

Theorizing an equitable and promising future for scientific progress in Africa: a bioethical and human rights-based approach to clinical trials

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ABSTRACT: This study focuses on clinical trials in Africa and suggests that a human rights-based and biolegal approach is a viable solution for ensuring effective protection and for promoting the freedom of research, ethical experimentation and the equitable enjoyment of the benefits of scientific progress, and for ensuring availability and accessibility of drugs at fair conditions. International cooperation within the African Union and the NEPAD Agency is advanced as the appropriate framework for debate and mediation between divergent positions, by relying on helpful international instruments and promoting justiciability, especially through the African Court on Human and Peoples' Rights.

KEYWORDS: Clinical trials; African Union; NEPAD Agency; Pharmaceutical market; Pharmaceutical corporations

SUMMARY: 1. Introduction. – 2. A promising present for Africa between past unethical medical experimentation and a future of hope. – 3. The relevant international instruments. – 4. The weaknesses of the African system and clinical trials: making the point. – 4.1 The African landscape: tackling systemic weaknesses. – 4.2 A focus on clinical trials. – 4.3 The ascent of contract research organizations (CROs). – 5. Theorizing a human rights-based and biolegal approach to clinical trials within the African Union. – 5.1 Mainstreaming human rights through international cooperation within the African Union. – 5.2 The use of the normative technique of criminalization as a means for enhancing harmonization between domestic legal systems. – 5.3 Pursuing some further specific paths – 6. Conclusions.

1. Introduction

The protection of the right to science, the right to benefit from scientific progress and freedom of research becomes particularly challenging when the focus is set on poor countries, especially when respect for human rights in clinical trials is considered¹.

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¹ Clinical trials affect various rights, ranging from the right to life, the right to health, physical integrity to non-discrimination, informed consent and confidentiality. The enjoyment of the right to science is affected too, although its content is still undefined to some extent. The expressions "right to science", "right to benefit from scientific progress" and "freedom of research" refer to the multifaceted entitlement whose international legal basis was identified in Article 27 of the United Nations' Universal Declaration of Human Rights

This study analyses the current landscape in Africa, to highlight the strengths and weaknesses of a world region that is attempting to overcome the experiences of unethical medical experimentation practiced during the last century, from forced contraception in former Rhodesia to meningitis testing in Nigeria, in order to build a future of medical excellence.

Some countries have made several steps towards better healthcare and scientific research progress, and the ambitious programmes adopted by Kenya, Tanzania, Uganda, Zambia and Nigeria are clear evidence that a different future is indeed possible for Africa².

Nevertheless, many weaknesses, often systemic, still need to be tackled: firstly, the lack of regional, effective cooperation and the absence of appropriate regulatory and institutional frameworks comparable to those existing in Europe and in the United States. Inadequate governance and policy guidance are widespread and usually coupled with inadequate resources.

Secondly, there is a definite need to increase research participants' self-determination and awareness about the clinical trials in which they are involved and about their rights. This is a necessary precondition for preventing abuses and re-establishing their trust relationship with medical operators and foreign sponsors.

Finally, responsibility of the different actors involved, in particular of States and pharmaceutical corporations, is a basic goal. The lack of tailored remedies to violations, especially from a judicial perspective, is still a major issue, above all for indigent and illiterate people.

and Article 15 of the International Covenant on Economic, Social and Cultural Rights. The latter, in particular, refers to the right to benefit from scientific progress and freedom of research in two different paragraphs. Again, Yvonne Donders, at the 2009 Experts' Meeting in Venice, suggested to identify four contents of the right to science, namely: 1) scientific freedom; 2) the right to be protected from possible harmful effects of science; 3) the access (including participation); and 4) international cooperation. Paragraph 4 expands on the issue in order to assess it in relation to the African human rights system. A wider analysis of the right to science, including the issues related to its definition and scope, can be found in M. MANCISIDOR, *Is There Such a Thing as a Human Right to Science in International Law?*, 4(1), 7 April 2015, ESIL Reflections, available at <http://www.esil-sedi.eu/node/896> (last visited 10/02/2018).

² With regard to clinical trials, the specific references are: Uganda National Council for Science and Technology. National Guidelines for Research Involving Humans as Research Participants. Kampala, Uganda: Uganda National Council for Science and Technology; 2007, available at <http://www.uncst.go.ug/dmdocuments/Guideline,%20Human%20Subjects%20Guidelines%20Marc.pdf> (last visited 08/02/2018); Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. By the National Council for Science and Technology (NCST No.45, 2004), available at https://www.nacosti.go.ke/newsletter/doc_download/69-guidelines-for-ethical-conduct-of-research-involving-human-subjects-in-kenya (last visited 08/02/2018); with reference to Nigeria, National Agency for Food and Drug Administration and Control (NAFDAC), Good Clinical Practice Guidelines 2016 V 13, available at <http://www.nafdac.gov.ng/images/GUIDELINES/DRUG%20GUIDELINES/NAFDAC%20GOOD%20CLINICAL%20PRACTICE%20GUIDELINES%202016%20V%2013.pdf> (last visited 08/02/2018); as to Zambia, Zambia Medicines Regulatory Authority (ZAMRA), Guidelines on Regulating the Conduct of Clinical Trial in Human Participants, available at <https://www.tfda.go.tz/index/sites/default/files/guidelines%20for%20application%20to%20conduct%20clinical%20trials%20in%20tanzania.pdf> (last visited 08/02/2018); as to Tanzania, Tanzania Food and Drugs Authority, Guidelines for Application to Conduct Clinical Trials in Tanzania, Made under Section 63(1) of the Tanzania Food, Drugs and Cosmetics Act, 2003, Second Edition, available at <https://www.tfda.go.tz/index/sites/default/files/guidelines%20for%20application%20to%20conduct%20clinical%20trials%20in%20tanzania.pdf> (last visited 08/02/2018).

Moving from this premise, this study suggests that a human rights-based and biolegal approach that, specifically, relies on the African human rights framework,³ is a viable solution to ensure effective protection and the re-affirmation of ethics in the framework of clinical trials, for promoting the freedom of research, ethical experimentation, equitable enjoyment of the benefits of scientific progress, and for ensuring availability and accessibility of drugs at fair conditions.

This view builds on the capacity of international human rights law to convey shared values and to provide effective standards for both international and domestic implementation in bio-ethical and medical practice, which is remarkable in a field such as biolaw, where international consensus is often lacking. International cooperation is suggested as the appropriate framework for debate and mediation between divergent positions.

In this regard, the experience of the East African Community,⁴ in particular the Medicines Regulatory Harmonization (EAC MRH) Programme, is taken into consideration as an interesting pattern. Again, some inspiration for advancing feasible solutions is drawn from other systems, as the European Union, the United Nations⁵ and the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, and the Council of Europe's experience in promoting human rights

³ This study aims at providing an innovative perspective through reference to the African human rights system, by assessing its capacity to provide satisfactory responses to human rights violations in clinical trials within the legal and political framework of the African Union (AU) in cooperation with the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency (NEPAD Agency). This framework, indeed, is taken into consideration and assessed as a suitable context for elaborating targeted policies and programmes, also in relation to its capacity to provide implementation and ensure Member States' compliance with AU's acts. What is more, issues of justiciability are taken into consideration in relation to the role of the African Court on Human and Peoples' Rights and the use of the African Charter on Human and Peoples' Rights in its jurisprudence as a parameter of constitutionality against which to assess the legislation and the measures adopted at the domestic level.

⁴ The East African Community (EAC) is an intergovernmental organization whose Partner States are the Republics of Burundi, Kenya, Rwanda, South Sudan, the United Republic of Tanzania, and the Republic of Uganda. The EAC was created in 1999 for the purpose of enhancing political, economic and social cooperation among its Partner States. Interesting and encouraging steps ahead were made by the East African Customs Union, the establishment of the Common Market in 2010 and the implementation of the East African Monetary Union Protocol. The Treaty for the Establishment of the East African Community is available at http://www.jus.uio.no/english/services/library/treaties/09/9-05/east_africa_economic.xml (last visited 08/02/2018).

⁵ The United Nations is an international organization that was founded in 1945 and counts 193 Member States. It is guided by the purposes and principles enshrined in its founding Charter and it is committed to the maintenance of peace and security, the protection of human rights, the deliverance of humanitarian aid, the promotion of sustainable development and aims at upholding international law. In order to fight drug trafficking, the United Nations has adopted the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 19 December 1988, available at <https://www.unodc.org/unodc/en/treaties/illicit-trafficking.html> (last visited 08/02/2018). This Treaty provides an array of measures, for example against money laundering and the diversion of precursor chemicals, and provides for international cooperation through, for instance, extradition of drug traffickers, controlled deliveries and transfer of proceedings. It is one of the International Drug Control Conventions together with the Single Convention on Narcotic Drugs of 1954 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971.

through criminalization of the violations. In particular, some solutions are inspired by the Convention against Trafficking in Human Organs⁶ and to the Convention on Action against Trafficking in Human Beings;⁷ moreover, a helpful pattern in the field of drugs counterfeiting is the Medicrime Convention,⁸ which overcame the exclusive focus on intellectual property rights of the Agreement on Trade Related Aspects of Intellectual Property Rights⁹ and the Anti-Counterfeiting Trade Agreement.¹⁰ One common feature of these instruments is the technique of criminalization, which offers an interesting path for adapting domestic legal landscapes to the challenges often posed by international and transnational issues and threats.

A special focus is set on the African Union¹¹ and the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency (hereinafter, NEPAD Agency)¹² as an appropriate insti-

⁶ Council of Europe Convention against Trafficking in Human Organs, opened for signature 25 March 2015. The Convention will enter into force on 1 May 2018. Reference, CETS No. 216, available at <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216> (last visited 18 September 2017).

⁷ Council of Europe Convention on Action against Trafficking in Human Beings, opened for signature 16 May 2005, entered into force 1 February 2008, CETS No. 197, available at <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/197> (last visited 08/02/2018).

⁸ Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. Reference, opening of the Treaty 28/10/2011, entry into force 01/01/2016, CETS No. 211, available at <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211> (last visited 18/09/2017). It seems interesting to stress that Burkina Faso and Guinea are Parties to the Medicrime Convention. Guinea was one of the first States to sign and ratify the Convention, whilst Burkina Faso signed the agreement on 16 February 2017 and ratified it on 27 July 2017. For some interesting views on the Medicrime Convention, see: S. KEITEL, *The MEDICRIME Convention: criminalising the falsification of medicines and similar crimes*, in *Generics and Biosimilars Initiative Journal* (GaBI Journal), 1(3-4), 2012, 138-141; A. M. VIENS, J. COGON, A. S. KESSEL (eds.), *Criminal Law, Philosophy and Public Health Practice*, Cambridge, 2013, 256 ff; Also see: Global pharmaceutical associations welcome MEDICRIME convention, landmark tool to curb global medicines counterfeiting, available at <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/151001-global-pharmaceutical-associations-welcome-medicrime-convention-landmark-tool-to-curb-global-medicines-counterfeiting/> last visited 19/09/2017.

⁹ World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), constituting Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, concluded on April 15, 1994, entered into force on January 1, 1995, available at https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm last visited 08/02/2018.

¹⁰ Anti-Counterfeiting Trade Agreement (ACTA), signed on 1 October 2011, not in force, available at https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/acta_text.pdf last visited 08/02/2018.

¹¹ The African Union was created in 1999 when it replaced the Organization of the African Unity, for the specific purpose of promoting democracy, governance and the rule of law in Africa. The Constitutive Act of the African Union is available at <https://au.int/en/treaties/constitutive-act-african-union> last visited 08/02/2018.

¹² The NEPAD Planning and Coordinating Agency (NEPAD Agency) was established in 2010 as a result of the integration of the New Partnership for Africa's Development (NEPAD) into the African Union's structures and processes. It replaced the NEPAD Secretariat which had coordinated the implementation of NEPAD programmes and projects since 2001. The strategic direction of the NEPAD Agency addresses six fields, namely: Agriculture and food security; Climate change and natural resource management; Regional integration and infrastructure; Human development; Economic and corporate governance; Cross-cutting issues – gender, ICT, capacity development and communications. Each area has been developed into specific programmes as, for

tutional, political and legal framework for developing adequate responses, also by relying on budgetary resources to ensure effective and comprehensive policy and strategy implementation. In particular, the establishment of an African Medicines Agency is suggested as a primary objective, as the hub of a regionally concerted system of cooperation, at both the institutional and regulatory level.

Indeed, both systems have proven capable of promoting human rights protection, and the African Charter on Human and Peoples' Rights¹³ is taken into consideration as a basic instrument for providing a more specific and satisfactory definition of rights' content and States' corresponding duties, also thanks to the peculiar features of the Charter and the catalogue of entitlements it enshrines. In this regard, this study also suggests that the African Court on Human and Peoples' Rights (AfCHPR)¹⁴ may play an essential role in ensuring justiciability, which seems all the more appropriate in light of its purposeful approach and scrutiny, which has even led some scholars to define this Court a regional 'constitutional' Court, capable of a pervasive impact on national legal orders and political choices when human rights are at stake.

2. A promising present for Africa between past unethical medical experimentation and a future of hope

This study drew much inspiration from the wise words of the late Professor Stefano Rodotà, who prophetically claimed that: 'Fundamental rights serve the purpose of protecting life, and none of its manifestations can be commercialized'.¹⁵

Nowadays we live in a world where economic interests often seem to be overriding and to dim ethical values and what these values primarily aim at ensuring: the human dignity and the human being.¹⁶ All too often these values are jeopardized in our society, which on many occasions has

instance the Comprehensive Africa Agriculture Development Programme (CAADP), the Programme for Infrastructure Development in Africa (PIDA) and the African Science Technology and Innovation Programme.

¹³ Organization of African Unity (OAU), African Charter on Human and Peoples' Rights ("Banjul Charter"), adopted 27/06/1981, entry into force 21/10/1986, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), available at <http://www.achpr.org/instruments/achpr/> (last visited 17/09/2017).

¹⁴ The African Court on Human and Peoples' Rights (AfCHPR) was established within the Organization of African Unity (OAU), by the Protocol to the African Charter on Human and Peoples' Rights on the Establishment of an African Court on Human and Peoples' Rights, adopted 10/06/1998, entry into force 25/01/2004, available at <http://www.achpr.org/instruments/court-establishment/> last visited 08/02/2018. The Court is entrusted with ensuring the protection of human rights in Africa and complements and enhances the functions of the African Commission on Human and Peoples' Rights. Thirty States have ratified the Protocol, namely: Algeria, Benin, Burkina Faso, Burundi, Cameroon, Chad, Côte d'Ivoire, Comoros, Congo, Gabon, Gambia, Ghana, Kenya, Libya, Lesotho, Mali, Malawi, Mozambique, Mauritania, Mauritius, Nigeria, Niger, Rwanda, Sahrawi Arab Democratic Republic, South Africa, Senegal, Tanzania, Togo, Tunisia and Uganda. Only eight of them have also made the declaration recognizing the competence of the Court to receive cases from NGOs and individuals, in particular Benin, Burkina Faso, Côte d'Ivoire, Ghana, Mali, Malawi, Tanzania and Tunisia.

¹⁵ S. RODOTÀ, *La Vita e le Regole. Tra Diritto e Non Diritto*, Milano, 2006, at p. 38: 'I diritti fondamentali si pongono a presidio della vita, che in nessuna sua manifestazione può essere attratta nel mondo delle merci'.

¹⁶ R. ANDORNO, *El principio de dignidad humana en el bioderecho internacional* available at <http://ppct.caicyt.gov.ar/index.php/bcaeem/article/download/1059/929> (last visited 18/09/2017); M. CASADO, *¿Gratuidad o precio? Sobre el cuerpo humano como recurso*, in M. CASADO (ed.), *De la Solidaridad al*

become a 'market society',¹⁷ where the risks of human exploitation and commercialization have sadly become major threats. As Professor Salvador Darío Bergel has stressed as a caveat, the market is governed by principles and rules that have nothing to do with ethics, and nowadays it has become a major actor in the debate, often capable of producing a decisive impact on States when they exercise their powers.¹⁸

This is a serious concern also for clinical trials, especially when they are carried out in poor countries. The risks of human exploitation have often turned into unethical medical experimentation and, in this respect, the African experience is an appalling example of this practice. Unfortunately, unethical medical experimentation affects developing countries in every part of the world: this unacceptable practice is a reality in many South American and Asian countries, and even developed States make no exception, since vulnerable people, especially the economically disadvantaged and the poorly educated, are an easy target in wealthier societies too.¹⁹

There are several reasons why this study, which attempts to suggest some feasible ways to improve the ethical quality of clinical trials, has chosen to focus on the African experience: these reasons relate to the past and the future of this Continent. Historically speaking, Africa has undergone one of the most dramatic experiences with unethical and unregulated medical experimentation. The early case dates back to the end of the 19th and the beginning of the 20th century in German South-West Africa, which is now part of Namibia, when a German doctor, Eugen Fischer, carried out sterilization experiments on the Herero women for the purpose of providing some scientific justification for banning mixed-race marriages.²⁰ It not surprising to learn that Doctor Fischer continued his sterilization trials under the Nazi regime some decades later, in Jewish concentration camps. Fast forward to the second half of the 20th Century, the 1970s were marked by forced contraception in

Mercado. El Cuerpo Humano y el Comercio Biotecnológico, Barcelona, 2017, 17-34, 28 ff; M.J. SANDELL, *What money can't buy. The moral limits of markets*, Milan, 2012; S. CANESTRARI, G. FERNANDO, C.M. MAZZONI, S. RODOTÀ, P. ZATTI, *Trattato Di Biodiritto. Il governo del Corpo*, Milan, 2011.

¹⁷ A. ROYES, *¿Qué hay que el dinero no pueda comprar?*, in M. CASADO (ed.), cit., 97-104, 100; A. RUBIO, *Sujeto, cuerpo y mercado. Una relación compleja*, in M. CASADO (ed.), cit., 65-96.

¹⁸ S.D. BERGEL, *Bioética, cuerpo y mercado* in *Revista Colombiana de Bioética*, 2 (1), enero-junio, 2007, 133-164, at p. 136: «El mercado, nuevo agente que se ha incorporado al debate - con un papel protagónico esencial - se rige por reglas y principios que nada tienen que ver con la ética ni con la bioética y que ejercen una influencia mucha veces decisiva sobre los poderes del estado».

