



Development of the TDR Global Competency Framework for Clinical Research

WHO Library Cataloguing-in-Publication Data:

Development of the TDR global competency framework for clinical research.

1.Clinical Trial. 2.Research. 3.Data Collection. I.UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases.

ISBN 978 92 4 151156 8

(NLM classification: W 20.5)

Copyright © World Health Organization on behalf of the Special Programme for Research and Training in Tropical Diseases 2016

All rights reserved.

The use of content from this health information product for all non-commercial education, training and information purposes is encouraged, including translation, quotation and reproduction, in any medium, but the content must not be changed and full acknowledgement of the source must be clearly stated. A copy of any resulting product with such content should be sent to TDR, World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland. TDR is a World Health Organization (WHO) executed UNICEF/UNDP/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases.

The use of any information or content whatsoever from it for publicity or advertising, or for any commercial or income-generating purpose, is strictly prohibited. No elements of this information product, in part or in whole, may be used to promote any specific individual, entity or product, in any manner whatsoever.

The designations employed and the presentation of material in this health information product, including maps and other

illustrative materials, do not imply the expression of any opinion whatsoever on the part of WHO, including TDR, the authors or any parties cooperating in the production, concerning the legal status of any country, territory, city or area, or of its authorities, or concerning the delineation of frontiers and borders.

Mention or depiction of any specific product or commercial enterprise does not imply endorsement or recommendation by WHO, including TDR, the authors or any parties cooperating in the production, in preference to others of a similar nature not mentioned or depicted.

The views expressed in this health information product are those of the authors and do not necessarily reflect those of WHO, including TDR. WHO, including TDR, and the authors of this health information product make no warranties or representations regarding the content, presentation, appearance, completeness or accuracy in any medium and shall not be held liable for any damages whatsoever as a result of its use or application. WHO, including TDR, reserves the right to make updates and changes without notice and accepts no liability for any errors or omissions in this regard. Any alteration to the original content brought about by display or access through different media is not the responsibility of WHO, including TDR, or the authors. WHO, including TDR, and the authors accept no responsibility whatsoever for any inaccurate advice or information that is provided by sources reached via linkages or references to this health information product.

Cover design: Lisa Schwarb, Lausanne

Printed by the WHO Document Production Services (DUP), Geneva, Switzerland

Acknowledgements

This document is the result of a commissioning by TDR, the Special Programme for Research and Training in Tropical Diseases. TDR is hosted at the World Health Organization (WHO), and co-sponsored by UNICEF, UNDP, the World Bank and WHO.

Researchers from The Global Health Network were selected to draft and test this framework. Tamzin Furtado, Amélie Julé, Liam Boggs, Francois van Loggerenberg, Victoria Ewing and Trudie Lang from The Global Health Network, University of Oxford, comprised the technical team. They identified the roles to be covered and performed a literature review to locate existing high-quality frameworks and documents outlining the responsibilities for certain clinical research roles. The information contained on the competencies and tasks required during a study was systematically categorised into themes. Initially, a few broad themes (inspired from the most generic pre-existing framework, developed by MRCT) were used to categorise the text data.

Job descriptions were then collected from global partners and from the internet, to cover a broad range of clinical study types and locations (including low- and middle-income countries). Those were analysed as described above, which led to the creation of new, more specific themes to cover all aspects of the rich data collected. The process continued until 116 job descriptions were included, alongside the 28 frameworks and guidelines. At this point, the analysts were satisfied no new theme was needed to describe the data.

All data was then re-examined for consistency of categorisation, and to create a synthesized description for each of the themes, which correspond to the competencies within the global framework. This work has since been refined by iterative expert review. In particular, it was presented at a TDR stakeholder meeting: this was the occasion for external clinical research experts to provide feedback and contribute to the current framework and tools.

The authors would like to thank the following individuals for their reviews and feedback on the framework during the workshop on the development of a global core competency framework for clinical research held at the WHO head quarter, Geneva, Switzerland on 29-30 September 2015: Barbara E. Bierer, Christian Burri, Núria Casamitjana, C. Padma Chandrasekaran, Roma Chilengi, Helen Demarest, Michäel Kaeser, David Laloo, Kamal Mansinho, Renata Mendizabal Sole de Cabrera, Wilfried Mutombo Kalonji, Jean Nachege, Raffaella Ravinetto, Morven Roberts, Nidia Rizzo, Nandi Siegfried, Nathalie Strub Wourgaft, Alfred Tiono, Jeremy Whitty. The authors would also like to thank Elizabeth Allen and Cordelia Reddy of the University of Cape Town, and Barbara Farrell of the UK Trial Managers Network, for their invaluable support and feedback in the initial stages of development.

Specific support was provided by the Bill & Melinda Gates Foundation through the Career Development Fellowship programme.

Abbreviations

AE	Adverse Event
CRF	Case Report Form
CRO	Contract Research Organisation
DMS	Document Management System
DSMB	Data Safety Monitoring Board
GCP	Good Clinical Practice
GCLP	Good Clinical Laboratory Practice
GXP	Good Practice guidelines and regulations
IMPs	Investigational Medicinal Products
IT	Information Technology
LMICs	Low- and Middle-Income Countries
MRCT	Multi Regional Clinical Trial Center of Harvard
R&D	Research and Development
QMS	Quality Management System
SAEs	Serious Adverse Events
SOPs	Standard Operating Procedures
SUSAR	Suspected Unexpected Serious Adverse Reaction

Table of Contents

Acknowledgements	i
Abbreviations	ii
Summary	1
Introduction	2
Background	2
Justification for the methodological approach	3
Working definitions	4
Report outline	5
Methods	5
Initial development	5
Expert review	10
Results: A comprehensive TDR Global Competency Framework for Clinical Research, supported by practical implementation tools	10
Discussion	13
Suggestions for validation and next steps	14
References	16

Summary

Developing the capacity for clinical research requires a detailed understanding of the roles and responsibilities of those involved with that research (investigators, trial managers, nurses, etc.), alongside the suggestion of career pathways. Several groups have developed competency frameworks for different job roles within the research team, but a more integrated approach, looking at all the roles in parallel so as to identify interconnections between those, could create a single and flexible framework that may be practically used over the full study lifecycle. This would facilitate appraisal of staff, promote career development by highlighting acquired skills, and illuminate areas where training opportunities are lacking.

