training in clinical pharmacology, research & prescribing
Pharmacist	Pharmacists are expert generalists in the use of medicines, with many specialising to an advanced level in specific therapeutic areas. Although the focus of the profession has become more patient facing and clinical in nature, they are still trained as scientists, albeit with an application to clinical practice. Within a few years all pharmacists will graduate as independent prescribers, and a programme is being established to furnish the existing workforce with the same skills. The programme to place up to 7000 pharmacists into general practice, the increasingly clinical nature of community pharmacy, the specialist nature of hospital pharmacy, pharmacy consultant practice and the increasing interest in pharmacy clinical academic careers provide an ideal opportunity for pharmacists to work synergistically with clinical pharmacologists and healthcare scientists to forward the specialism of pharmacogenomics and become experts in this field Role in the medicines-service network:

	• Patient Facing interaction with patients including undertaking structured medication review at scale, with clinical pharmacology support for more complex patients. • Strategic pharmacy networks in the ICS interacting with the Clinical Pharmacology Service.
Specialist medicines service	
Genomic scientist	The science and testing capability relating to genomics. Genomic science forms the base on which systems pharmacology can develop. Genomic experimental and computational approaches enable systems pharmacology to obtain holistic, mechanistic information on disease networks and drug responses, and the information to identify new drug targets and specific drug combinations. Network genomic analyses of interactions involved in pathophysiology and drug response across various scales of organisation, from molecular to organismal, will allow the integration of the systems-level understanding of drug action with genome medicine. The interface of the two fields will enable drug discovery for personalised medicine. Genomic scientists provide the links and relationships between the genome, proteome, disease and drugs. Role in the medicines-service network: • To generate and interpret the genomic information in the diagnosis of disease and in prescribing treatment
Clinical geneticist	Clinical Geneticists are the patient facing workforce that synthesises the interpreted genomic science into information that patients can understand. They link the information to the clinical features and symptoms presented in patients and family members and provide to patients the genome medicine information in a way that enables that genomic information from a patient to help in the diagnosis or treatment of disease. Role in the medicines-service network: • Working directly with patients and their families, clinical geneticists can help to identify genomic variation between individuals to affect the origin and progression of diseases, as well as drug response.
Clinical pharmacology scientists	The broad purpose of the occupation is to design, analyse, interpret and report clinical research and clinical trials aimed at understanding what a drug is doing to the body (pharmacodynamics), what happens to a drug in the body (pharmacokinetics), and how it works in terms of treating a particular disease. They also offer clinical pharmacology expertise to resolve issues that arise during conduct of studies. It is a varied role, supporting the discovery and development of new medicines, and improving understanding of existing ones. The Clinical Pharmacology Scientist is well-placed to aid in all aspects of medicine management. For example, they can provide specialist advice to healthcare professionals and researchers on the interactions of different medicines and how these might affect patients and research participants. In addition, the Clinical Pharmacology Scientist will form a key component of National Institute for Health Research (NIHR) Biomedical Research Centres (BRCs), Clinical Research Facilities (CRFs) and other academic groups, with a focus on driving the development and translation of novel therapeutics in an academic setting. They will also provide expertise in preparation and writing of grant applications. The Clinical Pharmacology Skills Alliance has developed a level 7 Clinical Pharmacology Scientist apprenticeship in response to critical skills gaps.

	Importantly, this training route is one way of building research capability in the wider workforce – the programme could be taken by a range of other professionals (e.g. pharmacists) as part of their training. Role in the medicines-service network: • A Clinical Pharmacology Scientist might also form part of the core medicines-network service • They would work in Clinical Research Facilities, Biomedical Research Centres and across the ICS, including at the preclinical-clinical interface, determining whether a potential new medicine is safe, establishing whether it works in humans, right through to ensuring the right data are available to support regulatory interactions so that patients get the medicines they need as soon as possible. They will work through phases 1 to 4 of drug development (i.e., from testing whether a drug is safe to use to determining what the long-term risks and benefits are) as well as life cycle management (e.g., developing more palatable or easier to swallow tablets for patients).
Clinical academic	Clinically qualified researchers are research-trained clinicians. In the context of the medicines-service network they will have expertise in trial design and delivery. They contribute to the development of new treatments and treatment paradigms and are also involved in teaching and mentoring clinicians who are interested in developing an academic career track. HEE's Research and Innovation Strategy commits to the development of a "transparent and integrated multi-professional clinical academic career framework, which enables all partners to be clear about the strategic approach to developing the clinical academic workforce for patient benefit." Role in the medicines-service network: • If the clinician academic is a clinical pharmacologist, they will play a role in the core medicines-service • Disease specialists can advise on and run trials, and support the education and training of the wider workforce.
Pharmaceutical physicians	Pharmaceutical physicians are responsible for the research, development and monitoring of new medicines. They use their clinical skills and knowledge of human biology to deliver pioneering medicines and ensure they are safe and effective for patients. They work in many different environments, including the pharmaceutical, biotech and device and diagnostic industries, contract research organisations, academia and drug regulatory authorities. They seek, through the stages of clinical trials and medical affairs and regulatory activities, to establish the benefit:risk profile of a novel medicine. Pharmaceutical physicians are responsible for ethical design of clinical trials and for ensuring the safety and well-being of patients and volunteers taking part in trials. They are also the gatekeepers for the 'summary of product characteristics' (SmPC) and patient information leaflets that accompany medicines and support their effective and safe use. As some pharmaceutical physicians work in commercial settings, they will require a depth of knowledge that encompasses not only the science of medicines development, but also pharmacoeconomics, business administration and the social and political changes affecting patients and public health. Pharmaceutical medicine is a global discipline and requires close international collaboration with other specialists, companies and regulatory bodies in many jurisdictions. Role in the medicines-service network: • Providing education and training to principal investigators and clinicians on good clinical practice and safe and ethical medicines development • Interface with the life sciences industry

Case study 2: building on national pharmacy strategy

Clinical pharmacists are increasingly working as part of general practice teams. They are highly qualified experts in medicines and can help people in a range of ways. This includes carrying out structured medication reviews for patients with ongoing health problems and improving patient safety, outcomes and value through a person-centred approach. NHS England commissioned the University of Nottingham to independently evaluate a pilot scheme testing the impact of clinical pharmacists into general practice over a one-year period. The pilot was successful in showing that clinical pharmacists in general practice are benefiting patients. The full evaluation and executive summary was published in July 2018 and can be found on the University of Nottingham's website.