¹⁹ C.C. DENNY, C. GRADY, *Clinical research with economically disadvantaged populations* in *Journal of Medical Ethics*, 33(7), July, 2007, 382-385; H.-J. JI, *The Challenges of conducting clinical trials in Asia*, 2016 KONECT International Conference, available at http://www.konectintconference.org/rang_board/inc/download.php?code=notice&num=10 (last visited 16/09/2017); K. HEARN, *The Rise of Unregulated Drug Trials in South America* in *The Nation*, 10 October 2011, 2011 Issue, available at <https://www.thenation.com/article/rise-unregulated-drug-trials-south-america/> (last visited 15/09/2017); S. MWALE, *Healthy Volunteers in Commercial Clinical Drug Trials: When Human Beings*, Cham, 2017; F.A. THIERS, A. J. SINSKEY, E. R. BERNDT, *Trends in the globalization of clinical trials*, in *Nature Reviews Drug Discovery*, AOP, published online 2/11/2007.

²⁰ A. VON FLEISCHER, *Ebola, Aids, and the Biological Warfare Program to Eradicate the Black Race*, 2014; B. MADLEY, *From Africa to Auschwitz: How German South West Africa incubated ideas and methods adopted and developed by the Nazis* in *European History Quarterly*, 35, 2005, 429-464; J. HARITAWORN, *The Biopolitics of Mixing: Thai Multiracialities and Haunted Ascendancies*, Abingdon, 2016, pp. 1 ff.; N. BAUMSLAG, *Murderous Medicine: Nazi Doctors, Human Experimentation, and Typhus*, Westport, Connecticut; London, 2005, 130 ff.

Rhodesia, now Zimbabwe,²¹ and by forced sexual reassignment in South Africa,²² which also continued in the 1980s. Forced contraception in Rhodesia represented one of the earliest significant examples of unethical practices related to drug administration. Depo-Provera, after being clinically tested on African women and then approved worldwide also in the pharmaceutical markets of developed countries, was used as a means for population control in violation of female patients' will, informed consent and reproductive health, through systematic coercion and threats, such as losing their employment in white-run farms or being denied healthcare for their children.²³ A similar use of Depo-Provera was made in South Africa during the apartheid.²⁴ Unethical drug experimentation returned to the African scene once again in the mid-1990s with two emblematic cases: firstly, again in Zimbabwe, which hosted in its University the testing of a substance called zidovudine (in brief, AZT) by some American researchers. An intensive regime of administration of zidovudine had proven capable of interrupting the mother-to-child transmission of HIV and researchers aimed at testing whether a less intensive, and thus cheaper, regime of the substance could still be effective. In order to speed up the test and obtain useful results as soon as possible, the control group (fifty percent of the participants) was not treated with the intensive regime of zidovudine, as the ethical rules and the applicable standards would have required in the United States and in Europe, but with a placebo. What is ethically unacceptable is that researchers knew that, by administering a placebo instead of the intensive zidovudine regime, they would cause roughly one in six newborns to develop HIV infection, as this rate had already been ascertained by the research and testing formerly conducted on AZT.²⁵ In practice, as a result, about one thousand children born from women who

²¹ J. DE GRUCHY, L. BALDWIN RAGAVEN, *Health Professionals Complicit in Human Rights Abuses*, in O. NNAEMEKA, J.N. EZEILO (eds.), *Engendering Human Rights: Cultural and Socioeconomic Realities in Africa*, New York, 2005, 39-60, 42 ff.; S. ELIAHU CHAI, lawyer for the Association of Civil Rights in Israel (ACRI), *Findings from investigations into the use of Depo Provera are extremely worrisome, raising concerns of harmful health policies with racist implications in violation of medical ethics*, available at <http://www.1037thebeat.com/wp-content/uploads/2013/06/DEPO-PROVERA-DEADLY-REPRODUCTIVE-VIOLENCE-Rebecca-Project-for-Human-Rights-June-2013-2.pdf> (last visited 19/09/2017); M. POTTS, J. M. PAXMAN, *Depo-Provera - ethical issues in its testing and distribution*, in *Journal of medical ethics*, 1, 1984, 9-20.

²² F.R. FRANKENBURG (ed.), *Human Medical Experimentation: From Smallpox Vaccines to Secret Government Programs*, Santa Barbara-Denver, 2017, 168 ff.

²³ In this regard, see: J.I. LEVITT, *Black Women and International Law: Deliberate Interactions, Movements and Actions*, Cambridge, 2015, 234 ff.; H.A. WASHINGTON, *Medical Apartheid*, New York, 2006, 390 ff.; A. KALER, *A Threat to the Nation, A Threat to the Man. The Banning of Depo-Provera in Zimbabwe 1981*, in W. WOODWARD, P. HAYES, G. MINKLEY (eds.), *Deep Histories: Gender and Colonialism in Southern Africa*, Amsterdam, New York, 2002. Also see: M. POTTS, J.M. PAXMAN, cit.; *Depo-Provera – Deadly reproductive violence against women*, The Rebecca Project for Human Rights, available at https://www.academia.edu/11096822/DEPO-PROVERA_DEADLY_REPRODUCTIVE_VIOLENCE_AGAINST_WOMEN (last visited 18/09/2017).

²⁴ H.A. WASHINGTON, cit., 390 ff.; D. ROBERTS, *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty*, New York, 2015, 145 ff. Also see: J. NORLING, *Family Planning and Fertility in South Africa under Apartheid*, Presented at New Frontiers in African Economic History Workshop, London School of Economics and Political Science, October 26, 2014 available at <http://www.johannesnorling.com/wp-content/uploads/Norling-Family-Planning-in-South-Africa.pdf> (last visited 19/09/2017).

²⁵ M. ANGELL, *Medical Research: The Dangers to the Human Subjects in New York Review of Books*, 19 November 2015, available at <http://www.nybooks.com/articles/2015/11/19/medical-research-dangers-human-subjects/> (last visited 17/09/2017).

had participated in the research as part of the control group became infected with HIV. The zidovudine testing conducted in Zimbabwe caused a sensation and gave rise to fierce dispute over the ethical admissibility of administering placebos in research projects carried out in Third World countries.²⁶ The arguments given in support of this practice failed to convince a huge part of the scientific community, which firmly rejected the two main justifications given, firstly, that an intensive regime was too expensive for the market of developing countries, although affordable in developed countries. Secondly, it was argued that the control group was to be treated with the available 'local' treatment instead of the 'best' available treatment. The difference between the two notions may appear theoretically negligible but its impact in practice is significant. It allows placebo administration when at the local level, in a developing country, no treatment is available even though an effective and approved therapy exists and is commonly administered in developed countries (that is to say the 'best' treatment).²⁷ The dispute led to some amendments to the provisions of the primary global soft law, the Helsinki Declaration.²⁸ It was specified that the control group can be treated with the placebo only on condition that no alternative, effective treatments exists.

The second case that shook the world's conscience concerned the meningitis testing conducted in Nigeria more or less in the same period of zidovudine experimentation, in the mid-1990s.²⁹ During a meningitis outbreak in the country, the pharmaceutical tycoon Pfizer launched the testing of an antibiotic it had developed, Trovan (whose active ingredient is trovafloxacin). In this case, the research was conducted against the best available treatment at the time, which was ceftriaxone, the active ingredient of the approved antibiotic Rocephin. Two hundred children were recruited. Eleven children participating in the experimentation died; the survivors reported serious impairments, such as blindness, deafness and brain damage. Nevertheless, since such impairments are quite common aftermaths of meningitis, proving the etiological connection between their onset and Trovan is rather difficult. However, a panel of medical experts, entrusted with assessing the facts, found Pfizer implicated insofar as the Trovan clinical trial turned out to be illegal, since it had been conducted without the authorization of the Nigerian government and without the informed consent of

²⁶ M. ANGELL, *The Ethics of Clinical Research in the Third World* in *The New England Journal of Medicine*, 337(12), 2013, 847-849, 847.

²⁷ M. ANGELL, *The Ethics of Clinical Research in the Third World*, cit., 848.

²⁸ World Medical Association, Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996; 52nd WMA General Assembly, Edinburgh, Scotland, October 2000; 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added); 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added); 59th WMA General Assembly, Seoul, Republic of Korea, October 2008; 64th WMA General Assembly, Fortaleza, Brazil, October 2013. Ferney-Voltaire, France: World Medical Association; 2014. Available from: [http://www.wma.net/en/20activities/10ethics/10helsinki/index.html.pdf?print-media-type&footer-right=\[page\]/](http://www.wma.net/en/20activities/10ethics/10helsinki/index.html.pdf?print-media-type&footer-right=[page]/) (last visited 19/09/2017).

²⁹ D.M. CARR, *Pfizer's Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries*, in *Case Western Reserve Journal of International Law*, 35(1), 2003, 15-54.

the parents of the children participating in the trial.³⁰ As a result, they filed a lawsuit in Nigeria over informed consent, alleging that ‘Pfizer, working in partnership with the Nigerian government, failed to secure the informed consent of either the children or their guardians and specifically failed to disclose or explain the experimental nature of the study or the serious risks involved involved’.³¹ Nor had the parents been informed that, in the same facilities where their children were treated, an alternative treatment of proven efficacy, Rocephin, was available from *Médecins sans Frontières*.³² As a result of the lawsuit filed before the Nigerian Supreme Court, in 2011 Pfizer reached an out-of-court settlement of the dispute with the Nigerian government, under which each of the families of four victims received USD 175 million in compensation. The Nigerian government alleged that Pfizer had lied about the experimentation, arguing it had been deceived by the pharmaceutical corporation about the purposes of the research, allegedly intended to pursue humanitarian aims among the local population. What is more, in the parallel lawsuit filed before the District Court of Connecticut in the United States, Pfizer was found responsible for the dramatic outcome of Trovan experimentation under the Alien Tort Statute or Alien Tort Claims (ATCA),³³ and the United States Court of Appeals for the Second Circuit upheld the ruling. What is more interesting is the legal reasoning of the Second Circuit Court, which relied on international human rights law standards, namely Article 7 of the International Covenant on Civil and Political Rights (ICCPR),³⁴ to find Pfizer accountable for the violation of the right to informed consent of the victims and their parents. As can be deduced, there is a dramatic *fil rouge* linking the two cases, which substantiates in the violation of informed consent³⁵ and in the breach of some further standards of medical experimentation, remarkably equipoise.³⁶

³⁰ *Abdullahi v. Pfizer*, 2009 U.S. App. LEXIS 1768 (2d Cir. 2009). A. OLUFOWOBI, *Protecting the Rights of Children as Human Subjects in Developing Countries: Revisiting Informed Consent*, in *Law School Student Scholarship*, Seton Hall Law, 2014, 544.

³¹ *Abdullahi v. Pfizer*, cit. See M. GRODIN, D. TARANTOLA, G. ANNAS, S. GRUSKIN, *Health and Human Rights in a Changing World*, New York, Abingdon, 2013, 108.

³² G. J. ANNAS, *Globalized Clinical Trials and Informed Consent* in *The New England Journal of Medicine*, 360 (20), 2009, 2050-2053. A. OLUFOWOBI, *op. cit.*, 544.

³³ 28 U.S. Code § 1350 - Alien’s action for tort, available at <https://www.law.cornell.edu/uscode/text/28/1350> (last visited 08/02/2018). For more information see https://www.law.cornell.edu/wex/alien_tort_statute (last visited 08/02/2018).

³⁴ UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171, available at <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx> (last visited 08/02/2018). M. KOEBELE, *Corporate Responsibility under the Alien Tort Statute: Enforcement of International Law through US Tort Law*, Leiden, Boston, 2009, 114 ff.; S. B. LEE, *Informed consent: enforcing pharmaceutical companies’ obligations abroad*, John Hopkins Carey Business School, Baltimore, Maryland, USA, available at <https://scholarship.library.jhu.edu/bitstream/handle/1774.2/33526/Stacey%20Lee%20-%20Informed%20Consent%20-%20Pharmaceutical%20Obligations%20%28%29.pdf?sequence=1&isAllowed=y> (last visited 17/09/2017); F. E. MAROUF, B.S. ESPLIN, *Setting a Minimum Standard of Care in Clinical Trials: Human Rights and Bioethics as Complementary Frameworks*, in *Health and Human Rights*, 17(1), June 2015, 31-42.

³⁵ B.M. MEIER, *International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent*, in *Berkeley Journal of International Law*, 20(3), 2002, 514-554; A. OLUFOWOBI, *op. cit.*, 544.

³⁶ Equipoise or the “uncertainty principle” entails that a subject can be recruited for a randomized clinical trial only if there is true uncertainty about which trial treatment will most likely benefit the patient. See J.F.

Africa has learned a dramatic lesson from these experiences by paying an appalling human cost: it has reported a high loss of human lives and an impressive number of participants have been affected by serious impairment. Nowadays Africa, which still shows the deep scars of its past in the lives and memories of the survivors and the families of the victims, has decided to turn over a new leaf on the dramatic experience it has undergone and is paving the way to a different future with commendable efforts. Taking effective action is a basic requirement, all the more if one considers that Africa still represents a particularly appealing market for foreign sponsors.³⁷ This is so, primarily, due to the low costs of experimentation and the possibility of speeding up the clinical trials conducted, as timing is a key factor with respect to getting drugs rapidly licenced and approved in a market in which competition is relentless. What is more, these factors are coupled with the further advantage – for sponsors – of fragmentary regulation which is weakly enforced, and leaves the door open to practices that benefit sponsors but are a detriment to local populations participating in trials. Along with these factors, sadly common to developing countries in all areas of the world, another important feature makes Africa so appealing, namely ethnic variety. This allows sponsors to easily recruit ethnically differentiated groups of participants in relatively small geographical areas. This means, in practice, the possibility of testing drugs checking their effects on various somatic and immunologic typologies all together, quite often also on treatment-naïve research participants.³⁸ Therefore, Africa is now tackling the issue of clinical trials, trying different methods of approach that, albeit perfectible, reveal the awareness that has matured on this Continent, among its governments, institutions and in the framework of some experiences of regional integration. This renewed and purposeful attitude is the second reason for focusing this discussion on Africa. This Continent's will to overcome its dramatic history of unethical medical experimentation has led to interesting practical initiatives. On a wider level, it has led to some coordinated regional programmes, such as the African Medicines Regulatory Harmonization and the East African Community's Medicines Regulatory Harmonization (EAC MRH) Programme.³⁹ Again, several States have adopted individual initiatives that reveal an increasing commitment to a change in health policies, in the attempt to create domestic healthcare systems aiming at medical excellence.

FRIES, E. KRISHNAN, *Equipoise, design bias, and randomized controlled trials: the elusive ethics of new drug development*, in *Arthritis Research & Therapy* 6(3), 2004, R250, R255. M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit. For a wider overview of the principle of equipoise, also see: R. KURZROCK, D.J. STEWART, *Equipoise abandoned? Randomization and clinical trials*, in *Annals of Oncology*, 24, 2013, 2471–2474; C. WEIJER, S. SHAPIRO, K.C. GLASS, *Clinical equipoise and not the uncertainty principle is the moral underpinning of the randomized controlled trial*, in *British Medical Journal*, 321, 2000, 756–757.

³⁷ To obtain an idea of the proportions: the African pharmaceutical market is esteemed to reach a business opportunity of 45 billion dollars in 2020; for further information, see <http://www.prnewswire.com/news-releases/african-pharmaceuticals-market-forecast-to-2020-300389669.html> (last visited 18/09/2017).

³⁸ G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *Conducting clinical trials in emerging markets of sub-Saharan Africa: review of guidelines and resources for foreign sponsors* in Dovepress, 7, 2015, 23-34.

³⁹ J. MASHINGIA, A. PATEL, *Pharmaceutical Policy in the East African Community: Burundi, Kenya, Uganda, Rwanda, Tanzania*, in Z. BABAR (ed.), *Pharmaceutical Policy in Countries with Developing Healthcare Systems*, New York, 13-24, 2017; Medicines Regulation in the East African Community: Landscape Summary Report, PATH, July 2016, available at <http://www.path.org/publications/detail.php?i=2635> (last visited 18/09/2017).

This can be clearly observed and appreciated in the regulatory frameworks adopted, in particular, by Kenya, Nigeria, Tanzania, Uganda, and Zambia, which have included clinical trials in their programmes and have taken research-friendly and ambitious action.⁴⁰ These countries have developed several guidelines, marked by the primacy of the patient in clinical trials.⁴¹ The national guidelines adopted generally provide a mechanism of oversight of clinical trials, often complemented by a registration and an authorization system.⁴² In some cases, as in Kenya, prior assessment of the research is made by the Pharmacy and Poison Board (PPB)⁴³ and thorough standards are provided to ensure informed consent.⁴⁴ At the same time, the regulatory framework put in place by these countries is also designed to attract foreign sponsor. Support services for registered clinical trials, the presence of large hospitals treating high numbers of patients, and the availability of transport are important factors. Moreover, these countries can also rely on the linguistic advantage of having populations that speak English, French or Portuguese, which facilitates communication with the research staff. Last but not least, a key factor is the budgetary support that these national frameworks can rely on: financial resources are provided by governments, non-governmental organizations and private investors.⁴⁵ These countries' ability to strike a balance between the competing interests of the participants and of the sponsor is paying off, as shown by compelling evidence. Clinical trials have become a significant driver of growth and wealth: whilst traditional pharmaceutical markets offer increasingly fewer opportunities of growth for the pharmaceutical industry, African countries have progressively realized that they might benefit from improving their systems, not only economically but also from the perspective of public health. The figures of improvement in the fight against HIV, in the framework a multi-partner programmes carried out in Kenya, Nigeria, Tanzania, Uganda, and Zambia and coordinated by the World Health Organization (WHO) are eloquent: reports showed a 32% decline in HIV deaths in South Saharan countries from 2005 to 2011

⁴⁰ C.C. DENNY, C. GRADY, *op. cit.*, 382–385; G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34, 25 ff.

⁴¹ Uganda National Council for Science and Technology. National Guidelines for Research Involving Humans as Research Participants, *cit.*; Guidelines for ethical conduct of biomedical research involving human subjects in Kenya. By the National Council for Science and Technology, *cit.*; with reference to Nigeria, National Agency for Food and Drug Administration and Control (NAFDAC), Good Clinical Practice Guidelines 2016 V 13, *cit.*; as to Zambia, Zambia Medicines Regulatory Authority (ZAMRA), Guidelines on Regulating the Conduct of Clinical Trial in Human Participants, *cit.*; as to Tanzania, Tanzania Food and Drugs Authority, Guidelines for Application to Conduct Clinical Trials in Tanzania, *cit.*

⁴² G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34.

⁴³ For an overview of the Pharmacy and Poison Board: <http://www.pharmacyboardkenya.org/> (last visited 18/09/2017).

Kenya's approach to healthcare and, especially, clinical trials is particularly interesting; in this respect, see: J. SCHILDMANN, V. SANDOW, O. RAUPRICH, J. VOLLMANN, *Human Medical Research: Ethical, Legal and Socio-Cultural Aspects*, Basel, 2012; K. SIMIYU, H. MASUM, J. CHAKMA, P.A SINGER, *Turning science into health solutions: KEMRI's challenges as Kenya's health product pathfinder* in *BMC International Health & Human Rights*, 10 (Suppl 1), 2010, S10.