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 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 competencies – knowledge-, skill- or task-based. The initial draft framework obtained from this analytical approach is then subjected to an expert panel for in-depth review and suggestions for improvement. The resulting framework, inclusive of stakeholders' feedback, counts 50 competencies required throughout the research study lifecycle, 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.

Introduction

Background

Capacity development for clinical research is a well-documented need in low and middle income countries (LMICs), so as to support high-quality research which will address local health needs [1–3]. ‘Capacity development’ initiatives aim to increase the overall capability and empowerment of local institutions to undertake high quality research [4]; however, in practice, this concept remains elusive and multi-faceted, as different groups tend to approach and define it in varying manners [5–7].

A common theme in various theoretical frameworks and initiatives is the interlinked aspects of training, supervision and knowledge exchange for capacity development. For example, in an integrative model for capacity strengthening, Potter and Brough [7] describe the necessity of having appropriately trained staff who have both the skills and ability to perform their work, alongside some organisational support and an understanding of the systems and roles involved in the project in which they are embedded. Similarly, the ESSENCE on Health Research Initiative emphasises the need for skilled staff by referring to their development in two of their Seven Principles for Good Practice in Research Capacity Strengthening [4]. They encourage research groups to ‘embed strong support, supervision and mentorship structures’ (principle 6), and to ‘network, collaborate, communicate, and share experiences’ (principle 1).

Although on the rise, the availability and accessibility of adequate training programmes remain limited for many research staff [1,8]; and particularly for those who are not qualified as medical doctors [8]. In recent years, many initiatives have begun to offer online training in the form of eLearning courses (e.g. The Global Health Network [9–11], PharmaLessons [12]) and Massive Open Online Courses commonly referred to as ‘MOOCs’ (e.g. Coursera [13], EdX [14]), many of which can be accessed for free. Distance learning programmes associated to scholarships for individuals from low-resource countries (e.g. MSc in Clinical Trials at the London School of Hygiene and Tropical Medicine [15]) have also broadened the range of training opportunities for clinical research professionals around the world. However, there is still a great demand from LMICs for training options for the whole research team [8,16].

With a lack of understanding of the clinical research skills that need to be developed, it is also not clear whether existing ‘clinical trials’ curricula cover the full range of topics to be mastered by research staff. In that context, it is necessary to primarily define a set of competencies for all clinical research professionals; and it would be important to do so by looking at the clinical trial team as an integrated unit, rather than looking at each role in isolation. Potter and Brough [7] and ESSENCE [4] underline that capacity development of the workforce should not solely be about training: it is important to also develop a clear understanding of the activities, roles and responsibilities of those involved in research, and of how roles may evolve within the organisational structure. As a result, it is important to consider training opportunities in relation to the ‘structures’ that will implement them, so as to suggest feasible means for staff to fill their knowledge gaps and develop their career.

Published work suggests that many core roles within clinical research are still relatively unrecognised as a viable career pathway [8,17], and this is certainly the feedback received by the authors during evaluation of training exercises that they regularly conduct in LMICs. In particular, the role of research nurses, trial

managers, and data staff are little understood. In some countries, organisations such as the UK Trial Manager's Network [18] have created networks which aid researchers of that role in sharing knowledge and experience with others, and go some way to helping to formalise that role. However, few such organisations exist that are accessible to and address the needs of LMICs. The Global Health Network and TDR have made efforts to remedy this through their open access communities and 'Professional Membership Scheme' [19], a free scheme aiming to track the continued professional development of different roles in the clinical research team. This initiative also highlighted that further research is required to understand the roles of researchers, so as to be able to direct individuals to relevant training and guidance.

In the past, several groups have created useful 'competency frameworks' for specific roles within the clinical research team, including investigators, trial managers, research nurses, as well as ethics committees. The Multi Regional Clinical Trials Center (MRCT) Harmonized Core Competency Framework [20–22] makes an excellent move towards combining the information about different roles into one set of knowledge domains; and applies the resulting generic framework to the roles of Principal Investigator, Clinical Research Coordinator and Clinical Research Associate. The MRCT framework was developed through iterative consultation with experts and stakeholders of clinical research, thus in a 'top-down' manner, and is meant to be further refined as it is used and feedback is gathered.

Justification for the methodological approach

In the present report, we propose an alternative approach to building competency frameworks for clinical research professionals, thus helping to complete the picture of competencies used by all roles. Our approach aims to build on 'real-life' data before expert knowledge. We look at the complete set of activities needed for a trial to take place regardless of which individual may perform them, and then use this information to determine the competencies (tasks, skills and knowledge) required to achieve each activity. Those competencies can then be attributed and distributed between different roles (trial manager, research nurse, data staff, etc.) depending on the team who will undertake the research project. Developing a framework from the 'bottom-up' – that is, beginning from the wider context of assessing all of the responsibilities and activities undertaken by a trial team when conducting a research project, provides a flexible and integrative framework that can be adapted to serve diverse projects rather than being limited to one role. The usual roles and their associated responsibilities as defined in job descriptions corresponding to each role are also illustrated, but they can be adapted depending on the trial in hand.

The rationale for this approach is that each research project and each research site is different, and distributions of roles and responsibilities within the team are likely to vary depending on the size and demands of the study, type of funding (e.g. academic or industry), location and the research site and team available to conduct the trial on the ground. However, in any research project no matter how big or small, there are core aspects that need to be covered: a protocol must be written and reviewed, ethics approval must be obtained, data must be collected, verified and analysed, and so on. Therefore, we suggest that the research process can be usefully split into 'competency areas' with further breakdown of the tasks, knowledge and skills involved.

The global competency framework presented here has the potential to be beneficial in multiple ways. Firstly, it illuminates the specific competency areas that are required to successfully complete each activity of the clinical research cycle. This flexible approach will allow the framework to be adaptable across diverse research types and teams.

In line with the Organisation for Economic Cooperation and Development (OECD) recommendations [23], this project therefore aims to develop a concept of 'Global Core Competencies' for diverse clinical research studies, by looking at the different activities and roles in the clinical research team and analysing the competency areas required to successfully perform in each. Existing competency frameworks built by other groups and a varied range of job descriptions have been utilised as a basis for this exploration.

