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Review Article

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# Evolution of Clinical Trial Regulations in Cote D'Ivoire

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## Abstract

Clinical trials are an essential step in bringing innovative medicines to market. Their effective regulation, which protects participants in these trials, is important in West African's heavy dependence on foreign sources for medicines context, and particularly in Côte d'Ivoire where the government has expressed its desire to develop the local pharmaceutical industry, including innovation. The objective of this study was to describe the regulations governing clinical trials in Côte d'Ivoire. The methodology used consisted in identifying and then analyzing the applicable texts to clinical trials as well as the reports emanating from the bodies involved in the regulation of clinical trials. The results of our study reveal that in Côte d'Ivoire, since 1987, clinical regulation trials, characterized by the creation and organization of the main bodies in charge of managing these trials, has not really evolved. It took about thirty years to observe a major evolution in regulations with the adoption of Presidential Decree No. 2020-407 of April 22, 2020 regulating clinical trials in Côte d'Ivoire. This salutary text incorporates general principles universally accepted in this area such as the protection of persons and their free and informed consent before any testing is conducted. This confirms the role of the Ivorian Pharmaceutical Regulatory Authority in clinical trials monitoring, while still considering National Ethics Committee mandatory opinion. This development in Ivorian regulations is part of a sub-regional project to regulate clinical trials and will become effective with implementing regulations adoption.

**Keywords:** medicine; clinical trials Regulation; Côte d'Ivoire; Organizations of Medical Sciences (CIOMS); National Ethics Committee

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## 1. Introduction

Clinical trials are scientific studies conducted in human medical therapy to evaluate the efficiency and safety of a diagnostic method or treatment. (1) The goal is to bring safe and effective health products to market, and to surround these different products with a high level of trust. (2) Clinical trials adhere to a rigorous methodology and are subject to a precise legislative and regulatory framework, as well as rules of good practice, (3) from various international organizations, such as the Council for International Organizations of Medical Sciences (CIOMS), which are essential. Conducting a clinical trial is never easy. In France in 2016, clinical trial Phase I of the analgesic molecule BIA 10-2474 from the Portuguese laboratory Bial resulted in the hospitalization of five participants and the death of one. (4) In sub-Saharan Africa, clinical trials are mostly necessary to ensure the efficiency and safety of medicines in order to address the high disease burden, primarily due to infections. However, less than 10% of global clinical trials are conducted in this geographic area, (5) which faces certain challenges in the regulation of clinical trials. This is how a clinical trial conducted without regulatory authorization resulted in the deaths of patients in Nigeria in 1996. (6) In Côte d'Ivoire, given pharmaceutical companies' capital opening to non-pharmacists, (7) efficient regulation of clinical trials is essential for the establishment of an innovative pharmaceutical industry as envisioned by the government. Furthermore, Côte d'Ivoire's dependence on foreign sources for pharmaceuticals increases the need to protect clinical trial participants through appropriate regulations. The objective of this study was to describe the evolution of regulations concerning clinical trials in Côte d'Ivoire.

This is about the clinical trials at the national, sub-regional in West African Economic and Monetary Union (WAEMU), and international levels; the evaluation reports of clinical trial applications and the opinions issued by the Pharmaceutical Regulatory Authority and the National Ethics Committee; and the reports of seminars and other meetings related to clinical trial regulations in Côte d'Ivoire. The texts and other documents constituting the research material were identified and analyzed. From this, we deduced the different components of clinical trial regulations in Côte d'Ivoire.

In Côte d'Ivoire, clinical trials are subject to legal texts at different hierarchical levels, creating several bodies involved in their regulation according to a well-established procedure.

## 2. Legal Texts Applicable to Clinical Trials in Côte D'ivoire

The textual provisions applicable to clinical trials in Côte d'Ivoire can be grouped into international, sub-regional and national provisions.