⁴⁴ C.C. DENNY, C. GRADY, *op. cit.*, 382-385; G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34, 25 ff.

⁴⁵ G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34, 25 ff.

and a 24% decline in children newly infected with HIV.⁴⁶ This is evidence of the fact that a coordinated, human-rights based approach is a successful route, which is likely to help tackling the systemic and historically rooted problems of this region.⁴⁷

3. The relevant international instruments

Before assessing more in depth the regional landscape and feasible paths of protection within the African Union and the NEPAD Agency, it seems necessary to consider how the international community has so far tackled the issues related to clinical trials and, more widely, biomedical research, which has been the focus of several relevant international hard and soft law instruments.

Clinical trials represent a phase of biomedical research that is characterized by the participation of human volunteers. Biomedical research affects human rights from several perspectives and raises issues of primary concern with regard to human dignity and, among the various entitlements affected, physical integrity, health, protection from torture and inhuman treatment, non-discrimination, informed consent and the protection of confidentiality of data. The rights involved are various and they may be different at the distinct stages of biomedical research. For instance, the protection of the participants raises distinct concerns at the different phases of biomedical research when it implies the taking of human biological materials. Until the taking, physical integrity is of primary relevance whilst it is not at stake in the following stages.

As scholarship has underlined,⁴⁸ two approaches to biomedical research were developed, addressing the “therapeutic obligation” paradigm and the “non-exploitation” paradigm, which entail various principles that are intended to inspire biomedical research and, thus, clinical trials. The “therapeutic obligation” primarily implies the beneficence principle and its twin duty of non-maleficence, according to which the interest of the participant should always be prioritized over the interests of the research. Another principle related to the therapeutic obligation is represented by the above-mentioned principle of equipoise or “uncertainty principles”. Of course, besides the state of uncertainty about the outcome of a given experimentation, equipoise also requires that an adequate level of information has to be achieved in order to allow the testing of a given agent.⁴⁹ The “non-exploitation paradigm” entails that patients should not be exposed to excessive risks for the benefit of

⁴⁶ A. SHAH, [webpage on the Internet], *AIDS in Africa* in *GlobalIssues.org*, 2009, available at <http://www.globalissues.org/article/90/aids-in-africa>, last visited (10/09/2017); A. B.M. KHARSANY, Q. A. KARIM, *HIV Infection and AIDS in Sub-Saharan Africa: Current Status, Challenges and Opportunities* in *Open AIDS Journal*, 10, 2016, 34-48; UNAIDS, *Regional Fact Sheet 2012: Sub-Saharan Africa*. Geneva, Switzerland: UNAIDS, 2012, available at: http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/2012_FS_regional_ssa_en.pdf, (last visited 02/09/2017); G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34, 25 ff.

⁴⁷ C.S. KOSACK, A.L. PAGE, G. BEELAERT, T. BENSON, A. SAVANE, A. NG'ANG'A, B. ANDRE, J.P. BN ZAHINDA, L. SHANKS, K. FRANSEN, *Towards more accurate HIV testing in sub-Saharan Africa: a multi-site evaluation of HIV RDTs and risk factors for false positives*, in *Journal of International AIDS Society*, 20(1), 2017, 1-12.

⁴⁸ N. COMORETTO, *Rethinking the Therapeutic Obligation in Clinical Research*, in J. SCHILDMANN, V. SANDOW, O. RAUPRICH, J. VOLLMANN (eds.), *Human Medical Research*, Basel, 2012, 55-63.

⁴⁹ N. COMORETTO, *op. cit.*, 56.

the scientific research, either the “sacrifice” imposed is a permanent prejudice to their health or a temporary but serious discomfort.⁵⁰

In practice, striking an appropriate balance between the respective interests of the patients and of the research or the trial themselves is not an easy task. The conception of the position of the subjects participating in clinical trials has evolved through the decades, as well as the principles applicable.

During the World War II a utilitarian approach to research prevailed and advanced the view that individual sacrifice was justified by the predominant interest of the whole society. Development of such treatments as vaccination and antibiotics needed to be sped up. In practice, this allowed the enrolment of vulnerable subjects - who did not need any treatment - as prisoners, children from orphanages and hospitalized persons affected by psychological and emotional diseases.⁵¹ At the end of the War World II, in 1947, the atrocities perpetrated during the conflict and the unethical (and, one could say, inhuman) experimentation conducted by the Nazi-regime in total disregard of human beings led up to the adoption of the Nuremberg Code,⁵² in the context of the Doctors Trial,⁵³ which enshrined the primacy of the patient and provided informed consent to experimentation as a primary and inviolable rule. Indeed, the first provision of the Nuremberg Code foresees that “The voluntary consent of the human subject is absolutely essential”. The Nuremberg Code did not only provide the rule of voluntary participation in experimentation, but also required the “legal capacity” of the subjects involved, that meant prohibiting to recruit children and persons who were not capable of expressing their will. It also requires that informed consent be expressed after adequate information about benefits, risks and disadvantages is provided to participants and they have appropriately considered it. Furthermore, the Nuremberg Code set further requirements, which cannot be waived by the research participants and which are aimed at ensuring the social value of the research, its scientific validity and a favourable risk-benefit ratio. It is important to stress that the Nuremberg Code was based on international natural law, which means that it set basic standards of protection that cannot be lowered or derogated by any national rule.⁵⁴

However, the evolution of the protection ensured in practice was not as fast as expected. The American experience is eloquent in this regard. In the late Sixties, in the United States research was still inspired to a paternalistic approach, a common ideology among medical practitioners, that relied on the care and the integrity of the researchers as the most suitable guarantee for ensuring adequate protection to the participants. It was only in the early Seventies that informed consent began to be seen as a primary guarantee and no longer as a minor standard of protection.⁵⁵ In particular,

⁵⁰ N. COMORETTO, *op. cit.*, 57.

⁵¹ E.J. EMANUEL, C. GRADY, *Four Paradigms of Clinical Research and Research Oversight*, in *Cambridge Quarterly of Healthcare Ethics*, 16, 2006, 82–96, 84.

⁵² The Nuremberg Code, available at <https://history.nih.gov/research/downloads/nuremberg.pdf> (last visited 19/09/2017); M. ANGELL, *Medical Research: The Dangers to the Human Subjects* in *New York Review of Books*, cit.; R.B. GHOOI, *The Nuremberg Code – A critique*, in *Perspectives in Clinical Research*, April-June 2(2), 2011, 72–76. M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit.

⁵³ M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit.

⁵⁴ J.J. MICHALCZYK, *Medicine, Ethics, and the Third Reich: Historical and Contemporary Issues*, Kansas City, 1994, 111.

⁵⁵ H. BEECHER, *Ethics and clinical research*, in *New England Journal of Medicine* 274, 1966, 1354–1360.

the case of unethical experimentation of Tuskegee Syphilis Study,⁵⁶ conducted in Alabama between 1932 and 1972, raised the awareness that a shift of perspective was necessary. This led to the Belmont Report,⁵⁷ that was issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in 1974.

The Belmont Report set three ethical principles, namely autonomy (or respect for persons), beneficence and justice,⁵⁸ which were translated into three requirements: informed consent, determination of a favourable risk-benefit ratio and fair selection of participants. Equipoise was not included yet. However, to some extent, some paternalistic approach could still be found in the Belmont Report, where it provided that several categories of vulnerable subjects could not be enrolled, as prisoners and pregnant women. This was clearly a limitation of their self-determination as it precluded their possibility to choose to join medical experimentation.

At the global level, several sources relevant for clinical trials or specifically addressing them were adopted, in particular in the framework of the World Medical Association (WMA), the World Health Organization (WHO), the United Nations Educational, Scientific, and Cultural Organisation (UNESCO), and the Council for International Organizations of Medical Sciences (CIOMS).

International organizations have played a basic role in the promotion of an ethical approach to clinical trials, attempting to provide common standards of protection. The instruments they have adopted attempted to tackle the weaknesses of the Nuremberg Code, which had raised some criticism among physicians who considered that Judges at the Doctors' Trial had played too much influence on it. A difference can be appreciated when the Helsinki Declaration⁵⁹ is taken into consideration, as it conveys more clearly a medical perspective. This instrument was adopted in 1964 in the framework of the World Medical Organization for the purpose of providing a renewed and up-to-date approach to clinical trials, founded on the primacy of human being and the prevalence of the interests of participants in the experimentation over conflicting interests of pharmaceutical industry and researchers. The Helsinki Declaration reaffirmed the centrality of informed consent as the

⁵⁶ The Tuskegee Syphilis Study lasted for forty years and involved 600 black men – 399 with syphilis, 201 who did not have the disease, without appropriately obtaining their informed consent but convincing them to participate in the research by promising such advantages as free medical exams, free meals, and burial insurance. For more information see <https://www.cdc.gov/tuskegee/timeline.htm> (last visited 10/02/2018).

⁵⁷ Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, adopted by the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research on issued on 30 September 1978 and published in the Federal Register on 18 April 1979, available at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html> (last visited 10/02/2018). See: E. J. EMANUEL, C. GRADY, *op. cit.*, 88 ff.; J. F. FRIES; E. KRISHNAN, *op. cit.*

⁵⁸ Autonomy refers to the protection of patient's self-determination and its exercise, except for the specific protection granted to incapable persons or coercion. Beneficence refers to a conception of research that aims to maximize to the greatest degree possible benefits and to minimize the risks posed to the patient. Justice refers to fair distribution of the benefits and burdens of research; see J. F. FRIES; E. KRISHNAN, *op. cit.*, R253.

⁵⁹ M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit.; R. ASHCROFT, *The declaration of Helsinki*, in E.J. EMANUEL (ed.), *The Oxford Textbook of Clinical Research Ethics*, Oxford, 2011, 141-148; J. KIMMELMAN, C. WEIJER, E.M. MESLIN, *Helsinki discords: FDA, ethics, and international drug trials* in *Lancet*, 373, 2009, 13-14.

Nuremberg Code⁶⁰ but, at the same time, it represented a more flexible instrument since, as scholarship put in evidence “tension between the required informed consent stressed in the Nuremberg Code and the preferred prior peer review in The Declaration of Helsinki has led physicians to all but abandon the Code in favor of the more lenient Declaration”.⁶¹ The Helsinki Declaration also ensured transparency with regard to funding of the trial, the study design and possible conflicts of interest and valorises the social value of the research, which is particularly important when one considers that a huge part of the pharmaceutical products tested in developing countries is destined to suit the needs of wealthy nations and their populations. The risks related to exploitation are a serious concern when developing countries’ population is at stake, as often participation in the medical experimentation may be the only chance to access medications, due to the poor conditions of life they have to endure. Again, the Helsinki Declaration prohibited the double standard of care, according to which a universal standard of care has to be adopted, without any distinction between different areas of the world, especially between developed and developing countries. This view closely relates also to another important issue, namely ethics dumping, which refers to the adoption of substandard practices in developing countries.⁶² That being said, it is important to stress that so far the Helsinki Declaration has found widespread acceptance in developed countries, becoming the most authoritative reference at the global level, on some occasions often invoked before domestic Courts in such countries as the United States of America and Canada in individuals’ claims against pharmaceutical companies.⁶³ The rules of protection enshrined in the Helsinki Declaration are also contemplated by other relevant international soft law instruments addressing clinical trials involving human subjects. In this respect, reference here is made to the International Ethical Guidelines for Biomedical Research Involving Human Subjects adopted in 1982 within the Council for International Organizations of Medical Sciences (CIOMS),⁶⁴ and the UNESCO Universal Declaration on Bioethics and Human Rights.

Similarly to the Helsinki Declaration, the International Ethical Guidelines for Biomedical Research Involving Human Subjects aimed at tackling the weaknesses of the Nuremberg Code,⁶⁵ besides helping the implementation of the Helsinki Declaration. These Guidelines provide the ethical principles under which research projects have to be formulated. In particular, they contemplate respect for

⁶⁰ The Nuremberg Code, available at <https://history.nih.gov/research/downloads/nuremberg.pdf> (last visited 19/09/2017); M. ANGELL, *Medical Research: The Dangers to the Human Subjects* in *New York Review of Books*, cit.; R.B GHOOI, *The Nuremberg Code – A critique*, in *Perspectives in Clinical Research*, April-June 2(2), 2011, 72–76.

⁶¹ J. ROMAN, *U.S. Medical Research in the Developing World: Ignoring Nuremberg*, in *Cornell Journal of Law and Public Policy*, 11(2), 2002, 441-460.

⁶² G. NOVOA-HECKEL, R. BERNABE, J. LINARES, *Exportation of unethical practices to low and middle income countries in biomedical research*, in *Revista de Bioética y Derecho*, 40, 2017, 167-177.

⁶³ I.R. PAVONE, *Medical Research in Developing Countries and Human Rights*, in J. SCHILDMANN, V. SANDOW, O. RAUPRICH, J. VOLLMANN (eds.), *Human Medical Research*, Basel, 2012, 65–87, 70.

⁶⁴ International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS), adopted in 1982 and last revised in 2016, available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (last visited 08/02/2018).

⁶⁵ J. ROMAN, cit., 447.

persons, beneficence and justice. Moreover, this instrument considers waiver as exceptional and which conditions its effectiveness to a prior evaluation by the competent ethics committee.⁶⁶ Indeed, the role of ethics committee is fundamental in the field of clinical trials, and independent review is another basic principle, which is closely related to public accountability.

The Universal Declaration on Bioethics and Human Rights is another important reference at the global level and is an example of the UNESCO's commitment in relation to bioethics. It was adopted by UNESCO's General Conference on 19 October 2005, and it stands out because it embraces the relevant principles concerning biomedical research and frames them in a human rights context.⁶⁷

Another interesting source is the UNAIDS Guidance Document on Ethical Considerations in HIV Preventive Vaccine Research adopted in 2000 in the framework of the Joint United Nations Programme on HIV/AIDS (UNAIDS). This document, besides embracing the globally shared and reaffirmed above-mentioned principles, has demonstrated the effectiveness of international consultation in a field where a particular variety of interests and cultural differences were at stake.⁶⁸ The WHO Guidelines for good clinical practice (GCP) for trials on pharmaceutical products⁶⁹ as well aimed at providing some globally consistent guidance between States, as they were adopted (in the mid-Nineties) under the auspice that they could be adopted, partially or completely, by national health authorities when national regulation is lacking or needs integration. Their distinguishing feature is the attention dedicated to the responsibilities of the investigator and the sponsor.

Despite all these instruments are not hard law, they have an important political and moral relevance for States, whose consent has widely converged over these tools. What is more, the constant and reiterated reaffirmation of the principles enshrined in these soft law source may become international customary rules where supported by *diuturnitas* and *opinion iuris*.⁷⁰ For example, the Helsinki Declaration was already recalled by some domestic Courts as "accepted custom or practice of nations".⁷¹

In scholarship it was also highlighted that the proliferation of such instruments poses risks of fragmentation and overlapping,⁷² except in the event there is a clear difference in their approach and

⁶⁶ B.M. MEIER, *op. cit.*, 514-554; A. OLUFOWOBI, *op. cit.*, 544.

⁶⁷ R. ANDORNO, *Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights*, in *Journal of Medical Ethics*, 33(3), March 2007, 150-154.

⁶⁸ The Joint United Nations Programme on HIV/AIDS [UNAIDS] Ethical considerations in HIV preventive vaccine research: UNAIDS guidance document. Geneva: UNAIDS; 2000. Available at http://www.unaids.org/html/pub/publications/irc-pub01/jc072-ethicalcons_en_pdf.pdf (last visited 10/02/2108). See: D. GUENTER, J. ESPARZA, R. MACKLIN, *Ethical considerations in international HIV vaccine trials: summary of a consultative process conducted by the Joint United Nations Programme on HIV/AIDS (UNAIDS)*, in *Journal of Epidemiology and Community Health*, 26, 2000, 37-43, available at <http://jme.bmj.com/content/26/1/37> (last visited 11/02/201).

⁶⁹ Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products. WHO Technical Report Series, No. 850, Annex 3, WHO Expert Committee on Selection and Use of Essential Medicines, Sixth Report, 1993, available at <http://apps.who.int/medicinedocs/en/d/Jwhozip13e/7.4.html> (last visited 08/02/2018). For further analysis see J. E. IDÄNPÄÄN-HEIKKILÄ, *WHO guidelines for good clinical practice (GCP) for trials on pharmaceutical products: responsibilities of the investigator*, in *Annals of Medicine*, 26(2), April 1994, 89-94.

⁷⁰ I.R. PAVONE, *op. cit.*, 70.

⁷¹ I.R. PAVONE, *op. cit.*, 70.

⁷² I.R. PAVONE, *op. cit.*, 69.

scope. For example, as Professor Andorno stressed, while the approach of the UNESCO tends to produce “general normative frameworks of a predominantly philosophical and legal nature”, WHO tends to adopt a more technical approach and to focus on specific health-related issues. However, what can be generally observed is the affirmation of a collaborative partnership between the different stakeholders involved in the research.⁷³

Despite the international efforts to adopt common rules on clinical trials, currently a targeted international binding tool specifically is still lacking. This is so notwithstanding the expectations in this regard, that were also raised by the existence of the project of a convention for the prevention and the suppression of unlawful experimentation, which was formulated in the mid-Eighties.⁷⁴

Nonetheless, when we consider international hard law, we can find an interesting reference, that is the Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research (hereinafter, in this paragraph, the “Additional Protocol”).⁷⁵ The Additional Protocol builds on the principles enshrined in the Convention on Human Rights and Biomedicine (hereinafter the “Oviedo Convention”), which was adopted in the framework of the Council of Europe (COE) in 2007, and aims at suiting more adequately the exigencies and challenges related to biomedical research involving human beings by focusing on the protection of free, informed, express, specific, and documented consent of the participants, the protection of incapable persons, independent review, the right to information, confidentiality, undue influence, safety and duty of care. In particular, a provision of the Additional Protocol is relevant for African States hosting a clinical trial, namely Article 29, which provides that “[s]ponsors or researchers within the jurisdiction of a Party to this Protocol that plan to undertake or direct a research project in a State not party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based” and that “[w]here necessary, the Party shall take appropriate measures to that end”. For example, States Parties might adopt appropriate domestic legislation to introduce adequate ethical rules to be observed by sponsors and researchers in States not Parties to the Protocol.

Further protection can be sought in international hard law with reference to generalist and thematic human rights treaties, ranging from the guarantees they provide to self-determination and informed consent in relation to medical treatments, to the protection they ensure to life, health

⁷³ E.J. EMANUEL, C. GRADY, *op. cit.*, 92. E.J. EMANUEL, D. WENDLER, J. KILLEN, C. GRADY, *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*, in *The Journal of Infectious Diseases*, 189, 2004; 930–937.