Working definitions

It is worth noting that this project aims to include information relating to diverse clinical research projects, and not just clinical trials – though of course many clinical research studies are indeed clinical trials. The WHO defines clinical trials as *“any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”* [24]. However, many of the same steps and competencies are relevant for other types of research such as public health studies and observational studies. This report is therefore focused on clinical trials but the resulting framework and training analysis should be applicable also to other types of studies.

As a working definition, the Royal College of Nursing's definition of a competency [25] will be used:

“The ability to demonstrate the application of knowledge, understanding, practical and thinking skills to achieve effective performance in a professional or occupational role”

As such, a competency is not an activity, but the knowledge or skill required to carry it out. Our framework distinguishes between the following three types of competencies:

- The **theory, or knowledge-based competency**, which reflects a level of theoretical understanding of a particular topic, and which can be acquired through learning about a field;
- The **capability, or task-based competency**, which necessitates the application of technical or practical knowledge to the performance of a specific task, and which is better learnt by doing;
- The **trait, or skill-based competency**, which corresponds to the demonstration of appropriate behaviours in front of various situations, and which is better developed by experiencing and reflecting on the experience.

An interesting and extensive discussion of the different types of competencies and how identifying them can help to develop staff is provided in Lucia and Lepsinger's work on Competency Models [26].

Although there might exist theoretical courses and practical workshops to develop any competency regardless of its type, trainers may want to keep in mind the differences between knowledge-based, task-based and skill-based competencies to design their curricula in the most appropriate and effective fashion.

Report outline

This report details the development of the TDR Global Competency Framework for Clinical Research. The methodology followed for early design is explained, before briefly presenting the framework and discussing the limitations and future work.

Methods

This project aims to build a Competency Framework for the clinical research team, using a data-driven, evidence-based approach. Qualitative methods, inspired from social sciences, and whose recognised value and uptake in the field of health research is on the rise [27], were thus employed. This enabled the systematic analysis of existing, varied bodies of research on competencies for the clinical research team, while at the same time combining them with real-life materials used by research teams and employers to describe the roles of staff.

The framework resulting from this empirical work was then submitted to a panel of experts for review.

Initial development

Firstly, researchers based at The Global Health Network refined the scope of the project in agreement with TDR; and in particular, identified the job roles to be covered. The retained roles are drawn from the full clinical research team regardless of people's levels, and are presented in Table 1. We initially intended to cover pre-clinical research jobs as well; but the set of skills used by individuals in such roles proved too different, and the collection of data on those roles for inclusion in the competency framework was discontinued.

One 'role' may encompass several job titles, especially as job titles tend to vary between employers, and to evolve with the level of experience and expertise without fundamentally changing the underlying role. The titles suggested in Table 1 reflect those found in the data included in the analysis.

After clarification of the roles and corresponding titles, The Global Health Network's researchers performed a literature review to locate existing high quality competency frameworks for clinical researchers, either generic or specific to one role. This information was pooled with other documents which clearly outline responsibilities for certain roles, such as the ICH-GCP guidelines. As most documents on the matter of clinical research competencies come from the grey literature (as opposed to academic, peer-reviewed papers), the authors did not attempt a systematic review, but rather used Google searches and their own experience of the field to identify relevant literature.

Table 1 – List of roles included. Job titles correspond to those found in the different job descriptions analysed.

Role	Junior	Senior	Expert or Specialist setting
Data staff	Data clerk; Data assistant; Data entry and administration personnel	Data manager; Senior or Lead data manager	Biostatistician
Laboratory scientist	Laboratory (lab) technician; Scientific lab technician; Lab technologist; Lab research assistant	Assistant lab manager; Lab manager; Lab scientist; Head of laboratory (at site)	Head of laboratory(ies); Chief specialist scientist; Research scientist (medical); Senior lab analyst; Science lead; Clinical pharmacologist
Trial pharmacist	Pharmacy administrator/coordinator; Trial pharmacist; Pharmaceutical technologist; Pharmacy technician	Lead pharmacist	
Community engagement staff	Fieldworker; Research assistant	Senior fieldworker; Field research officer; Community engagement or liaison officer; Community engagement and ethics coordinator	Counsellor
Research nurse	Nurse; Nurse assistant; (Clinical) research nurse; Study nurse; Vaccination nurse	Clinical research coordinator; Study coordinator	
Study physician	(Clinical) research physician; Clinical development physician; Study physician; Medical officer; Research clinician; Clinical investigator	Sub-investigator; Lead clinical research physician	(Clinical) safety physician; Pharmacovigilance physician; Public health officer
(Principal) investigator	Investigator (at site); Co-investigator; Medical science physician	Principal Investigator; Head of clinical trials; Global clinical Leader; Senior director of clinical R&D; Senior global clinical pharmacologist	
Trial manager or Project coordinator	(Clinical) research/trial coordinator; Project/study coordinator; (Clinical) research/trial manager; Clinical research operations manager; Clinical research administrator; Trial clinical officer; Support officer; Clinical trials facility manager	Senior research coordinator; Chief trial manager	
Quality Control monitor	Clinical trial monitor; Quality assurance manager; Quality control specialist; (Clinical) Research associate (<i>industry</i>)	Lead monitor; Monitoring senior associate; Monitoring team leader; Quality assurance officer	Data quality controller; Safety specialist; Regulatory affairs specialist; Regulatory coordinator Senior ethic clinical trials specialist

Role	Junior	Senior	Expert or Specialist setting
ECs and IRBs	Ethics Committee (EC) or Institutional Review Board (IRB) member (permanent or lay)	EC/IRB coordinator; EC/IRB vice-chair or chair	
Sponsor	Not applicable		

The 28 documents identified and included in the analysis are listed below. It was not possible to locate any document of relevance for community engagement staff, nor for data staff.

