

EHR4CR Area 4:

Certification of Professional individuals to complement the Certification of Software & Accreditation of Research Centres

Phase 1: Delivered (Feb 2014) – Briefing Paper

- The current status (the scope and scale) of professionalism in Clinical Research, in Europe
- An outline of key criteria necessary to ensure the staff in research centres are evaluated to consistent standards as part of an accreditation process, regardless of country and sector

Phase 2: Ongoing (by Aug 2014) – Code of Conduct & Competence Framework

- For Clinical Research professionals which will ensure individuals commit to consistent professionalism and to facilitate professional mobility within and between multinational Clinical Research Centres
- Proposals on detailed professional standards of competence for Clinical Research professionals as the basis to demonstrate fitness to practice through a process of independent certification and registration

Phase 3: Planned (by Dec 2014) – Certification Process Development

- To develop an certification & registration process for clinical research staff to be included as a component in a multinational accreditation scheme for Clinical Research Centres
- To develop proposals for the operational infrastructure to support a pan-European accreditation process and registration scheme

We would like your help please!

- To provide examples of Codes of Ethics & Conduct;
- To identify Job Roles & Responsibilities in Clinical Research;
- To join a Working Group to help develop and provide feedback & comments on:
 - o Draft Code of Conduct;
 - o Qualification and competency requirements;
 - o Proposals for the certification & registration of Clinical Research staff.

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