Report:

Towards a sustainable sharing of data & samples collected during trials effectuated in resource-limited countries

Editor: Solveig Fenet
solveig.fenet@inserm.fr

Workshop organized by the Inserm Ethical Committee, Fondation Mérieux & the Global Forum on Bioethics in Research (GFBR)

“Les Pensières” Fondation Mérieux Conference Center
Veyrier du Lac - France
(November 5th, 2015)
Towards sustainable sharing of data & samples collected during clinical trials in resource-limited countries

The sharing of data and biological samples, essential for the advancement of research on human beings, proves to be a problem affecting the whole scientific sphere. The globalization process, which has gradually been extended worldwide, has brought to the field of biomedical research substantial benefits by promoting greater sharing of knowledge and the extension of collaborative projects. Nonetheless, it has also highlighted differences in institutional organisations, cultural approaches, national priorities and legal frameworks. It was proven that benefits sharing derived from internationalization of research projects in resource-limited countries benefited more industrialized countries than countries with low and middle income, where clinical trials are conducted. This observation raises ethical issues of equilibrium between risks and benefit sharing capacities: risks for patients’ security, safety and integrity, and the necessity of addressing inequalities and asymmetries between actors of scientific research, especially among “resource-limited countries” and “industrialized countries”.

On the 5th of November 2015, the Inserm Ethics Committee, Fondation Mérieux and the Global Forum on Bioethics in Research (GFBR), organized a workshop at Les Pensières, Annecy (France), bringing together more than thirty scientists and ethicists, from twenty countries around the world, to debate the way to ensure better sharing of data and biological samples collected during trials in countries with limited resources. The debate highlighted the successes and challenges in various experiences. So the expectations from this workshop were to gather and learn lessons from the field experiences of the different participants, and to address specific ethical tensions in internationalized clinical trials that should help to set in motion guidance and/or good practices for stakeholders of scientific research (researchers, REC members, key community representatives) and policy makers (ministers, agencies):

The issues raised were the following:

- How to organize equitable relations in scientific research while fostering international collaboration in the same time?
- How to protect the interest of the study participants by sharing the beneficial knowledge gathered from data and/or biological samples?
- How to contextualize consent addressed to illiterate populations and make explicit the meaning of their own data and/or biological samples when collected?
Workshop agenda

Introductory lectures, chaired by Katherine Littler (GFBR and the Wellcome Trust)

- From HIV to Ebola, ethical reflection on health research in the Global South and propositions from Inserm and Institut de Recherche et Développement, a joint note, by Christophe Longuet (Inserm Ethics Committee and Fondation Mérieux)
- Regulatory recommendations for the use of personal data, by Yaël Hirsch (Simmons & Simmons)
- Data-sharing and bio-banking - Developing global norms for public health emergencies, by Cathy Roth (World Health Organization, Health Systems and Innovation cluster)

Roundtable discussion: Experience of researchers from different horizons: Successes and challenges, chaired by François Hirsch (Inserm Ethics Committee)

- François Bompart (Sanofi, Access to Medicines)
- Caroline Carbonnelle (Jean Mérieux-Inserm BS4 Laboratory)
- Aïssatou Toure (Institut Pasteur Dakar, Sénégal)
- Godfrey Tangwa (Cameroon Bioethics Initiative)

Breakout group session

- Toward better sharing of data, facilitated by Douglas Wassenaar (Sareti & University of KwaZulu-Natal, Durban)
- Toward better sharing of biological samples, facilitated by Aïssatou Toure (Institut Pasteur Dakar)

Conclusion by Marc Brodin (Inserm Ethics Committee)
Introductory lectures, chaired by Katherine Littler (GFBR and the Wellcome Trust)

From HIV to Ebola, ethical reflection on health research in the Global South and propositions from Inserm and Institut de Recherche et Développement, a joint note, by Christophe Longuet (Inserm Ethic al Committee and Fondation Mérieux):

This workshop has been initiated thanks to a joint note written by the INSERM south group and the IRD. The note gives an ethical reflection on health research in the Global South and a retrospective analysis of experiences from HIV and EBOLA outbreaks. In order to be ready to cope with the next outbreaks, the note suggests also recommendations. The Inserm, the National French Institute for Health and Medical Research, is specialized in basic and applied biomedical research and epidemiology, and the IRD, the Institut de Recherche pour le Développement, is an interdisciplinary research institute contributing to development in low and middle income countries. These institutes have both interacted with the ANRS (French Agency of Research against AIDS and Hepatitis) coordinated action “developing countries”.

