Kick-off Meeting Report

Kate Chatfield and Doris Schroeder

Project full title:	Creating and enhancing **TRUST**worthy, responsible and equitable partnerships in international research
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Background

This report describes the first meeting of the TRUST project, co-organised by UNESCO and UCLan. At this meeting, representatives of the thirteen partners came together with project advisors and representatives of three funding bodies for the launch of the three-year project.

Achieving equity in international research and the avoidance of "ethics dumping" is one of the pressing concerns of the 21st century. Many international groups and organisations are working on governance frameworks and standards to guide research activities after progressive globalization. In an interdisciplinary collaboration between multi-level ethics bodies, policy advisors, civil society organisations, funding organisations, industry and academic scholars from a range of disciplines, the TRUST project combines long-standing, highly respected efforts to build international governance structures with new exciting network opportunities between Europe, India, Sub-Saharan Africa, China and Russia.

> ***Ethics "Dumping":***
> The term "dumping" is traditionally used to describe predatory pricing policies. Large entities can afford to undercut local competitors for a given period, to drive them out of the market. In the context of research ethics, the TRUST project means *both* purposeful exploitation of third country research participants/ resources as well as exploitation based on insufficient ethics awareness.

TRUST will open up new horizons in improving adherence to high ethical standards in research globally. The project's strategic output are three sets of tools based on participatory engagement covering all continents: (1) a global code of conduct for funders, (2) a fair research contracting on-line tool and (3) a compliance and ethics follow-up tool, which takes limited resources into account.

TRUST project members at UNESCO, 4-5 October 2015, © UNESCO/P. Chiang-Joo

Front row from right to left: Amy Dean, Vasantha Muthuswamy, Francois Hirsch, Paul Woodgate, Dafna Feinholz, Doris Schroeder, Elena Tavlaki, Ivan Ginga, David Morton, Roger Chennells, Olga Kubar

Middle row from right to left: Michelle Singh, Sandhya Kamat, Myriam Ait Aissa, Han Bing, Rachel Wynberg, Jane Wathuta, Najia Musolino, Andries Steenkamp, Michael Makanga, Pam Andanda, Kate Chatfield, Francois Bompart, Giorgio Sirugo, Jaci van Niekerk, Dominique Roome, Karin Schmitt, Klaus Leisinger, Roberta Monarchello, Joshua Kimani, Miriam Shuchman.

Back row Dimitris Micharikopoulos, Miltos Ladikas, Mihalis Kritikos, Johannes Rath, Victor Gomes

Opening Session

Welcome

Dr Dafna Feinholz, UNESCO

"Just reading the agenda for this meeting we can already say that this is something different and exciting"

Dafna Feinholz

DF began the day by welcoming everyone to this important and exciting project, paying tribute to what she described as, "an incredible group, impressive because of the range of representatives we have".

Dafna Feinholz and Doris Schroeder

DF described the importance of the project for UNESCO, explaining how the activities of UNESCO match the objectives of the project. UNESCO deals with both global and regional perspectives, bringing regional voices to the international arena and vice versa. One of the reasons why this project is so relevant is because it is trying to achieve a global perspective on some of the major ethical issues in research. DF highlighted the importance of finding the risks of "ethics dumping" and the fact that while there is a lot of regulation built into the practice of medicine, in research it is not the same, especially in other disciplines (such as social sciences or animal research).

> *An incredible group, impressive because of the range of representatives we have.*
> Dafna Feinholz

The TRUST Co-ordinator, Prof. Doris Schroeder, provided the aims of the meeting and the context, which were transcribed in full.

Aims of the Meeting and Context

Prof. Doris Schroeder

"This is the one project I have been waiting for about 10 years"

Doris Schroeder

This is the one project I have been waiting for about 10 years and I think - with this group - we are going to have a big impact. We are going to deliver everything we have promised in the contract, but we can do a lot more because this is a coordination action, which means our task is to make something happen. The topic of the call was to avoid exploitation in research and innovation taking place in LMICs. Three years with this group is going to make a big difference, especially because we also have funders here. I'm very grateful to all of you that you have agreed to the experimental set up so that you can all meet each other.

> *This is a coordination action, which means our task is to make something happen.*
> Doris Schroeder

Everybody only has five minutes and no power point slides with lots of text, only pictures are allowed. I would like to talk you through the aims of the day and the project.

We are representing the entire planet; there is not a single continent other than Antarctica that we are not covering. At the same time we have five institutions that do global work: UNESCO; Global Values Alliance from Switzerland; COHRED from Switzerland, Action against Hunger from France; and the European and Developing Countries Clinical Trials Partnership from the Netherlands. At this meeting we also have three funders, represented by four people, and I'm very grateful to the ERC, the Wellcome Trust and the EC's DG research.

Welcome slide from DS presentation

We also have specialist expertise, and I'm very proud that we could interest David Morton on the topic of animals, Johannes Rath on dual use and misuse, and Francois Bompart for an industry perspective on drug trials. We are a diverse intercultural and interdisciplinary group. How can we make order from chaos and achieve something in the next three years?

Clear Goals

The first thing is clear goals. We wouldn't have received the funds from the European Commission without this. It is all in the contract it is something we have agreed.

We are going to deliver a global code of conduct of principles that will cut across disciplines, and be globally applicable, so that is a very ambitious goal.

First Goal

The second goal is to build on the COHRED Fairness Index and provide a tool for fair research contracting that people in LMICs can use when they don't have access to expensive lawyers and to roll it out beyond medicine.

Second Goal

Third Goal

The third item we are going to produce is a follow up tool. This will be especially helpful for funders. They will have a means for follow-up that can be used even in resource- poor countries

These are our three goals.

Good Leadership

Another way of reducing the chaos is through good leadership. It is fabulous that we have four women work package leaders, and two male work package leaders. Amongst these six, we have four leaders from LMICs and two from high income countries. In terms of engagement and ability to raise voices, the set up of the leadership will be very helpful.

Teamwork

Then there is teamwork, and here I have a message from David Coles (UCLan) [DS shows greetings from David Coles]. He is looking forward to working with all of you on TRUST.