⁷⁴ I.R. PAVONE, *op. cit.*, 67.

⁷⁵ Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS 195), opening of the Treaty 25/01/2005, entry into force 01/09/2007.

and physical integrity. More specific reference is made here to the ICCPR, the Convention on the Rights of persons with Disabilities⁷⁶ and the Convention on the Rights of the Child.⁷⁷

Article 7 of the International Covenant on Civil and Political Rights⁷⁸ is particularly interesting in this respect and deserves to be specifically addressed here. Indeed, this provision relates the breach of free consent to the violation of the prohibition of torture or to cruel inhuman or degrading treatment or punishment, where it provides that “no one shall be subjected without his free consent to medical or scientific experimentation”. A similar provision can be found in the Convention on the Rights of Persons with Disabilities, whose Article 15 echoes Article 7 of the ICCPR, though the latter has a wider scope of application being contained in a generalist human rights treaty. It is interesting to highlight that Article 7 of the ICCPR was taken into consideration by the Judges of the District Court of Connecticut: when ruling in the case of meningitis drug trial in Kano, the Court recalled this provision as an international normative reference and as a standard to apply since the requirement of informed consent was a customary norm of international law as it was universal and obligatory, specific and definable and of mutual concern.⁷⁹ However, scholarship has stressed that currently there is not an adequate State practice to support this view.⁸⁰

That being said, it should be stressed here that international human rights law has peculiar relevance with regard to justiciability in the African human rights system. In fact, pursuant to Article 7 of the Protocol to the African Charter on Human and Peoples’ Rights on the Establishment of the African Court on Human and Peoples’ Rights, the African Court on Human and Peoples’ Rights is allowed to *apply* “any other relevant human rights instruments ratified by the States concerned” besides the African Charter on Human and Peoples’ Rights. Therefore, this provision helps enhancing human rights’ justiciability, either informed consent - and regardless of its non-customary nature - or any other right protected under international human rights law applicable to African States – for instance life, physical integrity, health, non-discrimination – is at stake. These issues are analysed more in depth in paragraph 5 of this article.

⁷⁶ UN General Assembly, Convention on the Rights of Persons with Disabilities: resolution / adopted by the General Assembly, 24 January 2007, A/RES/61/106, available at <https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/convention-on-the-rights-of-persons-with-disabilities-2.html> (last visited 10/02/2018). All African States are Parties to the Convention except for Botswana, Ethiopia, Eritrea, Morocco and South Sudan. Cameroon, Chad and Libya have signed but not ratified it.

⁷⁷ UN General Assembly, Convention on the Rights of the Child, 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3, available at <http://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf> (last visited 10/02/2018). All African States are Parties to the Convention except for Morocco.

⁷⁸ UN General Assembly, International Covenant on Civil and Political Rights, cit.

⁷⁹ *Abdullahi v. Pfizer*, cit.

⁸⁰ I.R. PAVONE, *op. cit.*, 72; B.M. MEIER, *International protection of persons undergoing medical experimentation: protecting the right of informed consent*, in *Berkeley Journal of International Law*, 20, 2003, 513–555, 535.

International criminal law too addresses unlawful medical experimentation in wartime and provides it as a war crime.⁸¹ In this respect, it seems noteworthy to recall that recently, it was advanced⁸² that massive experiments conducted in violation of bioethical principles and of human rights may amount to crimes against humanity under international criminal law.

Once the state of art in international law is considered, analysis can focus on the African system, to assess the impact of the international landscape on the regional framework and, above all, the capacity of the African human rights system to provide effective solutions to the challenges posed by clinical trials.

4. The weaknesses of the African system and clinical trials: making the point

4.1. The African landscape: tackling systemic weaknesses

Africa is striving to build a different, ambitious future of ethical and competitive healthcare, including clinical trials: as argued in the previous section, change is no longer just a hope, and some fruitful regional and national experiences indicate that the first steps have already been taken.

Nevertheless, some major weaknesses still need to be addressed. Some of these problems are often systemic and historically rooted. In particular, governance and policy direction are inappropriate at all level of governance and cannot rely on adequate resources; at the regional level, effective cooperation lacks and major shortcomings affect the regulatory and institutional regime, that cannot compare to those existing in Europe and in the United States.⁸³

From the regulatory viewpoint, the situation is heterogenous and fragmented, since no regional coordinated standards or guidelines have been adopted and this gap is not balanced by appropriate domestic solutions.⁸⁴ Only a few African countries have adopted regulatory instruments, and implementation is generally relatively weak or absent. In this respect, the adoption of the International Ethical Guidelines for Biomedical Research involving Human Subjects as the minimum requirement at the Health Research Ethics seminar in Africa, in 2001, failed to make a difference, as its rules did not receive widespread acceptance and States continued to follow different paths. Similarly, the international standards on clinical trials have not been uniformly implemented in Africa.

⁸¹ I.R. PAVONE, *op. cit.*, 67. M. BASSIOUNI, *Introduction to international criminal law*, New York, 2003.

⁸² S. NEGRI, *Unethical Human Experimentation in Developing Countries: Old Wine in New Bottles?*, in *International Criminal Law Review*, 17, 2017, 1022-1048.

⁸³ M. ANGELL, *The Ethics of Clinical Research in the Third World*, *cit.*, 847; For wider and deeper analysis, see A. BOGGIO, *Informing participants about research results*, in B. ELGER, N. BILLER, R. ANDORNO, A. MAURON, A.M. CAPRON, *Ethical and regulatory aspects of human genetic databases*, Farnham, 2008; A. GREEN, *Africa's clinical trial: Big Pharma deploys R&D in Africa*, available at <http://www.thisisafricaonline.com/News/Africa-s-clinical-trial-Big-Pharma-deploys-R-D-in-Africa?ct=true> (last visited 18/09/2017); for deeper and comprehensive analysis, see D. MAÏGA, B. D. AKANMORIC, L. CHOCARROA, *Regulatory oversight of clinical trials in Africa: Progress over the past 5 years*, in *Vaccine*, 27, 2009, 7249–7252.

⁸⁴ G. NOVOA-HECKEL, R. BERNABE, J. LINARES, *Exportation of unethical practices to low and middle-income countries in biomedical research*, in *Revista de Bioética y Derecho*, 40, 2017, 167-177; J. MASHINGIA, A. PATEL, *op. cit.*, 13-24.

This is the case for the Helsinki Declaration⁸⁵ which, on the contrary, as has been stressed above, has been widely implemented in developed countries. Similarly, practice in Africa has not implemented the rule of informed consent as enshrined in the International Ethical Guidelines for Biomedical Research Involving Human Subjects adopted within the Council for International Organizations of Medical Sciences (CIOMS),⁸⁶ and its provision conceiving waiver as exceptional⁸⁷

Some progress was made only when, in 2005, several capacity building initiatives in the field of vaccination were implemented under the guidance of the WHO, which helped to create a forum for collaboration and exchange of practices and information between African countries. The debate focused on the common challenges faced by the region's States to foster harmonization of the different frameworks through common procedures for the assessment and oversight of clinical trials. This resulted in the definition of model procedures for submission of clinical trial applications and for the importation and release of clinical batches, which provided the basis for a concerted review of clinical trial applications and on-site inspections under the guidance of the WHO. The outcome of these concerted efforts led to the creation of the African Vaccine Regulatory Forum (AVAREF),⁸⁸ intended to host the debate among stakeholders, such as foreign drug manufacturers, researchers, National Regulatory Authorities (NRAs) and Research Ethics Committees (RECs).⁸⁹ Generally speaking, the success of the initiatives carried out under the auspices of the WHO stems from a key element, namely the responsibility of participating States to implement their share of the agreed activities. However, implementation of those results has been unsatisfactory, once again largely due to the institutional, structural and systemic problems of coordination and enforcement at national level.⁹⁰ Regulatory fragmentation and deficiencies along with lack of coordination in the enforcement of standards and in the harmonization of practices is still a major weakness in Africa.

This situation is further exacerbated by the absence of a central, regional-level authority empowered with coordination and oversight of the national systems. Indeed, in Africa, there is no agency comparable to Medicine Agencies or similar authorities, which impacts mutual assistance and cooperation between State schemes as well. In this regard, some significant efforts to set up the African Medicines Agency are being made within the African Union, in the framework of the NEPAD Agency which, as discussed below, is an important role model for advancing feasible solutions for

⁸⁵ M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit.; R. ASHCROFT, *The declaration of Helsinki*, in E.J. EMANUEL (ed.), *The Oxford Textbook of Clinical Research Ethics*, Oxford, 2011, 141-148; J. KIMMELMAN, C. WEIJER, E.M. MESLIN, *Helsinki discords: FDA, ethics, and international drug trials* in *Lancet*, 373, 2009, 13-14.

⁸⁶ International Ethical Guidelines for Health-related Research Involving Humans, cit.

⁸⁷ B.M. MEIER, *op. cit.*, 514-554; A. OLUFOWOBI, *op. cit.*, 544.

⁸⁸ For further information on the African Vaccine Regulatory Forum (AVAREF), please visit the official website at http://www.who.int/immunization_standards/vaccine_regulation/africa_network/en/ (last visited 19/09/2017).

⁸⁹ D. MAÏGA, B.D. AKANMORIC, L. CHOCARROA, *op. cit.*, 7250; for a comprehensive view, see W. O. KIM, *Institutional review board (IRB) and ethical issues in clinical research*, in *Korean Journal of Anesthesiology*, 62(1), January 2012, 3-12.

⁹⁰ D. MAÏGA, B.D. AKANMORIC, L. CHOCARROA, *op. cit.*, 7250; for deeper analysis, see J. MASHINGIA, A. PATEL, *op. cit.*, 13-24; for wider analysis, see W. O. KIM, *op. cit.*

improvement. Institutional difficulties can be found at national level too. NRAs have not been established in all countries; in some States, for example in Burundi and in Rwanda, some competences and functions in the pharmaceutical field are conferred upon the Ministries of Health (MOH).⁹¹ This is cause for serious concern: Ministries are political authorities and, even where they act in compliance with their mandate with professionalism and expertise, they inherently lack the requirements of independence and impartiality that characterize regulatory and oversight bodies. The freedom of research might be undermined – even compromised – by conflicting interests. What is more, research ethics review capacity still needs enhancement, as many countries have not yet established research ethics committees and ethics standards require stronger implementation. In 2005, only 64% of African States had established research ethics committees; for the purpose of offering support for analysing and enhancing African research ethics capacity, the Mapping African Research Ethics Capacity (MARC) Project was launched.⁹² The MARC Project has a large partnership, including EDCTP (the European & Developing Countries Clinical Trials Partnership), COHRED (the Council on Health Research for Development) and the University of KwaZulu-Natal (UKZN), in particular, the South African Research Ethics Training Initiative (SARETI) located in the School of Psychology of the UKZN in Pietermaritzburg, and some aspects of the project are sponsored by Pfizer. Since its launch, the MARC Project has led to the creation of some interactive web tools which are constantly developed and updated, also thanks to the self-uploading of information by the Research Ethics Committees and the National Regulatory Authorities. In 2014, thanks to the MARC Project, 170 Research Ethics Committees operating across the Continent were identified; their capacities, skills, membership and efficiency are variable. Nevertheless, many countries, such as Angola, Sierra Leone and Somalia, still had no Ethics Committee as late as 2015 according to WHO data,⁹³ and figures still show the need for improvement. To this end and to the benefit of the regional framework as a whole, some guidance might be offered by the South African model, which foresees an efficient research ethics review system, capable of interrelating with sponsors with well-devised web resources, which also serve as information dissemination tools.

With regard to protection of the affected population, there is a strong need to increase patients' self-determination and awareness about the clinical trials in which they are involved and about their rights. Participants are often persons with a low level of education or even illiterate, which makes them easy targets for abuses. One very common feature that has emerged with appalling frequency is that patients may not be aware that they are participating in a clinical trial. This often happens when patients are not purposefully recruited but attend hospital to receive treatment or

⁹¹ G. PUPPALWAR, M. MOURYA, G. KADHE, A. MANE, *op. cit.*, 23-34; for deeper analysis, see J. MASHINGIA, A. PATEL, *op. cit.*, 13-24; Medicines Regulation in the East African Community: Landscape Summary Report, cit.

⁹² C. ISSSELMUIDEN, D. MARAIS, D. WASSENAAR, B. MOKGATLA-MOIPOLAI, *Mapping African ethical review committee activity onto capacity needs: the MARC initiative and HRWeb's interactive database of RECs in Africa*, in *Developing World Bioethics*, 12(2), August 2012, 74-86; B. MOKGATLA, C. ISSSELMUIDEN, D. WASSENAAR, M. KASULE, *MARC (Mapping African research ethics review) project*, in *Developing World Bioethics*, 5 May 2017, available at [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1471-8847/earlyview](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1471-8847/earlyview) (last visited 17/09/2017); Research Ethics Web – Mapping African Research Ethics Review Capacity, official website and database: <http://www.researchethicsweb.org/> (last visited 17/07/2017).

⁹³ World Health Organization, List of National Ethics Committees, 2015.

were previously hospitalized or treated. Physicians propose a certain therapy, describing it very summarily, but provide no proper information about the trial; nor is any rule followed to guarantee that informed consent is genuinely given.⁹⁴ This widespread practice has progressively undermined trust between physician and patient, specifically, with foreign medical operators and sponsors. An emblematic example is the boycott of polio vaccination in Kano in 2004, following the dramatic experience undergone by that community with the Trovan trial.⁹⁵ Restoring trust between the local population and foreign medical operators and sponsors is a basic goal and cannot be delayed any longer. This is a necessary precondition for the success of trials and for ensuring they are conducted in line with human rights: it is an essential step for the fulfilment of the right to science and the freedom of research. Last but not least, trust and cooperation between the stakeholders is necessary for the achievement of scientific and technological reality.⁹⁶

Another basic goal is ensuring access to justice and compensation for patients and, more widely, research participants, whose rights were violated and who suffered harm. The key means for tackling this issue is providing appropriate legal support and advice. Again, low education is a major concern, as many people are entirely unaware of their rights and of the legal means available for their protection. Cultural vulnerability is often coupled with economic poverty and deficient legal aid systems, which are generally inappropriately regulated and uncoordinated.⁹⁷ The response of

⁹⁴ G.J. ANNAS, *op. cit.*, 2052. For further analysis of the issues related to informed consent, see: A. BOGGIO, *op. cit.* Focusing on unregulated clinical trials in South America: K. HEARN, *op. cit.*

⁹⁵ G.J. ANNAS, *op. cit.*, 2052; A. FRISHMAN, *Major reasons for Nigerian boycott of Polio vaccine*, in *Health Affairs*, November 2009.

⁹⁶ Trust and cooperation between all the stakeholders involved is a basic factor, which deeply relates to transparency and informed consent of the research participants. This interconnection affects pharmaceutical experimentation since from the early stages, for example as to the recruitment of a suitable research group, that can both suit best the purposes of the research and significantly benefit participants' health. This helps a human rights consistent management of clinical trials, capable of promoting scientific and technological progress and its enjoyment. It may also be argued that it may represent an important motivational factor for potential participants to join the research, which is particularly important in contexts where the risk of exploitation of economically vulnerable subjects is high due to their poor conditions of life. Indeed, these subjects often see participation in pharmaceutical experimentation as a means of livelihood or, sometimes, as the only way to access medical care. Focusing on a practical example of the consequences of the trust violation, the experience of the Kano boycott of polio vaccine is interesting evidence. Between July 2003 and August 2004, five Northern Nigeria States, namely Kano, Zamfara, Kaduna, Bauchi and Niger, suspended the polio vaccine (OVP). Kano was the most reluctant to resume the OVP, and the dramatic experience with the Trovan experimentation was a particularly determinant factor, along with other causes that affected the whole region.

⁹⁷ Danish Institute for Human Rights, *A comparison of the legal aid schemes used in the region and the level of cooperation and coordination between the various actors*, 2011, available at <https://www.human-rights.dk/publications/access-justice-legal-aid-east-africa> (last visited 18/09/2017); Leitner Center for International Law and Justice, 'Access to Justice in Africa: The Experience of the Legal Aid Scheme in Ghana Event Details', available at <http://www.leitnercenter.org/news/94/> (last visited 13/09/2017); M. M. BARRY, F. CZERNICKI, I. KRAŚNICKA, M. LING, *The Role Of National and Regional Clinical Organizations in the Global Clinical Movement*, in F. S. BLOCH, *The Global Clinical Movement: Educating Lawyers for Social Justice*, Oxford, 2010, 279-296, 285 ff.; Penal Reform International and Bluhm Legal Clinic of the North-western University School of Law, *Access to Justice in Africa and Beyond: Making the Rule of Law a Reality*, National Institute for Trial Advocacy, Boulder, 2007.

State authorities to these issues is largely unsatisfactory, both institutionally and operatively. Thus, most of the support is provided by non-governmental organizations that are actively committed to filling the gap. Access to justice and responsibility should be placed on the agenda of the African States if these countries really intend to make the benefits of science, the freedom of research and access to scientific and technological advances not merely theoretical but justiciable rights, supported by an adequate normative regime of responsibility.

4.2. A focus on clinical trials

The overview of the specific weaknesses affecting the African reality needs to be coupled with analysis of the main strengths and weaknesses of clinical trials, in order to assess in depth the relevant challenges.

Clinical trials represent a basic component of biomedical research. Their aim is to test and ensure the effectiveness and safety of drugs and devices already tested in laboratories or on animals, by moving to the stage of human experimentation. At this stage, biolaw starts to play a key role in the drug development process: the involvement of human beings marks the transition of clinical trials to the field of human rights.⁹⁸ Calls for ethical experimentation are based on the fundamental need to protect human dignity, by ensuring that self-determination, physical integrity, health and even the life of the participants are adequately protected.⁹⁹ Nevertheless, experience shows that the human dimension of clinical trials may clash with the conflicting interests at stake, especially the economic ones. The stakeholders in clinical trials, namely research participants, researchers and public and private sponsors, are driven by strong needs that may not point in the same direction. Participants can be either healthy subjects or patients suffering from specific diseases. They may join the clinical trial for a number of reasons: sometimes, patients affected by a given disease can be induced by the hope of accessing experimental medication that might turn out to be more effective than the medications available. In other cases, volunteers may wish to contribute to scientific progress. Last, but not least, the most problematic and worrisome reasons that may lead volunteers to join a trial is that they are economically disadvantaged persons, often poorly educated or even illiterate. The offer of a financial reward is a dangerous recruitment method, as it often targets subjects that do not have the cultural or technical knowledge to weigh the risks and benefits involved, especially the possible impact of participation on their immediate and/or long-term well-being and health. Financial interests have a great impact on clinical trials, especially from the sponsors' point of view. Drug testing is expensive and not always remunerative: in this respect, it is worth noting that only 10% of all tested drugs are eventually approved.