Generic frameworks or guidelines

- **The Global Health Network Professional Membership Scheme** [19]
- **MRCT's Harmonized Core Competency Framework for the Clinical Research Professional** [22]
- **Responsibilities, Liabilities and Risk Management in Clinical Trials of Medicines** (UK Dept. of Health) [28]
- **Research Governance Framework for Health and Social Care** (UK Dept. of Health) [29]

Laboratory scientist

- **Laboratory Technician Job Profile** (National Careers Service) [30]
- **Research Scientist – Medical** (Prospects Career Information) [31]
- **Scientific Laboratory Technician** (Prospects Career Information) [32]

Trial pharmacist

- **Professional Guidance on Pharmacy Services for Clinical Trials** (Royal Pharmaceutical Society) [33]
- **Pharmacy Support for Clinical Trials** (Barts Health NHS) [34]
- **Pharmacy: Clinical Trials** (Blackpool Teaching Hospitals NHS) [35]

Research nurse

- **Competency Framework for Clinical Research Nurses** (Royal College of Nurses) [25]

Study physician

- **Research Competencies Framework for Clinicians** (Royal College of Surgeons) [36]

(Principal) investigator

- **Référentiel général de contenu d'une formation à la recherche clinique sur le médicament pour les investigateurs** (AFSSaPS) [37]
- **Investigator Responsibilities Principal Investigators, Co- Investigators and Consent Designees, Post-Doctoral Fellows, and Ph.D.s** (Johns Hopkins Medicine) [38]
- **Investigator's Responsibilities** (ICH-GCP) [39]

Trial manager/Project coordinator

- **CRC Research/Trial Administrator Competency Framework** (NISCHR) [40]
- **Task, Knowledge and Competency Framework for Trial Managers** (NIHR Trial Managers Network) [18]

Quality control monitor

- **A day in the Life of a Monitor** [41]
- **Training Needs of Clinical Research Associates** [17]
- **Monitoring Responsibilities** (ICH-GCP) [42]
- **Clinical Research Associate** (Prospects Career Information) [43]

Ethics committee (EC)/Institutional review boards (IRBs)

- **Core Competencies for Clinical Ethics Committees** (UK Clinical Ethics Network) [44]
- **Roles and Responsibilities in Clinical Trials: Institutional Review Boards (IRBS)** (The CRA's Guide to Monitoring Clinical Research) [45]
- **Operational Guidelines for Ethics Committees That Review Biomedical Research** (WHO) [46]
- **Institutional Review Board/Independent Ethics Committee (IRB/IEC) Responsibilities** (ICH-GCP) [47]

Sponsor

- **Roles and Responsibilities in Clinical Trials: Sponsors** (The CRA's Guide to Monitoring Clinical Research) [45]
- **Sponsor's Responsibilities** (ICH-GCP) [48]
- **Sponsorship Principles** (NHS R&D Forum) [49]

NVivo, a software programme to support qualitative research, was used to categorise the information found in these documents into themes or 'nodes', an operation commonly referred to as 'coding' the qualitative data [50]. Eight broad themes, highly inspired from the MRCT Competency Domains, were initially used as a basis for coding – Scientific concepts, Ethics, Clinical trial operations, Site management, Data management & Information Technology (IT), Communication and reporting, Teamwork and Professionalism, Other (not falling in any of the previous categories). The MRCT's Harmonized Core Competency Framework [22] was chosen as a basis for categorisation because it is the broadest pre-existing framework in terms of roles observed, and most flexible due to its comprehensive knowledge domains.

Following this literature search and analysis, real-life job descriptions for each role were then collected by contacting global collaborative groups and by performing repeated, purposive Google searches for job descriptions of the aforementioned roles and titles (Table 1). In line with the broad scope of the project, care was taken to ensure that information originated from a broad range of locations and study types (maximum variation sampling), with particular attention given to LMIC settings. An overview of the achieved coverage for different world regions (using WHO classification [51]), country income groups (World Bank classification [52]) and type of sponsorship or funding (public or private) is provided in Table 2 below.

The job descriptions were coded and categorised alongside the existing frameworks and guidelines in NVivo. The coding activity was performed by two coders working in close collaboration. As the database grew to 116 job descriptions, the coders gained new insights into the activities and responsibilities of research professionals, which led to continuous reshaping of the coding scheme into categories and sub-categories. The need for creating and grouping new nodes was systematically discussed and agreed between the two coders. The process of data collection, coding and refinement of categories was continued until saturation was reached: at this point, the two coders were satisfied that new job descriptions or other documents could be fully coded using pre-existing nodes and did not bring any information that was not previously encountered.

At this point, the content of each node (about 20 to 200 quotes from the analysed documents), was re-examined and synthesised into a description for each node, with associated keywords most frequently occurring into the quotes. Those descriptions readily gave the definitions for the competencies included in the Competency Dictionary associated to the TDR Global Competency Framework for Clinical Research.

Table 2 – Settings of the source documents analysed, by job role. Each analysed framework, set of guidelines or job description was assigned a type of funding/sponsorship, a World Bank income group, and a WHO world region, depending on its source and its intended audience. For each job role, the total number of documents analysed is indicated, with some documents relevant to several job roles. The sponsor is not shown, as only 5 documents could be found for that role, with very little variation. Of note, some documents could not be categorised (e.g. not country-specific). No single document could be found originating from or specifically applying to the Eastern Mediterranean WHO world region. QC: Quality Control. EC/IRBs: Ethics Committees/Institutional Review Boards.

	Total	Funding / Sponsorship			Income group			World region		
		private	public	high	middle	low	Africa	Americas	Europe	Asia / Pacific
Data staff	12	2	10	2	5	5	8	1	1	2
Lab scientist	15	5	10	8	4	3	6	0	7	2
Trial pharmacist	10	2	8	4	3	1	2	0	5	2
Community engagement staff	14	0	14	2	6	6	11	0	2	1
Research nurse	15	1	14	2	7	6	11	0	2	2
Study physician	16	7	8	9	5	2	5	0	9	2
Investigator	10	4	6	7	3	0	2	2	5	1
Trial manager	21	2	19	4	13	4	8	1	4	8
QC monitor	22	8	14	4	13	4	8	2	2	9
EC / IRBs	11	3	7	8	3	0	0	4	6	1

Expert review

The initial development as described above resulted in a draft version of the TDR Global Competency Framework for Clinical Research, to lay the groundwork for expert review and discussion. The draft version of this report and its accompanying framework was delivered to TDR by The Global Health Network in February 2015. The subsequent experts' meeting took place in late September 2015 in Geneva, under the leadership of TDR. The aim of the meeting was to assess the proposed draft, and to develop a strategy for validation and implementation in practice of the competency framework.

As per January 2016, feedback from experts, as collected at the meeting and over emails in the last quarter of 2015, has been accounted for into the version here presented. Major changes, especially regarding the design and organisation of the framework, have been submitted to the group for confirmation. Conflicting views expressed by the participants were resolved by The Global Health Network in collaboration with TDR. The decision-rule was as follows: modifications, especially if implying creation of new nodes (competencies), were kept to the minimum, with rephrasing, reorganising and building on pre-identified competencies being preferred. The rationale for that approach was to keep consistent with the initial development phase, which aimed to be life data-driven.