Our acronym is TRUST and when one looks at TRUST there are already certain elements that are important: commitment, integrity, competence, consistency and sincerity, but there is one thing missing from this list, RESPECT.

A majority of women as work package leaders and a majority of work package leaders from LMICs
Doris Schroeder

In an international and interdisciplinary, intercultural group this is very important. One of the reasons I set up this workshop experiment is because I believe respect can be shown if everybody listens to the others and tries to get to know them. And this is easier if everybody only has 5 minute presentations because then there is room for everybody to talk, everybody fits onto the programme. Under these conditions, if anyone talks for 15 minutes that is not very respectful. At this first meeting I want everybody to say their one challenge their one idea, their one vision.

What are we going to do here in this room today?

All of the sessions are about ideas about what went wrong, how this could be overcome, or visions for the future. All of them are only short presentations. The main reason for doing it this way is so we can see who we have here. By presenting something that you feel strongly about I hope the others will get to know you better.

TRUST slide from DS presentation

Then we want to return from here knowing what our homework is. So in the afternoon tomorrow we will drill down into the details of the contract. So we don't just leave here with big ideas but we want to leave here knowing what we are going to do.

Lastly, I have messages from two advisors who cannot be here.

To reduce the likelihood of exploitation of indigenous peoples, long-term relationships need to be built with researchers and innovators.

Prof. Jack Beetson, Australia

In research ethics, the law is not enough. To claim rights, committed advocates must support vulnerable populations to speak with their own voice.

Prof. Fatima Castillo, Manila

Now I would like to open the floor to all of you.

Panel 1: Cases – Challenges to overcome

Chair: Prof. Doris Schroeder (DS)

Indigenous communities

Dr Roger Chennells (RC) and Andries Steenkamp (AS)

They took it away and very seldom did it come back in any form
Andries Steenkamp

AS began by explaining that he will speak in Afrikaans, RC will conduct the translation. Whilst they spoke, pictures of the San in the Kalahari were shown.

AS is from the San, also called the Bushmen, in the Kalahari. The San people are the most researched indigenous group in the world. A lot of research has been about the plants that they use, but often research is about other things that they didn't understand.

Roger Chennells and Andries Steenkamp

> "A lot was about things that are close to our hearts, sensitive matters. In most cases they took it away and very seldom did it come back in any form."

In recent years the San leadership has received training in matters of research but the communities remain vulnerable to research and researchers. The San leadership has been trying to rectify these problems, but often the researchers go into communities and make promises that are not kept. One example was described by AS:

> In 2010 a number of researchers came to Namibia to conduct research with elderly San people. They avoided the leadership, addressed the people directly, and carried out genetic testing on these elderly people. Reports of the research included sensitive matters that the San leadership felt should not have been published. Following this experience the leadership decided that they must only work with researchers who protect the interests and needs of the San people.

AS described a typical response of the researchers to being asked about their conduct. They said that they have complied with their ethical codes, but the San response is, 'this is not right by us'. That is why they have been working with people like DS, and RC to make sure it does not happen again.

"This is not right by us"
Andries Steenkamp, San Leader

RC has worked as a lawyer with the San people and explained how, in the case described by AS, none of the research ethics committees that approved the research required the researchers to respect the values of the San people. This is a good example of where the law is not enough; well-meaning people doing well-meaning research had hurt a community a lot.


San harvesting Devil's Claw, Photo: Paul Weinberg

DS expressed thanks to RC and AS for coming directly from the plane to speak and said that this example captures the theme, or the essence, of what TRUST is about.

"If we develop something that one side complies with, but the other side is completely unhappy with, this will not avoid exploitation in LMICs. We are looking for *equitable* relationships between researchers and communities."

Rural and illiterate communities

Dr Vasantha Muthaswamy (VM)

"Is human life cheap in India?"
Vasantha Muthaswamy

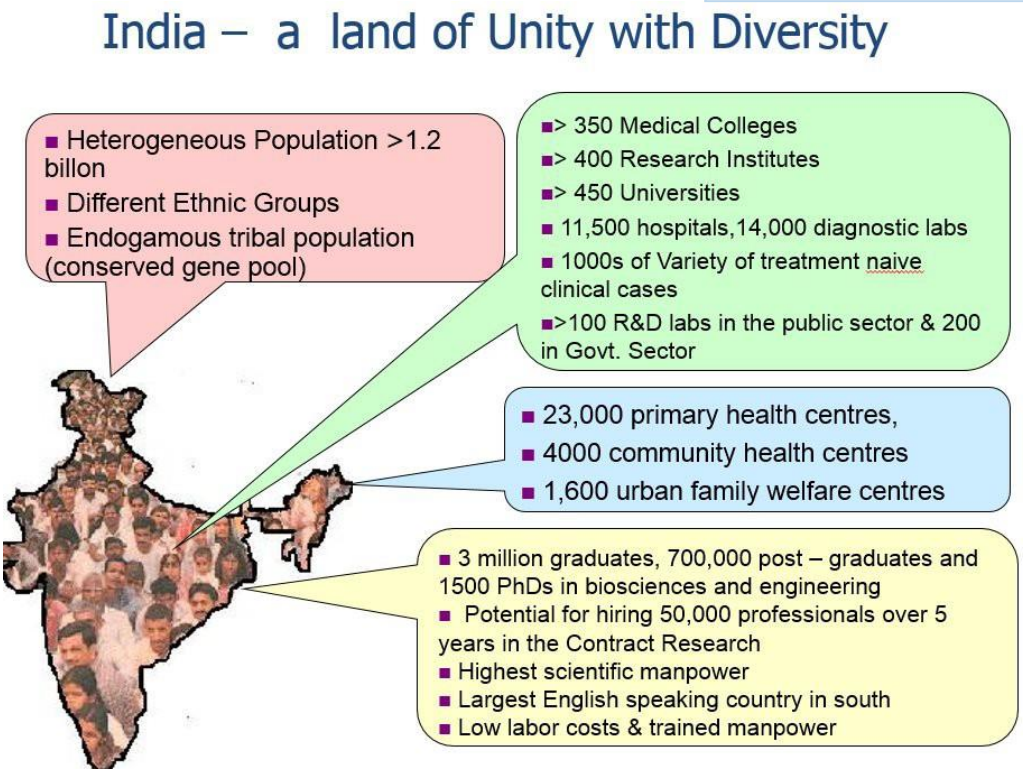
VM spoke about the Indian perspective and described the complexities of working in a large country with many different ethnic groups and huge infrastructures. On the one hand there are some of the best healthcare facilities in India, encouraging medical tourism, but at the other extreme there are many slum areas, served by government hospitals, often with no beds for patients to lie down. Clinical research is conducted in both of these extreme situations and India is now the second most preferred destination for international collaborative research.