### 2.1 International texts

**Table 1.** International legal texts and guidelines applicable to clinical trials in Côte d'Ivoire

| Year | Title of the act | Scope of application |
|---|---|---|
| **1947** | Nuremberg Code | Participant consent |
| **1948** | Universal Declaration of Human Rights | Protection of people |
| **1964, Last revised: 2013** | Helsinki Declaration of the World Medical Association | Ethics applied to medical research |
| **1981** | Declaration of Manila by the WHO and the Council for International Organizations of Medical Sciences (CIOMS) | Biomedical research involving human subjects |
| **1993 Last revised: 2016** | Ethics guidelines in medical research from the Council for International Organizations for Medical Sciences (CIOMS) | Ethics applied to medical research |
| **1996 Last revised: 2023 adopted on January 6, 2025** | ICH E6 (R3) Good Clinical Practices (GCP) | GCP rules for sponsors, investigators, and anyone involved in clinical trials |

### 2.2 Sub-regional legal texts relating to clinical trials

Côte d'Ivoire is a Member State of the Economic Community of West African States (ECOWAS) and the West African Economic and Monetary Union (WAEMU), two sub-regional economic communities that have initiated pharmaceutical regulations harmonization process in West Africa. At the WAEMU level, this process led to the adoption of an initial text, Regulation No. 02/2005/CM/WAEMU concerning the harmonization of pharmaceutical regulations in WAEMU Member States, and several other texts covering various areas of the pharmaceutical sector, some of which have been revised.

Clinical trials are among the topics of common interest to be harmonized according to the new Regulation No. 01/2022/CM/WAEMU of June 24, 2022, concerning the harmonization of pharmaceutical regulations in WAEMU Member States. Furthermore, Directive No. 06/2020/CM/WAEMU of September 28, 2020, concerning the status of the Pharmaceutical Regulatory Authorities of the Member States of the WAEMU, sets out the missions of these Authorities, one of which consists of the control of clinical trials and the inspection of research sites in health products.

### 2.3 National Regulations applicable to Clinical Trials

**Table 2.** Legal Texts and Clinical Trials Applicable National Technical Standards in Côte d'Ivoire

| Title of the act | Scope of application |
|---|---|
| Ministerial Decree No. 317/SP/DSPH of July 14, 1987, regulating clinical trials of medicinal substances before and after marketing in Côte d'Ivoire | Clinical trials of drug substances |
| Presidential Decree No. 2001-12 of 3 January 2001 concerning the organization of the Ministry of Public Health | Creation of the National Ethics and Research Committee |
| Ministerial Decree No. 871/MSHP of May 17, 2018, concerning the organization and operation of the National Ethics Committee for Life Sciences and Health | Organization and operation of the National Ethics Committee for Life Sciences and Health (CNESVS) |
| Law No. 2017-541 of August 3, 2017 relating to pharmaceutical regulation | Creation of the Ivorian Pharmaceutical Regulatory Authority (AIRP) |
| Presidential Decree No. 2018-926 of December 12, 2018, concerning the organization and operation of the Ivorian Pharmaceutical Regulatory Authority | Organization of the Ivorian Pharmaceutical Regulatory Authority (AIRP) |
| Presidential Decree No. 2020-407 of April 22, 2020, regulating clinical trials | Regulation of clinical trials in Côte d'Ivoire |
| Guidelines of June 2024 concerning clinical trials, applications for authorization and substantial amendment | Clinical trials authorization application |

Several draft texts specific to clinical trials and applicable in Côte d'Ivoire are currently being developed and/or validated at both the national and community levels. These include a draft Ministerial Decree establishing the conditions for authorizing a clinical trial in Côte d'Ivoire and a draft WAEMU guideline concerning the regulatory framework for conducting clinical trials in WAEMU Member States.