Researchers too, who serve the purposes of science and scientific progress, may pursue interests that conflict to a certain extent with the participants' own interests and well-being: this occurs because sometimes strict observance of ethical and protective rules, intended to safeguard the rights

⁹⁸ For deeper analysis, see J. MASHINGIA, A. PATEL, *op. cit.*, 13-24; A. BOGGIO, *op. cit.*; F.E. MAROUF, B.S. ESPLIN, *op. cit.*, 31-42; B.M. MEIER, *op. cit.*, 514-554; A. OLUFOWOBI, *op. cit.*, 544.

⁹⁹ R. ANDORNO, *El principio de dignidad humana en el bioderecho internacional*, cit.; H.G. ESPIELL, *La Dignidad Humana en los Instrumentos Internacionales sobre Derechos Humanos*, in *Anuario de Derechos Humanos, Nueva Época*, 4, 2003, 193-223.

of volunteers, may slow down the research hence the production of results that are hoped to prevent loss of life by ensuring that effective medication becomes available more rapidly.¹⁰⁰

One of the main disputes of this kind concerned whether placebos should be used in drug testing whether or not an approved effective alternative therapy already existed. This debate was one of the factors that caused some reluctance in the United States against the Helsinki Declaration, which prohibited this practice. Although the Helsinki Declaration was eventually amended and currently allows the use of placebos on condition that no alternative approved therapy is available, this was not enough to allow a generalized, unconditional use of placebos.¹⁰¹

The United States are one of the developed countries where the international soft law standards on clinical trials are seen with some bias. This in 2008 led the Food and Drug Administration (FDA) to depart from them and to adopt as reference guidelines the International Conference on Harmonization's Guideline for Good Clinical Practice (GCP). The FDA claimed that frequent revision of the Helsinki Declaration caused too much uncertainty about which standards to follow.¹⁰² This justification is not persuasive: the Helsinki Declaration, as already stated, is the global reference for guidance, especially from an ethical viewpoint. Moreover, the International Conference on Harmonization counts among its members the United States, the European Union and Japan; developing countries are not partners in this experience. What is more, despite the GCP's claim that its goal is 'consisten[cy] with the principles that have their origin in the Declaration of Helsinki',¹⁰³ it neglects some key ethical issues which are instead addressed by the Helsinki Declaration. For example, the GCP lacks any reference to fundamental ethical standards such as those concerning transparency about clinical trial funding, the disclosure of results, rules to ensure benefit sharing for developing countries and post-trial access to treatment. Furthermore, we should not forget that the United States are the largest pharmaceutical market in the world with a value of \$339.694 billion, hosting 20 of the largest pharmaceutical and biotech corporations in the global market, including Johnson &

¹⁰⁰ For instance, faster ways of conducting clinical trials for achieving results might pose higher risks for the health and the physical integrity of the participants. A clear example was given by M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit., when dealing with HIV vaccine testing. A faster way for testing an HIV vaccine's effectiveness would entail injecting HIV in healthy participants and treat with the vaccine only a group of them, in order to assess and compare the infection rate with the other group of participants. It would clearly violate participants' right to health and to physical integrity, for example, and would also breach several ethical rules, as the principle of beneficence and the twin principle of nonmaleficence.

¹⁰¹ M. ANGELL, *Medical Research: The Dangers to the Human Subjects*, cit.; J. KIMMELMAN, C. WEIJER, E.M. MESLIN, *op. cit.*, 13-14; F. E. MAROUF, B.S. ESPLIN, *op. cit.*, 31-42; W. O. KIM, cit.

¹⁰² J. KIMMELMAN, C. WEIJER, E. M. MESLIN, *op. cit.*, 13-14; International Conference on Harmonization's Guideline for Good Clinical Practice (GCP), 1996, available at https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf. (last visited 18/09/2017) H. WOLINSKY, *The battle of Helsinki: Two troublesome paragraphs in the Declaration of Helsinki are causing a furore over medical research ethics*, in *EMBO Reports*, 7(7), July 2006, 670–672.

¹⁰³ J. KIMMELMAN, C. WEIJER, E.M. MESLIN, *op. cit.*, 13-14; International Conference on Harmonization's Guideline for Good Clinical Practice (GCP), 1996, available at https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf (last visited 15/09/2017). For further information on the International Conference on Harmonization, please visit the official website at: <http://www.ich.org/home.html> (last visited 15/09/2017).

Johnson and Pfizer,¹⁰⁴ respectively the world's first and second-largest companies, which clearly shows America's undisputable primacy in the pharmaceutical sector. The impact of American dominance is strongly felt worldwide, especially in those developing countries that host research projects and trials carried out and sponsored by U.S. pharmaceutical companies. This already problematic scenario is now becoming even more complex due to the expanding practice of outsourcing, which means involving a wider array of private subjects in the field of clinical trials. Contract research organizations (CROs) are emblematic in this respect.¹⁰⁵

4.3. The ascent of contract research organizations (CROs)

With specific reference to clinical trials, these organizations are defined by the International Conference for Harmonization as '[a] person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions', which stresses their role of providing outsourced research services on a contractual basis to pharmaceutical, biotechnology, and medical device industries. Basically, CROs are entrusted with trials, performing functions and duties of both private companies and public subjects such as governmental institutions, foundations, and universities. For example, they can be tasked with performing biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance. In particular, CROs can be entrusted with complete processes or with just one or more specific stages, possibly also according to their size, which may vary from international full-service companies to small specialized groups.

Economically and financially speaking, CROs represent an impressive phenomenon, as they have recorded exponential growth since the early 2000s to a market size of about \$20 billion, a figure that has doubled at an outstanding rate. The astounding rise of CROs and their growing role in the pharmaceutical market can be understood when we consider their capacity to provide outsourced services that are essential for clinical research at very competitive prices.

It follows that the pharmaceutical industry relying on CROs can afford drugs research and experimentation at lower costs, which means an increase in drug testing and the possibility of developing research also in niche markets. However, the advantage of lower costs for the pharmaceutical industry and of an expansion of clinical research and drugs experimentation has a downside that cannot be overlooked. Indeed, to limit their costs, CROs have turned to developing countries' markets, as they are cheaper and subject to less stringent regulation. This phenomenon is assuming

¹⁰⁴ In this regard, please see: <https://www.statista.com/topics/1719/pharmaceutical-industry/>; <https://www.statista.com/topics/1764/global-pharmaceutical-industry/>; <https://www.forbes.com/sites/corinnejourney/2016/05/27/2016-global-2000-the-worlds-largest-drug-and-biotech-companies/#72782b8bcf19> (last visited 18/09/2017).

¹⁰⁵ K. HEARN, *op. cit.*; J. MIERA, *CRO – Contract Research Organization: How Drug Research is Evolving: How Drug Research Is Evolving*, Hamburg, 2014; K. STONE, *A Growing Sector, CROs Play a Major Role in Drug Development*, 19 February 2017, available at <https://www.thebalance.com/contract-research-organizations-cro-2663066> (last visited 14/09/2017); F.A. THIERS, A.J. SINSKEY, E.R. BERNDT, *op. cit.*

alarming proportions and is recorded, for instance, in South America, a continent currently undergoing an experience of unregulated medical experimentation that echoes the African experience of the 1990s.

5. Theorizing a human rights-based and biolegal approach to clinical trials within the African Union

5.1. Mainstreaming human rights through international cooperation within the African Union

Globalization is a relentless process in constant expansion, which has also come to affect the scientific world. Clinical trials are no exception¹⁰⁶ and, as described above, they are undergoing major expansion in the African market. The globalized dimension that scientific experimentation and drug development have now assumed demand more than ever coordinated responses and strategies adopted through global debate since, as the African system has shown, uncoordinated national-level solutions are inappropriate and have become obsolete.

As authoritatively clarified by legal literature, the international community is now faced with ‘general interests’ rather than with ‘common interests’, which require a collective approach especially in such fields as biolaw, where strong ethical implications are involved and important efforts are necessary to cope with the lack of global consensus in order to provide if not unanimous, at least, shared standards, a view that was interestingly and efficaciously conveyed in the ‘but of course test’.¹⁰⁷ In this regard, human rights play a basic role, as they have proven to be capable of conveying global values, which can help reach a compromise in a field where moral relativism is high.¹⁰⁸ To date, human rights have provided an effective ethical ‘minimum common denominator’. They have made it possible to develop important global or regional standards and to translate them into tools of protection. This was the case for the Universal Declaration on Human Genome and Human

¹⁰⁶ B. BENNET, G.F. TOMOSSY (eds.), *Globalization and Health: Challenges for health law and bioethics*, Dordrecht, 2006; M. ISHAY, *The History of Human Rights. From Ancient Times to the Globalization Era*, Berkeley, Los Angeles, London, 2008; F.A. THIERS, A.J. SINSKEY, E.R. BERNDT, *op. cit.*

¹⁰⁷ The “but of course test” was elaborated by Professor Thomas Franck; see T.M. FRANCK, *Non-Treaty Law-Making: When, Where and How?*, in R. WOLFRUM, V. RÖBEN (eds.), *Developments of International Law in Treaty Making*, Berlin, 2005, 417-436. See D. I. GARCÍA SAN JOSÉ, *European Normative Framework for Biomedical Research in Human Embryos*, Cizur Menor, 2013, 44, 47 ff.

¹⁰⁸ R. ANDORNO, *Biomedicine and international human rights law: in search of a global consensus*, in *Bulletin of the World Health Organization*, 80, 2002, 959-963, 960 ff.; R. ANDORNO, *Principles of international biolaw: Seeking common ground at the intersection of bioethics and human rights*, Brussels, 2013; Á. APARISI MIRALLES, *El principio de la dignidad humana como fundamento de un bioderecho global*, in *Cuadernos de Bioética XXIV* 2013/2ª; J. DONNELLY, *Cultural Relativism and Universal Human Rights*, in *Human Rights Quarterly*, 6(4), November 1984, 400-419; D.I. GARCÍA SAN JOSÉ, *International Bio Law. An International Overview of Developments in Human Embryo Research and Experimentation*, Murcia, 2010; J. HERRERA FLORES, *Los derechos humanos como productos culturales: Crítica del humanismo abstracto*, Madrid, 2005, 18-25; J. NICKEL, D. REIDY, *Relativism, Self-Determination, and Human Rights*, available at <http://web.utk.edu/~dreidy/nickelreidyfinaldraft2005.pdf> (last visited 17/09/2017); T. SPAAK, *Moral Relativism and Human Rights*, in *Buffalo Human Rights Law Review*, 13, 2007, 73-85.

Rights,¹⁰⁹ the International Declaration on Human Genetic Data,¹¹⁰ the Universal Declaration on Bioethics and Human Rights,¹¹¹ legal instruments adopted within UNESCO, and the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, more briefly known as the Oviedo Convention,¹¹² and the Additional Protocols, the first international binding instruments adopted in the field of biolaw as the result of the commitment to bioethics of the Council of Europe. These considerations suggest that international cooperation would suit as well the protection requirements related to clinical trials. In particular, intergovernmental dialogue and an international human rights-based and biolegal approach would help to promote the freedom of research, ethical experimentation and equitable enjoyment of the benefits of scientific progress, and to ensure availability and accessibility of drugs at fair conditions.¹¹³

In this respect, the African Union (AU) seems to offer a useful framework for mainstreaming a bio-legal and human-rights based approach to clinical trials in Africa.

This is so for a number of reasons: first of all, from a political viewpoint. Although the African Union (AU) is quite a young international organization¹¹⁴ in comparison with the Council of Europe or the Organization of the American States, which have a history of decades, it has already proven to be a

¹⁰⁹ UN Educational, Scientific and Cultural Organisation (UNESCO), Universal Declaration on the Human Genome and Human Rights, 11 November 1997, available at: <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/> (last visited 18/09/2017).

¹¹⁰ UN Educational, Scientific and Cultural Organisation (UNESCO), International Declaration on Human Genetic Data, 16 October 2003, available at <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/> (last visited 18/09/2017).

¹¹¹ UN Educational, Scientific and Cultural Organisation (UNESCO), Universal Declaration on Bioethics and Human Rights, 19 October 2005, available at: <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/> (last visited 18/09/2017). For an in-depth analysis, please see R. ANDORNO, *Global bioethics at UNESCO: in defence of the Universal Declaration on Bioethics and Human Rights*, cit.

¹¹² The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164) was opened for signature on 4 April 1997 in Oviedo (Spain), entered into force on 1st December 1999, available at <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164> (last visited 18/09/1999).

¹¹³ R. ANDORNO, *Biomedicine and international human rights law: in search of a global consensus*, cit., 960 ff.; Á. APARISI MIRALLES, *op. cit.*

¹¹⁴ The African Union was created in 1999 when it replaced the Organization of African Unity, for the specific purpose of promoting democracy, governance and the rule of law in Africa. For more in-depth analysis, please see S. M. MAKINDA, F. WAFULA OKUMU, D. MICKLER, *The African Union: Addressing the challenges of peace, security, and governance*, Abingdon, New York, 2015; A. MBATA MANGU, *The African Union and the promotion of democracy and good political governance under the African Peer-Review Mechanism: 10 years on*, in *Africa Review*, 6(1), 2014, 59-72. For an interesting assessment of the objectives achieved by the African Union while awaiting US President Barack Obama's speech in 2015, see C. GROVEN, *What is the African Union and has it proven to be successful?*, 28 July 2015, available at <http://www.telegraph.co.uk/news/worldnews/africaandindianocean/11766227/What-is-the-African-Union-and-has-it-proven-to-be-successful.html> (last visited 14/09/2017).

fruitful forum for debate and integration in the region, and on its 10th anniversary, it celebrated its credibility and its ascent as an undiscussed partner in the global landscape.¹¹⁵

Integration and cooperation are two basic features of the AU's mission, and they have so far been translated into important practical experiences of collaboration between member States and with other important international actors. In this respect, the health policies undertaken by the AU are no exception, and they can rely on an comprehensive institutional framework. This is a basic element for adequate decision-making and subsequently for fostering compliance by all member countries through appropriate implementation.¹¹⁶ In this regard, the Assembly plays a central role,¹¹⁷ by monitoring the implementation of the decisions of the AU and by relying on the power to impose sanctions on Member States in given circumstances, for example in case of budgetary non-compliance, according to Article 23 of the AU Constitutive Act. Article 23 was also used by authoritative doctrine to affirm the binding nature of the Assembly's decision on Member States, which is also supported by a contextual reading of the AU Constitutive Act and by reference to the doctrine of implied powers.¹¹⁸

In this institutional framework, as mentioned, the efforts of the AU have also addressed health issues in the region through the promotion of two major projects, namely the African Medicines Regulatory Harmonisation (AMRH) and the Pharmaceutical Manufacturing Plan for Africa (PMPA).¹¹⁹ Basically, the main objectives pursued by these Programmes are respectively to 'establish and improve standards and requirements related to the regulation of and access to safe, high-

¹¹⁵ S.M. MAKINDA, F. WAFULA OKUMU, *EU Strategies on Governance Reform: Between Development and State-building*, Abingdon, New York, 2007; J. PRETORIUS (ed.), *African Politics: Beyond the Third Wave of Democratization*, Cape Town, 2008.

¹¹⁶ J.M BISWARO, *The Assembly, Executive Council and Commission*, in A. A. YUSUF, F. OUGUERGOUZ, *The African Union: Legal and Institutional Framework: A Manual on the Pan African Organization*, Leiden, Boston, 2012, 79 ff.

¹¹⁷ S.M. MAKINDA, F. WAFULA OKUMU, D. MICKLER, *op. cit.*; J. M BISWARO, *op. cit.*, 79-94 ff.

¹¹⁸ L. BOISSON DE CHAZOURNES, *Interactions between Regional and Universal Organizations: A Legal Perspective*, Leiden, Boston, 2017, 190 ff.; M. DU PLESSIS, C. GEVERS, *The Obligation of African Union States to Implement ICC Arrest Warrants*, *EJIL Talk* 4 February 2011, available at <https://www.ejiltalk.org/the-obligation-of-african-union-states-to-implement-icc-arrest-warrants/> (last visited 18/09/2017); E. HELLQUIST, *Regional organizations and sanctions against members: explaining the different trajectories of the African Union, the League of Arab States, and the Association of Southeast Asian Nations*, in *KFG Working Paper*, 59, January 2014, 1-45; Institut d'Etudes de Sécurité – Institute for Security Studies, *Balancing competing obligations. The Rome Statute and AU decisions*, available at <https://issafrica.s3.amazonaws.com/site/uploads/Paper225.pdf> (last visited 17/09/2017).

¹¹⁹ For further information on the Programmes, please see the following websites: with reference to the African Medicines Regulatory Harmonisation (AMRH) <http://www.nepad.org/content/african-medicines-regulatory-harmonisation-armh-programs>, (last visited 18/09/2017); with reference to Pharmaceutical Manufacturing Plan for Africa (PMPA), an interesting overview can be found at <http://www.carmma.org/update/pharmaceutical-manufacturing-plan-africa-facilitate-local-production-medicines-africa> and at <http://apps.who.int/medicinedocs/documents/s20186en/s20186en.pdf>, (last visited 18/09/2017). For deeper analysis, see: Institute of Medicine, *International Regulatory Harmonization Amid Globalization of Drug Development: Workshop Summary*, Washington DC, The National Academies Press, 2013, 31 ff.; Strengthening Pharmaceutical Innovation in Africa. Designing strategies for national pharmaceutical

quality medicines for the African population' and 'strengthening [the production] of high quality, affordable pharmaceuticals across all essential medicines'. Again, the AMRH also aims at establishing the African Medicines Agency (AMA), which will be tasked with oversight of the 'registration of a selected list of medicines and coordinate regional harmonisation systems on the continent' under the authority of the AMRH.¹²⁰

These projects are significant not only because they prove the will and the capacity of the AU to undertake practical and effective action in the pharmaceutical field, but also because they help to highlight its budgetary potential and its capacity to mobilise resources through its strong connection with the NEPAD Planning and Coordinating Agency (NEPAD Agency).

The NEPAD Agency¹²¹ is the result of the incorporation within the AU of the NEPAD, and was established in 2001 as a partnership programme between Africa and the G8 countries in the framework of the Millennium Africa Recovery Plan (MAP) and the Omega Plan for Africa, with the main purpose of effectively promoting development in the Continent through enhancement and mainstreaming of good governance. Politically speaking, it is not a coincidence that the NEPAD was created only two years after the AU replaced the Organization of the African States (OAU) with the intent of overcoming the weaknesses which had characterized the previous experience of integration in Africa and which had failed in one of the fundamental spheres, that is development.¹²²

The positive outcomes of NEPAD and its capacity to affirm itself as a strategic and effective partner have led to its incorporation in the AU, to enhance connection and the fruitful cooperation between these two entities in the pursuit of common objectives translated into specific programmes.