VM described one recent study that received a lot of attention, the testing of the HPV vaccine in teenage girls. Thousands of girls living in urban, rural and tribal populations were vaccinated in this study. Critics of the study noted that participants were not aware they were part of a study and procedures for obtaining consent were inadequate. The Indian government initiated an inquiry, which concludes that there had been violations of the rights of the participants and of regulatory procedures.

VM expressed concern that human beings are used as guinea pigs in India. "Is human life cheap in India?" People are not able to check properly for compliance.

DS commented that India is absolutely essential in this project because there is capacity for a lot of research but there are also many exploitative issues and possible breaches of ethical conduct etc.

Vasantha Muthuswamy



Slide from VM presentation

Summary of discussion

Colleague at UNESCO asked the speakers what they thought was missing in the cases they presented and whether we need new principles, better principles or better implementation of the current principles?

VM responded that we do not need new principles, we have very good principles but the implementation and interpretation mechanisms are badly lacking. Whereas AS stated that the San people believe both are required. There are principles that don't get complied with, but there could be improvements to the principles as well.

Participants at TRUST Kick-off Meeting

David Morton (DM) commented, that in the Western world we are used to dealing with principles but it could be that in other situations principles may be misunderstood or in conflict. DS added that research has to be a voluntary exercise, so if the two parties cannot come to an agreement then it should not take place.

AS pointed out that the San do not want to make things difficult, they approve of research generally. The important thing is that rules are made collectively and there is an understanding of each other in the making of the rules.

> *"The important thing is that rules are made collectively"*
> Andries Steenkamp, San Leader

Klaus Leisinger

Klaus Leisinger (KL) stressed that we strive for a global code of conduct, with wonderful principles, but everyone interprets them differently. There are some issues where we all agree but the real problems come from the grey areas that are not so clear. He posed the question as to whether we need a different code of conduct or to find principles to interpret the code of conduct in different cultural settings.

In response DS made the point that principles can be about process and that, in TRUST, we can start afresh with our code of conduct and we do not have to follow any set plan. KL stressed that it is indeed very important to remember that it is content *and* process. It is always both, never just one.

AS & RC remarked that there does not seem to be an accepted mechanism or process to check on compliance, to assess whether people have kept to those principles at some point further down the line. DS answered that in this project we are going to develop a compliance tool for exactly that purpose.

Dependent populations

Myriam Ait Aissa (MAA)

MAA works for Action Against Hunger (ACF), an international organisation that takes a multi- sector approach to ensure nutrition security. ACF intervenes in situations where nobody else can, such as during and post-conflict situations, as well as natural disasters, where there is little or no other support. These are extreme settings.

Miltos Ladikas / Myriam Ait Aissa

Research is promoted within the organisation and they currently have around 20 research activities mainly to do with nutrition and health. ACF work with vulnerable individuals in their research and there are a lot of ethical questions in humanitarian environments. Humanitarian situations need specific ethical guidance as was clearly demonstrated with the conduct of research during the Ebola crisis.

Slide from ACF presentation

Dual use and misuse in LMICs

Dr Johannes Rath (JR)

The security of one country is the insecurity of another country.
Johannes Rath

JR spoke of the issue of dual use/misuse and security in the research context and how it affects the way research is conducted globally. If trust in a security context goes wrong, it goes wrong very badly. Security is part of global research and impacts on global research tremendously. JR gave two examples. The first example involved a security research project,

an international project with the aim of developing a worst-case scenario with a dirty bomb. The project was not permissible in the EU where the explosion of such a bomb was illegal, but there was a partner in a non-EU country who offered to seek permission to explode the live dirty bomb for testing. The recommendation of the advisory board was not to do this and, as an alternative, a mock up was developed and tested.

Slides from JR presentation


Johannes Rath

The second example involved the study of H5 viral strains. Some of the strains came from LMICs. They provided the base information in the form of samples but the findings from the studies were not distributed back to these countries. JR's interpretation of exploitation in a security context relates here to taking samples from an LMIC, bringing them to Europe for analysis and then, for security reasons, refusing to share the findings from the analysis of the samples.

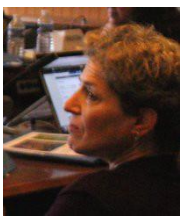
According to JR, the heart of the problem is that the security of one country is the insecurity of another country and that we must build trust for work between that is done for different countries.

Summary of discussion

VM commented that many researchers are not aware of codes of conduct for dual use research, even ethics committees. JR responded that the framing of dual use will influence the way in which research is presented. Ethics is a difficult topic when discussing security issues, because security issues are not about ethics, they are about political interests. We cannot undertake an ethics review if the information is security sensitive. For instance, there is biosecurity guidance but the document is abstract, not operational and cannot be applied.

Vasantha Muthuswamy

Miriam Shuchman (MS) made a point about non-operational codes of conducts and the perception of many that the burden of regulation is blocking and hampering innovation. She asked the group to ponder what we (TRUST) are going to do that we won't be accused of adding just another component that is unworkable.


Miriam Shuchman

RC asked MAA who they contact in communities that are poorly structured. Who represents the collective? MAA's response was that ACF work at the community level and it really depends upon the context and organisation of the community.

Panel 2: Ideas – Ways to overcome challenges

Chair: Prof David Morton (DM)

Industry Initiatives I

Prof Klaus Leisinger (KL)

People all over the world must benefit from research.
Klaus Leisinger

KL made a few short statements. He began with the position that trust is something that is donated and developed but cannot be bought. Many people do not trust industries to behave in an ethical and responsible manner. He believes that the notion of 'leaving no one out' is vital as people all over the world must benefit from research. There are many challenges for deciding about the responsible course of action. For example, definitions are culturally loaded. The Helsinki principles may seem fine to us, but who defines 'voluntary' under conditions of abject poverty? What is voluntary if you earn money as a healthy adult in clinical studies?