With the HIV epidemic, the ethics of health research has evolved in the North and in the South. A better understanding of contextual vulnerabilities and the conditions to transform them into capabilities was described as necessary in order to protect research participants from low income countries. The engagement of bigger communities in research process and the multiplication of collaborative research projects raise issues, of benefit sharing, data protection or informed consent process. Furthermore, the HIV epidemic which lasts for several decades worldwide shows the importance of taking seriously the biopolitical dimensions of health research. Researchers and health bodies need support from government in launching national prevention and vaccination campaigns.

With the West African Ebola outbreak, research faced some new ethical challenges:
- Weakness of health services and populations new vulnerabilities;
- Difficulties in communicating with the communities on an unknown disease;
- Sharing of research costs and benefits.

Some recommendations from the above lessons learned are thus proposed:
- Promote multidisciplinary research, because interaction between biomedical research and social sciences is crucial to understand and negotiate appropriately cultural values and systems;
- Foster reciprocity in the collaboration between researchers from the North and the South;
- Develop the reflection on benefits sharing for research participants and populations, co-producers of knowledge;
- Maintain high ethical standard, even in outbreak situation and context of limited resources;
- Establish mechanisms for rapidly sharing scientific results both locally and internationally during outbreaks and public health crisis.
Presentation of the Inserm Ethic Committee, by François Hirsch from the Inserm:
The Inserm Ethic Committee is composed by 15 members appointed every 3 years. Members are divided into 5 working groups addressing current societal issues:
- Human embryo & development
- Unexpected/incidental research findings
- Gender & health research
- Perception of relationship with lab animals by the researcher
- Ethics and health research in less developed countries
By trying to forge a relationship between the scientific world and society, the committee promotes ethical awareness among Inserm staff on ethical issues raised by scientific medical research and health research. Reflections led during the monthly plenary meetings are then aimed to anticipate and address new ethical challenges linked to the evolution of research in life sciences. The aim is to contribute to the organization of debates in emerging areas of biomedical innovation, members organize workshops reflection, write position papers, and report and summarize this work during the annual Inserm ethics committee Day, were is presented to the Inserm researchers and to general public.

The committee is an open institution, which interacts with other public research bodies concerned with ethical issues.

Regulatory recommendations on the use of person data, by Yaël Hirsch from Simmons & Simmons:
Along with the rapid growth of the digital economy, the need for regulations adapted to the use of information technology and communications (ICT) and harmonized internationally, intensifies. In the absence of a truly unified international or regional regulation, a draft international scale requiring treatment of personal data (e.g. collection, data transfer, etc.) usually involves an obligation to get informed about and to respect the local regulations involved, in each state concerned by the treatments of data.

In general, concerning the protection of personal data, the same definitions and principles are reflected from one State to another. For example, the personal data definition of the African Union draws heavily from that adopted by the European Union: "any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity". Furthermore, in terms respect of principles, for most African states as in states of the European Union, formalities should be accomplished with the competent authorities (declaration or authorization), the collected personal data must be kept for a reasonable and limited time, security and confidentiality of data must be ensured and it is necessary to inform data subjects about the

---

1 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
identity of the controller and of the recipient of the data, the goal of treatment and their rights, etc.

Health personal data are generally considered as sensitive data requiring special protection and require specific enhanced protection. The processing of personal data in the context of a clinical study must generally be authorized by the competent authorities. The collection of this sensitive data must be adequate, relevant and not excessive in light of the purposes. The personal data processed in the field of health research must, as far as possible, be anonymous and the information regarding the identity of participants in clinical studies must be kept confidential. Participants must be clearly informed on the processing of their data (purpose(s), recipient, identity of the data controller, etc.) and shall give their written consent to said processing in accordance with national applicable regulations. Any breach of personal data regulation may lead to administrative and criminal sanctions.

In Africa, several countries\(^2\) have adopted regulations for the protection of personal data. These legislative and regulatory measures show that personal data protection is a global concern. This issue must be carefully considered at the national and regional levels where personal data processing is implemented.

