

A process to implement accredited registration for Clinical Research Practitioners

Position paper including consultation response

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Purpose of the initiative

The purpose of this project is to establish a process that will deliver an Accredited Register for Clinical Research Practitioners (CRPs). The project is being led by the NIHR Clinical Research Network (CRN) and is being delivered in collaboration with the Academy for Healthcare Science (AHCS). Under the AHCS Accredited Registers programme, practitioners on the register are able to display the Accredited Register quality mark of the Professional Standards Authority (PSA) to show that their robust standards have been met.

The difference that accredited registration will make for Clinical Research Practitioners is that their skills and expertise can be assured to patients, service users in social care, participants in and other settings and the public. In addition, the skills and expertise of individual Clinical Research Practitioners can be better valued and developed and, as a group, the professional identity of Clinical Research Practitioners will be strengthened within the delivery of research and the health and social care workforce.

Summary of the approach

Background

A proposal outlining the process and value of establishing accredited registration for CRPs was reviewed initially by the Department of Health, December 2017 and received approval from the CRN Executive to proceed.

The proposal described a staged approach for progression towards an accreditation process for Clinical Research Practitioners (CRPs). The proposed actions are aligned with current policy and practice in professional standards and the development of professional identity in comparable occupational groups, particularly those that are part of the Healthcare Scientists Careers Framework.

The research delivery workforce is expanding and evolving in response to rapid change across the NHS and wider health and care research landscape and Clinical Research Practitioners form a valued and essential part of this workforce. The term Clinical Research Practitioner (CRP) serves as an umbrella title for a family of roles in research delivery that have a patient-facing element and where the post holder isn't currently registered to a healthcare profession. The post holder will often be a degree graduate, though not always, who may be working to deliver research in a variety of different settings, including community and social care environments and as part of public health initiatives.

CRP Directory

The CRP Directory was launched in September 2018 and is administered by the Academy for Healthcare Science (AHCS). The CRP Directory offers infrastructure to a workforce community that is growing and is committed to developing their professional identity in clinical research delivery. Those applying to join the CRP Directory are asked to confirm that their role involves direct contact with study participants and activity in clinical environments and other health and social care research settings. The CRP Directory has been established primarily to bring together those in research delivery who are not currently registered professionals but who may be interested in becoming a registered professional. The £10 annual joining fee supports this infrastructure as a platform for coordinated communication with this dispersed virtual community and will be deductible from the fee to become registered (when established), which would then be £20 rather than £30 for the first year.

Benefits of the CRP Directory to support registration for individuals

Being listed on the CRP Directory means being directly informed and involved in how this research delivery profession is being defined as part of the initiative to establish CRPs as a registered profession, accredited by the Professional Standards Authority and regulated by the Academy for Healthcare Science. Tangible benefits for individuals listed on the CRP Directory are intended to support this focus on developing the professional identity and currently include:

- public visibility of your listing on the Directory, which is searchable by name and Town/City of current employer
- identify other CRPs to network locally/regionally
- receive newsletters and invitations to participate in surveys
- notification of meetings/workshop activities and updates from these
- direct consultation on the development of scope and standards for accredited registration, including criteria to become registered and ongoing practice
- access to dedicated community forum space offering relevant learning resources including the value of professional identity, professional regulation in healthcare, changes in the clinical research landscape and enhancing the visibility of roles in the research delivery team

Pending approval from the Professional Standards Authority for accreditation of the proposed registration process and beyond, the CRP Directory will continue to exist alongside the register, serving as a platform to support those working towards an application and/or looking to develop their professional identity in clinical research delivery more generally. Those listed and maintaining intent to register are therefore encouraged to proceed with the renewal process.

Current progress and timelines

Winter 2020: The AHCS submitted a notification of change to the Professional Standards Authority (PSA). The Authority will review the proposed changes to ensure ongoing compliance with the Standards for Accredited Registers.

Feb-April 2020: Pilot of application process begins with early adopters seeking registration

March 2020: Engagement event and continuing engagement activity to promote understanding

Spring 2020: *provisional timeline* - accredited registration for CRPs is agreed and operational

The development of Scope of Practice and Standards of Proficiency

The expertise and knowledge of individuals and communities from across the NIHR infrastructure has been critical to the development of this initiative. Workshop activities contributed to the iterative development of a draft scope of practice and standards of proficiency for Clinical Research Practitioners, which articulate both the expectation of registered individuals and the distinct knowledge and skill set that identifies the emerging profession. Survey of the CRP Directory Community has provided insight on education, training and experience and helped to define the requirements for registration and the expectations of clinical knowledge and skills that are captured within the scope of practice.

Consultation and response

The draft scope and standards documents were made available via the CRP Directory website in the autumn of 2019. Feedback was received from 112 respondents including CRPs, R&D managers, workforce leads and others with an interest in the research workforce and this development. Responses were favourable with 70% of respondents indicating their support for the implementation of an Accredited Register as a welcome and necessary development. The initiative was on the whole seen as relevant and covering the range of activities that CRPs carry out. There was also strong agreement that the register will increase recognition of the professional identity of CRPs and that the register provides an opportunity to better value and develop skills. There was less certainty expressed about how the register will provide assurance about the skills and expertise of CRPs to patients and the public. This uncertainty was also evident in some of the comments submitted and highlighted that there is still a lack of understanding about how accredited registers work within the overall regulatory landscape and some more specific concerns about Clinical Research Practitioners.