Klaus Leisinger

In addition, collectivistic societies have a different attitude towards the individual than individualistic societies, leading to the question of whose legitimacy is at stake? In the pharmaceutical industry there are matters of intellectual property to be considered, and patents that come from trials in situations where the people involved have to bear the risk but possibly cannot afford the product.

Industry Initiatives II

Dr Francois Bompart (FB)

Informed consent is a problem everywhere in the world, including access to drugs after trials.
Francois Bompart

FB explained that large companies are faced with multiple ethical concerns but he will focus on clinical research. The pharmaceutical industry has a terrible image. They are accountable to many and under the scrutiny of ethics committees, journals, the public and so on. Informed consent is a problem everywhere in the world, including access to drugs after trials, ability to understand what is involved, and the ability to understand that participation is something completely different from access to healthcare.


Francois Bompart

The topic FB presented for discussion was that of healthy volunteers who take part in clinical trials in LMICs. In high income countries, most volunteers come from medical schools; they understand what is involved and the money

"An important issue to look at for TRUST are healthy volunteers in LMICs".
Francois Bompart

they make can be viewed as pocket money. In LMICs there is often a very poor understanding of scientific issues and for some people participation in trials could be way of earning a living. Some countries have good safeguards to prevent healthy individuals from becoming professional volunteers but others do not. It is of concern for the individuals involved because it can affect their health but it is also a concern for the scientific validity of the studies. FB requested that the TRUST project look at the issue of healthy volunteers in research.

Summary of discussion


David Morton

DM commented that trust depends on people being trustworthy and that the pharmaceutical industry has an image problem because of its history in demonstrating its trustworthiness.

Prof. Rachel Wynberg (RW) asked how we can ensure that research benefits everyone, and is needs driven, when the needs may not necessarily generate the greatest profits. FB replied that this true that their mainstream research is driven by market assessment. But added that there are mechanisms to address neglected diseases, where there is no money to be made. He affirmed that there need to be alternative mechanisms in place to deal with neglected diseases and neglected patients.

KL remarked that we (TRUST) are a group that want to do things differently. The old model is money driven. He suggested that we might adopt lateral thinking and gave the example that for every company that comes up with a cure for a tropical disease, they might be awarded an additional year for the patent of one of their top sellers. This would act as a stimulus. His advice was to look at where the incentives are.

Dr Michael Makanga (MM) was also concerned about the issue of healthy volunteers in LMICs as there is an increasing capacity to conduct trials in LMICs. DS reminded the group that three policy briefs need to be written in TRUST and that she will collect ideas throughout the project. The topic of healthy volunteers in LMICs could be a possibility for a policy brief.

KL also expressed his concern about healthy volunteers in LMICs. He informed the group that healthy volunteers in Basel get around 2500 Swiss Francs per month and that they are 99% medical students. If you pay the same amount in the South of India you would create a new industry, which nobody wants. If you pay less you can be accused of saying, 'an Indian life is less valuable than a Swiss life'. VM added that this is a major concern in India. A large number of healthy volunteers take part in multiple trials simultaneously. The use of biometry is to be introduced in India to try and prevent this from happening. If the amounts of money given in

India were the same as in high income countries, it would become a great inducement for participation.

NGO/think tank initiatives Geneva

Dr Najia Musolino (NM)

We do not need extra guidelines.
Najia Musolino


Najia Musolino

NM represented the Council on Health Research for Development (COHRED), which developed the COHRED Fairness Index, an example of an NGO/think tank initiative to reduce exploitation of LMICs. This system is designed to enable institutions to comply better with existing guidelines and codes of conduct. NM believes that we do not need extra guidelines, just effective systems to help with compliance. The COHRED Fairness Index is not an index of ranking, rather it is a system that can be embedded within different systems to help foster different partnerships. Currently there is a technical working group working on demonstration studies to see how improvements can be made.
For more information, please see: http://cfi.cohred.org/

NGO/think tank initiatives Nairobi

Dr Joshua Kimani (JK)


Audience

JK works with sex workers in Nairobi, both females and males, through a care programme that is supported by donors. Sex work, gay sex and drug use is illegal in Nairobi so they are working with very vulnerable populations. Through this programme care and treatment for HIV, STIs and other infections are offered to people who do not feel comfortable going to regular healthcare providers because of the stigma they perceive from healthcare workers.

"When individuals volunteer for the research studies, there is a problem with ensuring that participation is entirely voluntary".
Joshua Kimani

From a research perspective, the main ethical challenge has been that people come to the programme for care and treatment, but the research studies are built on these programmes.

People present at the programme for access to treatment, not research, so this makes things tricky for recruitment. When individuals volunteer for the research studies, there is a problem with ensuring that participation is entirely voluntary. JK stressed the need in TRUST for the inclusion of marginalised populations to empower them to discuss their needs and wants from studies.


Roberta Monachello and Joshua Kimani

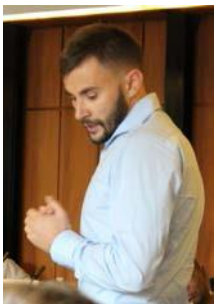
DS reminded the group that the case of the sex workers in Nairobi is one of two major case studies for the project. A meeting will be held in Nairobi and sex workers will have input into the TRUST study throughout.

Funder Initiatives

EC DG Research

Dr Ivan Ginga (IG)

IG described the activities of the ethics team at DG Research of the European Commission. They are a small team of people conducting ethical screenings, assessments, and ethics follow up processes. The new idea that has made a difference, in their view, is the ethics follow up. IG stressed that while we have lots of codes, what the team are trying to do is to create an ethics culture that will go beyond ethical compliance. This is, as he perceives, the challenge.