In fact, the NEPAD Agency is a basic strategic partner for success of a wide range of projects and initiatives undertaken in the African Union, covering a number of operational fields including health, the environment, economic development and human resources. The Agency is a major financial partner of the AU, as it mobilises resources and partners for implementation of the programmes. Its strategic role also includes providing expertise and technical assistance by conducting and coordinating research and knowledge management in the region. The NEPAD Agency is also a key player in Africa's international dialogue, engaging in cooperation with global partners. Its fruit-

innovation: choices for decision makers and countries, available at http://www.cohred.org/downloads/cohred_publications/Strengthening_Pharmaceutical_Innovation_Africa_Report.pdf (last visited 17/09/2017).

¹²⁰ Please see http://www.nepad.org/content/african-medicines-regulatory-harmonisation-armh-programs?qt-programme_page=1, (last visited 18/09/2017).

¹²¹ For further information on the New Partnership for Africa's Development (NEPAD) Agency, see the official website at <http://www.nepad.org/>, (last visited 19/09/2017).

¹²² J.K. AKOKPARI, *The AU, NEPAD and the Promotion of Good Governance in Africa*, in *Nordic Journal of African Studies* 13(3), 2004, 243–263; I. BIJAOU, *Multinational Interest & Development in Africa: Establishing a People's Economy*, New York, 2017, 33 ff.; A. MEHLER, H. MELBER, K. VAN WALRAVEN (eds.), R. HOFMEIER (sub-ed.), *Africa Yearbook Volume 8: Politics, Economy and Society South of the Sahara in 2011*, Leiden, Boston, 2012, 1 ff., 17 ff., 38 ff.; E. KANNYO, *The New Partnership for Africa's Development*, in A.A. YUSUF, F. OUGUERGOUZ (eds.), cit., 218 ff.

ful relationship with the European Union, which endorsed the creation of the Agency from its earliest days, is clear evidence of this role.¹²³ These forms of cooperation are a key driver of the success of the programmes developed by the NEPAD Agency, since the support of global partners and their lasting commitment allow the adoption of ambitious and long-term initiatives.¹²⁴ For example, alt-

¹²³ G. ABRAHAM, *Africa, the tragedy; Africa, the challenge: NEPAD and the new humanitarian agenda*, in IRCC, 85 852, December 2003, 717-736; *African Cities Driving the NEPAD Initiative*, UN HABITAT, United Nations Settlements Programme, Report of the First Phase, the NEPAD Cities Programme, 2006, K. VON GREBMER, J. BERNSTEIN, D. NABARRO, N. PRASAI, S. AMIN, Y. YOHANNES, A. SONNTAG, F. PATTERSON, O. TOWEY, J. THOMPSON, *The 2016 Global Hunger Index Africa Edition*, International Food Policy Research Institute (IFPRI), Concern Worldwide, and Welthungerhilfe in conjunction with NEPAD, 2017; T. KARBO, *The AU New Partnership for Africa's Development (NEPAD): the next 10 years*, in T. MURITHI (ed.), *Handbook of Africa's International Relations*, London, New York, 2014; I. MAYAKI, *In 10 years, NEPAD has achieved a lot*, December 2011, available at <http://www.un.org/africarenewal/magazine/december-2011/%E2%80%9810-years-nepad-has-achieved-lot%E2%80%99> (last visited 17/09/2017); for an overview of weaknesses and strengths of NEPAD's implementations, see J. MORBI, *Is NEPAD an effective development organisation?*, E-International Relations Students, 26 October 2011, available at <http://www.e-ir.info/2011/10/26/is-nepad-an-effective-development-organisation/> (last visited 16/00/2017); S. OLUWAROTIMI OLOWOYE, *The new partnership for Africa's Development (NEPAD): An analysis of the perceptions and challenges*, ETD Collection for AUC Robert W. Woodruff Library, Paper 33, 2008.

¹²⁴ The role of the NEPAD Agency is acknowledged to be of pivotal importance for the African Union, especially insofar as it concerns international dialogue and cooperation. This is so notwithstanding the fact that the NEPAD Agency's commitment may be improved from several viewpoints, for example with respect to the mobilization of domestic resources (some steps forward have been made, as can be seen here <http://www.nepad.org/resource/mobilizing-domestic-financial-resources-implementing-nepad-national-and-regional-programmes> and here <http://www.nepad.org/content/nepad-takes-stock-readies-domestic-resource-mobilization-implement-program>, last visited 17/09/2017), and, again, in relation to the dialogue with civil society, in order to enhance the perception of the NEPAD Agency's functions and positive contribution for Africa's development. In this regard, some interesting analyses (among the various existing assessments, including those cited above, which are relevant as a reference here as well) were made by S. OLUWAROTIMI OLOWOYE, *op. cit.* Also see U. ENGEL, H. ZINECKER, F. MATTHEIS, A. DIETZE, T. PLÖTZE (eds.), *The New Politics of Regionalism: Perspectives from Africa, Latin America and Asia-Pacific*, Abingdon, New York, 2017. Acknowledgment and evidence of the fruitful role of the NEPAD Agency at the global level, as a strategic partner for the African Union in paving the way to international cooperation and mobilization of financial resources and expertise, can be found in the following references. Among others: with further regard to European countries, for example: Spain, <http://www.nepad.org/content/nepad-spanish-fund-approves-82-million-euros-african-women%E2%80%99s-projects> (last visited 17/09/2017); Germany, <https://www.giz.de/en/world-wide/28079.html> (last visited 17/08/2017). In relation to global cooperation, <http://www.oecd.org/daf/inv/investment-policy/africa.htm> (last visited 17/09/2017).

V. MOSOTI, *The New Partnership for Africa's Development: Institutional and Legal Challenges of Investment Promotion*, in *San Diego International Law Journal*, 5, 2004, 145-178; F. BEVERIDGE (ed.), *Globalization and International Investment*, Abingdon, New York, 2016, 405-438, 422 ff; United Nations. Office for ECOSOC Support and Coordination, *Resources Mobilization and the Creation of an Enabling Environment for Poverty Eradication in Least Developed Countries. Dialogues at the Economic and Social Council*, United Nations, New York, 2005, 43 ff, 86 ff, 112 ff, 189 ff. With regard to the dialogue with Asian Countries, the interesting view of Professor H. WENPING, *Engaging with NEPAD: A View from China*, for the Conference China in Africa in the 21st Century: Charting the Future Johannesburg, 16 – 17 October 2006 available at <https://www.saiia.org.za/images/upload/HeWenping-Engaging%20with%20NEPAD.pdf> (last visited 17/09/2017); <http://www.nepad.org/content/nepad-agency-and-japan-explore-areas-collaboration-sadc> (last visited

though the EU does not see the NEPAD Agency as a 'channel for financial resources or new cooperation instrument',¹²⁵ it has committed to supporting the Agency since the beginning of their cooperation, collectively with other donors and with the G8 countries. The EU is progressively strengthening its relationship with the NEPAD Agency and has addressed specific areas of cooperation, such as promoting peace and security, strengthening institutions and governance, promoting trade, investment, economic growth and sustainable development.¹²⁶ The EU's engagement with the NEPAD Agency is consistent with the Union's external action, which is built on values such as democracy, good governance, the rule of law and human rights, which are also the founding values of the NEPAD Agency.¹²⁷

The nature of the founding values and the political justification for the NEPAD are relevant to the purpose of this study. These elements allow us to identify the Agency as the appropriate framework for the development of a programme on clinical trials based on the mainstreaming of human rights and on political cooperation between States, one which also outlines a system of responsibilities built on specific human rights duties.¹²⁸

Therefore, the NEPAD Agency arguably provides a suitable framework for the planning and enforcement of a clinical trial programme within the African Union.

In this regard, postulating the definition of a human rights-based approach capable of identifying specific and tailored States' duties in the field of clinical trials and to promote and ensure the right to science, the right to enjoy the benefits of scientific progress and the freedom of science, along with the protection of self-determination, health and life of the participants finds its justification in the human rights landscape to which African countries have committed.¹²⁹

17/09/2017); <http://www.un.org/africarenewal/news/nepad-and-china-strengthen-transparent-and-accountable-partnerships-africa> (last visited 17/09/2017). It is interesting also to see J. F. ARVIS, R. C. CARRUTHERS, G. SMITH, C. WILLOUGHBY, *Connecting landlocked developing countries to markets: trade corridors in the 21st century*, World Bank, Washington DC, 2011, 28 ff. As far as concerns South America: <http://www.nepad.org/content/nepad-and-brazil-partner-increase-food-and-nutrition-security-africa> (last visited 17/09/2017); <http://www.nepad.org/content/nepad-prepares-partner-argentina> (last visited 17/09/2017). It is also interesting to consider the NEPAD Agency's commitment in the scientific and technological field, in this respect see <http://www.hsrc.ac.za/uploads/pageContent/5481/Science,%20Technology%20and%20Innovation%20Strategy%20for%20Africa%20-%20Document.pdf> (last visited 18/09/2017).

¹²⁵ F. GRANELL, *The European Union and the New Partnership for Africa's Development (NEPAD)*, *The Courier ACP-EU*, 194, September-October 2002 available at http://ec.europa.eu/development/body/publications/courier/courier194/en/en_028.pdf (last visited 17/09/2017); for a wider overview of the European Union's policy in relation to clinical trials in developing countries, see <https://ec.europa.eu/research/health/index.cfm?pg=policy&policyname=edctp> (last visited 18/09/2017).

¹²⁶ F. GRANELL, cit.; J. MANGALA, *Africa and the European Union: A Strategic Partnership*, New York, 2012; W. HOUT (ed.), *EU Strategies on Governance Reform: Between Development and State-building*, Thirdworlds TWQ Series, Abingdon, 2012, 52 ff.

¹²⁷ W. HOUT, cit., 52 ff.; D. SHELTON, P.G. CAROZZA, *Regional Protection of Human Rights*, Volume 1, 2nd Ed. Oxford, 2013, 81 ff.

¹²⁸ R. MURRAY, *Human Rights in Africa: From the OAU to the African Union*, Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore, São Paulo, 2004; D. SHELTON, P.G. CAROZZA, cit., 81 ff.; P.T. ZELEZA, P.J. MCCONNAUGHAY (eds.), *Human Rights, the Rule of Law, and Development in Africa*, Philadelphia, 2004.

¹²⁹ For a wider overview of protection of human rights in Africa and some interesting comparisons, see L. POLI, *La Corte di Giustizia dell'ECOWAS: quali prospettive per un concreto miglioramento della tutela dei diritti umani in Africa?*, in *Diritti Umani e Diritto Internazionale*, 8, 2014, 133-158.

One primary, immediate reference is found in the African Charter of Human and People's Rights (hereinafter 'the Banjul Charter' or simply 'the Charter'),¹³⁰ in particular Article 16, on the right to health, and Article 22, the right to development. Pursuant to Article 16, States are under the obligation to ensure the enjoyment of the 'best attainable state of physical and mental health' by committing to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick'. What is noteworthy is that the Banjul Charter does not establish the principle of progressive realization within the maximum available resource, which means that States are under the obligation of guaranteeing health care in all circumstances.¹³¹ This is a significant difference from the protection afforded by Article 12 of the United Nations' International Covenant on Economic, Social and Cultural Rights (ICESCR),¹³² to which all African States are parties with the exception of Botswana, Mozambique and South Sudan. Under this provision, States are duty bound to ensure the enjoyment of the 'highest attainable standard of physical and mental health', but subject to the principle of progressive realization.¹³³ Therefore, it can be argued that States have to meet a particularly appreciable standard of protection of the physical and mental health of the participants in clinical trials to comply with the Charter, though some allowance was made for the difficulties that African countries may encounter in practice, due to their limited financial resources. Nevertheless, despite economic difficulties, all States would be equally bound to ensure compliance with the 'core obligations' relating to the right to health, i.e. the minimum level of health that must be guaranteed and which includes, for example, safe and potable water and food supply, nutrition and, something particularly relevant for this study, the provision of essential drugs, appropriate treatment of common diseases and injuries, immunization against major infectious diseases and the prevention of epidemics.¹³⁴ The core duties under Article

¹³⁰ Organization of African Unity (OAU), African Charter on Human and Peoples' rights, cit. All African States are Parties to the African Charter on Human and People's Rights with the exception of South Sudan.

¹³¹ Vincent Obisienunwo Orlu Nmehielle has authoritatively criticized this interpretation of the clause, stressing the critical financial conditions that African States often have to cope with. Therefore, in Professor Nmehielle's opinion, a stricter reading of the scope of the provisions should be undertaken, limiting the content of States' duty to healthcare instead of the best attainable level of physical and mental health. In fact, according to Professor Nmehielle, other clauses of the Charter allude to mental and physical health and may provide protection. In this regard see: V. O. O. NMEHIELLE, *The African Human Rights System: Its Laws, Practice, and Institutions*, The Hague, London New York, 2001, 126.

¹³² UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, available at <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (last visited 17/09/2017). All African States are Parties to the ICESCR except for Botswana, Mozambique and South Sudan.

¹³³ Interesting views are expressed by S. KIAPI, *Interpreting the right to health under the African Charter*, in *East African Journal of Peace and Human Rights*, 11(1), 2005, 1-20, and O. C. OKAFOR, *A regional perspective: article 22 of the African Charter on Human and Peoples' Rights*, in *Realizing the Right to Development, Essays in Commemoration of 25 Years of the United Nations Declaration on the Right to Development*, United Nations, 31 December 2013, 373-384.

¹³⁴ The Committee on Economic, Social and Cultural Rights has recalled and elucidated the concept of 'core obligations' in the following General Comments: General Comment no. 3 (1990) on the Nature of State Parties Obligations, para. 10; General Comment No. 12 (1999) on The Right to Adequate Food, para. 8; General Comment No. 13 (1999) on the Right to Education, para. 57; General Comment No. 14 (2000) on the Right to the Highest Attainable Standard of Health, para. 43-45. In this regard, guidance is offered also by Primary health

16 of the African Charter mirror the minimum obligations relating to the right to health arising from the ICESCR. Making further comparison between the treaties under consideration, the definition of the standards of protection of the right to health in Africa, where possible, would benefit from reference to Article 12 of the ICESCR, especially with respect to the so-called '4-A scheme', which helps to elucidate the States' obligations about the conditions for best enjoyment of the right.¹³⁵ The '4-A scheme' hinges on availability, accessibility, acceptability and adaptability which turns into quality when health is at stake. This approach, as illustrated in the General Comments of the Committee on Economic, Social and Cultural Rights,¹³⁶ indicates the content of such standards of enjoyment, and some suggestions can be made as to their application to clinical trials: availability of sufficient quantity of health services, goods and facilities; non-discrimination, with special regard to vulnerable groups, which can apply when these individuals are involved in clinical trials for particular scientific purposes; economic accessibility, which may be intended as affordable treatment for participants once the trial is over.¹³⁷ Access to information is particularly important in clinical trials as it may be seen, on the one hand, as transparency of the key information about the experimentation and, on the other, as confidentiality of the data collected in clinical trials; to some extent information accessibility might be read in conjunction with informed consent.

Acceptability may be intended as respect for medical ethics in the conduct of the trial and for specific cultural needs of participants; finally, quality concerns the medical and scientific appropriateness of the health facilities, goods, services and personnel. For instance, quality may relate to the standard of the medications available, in order to ensure access to quality drugs and prioritize availability of brand-name products over generic drugs. In light of these considerations, it can be argued

care: report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, jointly sponsored by the World Health Organization and the United Nations Children's Fund and by the UN Committee on Economic, Social And Cultural Rights, Guidelines on Reporting Questions Relating to Article 12 Of The Cescr, UN Doc. E/1991/23, pp. 88-110. The latter also provides some indicators or benchmarks for assessing States' commitment to ensure the minimum level of health through their policy and resources management. Interesting analysis is made by: Y. DONDEERS, *The right to enjoy the benefits of scientific progress: in search of state obligations in relation to health*, in *Medicine, Health Care, and Philosophy*, 14(4), November 2011, 371-381; L. FORMAN, C. BEIERSMANN, C.E. BROLAN, M. MCKEE, R. HAMMONDS, G. OOMS, *What Do Core Obligations Under the Right to Health Bring to Universal Health Coverage?*, in *Health and Human Rights Journal*, 18, 2, 5 December 2016, available at <https://www.hhrjournal.org/2016/12/what-do-core-obligations-under-the-right-to-health-bring-to-universal-health-coverage/> last visited 15/09/2017; D. I. GARCÍA SAN JOSÉ, *Crisis económica, vulnerabilidad multidimensional y cambio climático: la 'tormenta perfecta' para el derecho a la salud en europa*, in *Bioderecho.es, Estudios de Vulnerabilidad*, 5, 2017, available at <http://revistas.um.es/bioderecho/article/view/290821> (last visited 17/09/2017); S. KIAPI, *op. cit.*, 6 ff.

¹³⁵ Y. DONDEERS, *op. cit.*, 379 ff. M. MANCISIDOR, *op. cit.* For further views and assessments on human rights in general and, in particular, on the right to science, it may also be interesting to visit the blog of Dr. Mikel Mancisidor at <http://mikelmancisidor.blogspot.it/> (last visited 18/09/2017). For a wider overview, see, A. PETERS, *Beyond Human Rights: The Legal Status of the Individual in International Law*, Cambridge, New York, 2016, 439 ff. Last but not least, it is interesting here to recall that in 2015 experts in the field of science and human rights established the International Institute for the Human Right to Science.

¹³⁶ In particular, see: UN Committee on the Elimination of Discrimination Against Women 1999, paras 6-13; UN Committee on Economic, Social and Cultural Rights 2000, para. 12; UN Sub-Commission on the Promotion and Protection of Human Rights 2003, para. 12).