**Data-sharing and bio-banking - Developing global norms for public health emergencies, by Cathy Roth from the World Health Organization:**

**Data-sharing:**
Recent years have seen the growth of clinical trial registries, data-sharing platforms and repositories. However many scientists remain reluctant to share information prior to publication. They fear impediments to publication in good journals, and have understandable concerns about recognition and stealing of data.

However, during an outbreak or public health emergency, rapid sharing of data and other pertinent findings is essential to designing the appropriate response with the necessary public health impact. Data-sharing must be the global norm in public health emergencies. Appropriate systems have to be designed and put in place, with the right incentives and protections for each group. In this process, WHO must attend to the needs of all Member States, but special attention must be paid to the needs of low and middle income countries.

Recent advances have included the agreement of major scientific and biomedical journals that sharing of data for public health purposes during a public health emergency will not negatively prejudice subsequent scientific publication. There have also been examples of early sharing of genomic data. However, more remains to be done in order to systematize data-sharing practices by researchers, and other groups which compile and assess data, including epidemiological/surveillance data, and clinical data.

\(^2\) 16 African states and the African Union has recently adopted an international convention on cybersecurity and including a part on the protection of personal data
Several measures should be adopted to encourage further data-sharing in public health emergencies:

- The recognition that data belong to the countries where they are generated is important, but a shift towards an opt-out policy for data sharing during public health emergencies has to be made.
- The pre-publication sharing of key information of public health importance should not be penalized by publishers, and the scientific community.
- Science funders should consider imposing contingencies in their grants that agreement to share key data and results prior to publication, if demanded by public health events, is required for disbursement of funds.
- The pharmaceutical and biotechnology sectors should have a continued commitment to make research data publicly available.

**Biological samples-sharing and bio-banking:**

For epidemics of severe emerging diseases, biological samples represent precious and non-renewable resources which offer opportunities to advance knowledge and improve disease control. There is a moral imperative to use them prudently to illuminate priority research questions. Safety and biosecurity must be ensured. WHO is working to initiate to initiate a global collaboration for biobanking for severe emerging diseases with the potential to provoke a public health emergency or severe outbreaks. This initiative was stimulated by the EVD epidemic, but the issues are similar for other priority severe emerging diseases.

Several issues have been raised with Ebola virus disease samples from the current West African EVD epidemic, now distributed in many countries. Some related to the restrictions on movements from BSL4 laboratories, the availability of technologies, skills, and containment. Other issues to be addressed include the ownership, the access to benefits and outcomes of research, and the control and involvement in decisions concerning the research to be conducted with samples, initially, and, when relevant, with subsequent use. Ethically acceptable models of consent must be developed for emergency situations and an ethical basis for research decisions must be established for those situations when obtaining retrospective informed consent is not possible.

The existing bio-banks in Africa encounter complex challenges associated with infrastructure, and sustainability. They had to explore many options to determine mutually acceptable processes for international exchange of samples. There is much to be learned from their experiences in creating their eventual governance and legal frameworks.

Possible “realistic” bio-banking issue options for a global collaboration are:

- An international collaboration with a distributed virtual resource of national biobanks, a common IT system sharing inventories and information, and a system of governance and decision-making.
- Special requirements for existing and accruing EVD-related samples include selecting one or more regional laboratories to serve as the repository for samples until more local capacity is developed.
- Support to the creation of sub-regional reference laboratory capacity in West Africa, though establishment of the relevant facilities will require time and significant resources.
In the meantime, urgent interim measures must be taken to ensure the secure storage and the correct conditions for the preservation of samples remaining in intensely affected countries until decisions about the eventual destinations can be made.

More widely and for the future, systems and planning should be ready for the predictable biobanking, sample-sharing and research management needs arising in severe epidemics. A crisis is the worst time to develop systems to deal with complex issues. These systems must be prepared in advance:

- Nationally: research management system with appropriate tools and connection to national public health and biomedical capacities.
- Internationally: templates for Material Transfer Agreements (MTAs) and Memorandum of Understanding (MoU)
- Platform(s) for data and knowledge sharing
- Clear agreements for access to benefits
Round table - Perspective of researchers from different horizons, chaired by François Hirsch (Inserm Ethics Committee)

The testimony of the researchers invited to the roundtable discussion provided an overview of the successes and challenges met by the various actors. Three cases have been shared, from a global pharmaceutical company, a BSL4 laboratory involved in research during the West African Ebola epidemic, and an African research institute based in Dakar, Senegal. A philosopher and ethicist from the University of Yaoundé in Cameroon has also shared his thoughts on a broader perspective.