An analysis of comments where reservations were expressed shaped the final development of the Scope of Practice and Standards of Proficiency and this also informed a continuing engagement activity in order to promote understanding of how accredited registers work.

1. A greater emphasis on the boundaries of the CRP role within clinical research delivery and a clear articulation that CRPs perform their duties as part of a team and that the role is distinct from a nurse or nurse associate role.
2. The requirement to act from within their existing knowledge base that will vary according to the requirements of each research protocol, local policy and will involve active liaison with statutory registered professionals.
3. Concerns about the absence of a national training pathway and the possible impact of local variation in education and training routes were expressed. The development of the register has the potential to influence the development of a consistent and more standardised national approach to education. The process of working towards registration will provide opportunities to contribute to an informed view about possible shortfalls in education and training and how these can be addressed at national level as well as

highlight the opportunities that are available. Documenting training and educational achievements will be part of the requirements for registrants and the use of recognised competency frameworks at local level also provides a framework for skill development.

4. A number of responses raised concerns about a perceived lack of rigour of the proposed register in comparison with statutory registers. In response the NIHR CRN s holding an engagement event to include both the PSA and AHCS to provide an opportunity for strategic leaders to understand how accredited registers function as part of the existing regulatory landscape. This includes articulation of external audit requirements and how the register will be governed. AHCS Registrants are asked to renew their declaration annually to confirm that they continue to meet the relevant Standards of Proficiency their registration through evidencing their continuing professional development.

Eligibility to Register

Requirements of applicants seeking registration have been defined as part of the Quality Assurance Framework for the CRP Register. Applications are being piloted currently for implementation locally through a standardised process.

The requirements include essential education and training together with a portfolio of evidence to be assessed by the Academy for Healthcare Science. The portfolio of evidence will include a critical narrative of 3 specified reflections and documented assurance of practice development, statutory and mandatory training and competence with respect to an organisational competency framework that is aligned with the [NIHR Integrated Workforce Framework](#).

Benefits

Establishing accredited registration for Clinical Research Practitioners (CRPs) is expected to deliver an initial set of benefits that will provide a firm foundation of expectations and standards that demonstrate a commitment to public safety and promote public confidence in CRPs as a professional group.

A right-touch (proportionate) benefits management and realisation approach will demonstrate success by specific measures for the immediate and longer term, within the clinical research delivery environment and the wider health and social care context.

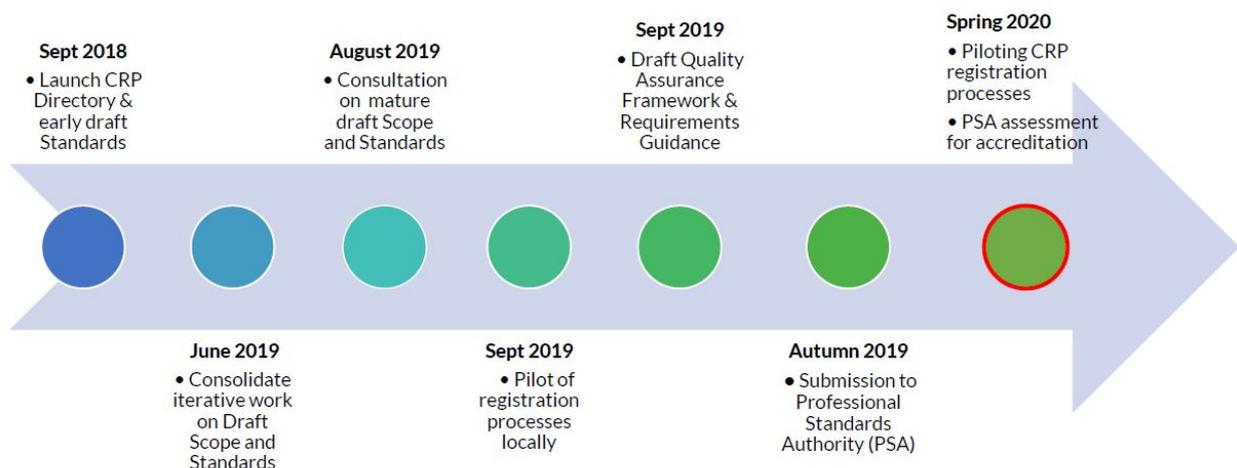
Immediate benefits

1. The initiative is expected to deliver an accredited register for CRPs and enable individual practitioners to articulate the scope and standard of their expertise
2. This register will precipitate a step change in assurance, professionalism and workforce development focus
3. CRPs will become more visible as a distinct group alongside raised awareness of clinical research teams and professionals within the wider healthcare science workforce

Longer term benefits of the staged approach

1. Quality assurance of across the research delivery workforce to agreed to standards meeting PSA accreditation
2. Promotion of a professional NIHR Clinical Research Delivery workforce to the Life Sciences Industry
3. More effective educational provision for CRPs
4. Mechanism to standardise role descriptions and training
5. A platform for the development of other roles within the research delivery workforce
6. Improve future workforce supply and security

Summary timeline to establishing a CRP register



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