¹³⁷ An Asian outlook on drugs accessibility: L. HSU, *Trade, Investment, Innovation and their Impact on Access to Medicines: An Asian Perspective*, Cambridge, 2016.

that reference to Article 12 of the ICESCR would benefit the protection that can be granted in the African system. Such joint reading with the Charter was also supported by the African Commission on Human and People's Rights when it suggested that the right to health under the Charter must be read in accordance with international standards in the case *Social and Economic Rights Action Center (SERAC) and Center for Economic and Social Rights (CESR) v. Nigeria*.¹³⁸

What is more, as pointed out in the legal literature, in the same case the African Commission on Human and People's Rights suggested a reading of Article 16 of the Banjul Charter – which was invoked in the case together with Article 24, on the environment - 'that subscribe[d] to a rights-based and rights-framed model of development, one in which the goal of development activities is imagined, at least in part, as the fulfilment of the economic and social rights of a people'.¹³⁹ While no violation of Article 22 of the Charter was alleged in the case, the reading given by the African Commission offers important guidance referable to the right to development. In this respect, again, the ICESCR is a relevant reference, in particular its Article 15,¹⁴⁰ which is widely identified as the international legal basis of the right to science, along with Article 27 of the Universal Declaration of Human Rights of 1948,¹⁴¹ which is extensively echoed in the wording of Article 15.¹⁴² This provision establishes the right to 'enjoy the benefits of scientific progress and its applications', which expands to the 'conservation, the development and the diffusion of science' along with the duty 'to respect the freedom indispensable for scientific research'. Therefore, Article 15 of the ICESCR may offer some further support, in the African human rights landscape, to the affirmation of access to quality and affordable medicines, in the long-term and for the benefit of future generations, by also aiming at protecting the freedom of scientific research from any undue interference, for instance, from the economic interests of the pharmaceutical industry when conducting clinical trials. To complete the landscape of the human rights to which African countries have committed, reference should to be made to the protection offered by Article 7 of the International Covenant on Civil and Political Rights (ICCPR),¹⁴³ which lays down the right to free and informed consent in connection with the prohibition of torture, inhuman or degrading treatment. The Human Rights Committee (HRC), the monitoring body of the ICCPR, has clarified the scope of the provision, specifying that it imposes a duty on States under international law to ensure 'special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment', in order to protect these vulnerable subjects from any

¹³⁸ African Commission on Human and Peoples' Rights, *155/96 Social and Economic Rights Action Center (SERAC) and Center for Economic and Social Rights (CESR) / Nigeria*, available at <http://www.achpr.org/communications/decision/155.96/> (last visited 17/09/2017).

¹³⁹ O. C. OKAFOR, *op. cit.*, 377.

¹⁴⁰ Y. DONDEERS, *op. cit.*, 377 ff.

¹⁴¹ UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III), available at <http://www.un.org/en/universal-declaration-human-rights/> (last visited 14/09/2017).

¹⁴² For a deeper analysis, see: M. MANCISIDOR, *op. cit.*; J. MORSINK, *The Universal Declaration of Human Rights: Origins, Drafting and Intent*, Philadelphia, 1999.

¹⁴³ UN General Assembly, International Covenant on Civil and Political Rights, *cit.* It is interesting to recall here that all African States are parties to the ICCPR with the exception of South Sudan and Western Sahara.

‘medical or scientific experimentation that may be detrimental to their health’.¹⁴⁴ For this purpose, the HRC has invited States to adopt ‘legislative, administrative, judicial and other measures [...] to prevent and punish acts of torture and cruel, inhuman and degrading treatment in any territory under their jurisdiction’, which entails taking practical action that goes beyond the criminalization of the prohibition of torture and inhuman or degrading treatment. It can be argued that Article 7 of the ICCPR helps to elucidate the content of States’ duty to ensure informed consent in clinical trials, and complements the obligations existing in relation to the right to health, the right to development and the right to science, enhancing the protection of self-determination in clinical experimentation regardless of its success or failure.

In light of this assessment, putting States’ role and responsibility at the centre of the approach to the protection and mainstreaming of human rights in clinical trials appears not only feasible but especially apt. This requirement becomes even stronger when we consider the States’ position as guardians of legality against the unlawful acts of private companies – which are usually the main perpetrators of violations in medical experiments.

In this respect, States have a duty to respect and protect human rights against corporate violations, in addition to being directly responsible for any violations committed by public bodies such as public research institutions. As human rights treaties cannot set obligations on private corporations, urging serious and effective States commitment is the only feasible – and the best – way of securing protection.¹⁴⁵

Unsurprisingly, the United Nations and the Committee on Economic, Social and Cultural Rights have urged the States’ commitment, a view that is stated clearly in the UN Guiding Principles on Business

¹⁴⁴ UN Human Rights Committee (HRC), CCPR General Comment No. 20: Article 7 (Prohibition of Torture, or Other Cruel, Inhuman or Degrading Treatment or Punishment), 10 March 1992, para. 7, available at: <http://www.refworld.org/docid/453883fb0.html> (last visited 16/09/2017). For a wider outlook on the issue see: European Center for Constitutional and Human Rights, Case Summary, *Human rights violations in clinical trials in India, the case of HPV vaccination programme*, available at https://www.ecchr.eu/en/our_work/business-and-human-rights/clinical-trials.html?file=tl_files/Dokumente/Wirtschaft%20und%20Menschen-rechte/Case%20Summary%2C%20Clinical%20Trials%2C%202014-02-11.pdf (last visited 17/09/2017). For broader analysis, also see: M. FREEMAN, S. PATHARE, *WHO Resource Book on Mental Health, Human Rights and Legislation*, World Health Organization, Geneva, 2005, 66 ff.; F.E. MAROUF, B.S. ESPLIN, *op. cit.*, 31-42; S. B. LEE, *op. cit.*; J. SCHILDMANN, V. SANDOW, O. RAUPRICH, J. VOLLMANN (eds.), *op. cit.*, 70 ff.

¹⁴⁵ D. DESIERTO, *China’s ‘One Belt, One Road’ Initiative: Can A Bilaterally-Negotiated ‘Globalization 2.0’ Internalize Human Rights, Labor, and Environmental Standards?*, EJIL Talk, 16 May 2017, available at <https://www.ejiltalk.org/chinas-one-belt-one-road-initiative-can-a-bilaterally-negotiated-globalization-2-0-internalize-human-rights-labor-and-environmental-standards/> (last visited 14/09/2017); D. DESIERTO, *The ICESCR as a Legal Constraint on State Regulation of Business, Trade, and Investment: Notes from CESCR General Comment No. 24 (August 2017)*, EJIL Talk, 13 September 2017, available at <https://www.ejiltalk.org/the-icescr-as-a-legal-constraint-on-state-regulation-of-business-trade-and-investment-notes-from-cescr-general-comment-no-24-august-2017/> (last visited 17/09/2017). Also see S. KIAPI, *op. cit.*, 9 ff.; *The Corporate Responsibility to Protect Human Rights. An Interpretive Guide*. United Nations, 2012; W. VANDENHOLE, *Contextualising the state duty to protect human rights as defined in the guiding principles on business and human rights*, in *Revista de Estudios Jurídicos*, 12, 2012 (Segunda Época), 1-10. With regard to extraterritorial duties, also see: *States’ obligations to respect and protect human rights abroad. Joint Statement on John Ruggie’s Draft Guiding Principles*, available at https://www.fidh.org/IMG/pdf/States_obligations_to_respect_and_protect_human_rights_abroad-2.pdf (last visited 16/09/2017).

and Human Rights (UNGPS) and in the General Comment on State Obligations under the ICESCR in the Context of Business Activities.¹⁴⁶

What is more, from a perspective of justiciability of the relevant rights, the African Court of Human and People's Rights (AfCHPR) may be argued to have certain powers of scrutiny over States' duties, under the African Charter on Human and People's Rights, in particular Article 16 and 22. Moreover, further support for the Court's role in establishing the States' duty to ensure the right to science, the right to enjoy the benefits of scientific progress and the freedom of research could be found in the obligations under Articles 12 and 15 of the ICESCR, since Article 7 of the Protocol to the African Charter on Human and Peoples' Rights on the Establishment of the African Court on Human and Peoples' Rights¹⁴⁷ entrusts the AfCHPR with a human rights mandate that enables the scrutiny referred to the Charter and to 'any other relevant human rights instruments ratified by the States concerned'. This is especially significant in light of the praiseworthy approach developed by the AfCHPR, since the Court has proven capable of addressing the States' duties under the Charter and their compliance in a purposeful way, by ordering them to adopt such pervasive measures as amending their legislation or resuming the investigation of a criminal case, in order to ensure compliance with the Charter.¹⁴⁸ Legal literature has also suggested that, in the near future, the AfCHPR

¹⁴⁶ For wider analysis of the UN Guiding Principles on Business and Human Rights, see: <https://business-humanrights.org/en/un-guiding-principles> (last visited 19/09/2017). The text of the UN GP on Business and Human Rights is available at: http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf (last visited 18/09/2017). Some interesting views concerning the Council of Europe can be found in D. AUGENSTEIN, W. VAN GENUGTEN, N. JÄGERS, *Business and Human Rights Law in the Council of Europe: Noblesse oblige*, EJIL Talk, 10 February 2014, available at <https://www.ejiltalk.org/business-and-human-rights-law-in-the-council-of-europe-noblesse-oblige/> (last visited 17/09/2017). Economic and Social Council, General comment No. 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities, 10 August 2017, E/C.12/GC/24, available at <http://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmIBEDzFEovLCuW1a0Ssab0oX-TdlmnsJZZVQclMOuuG4TpS9jwlh-CJcXiuZ1yrkMD%2fSi8YF%2bSXo4mYx7Y%2f3L3zvM2zSUBw6ujlnCawQrJx3hIK8Odk6DUwG3Y> (last visited 18/09/2017). For an interesting analysis see D. DESIERTO, *The ICESCR as a Legal Constraint on State Regulation of Business, Trade, and Investment: Notes from CESCR General Comment No. 24 (August 2017)*, cit. Also see: D. DESIERTO, *China's 'One Belt, One Road' Initiative: Can A Bilaterally-Negotiated 'Globalization 2.0' Internalize Human Rights, Labor, and Environmental Standards?*, cit.

For a wider overview of the relevant issues and of States' position with respect to human rights violations committed by corporations or other private subjects, also see: B. BAGLAYAN, *Corporate Liability Debate still Alive and Kicking in US Courts*, EJIL Talk, 30 May 2016, available at <https://www.ejiltalk.org/the-corporate-liability-debate-is-still-alive-and-kicking-in-us-courts/> (last visited 15/09/2017). Also see: *States' obligations to respect and protect human rights abroad. Joint Statement on John Ruggie's Draft Guiding Principles*, available at https://www.fidh.org/IMG/pdf/States_obligations_to_respect_and_protect_human_rights_abroad-2.pdf (last visited 16/09/2017).

¹⁴⁷ Organization of African Unity (OAU), Protocol to the African Charter on Human and People's Rights on the Establishment of an African Court on Human and People's Rights, cit.

¹⁴⁸ See, for example: *Tanganyika Law Society and The Legal and Human Rights Centre v the United Republic of Tanzania and Reverend Christopher Mtikila v the United Republic of Tanzania*, App. No. 009&011/2011. The decision is particularly emblematic of the African Court's human rights-based approach to the national Constitution while scrutinizing them with regard to the Charter.

might even go so far as ‘pronounc[ing] itself on the legal findings of a national Supreme Court’.¹⁴⁹ This kind of scrutiny is so pervasive that it goes even beyond the important results achieved by the case law of the European Court of Human Rights (ECtHR), which is the undisputed global reference and inspiration in the area of international judicial protection of human rights. Therefore, it may be recommended that where the Court finds any breach of the right to science or of the right to enjoy the benefits of scientific progress, or a breach of the freedom of research, it might articulate the contents of the States’ duties in greater detail when ‘mak[ing] appropriate orders to remedy the violation’ pursuant to Article 27 of the Protocol to the African Charter on Human and Peoples’ Rights on the Establishment of the African Court on Human and Peoples’ Rights.¹⁵⁰ But this is not the only noteworthy strength in the approach of the AfCHPR: indeed, the Court has undertaken an outstanding approach of scrutiny of the States’ legislations and constitutions that relies on the Charter as a parameter of constitutionality. For these reasons, legal scholars have suggested that we could possibly look on the Court as an emerging ‘Supreme Court for Africa’.¹⁵¹

In light of the considerations made, the development of a regionally concerted programme to be developed within the framework of the African Union and of the NEPAD Agency seems an adequate and effective means of tackling the weaknesses of clinical trial management in Africa, relying on a human-rights based and biolegal approach.

Some measures should be considered as primary means for putting into practice this purpose. One of the major weaknesses of the African system is represented by the structural inadequacies of institutions and by the lack of regional-level coordination. The creation of a regional authority en-

¹⁴⁹ G. PECORELLA, *The African Court on Human and Peoples’ rights and its case law: towards a Supreme Court for Africa?*, 22 June 2015, available at <https://aninternationallawblog.wordpress.com/2015/06/22/the-african-court-on-human-and-peoples-rights-and-its-case-law-towards-a-supreme-court-for-africa/> (last visited 17/09/2017).

¹⁵⁰ See, for example: *Peter Joseph Chacha v The United Republic of Tanzania*, App. No. 003/2012, available at <http://www.african-court.org/en/index.php/55-finalised-cases-details/850-app-no-003-2012-peter-joseph-chacha-v-united-republic-of-tanzania-details> (last visited 17/09/2017).

¹⁵¹ G. PECORELLA, cit. For some brief comparison with individual petitions before the East African Court of Justice, see A. POSSI, *Time-limitation Clause Against Private Litigants of the East African Court of Justice: A Call for a Purposive Interpretation of Article 30(2) of the East African Community*, 7 August 2017, available at <https://aninternationallawblog.wordpress.com/2017/08/07/time-limitation-clause-against-private-litigants-of-the-east-african-court-of-justice-a-call-for-a-purposive-interpretation-of-article-302-of-the-east-african-community/> (last visited 17/09/2017). Again, see *Tanganyika Law Society and The Legal and Human Rights Centre v the United Republic of Tanzania and Reverend Christopher Mtikila v the United Republic of Tanzania*, App. No. 009&011/2011. For deeper analysis of the African Court’s approach: J. B. CARTES RODRÍGUEZ, *El Tribunal Africano de Derechos Humanos y de los Pueblos: ¿hacia un África en paz?*, in *Anuario Mexicano de Derecho Internacional*, vol. XVII, 2017, 251-289. For more in-depth analysis, see S. FENNELL, D. ANDONI, *The African Court of Human Rights and Peoples’ Rights: Basic Documents*, Oisterwijk, 2014. For an overview of International Courts’ efforts to ensure protection to human rights, with particular regard to the European Court of Human Rights but with important reference to the East African Court of Justice and to the Court of Justice of the Economic Community of West African States (ECOWAS), see: L. R. HELFER, *The Successes and Challenges for the European Court, Seen from the Outside*, EJIL Talk, 14 May 2014, available at <https://www.ejiltalk.org/the-successes-and-challenges-for-the-european-court-seen-from-the-outside/> (last visited 15/09/2017).

trusted with coordination, monitoring and oversight and having regulatory powers should be a priority. This authority would be at the top of a comprehensive system based at national level on the existing National Regulatory Authorities (NRAs), in order to take advantage of their expertise and experience and of the institutional framework already in place. The regional authority might be a newly created body or the African Medicines Agency. The latter seems an interesting option, also in light of the words of Mrs Margareth Ndomondo-Sigonda, the NEPAD Agency Head of Health Programmes, who has remarked on the importance of a strong institutional framework for ensuring equitable and qualitatively appropriate access to medical products, and has clarified that the AMA 'will also contribute to establishing an enabling environment for the development of the pharmaceutical industry and lead to better coordination of different partners and stakeholders undertaking medicines regulatory strengthening and harmonisation efforts on the continent'.¹⁵²

From an operational perspective, adoption of a 'multilevel' approach, complemented by mutual support between States, seems a suitable route for the implementation of the programme and the achievement of its objectives, for the purpose of ensuring effective coordination between the regional authority and the NRAs. In this respect, some inspiration can be drawn from the experience of the East African Community with the Medicines Regulatory Harmonization (EAC MRH) Programme. The programme was adopted within the East African Community Medicines and Health Technologies Policy, which is currently under development to complement several provisions of the EAC Treaty.¹⁵³ Some of the relevant provisions are Article 118 of the EAC Treaty, concerning health, contained in Chapter 21, on Regional cooperation on health, social and cultural activities, and Article 117, opening Chapter 21. The latter provision sets a duty of cooperation on Partner States within the scope of Chapter 21 for the purpose of achieving the objectives of the Community contemplated in Article 5 of the EAC Treaty, according to which Partner States shall undertake to 'develop policies and programmes aimed at widening and deepening co-operation' in the field of research. Finally, the reference framework on which adoption of the (EAC MRH) Programme relies is complemented by the EAC Common Market Protocol that contemplates integration in the health sector as the main policy priority.¹⁵⁴

The (EAC MRH) Programme provides an interesting model as far as concerns its strategies for reducing the time necessary for registering essential medicines to treat priority diseases and the mechanism of mutual recognition of the decisions taken by NRAs in Partner States. Additionally,

¹⁵² In this regard, see <http://www.nepad.org/content/african-medicines-agency> (last visited 17/09/2017).

¹⁵³ Treaty Establishing the East African Community, Arusha, 30 November 1999, in force 7 July 2000, 2144 UNTS 255.

¹⁵⁴ Protocol on the Establishment of the East African Community (EAC) Common Market which entered into force on 1 July 2010. For deeper analysis, see J. MASHINGIA, A. PATEL, *op. cit.*, 13-24. Medicines Regulation in the East African Community: Landscape Summary Report, cit. For a human rights outlook, also see: E. RWABYO, *East African Community System And The Protection Of Human Rights* available at https://www.academia.edu/21692906/EAST_AFRICAN_COMMUNITY_SYSTEM_AND_THE_PROTECTION_OF_HUMAN_RIGHTS (last visited 19/09/2017). For some information on the approach of the East African Court of Justice when human rights implications are at stake, see A. POSSI, *The East African Court of Justice: Towards Effective Protection of Human Rights in the East African Community*, in *Max Planck Yearbook of United Nations Law*, 17, 2013, 173-195, and <http://www.ijrcenter.org/regional-communities/east-african-court-of-justice/> (last visited 17/09/2017).

the East African Health Research Commission might inspire the establishment of a body responsible for the coordination and the promotion of joint research programmes, aimed at enhancing research capacity and at exchanging and sharing expertise, knowledge and data concerning clinical trials promptly and easily, for instance by means of databases.¹⁵⁵

5.2. The use of the legislative technique of criminalization as a means for enhancing harmonization between domestic legal systems

To complete the system suggested above and to improve harmonization of States' policies and legislative landscapes, this study suggests that the authority should also be empowered with recommending targeted measures to States, for example of a legislative nature, to enhance the national legal response to human rights violations committed in their territory and for improving the conduct of research. In this regard, some guidance can be offered by the experiences of several international binding instruments that have fruitfully combined a human rights-based approach with the legislative technique of criminalization of the infringements. This entails that States Parties, when implementing their duties under the Conventions, introduce in their legal orders specific provisions criminalizing the violations and establish a punitive and judicial response under criminal law. The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances¹⁵⁶ and, within the Council of Europe, within the Council of Europe, the Convention against Trafficking in Human Organs,¹⁵⁷ the Council of Europe Convention on Action against Trafficking in Human Beings¹⁵⁸ and the Medicrime Convention are all examples of international agreements that

¹⁵⁵ Some inspiration can be drawn from: *Medicines Regulation in the East African Community: Landscape Summary Report*, cit. For further analysis of the East African Community's framework, also with respect to the sources of law and with justiciability, see: T.P. MILEJ, *What Is Wrong about Supranational Laws? The Sources of East African Community Law In Light of the EU's Experience*, in *ZaöRV*, 75, 2015, 579-617, Max-Planck-Institut für ausländisches öffentliches Recht und Völkerrecht; J. E. RUHANGISA, *Rule of Law and Access to Justice in East Africa: The East African Court of Justice*, A Paper for Presentation During the Premier Course on the East African Community, organized by the Kituo cha Katiba, Hotel Africana, Kampala, Uganda, 12th – 15th September, 2012.