François Bompart from Sanofi:
Sanofi is a global integrated healthcare company engaged in the research, development, manufacturing and marketing of healthcare products.

The Sanofi Bioethics Committee has a mandate to help ensure that Sanofi:
- Continues to follow the highest ethical standards for clinical trials everywhere in the world;
- Is positioned as an actor of change and progress, through specific initiatives in the field of ethics;
- Has processes to ensure that new issues and developments in the field are addressed.

The Sanofi Bioethics Committee has implemented an Informed Consent Process Initiative to address the complexity of this process everywhere in the world and, in particular, address issues related with participants’ vulnerability\(^3\). The 5 key principles of this initiative are:
- The study participant must be at the centre of the informed consent process;
- Information provided must be selected for its relevance for the participant’s decision to participate or not in the study;
- Information must be provided both orally and in writing;
- Information materials must be designed to ensure that all information provided are understandable by the participant;
- Once informed, the participant must be free to decide on his/her participation in a study without incurring any prejudice.

In keeping with these 5 principles, potential participants must be explicitly informed on the following 11 key elements:
- Purpose and methodology of the study;
- Difference between participation in a study and medical care;
- Study-specific constraints;
- Potential risks and benefits related to participation in the study;
- Alternative to participation in the study;
- Compensation for expenses during the study;
- Indemnification of adverse events;
- Participant’s post-study access to tested medicine / vaccine;

\(^3\) “Vulnerability” refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, General ethical principles)
- Study interruption and consent withdrawal;
- Access to information;
- Participant’s privacy and confidentiality of individual data.

Work is in progress regarding data re-use, transfer to third party, genetic analyses, and unplanned re-use of samples. Is “broad consent” permissible? Is “à la carte” informed consent possible? How to ensure compliance with upcoming changes regarding EU and US regulations? How to deal with these issues in ways that are as clear as possible for study participants, especially the most vulnerable ones? These are key questions that the Sanofi Bioethics Committee is currently looking at. The company is in favour of patient-level data and other clinical trial information sharing, provided patient’s privacy and informed consent are well respected.

A challenge, when conducting multinational clinical trials, is the lack of harmonized regulation.

**Caroline Carbonnelle from the Jean Mérieux-Inserm BSL4 Lab:**

The recent EBOLA virus outbreak in West-Africa has caused the death of thousands of people despite the huge international rallying. As a matter of fact, although a very large mobilization of the scientific and public health community has led to the containment of the progression of the disease, this assessment demonstrates the need for an improvement in the management of this kind of crisis.

The Jean Mérieux Inserm BSL4 laboratory has been broadly involved in this EBOLA outbreak. This involvement has covered a broad spectrum of activities including the identification of the causative virus of the outbreak, the deployment of diagnosis capacities in the field and the participation to research programs and clinical assays. If the different actions have been efficient in many domains including the implementation of high-level collaborative projects involving local and European capacities, some difficulties and challenges have been faced at each step of this turbulent story.

The main lessons learned during this period in our field of activities have led to the identification of a list of improvements that should help to better face outbreaks associated to emerging pathogens such as EBOLA. This list includes in particular:

- To develop commercial tools in the frame of public/private partnership (specially for diagnosis)
- To include in health care systems capacities to manage infected patients
- To design and purchase adapted field equipment
- To maintain the scientific dynamic initiated during the crisis:
  - To better understand the physiopathology of these diseases
  - To have pertinent therapeutic and prophylactic candidates available
- To maintain the needed infrastructures
- To train people in all domains of activity / to initiate intensive training program in the field

---

4 Large consent: biological samples stored/banked for future research, the participant agrees that his/her samples will later be used in another search.
5 Consent "à la carte": there would have, in addition to the mandatory standard measures, a contextualization of its implementation, leaving to the participant the opportunity to choose among the proposed measures.
• To develop the links between partners inside consortia
• To harmonize protocols and practices and to improve the protocols to be implemented in the field
• To take into account biosafety and regulatory aspects and to adapt these aspects in the field