Ivan Ginga

European Research Council

Dr Victor Gomes (CG)

VG explained that the European Research Council (ERC) is part of Horizon 2020, the major funding programme of the European Union. They are involved with frontier research and hence there are invariably ethical problems. He provided an example of a project that the ERC is funding in a South American country which had an oppressive regime in the past. The study is investigating the oppression but while the former dictator is dead, supporters of the old regime are still alive. This can lead to problems, also of an ethical nature, because sometimes the victims come to complete the paper work for the study and they are faced with former employees of the old regime.


Victor Gomes

Wellcome Trust

Paul Woodgate (PW)


Paul Woodgate

PW described the Wellcome Trust as a legacy funding foundation based in London. The Wellcome Trust fund a whole range of research relevant to health and primarily their review committees are looking for excellence in the research that is being proposed. Many of the projects have built in ethical reflection but one thing they often note is the unevenness of the collaborations. Some partners, from well-resourced backgrounds, are working with people who are not so well resourced, leading to imbalances. PW gave the example of genomic research where samples taken from people in an LMIC are brought back to UK for analysis. Partners from high income countries often gain more credit for the research than those in LMICs. A primary concern for the Wellcome Trust is the need to try to move their involvement more to arm's length; initiatives (in Africa particularly) are becoming more autonomous.

Summary of discussion

Commenting on inequitable relationships, DM commented that what may be needed is an ethics advisor from the local community to provide continuing ethics input into projects. KL pointed out that in many cases damage is done in spite of laws, regulation and ethical codes for medical researchers. He believes the challenges stem from the culture and the leadership.

DS asked the funders to inform the TRUST project of any ways that they could be supported by the project. TRUST wants to have impact, she said, and the funders might want to have advice from a group as well informed as this one.

> *"We would like to work with funders for the duration of TRUST to achieve impact".*
> Doris Schroeder

In reference to IG's talk, DM expressed the view that a culture of care is making sure ethics is not separate from science. It needs to be part of everyday practice for doctors and scientists. RC asked how we can go beyond the guidelines and how this would be defined. Would it require a global set of values or regional?

FH made the point that in his experience, the inclusion of community leaders is never a requirement of the ethics review. This was reinforced by Roberta Monachello (RM), who stated that at the EU level there is no requirement for an ethical advisor from the local community.

It was added that it might be seen as a contradiction when the emphasis is upon excellence in research; people from indigenous communities may have no CV.

Panel 3: Ideas – Vision and ideas

Chair: Dr Miriam Shuchman (MS)

For Africa I

Dr Michael Makanga (MM)

There is an inverse relationship between the disease burden versus the capacity to conduct research.
Michael Makanga

Michelle Singh / Michael Makanga

MM began by describing the activities of the European and Developing Countries Clinical Trials Partnership (EDCTP) whose main activities are in Europe and Sub-Saharan Africa. The main idea that MM wished to express was the idea of having a good balance between healthy regional cooperation between ethics committees, and their having sovereignty in making informed independent decisions about research. Currently, he believes, there is a gap between the two. The EDCTP have provided seed funding at a national and institutional level where the institutions that have capacity to support clinical trials work in collaboration with upcoming institutions that have the capacity but need to be developed. A similar concept has successfully been implemented at the regional level in Africa by national regulatory authorities forming the Africa Vaccine Regulators Forum. This approach could be applied to ethics to provide a regional or sub-regional platform or network.

There is an inverse relationship between the disease burden versus the capacity to conduct research. The countries that have the greatest disease burden have the least capacity to conduct research. When regulators from different countries come together those countries who have the competence are able to help those who have limited competence through joint reviews. MM is proposing a similar construct in terms of ethics to promote healthy collaboration between committees, institutional or regional. They can review complex applications jointly but then make informed decisions independently without compromising their sovereignty.

For Africa II

Prof. Pamela Andanda (PA)

Increased bureaucratic procedures in high income countries promote 'forum shopping'.
Pamela Andanda

PA spoke of compliance with ethics in a globalised research environment, beginning with an overview of the challenges. There is an increased workload for ethics committees in LMICs, too much work to be done, and limited resources. This affects compliance, and focussing on what is driving the increased workload does not resolve the problem. For PA, the issues is,

irrespective of the workload, how to ensure compliance with ethical requirements. Increased bureaucratic procedures in high income countries promote 'forum shopping' so that people go to LMICs to get approvals and conduct research there. There is an inconsistent application of principles and a culture of mistrust.

PA described an initiative in two countries, South Africa and Kenya, to introduce an accreditation system for ethics committees. In order to function they need to be accredited by a national body. This system has been audited in South Africa. The report suggested two points:

1. Monitoring of projects must be active rather than passive. One must not rely on reports from researchers, but go there and see for oneself.
2. There is a need for ongoing training, people need to be prepared for sitting on an ethics committee.


Pamela Andanda

In PA's opinion, the tools that TRUST develop should be able to facilitate accreditation, active monitoring and monitor compliance.

For Russia

Prof. Olga Kubar (OK)

The future of research ethics is global, not local.
Olga Kubar

OK spoke about research ethics in Russia and provided an example for consideration. The study, presented to a local ethics committee, but externally sponsored, investigated the safety and immune response of children under 6 months to the vaccine for haemophilus infection. One criteria for exclusion was that the children could not be vaccinated against hepatitis B. The study was not approved by the ethics committee because it is considered important in Russia to be vaccinated against hepatitis B. This vaccine is free and may be given to newborns within 24 hours of birth. On the other hand, the haemaphilus vaccine is not free so it may have been an incentive for people to refuse the hepatitis B in order to receive the haemophilus vaccine. In conclusion OK noted that the future of research ethics is global, not local.


Olga Kubar, Dafna Feinholz, Doris Schroeder

For China

Dr Han Bing (HB)

HB report that in recent years, the Chinese government has strengthened relevant ethics regulations. For example, in April 2014, the National Health and Family Planning Commission of China has released the draft of the revised Measures for Ethics Review for Biomedical Research Involving Human Subjects, which solicits comments and may be published at the end of 2015.

HB then went on to note that to make research more ethical in China, potential strategies may include improving the review and supervision systems, formulating new relevant regulations, and ensuring observance of relevant rules, i.e. compliance. In this respect, the goal of Trust to develop a compliance and ethics follow-up tool for conditions of high vulnerability will be useful and helpful in practice in China. In addition, a global code of conduct for funders world-wide to foster ethical research and equitable partnerships also could be a good manner to prevent ethics dumping in LMICs.