There are currently over 3000 Full Time Equivalent clinical pharmacists working across the country through the NHS England Clinical Pharmacists in General Practice Programme since it started in 2015. There is now a commitment to increase and fund this to 7000 clinical pharmacy professionals in PCNs through the Additional Roles Reimbursement Scheme (ARRS). All of these pharmacists undergo extensive additional training through the Centre for Pharmacy Postgraduate Education (CPPE) Primary Care Pharmacy Education Pathway (PCPEP), and many are independent prescribers. In addition to this, there are a number of clinical pharmacists working in general practice outside of these schemes. Whilst these pharmacists are able to work in a generalist setting, specific training in areas such as pharmacogenomics would allow them to work with more complex patients and provide specialist support, along with colleagues from other disciplines, in areas that are developing at pace. As community pharmacists undertake an increasingly clinical role, including independent prescribing (all pharmacists will soon graduate as Independent Prescribers) then the need for this more specialist support will become even more important and provide an expertise to allow addressing some of the clinical concerns highlighted in this paper at scale.

In August 2018, NHS England and NHS Improvement announced the launch of a new programme, supported by the **Pharmacy Integration Fund**, to test how NHS pharmacy and medicines optimisation/safety can be integrated into **Sustainability and Transformation Partnerships (STP) and Integrated Care Systems (ICS)** .

The Integrating NHS Pharmacy and Medicines Optimisation (IPMO) programme aimed to develop a framework which set out how to systematically tackle the medicines optimisation priorities for the local population in an STP/ICS footprint and use the expertise of pharmacy professionals in the strategic transformation of systems in order to deliver the best patient outcomes from medicines and value to the taxpayer.

Pharmacy is also a relatively untapped resource in terms of potential research capability. With over 11,000 community pharmacies and approximately 50,000 pharmacists, developing pharmacy research capability in all sectors could make a significant difference to research capacity across the system. As experts in research capability, clinical pharmacologists will have a leading role in supporting this development and helping pharmacists to become significant contributors to the research agenda.

The current proposal builds on this vision for integrated pharmacy networks and shows how they can be part of the wider medicines-focused workforce and research capability.

Case study 3: the SW London pilot clinical pharmacology service

A pilot clinical pharmacology service has been established as a collaborative project between clinical pharmacology and pharmacy to support medicines optimization across SW London. The clinical pharmacology team has been set up as a clinical and academic group, working in the NHS, in the Pharmacy and Medicines Directorate of St George's Hospital Trust under the direction of the Chief Pharmacist, and in St George's, University of London in the Centre for Clinical Education.

The clinical pharmacology team work closely with pharmacy, with healthcare practitioners across primary and secondary care, clinical geneticists, clinical research delivery staff, academic researchers, educators, service managers and many others. Their positioning allows them to link clinical practice with national medicines policy and research, and undergraduate education with postgraduate training.

This new, innovative service currently has a main focus on polypharmacy and multimorbidity but is also enabled to support pharmacogenomics and clinical research in SW London as the region refreshes and restarts after the pandemic. Clinical pharmacologists in the team have expertise in pharmacogenomics and are already contributing regionally and nationally to multidisciplinary teams (e.g. through representation on the NHS South East Genomic Medicine Service Alliance and joint NHS England and Genomics England pharmacogenomics working group) to development of guidelines and service descriptors. SW London clinical pharmacologists also conduct clinical research in areas including Mendelian randomization [e.g. PMID:33393675], pharmacokinetics, [e.g. PMID:32989452], polypharmacy [e.g. PMID:32058606], pharmacogenomics [e.g. PMID:31454087,33638977] and clinical trials [e.g. PMID:26917577].

Care for patients with complex polypharmacy and multimorbidity is mainly delivered in primary care. Therefore, the Clinical Pharmacology service supports primary care teams in the management of patients with complex polypharmacy and multimorbidity using a flexible model, developed in consultation with GPs and pharmacists across primary care. In practical terms, the Clinical Pharmacology Service is delivered by a 'clinical pharmacology team of the week', which provides a weekly clinic, advice and guidance service and education and training.

- Advice and guidance – pharmacists and GPs across SW London have same day (Mon-Fri) access to advice and guidance from the clinical pharmacology team through a secure system (kinesis) or via an NHS email link (stgh-tr.clinpharm.enquiries@nhs.net).
    - *Example queries*: how to taper diazepam for a patient who had been taking it for over 50 years; management of patient on multiple pain medicines; persistent hypokalaemia as an adverse drug reaction to multiple medications; combination therapies avoiding drug interactions
- Multidisciplinary team meetings – clinical meetings with primary care network (PCN) pharmacists and GPs to discuss the management of patients with complex polypharmacy. Video conferencing has made it easier to deliver this across the integrated care system
    - *Examples*: Fortnightly case meetings with Wandsworth PCN pharmacists, 'deep dives' with Wandsworth GPs, Richmond PCN pharmacist joint supervision meetings
- Secondary care liaison – rapid liaison with multiple secondary care organ-based specialists to resolve complex prescribing issues
    - *Example*: Cardiology and neurology input to discussion around stroke aetiology and need for anticoagulation in patient with complex multimorbidity including ischaemic and embolic strokes, falls and anaemia
- Virtual reviews – systematic assessment of diagnoses and medicines with recommendations to support healthcare professionals in discussing complex medicines with families
    - *Example*: A simulated clinical pharmacology structured review as provided by this service
- Direct patient reviews – clinic to see patients referred from primary or secondary care
    - *Examples*: Specialist review requested by PCN pharmacist or GP after structured medication review or consultation, by secondary care doctors or pharmacists (e.g. where polypharmacy is thought to be contributing to multiple admissions) or by patients