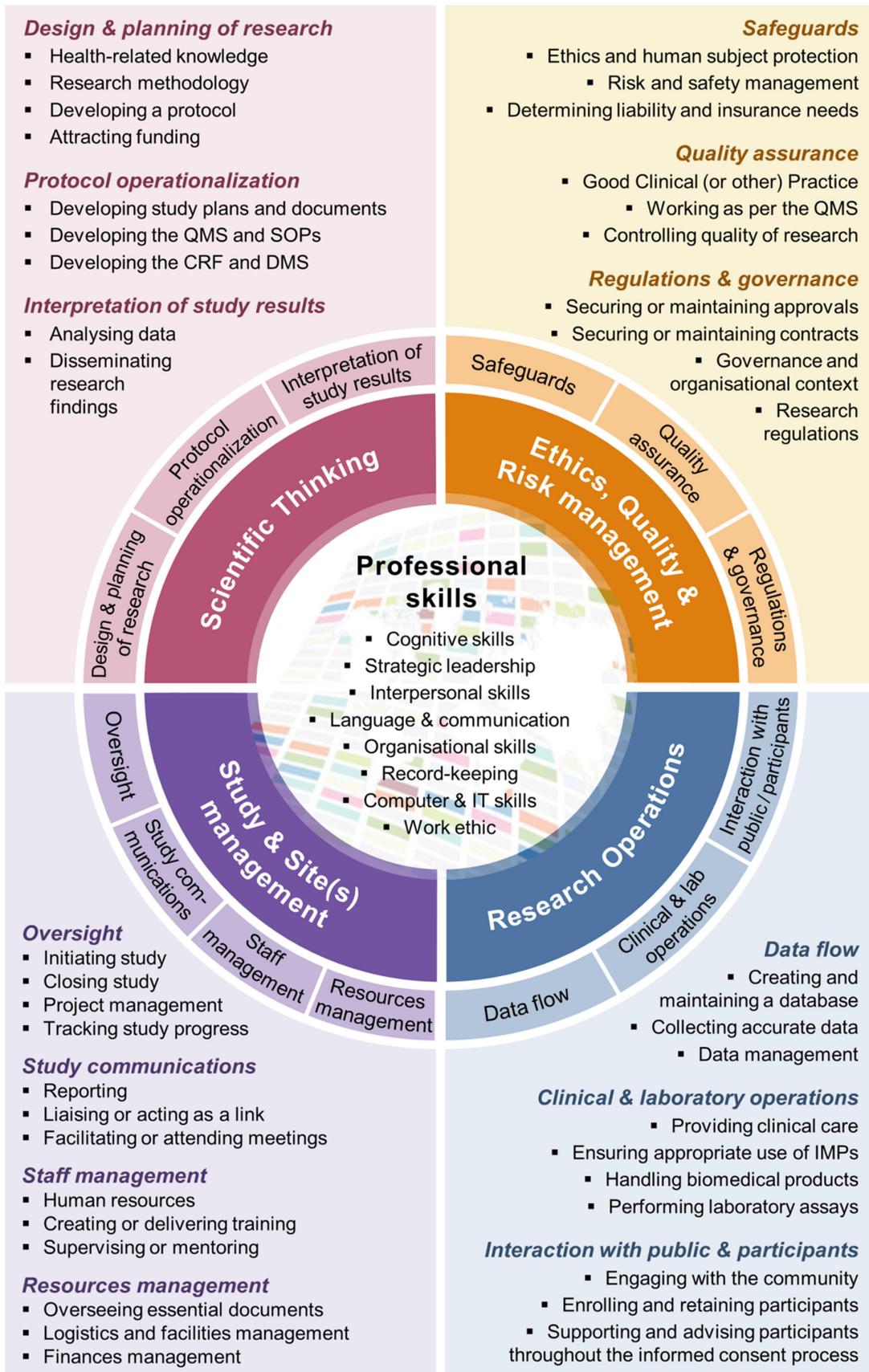
In the near future, it is expected that working groups will be formed to further refine the competency framework with The Global Health Network and TDR, especially to continually update and improve it as it gets released and used, to adapt it back to specific roles, and to eventually assess its impact.

Results: A comprehensive TDR Global Competency Framework for Clinical Research, supported by practical implementation tools

The finalised **TDR Global Competency Framework for Clinical Research** consists of a Competency Wheel (Figure 1, page 11) and multiple supporting tools.

The Competency Wheel visually presents the framework with its *50 competencies*, distributed into *5 categories*. The core 'Professional Skills' category is surrounded by 4 thematic categories ('Scientific Thinking', 'Ethics, Quality & Risk management', 'Study & Site(s) management' and 'Research Operations'). The thematic categories are each further divided into 3 to 4 areas of competencies.

Figure 1 – Competency Wheel: an Overview of TDR Global Competency Framework for Clinical Research.



The Competency Wheel (Figure 1, page 11) is supported by the following tools, which aim to clarify it and to facilitate its use and continued improvement:

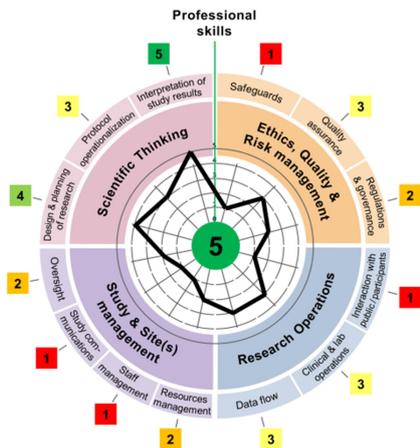
Competency Dictionary

Scientific thinking

Design & planning of research

Competency	Health-related knowledge
Type	Theory (knowledge-based)
Definition	The individual has enough knowledge of a specific area linked to health, either with a background in fundamental or social sciences. This knowledge enables them to understand the purpose, concept and topic of a study. They have an appropriate education or experience in health sciences dependent on their role, which they are able to apply daily to perform their research job appropriately (e.g. to provide clinical care or deliver the intervention to participants, to set clinical research questions or to analyse quantitative and qualitative data). They maintain their understanding and knowledge of new advancements in their specific field by engaging with the professional community, i.e. by attending conferences or seminars and by reading relevant articles.
Related competencies	Tasks based on this knowledge: Developing a protocol; Analysing data; Disseminating research findings; Providing clinical care; Ensuring appropriate use of IMPs; Handling biomedical products; Performing laboratory assays Similar knowledge: Research methodology Required skills: Cognitive skills; Work ethic
Keywords	Degree in life sciences and related; Health background (including nursing and pharmacy); Medical speciality (e.g. oncology, paediatrics); Epidemiology; Interest/Experience in a clinical research area (e.g. HIV/AIDS, malaria vaccines); Attending (academic) conferences and scientific training; Literature review.