Mihalis Kritikos, Han Bing

Summary of discussion

FH started the discussion by asking how it could be possible to develop an accreditation programme for ethics committees in Europe, where no one wants to hear about accreditation, and how we might get researchers to reflect upon performance indicators.

MM replied that the setting of indicators is very difficult but one has to strike a balance between having committees that just exist, and those that do quality work. This requires an analysis of the key functions of ethics committees and what they deliver. FH emphasised that we need to see more about the quality of reviews and not just data about how often committees meet and how many reviews they undertake. Indicators could be developed to measure efficiency and effectiveness. VM added that the guidelines from the WHO are very useful for the structure of ethics committees but not for assessing their quality. She also informed the group of standards they have developed in India for assessing the quality of ethics committees and an active programme in 12 countries with different collaborative groups where these standards are being followed.

> *"The setting of performance indicators for ethics committees is very difficult".*
> Michael Makanga

OK also reported on a Russian recognition programme for ethics committees that includes education, training and accreditation. JR commented that this is a very important topic because it introduces the principle of accountability.

In reference to VM's comment, DF described how the application of the standards in Latin America has not been as successful as in other regions. In South America it has been complicated because every country has their own regulations and there is clear disparity

between countries. MS added that the reality is that what might work in one place, will not necessarily work elsewhere.

Audience

FH concluded this part of the discussion with the suggestion that it would be very useful for the European research ethics committee network to obtain some insight into the aforementioned accreditation system.

For Europe I

Prof. Doris Schroeder

> *Equitable relationships cannot be about one person signing off rights whereas the other person just deals with the ethics committee.*
>
> Doris Schroeder

Doris Schroeder

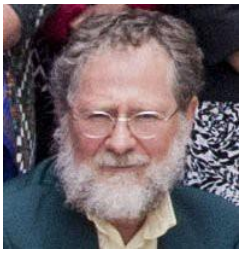
DS highlighted that what we are trying to do in TRUST is to build equitable relationships. These are respectful and trustworthy but they are also mutual and equal. By way of example, DS described her own experience of visiting the San community to make a film about the buchu plant where, in spite of having local collaborators and clear evidence of benefit, she was asked to sign a media contract. This contract described how the San people were happy to collaborate but in the past there had been incidents of exploitation they did not want to incur again. Normally it is the researcher who is asking someone else to sign something, placing all the emphasis of what is going to happen on a potentially vulnerable person. DS believes that equitable relationships cannot be about one person signing off rights whereas the other person just deals with the ethics committee. Instead there should be an engagement between the two. The researcher could also sign something, which could for instance, be the principles of the TRUST global code or something that is specific to the community.

For Europe II

Dr Francois Hirsch (FH)

Capacity building is an important part of trust building.
Francois Hirsch

FH described his experience of working in a medical research institute to help researchers to reflect upon ethical issues. The example he presented to the group was of a proposal for a project with the aim of measuring the impact of nanoparticles from car emission on human health. The project was a collaborative venture between European universities and partners from Latin America.


Francois Hirsch

All of the samples were to come from blood serum collected from children in Mexico but all the analysis was to be conducted in European countries. Following feedback from the ethics committee this was revised as they stipulated that some of the analysis must be undertaken in Mexico to enable capacity building, which FH stressed as an important part of trust-building.

Summary of discussion

DS began this discussion with a caution about the costs involved in any recommendations. Asking funders to send people out to review all projects could be extremely costly and TRUST is already committed to a follow up device that is not more costly than what is happening already. PA explained that, in their programme, compliance follow up is undertaken by local ethics committees. Some of these committees already have the capacity and their role would be to facilitate their work by empowering them with tools so that when they go to do their usual site visits they have 'more weapons' rather than extra tasks or costs. Just improving what they do already so that it helps with compliance. DM remarked that many projects are carried out in ways that differ from the application, it is a global rather than a regional problem. In his opinion, compliance can be checked through a sampling procedure rather than checking every project.


Venue - UNESCO building at night

In reference to DS' experience with the research and media contract, RC said that generally the people who are faced with the San contract are outraged. Some universities have turned away in disgrace. It is good to hear somebody appreciate what they are trying to do.

> *"Ethics committees need more 'weapons' rather than extra tasks or costs".*
> Pamela Andanda

For KL a key issue is transparency. If you ask people, they know the rules, they are obliged to stick to them, and yet under pressure they do not. Whistle blowing could be an important

mechanism for checking compliance. People need to have the opportunity to speak out without fear of retribution. Amy Dean (AD) added that indigenous films may contribute to the assessment of compliance and that the media is underused, in her view.

PA commented that passive monitoring often amounts to a simple tick list and that active monitoring is rare. However, there is a model for active monitoring and it is important to use what is already there.

MM described a clinical trial he was involved in where the availability of a tool for audit of the project and assessing compliance prevented haphazard practice and helped with record keeping.

RW added that for bioprospecting the government can provide consent on behalf of communities. Hence it is important to distinguish between the national level and the indigenous community level.

Panel 4: Special Cases – Challenges to overcome

Chair: Dr Mihalis Kritikos (MK)

This project is a unique opportunity to deliver something that is of practical use.
Mihalis Kritikos

MK gave his views on what the funder is expecting from this project. He noted that other projects have been funded in this area, but this one will hopefully provide fresh ideas and useable tools to overcome existing challenges for ethical research in LMICs. Current capacity building and benefit sharing requirements, he noted, are sometimes not enough and are sometimes too heavy. MK therefore asked for more nuanced tools that funders can employ. He also emphasized that it is important to go beyond the traditional biomedical field and include social sciences and the humanities in any recommendations.

Social Science research in LMICs

Kate Chatfield (KC)

There is a notable paucity of literature that deals specifically with the ethical dimensions of North/South collaborative social science research in LMICs.
Kate Chatfield

KC explained that while social science is a vast field, there is a notable paucity of literature that deals specifically with the ethical dimensions for North/South collaborative social science research in LMICs.