- Education and training – case-based training on management of complex polypharmacy
    - *Examples:* 'Tackling problematic polypharmacy' webinar through the SW London training hub (https://www.youtube.com/watch?v=pUYSvH9ZlBo); GP trainee case based training session on managing polypharmacy, British Pharmacological Society polypharmacy workshop

Provision of a specialist service creates an environment for knowledge generation and research. The team is currently researching the barriers and enablers to 'tailoring' medicines for patients with polypharmacy on the ground in SW London and how service innovation can address these to make a real difference for patients. They are collaborating in this with Professors Joanne Reeve and Tess Harris, Professors of Primary Care Research. They are also building a shared learning resource to capture multi-team consensus decision making around deprescribing – an area where there is poor evidence to support practice.

Service impact

Direct patient care: The benefits of a specialist polypharmacy clinic include a reduction of 4 ((2-5), median interquartile range) medicines per patient, reduction in adverse drug reaction symptom burden and an annualised cost saving of around £200 per patient [Bennett et al Future Healthc J Oct 2020, 7(3) 208-211]. Around 400 patients per year (8 patients per week) can currently be seen in the polypharmacy clinic (medicines cost savings ~£82,000 per year), which can be expanded as demand increases.

Wider impact: The service has potential to have impact far beyond that seen in a weekly clinic. Structured medication reviews (SMRs) - a '*comprehensive review of a patient's medication, taking into consideration all aspects of their health*' – are a new PCN service requirement that can improve experience of and quality of care and reduce medicines related harm and waste. In SW London there are at least 66,000 people (those taking ≥10 medicines) who would benefit from a structured medication review. There is a growing workforce of clinical pharmacists (across 168 practices, 36 PCNs and 6 boroughs), who have mostly been redeployed to the COVID vaccine effort but are now returning to clinical practice and turning their attention to SMRs. Support, education and training for this workforce by the SW London polypharmacy service will speed the implementation of SMRs. The value that PCN pharmacists place on this service is exemplified by a recent email from a colleague - '*as our vaccine clinics are starting to wind down and we transition back to "normal practice" we are keen to resume our polypharmacy meets with you. High on the PCN agenda is Structured medication reviews and the focus on polypharmacy as always is paramount!'*

Service evaluation

This is embedded in the clinical pharmacology service pilot and the evidence collected will develop as the service continues and expands. Measures will include:

Short term: Volume of referrals, feedback from patients, carers and healthcare professionals
Medium term: Patient outcomes – health status, adverse drug reaction burden; Service outcomes – value of education and training, change in how 'polypharmacy/SMR enabled' the workforce is; Increase in delivery of SMRs across SW London
Long term: Change in polypharmacy prescribing comparators, showing less problematic polypharmacy

Extending the model

The clinical pharmacology team in SW London is well set up to deliver advice and support through the channels developed for the polypharmacy service as pharmacogenomics services are developed in the SW London integrated care system. Pharmacogenomics training is part of the clinical pharmacology specialist training curriculum.

SW London clinical pharmacologists lead the St George's BSc in Clinical Pharmacology, a new degree that aims to produce the next generation of clinical pharmacology scientists and clinical trial specialists. The degree has arisen from collaborations between NHS/university clinical pharmacologists and employers across the drug development landscape (including Pharma, contract research organisations, small and medium enterprises, regulatory affairs, NHS clinical trials units and NIHR research delivery). The novel design of this degree ensures that students

learn about how drugs are discovered and developed alongside how they are used in healthcare. These collaborative approaches are essential to ensure that the strong relationships between industry, universities and healthcare that have emerged in the pandemic are maintained for the development of new medicines in the future.

Overall, the way the medicines-focused workforce operates in SW London demonstrates the potential of the model we have presented.

Case study 4: how clinical pharmacology embedded research in primary care during COVID-19

The AGILE trial clinical pharmacology team pioneered expanding early phase research into primary care and the community during COVID-19. Beyond the pandemic, primary care is where the majority of disease burden lies and so creating platforms that are not reliant on recruitment through secondary care removes barriers to patient engagement with research. Moreover, widening participation in this way may address unacceptable health inequalities, ensuring recruitment is representative of the population for which the medicines are being developed. Investing in clinical pharmacology supports such research to go ahead because clinical pharmacologists are qualified to be principal investigators on first in human trials, mitigating against the higher risk associated with early phase research.

> *Through AGILE, we are filling a gap in potential treatments for COVID-19 by looking earlier in the disease – trying to stop people from getting sick to begin with. The pandemic has challenged us to think creatively about how we do research. We have been actively recruiting patients by embedding our work into primary care and the community - chasing up on positive test results and recruiting people with early symptoms.*
>
> *We've seen lots of benefits for the patients and have been able to refer those who need further care onto services through the trial rather than putting additional burden on A&E departments. We've seen tremendous buy in from patients and primary care – even to the extent that we set up a portacabin in a GP car park! Our experience is that patients are much more aware of the benefits of research now and want to get involved. We have noticed that the healthy volunteer recruitment is much higher than usual, and we are starting to see this transferring over to other disease areas too.*
>
> *There's a real opportunity to build on this, and with more clinical pharmacologists the UK could do even more of this work.*
>
> - Dr Richard Fitzgerald, Director of the NIHR Royal Liverpool and Broadgreen Clinical Research Facility, consultant clinical pharmacologist, and one of the leads on the AGILE trial.