1. A **Competency Dictionary** which provides detail on what is meant by each of the 50 competencies. The Competency Dictionary thus explains the overall, generic framework by suggesting a *definition*, further clarified with *keywords*, for each competency. Essential skills and knowledge required to master the competency are also listed along with the *competencies that are related* to it and that appear elsewhere in the framework. Usual *abilities* associated with the competency are given – but without those illustrative examples being job-specific.



2. A **Competency Radar**, which can be used to grade individuals on each of the areas of competency. An empty template sheet is provided and can be photocopied for re-use; and a completed sheet is also given as an example (shown aside). Some guidance on scoring and evaluating one's level is included, which builds on the grading scheme developed for The Global Health Network Professional Membership Scheme [19]. Consistent grading should be used as much as possible, to facilitate comparisons of competency levels, over time and between individuals.

3. The Competency Radar and grading scheme can be used with the **Role-specific Frameworks**. The latter are still in development as of September 2016, and are envisioned at least for the 11 different roles in clinical research included during the framework development stage. Each role-specific framework will add a layer of detail by illustrating the specific *abilities* associated to the competencies that are relevant for that particular role. Where relevant, abilities are also labelled as *junior/senior* levels to show the difference in the level of competency expected from various staff. With this added level of detail, the Role-specific Frameworks should therefore help the individual find the appropriate score corresponding to their demonstrated behaviour.

To facilitate both the reading of this report and the practical use of the framework, none of the supportive documents is included within this section, but they form the core of one separate document, and can be accessed at: <https://globalhealthtrials.tghn.org/global-competency-framework-clinical-research/>.

Discussion

The Global Competency Framework and its supportive documents aim to provide a ‘best of both’, in terms of providing on the one hand a *flexible, adaptable*, and thus *generic* framework and dictionary which can be applied to any research team; and, on the other hand, *specific*, evidence-based individual frameworks which more fully cover each of the 11 roles discussed. The resulting role-specific frameworks will be fully integrated within the broader framework here presented: this should help individuals develop career progression plans, by highlighting the competencies that are relevant to alternate roles. The role-specific frameworks aim to provide a ‘usual case’ of the job roles described, and can therefore also be used to create job descriptions, learning curricula, and so on.

As described, the frameworks have been carefully developed by researchers at The Global Health Network and reviewed by clinical trials experts, whose feedback was incorporated as required. Further evaluation was outside the scope of the project so far, but is recommended so as to iteratively improve and validate the work, and especially for the reasons outlined below.

Breadth could hamper practicality and applicability to all research settings

This framework aims to cover globally applicable research, and thus job descriptions from many diverse locations and trial types were taken into consideration. While this provides the widest possible range of competencies and highlights the connections between apparently different roles, it also means that some of the tasks and roles will not be applicable to some locations/situations. Further validation with users would enable the authors to test how teams need to adapt the generic Global Competency Framework while in use, and provide appropriate instructions and support to future users.

It is our hope that the global picture provided will facilitate career development and therefore help to build the research capacity in LMICs, by emphasising the bridges that exist between job roles, e.g. research nurses and trial managers, or study physicians and (principal) investigator.

Job descriptions are a real-life, pragmatic source of data, but might not always be accurate

Job descriptions have been used as an easily accessible means of determining the roles, tasks, and ideal attributes of applicants. They were an ideal basis for the scope of this project since they clearly provide a list of the activities each individual undertakes, the training basis required for that role, and which key skills

or personal attributes are desirable or essential. However, there could of course be a discrepancy in what a job description describes and the actual day-to-day tasks undertaken by an individual. Further means of refining the framework and especially its competency dictionary, with tasks and behaviours required for each competency, are therefore suggested below.

Now that the global picture has been developed, refinement is needed on some specific roles

Some of the job roles were problematic in the analysis for varying reasons, warranting further evaluation of their specific framework in practice. For example, the role of sponsor in particular would benefit from further study; job descriptions for 'sponsor' roles are not available, and thus it will be difficult to develop a specific framework for this role, which would rely solely on documents such as the ICH-GCP guidelines outlining the responsibilities of the sponsor. Further study which seeks to address the responsibilities and activities of the sponsor, perhaps particularly focussing on the difference between industry and academia, would be interesting and necessary to complement the limited information collected with the present approach. From the experience of the authors and TDR, clarifications of the boundaries between the role and responsibilities of sponsors, funders and investigators would be particularly helpful to researchers in LMICs seeking to carry out a locally-led clinical study.

A different but linked problem is evident with job roles such as the trial manager. In contrast to the sponsor, a huge amount of very diverse information was available on the activities of the trial manager, showing that this role can cover all manner of tasks depending on the situation. Therefore, the anticipated 'specific' trial manager framework will still be extremely extensive, and will require further editing each time it is used, depending on the level of responsibilities that the team in question is attributing to their trial managers. The same could be said of research nurses, who may be fulfilling the tasks of trial managers in many situations, and a great deal of crossover was noted between the two roles: this, again, supports the value of a single generic framework.

Suggestions for validation and next steps

In light of the general support given to the framework by the expert panel, we recommend bringing it to practice, so as to learn from the experience of early adopters. From the authors' experience, once an overall design and categorisation of competencies had been agreed, it was possible to update the framework very easily, without significantly altering its overall structure: this goes in favour of moving the framework forward. It is expected that feedback from working groups, collaborators and users of the framework will require continuous modifications, which will lead to rephrasing competencies, adding some new ones under broader areas, and updating the dictionary accordingly, but without fundamentally questioning the overall structure.