Pam Andanda and Kate Chatfield

The case that KC described concerned the investigation of suicide risk in LMICs. Suicide prevention is an integral part of the WHO mental health action plan, but very few countries have national suicide prevention strategies. There is cultural variability in suicide risk and

hence strategies need to be tailored to each country's cultural and social context. The findings from research in one country cannot be simply applied to another. Research must be conducted in each country to find out what is happening, why it is happening and how things could be improved. This can be extremely challenging, especially in environments where there is stigma attached to mental health problems, where the topic of suicide is a taboo subject and in countries where suicide is illegal. Many ethically sensitive questions are raised:

- Who do the researchers talk to?
- How are they identified?
- From whom do they seek consent and how?
- What measures are needed in case of distress caused during the interview/focus group?
- What incentives are there for people to engage with the research?

Summary of discussion

PW asked whether the countries, which already have a suicide prevention strategy are mostly high income countries. KC confirmed that this is the case. PW asked further whether there are any interesting insights from the existing prevention strategies. KC replied that access to means to kill oneself are one of the main foci. In LMICs, these are mostly agricultural chemicals. MS noted that mental illness in LMICs has often been dealt with by the families only. The question is then can the health service identify mental illness and bring it into the public discourse. Suicide prevention could be part of this effort. KC agreed. KL noted from his work in India that suicides can be caused by societal issues such as domestic rape. He believes that looking at suicide only from a mental health perspective is deficient. KC replied that she quoted the approach of the World Health Organization (WHO) but welcomes this comment.

Paul Woodgate, Dafna Feinholz, Doris Schroeder, Elena Tavlaki, Ivan Ginga

FH asked whether KC has any figures on suicide rates as a comparison between high income countries and LMICs. KC replied that even the WHO state the reliable figures cannot be obtained because suicide is not standardly mentioned on death certificates in LMICs. What they are saying, though, is that numbers are increasing in LMICs. PA agreed with KC and explained that there are societal conditions and structures that lead to mental health issues and suicide. We have to tackle the root of the weed, not only the weed, she said, but it is a neglected area. DM and DF talked about the countries where suicide is illegal. KC confirmed that this makes research very difficult. How can one obtain consent to talk about an illegal activity? MK asked what is the most challenging issue, is it obtaining consent? KC noted that the most challenging issue is finding the right people to work with and getting their trust. RC commented that financial shame and financial fear might be major factors in countries without safety nets.

Animal research in LMICs

Prof. David Morton (DM)

Research ethics committees must act as the advocates of the animals, it is they who provide consent for the animals.
David Morton

DM explained that animals have a different status in LMICs and that standards of welfare vary widely. This tempts some researchers to conduct animal research in LMICs thereby exporting cruelty to LMICs.

Academic journals are looking into the ethical aspects of submitted animal research papers now, as are research sponsors in their consideration of proposals, but there are difficulties in weighing harms and benefits when considering different species. Research ethics committees must act as the advocates of the animals, it is they who provide consent for the animals. There are two main aspects that need careful consideration: whether the research is worth doing, and the ethics of the research process itself (application of the three Rs etc). Animal husbandry must be part of this evaluation as animals spend 100% of their time in their cages.


David Morton

Summary of discussion

KL said that it is our own standards that matter. What recommendations would we give behind a veil of ignorance [referring here to John Rawls' Theory of Justice]. As a researcher you need to defend what you are doing in front of your own conscience. If you can do that, you are in a much better position.

"It is our own standards that matter".
Klaus Leisinger

VM raised the question of what TRUST will do about animal research and DS replied that it is not a main part of the work, but that the project would be incomplete without it. As we cannot have animal welfare experts around the world working with us, we have DM to provide advice to country experts, who will then extract information locally. FB added that TRUST must address double standards. The pharmaceutical industry he works with has research sites around the world, but they make sure that double standards are avoided through global guidelines.


Elena Tavlaki

DM concluded that there is a big difference between human and animal research. There is no limit to the amount of suffering to which animals can be exposed if the researchers can justify it. KL replied that there are higher and lower purposes for involving animals in research.

Biobanks in LMICs

Dr Giorgio Sirugo (GS)

Biobanks can offer fantastic opportunities to address fundamental issues in research of complex diseases.
Giorgio Sirugo


Giorgio Sirugo

GS started by referring to a Science paper from 2007, which discussed the existence of biobanks in LMICs. At the time, there were only four, one in the Gambia [which Sirugo set up], one in Mexico, one in India and one in China. Since then a lot of progress has been made on the technology needed to run biobanks in LMICs. GS explained the need for biobanks in LMICs, especially in Africa where the greatest amount of genetic diversity is to be found as well as the greatest burden of infectious diseases. He noted that biobanks can offer fantastic opportunities to address fundamental issues in research of complex diseases. However, the biobank has to contain quality phenotypic information to be useful. GS mentioned the MalariaGen and H3 Africa initiatives, co-funded by the Wellcome Trust and emphasizing that the new technologies available at low prices could stimulate excellent work in Africa. New biobanks have already been established in Nigeria, South Africa and Uganda and one can hope that they will finally be led by African leadership.

Summary of discussion

MS asked how likely it is that African leadership will be established. Are there rules of the biobanks? GS replied that the analysis of genetic data can nowadays be undertaken very well in African countries. If intellectual contribution will come from there, it will ensure the future of these projects. RW asked about the commercial implications, will there be collaborations with non-African countries given the amount of funds needed to file for patents. GS replied that we will have to come to terms with that. He said that if we want to go from basic findings into drugs and vaccines, a collaboration with the private sector is unavoidable. However, this can be a mutually convenient relationship. JK asked how one can go about obtaining proper consent for a biobank. Is it a blanked consent? GS replied that this is one of the main ethical problems of biobanks and that a lot of progress has been made with local guidelines. KL commented that he does not understand why public institutions are afraid of patent law. A patent does not force you to make a profit with it, but it can help you protect the area of your research. Otherwise you have a very powerful side play against you rather than using it to your own benefit. GS agreed. PA commented that there is a need for international legal and ethical frameworks for research involving biobanks, especially on data sharing.