Case study 5 – blueprint for how a clinical pharmacology service could enhance drug discovery and development capability in the NHS

In figure 2, we have illustrated the contribution that the clinical pharmacology service could make in embedding drug discovery and development, including precision medicine, across the NHS.

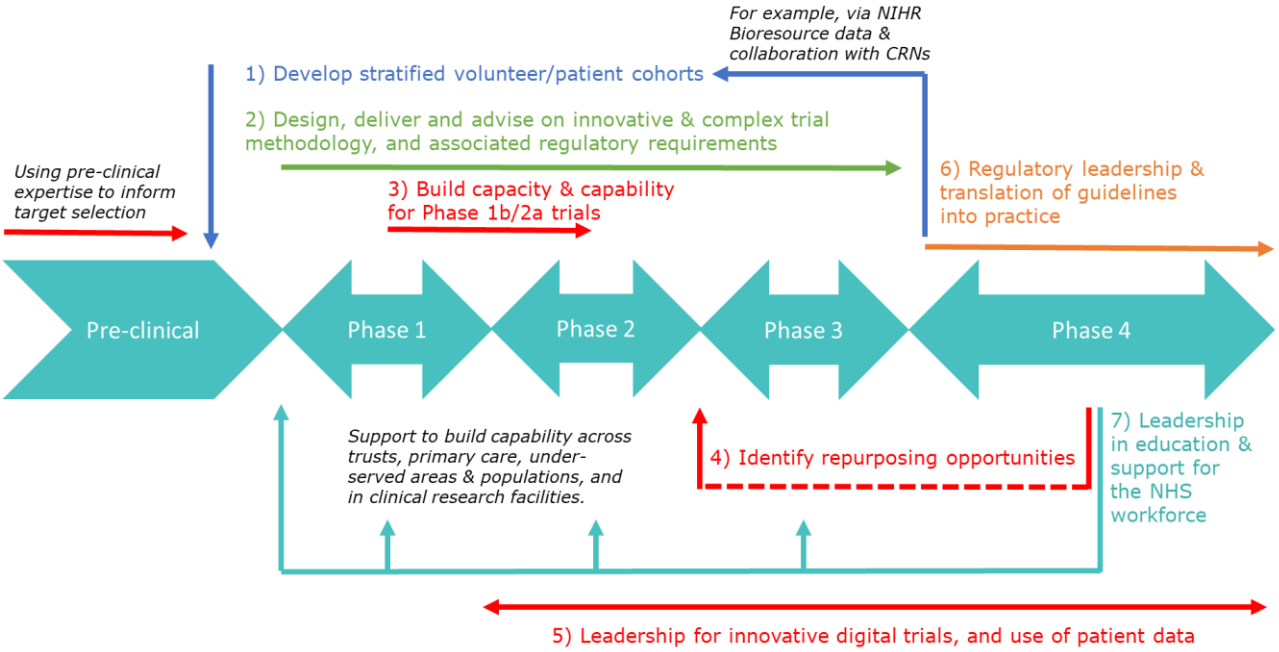

Figure 2. Blueprint for how a clinical pharmacology service can build capability for drug discovery and development in the NHS. *Effective trial design and delivery requires a multidisciplinary team. A clinical pharmacology service would work in partnership with disease specialists, genomic experts, research delivery staff, and clinical trial statisticians (in the NHS and industry) to design, deliver and advise on trial methodology and associated regulatory requirements (including hybrid and adaptive designs, master protocols and efficient platform trials) that meet the needs of the researcher and patients in the real world – including reaching the patients who need the benefit by training and supporting healthcare professionals and researchers to deliver research in under-served areas and populations. The service can help ensuring that the right patient receives the right medicine through stratification, of disease embedded into trials, and in clinical practice by using genomics and other biomarkers to guide treatments to specific populations, including the development and implementation of companion/complementary diagnostics – and reducing harms and improving efficacy through pharmacogenomics and therapeutic drug monitoring approaches. Clinical pharmacologists also have the pre-clinical expertise to identify the most promising, and transformational therapeutics, and to deliver the riskier early phase trials that are needed to test them safely.*

This model building on learnings from the contributions of clinical pharmacology during the COVID-19 pandemic. For example, the UK RECOVERY trial, jointly led by Professor Peter Horby and Professor Martin Landray, (which demonstrated the benefits of dexamethasone, and tocilizumab, the Regeneron monoclonal antibody combination, and failed to show a benefit of hydroxychloroquine, aspirin, ritonavir/lopinavir and colchicine) has influenced COVID-19 treatment worldwide. The UK COVID Therapeutics Advisory Panel (UK-CTAP) advises the Chief Medical Officer on drugs that can be prioritised for the major UK platform trials (including RECOVERY, PRINCIPLE, REMAP-CAP, AGILE, PROTECT and HEAL) and has three clinical pharmacology members: Professor Sir Munir Pirmohamed, Professor Duncan Richards and Professor Ian Hall. The UK AGILE trial platform was set up by clinical pharmacologists at the University of Liverpool, principally, Professor Saye Khoo, Dr Richard Fitzgerald and Dr Lauren Walker, and is a novel adaptive phase I/IIa trial platform to evaluate novel compounds for the treatment of COVID-19. Professor Mark Caulfield (Chief Scientist for Genomics England), worked with a UK wide genomic consortium (GENOMICC) to run whole genome sequencing in patients with COVID-19 to identify new therapeutic opportunities. Professor Sir Munir Pirmohamed (Chair of the Commission on Human Medicines) and other clinical pharmacologists including Professor Jamie Coleman were responsible for advising the MHRA, ensuring COVID-19 vaccines meet the highest standards of safety, effectiveness and quality. Professor Sir Munir Pirmohamed (with HDR-UK) led development of data infrastructure to support research following the roll-out of vaccines.

