

Stakeholder Review Workshop 17 Dec 2020 Report

Version 3.0 04 March 2021

Authors:

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<u>Summary</u>

The Global Health Network and the Special Programme for Research and Training in Tropical Diseases (TDR) hosted a *"Stakeholder Review Workshop"* to validate the proposed Essential Research Skills Training Curriculum framework.

The aim of the study for **Developing an Evidence Based Essential Research Skills Training Curriculum** was to identify what constitutes the minimum set of skills, knowledge and key principles that would enable those with limited or no previous experience, to undertake high-quality research for health. The study design was underpinned by a three-stage methodology: a knowledge gap analysis, an e-Delphi consensus building process and this *Stakeholder Review Workshop*.

This workshop was a closed methodological step and the participants were selected on the basis that they were a manageable sized group to run a meaningful process whilst representing the wide geographies, research areas and organisations types of the required stakeholders.

The aim of this workshop was to review the methodology used in the previous stages of the study, the suitability of proposed theme groupings used for the results, and to evaluate the applicability of the proposed Essential Research Skills Training Curriculum findings to the global research community. This workshop focused on capturing stakeholder feedback to validate and confirm the previous stages results and the methodology used.

The workshop polling showed substantial agreement between the Delphi panel's ratings and the opinions of the workshop stakeholders. This provides support for the acceptability of the proposed curriculum as a global standard for health research training. A follow-up open workshop will be widely advertised workshop and will focus on identifying the best mechanisms for implementing this training framework and how to integrate it with existing training in different global settings. The aim, in what will be the final step, is to have strong representation from study participants (the research and healthcare community) and wider stakeholders (such as funders, regulators, public health agencies and health organisations).





Introduction

On the 17th of December 2020, The Global Health Network (TGHN) and the Special Programme for Research and Training in Tropical Diseases (TDR) hosted a virtual "*Stakeholder Review Workshop*" to validate the proposed curriculum framework. This workshop contributed to the third and final stage of the study process for *Developing an evidence-led Essential Research Skills Training Curriculum*. In response to the COVID-19 pandemic, the workshop was hosted virtually, using the zoom video conferencing system. Here we report the results of this workshop.

Date of Workshop - 17 Dec 2020, 13.00-14.30 GMT

Workshop chairing panel

- *Trudie Lang,* Professor of Global Health Research at the University of Oxford and Director of The Global Health Network
- Dermot Maher, Unit Head, Research Capacity Strengthening at TDR
- *Pascal Launois,* Research Capacity Strengthening Scientist at TDR and Manager of the Career Development Fellowship programme.
- Arancha de la Horra, Clinical Research Specialist at The Global Health Network
- Bonny Baker, Regional Programme Lead, The Global Health Network
- Nicole Feune, Scientific coordinator, The Global Health Network
- Prabin Dahal, Statistician, Infectious Diseases Data Observatory

1. Background to the workshop

The aim of the study for **Developing an Evidence Based Essential Research Skills Training Curriculum** is to identify what constitutes the minimum set of skills, knowledge and key principles that would enable those with limited or no previous experience, to undertake high-quality research for health. The study design was underpinned by a three-stage methodology to ensure an evidence-led approach for establishing this evidence-led curriculum. The *Stakeholder Review Workshop* was part of stage 3.

Stage 1: Gap analysis

The first step was to conduct a comprehensive review of the responses from a series of i) training needs surveys, ii) research training workshops evaluations and iii) eLearning feedback, gathered by The Global Health Network from 2017 to 2019. We analysed the responses of 7167 participants from across 153 countries. This analysis provided us with a list of 98 research training themes identified by the global research community.

Stage 2: Two-round e-Delphi

The second step was to find consensus on what constituted the *minimum set* of skills, knowledge and key principles that would enable those without previous experience in research, to undertake highquality health research. We conducted a two round online Delphi survey to prioritise the outcomes of the gap analysis. The Delphi panel for this study was formed of both experts and stakeholders in the field of research for health and research for health training, with heterogeneous expertise and from diverse geographical regions. We sought to include views of researchers, research participants, research training facilitators, members of research advisory committees, research funders, authors of





peer-reviewed research training papers, authors of research training books/programmes, journal editors, research policy makers and regulators.

Delphi Round 1 - The Delphi Round 1 survey offered an opportunity for panellists to i) indicate which of the 98 themes derived from the stage 1 Gap analysis they considered *essential* for inclusion in the Essential Research Skills Training Curriculum, *and* ii) suggest any themes that might have been omitted.

The themes presented were scored by the panel on the basis of two classifications: [a] relevance (should this topic / theme be included?) and [b] clarity of each statement (is it clear what the category or theme reflected?)

There were 254 members on the Delphi panel for Round 1. The panel reached consensus on 43 listed themes to be *included* in the Essential Research Skills Training Curriculum. No consensus was reached for any theme to be outrightly *excluded* from the proposed framework.

The remaining 55 themes were re-evaluated in Round 2 (including 8 themes indicated as *unclear* in Round 1) and alongside 10 *new* themes generated by panellists in Round 1.

Delphi Round 2 - The Delphi Round 2 survey re-evaluated the remaining 55 themes including 8 themes indicated as *unclear* in the first round and alongside the 10 *new* themes generated by panellists in Round 1. For the purposes of Round 2, themes were scored using a nominal scale [yes/no] for both classifications; relevance and clarity. There were a total of 222 panellists participating in Round 2.

At the end of Stage 2, a final list of 108 themes was generated for inclusion in the curriculum. The research team grouped the themes into $\underline{13}$ 'parent modules' which were reviewed by the stakeholders attending this workshop (*see Annex 2*).

2. Objectives

This workshop was a joint collaboration between TDR and The Global Health Network. The aim of this workshop was to consider the results of the study, to:

- i) review the suitability of the theme groupings as an accurate reflection of the content *and*
- ii) to evaluate the applicability of the proposed Essential Research Skills Training Curriculum findings to the global research community

The research team gave a presentation offering an overview of the methodology undertaken and the findings of this study (see workshop agenda in annex 3). Stakeholders engaged in an interactive polling exercise to add to these findings. This workshop focused on capturing stakeholder' feedback to complement the Delphi study results, as the panel had only 3% stakeholder representation.





3. Stakeholder workshop participants' characteristics:

The workshop was attended by 42 stakeholders. The following figures describe their role as stakeholders in the field of health research.

a. What type of establishment do you primarily work for?

Stakeholders' work establishment	Total Numbers (n=42)
Academia (university, college,)	14
Commercial Research Organisation	0
Community Health Centre/Facility	0
Consultancy	1
Government Ministry	2
Government research organisation	4
Hospital (Private)	0
Hospital (Public)	1
Industry (including Pharma)	0
International organisation (IGO)	2
Journal / Publishing company	0
Non-government organisation (NGO)	4
Public Health institute	3
Regulatory organisation	0
Other research organisation	7
Self-employed	0
Unemployed	0
Other	4

Table 1: Stakeholders primary work establishment

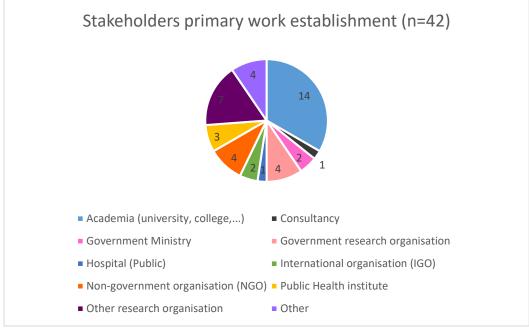


Figure 1: Stakeholders primary work establishment





b. Which of the following categories best describes your experience or role in research?

Experience in Research	Total Numbers (n=42)
I have experience leading research projects	28
I am currently working in research	33
I am/have been the named lead on grant applications	29
I deliver training in health research (e.g. GCP)	21
I mentor undergraduate/postgraduate/PhD students engaged in research	25
I am involved in the design or coordination of training curriculums that include research skills (e.g. undergraduate courses/medical courses)	18
I am a member of a research advisory committee/international review board	12
I work for a research funding organisation (e.g. Wellcome, EDCTP)	6
I have authored and published peer-reviewed research training papers	10
I have authored and published research-training themed books or manuals	3
I am an editor or on the editorial board of a health research journal	11
I am a policymaker or hold a position within the Ministry of Health	1
I work for/have experience working for a regulator (e.g. FDA)	2
I work for/have experience working within commercial industry (e.g. GlaxoSmithKline)	2
Research participant in a research study (i.e. as a patient)	5
Other	3

Table 2: Stakeholder experience (* multiple options could be selected)



Figure 2: Stakeholder experience (* multiple options could be selected)





c. What types of research methodology do you have experience in?

Research Methodology Experience	Total Numbers (n=42)
Clinical trials	22
Post registration / pharmacovigilance	3
studies	
Epidemiological studies	25
Case studies	11
Observational studies	23
Other Quantitative methodology studies	15
Qualitative methodology studies	15
Mixed methods research	20
Evaluation studies	10
Consensus-method studies	2
Action research	2
Document research	8
Not applicable (ie for research participants)	1
Other, please state	0

Table 3: Stakeholder research methods experience (* multiple options of studies could be selected)

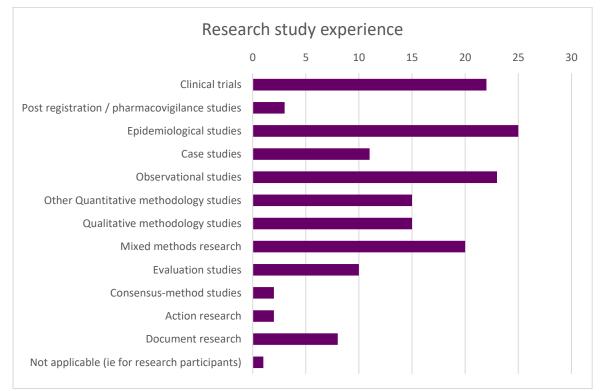


Figure 3: Stakeholder research methods experience (* multiple options of studies could be selected)





d. Which country/countries is your work primarily based in?

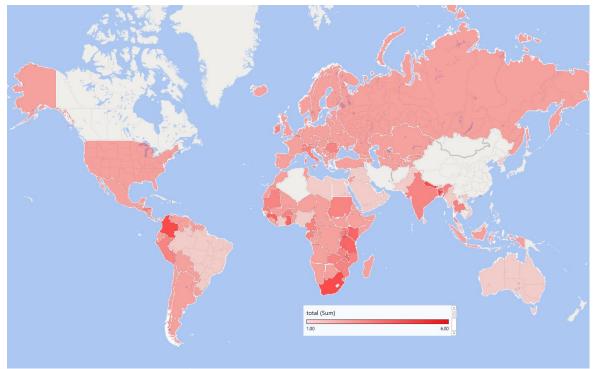


Figure 4: Map highlighting stakeholders' countries of work

4. Workshop polling

As part of the workshop, an interactive session sought to capture direct feedback and input from the stakeholders. Each question was presented to the audience in turn (with a yes/no answer option), and attendees were asked to answer live by selecting their response on their screens or device. Attendees were also invited to provide any further details or free-text answers to support their choice, in the Q&A feature of Zoom.

	Yes	No	No response
Objective 1: Validate the grouping of the themes	(potential mod	ule titles)	
a. Are these titles an accurate reflection of the content of the themes? (n=32)	31 (97%)	1 (3%)	11
b. Does this address the key Essential principles of the research process? (n=31)	31 (100%)	0	12
Objective 2: Global applicability of the findings			
c. Is this proposed curriculum globally applicable? (n=30)	26 (87%)	4 (13%)	13
d. Would this proposed curriculum be relevant to different types of research? (n=31)	23 (75%)	8 (25%)	12





After each poll, the results were calculated and shared live, before moving on to the next consecutive question. Attendees had the opportunity to see the collective responses and views, from across those actively participating. Not all attendees to the workshop contributed to the interactive polling review. Eight attendees did not complete any polling questions.

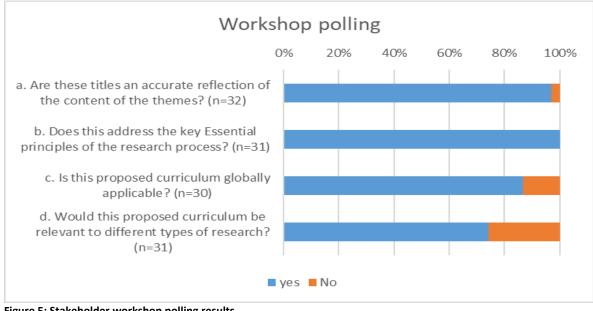


Figure 5: Stakeholder workshop polling results

5. Comments from attendees

Attendees were strongly encouraged to submit their comments in support of their voting options, especially if they had selected answer option "no" in the polling. The attendees' comments, suggestions and recommendations were collated and are summarised as follows:

- Suggestions regarding theme classification Attendees suggested to change terminology from *Good Clinical Practice* to *"Good Research Practice"* to encompass all research standards. This term has been incorporated into the themes grouping.
- *Monitoring and evaluation* and *audit* themes were re-allocated from "Running the research project" module to "Research governance and regulations" module as suggested by stakeholders.
- The module "Running the research project" was renamed as "Research administration and management" as suggested by the stakeholders. There were no suggestions for new modules. We would like to clarify that the themes listed within the modules <u>do not</u> represent individual lessons to be delivered, they are an indication of concepts to be included in the module.
- Mentorship was suggested as a positive way of supporting the delivery of the curriculum.
- Regarding the global applicability of the Curriculum, participants who selected "no" raised concerns regarding how to adapt the curriculum to different settings, particularly in low resource settings. This has been taken into consideration by the research team and will be explored in the upcoming *Implementation Workshop in February 2021*.
- Those concerned with the applicability of the curriculum to all types of research stated reasons including: *"some sections are relevant to all areas of health research; other sections*





or themes are more specific.....so perhaps a general basic view and knowledge is desirable, but in what regards methods, different "sub-branches" could be necessary".

6. Follow up action plan to contribute further to the research study objectives

While the *Evidence-led Essential Research Skills Training Curriculum framework* has now been validated in this workshop, the key final step is to ensure that these findings can be implemented within the highly varied settings where this curriculum is intended to bring impact. The final step in this research study will be to ask a wider group how they would like to use this curriculum and suggest various mechanisms by which it could be implemented.

Therefore, the research team will conduct a follow-up **open** Implementation Workshop, inviting the Delphi study panellists and a wide range of experts. The aim of this workshop will be to critically assess and understand the various ways this Essential Research Skills Training Curriculum could be implemented in order to guide easy, faster and better research in any given healthcare setting, with any or no previous experience. This workshop will determine

- The expectations of potential users and value of this curriculum training
- the implications of local context for implementing the curriculum
- o the applicability of the curriculum in the context of an outbreak scenario

Further reference material and supporting information are available here:

Essential Research Skills Training Curriculum webpage

Essential Research Skills Training Curriculum - Delphi survey round 1 report

Essential Research Skills Training Curriculum - Delphi survey round 2 report

7. Conclusion

The workshop polling showed substantial agreement between the Delphi panel's ratings and the opinions of the workshop Stakeholders. This provides support for the acceptability of the proposed curriculum as a global standard for health research training.





8. Acknowledgements of collaborations and sponsors

With thanks to all participants and panellists who contributed to this research project.



This research was conducted across projects supported by the following funding organisations:



BILL&MELINDA GATES foundation



This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No.s 734548, 734584, 734587







<u>9. Annexes</u>

Annex 1: List of stakeholders who participated in the *Stakeholder Review Workshop* hosted on 17th December 2020

First Name	Last Name	Organization	Job Title	Which country is your work primarily based in? Please list as many as applicable
Neal	Alexander	LSHTM	Professor of Medical Statistics and Epidemiology	United Kingdom
Jackeline	Alger	Unidad de Investigación Científica, Facultad de Ciencias Médicas, Universidad Nacional Autonoma de Honduras	Faculty	Honduras
Mir Nabila	Ashraf	Icddr,b	Research Fellow	Bangladesh
Caesar	Atuire	University of Ghana	Senior Lecturer	Ghana, UK, Italy
Joseph	Bonney	Komfo Anokye Teaching Hospital/ Kumasi Center for Collaborative Research in Tropical Medicine	Emergency Medicine Specialist/ Research Fellow	Ghana
Maria del Mar	Castro Noriega	Centro Internacional de Entrenamiento e Investigaciones Médicas (CIDEIM)	Clinical researcher	Colombia
Mathildah	Chithila- Munthali	Agency for Scientific Research & Training (ASRT)	Executive Director	Malawi
Anniza	De Villiers	South African Medical Research Council	Snr Scientist	South Africa
Jocelyn	DeJong	Faculty of Health Sciences, American University of Beirut, Lebanon	Professor and Associate Dean	Lebanon, Jordan, Middle East region primarily
Helen	Demarest	Medicines for Malaria Venture	Director Clinical Operations	Sub saharan Africa, South East Asia, Latin America
Noshin	Farzana	lcddr,b	Research Investigator	Bangladesh
Adama	Faye	Institut de Santé et Développement	Directeur	Sénégal
Morenike	Folayan	Obafemi Awolowo University, lle-Ife	Professor	Nigeria





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Toral	Gathani	University of Oxford	Senior Clinical Research Fellow and Consultant Surgeon	United Kingdom
Carlo	Giaquinto	University of Padova and PENTA	Professor	Europe
Nancy	Gore Saravia	CIDEIM	Director	Colombia
Mariam	Hassan	Shaukat Khanum memorial cancer hospital and research centre	Clinical Research Office	Pakistan
Andres	Jaramillo	CIDEIM	Cooordinator Research Promotion and Development Unit	Colombia
Sandra	Johnson	Medicines for Malaria Venture (MMV)	Outsourcing Director	UK, Australia, Zambia, Gambia, DRC, Congo, Cote d'Ivoire, Cameroon, Gabon, Tanzania, South Africa, Brazil, Thailand, Kenya
Leigh	Jones	Oxford University Clinical Research Unit (OUCRU)	Head of Training	Vietnam, Thailand
Wafa	Kammoun	Regional Training Center (EMR)-TDR-Institut Pasteur de Tunis-Tunisia		Tunis-Tunisia
Roxana	Lescano	Red de Comités de Ética de la Investigación del Perú - (REDCEI)	Directora, Gestion de la Investigacion	Peru
Eusebio	Macete	Manhica Foundation	Director	Moçambique
Yodi	Mahendradhata	Universitas Gadjah Mada	Associate Professor	Indonesia
Mahesh	Maskey	Nepal Public Health Foundation	Executive Chair	Nepal
Gustavo	Matta	Oswaldo Cruz Foundation	Full Research in Public Health	Brazil
Dr Sangeeta	Mishra	Paropkaar maternity and Womens Hospital	Hospital Director	Nepal, India
Aliya	Naheed	lcddr,b	Head Initiative for Non-communicable Diseases	Bangladesh
Pacifique	Ndishimye	Rwanda Biomedical Centre	Senior Researcher	Rwanda, Romania, Morocco
Thea	Norman	Bill & Melinda Gates Foundation	Senior Program Officer	United States
Chinwe	Ochu	Nigeria Centre for Disease Control	Ag. Director, Prevention, Programmes & Knowledge Management	Nigeria





Enabling research by sharing knowledge UNICEF.UNDP.World Bank.WHO				
Oluwagbenga	Ogunfowokan	Department of Family Medicine	Principal Investigator/ Consultant Physician	Nigeria
Lara	Pandya	European and Developing Countries Clinical Trials Partnership (EDCTP)	Strategic Partnerships Officer	Sub-Saharan Africa
Inma	Peñas	European Commission DG RTD	Policy Officer (focal point for the EDCTP)	Belgium
Mike	Penkunas	United Nations University International Institute for Global Health	Research Fellow	Malaysia
Thy	Pham	Bill and Melinda Gates Foundation	Senior Program Officer	USA
Steffi	Sowinski	European Commission	Policy Officer	Europe
Oscar	Tapera	SADTAP Health Research Institute	Director of Research & Evaluations	Zimbabwe
Mahnaz	Vahedi	Special Programme for Research and Training in Tropical Diseases (TDR)	Scientist	Switzerland
Abhinav	Vaidya	Kathmandu Medical College Public Limited	Professor of Community Medicine	Nepal
Cristiani	Vieira Machado	Oswaldo Cruz Foundation - Fiocruz	Vice-president	Brazil, other Latin American countries
Clare	Viney	The Careers Research and Advisory centre (CRAC)	CEO	United Kingdom
Sinéad	Whitty	The Global Health Network	Training Manager	Ireland, Kenya, South Africa, Malawi, Uganda, Nigeria, Tanzania, Congo, DRC, Burkina Faso, India, Nepal, Bangladesh, UK

Annex 2: Essential Research Skills Training Curriculum - Delphi themes mapping

Research Principles	
Critical thinking in research	93%
Development of a research question.	91%
Concept of health research.	88%
Good Research practice.	88%
Identifying a research gap.	88%
Understanding the difference between health	86%
research and standard of care, audit, evaluation.	
Critical appraisal of a research paper	85%
Legal issues in research	84%
How to form a research agenda.	81%
Research governance and regulations	
Monitoring and evaluation	87%
Governance and regulation	83%
Quality assurance systems	65%
Quality management systems	60%
Audit.	59%
Medicines Supply and Regulations	54%

Research Methodology	
Qualitative data collection methods.	93%
Quantitative data collection methods.	93%
Selection of control groups for comparison purposes.	92%
Quantitative sampling methods.	91%
Quantitative methodologies.	90%
Qualitative sampling methods.	89%
Steps to conduct a literature review.	89%
Epidemiological studies.	87%
Clinical trials.	87%
Qualitative methodologies.	86%
Experimental research.	85%
Qualitative analysis.	85%
Implementation research.	82%
Mixed Methods research.	76%
Research designs for outbreaks	75%
Methodology Research (research on research).	74%
Health Policy and Systems Research.	73%
How to search for secondary datasets in different databases.	70%
Social sciences and anthropological studies.	69%
Meta-analysis.	67%
Health economics and economic evaluations.	54%
Operational research.	52%





Protocol design	
Identifying research participants and selection criteria	94%
Definition and methods of randomization	89%
Writing a research protocol	88%
Calculation of participant sample size and sample power	88%
Writing a study budget	85%

Study set up	
Data collection tools (e.g. designing surveys and CRF's).	95%
Study set-up	92%
Writing a grant application and/or grant proposal	87%
Storage of research materials	81%
Development of Standard Operating Procedures (SOPs)	81%
How to set up study training	75%
Identifying various funding agencies/sources	68%

Research administration and management	
Study reporting procedures and practices	91%
Research Project management and planning.	88%
Pharmacovigilance principles and reporting adverse effects.	82%
Participant 'loss to follow-up'.	80%
Budget management.	79%
Research Time management.	79%
Contingency plans for research studies (in situations like pandemics, etc)	75%

Study close	
Study close (archiving data, sample storing, notification of closure processes).	87%
Best practices regarding referencing and plagiarism.	87%
Scientific writing for journal publications.	86%
Use of citation tools (i.e. Mendeley).	81%
Authorship in research	80%
Research registries	74%
Intellectual property rights	74%

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Ethics	
Informed Consent and assent.	98%
Participant's confidentiality and privacy.	98%
Ethical practices around data handling/management.	95%
Professional guidelines and codes of ethics which apply to the conduct of clinical research.	94%
Definition of vulnerable populations and ethics of working with these populations.	94%
Ethical issues related to biological samples.	91%
Ethical issues related to genetic procedures.	87%
Setting up an ethical review board or committee.	60%

Research data, management & data sharing	
Definition of data quality	92%
Statistics.	90%
Security issues during data collection and how to manage risk.	89%
Data management systems.	88%
Data presentation.	88%
Data sharing best practices and governance.	87%
Data analysis software (qualitative and quantitative).	85%
Principles of Big data analysis	70%
Mathematical Modelling.	50%

Community engagement	
Community engagement principles and activities.	84%
Good Participatory Practice (GPP).	80%
Participants' retention strategies.	79%
Attrition bias and prevention methods.	79%
How to manage expectations of study communities.	76%



Research laboratories	
Good Clinical Laboratory Practice (GCLP).	79%
Laboratory safety practices.	71%
Laboratory biosafety and how to manage hazards.	71%
Laboratory quality best practices.	70%
Laboratory sample handling and storage.	66%
Laboratory standards and regulations.	66%
Specific laboratory techniques and equipment handling.	60%
Setting up a research laboratory.	55%
Laboratory management.	53%



Research Team	
Teamwork	86%
Developing effective research teams with named roles and responsibilities for team	86%
Building trust within a team	81%
Networking and how to create collaborations	80%
Building your career in research	78%
Leadership in research.	67%
Ability to communicate and meet with funders.	65%
Handling and negotiating with a range of stakeholders	63%
Influencing at institutional level to enable research.	58%
Leading and managing complex research groups.	57%

Research uptake - How to make a difference with your findings	
Communicating research	92%
How to translate research results into policy (policy formulation and reviews).	91%
How to translate research results into practice within healthcare settings.	85%
Research Indexing	56%

Annex 3: Stakeholder Review Workshop - Programme agenda AGENDA

Workshop session	Thursday 17 December (13-15 hrs)	Time
Welcome	Aim and Objectives Trudie Lang and Dermot Maher Context setting: global research inequities Building on the shared goal of research capacity initiatives such as the Global Competency Framework for Clinical Research Study rationale and approach Objectives of this workshop	13:00-13:15
Examining the study process and results	<u>Developing an evidence-led Essential Research Skills</u> Training Curriculum: Overview of Study Methodology Arancha, Bonny and Nicole	13:15-13:30
	Questions & Answers	13:30 - 13:40
Polling & Discussion	Objective 1: Validate the grouping of the themes (potential module titles) Are these titles an accurate reflection of the content of the themes? yes/no (poll) – If not, why? (chat) Does this address the key Essential principles of the research process (poll)? If not, why? (chat) Objective 2: Global applicability of the findings Is this proposed curriculum globally applicable? yes/no (poll) – If not, why? (chat) Applicability to all research methodologies: Would this proposed curriculum be relevant to different types of research? yes/no (poll) – If not, why? (chat) Discussion section guided by TGHN	13:40-14:20
Reflection and wrap up	Trudie Lang and Dermot Maher	14:20-14:30