Aïssatou Touré from Institut Pasteur Dakar:
The DIELMO project, initiated in 1990 with the aim to better understand malaria infection, is taken as an example to share the lessons learned in a collaborative project in Africa. In this long-lasting project, an evolution towards better practices has been seen, like for instance, the organisation of meetings with local communities. Good partnership has proven essential and has helped to build local capacities.
A broad regularly renewed consent was used to enrol participants in the long term clinical and parasitical follow-up project, while “à la carte” consent or specific consents were used when specific projects not initially included in the first project were planned.
Sustaining the project has been an important challenge. The lack of equipment for appropriate storing of biological samples was considered a hurdle for the good implementation of the project.
Confidentiality has been another pivotal issue, and has to be emphasized, even after 20 years.
Training of the research team on the spot is also a critical need.
International collaborations offer great opportunities, however reciprocity is a necessary condition. The African researchers want to acquire the competence to analyse the samples, and not being providers only.

Godfrey Tangwa from the University of Yaoundé:
The philosopher has been leading the Cameroon Bioethics Initiative, which is a chapter of the Pan-African Bioethics Initiative. He expressed few thoughts about sharing in research.
First, there is no North, no South. We have to change our perception regarding the “resource-limited countries”. They cannot be considered under a unique concept as they are all different. The countries should be called by their name.
An important question in “ethical sharing” is how what is shared was obtained? Sharing should not come after a robbery. There should be reciprocity: the resource-limited countries can also benefit from data and samples sharing. Through our initiatives we can avoid the temptation of robbery.
Before ensuring better sharing, we have to find the ethical tools that can guarantee reciprocity.
The informed consent must make the data and samples “OK to collect”. To be ethical, the process of informed consent must give alternative choices to the research participants.
The “broad consent” is brandished as a model of informed consent, but if it is offered without any alternative it is ethically problematic; the “à la carte” model is a better model that gives choices, including broad consent, to the participants. Keeping a continuous communication with the community participating in the study should build confidence in the project and trust among the partners.
Towards better sharing of data - group discussion facilitated by Douglas Wassenaar from Sareti, University of KwaZulu-Natal, Durban:

The challenges in sharing research data expressed by the focus group are as follows.

- In many countries, the absence of a regulatory framework on data sharing fosters and would tend to result in non-compliance with ethical principles. And the Research Ethics Committees (RECs⁶) often have both in the "North" and the "South" a weak decision-making.

- Data extraction is often one-sided: the data come from low and middle income countries or from the "South" to go to the industrialized countries, “the North”, and stay there. Data sharing is only one of the ethical issues; the benefits sharing of research, including data sharing, is another major concern. Indeed, the data belong to the participants, but the benefits will go to scientists. The risks of the research are incurred by individuals who do not always receive the benefits of this research. In addition to this, it is sometimes difficult to identify the nature of the benefits and incorporate them in the agreements.

- In the framework of international collaborations, the choice of the language used in the collection and the sharing of data can be problematic, as the translation of informed consent in local languages, involving the risk of incorrect or missing information.

- The anonymity of research data is not systematically preserved. The sharing of information resulting from the research and the breach of the confidentiality of personal data can be potentially damaging to the communities from which they originate.

The recommendations made by the reflection group are as follows.

In general, the capacities of the ethical and contractual aspects of the research are to strengthen further.

- First, it is necessary to build trust between partners before sharing data: the success or failure depends on partnerships. Reciprocity and privacy of data sharing must thus be provided in the contract, mentioning the shared level of information. For example, do we talk about raw data or processed data?

- With the concept of public good, there should be an obligation to share data to maximize future profits. Indeed, in order for the agreement / contract to be more ethically acceptable and worthy of consent, it should not only mention the sharing of data, but also take into account the sharing of benefits with both the population (e.g. relevant health data) with scholars (e.g. fair publications). The study participants should be informed of their right to know the fate of their personal data and to know the benefits and results obtained through them. Furthermore, it is recommended to encourage participants to be more active in the

---

⁶ Also called Institutional Review Board (IRB)
implementation of the research, accountability would enhance the quality of research, but also ensure their protection against abuse, and safety. Each potential benefit should return closer to the population, and to do so, the benefits should be defined case by case in each research project.

- Meanwhile, the RECs exert moral authority over the agreement between partners: it is then proposed to strengthen their capabilities by making their decisions more binding, allowing them to ensure both the confidentiality of data and reciprocal sharing with the ability to challenge the agreement and propose amendments. Thus, RECs should then be able to arbitrate disputes between partners and to propose to the authorities that sanctions be imposed if necessary. Drawing lessons from these experiences, stakeholders in research should pay more attention to ethical issues in collaborative projects.