While work remains around the more detailed, role-specific frameworks, it is recommended that the overall validation of the framework seeks to:

- Show face validity, by ensuring that individuals who are currently working in each role understand the competencies suggested, and how they apply to their role;

- Determine whether key tasks have been identified and are clearly covered within one competency or another, through observation and/or discussion with individuals in each role;
- Determine what the 'predictors of success' are for each role, i.e. which behaviour demonstrates that the individual has mastered a competency and makes them stand out as a top performer. This will enable the creation of a more compressive grading scheme.

Lucia and Lepsinger [26] recommends that validation of core competency frameworks can be achieved through focus groups and surveys. Surveys with individuals of each role could encourage individuals to rate the relevance of each competency to their role, and how often they use that competency in their usual job's activities. Focus groups would provide in-depth information about how people feel about which competencies, skills and ways to apply them are key to performing their jobs well.

References

1. Franzen SRP, Chandler C, Enquesselassie F, Siribaddana S, Atashili J, Angus B, et al. Understanding the investigators: a qualitative study investigating the barriers and enablers to the implementation of local investigator-initiated clinical trials in Ethiopia. *BMJ Open*. The Global Health Network, Centre for Clinical Vaccinology & Tropical Medicine, University of Oxford, Oxford, UK.; 2013;3: e003616. doi:10.1136/bmjopen-2013-003616
2. Gonzalez Block MA, Mills A. Assessing capacity for health policy and systems research in low and middle income countries*. *Heal Res policy Syst*. 2003;1: 1. Available: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=151554&tool=pmcentrez&rendertype=abstract>
3. Pisani E, Whitworth J, Zaba B, Abou-Zahr C, E P, Whitworth J, et al. Time for fair trade in research data. *Lancet*. 2010;375: 703–705. doi:10.1016/S0140-6736(09)61486-0
4. ESSENCE on Health Research. Seven principles for strengthening research capacity in low- and middle-income countries: simple ideas in a complex world [Internet]. World Health Organization; 2014. Available: <http://www.who.int/tdr/publications/seven-principles/en/>
5. Bates I, Boyd A, Smith H, Cole DC. A practical and systematic approach to organisational capacity strengthening for research in the health sector in Africa. *Heal Res policy Syst*. 2014;12. doi:10.1186/1478-4505-12-11
6. Cooke J. A framework to evaluate research capacity building in health care. *BMC Fam Pract*. 2005;6: 44. doi:10.1186/1471-2296-6-44
7. Potter C, Brough R. Systemic capacity building: a hierarchy of needs. *Heal Policy Plan*. Department of Epidemiology, Statistics and Community Medicine, University of Wales College of Medicine, Cardiff, UK.; 2004;19: 336–345. Available: <http://www.ncbi.nlm.nih.gov/pubmed/15310668>
8. Lang T a., White NJ, Tran HT, Farrar JJ, Day NPJ, Fitzpatrick R, et al. Clinical research in resource-limited settings: enhancing research capacity and working together to make trials less complicated. *PLoS Negl Trop Dis*. Centre for Vaccinology and Tropical Medicine, University of Oxford, Churchill Hospital, Oxford, United Kingdom. trudie.lang@ndm.ox.ac.uk; 2010;4: 4–7. doi:10.1371/journal.pntd.0000619
9. Lang T. Advancing global health research through digital technology and sharing data. *Science (80-)*. American Association for the Advancement of Science; 2011;331: 714–7. doi:10.1126/science.1199349
10. Global Health eLearning Center [Internet]. [cited 15 Jan 2015]. Available: <http://www.globalhealthlearning.org/>
11. The Global Health Network: Welcome [Internet]. [cited 25 Feb 2015]. Available: <https://tghn.org/>
12. PharmaLessons. PharmaLessons: Meeting all your pharma training needs [Internet]. 2016 [cited 25 Feb 2016]. Available: <http://www.pharmalessons.com/>
13. Coursera Inc. Coursera [Internet]. 2015. Available: <https://www.coursera.org>
14. edX Inc. edX [Internet]. [cited 15 Jan 2015]. Available: <https://www.edx.org/>
15. London School of Hygiene and Tropical Medicine. Masters in Clinical Trials (Distance Learning) [Internet]. [cited 15 Jan 2015]. Available: <http://www.lshtm.ac.uk/study/masters/dmsct.html>
16. Whitworth A, Haining S, Stringer H. Enhancing research capacity across healthcare and higher education sectors: development and evaluation of an integrated model. *BMC Heal Serv Res*. 2012;12: 287. doi:10.1186/1472-6963-12-287
17. Ajay S, Bhatt A. Training needs of clinical research associates. *Perspect Clin Res*. Clinical Operations, Feasibility and Site ID, Quintiles India, 5th Floor, Leela Business Park, M. V. Road, Andheri (E), Mumbai - 400 059, India.; 2010;1: 134–138. doi:10.4103/2229-3485.71771
18. Cooper HJNM, Meadows LC. Task, Knowledge and Competency Framework for Trial Managers [Internet]. 2012. Available:

http://c.ymcdn.com/sites/www.tmn.ac.uk/resource/resmgr/Competency_Framework/Task_knowledge_Competency_Fr.pdf