Further, the clinical pharmacology service in SW London (case study 2) is made up of research leaders who contribute to clinical trial design and delivery and is well-positioned to support the education and training of the wider workforce through the ICS model shown in figure 1 of the main paper.

The team have also demonstrated how clinical pharmacologists can make a distinctive contribution to the NHS research team, for example by:

- Acting as Principal Investigators for earlier phase clinical trials, where medicines are more experimental.
    - *Example:* PI for TACTIC E, a clinical trial testing whether novel therapeutic agents or novel combinations of approved agents can prevent the development of severe symptoms in patients hospitalised with confirmed COVID-19.
- Designing and delivering pharmacokinetic studies in the NHS
    - *Example*: ABDose, A study of β-Lactam antimicrobial pharmacokinetics and target attainment in critically ill patients aged 1 day to 90 years
- Doing research in generalist settings
    - *Example*: SW London clinical pharmacologists have contributed to research across acute medicine, general medicine and intensive care medicine settings during the COVID pandemic. The positioning of their specialist clinical service at the interface between primary and secondary care and with close links with PCN pharmacists equips them to support delivery of clinical trials in primary care

Case study 6: the scientific workforce in the medicines-service network

Scientific and research skills are central to the medicines service network. There is a particular opportunity to develop the necessary specialist services for pharmacogenomics and clinical research. Developing career pathways that are standalone (e.g., to Clinical Scientist Consultant in Pharmacogenomics; Clinical Pharmacology Scientist), and allow integration with other training programmes (e.g., out of programme training for doctors and pharmacists to build specialist skills) is an opportunity to develop rewarding and flexible careers.

The full clinical scientist career pathway offers a route to consultant, and the opportunity to build capacity and capability in specialist skills across the ICS at all levels of training.

Example: level 8 workforce planning for pharmacogenomic scientists

Higher Specialist Scientist Training (HSST) is a five-year, level 8 workplace-based training programme that provides opportunities for clinical scientists to train to become eligible to apply for consultant clinical scientist posts. There will be a need to invest in the non-medical pharmacogenomics and workforce and HSST training offers a valuable route. It would also potentially be a route for building the non-medical clinical research workforce.

We have modelled on obtaining 70-100 specially trained pharmacogeneticists by 2031, based on our knowledge of workforce requirements from ongoing scoping work e.g. via the genomic implementation and workforce programmes running via NHSEI and HEE, and recommendations emerging from the BPS-RCP joint working group.

The table shows a route to building this workforce based on reaching NHS AFC pay band 8a and inclusion of trainer salaries (band 8b) and training grants (£16K per trainee). This would need to be adjusted to account for medical salaries should medical professionals wish to use this route for out of programme training. This has been modelled for England only, but could be expanded.

HEE /GLH Training region	*EOE*	*Lon*	*Mid*	*NE Yorks*	*NW*	*SE*	*SW*	Cost over 5 years for 2 HSST in pharmacogenomics per HEE/GLH if **FULLY FUNDED** N = 14 / year N **= 70 by 2031**	Cost over 5 years for HSST in pharmacogenomics per HEE/GLH **50% FUNDED** N = 14/ year N = **70 by 2031**	Cost over 5 years for 3 HSST in pharmacogenomics per HEE/GLH **50% FUNDED** N = 21 N = **105 by 2031**
HSST in PGx 2022-27	2/3	2/3	2/3	2/3	2/3	2/3	2/3	£ 4, 795,112	£ 2,957,570	£ 4,436,355
HSST in PGx 2023-28	2/3	2/3	2/3	2/3	2/3	2/3	2/3	£ 4, 95,112	£ 2,957,570	£ 4,436,355
HSST in PGx 2024-29	2/3	2/3	2/3	2/3	2/3	2/3	2/3	£ 4, 95,112	£ 2,957,570	£ 4,436,355
HSST in PGx 2025-30	2/3	2/3	2/3	2/3	2/3	2/3	2/3	£ 4, 95,112	£ 2,957,570	£ 4,436,355
HSST in PGx 2026-31	2/3	2/3	2/3	2/3	2/3	2/3	2/3	£ 4, 95,112	£ 2,957,570	£ 4,436,355
TOTAL COST								23, 975,560	14,787,850	22,181,775
Trainers in pharmacogenomics- 8B	1	1	1	1	1	1	1	£ 517,519.8	£ 517,519.8	£ 517,519.8
TOTAL								**£ 24, 493,080**	**£15,303,369**	**£22,697, 194**

The HSST scheme has broad scope and could be used to develop level 8 roles that meet the broader scientific needs of the medicines-service network e.g. in clinical research.

Example: level 7 Clinical Pharmacology Scientist qualification

The Clinical Pharmacology Scientist apprenticeship was developed by the Clinical Pharmacology Skills Alliance. The Alliance built an employer-led 'Trailblazer' group to deliver the programme in response to the UK government's Life Sciences Industrial Strategy – and the need for these critical skills has been reinforced by the new Life Sciences Vision.

The apprenticeship will provide a very specific training track, so it is a clear pathway into a clinical pharmacology scientist career with a recognised qualification. It was developed in response to employer concerns that clinical pharmacology training tends to be done 'on the job' and training needs are not clearly defined – and a lack of a clear career pathway.

The scheme aims to help potential clinical pharmacology scientists become aware of and access the many opportunities to play a leading role in clinical research and clinical trials within academia, industry and the NHS. This apprenticeship aims to help people to move between commercial to public sector research – these types of moves are pivotal for the success of a vibrant, connected sector. Training these people will help the UK be even more attractive as a research base, and improve clinical trial capacity.

Full details of Clinical Pharmacology Scientist roles are given in case study 1, but in brief the purpose of the occupation is to design, analyse, interpret and report clinical research and clinical trials. Training these scientists at level 7 provides a potential pipeline into HSST Training at level 8.