¹⁵⁶ UN Economic and Social Council (ECOSOC), United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, cit. For some interesting considerations see: P. ANDREAS, *When Policies Collide. Market Reform, Market Prohibition, and the Narcotization of Mexican Economy*, in H.R. FRIMAN, P. ANDREAS (eds.), *The Illicit Global Economy and State Power*, Lanham, Boulder, New York, Oxford, 1999, 125-142, 126 ff.

¹⁵⁷ Council of Europe Convention against Trafficking in Human Organs, cit. The Convention addresses cases where there has been no human trafficking, which fall within the scope of the Council of Europe Convention on Action against Trafficking in Human Beings that addresses cases of human trafficking for the purpose of organ removal. For deeper analysis, see M.À. PORXAS ROIG, *La Convención sobre la lucha contra el Tráfico de Órganos, una mirada desde la bioética*, in *Revista de Bioética y Derecho*, 40, 2017, 141-155.

¹⁵⁸ Council of Europe Convention on Action against Trafficking in Human Beings, cit. For further information on the implementation of the Convention and for a practical example, see Group of Experts on Action against Trafficking in Human Beings (GRETA), Secretariat of the Council of Europe Convention on Action against Trafficking in Human Beings (GRETA and Committee of the Parties) Council of Europe, *Report concerning the implementation of the Council of Europe Convention against Trafficking in Human Beings by Albania, Second Evaluation Round*, Council of Europe, Strasbourg, 2016, available at <https://rm.coe.int/168065bf87> (last visited 08/02/2018).

have adopted the technique of criminalization. Among these instruments, the Medicrime Convention¹⁵⁹ is the most significant reference for the purpose of this study, as it addresses drugs counterfeiting¹⁶⁰ and has departed from the traditional approach of international law to issues relating to medicines and the pharmaceutical industry, which focused on intellectual property rights and the interests of rights holders. The Trade Related Aspects of Intellectual Property Rights (TRIPs)¹⁶¹ and the Anti-Counterfeiting Trade Agreement (ACTA)¹⁶² are examples of this traditional approach.

In light of these consideration about the Medicrime Convention, it may be argued that criminalization measures inspired by the Convention might be recommendable – on the part of the regional authority that this study suggests is established – also to develop effective responses to human rights violations in clinical trials. In particular, the regional authority might provide guidance for the

¹⁵⁹ Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, cit.

¹⁶⁰ Africa is seriously affected by drug counterfeiting. For example, only last December, Ugandan Authorities seized the counterfeit version of Avastin, a cancer drug, which was on sale in Kampala. The WHO had already launched an alert in this respect last August (available at http://www.who.int/medicines/publications/drug-alerts/WHO_ALERT_Avastin_and_SutentN3_2017EN.pdf last visited 08/02/2018, last visited 18/09/2017). Sub Saharan Africa is one of the most targeted areas: the WHO esteems that counterfeit drugs make up more than 50% of global drugs market and Sub-Saharan Africa accounts for 42% of reports of counterfeit and low-quality products received by the United Nations Agency since 2013. Counterfeit drugs in African market are mainly fake antimalaria and fake antibiotics, which has also determined an increase in the rate of antimicrobial and drugs resistance, as the WHO has recently stressed. Again, in 2016, the WHO had already reported that more than 122.000 children die every year in Africa due to the administration of substandard antimalarial drugs alone. For further information see <https://blueline.news/drug-testing/war-on-drugs/african-countries-are-developing-ways-to-combat-the-fake-drug-problem/> last visited 08/02/2018. Many efforts were made through the years for trying to tackle the problem and Nigeria seems to have adopted interesting solutions that, to some extent, have proven helpful, though serious criticalities still remain. For an interesting overview of the main aspects of the issue see *A bitter pill to swallow: the problem of, and solutions to, Sub-Saharan Africa's counterfeit pharmaceutical trade*, in *The Journal of Global Health*, 1 November 2014, available at <http://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/> last visited 08/02/2018 and see <http://afro.who.int/about-us/governance/sessions/sixty-sixth-session-who-regional-committee-africa> last visited . The interconnection between drug falsification and clinical trials appears close for several reasons: causes are very similar, namely the lack of an appropriate regulatory framework and coordinated measures, along with political instability; again, inaccessibility of drugs is a major cause, and it pushes people in need to rely on the unsafe internet market. By reverse, on some occasions, drugs can be bought in open drug market, where drugs are sold in the open air at the corners of the streets without any kind of control. Another basic criticality is that drugs, in huge part, are imported, especially from China and India, which are two of the biggest sources of counterfeit drugs, and preventing fake drugs to access African States through appropriate control is quite hard. In this respect, it may be argued that ensuring some guarantees to research participants also after the termination of clinical trials, might be one of the solutions for additionally helping to prevent people in need's access to counterfeit drugs. For example, continuing treatment may be a viable solution in this regard. Again, applying a differentiated patent regime would help. What is more, besides the issues highlighted, it seems particularly unfair that Africa is so widely involved in drugs testing and, at the same time, access to safe drugs, especially safe basic drugs, is largely precluded to African people.

¹⁶¹ World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), cit.

¹⁶² Anti-Counterfeiting Trade Agreement (ACTA), cit.

harmonization of domestic systems in order to define a legislative framework of criminal responsibility of the perpetrators of the violations and a satisfactory mechanism ensuring protection and redress for victims. This could represent an effective response to the human rights violations committed by corporations, and might also have deterrent effects. What is more, such a solution would enable constitute States to fulfil their duty to respect and protect human rights against corporate violations. violations.¹⁶³

5.3. Pursuing some further specific paths

Furthermore, the promotion of harmonization could also benefit from some lessons coming from the European Union, which has succeeded in tackling the weaknesses of its previous framework on clinical trials as laid down in Directive 2001/20/EC.¹⁶⁴ The scientific community had criticised the Directive, arguing that it hindered scientific research by increasing significantly the administrative burden and the cost of academic clinical trials. Now, Regulation 536/2014,¹⁶⁵ which will come into force in 2019, has overcome these weaknesses and has put forward a new, widely welcomed system. In this regard, some inspiration could be drawn from the highest safety standards set in favour of participants, for example, the functions of assessment of the responsible ethics committee within the safety reporting mechanism and the procedure of substantial modification of the trial, that includes any change capable of having an impact on the rights of participants. Again, some inspiration could be drawn from the EU's approach to transparency, by ensuring public availability of information concerning the authorisation, the conduct and results of each clinical trial carried

¹⁶³ Possibly, the adoption of a targeted agreement by African States would be recommendable, arguably within the framework of the African Union. However, as the conclusion of an international agreement would take time and efforts, it would also be recommendable to adopt regionally concerted measures and policies to fight unlawful and unethical experimentation in the framework of the African Union through the means described above, which seems a solution more easily achievable in the short term and which is the main view that this paper wishes to suggest.

¹⁶⁴ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practices in the conduct of clinical trials on medicinal products for human use' (the 'Clinical Trials Directive'), available at https://ec.europa.eu/health/human-use/clinical-trials/directive_en (last visited 17/09/2017). The website also offers an overview of the main issues related to the Directive. For more in-depth analysis, see P. DAMAS, K.J. FALKE, J. MANCEBO, A. PESENTI, *The European Union Directive on Clinical Research: present status of implementation in EU member states*, in *Intensive Care Medicine*, April 2005, 476-479.

¹⁶⁵ Regulation EU No 536/2014, available at https://ec.europa.eu/health/human-use/clinical-trials/regulation_en (last visited 17/09/2017); T.K. HERVEY, J.V. MCHALE, *European Union Health Law: Themes and Implications*, Cambridge, 2015, 302 ff.; P. VAN PHAM, A. ROSEMAN, *Safety, Ethics and Regulations*, Cham, 2017, 202 ff.; I. VERMEULEN, *Regulatory requirements*, in D. SHAMLEY, B. WRIGHT (eds.), *A Comprehensive and Practical Guide to Clinical Trials*, London, San Diego, Cambridge, Kidlington, 2017, 36 ff. Some criticism was expressed as to the former EU framework on clinical trials, namely, the view which the British Parliament had expressed, shared by scientists in the United Kingdom as well: <https://www.parliament.uk/mps-lords-and-offices/offices/bicameral/post/work-programme/biology-and-health/clinical-trial-regulation-in-the-uk/> (last visited 18/09/2017). See White Paper. The EU Clinical Trials Regulation – Main Changes and Challenges, CROM Source, available at <https://www.cromsource.com/wp-content/uploads/2015/02/The-EU-Clinical-Trials-Regulation-Main-Changes-and-Challenges.pdf> (last visited 17/09/2017).

out in the EU. Such rules on transparency increase the efficiency of clinical trials and help to prevent their unnecessary duplication and their repetition when found to be unsuccessful, which also helps to save resources.

The experience of the EU may also provide some interesting guidance for improvement of the Pan African Clinical Trials Registry (PACTR),¹⁶⁶ a regional register of the clinical trials conducted in Africa, which can be registered on it free of charge. The purposes of the PACTR are praiseworthy, however it might benefit from upgrading of its functions and from the establishment of a functional connection with oversight authorities and ethics committees (namely, in the system suggested here, the central regional authority to be established, which may be the AMA), the NRAs and the Research Ethics Committees (RECs). In this respect, a key suggestion is to make registration of clinical trials compulsory, to ensure adequate assessment of the applications for clinical trials and their compliance with ethical and human rights standards, to ensure oversight and monitoring throughout the trial and, last but not least, to ensure transparency and confidentiality of the data collected during the trial. Possibly, although this is objectively a very ambitious goal, creating a section of the register listing the participants in clinical trials per State would be helpful for monitoring the experiments and for protecting better the rights of participants. For example, registration could help to ensure continuing treatment to participants where the medications they received during the testing proved to be effective.

This reflection paves the way for some further proposals as to the continuing obligations of sponsors, which seem necessary under a human rights-based approach intended to transcend the individual sphere and lay the basis for a long-term legacy. For example, with reference to sponsors' continuing obligations, access could be provided at facilitated conditions to a wide set of drugs, which can be complementary, for better results of the treatment. Again, facilitated conditions would become particularly relevant where access to medications is hindered by the patent regime, a likely threat for patients, especially in developing countries, as important scholarship has pointed out.¹⁶⁷ Some solutions might be to impose differential pricing or to introduce a specific clause on patents, in order to allow facilitated conditions of access where medications might be life-saving

¹⁶⁶ A. ABRAMS, N. SIEGFRIED, *A Pan African Clinical Trials Registry for the specific needs of triallists on the continent*, in *South African Medical Journal*, 4, 100(5), May 2010, 294-295; A. ABRAMS, N. SIEGFRIED, *Growing everyday: the Pan African Clinical Trials Registry*, in *Journal of Evidence Based Medicine*, 4(3), 2011, 172-178; A. ABRAMS, N. SIEGFRIED, *The Pan African Clinical Trials Registry: year one data analysis of the only African member of the World Health Organization Network of Primary Registries*, in *Journal of Evidence Based Medicine*, 3(4), November 2010, 195-200. Wider information on the Pan African Clinical Trials Registry (PACTR) can be found at <http://www.pactr.org/> (last visited 17/09/2017).

¹⁶⁷ For an in-depth analysis of feasible, interesting solutions and of the relevant issues at stake, see: I. CANGELOSI, *Patent Pool and Access to Medicines. Innovative strategies for spreading antiretroviral drugs*, 2012; S. JUNEJA, A. GUPTA, S. MOON, S. RESCH, *Projected savings through public health voluntary licences of HIV drugs negotiated by the Medicines Patent Pool (MPP)*, in *PLoS One*, 12(5), 2017, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444652/> (last visited 19/09/2017); M. MORLA GONZÁLEZ, *Las patentes farmacéuticas y el comercio del medicamento*, in *Ius et Scientia*, 3(1), 2017, 183-194; M. ORTEGA, *El derecho de acceso a los medicamentos y el derecho de patente en países en desarrollo*, in *Revista de Bioética y Derecho*, 37, 2016, 23-36.

or, in relation to particular treatment needs, for example where a given treatment has proved effective in patients difficult to treat by other means.

Furthermore, in a long-term perspective, the sponsors may be theorized to have duties to educate the local staff involved in the clinical trial. Sharing of knowledge, expertise and good practices could be an important resource for the local personnel and for the community, which could represent a valuable legacy also for future generations of physicians and medical professionals in general and for patients.

Finally, the establishment of targeted bodies in partnership with NRAs would help to provide technical support to the authorities from both a medical and a legal viewpoint. Language support would be an added value, since communication between the medical staff and participants is often hampered by language barriers. Moreover, the staff of such bodies could be trained to provide support and advice to participants as well, to help to fill the gap in the dissemination of legal information and in ensuring access to protection and to legal remedies.

6. Conclusions

Globalization of clinical trials has become a major challenge for the 21st-century world, especially for the international community that is committed more than ever to human rights as a means for providing effective solutions to an unprecedented global reality.

The protection of the right to health and to development, self-determination, the right to science and to enjoyment of the benefits of scientific progress and of freedom of research in clinical trials require concerted efforts that transcend the boundaries of States and cultural and economic differences, for the general and no longer common interest of reaffirming human dignity and ethics. Practices such as unregulated experimentation and unethical rules dumping are some of the most subtle and unacceptable practices of commercialization of human beings.

Nowadays, Africa is doing its best to overcome its dramatic past and the world, especially the most developed countries cannot leave this Continent alone in this struggle.

In order to effectively support Africa's effort to affirm ethics and human rights in medical experimentation, developed countries should overcome their paternalistic approach. While providing economic support and medical aid are helpful as short-term responses and should hopefully be ongoing, in the long term a more stable and long-lasting regional balance has to be created. What Africa arguably needs is to build a strong and concerted management capacity to deal with clinical trials, and to develop local education and training centres for present and future medical professionals and researchers. Human rights and ethics should be mainstreamed in training as a basic component.

African States should be the main protagonists in this process, and the measures suggested in this paper intend to enhance their role and place their responsibility at the centre: since private actors, in particular corporations, which are the main perpetrators of human rights violations in medical experimentation in developing countries are not bound by human rights treaties and specific duties, States have to be put in charge. This is consistent with their duty to protect, respect and uphold human rights, and this view has found general acceptance in the international community.

The call for effective commitment by the States is clearly expressed in the recently approved General Comment No. 24 (2017) on State obligations under the International Covenant on Economic, Social and Cultural Rights in the context of business activities.

The importance of granting appropriate protection to human rights against the acts of private subjects is such that it transcends national borders and assumes extraterritorial relevance.

The need to develop a satisfactory response is especially clear when we consider that Principle 13 of the UN Guiding Principles on Business and Human Rights addresses corporations and invites them to ‘seek to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts’.¹⁶⁸

It follows that dialogue and negotiation between African States and private players within their jurisdictions are recommendable to ensure compliance with human rights’ standards in all operational fields, including clinical trials.¹⁶⁹ This approach should be accompanied by appropriate legislative, administrative and judicial measures and remedies within a coordinated regional framework. In this regard, the African experience so far has given us an important lesson: isolated or fragmentary attempts to provide solutions may be promising but need to expand beyond national borders and translate into regional-level joint cooperation. Public health needs inter-State dialogue and coordination, especially to prevent the creation of ‘research tourism’ and medical experimentation-paradises for the pharmaceutical industry where ethics dumping takes over. This is what is currently happening, for example, in South-America, a world region that should look to Africa for inspiration and to avoid similar mistakes.

¹⁶⁸ The purpose of the UN Guiding Principles on Business and Human Rights is indeed to provide an effective response to human rights violations linked to business activity from an overall perspective, by addressing more specifically corporations as perpetrators as well. In particular, UN Commission on Human Rights’ Resolution E/CN.4/RES/2005/69 (available at http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2005-69.doc last visited 08/02/2018. For further information see <http://www.ohchr.org/EN/Issues/Business/Pages/BusinessIndex.aspx>, last visited 08/02/2018) stated clearly the objective of “identify[ing] and clarify[ing] standards of corporate responsibility and accountability for transnational corporations and other business enterprises with regard to human rights” while requesting the appointment of a special representative of the Secretary-General (SRSG), who then adopted the UN Guiding Principles on Business and Human Rights. This perspective helps to enrich States’ position and duties recalled above at page 30, as Principle 11 states that: “The responsibility to respect human rights is a global standard of expected conduct for all business enterprises wherever they operate. It exists independently of States’ abilities and/or willingness to fulfil their own human rights obligations, and does not diminish those obligations. And it exists over and above compliance with national laws and regulations protecting human rights” and additionally clarifies that “[b]usiness enterprises should not undermine States’ abilities to meet their own human rights obligations, including by actions that might weaken the integrity of judicial processes.”

¹⁶⁹ Dialogue between African States may help to adopt a consistent approach to be coordinated and implemented at the regional level within the African Union and the NEPAD Agency, for example through the solutions that this study aims at suggesting. Again, dialogue and negotiation between African States and pharmaceutical corporations may be more effective when carried out not by each State individually but jointly, which would also help to adopt common standards and guarantees for research participants in Africa, for example by adopting some of the measures suggested as continuing treatment, support for education of local staff and differentiated patent regimes.

The Judges of the District Court of Connecticut, in the United States of America, have attempted to advocate an accountability regime based on international human rights law to address the chilling commercialization of children in Kano. They tried to pave the way for the incorporation of the universal values enshrined in human rights law in domestic litigation to affirm the corporations' responsibility. However, the obstacles are still many and this courageous interpretation took too long a step with respect to the rules on application of international law and its impact on the domestic legal systems.

Beyond the States' obligations, treaties and commitments, there is something more that we should not forget: humanity. Human rights are not simple duties for States and proclamations for advocates, human rights are the ultimate essence of humanity, despite and beyond the cultural relativism that threatens to overwhelm our world. And while it is a fact that law lags behind relentless scientific progress,¹⁷⁰ it is also true that we cannot let biolaw lag behind humanity.

¹⁷⁰ For in depth analysis of this view, see D.I. GARCÍA SAN JOSÉ, *International Bio Law. An International Overview of Developments in Human Embryo Research and Experimentation*, cit., 149, 164, 179, 189, 192.