Agricultural research in LMICs

Prof. Rachel Wynberg (RW)

Rachel Wynberg, Jane Wathuta, Najia Musolini, Andries Steenkamp, Michael Makanga

RW described how research ethics in agriculture is underdeveloped and there are challenges for global applicability because the Western model of agriculture is very different from those in LMICs. High income countries are exporting unsustainable models of agriculture as most of the world's food originates from Gene Giants who supply a small number of species. These species are often not designed to meet the needs in LMICs of resilience and climate change adaption, and these large companies are often the only funders of agricultural research. Currently much of research is undertaken in high income countries and the results applied to LMICs to secure the commercial release of crops etc. This is not sustainable and raises a range of ethical issues in research, including on benefit sharing and risks of new technologies. RW noted that one of her expectations of TRUST is that it helps to conceptualize ethical issues in agricultural research further.

Summary of discussion

MS comments that, in the US, it is not allowed to use foreign trials to justify import or local trials. What is the situation in South Africa, she asked. RW replied that the law is not very progressive and neither is it comprehensive. As long as a risk assessment has been undertaken, it is not required to undertake another one locally. RC asked how the solution would look like. How can one strengthen the laws? RW replied that there are improvements especially in terms of broadening the base of advice obtained on laws.

Panel 5: Expectations and Wishes

Chair: Prof. Doris Schroeder

Each partner and advisor was asked to give a short statement on their wishes and expectations for TRUST.

Partner	Expectations and Wishes
COHRED Council on Health Research for Development	NM emphasised the need to look beyond the corporate agenda. She also noted that COHRED is delighted to be part of TRUST and staff are willing to give substantial input.
FERCI	VM noted that FERCI is very happy to share the considerable experience they have in research ethics. She also stated that this is a unique project and that it is mind-boggling at the moment, but will be a great learning opportunity and rich experience.
	DF noted that the topic of TRUST is part of the everyday life of her unit's work and she is happy to share experiences and resources within this rich partnership. She believes that UNESCO will benefit

	widely from the project, working at normative and educational levels.
South African San Institute SASI	RC explained how the approach of involving multiple levels and types of organisations (including users) fits completely with the needs of the San people. They want tools they can apply to facilitate participation in research without being damaged or abused as in the past.
	FH remarked that he is looking forward to the 'North' learning from the 'South' for a change.
PHDA Partners for Health and Development in Africa	JK is looking forward to developing a code of conduct that will help his organisation to navigate through the minefield of undertaking research on sex workers.
	MAA wants guidance on research in extreme settings that will help ACF resolve practical dilemmas. ACF appreciates the multi-sectoral approach of TRUST.
University of Cape Town · iYunivesithi yaseKapa · Universiteit van Kaapstad	RW stated that TRUST presents a fabulous and timely platform to think more deeply about agricultural research partnerships. Hopefully we will be able to feed into international agreements on this topic, including on benefit sharing.
SIGNOSIS RESEARCH & CONSULTANCY	Elena Tavlaki (ET) described how, at Signosis, they see their role as supportive. They intend to take the burden of the administration and allow the other partners to focus on their core work. As a company, we also want to go one step further, we want to produce outputs to change the world, at least a little bit.
Stiftung Globale Werte Allianz	KL remarked that TRUST fits beautifully into the new UN Sustainability Goals. Leaving no one behind is the essence of these goals. He noted that we are facing significant societal changes but that TRUST is ideally positioned to make a difference by using human ingenuity in the ethical context and his think tank is committed to contributing its best.
EDCTP	MM noted that TRUST is a project the EDCTP takes part in with real excitement. He believes the inclusiveness of the project is unique, combining many different perspectives on ethics. He sees this as a symbiotic relationship that the EDCTP can contribute to but also learn a lot from.
University of the Witwatersrand Johannesburg	Jane Wathuta (JW) noted that it is an honour to be part of this ambitious project. She commented that the project must seek to capture the risks that are knowable and come up with tools that are workable. This will help to fill current gaps and serve stakeholders across the spectrum.
	DS reminded the group of the costs of this project. She hopes that each person will realise that they are in a privileged position and be fully committed to do the best they can to make TRUST successful. She is thus committed.

The TRUST advisors also formulated their expectations and wishes.

Advisor		Expectations and Wishes
Dr Han Bing		I hope that the outputs of this project will be practical, so that countries can use them to address specific challenges.
Dr Francois Bompart		Ethics is not exact science, one works a lot with attitudes. What I like about TRUST is that it will develop tools that are very concrete. I look forward to that and thanks for having us on board.
Prof Olga Kubar		My expectation for TRUST is that our discussions should be open and transparent. [In response, DS noted that even the workshop reports will be very detailed.]
Prof. David Morton		We each have a lot to learn from this group. I think that those involved in animal research and those involved in human research have a lot to learn from each other.
Dr Johannes Rath		One cannot create trust between countries, if there is no trust in security related questions. Likewise, in order to create trust in research, it is important that safety standards apply globally.
Prof. Miriam Shuchman		There is tremendous momentum here. And the timing is right. What are we going forward with after three years is also important given the promise we have.
Dr Mihalis Kritikos		I can see that there is so much potential here, I hope Doris can keep us all communicating and not deterioriate into a traditional project, with little interaction. I hope we can keep the communication between us alive. We have chemistry here!
Dr Giorgio Sirugo		A working party of experienced people who are eager to contribute while speaking their mind out. We started on a very good note and I expect future meetings to be even better.

Funders		Expectations and Wishes
Roberta Monachello, REA EC		I am impressed by the expertise assembled here and also the geographical spread. Hence, the expectations for this project are high and you must deliver what is described in the contract. An operational code of conduct would be very important for the European Commission. Good luck!

Victor Gomes, ERC		It was a pleasure to represent the ERC and I trust that TRUST will provide operationable output.
Ivan Ginga, DG Research, EC		I would like to start with a quote, namely that "science will bring society to the next level and ethics can keep us there". Ethics is an integral part of research and, together with you, we hope to achieve research excellence.
Paul Woodgate, Wellcome Trust		Ethics product that are useful and learning at lot have already been mentioned. As a funder I find it fascinating to hear different opinions from around the world.

We hope that the TRUST project can contribute to creating equitable research partnerships globally.

Slide from DS presentation, Picture bought from Shutterstock