- In the multicentred research projects, the agreement would be even more ethically acceptable if each country team could analyze their own data. Skills transfer is then an important aspect to consider for strengthening the capacity of stakeholders in low and middle income countries.

Towards better sharing of samples - group discussion facilitated by Aïssatou Toure from Institut Pasteur Dakar:

The challenges in sharing biological samples expressed by the focus group are:

- First, it often comes as the practices and regulations are not harmonized across countries. A well-established legal framework is generally absent, involving the blurring over 3 questions:
  - Who has the authority to make decisions regarding research samples?
  - Who owns the samples?
  - What is the applicable law when more countries are involved?

- In addition, sharing samples can sometimes be difficult. Surely many samples are taken, but only some type of sample, thus limiting the ability to share. Alternatively, samples are taken but not used, or there are no suitable facilities for storing them in secure conditions.

The recommendations for a better sharing of biological samples, compared to the above challenges are:

- First, in the context of collaborative projects, the regulations between countries should be harmonized to a certain level, giving at the same time flexibility to accommodate with national specificities. Meanwhile, at the national level, a legal framework with different levels of authority should be established. Some countries like Uganda offer good examples: a comprehensive material transfer agreement (MTA) has to be negotiated and signed, in which are addressed the issues related to material acquisition, ownership, storage, future use and commercialisation of derivatives and the applicable law. An autonomous body, established by law, such as “The Uganda National Council for Science and Technology” oversees the process. The MTA has to be approved by an Ethical Review Board.
It is recommended that MTA being comprehensive, answering the questions about what, who, how and when. And authorization should be required to lengthen the duration of the samples storage.

- Then the samples shall remain the property of the people and the country from which they come. In addition, special governance should be provided for the secondary use of samples in genomic research. To ensure the proper management of biological samples, a safety committee should ensure monitoring of the sharing of samples, allowing to know what goes in and what comes out of the biobank.

- Different forms for obtaining consent are possible to recruit research participants, the "broad consent" and "à la carte consent". In the context of the research, the type of consent used should be the one that best takes into account local characteristics and willingness of participants, always with the aim of protecting research participants.

- Finally, working respectfully with local communities, sociological aspects, and not only biological, related to the collection of samples also need to be identified (beliefs related to the blood, the woman symbol, etc.).
Conclusion by Marc Brodin, from the Inserm Ethics Committee

The concept of “North” and “South” appears to be too schematic. On one hand it doesn’t take enough into account the cultural or institutional diversity of the countries. On the other hand, researchers from both industrialized and resource-limited countries meet similar issues regarding data and sample sharing. However the magnitude of the challenges they face can differ greatly: the legal framework for data and sample sharing is lacking in many countries. The infrastructures can be very weak including for secure samples/data storage. The need for skill transfer to analyse data and samples is important in many places.

The data and sample collection could however be felt or perceived or understood as a robbery in certain circumstances. This practice must be replaced by a reciprocal sharing of the benefits of the research. The researchers of resource-limited countries expect that international collaborations would provide opportunities to strengthen their research capacity and enable them to analyse samples/data in their countries with appropriate skills and equipment. The communities involved in the study must also get some benefits of the research as the samples/data belong to the participants. “A la carte” informed consent allows them to decide how they want their information to be used, and if they accept the re-use of their data and samples in secondary studies.

The global environment is changing. In Europe, the parliament is looking for amendments for data protection regulation, and is trying to find balance between privacy and research freedom. In the USA, federal policy for the protection of human subjects is being changed, and a “broad consent” form may be proposed. In Africa, several countries have initiated a legislation covering data protection and cybersecurity. Development of national regulation frameworks is needed with a harmonized broad base and local adaptations. The WHO may be the right organization to set out guidance to harmonize research regulations and practices throughout the world.

This workshop helped to create an international network of scientists, researchers, ethicists, biologists, etc. developing and industrialized countries. The network activity should be maintained to continuously improve the understanding of the ethical issues raised by collaborative projects, but also to motivate ethical reflection on biomedical research innovations. Thereafter, a working group of the French research actors acting in the developing countries could be set up in order to share with them feedback of experiences raised in this report and advocate good ethical practices.