Spending review 2021: invest in clinical pharmacology to create the workforce of the future.

1. Executive summary

Investment in the UK clinical pharmacology workforce is an investment in the NHS of the future, helping build connectivity and synergy for delivery of the NHS Long-Term Plan[1], government vision for Clinical Research Delivery[2], and government vision for UK Life Sciences. The NHS Long-Term Plan promises a joined-up, coordinated, and more personalised approach to patient care. As part of this holistic, whole-person centred vision the plan recognises that the NHS must do more to reduce health inequalities and maximise prevention. It recognises that elderly people have complex healthcare needs (particularly in the management of multiple long-term conditions and complex polypharmacy) that will peak in the next decade. It sees the potential of genomic medicine, and the opportunity of a thriving medical science and innovation base that can deliver transformative treatments. Over the next 10 years, the NHS must invest in the workforce of the future - characterised by multi-professional teams working in integrated care pathways, embedding research into care and taking an evidence-based approach to the use of medicines. **Clinical pharmacology** is a small specialty that, through expert knowledge and partnership working, creates a multiplier effect in exactly these areas.

Clinical pharmacologists are **expert generalists**, using knowledge of how medicines work and affect the body to provide integrated assessment and care, including for complex polypharmacy. They are **research leaders** who investigate the mechanism(s) of action of potential therapeutics, translating these into clinical use through the design and delivery of innovative trials. They are **precision medicine leaders**, supporting stratification of trials and implementation of pharmacogenomics in the NHS. They are **regulatory and policy leaders**, ensuring safety, effectiveness, quality and value through regulatory evaluation, pharmacovigilance and health technology assessment. They are **education leaders**, supporting the NHS workforce to be skilled in the use of medicines and to engage in research. Clinical pharmacologists can help deliver the Long-Term Plan through leadership in:

Implementation of genomic medicine

To help ensure that the right patient receives the right medicine, clinical pharmacologists can:

- Lead implementation of pharmacogenomics (including education and training) to reduce harms and improve efficacy.
- Stratify by disease, genomics and other biomarkers, embedding this into trials and clinical practice to guide treatments to specific populations.
- Support functional genomics to improve the identification of potential drug targets

Increased capacity and capability in clinical research & life sciences

The development of new medicines and treatments is essential to address unmet clinical need, bringing benefit for both society and the UK economy. Clinical pharmacologists can:

- Advise on trial methodology and regulatory requirements, including hybrid and adaptive designs, digital and decentralised trials, master protocols and efficient platform trials.
- Deliver and support more innovative early phase trials.
- Lead use of electronic health record data, gaining insights via state-of-the-art analytics.
- Support and train the wider NHS workforce, so more healthcare professionals (including those in under-served areas) can reach patients with research.

Tackling multimorbidity and complex polypharmacy

An ageing population means that complexity of care and medicines management pose a major challenge for the NHS. In partnership with pharmacy, clinical pharmacologists can:

- Improve the safe, effective and cost-effective use of medicines[3] e.g., in complex polypharmacy, by decreasing adverse drug reactions and prescribing errors, and improved prevention and management of drug-drug interactions.
- Support education and training, so the NHS workforce is skilled in the use of medicines.

We propose investing <u>£57.5m by 2031 to double the number of clinical pharmacologists</u> in the NHS (to 215 consultants and 87 training posts) – people that the NHS needs to create the workforce of the future.

