

PA-116 **DEVELOPING A GLOBAL CORE COMPETENCY
FRAMEWORK FOR CLINICAL RESEARCH**

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Background Lack of recognition for working in clinical research is widely cited as an impediment to its conduct. There is a lack of career structure for the many roles involved (investigators, trial managers, nurses, etc.), and a lack of understanding of who does what. Competency frameworks exist for some individual job roles, but these are infrequent; thus the need for a global framework describing roles and responsibilities in a research team. This would facilitate appraisal of staff, promote career development by highlighting acquired skills, and illuminate areas where training opportunities are lacking.

Methods In this project, we combine 28 frameworks created by external groups, with information from 116 job descriptions obtained from partners in clinical trial units worldwide, including input from the EDCTP Networks of Excellence, and from the web, to create a widely-encompassing framework derived from 11 different roles. Using qualitative analysis software, we systematically assess the activities performed by the clinical research team to categorise them and define underlying knowledge-, skill- or task-based competencies.

Results The resulting framework counts 50 competencies required throughout the research life cycle, from assessment of scientific literature to results dissemination via project

management, public engagement or grant application. It is applicable to studies that may differ in design, geographical location, disease, etc., and can be adapted to the particular needs of specific projects or roles. The framework was subject to an initial validation through consultations with over 30 global health research experts in collaboration with WHO-TDR in September 2015, resulting in enhancements and its subsequent beta release.

Conclusions The adaptable 'Global Core Competency Framework for Clinical Research' is now accessible via The Global Health Network, alongside a protocol for individuals who may wish to pilot test it in their work. The framework may be further refined before being finally approved and launched in collaboration with WHO-TDR.