### 2.3.1 Ministerial Decree No. 317/SP/DSPH of July 14, 1987, regulating clinical trials of medicinal substances before and after marketing in Côte d'Ivoire

This 1987 Decree was the first Ivorian text specifically addressing clinical trials. It covered, on one hand, the regulation of clinical trials of medicinal substances before their marketing (phases I, II, and III) and, on the other hand, multicenter studies, i.e., clinical trials conducted on a drug already on the market. The provisions of this Ministerial Decree, which conflicted with the new regulations in this area, were repealed by those of Presidential Decree No. 2020-407 of April 22, 2020, regulating clinical trials.

### 2.3.2 Presidential Decree No. 2020-407 of April 22, 2020, regulating clinical trials

This Decree establishes more appropriate regulations for clinical trials in Côte d'Ivoire, incorporating universally accepted general principles of clinical trials. Article 2 stipulates that clinical trials must be designed, implemented, and reported in accordance with Good Clinical Practice (GCP) guidelines. Clinical trials are subject to rules that guarantee the protection of individuals participating in these studies. These rules primarily require that patients be provided with detailed information about the treatment they will receive. The Decree specifies the conditions for conducting clinical trials and the role of each body in the authorization process. Finally, it sets the amount of fees payable by the sponsor of clinical trials. The main provisions relating to of clinical trials conduct are summarized in Table III.

**Table 3.** Provisions relating to the conduct of clinical trials in Côte d'Ivoire

| Presidential Decree No. 2020-407 of April 22, 2020, regulating clinical trials | Aspects covered |
|---|---|
| **Structuring** | 8 chapters, 50 articles |
| **Number of definitions** | 28 definitions |
| **Scope** | - Phase I, II, III, and IV clinical trials<br>- Bioequivalence studies |
| **Sponsor's Obligations** | - Adherence to ethics, Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP)<br>- Scientific rigor<br>- Liability insurance coverage<br>-Import Authorization from Ivorian Pharmaceutical Regulatory Authority (AIRP) for importation of investigational medicinal products<br>- Notification of adverse events and incidents to the AIRP<br>- Signature of the final clinical trial report with the investigator before submission to the AIRP<br>- Data and document retention for 25 years |
| **Investigator** | - Pharmacist or physician registered with the professional order<br>- Dentist<br>- Observational studies: qualified person |
| **Clinical trial site** | - Site authorized by the Ministry of Health (first human administrations)<br>- Healthcare facility with a self-contained unit (phases I and II) |
| **Participants' rights** | - Protection and security<br>- Free and informed consent<br>- Right to refuse to participate in the trial or to withdraw at any time<br>- Pre-trial medical examination<br>- Compensation for expenses incurred and inconveniences experienced<br>- Provision of a permanent local contact<br>- Post-trial medical follow-up<br>- Compensation in case of adverse consequences |
| **Specific protection** | - Limited participation for minors<br>- Participation prohibited for pregnant women and breastfeeding mothers |
| **EC Management** | - Based on the current state of scientific knowledge and sufficient preclinical experimentation<br>- Fees for the EC application and substantial modifications<br>- AIRP authorization after a favorable opinion from the CNESVS<br>- Favorable benefit-risk balance for the participant |

## 3 Organizations Responsible for Managing Clinical Trials

### 3.1 The National Pharmaceutical Regulatory Authority (NPRA)

Law No. 2017-541 of August 3, 2017, concerning the regulation of the pharmaceutical sector in Côte d'Ivoire, established the Ivorian Pharmaceutical Regulatory Authority (AIRP), the competent body for evaluating applications for clinical trials and issuing authorizations. AIRP now assumes the responsibilities for clinical trials previously held by the NPRA, which was the Directorate of Pharmacy, Medicines, and Laboratories (DPML), a former central directorate attached to the Ministry of Health. AIRP is an independent administrative authority with legal personality and financial autonomy, possessing enhanced regulatory powers throughout the entire drug quality assurance chain. Its mission is to guarantee the quality, safety, and efficacy of medicines, from their initial design to their therapeutic use. Regarding clinical trials, AIRP is responsible for granting authorizations after receiving a favorable opinion from the national ethics committee; to ensure their proper execution in accordance with validated protocols and good practice standards; and to collect and evaluate all relevant information concerning pharmaceutical products in order to detect, reduce, and prevent adverse effects. AIRP's inspection responsibilities include ensuring compliance with good practices in the execution of pharmaceutical procedures and conducting quality control checks on health products and clinical trials. It must generally ensure compliance with applicable regulations concerning pharmaceutical establishments and clinical trials. Furthermore, AIRP implements the pharmacovigilance system and manages a clinical trials national database.