2. Current CPT distribution (consultant & pipeline numbers by region)

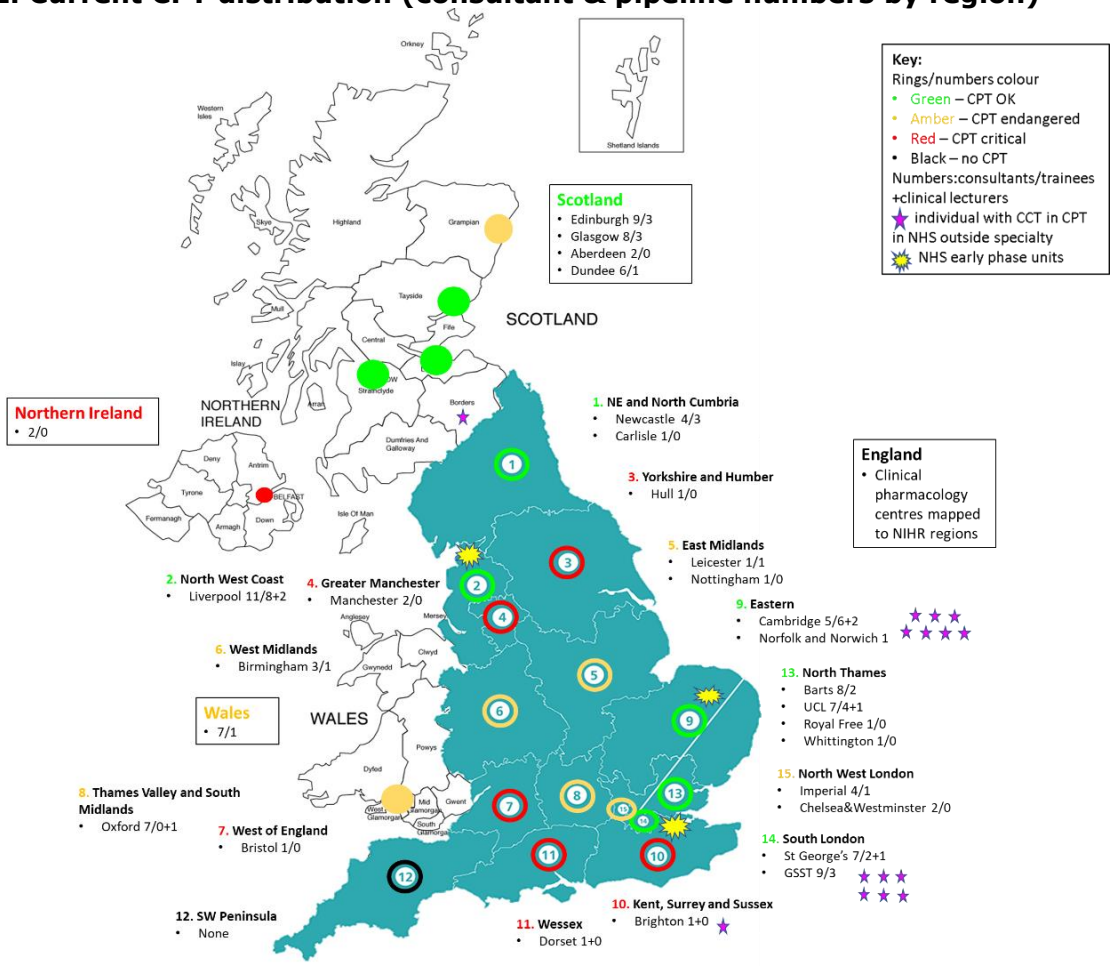

Fig 1. Clinical pharmacology & therapeutics (CPT) in the NHS mapped to the 15 NIHR clinical research network regions in England. Status codes: "good" (green; 6 regions, including Scotland as one region, but the centre in Dundee is amber); "at risk" (amber 4 regions); "critical" (red 5 regions); "completely absent" (black). Status of Scotland, Wales and Northern Ireland shown in separate boxes. Numbers indicate consultants/trainees + academic clinical lecturers in CPT. Individuals with a CCT in CPT not working in the specialty are shown as pink stars & early phase units with CPT engagement/recruiting NHS patients are shown as yellow splashes. ***Total consultants = 105 (13 new CCT in 2020, 12% growth).***

HEE training region	*East of England*	*London*	*Midlands*	*North east & Yorkshire*	*North west*	*South east*	*South west*	*Scotland*	*Wales*	*NI*	**Total**
ACF for 21/22		3			1						4
ACF IM1		1									1
ACF IM2		4			1						5
ACF IM3		1									1
Frozen - IM transition		6						1			
ST3	1	1	2	3					1		8
ST4		2			1			2			5
ST5	2	2			4			3			11
ST6	2	1									3
ST7		1			1			1			3
C lecturer	3	2			3						8
Total NIHR	**0/3**	**9/2**	**0**	**0**	**2/3**	**0**	**0**	**NA**	**NA**	**NA**	**11/8**
Total NHS	**5**	**13**	**2**	**3**	**6**	**0**	**0**	**7**	**1**	**0**	**37**

Figure 2. Current CPT training pipeline. We were successful in appointing a large cohort of London trainees to consultant posts in 2020/21 and are not able to recruit to our specialty until 2022 due to the IM transition.

3. Workforce strategy for UK clinical pharmacology

Phase	Detail
Status (current)	*Total number of filled CPT training posts in the NHS = 30 (ST3-ST7, *7 frozen)* *Total number of CPT consultants = 105*
1. Secure (2021-22) *Recommission posts lost in 2018.* *Return posts frozen in 2021.* *Reactivate CPT capacity in the NHS.* *Recruit new consultants to keep them in the specialty*	**StR training posts (12 new posts)** 1.1 In 2021, Recommission 5 training posts lost in 2018, reallocate to 'amber' areas in figure 1. 1.2 In 2022, Prevent any post loss due to IM3 training and ensure that all 7 posts frozen during the IM transition are recruited to in 2022. **Consultant sessions** 1.3 Reactivate existing CPT capacity in the NHS, by buying out PAs for clinical pharmacologists who are currently working outside the specialty, and also buying out PAs for existing consultants to support new fellows/trainees - plus backfilling the NHS service gap that would result. **Consultant posts (5 new posts)** 1.4 Funding for 5 new CPT consultant posts (3 in 2021, 2 in 2022) to ensure jobs for those reaching CCT in this period (see figure 2).
Status (projected, end August 2022)	*Total number of CPT training posts in the NHS = 42 (ST4-ST7)* *Total number of CPT consultants = 110*
2. Strengthen (2023 - 24) Sow seeds, by pump-priming with new fellowship post bids Feed the pipeline, with new training posts. *Recruit new consultants to keep them in the specialty.*	**Fellowships (20 fellowships)** 2.1 Allocate 20 fellowships to begin pump priming (14 in 2023, 6 in 2024) **StR training posts (23 new posts)** 2.2 Allocate 15 new training posts to green areas to strengthen clinical pharmacology representation in Integrated Care Systems (ICSs). 2.3 In 2023-4, Allocate 8 new training posts to strengthen red/amber areas. **Consultant posts (19 new posts)** 2.4 Funding for 19 new CPT consultant posts in 2023-24, to ensure jobs for those reaching CCT in this period.
Status (projected, end August 2024)	*Total number of CPT training posts in the NHS = 65 (ST4-ST7)* *Total number of CPT consultants = 129*
3. Grow (2025– 2031) Stabilise pump priming, continuing to support fellowships, but fewer. *Recruit new trainees, and new consultants to keep them in the specialty.* Re-epithelialise, turning all areas green & ensuring all ICSs have CPT support.	**StR training posts (22 new posts)** 3.1 In 2025-7, Allocate 22 new training posts, aiming to turn all areas green and boost ICS coverage. **Fellowships (16 fellowships)** 3.2 Allocate 16 fellowships to continue pump priming (6 in 2025, 3 in 2026, 5 in 2027, 2 in 2028) **Consultant posts (124 new posts)** 3.3 Funding for 124 new CPT consultant posts in 2025-31, to ensure jobs for those reaching CCT in this period.
Status (projected, end August 2031)	***Total number of CPT training posts in the NHS = 87 (ST4-ST7)*** *Total number of CPT consultants = 253* ***Total consultants included projected retirement = 215***
4. Maintain (2031 onwards)	4.1 Expectation is that each new consultant post added during phases 1-3 would transition to business as usual after 3 years of central funding. In phase 4, we would expect all new posts to be paid for by employers in accordance with business need – phases 1-3 having helped raised awareness and experience of the value of CPT. 4.2 NHSEI/HEE/CPSA to review pipeline investment against need/demand.