19. TDR, The Global Health Network. Global Health Network Professional Membership Scheme [Internet]. 2015 [cited 15 Jan 2015]. Available: <https://globalhealthtrainingcentre.tghn.org/cpd/>
20. Multi-Regional Clinical Trials Initiative. MRCT Resources [Internet]. Jan 2016 [cited 10 Jan 2016]. Available: <http://mrctcenter.org/resources/>
21. Thomas Jones C, Browning S, Gladson B, Hornung C, Lubejko B, Parmentier J, et al. Defining competencies in clinical research: Issues in clinical research education. *Res Pract.* 2012;3: 99–107. Available: https://www.researchgate.net/publication/235687754_Defining_competencies_in_clinical_research_Issues_in_clinical_research_education
22. Sonstein SA, Seltzer J, Li R, Silva H, Jones CT, Daemen E. Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional. *Clin Res.* 2014; 17–23. doi:10.14524/CR-14-00002R1.1
23. OECD Global Science Forum. Facilitating International Cooperation in Non-Commercial Clinical Trials [Internet]. 2011. Available: <http://www.oecd.org/sti/sci-tech/49344626.pdf>
24. World Health Organization. Health Topics: Clinical Trials [Internet]. 2015. Available: http://www.who.int/topics/clinical_trials/en/
25. Royal College of Nursing Research Society. Research Nurse Competency Framework - version 2 [Internet]. 2011. Available: http://www.rcn.org.uk/development/research_and_innovation/rs/publications_and_position_statements/competencies
26. Lucia AD, Lepsinger R. The Art and Science of Competency Models: Pinpointing Critical Success Factors in Organizations [Internet]. San Francisco: John Wiley & Sons, Inc.; 1999. Available: https://books.google.co.uk/books/about/The_Art_and_Science_of_Competency_Models.html?id=w5pjQgAACAAJ&pgis=1
27. Gilson L, Hanson K, Sheikh K, Akua Agyepong I, Ssengooba F, Bennett S. Building the field of health policy and systems research: social science matters. *PLoS Med.* *PLoS Medicine*; 2011;8. doi:10.1371/journal.pmed.1001079
28. Universities UK. Responsibilities, liabilities and risk management in clinical trials of medicines [Internet]. 2004. Available: http://www.cardiff.ac.uk/racdv/resgov/Resources/uniUK+DH_statement_on_legal_responsibilities.pdf
29. Department of Health (UK). Research Governance Framework for Health and Social Care [Internet]. 2005. Available: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf
30. National Careers Service. Laboratory technician Job Profile [Internet]. [cited 10 Jan 2015]. Available: <https://nationalcareersservice.direct.gov.uk/advice/planning/jobprofiles/Pages/laboratorytechnician.aspx>
31. Prospects. Research Scientist (Medical) [Internet]. 2013 [cited 10 Dec 2014]. Available: http://www.prospects.ac.uk/research_scientist_medical_job_description.htm
32. Prospects. Scientific Laboratory Technician [Internet]. 2014. Available: http://www.prospects.ac.uk/types_of_jobs_scientific_services.htm
33. Khalil C, Bedford C, Bowler H, Gazeley T, Gilroy J, Hodgson S, et al. Professional Guidance on Pharmacy Services for Clinical Trials [Internet]. 2013. Available: <http://www.rpharms.com/support-pdfs/professional-guidance--n-pharmacy-services-for-clinical-trials-141013.pdf>
34. Barts Health NHS. Pharmacy support for clinical trials [Internet]. 2015 [cited 15 Jan 2015]. Available: <http://www.bartshealth.nhs.uk/research/facilities/pharmacy-support-for-clinical-trials/>
35. Blackpool Teaching Hospital. Pharmacy: Clinical Trials [Internet]. [cited 25 Feb 2015]. Available: <http://www.bfwh.nhs.uk/departments/pharmacy/>

36. Royal College of Surgeons. Research Competencies Framework for Clinicians. 2007.
37. Agence française de sécurité sanitaire des produits de santé. Référentiel général de contenu d'une formation à la recherche clinique sur le médicament pour les investigateurs [Internet]. 2009. Available: http://ansm.sante.fr/var/ansm_site/storage/original/application/e8ad48dd1a01ba7abbf06b3658d97081.pdf
38. John Hopkins Medicine. Investigator Responsibilities Principal Investigators, Co- Investigators and Consent Designees, Post-Doctoral Fellows, and Ph.D.s [Internet]. 2010 [cited 15 Jan 2015]. Available: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/investigatorresponsibility.html
39. ICH GCP. 4. Investigator [Internet]. [cited 25 Feb 2015]. Available: <http://ichgcp.net/4-investigator>
40. NISCHR. CRC Research/Trial Administrator competency framework [Internet]. 2010. Available: http://www.wales.nhs.uk/sites3/documents/580/Band_4_NISCHR_CRC_competency_May_2011.pdf
41. Shah K. A day in the life of a monitor! *Perspect Clin Res*. Eisai Clinical Research Singapore Pvt. Ltd., Mumbai, India.; 2012;3: 32–34. doi:10.4103/2229-3485.92305
42. ICH GCP. 5.18 Monitoring [Internet]. [cited 25 Feb 2015]. Available: <http://ichgcp.net/518-monitoring>
43. Prospects. Clinical Research Associate [Internet]. 2014. Available: http://www.prospects.ac.uk/clinical_research_associate_job_description.htm
44. Larcher V, Watson A, Slowther A. Core competencies for Clinical Ethics Committees: A consensus statement from the UK Clinical Ethics Network [Internet]. 2007. Available: http://www.ukcen.net/uploads/docs/education_resources/consensus.pdf
45. Woodin KE, Schneider JC. The CRA's Guide to Monitoring Clinical Research [Internet]. CenterWatch; 2011. Available: https://books.google.co.uk/books/about/The_CRA_s_Guide_to_Monitoring_Clinical_R.html?id=x3T5tgAACAAJ&pgis=1
46. World Health Organization. Operational Guidelines for Ethics Committees That Review Biomedical Research [Internet]. World Health Organization; 2000. Available: <http://www.who.int/tdr/publications/documents/ethics.pdf>
47. ICH GCP. 3. Institutional Review Board/Independent Ethics Committee (IRB/IEC) [Internet]. [cited 25 Feb 2015]. Available: <http://ichgcp.net/3-institutional-review-boardindependent-ethics-committee-irbiec>
48. ICH GCP. 5. Sponsor [Internet]. [cited 25 Feb 2015]. Available: <http://ichgcp.net/5-sponsor>
49. NHS Research & Development Forum. Sponsorship Principles [Internet]. 2014. Available: http://www.ct-toolkit.ac.uk/__data/assets/pdf_file/0018/35433/sponsorship_principles_Nov14.pdf
50. Bazeley P. Qualitative Data Analysis with NVivo [Internet]. SAGE Publications; 2007. Available: <https://books.google.com/books?id=R2szyDxU6BwC&pgis=1>
51. World Health Organization. Health Statistics and Information Systems: Definition of Region Groupings [Internet]. 2015 [cited 10 Jan 2015]. Available: http://www.who.int/healthinfo/global_burden_disease/definition_regions/en/



ISBN 978 92 4 151156 8



9 789241 511568

TDR  **For research on diseases of poverty**
UNICEF • UNDP • World Bank • WHO

TDR/World Health Organization
20, Avenue Appia
1211 Geneva 27
Switzerland

Fax: (+41) 22 791-4854
tdr@who.int
www.who.int/tdr

The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration established in 1974. Its focus is research into neglected diseases of the poor, with the goal of improving existing approaches and developing new ways to prevent, diagnose, treat and control these diseases. TDR is sponsored by the following organizations:

