Funder Platform

Funder Platform Report

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of the European & Developing Countries Clinical Trials Partnership (EDCTP)

Project full title:	Creating and enhancing **TRUST**worthy, responsible and equitable partnerships in international research
Project acronym:	TRUST
Type of funding scheme:	Coordination and support action
Work programme topics addressed:	Reducing the risk of exporting non ethical practices to third countries, GARRI-6-2014
Project web-site:	www.trust-project.eu/
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Name of the Coordinator:	Prof. Doris Schroeder (dschroeder@uclan.ac.uk)

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1. Executive Summary

"Ethics dumping", or the application of double standards in research, involves the export of non-ethical research practices to low-and-middle-income countries. The TRUST project has ambitious and visionary objectives to counteract this practice. Over the course of the project we aim to, *inter alia*:

- agree on the generic risks of ethics dumping;
- develop a global code of conduct;
- provide tools that vulnerable populations can use themselves to avoid exploitation;
- develop a tool that can be used during and after research to ensure compliance.

The tool set developed by TRUST will include tools for powerful organisations and for vulnerable stakeholders. To do so requires considerable engagement activities. Central to the work of the TRUST consortium is the notion of 'co-creation'. As we work towards our goals of creating tools that will help to improve adherence to high ethical standards in research in low-and-middle income countries, we are engaging with a broad variety of stakeholders. This report focuses on our engagement activities with funding organisations.

In the TRUST project, the engagement with funders is organised through a 'funder platform' with members from research funding organisations around the world. Representatives from the funder platform were invited to attend a stakeholder workshop in London (June 2017) to hear first-hand about the TRUST activities and to provide feedback on developments to date. The contributions from funders at this meeting are summarised in this report. The valuable feedback we received from the funders will be incorporated into the TRUST tools, helping to ensure their fit for purpose and uptake.

"People of goodwill have a humbleness to learn from each other."
Prof. Klaus Leisinger, FGVA, TRUST partner

2. Introduction

The main goal of the EU-funded TRUST project is to catalyse a global collaborative effort to improve adherence to high ethical standards in research in low-and-middle income countries (LMICs).

The vision of the project:

We work for global, inclusive and fair research without double standards.	We build equitable research partnerships.
We include the voices of vulnerable populations.	We encourage others to do the same.

Achieving adherence to high ethical standards worldwide requires a systematic approach that has been tried and tested in other areas of ethics governance. Key to the fulfilment of this vision is the involvement of all relevant stakeholders, including research-funding bodies. This report provides the context for the engagement of funders by the TRUST project. It describes how funder input has helped us to consider ethical issues in North-South research collaborations from a funder perspective. In addition, it describes how we have sought funder feedback on the development of the TRUST project tools.

The TRUST project's strategic output will be three sets of tools that are developed via participatory engagement covering all continents. The three tools are:

1. a global code of conduct for North-South research collaborations for funders;
2. a fair research contracting on-line tool for vulnerable populations under non-ideal conditions;
3. a compliance and ethics follow-up tool, which takes limited resources into account.

Two of these tools are of direct applicability to funding agencies. The first tool, the global code of conduct for North-South research collaborations, is designed purposefully for implementation by the European Commission and funders worldwide to foster ethical research and equitable partnerships. Similarly, the compliance and ethics follow-up tool is expected to be most helpful to research funders. While the second TRUST tool for fair contracting is being developed for use by vulnerable

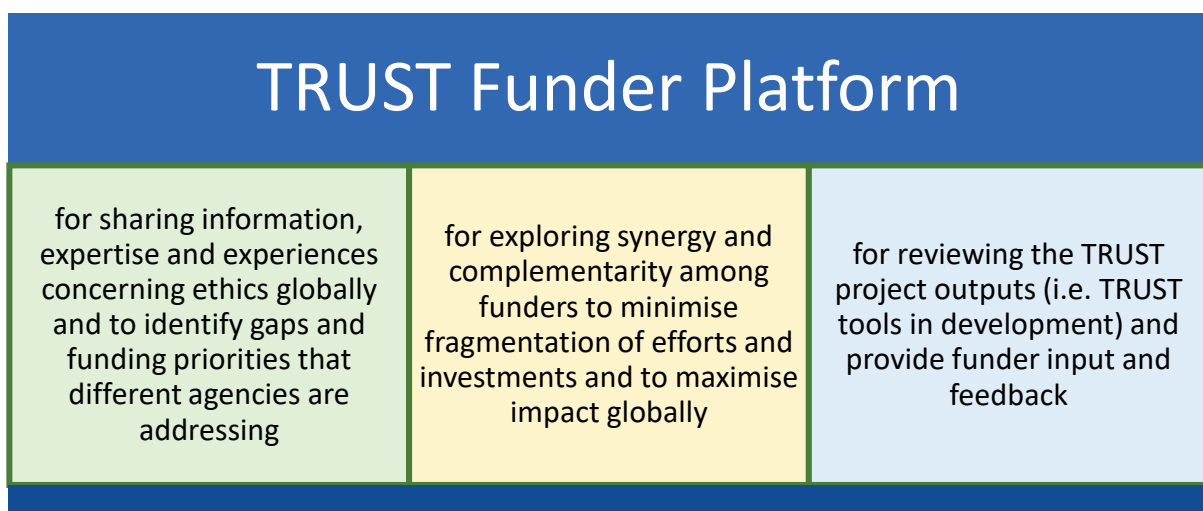populations, funding organisations can play an important role in ensuring its uptake and implementation.

Given that most funders make it a legal requirement to comply with their designated funding instruments, research funders exert great influence on global research ethics. Hence, as influential policy-makers in research ethics, it is vital that research funders are able to engage with, and implement, the TRUST project tools.

Global engagement and debate is foundational for the TRUST project activities and, as part of this engagement, a 'funder platform' was established to ensure effective dialogue with funders throughout the project. The lead for this task was the European & Developing Countries Clinical Trials Partnership (EDCTP), an organisation with more than a decade of experience of distributing funding to undertake clinical trials and create national and regional ethics committees throughout Africa (for more information about EDCTP, see section 5).

The following section describes how the funder platform was established. Subsequently, the outcomes from a workshop in London, June 2017 are described. At this workshop, funders came together with other stakeholders and members of the TRUST project to provide their perspectives and valuable feedback on the TRUST project activities to date.

3. The development of the TRUST Funder Platform

One of the operational objectives of the TRUST project was to establish a funder platform and potential participants were identified through a mapping process of research funders globally. Following an initial exchange of information and clarification of expectations, representatives who were interested in the TRUST mission and its objectives were invited by the EDCTP to join the platform in an advisory capacity.

TRUST Funder Platform

| for sharing information, expertise and experiences concerning ethics globally and to identify gaps and funding priorities that different agencies are addressing | for exploring synergy and complementarity among funders to minimise fragmentation of efforts and investments and to maximise impact globally | for reviewing the TRUST project outputs (i.e. TRUST tools in development) and provide funder input and feedback |

Advisory input has been sought from major funders of basic, clinical and operational /implementation research, based upon their funding expertise and experiences. The topics have included:

- current practices in research ethics in LMIC's;
- ethics committees/review boards in LMIC's;
- adherence to ethical standards and strategies for improvement; and
- ethical codes of conduct and best practices.

To date, the EDCTP has led and established the funder platform (Table 1) within the TRUST project by:

- developing an inventory of major funders of basic, clinical and operational/ implementation research;
- ongoing engagement with funders and like-minded stakeholders throughout the tool development stage;
- co-organising a stakeholders workshop in London (June 2017) for funder input on the three TRUST tools in development.

Table 1: TRUST Funder Platform (*membership as of 1 June 2017*)

Funder name	Type of organisation
Department for International Development	Development agency
Product Development Partnership Group	Product Development Partnership
Global Forum on Bioethics in Research	Other
The Aga Khan University	Academia
University College London	Academia
The Wellcome Trust	Charitable Foundation
National Institute of Health- Fogarty International Centre	Research centre/government funding agency
National Natural Science Foundation of China	Philanthropic/other
Medical Research Council, United Kingdom	Publicly-funded government agency
Drugs for Neglected Diseases initiative – Africa Regional Office	Product Development Partnership
South Africa Medical Research Council	Parastatal research organisation
Calouste Gulbenkian Foundation	Portuguese Private Foundation
WHO-TDR	Philanthropic/other

4. The London Stakeholders workshop

On 12-13 June 2017, the TRUST consortium held their stakeholders' workshop in London. The main aims were to highlight "*co-creation*"; to hear about good practice and challenges; and to seek feedback on the current versions of TRUST tools under development.

'Co-creation' is the key to the many successes of the TRUST consortium

From the TRUST consortium launch meeting in Paris (2015), through the case studies workshops in Mumbai and Nairobi (2016), and the launch of the first ever San code of research ethics in Cape Town (2017), the journey of co-creation continues…..

The London workshop was hosted by the Wellcome Trust and brought together representatives from funding agencies, the pharmaceutical industry, product development partnerships and civil society. Together, we were able to share experiences, lessons learnt and best practice approaches for enhancing ethical North-South collaborations in research.

4.1 Stakeholder meeting keynote address

In his keynote address, Executive Director of EDCTP, Dr Michael Makanga provided an overview of the ethics and regulatory capacities strengthening calls in EDCTP1, highlighted some of the North-South consortia funded in EDCTP2, and stressed the promotion of local ownership and leadership as a bedrock for sustainability and success in collaborations.

Dr Makanga also highlighted the responsibilities that funders have in their work. Through their monitoring and evaluation efforts and respective networks, funders have a responsibility to:

- Recognise the uneven capacities of LMICs, creating ethical awareness globally and at local levels.
- Continue support for the strengthening of ethics, and regulatory capacity and competences in countries where they fund research.
- Recognise the ethics activities of other funders, streamline efforts to minimise duplication of funding and promote synergistic North-South collaborative efforts.
- Conduct ongoing evaluation to better understand the ethics needs of researchers.
- Establish a common framework for sustainable research ethics review capacity. (Frameworks for health research oversight are non-existent and remain underfunded in Africa as governments are faced with competing socioeconomic challenges)
- Ensure that research aligns with local health policy and local research agendas.
- Ensure that a delayed response during emerging ethical challenges such as the Ebola crisis never happens again.
- Ensure that ethics training needs are updated as the global research agenda evolves with regional development and the growing complexity of clinical trial designs in LMICs. In addition to Good Clinical Practice and Good Clinical Laboratory Practice, advanced training that improves the competency of investigators (such as project management, accounting and finance management, and legal frameworks) are equally relevant (Ijsselmuiden *et al*., 2012; CC&DW, 2014).

From the opening session London stakeholder workshop (from left to right): Mr Paul Woodgate (Wellcome Trust), Prof. Doris Schroeder (UCLan), Mr Thomas Cueni (IFPMA),
Dr Nandini Kumar (FERCI), Dr Michael Makanga (EDCTP) and Dr Urmilla Thatte (FERCI)

During the opening session, the slide below, which outlines ethical issues in biomedical research, resulted in significant discussion amongst the audience, in particular raising the question of **accountability** and what is considered to be an appropriate **penalty** for non-compliance.

Source: Bopanna, 2007, 59th Indian Pharmaceutical Congress

Following a panel discussion that comprised representatives from the Forum for Ethics Review Committees in India (FERCI), EDCTP and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), further concerns emerged including: the challenge of clinical

trial designs as more complex diseases emerge; the empowerment of local individuals; the researchers' capacity for ethics; and patient protection.

London Stakeholder workshop (12-13 June 2017) Photo credit: Wellcome Trust

4.2 Ethical issues in North-South research collaborations from a funder perspective

Representatives from five different funding bodies outlined their primary concerns for North-South collaborative partnerships in this session. These perspectives are summarised below. No names are mentioned here as the opinions presented are representative of the funding organisations and not just the individuals who attended the workshop.

Medical Research Council (MRC UK)
- They work with the principle that ethical approval is already in place in the country where the research is being conducted
- There is a need for ongoing funder-partner dialogue
- There is a need for funder contingency plans
- There must be relevance in terms of geography; could the study be situated in another country?
- There is a need for reflection and more leaders from the South bringing new research ideas to light
- There is a need for Research Ethics Committees (REC's) and researchers to stay abreast of ethics
- They take the approach that "the best research is also the most ethically-compliant research".

Wellcome Trust

- There is a need for engagement and capacity strengthening of local regulators, as it is important that research is governed in a manner that is culturally appropriate but recognises the growing global and collaborative nature of research
- There is a need to engage with research populations and RECs to discuss issues associated with research that may not be familiar in different settings – i.e. models of broad consent
- There is a responsibility to fund the capacity building elements around research ethics governance
- There is evidence of a growing change among RECs but this needs to be supported by appropriate training, especially when it comes to new areas of research and emerging technologies
- Data management has been a classic example of the great North-South divide. Overcoming these disparities in data management capacities, can be best served by working in TRUSTED relations with targeted capacity strengthening and building up analytical ability.

WHO-TDR

- There is a role to play in strengthening RECs
- Grants to Masters/Doctoral fellows can help
- There is a need for equal partnerships to ensure timely deliverables.

Calouste-Gulbenkian Foundation

- At Calouste, a philanthropic institution, "there is no North-South collaboration, there is just collaboration"
- Health research is prioritised before clinical trial research
- There is a need to align research with the millennium development goals (MDGs) and the sustainable development goals (SDGs)
- There is a need to recognise the role of the private sector
- Capacity building can be enhanced through partnership with countries such as Angola; strengthened technical and financial capacity; masters and doctoral support along with WHO and the EDCTP
- All health research can be conducted in local institutions
- There is a need to promote local leadership capacity
- There is a need to communicate results back to the local community.

European Commission (EC)

- There is still much to be done to raise ethics awareness in both Northern and Southern countries
- There is a need to educate researchers about the process of ethics review
- The EC's funding of the TRUST project is also to raise ethics awareness
- Research must comply with local ethics laws and regulations in the country where research is being undertaken
- There is a lack of infrastructure in many environments and this needs to be taken into account in research
- There may be delay in receiving authorisation
- Where there is tension between North-South values, local values must be taken into account
- There is a need for stakeholder input
- The EC will support more funding calls that encourage "co-creation" and the bottom-up approach
- The EC commits to having the TRUST global code of conduct available in the EC participant portal, as guidance for North-South collaboration.

Panel discussion led by Dr David Coles (far left) with funder representatives from the European Commission, Wellcome Trust, WHO-TDR, Calouste Gulbenkian Foundation, MRC-UK and the EDCTP.

4.3 Feedback on the three TRUST tools in development

The current versions of the three TRUST tools under development (the global code of conduct for North-South research collaboration, the fair research contracting tool [FRC] and the compliance & follow-up tool), were presented to the stakeholders by members of the TRUST consortium. The stakeholder group included representatives from **funder** groups (WHO-TDR, Calouste Gulbenkian Foundation, Wellcome Trust, MRC-UK, and European Commission) and **industry** platforms (DND*i*, Sanofi, Roche, GlaxoSmithKline and Boehringer Ingelheim)[2].

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[2] The TRUST team have also developed an industry platform. Further information about the industry platform can be found in the TRUST report by Leisinger *et al*. (2016)

4.3.1 A draft global code of conduct for North-South research collaborations

The TRUST project coordinator, Professor Doris Schroeder, presented an update on the development of the global code of conduct. The foundation work for this draft included extensive analysis of existing ethics codes; broad collection of case studies of exploitation in North-South collaborative research; direct consultation with vulnerable research populations (sex workers and the San indigenous people in the Kalahari); and was further informed by the experiences of ethics committee members in India and Kenya. Following this broad consultation and literature review, 88 generic risks for exploitation were identified (Chatfield *et al*, 2016). These 88 generic risks were then mapped against ethics principles in existing ethics codes, guidelines and position statements to reveal the gaps where potential risks exist without any relevant guidelines (Singh & Schroeder, 2017).

Prof. Schroeder presented the proposed format of the global code. The code will be web-based, concise, clear, non-technical, inter-cultural and organised using the four TRUST values: **Respect, Fairness, Care and Honesty**. The code could potentially include links to case studies and the signing of a **Declaration of Honour** by researchers.

Proposed format of the global code of conduct
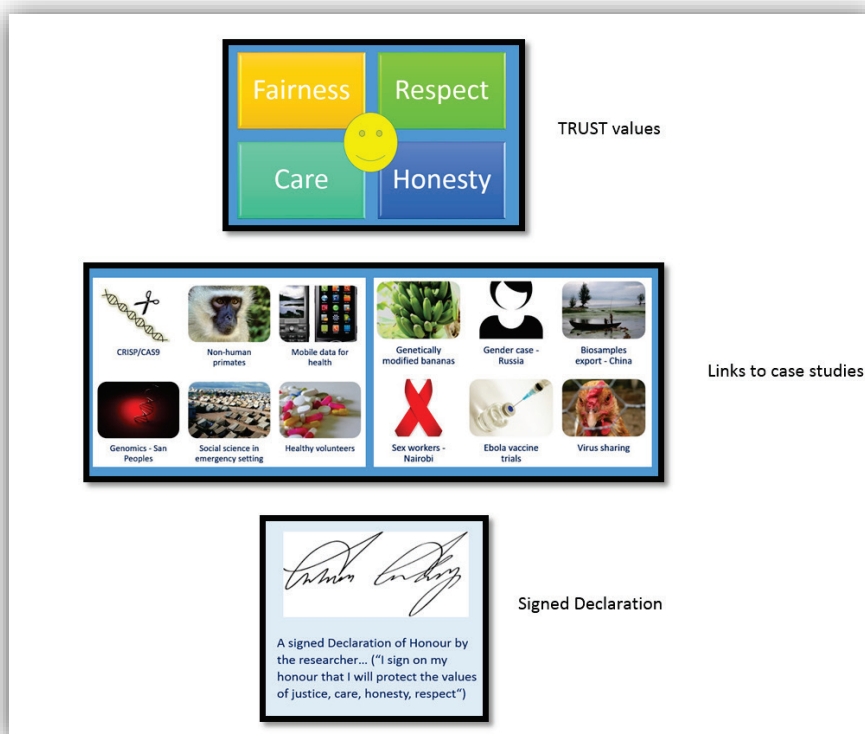
The TRUST consortium wishes to avoid:

- a tick-box mentality, as equitable North-South partnerships require committed, responsible, reflective and careful researchers and innovators;

- over-kill by funders, as equitable North-South partnerships require funders who have compliance mechanisms that do not create significant costs and burdens for successful, committed partnerships; and
- paternalism by Northern ethics committees, as equitable North-South partnerships require culturally sensitive ethics review rather than Northern ethics committee members imposing or neglecting conditions out of ignorance.

Stakeholder input and feedback. The following topics were noted during the feedback session and will be taken into consideration by the TRUST consortium:

1. The sustainability of the code.
2. A matter for informed consent: how consent is affected by translation and back-translation.
3. The question of gold standards for REC review capacity.
4. Comparisons between standard of care in different countries/environments.
5. Issues of language across boundaries.
6. New principles in ICMR Guidelines (2016) are to be considered: accountability, transparency & social responsibility.
7. There was a lot of discussion about the issue of signing a Declaration of Honour:
   - discomfort regarding signing on the part of vulnerable populations, especially when it is one-sided, only the research participant signs;
   - cultural-setting needs to be considered;
   - signing denotes a level of seriousness; and
   - it may imply evidence, contractual or for the purpose of litigation.

*Prof Schroeder clarified that the word **TRUST** remains at the core of this declaration, where an individual's word is valued as being very important.*

8. Existing (or lack of) governance structures.
9. The question of how the code relates to other relevant codes.
10. The potential for linking this code with others.

Prof Schroeder clarified that the global code of conduct deliverable from the TRUST project will be tailored to the regulations of Horizon 2020 for use by the EC.

4.3.2. Fair research contracting (FRC) web-tool

TRUST member and Director of COHRED (Africa), Jacintha Toohey, presented a draft online version of the Fair Research Contracting (FRC) web tool, for use by civil society organisations. The FRC is a best practice tool [http://www.cohred.org/frc/] for global health research contracting, which is still under construction. The FRC supports international health research at three levels:

- where no legal support exists;
- where there are limited legal resources; and
- where there is legal capacity.

The benefits of the FRC include:-

Increasing global competitiveness through:
- Knowledge about intellectual property rights
- Capacity building efforts
- Ownership/sharing of data
- Compensation for overhead costs
- Research contracting context.

Building institutional reputation and research capacity to ensure:
- Collaborations with both sides of the partnership have skilled contractors
- Facilitation of more efficient contracting arrangements
- Decreased complications during and after research
- Better contracts for improved intra-mural management of research
- Enhanced access to more resources for funding institution infrastructure such as buildings, research equipment, scholarships and staff.

The FRC initiative provides:
- Guidance tools (booklets and notes)
- Workshops
- Technical consultancy: Legal advice to research managers on specialised areas such as intellectual property, data sharing/ownership, and overhead cost recovery.

During the London stakeholder workshop, all attendees were afforded the unique opportunity of participating in an interactive review of the latest web-version of COHRED's FRC tool by logging onto the test website and conducting a pilot assessment via their smartphones or tablets (Toohey, personal communication, 2017). Following months of intensive research design and web development, the preliminary responses to the FRC tool described here are very encouraging[3]. Figure 1 shows the current fields of practice of the survey participants.

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[3] Preliminary data on the FRC tool presented in this report emanates from an anonymised survey conducted at the London Stakeholders' workshop by Jacintha Toohey, Director of COHRED Africa. The EDCTP has duly sought and received permission from COHRED Africa for use, analysis and reporting of these data, in this report.

Survey participants
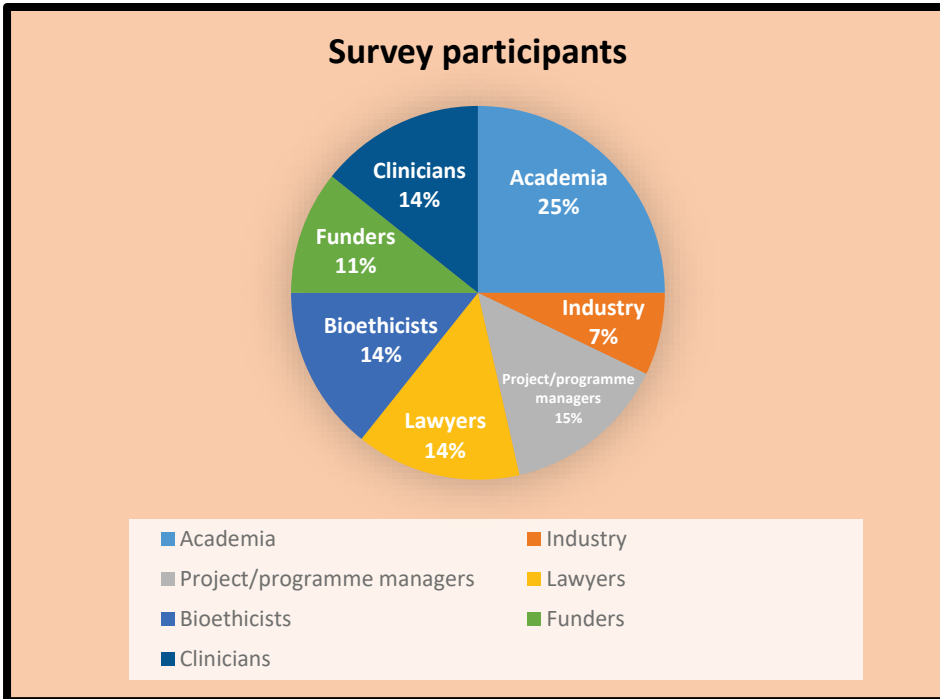
Figure 1. Participants by field of practice

More than 55% of the survey respondents agreed that the tool was easy to navigate (Figure 2); 52% agreed that potential end users could easily understand the purpose of the tool (Figure 3) and nearly half [48.1%] felt that the FRC tool could offer moderate support to its users (Figure 4).
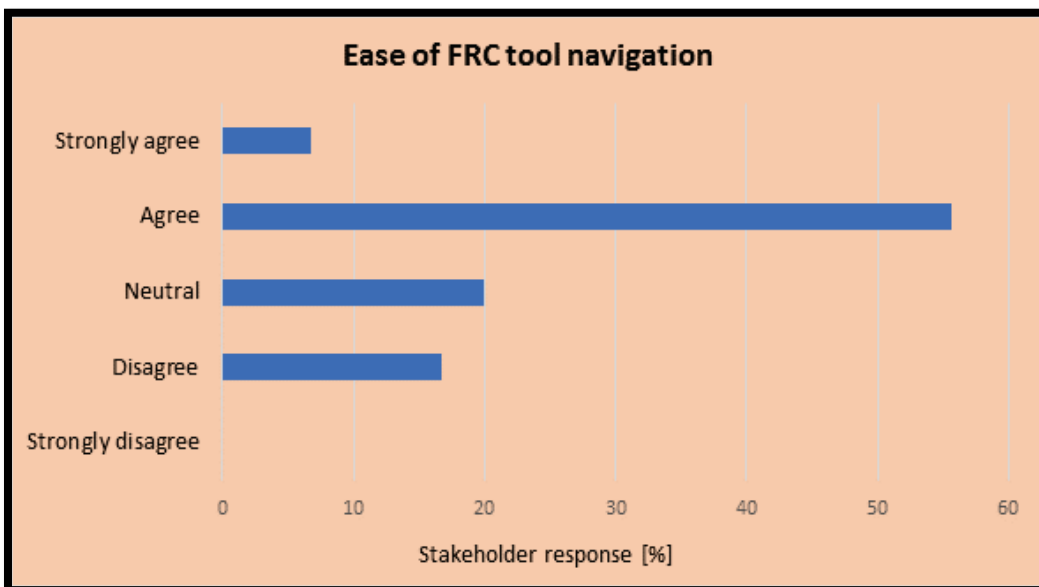
Figure 2: Ease of tool navigation
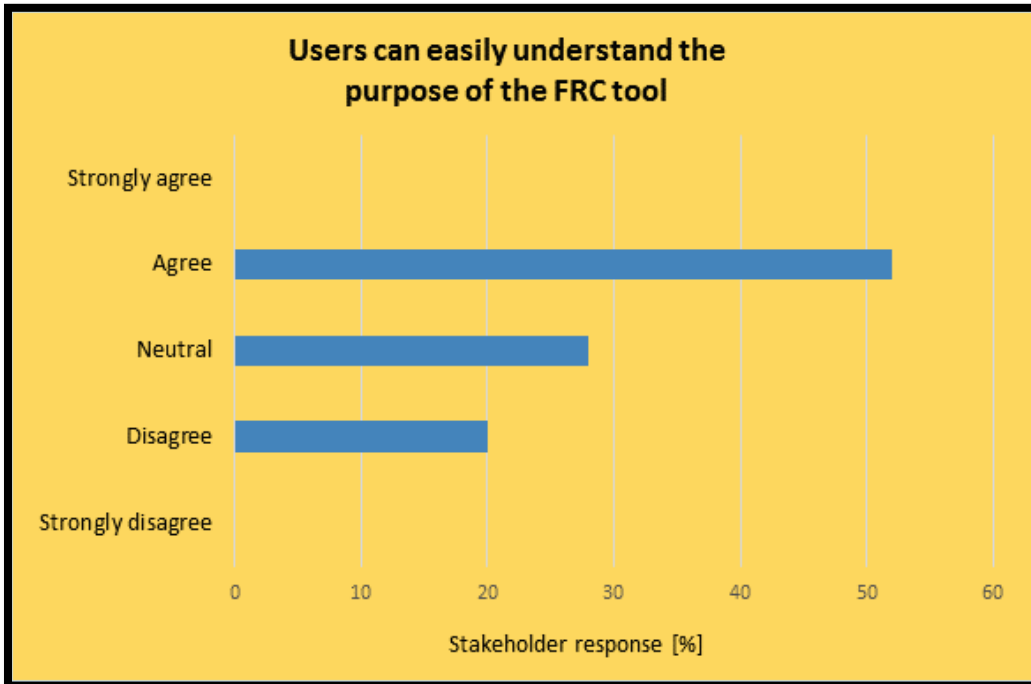
Figure 3: Users can easily understand the purpose of the tool
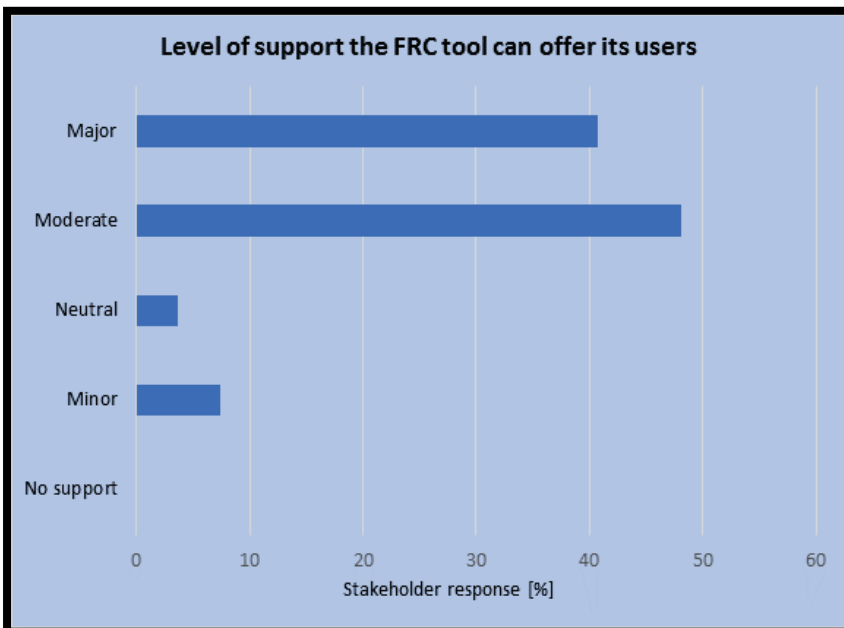
Figure 4: Level of support the FRC tool is able to offer its users

Valuable feedback from the stakeholder workshop will inform future developments of the FRC

4.3.3. Compliance and follow-up tool for north-south collaborations

Professor of Law, Dr Pamela Andanda from the University of the Witwatersrand (WITS) presented highlights from completed deliverables, tools and strategic approaches to ensuring compliance. Compliance failures/challenges and compliance gaps at different levels of governance (individual, institutional, regulatory) can lead to consequences for laws, institutional policies and ethical guidelines.

What leads to the risk of non-compliance?

Regulations, international ethics guidelines, best practice and/ or cultural norms exist, but have been ignored	Regulations, international ethics guidelines, best practice and/ or cultural norms do not exist
Compliance failures and compliance challenges	**Compliance gaps**
For example: - lack of training - lack of control/audit - lack of communication between structures - imposition of the norms of the host institution	For example: - no established structures - no authorization - no control/clearance

Factors leading to compliance gaps, failures/challenges in adherence with ethical standards in international collaborative research include:

- a lack of early engagement with all collaborating partners to define goals, expectations, contributions, roles, responsibilities and supportive action where partners are disadvantaged or in lower resourced settings;
- lack of respect for partner's local ethics regulatory authorities; and
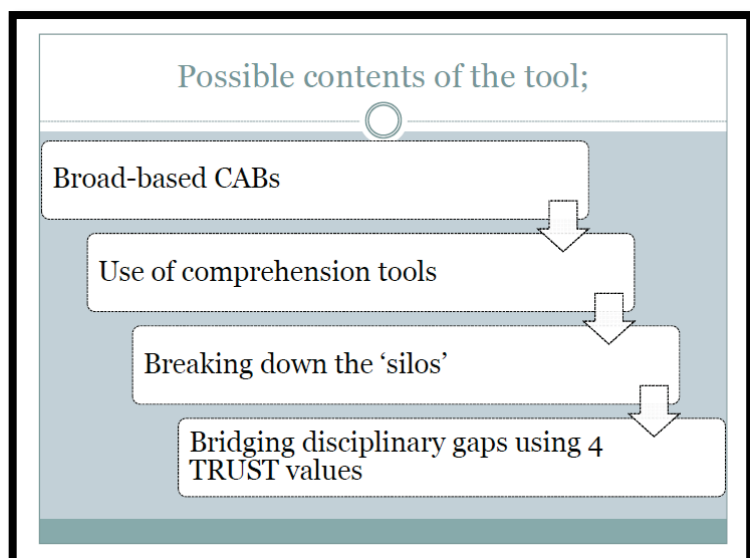- poor effort of partners to consider the legal obligations of researchers in their local context in varying jurisdictions (Andanda *et al*, 2017).

The foundational work for development of the compliance tool has incorporated extensive mapping of national and international compliance tools including existing EU norms, prominent international instruments, self-regulatory mechanisms and existing compliance tools. In addition, legal instruments of research-relevance were also mapped and analysed, including treaties, directives, international ethics guidelines, community specific ethical codes and professional ethical codes (Andanda *et al*, 2016).

Possible contents of the tool;

Broad-based CABs

Use of comprehension tools

Breaking down the 'silos'

Bridging disciplinary gaps using 4 TRUST values

Prof. Andanda outlined the possible contents of the compliance and follow-up tool when seeking feedback. This tool is based upon the underpinning assumption that all research, irrespective of type and where it is conducted, must comply with fundamental principles for the purposes of avoiding ethics dumping. This refers to compliance with institutional policies, ethics guidelines and laws.

Stakeholder input and feedback.
The following topics were noted during the feedback session and will be considered by the TRUST consortium:

1. We need to provide conceptual clarity regarding the compliance and follow up tool.
2. We need to clarify the purpose of the tool i.e., it is not about policy but aims to facilitate research.
3. Consider whether it could have a different name rather than "compliance tool", which denotes a connotation of imposed norms.

Prof Schroeder clarified that use of the term "compliance" is based on the consortium's grant agreement with the European Commission; we are not aiming to develop a tool to cope with compliance failures everywhere, but the tool should inspire people to adhere to high ethical standards. Therefore, 'compliance' is used from a contractual perspective and is legally binding. For instance, funders can use the tool to ensure that the funded research complies with the ethical standards such that failure to do so would amount to a breach of contract.

4. Don't re-invent the wheel of compliance; base the tool on existing practices.

In Task 4.6 of the TRUST contract WITS will be preparing draft proposals for strategic approaches to compliance in LMICs for input by SASI, PHDA and FGVA. This phase will entail detailed analysis of the contributions made by funders and industry stakeholders during the London workshop and incorporating them into the draft presented by WITS. This will be supplemented by additional information from desk review and other relevant TRUST deliverables, as well as input from SASI, PHDA and FGVA- regarding existing practices- before working on the draft strategic approaches.

5. Emphasise the need to take into consideration the local/cultural context.
6. This tool could be linked to the FRC tool in terms of dissemination.

WITS is currently in discussion with COHRED regarding the format that the tool should take to ensure that it is practical and accessible and at no significant cost to the intended users. Thus far, it seems clear that the strategic approaches in Task 4.6 can be applied to the compliance and follow up tool.

7. Propose transparent mechanisms for monitoring compliance in view of the different standards that currently exist in practice.
8. Ensure the sustainability of the compliance tool.

4.4 Conclusion of the meeting

The workshop was concluded by a 'visions' session. During this session, the following points were highlighted as important considerations for future developments:

- Continue stakeholder dialogue and consultation with policy-makers.
- Ensure sharing of lessons.

- Closely monitor the use of social media and mobile telephony in project enrolment as an important under-explored ethics issue in North-South collaborations.
- Search for creative ways to make the TRUST tools useful.
- We need quicker response to ethical dilemmas' posed by emerging situations (e.g. Ebola outbreak).
- Ensure that ethics attention is not only available in medical research in LMICs, but also, for instance, in agricultural research.
- Consider leveraging of existing long-standing partnerships.
- Remember the art of simplification.
- *Embrace a spirit of generosity to strengthen North-South research collaboration.*

4.5 Further Recommendations

As it was not possible to have all members of the industry and funder platforms in attendance, there was a strong recommendation that, once fully functional and ready for dissemination, all three TRUST tools should be formally circulated to all members in both platforms. In addition, the tools should be distributed to other TRUST consortium stakeholders' (for example, the engagement panel) for in-depth review and assessment.

All input and additional suggestions from this in-depth review should then be duly addressed by the respective partners and incorporated into the final version of the TRUST tools for presentation at the final TRUST plenary in 2018.
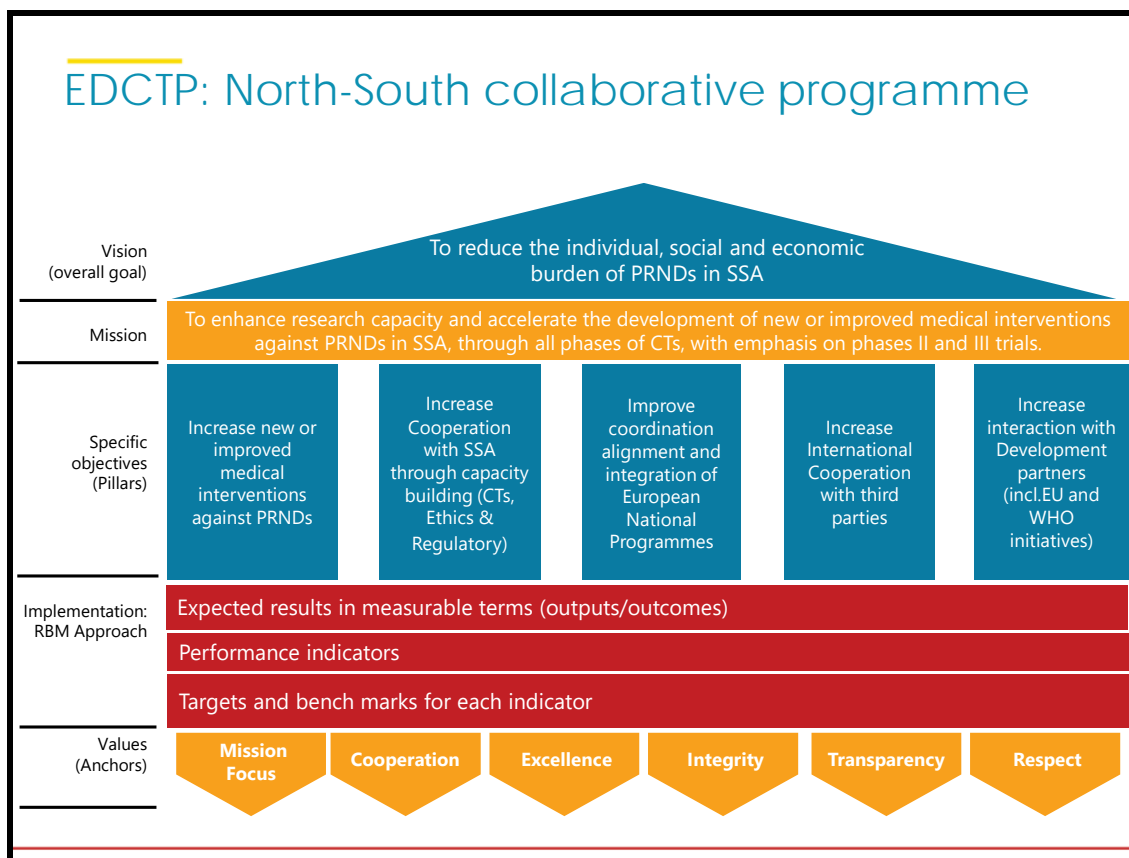
5. About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between 14 African and 14 European countries. These 28 countries, also called the Participating States, are members of the EDCTP Association. The Association is the legal structure for the implementation of the second EDCTP programme (EDCTP2; 2014-2024) and is co-funded by the European Union under its Framework programme for research and innovation, Horizon 2020.

The EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, Tuberculosis, Malaria and neglected infectious diseases in sub-Saharan Africa (SSA). The EDCTP funds mainly clinical research including clinical trials (Phase I to IV) and product-focused implementation research in sub-Saharan Africa. It also supports relevant individual, institutional, national and regional capacities for clinical research, as well as research ethics review and regulatory capacity in sub-Saharan countries.

Ethics and regulatory capacity strengthening during the first EDCTP programme (2003-2013) included the awarding of 75 grants in 23 SSA countries, strengthened ethics review frameworks in SSA institutions and countries, and the development of the appropriate human resources and infrastructures to establish functional, competent, independent and sustainable RECs in Africa. Through the ethics funding scheme, the EDCTP has funded the establishment and strengthening of ethics review framework for health research in countries with little or no ethics capacity. These include Benin, Democratic Republic of Congo, Gabon, Liberia, Mozambique, Rwanda and Togo (EDCTP Annual Report, 2012).

In addition, EDCTP also funded the establishment of the Pan-African Clinical Trials Registry (www.pactr.org) to support regional clinical trial registration in TB, HIV and Malaria. PACTR is the only WHO-endorsed primary register for the African continent.

The dynamic mapping of research ethics committees (RECs), and drug regulatory authorities by COHRED onto a web platform, were also supported by the EDCTP, together with funding from Pfizer and the NIH Fogarty International Centre. To date, the MARC project has successfully mapped 167 [level 1] RECs which are fully operational and the project continues to amass vital data regarding bioethics capacity strengthening (training, infrastructure, and membership) in Africa (Mokgatla et al, 2017).

EDCTP: North-South collaborative programme

Vision (overall goal)	To reduce the individual, social and economic burden of PRNDs in SSA				
Mission	To enhance research capacity and accelerate the development of new or improved medical interventions against PRNDs in SSA, through all phases of CTs, with emphasis on phases II and III trials.				
Specific objectives (Pillars)	Increase new or improved medical interventions against PRNDs	Increase Cooperation with SSA through capacity building (CTs, Ethics & Regulatory)	Improve coordination alignment and integration of European National Programmes	Increase International Cooperation with third parties	Increase interaction with Development partners (incl.EU and WHO initiatives)
Implementation: RBM Approach	Expected results in measurable terms (outputs/outcomes)				
	Performance indicators				
	Targets and bench marks for each indicator				
Values (Anchors)	Mission Focus	Cooperation	Excellence	Integrity	Transparency / Respect

The EDCTP's North-South research collaboration concerns are wide-ranging. They include:

- 2-28 partner institution involvement in a single project;
- a heterogeneous profile (disease profiles, research and ethics capacity);
- an inverse relationship between burden of disease and research and ethics capacity;
- the need to build both research, ethics and regulatory capacity while also being cognisant of potential conflicts of interest between them and the ongoing promotion of local ownership, excellence and leadership.

6. References

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