**Clinical pharmacology networks will support the strategy: by twinning strong centres with developing ones, by connectivity via fellowships, and by continuing grassroots visibility & engagement activities.*

Total cost = £57.5 million (£5.2m per year, 2021-31)

£27.24m for 57 new StR posts
£16.02m for 36 fellowship posts
£14.24m for 148 consultant posts (assuming funding continued by employer after 3-years, including PAs to buy time from existing consultants to support 1.3, and allowing for retirement)

Case study 1: Precision & genomic medicine
About 90% of drugs only work in 30-50% of patients, while approximately 6.5% of all admissions to our hospitals are due to adverse drug reactions. Precision medicine approaches allow the targeting of drugs to those who will respond favourably, thereby improving the benefit-risk ratio of existing drugs, and improve the development of new drugs. Genomics is the mainstay of precision medicine at present, and there is a need to mainstream genomics in the NHS.

Clinical Pharmacology has been playing a leadership role in pharmacogenomics, the study of how genetic variation affects drug response. Clinical Pharmacologists have worked with NHS England to identify gene-drug pairs which are ready for implementation into the NHS, including eligibility criteria for testing. The British Pharmacological Society is currently working with the Royal College of Physicians to define the need for pharmacogenomics in the NHS, including the educational, training and evidence requirements. This includes input from Health Education England in order evaluate the resources and learning needs to increase the skills of the workforce. In addition to implementation, clinical pharmacology continues to play a major role in discovery pharmacogenomics, including the use of polygenic risk scores, which will act to produce the evidence base to expand pharmacogenetic testing with the NHS genetics test directory.

Case study 2: Clinical research & life sciences
Investment in clinical pharmacologists will enable research in the NHS, in line with the government's vision for clinical research delivery[2]. For example, the British Pharmacological Society is partnering with the Royal College of Physicians to produce introductory e-learning on research to support education and confidence of the wider NHS workforce. The contributions of clinical pharmacology to research were powerfully illustrated[4] as part of the UK's response to the COVID-19 pandemic. Clinical pharmacologists used their expertise in evaluating risk-benefit, through a structured approach to level of evidence, mechanism, dose and safety to help deliver proven treatments and vaccines, and to support patients and clinicians to engage with clinical research on an unprecedented scale.

The UK RECOVERY trial, jointly led by Professor Peter Horby and **Professor Martin Landray,** (which demonstrated the benefits of dexamethasone and tocilizumab, and failed to show a benefit of hydroxychloroquine) has influenced COVID-19 treatment worldwide. The UK COVID Therapeutics Advisory Panel (UK-CTAP) advises the Chief Medical Officer on drugs that can be prioritised for the major UK platform trials (including RECOVERY, PRINCIPLE, REMAP-CAP, AGILE, PROTECT and HEAL) and has three clinical pharmacology members: **Professor Sir Munir Pirmohamed**, **Professor Duncan Richards** and **Professor Ian Hall**. The UK AGILE trial platform was set up by clinical pharmacologists at the University of Liverpool, principally, **Professor Saye Khoo**, **Dr Richard Fitzgerald** and **Dr Lauren Walker**, and is a novel adaptive phase I/IIa trial platform to evaluate novel compounds for the treatment of COVID-19. **Professor Mark Caulfield** (Chief Scientist for Genomics England), worked with a UK wide genomic consortium (GENOMICC) to run whole genome sequencing in patients with COVID-19 to identify new therapeutic opportunities. **Professor Sir Munir Pirmohamed** (Chair of the Commission on Human Medicines) and other clinical pharmacologists including **Professor Jamie Coleman** were responsible for advising the MHRA, ensuring COVID-19 vaccines meet the highest standards of safety, effectiveness and quality. **Professor Sir Munir Pirmohamed** (with HDR-UK) is leading development of data infrastructure to support research following the roll-out of vaccines.

Case study 3: Multimorbidity and complex polypharmacy
As the population ages, people increasingly have multiple co-existing chronic diseases (i.e., multimorbidity)[5], necessitating the use of multiple medicines - over 1 million people take 8 or more medicines per day – this is referred to as polypharmacy. As the number of medications increases so does the possibility of drug interactions and adverse drug reactions resulting in hospital admission and further morbidity[6,7]. Structured medication reviews are being implemented in primary care to optimise medicines to improve benefit and reduce the risk of harm. Barriers to tailoring medicines for patients with polypharmacy include lack of guidelines and permissions, lack of professional skills and confidence, lack of time and priority.

The Polypharmacy Service Consortium is a collaborative venture between Clinical Pharmacologists, Clinical Pharmacists, Geriatricians and General Practitioners with a vision that "every medicine brings worthwhile benefit to the person for whom it is prescribed". Members of the consortium include Clinical Pharmacologists in South West London who are working with primary and secondary care colleagues across the integrated care system to break down the barriers to tailoring medicines for patients with polypharmacy. Their innovative service includes rapid advice and guidance, face-to-face and virtual patient reviews, multi-professional meetings, and training and network development. This service has been developed in collaboration with primary care pharmacists and GPs to meet their requirements in managing patients with complex polypharmacy. Examples of areas where this service is already helpful include: managing complex multimorbidity where patients are cared for by multiple specialists, optimising medications for chronic pain, supporting withdrawal from prescribed medicines, discussing medicines optimisation with families where patients no longer have capacity.

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