### 3.2 The National Ethics Committee (NEC)

The NEC in Côte d'Ivoire was established by Presidential Decree No. 164/MSP/CAB of May 10, 2001, concerning the organization and operation of the National Ethics and Research Committee, which has since been repealed. Its new name is the National Ethics Committee for Life Sciences and Health (CNESVS), whose organization and operation are defined by Ministerial Decree No. 871MSHP of May 17, 2018. It is an advisory body attached to Health Minister office. The mission of this committee is to provide its opinion on the ethical considerations inherent in any medical research project, clinical trial, and any sociological or individual study affecting the field of public health or that may have a direct or indirect impact on public health. It is responsible for upholding human rights and protecting human dignity. Regarding clinical trials, this Committee is responsible for clinical trials compliance analysis and research projects undertaken in Côte d'Ivoire with ethical rules; issuing opinions on applications for clinical trials and research projects undertaken in Côte d'Ivoire; ensuring the supervision and inspection of clinical trials and research projects authorized and in progress in accordance with current ethical rules; proposing implementation suspension or cessation of any clinical trial or project in violation of the authorized protocol.

## 4. Preliminary Procedure for Obtaining Authorization to Conduct Clinical Trials in Côte D'Ivoire

Conducting clinical trials in Côte d'Ivoire requires authorization from the Ivorian Pharmaceutical Regulatory Authority (AIRP). The sponsor of a clinical trial project submits the clinical trial protocol to the AIRP, which then seeks the opinion of the National Ethics Committee for Life Sciences and Health (CNESVS).

### 4.1. Mandatory Opinion of the National Ethics Committee for Life Sciences and Health (CNESVS)

The CNESVS, formerly known as the National Ethics and Research Committee, gives its mandatory opinion on the ethical considerations inherent in any clinical trial project and on the substantial modifications that should be made to it where applicable. The CNESVS opinion can be expressed in three different ways: "favorable opinion," "favorable opinion subject to consideration of the committee's observations," and "unfavorable opinion."

### 4.2 Clinical Trial Protocol Review

The granting of clinical trial authorization follows clinical trial protocol review and CNESVS opinion by AIRP. Until 2019, the Directorate of Pharmacy, Medicines and Laboratories (DPML) received applications for clinical trial authorization and provided the secretariat for the Commission responsible for reviewing applications. This Commission could approve or reject the application after receiving an advisory opinion from the Ethics Committee. Since 2020, with the effective commencement of AIRP 's activities, this body is responsible for receiving and evaluating clinical trial applications.

### 4.3 Clinical Trial Authorization Issuance by AIRP

Before the establishment of AIRP, and upon approval of the clinical trial application, authorization to conduct clinical trials was issued by the Minister of Health. However, since 2020, authorization to undertake a clinical trial in Côte d'Ivoire is issued by the Director of AIRP after CNESVS favorable opinion. This authorization is required at all sites where the research activity will take place. AIRP is also responsible for site monitoring and inspection. Any amendment to a clinical trial protocol is submitted to CNESVS for review and then forwarded to AIRP for approval.

### 4.4 Obligations of the sponsor and penalties incurred in case of breaches

During the implementation of clinical trials, the sponsor must ensure compliance with applicable good practices and report any adverse events or incidents. Article 50 of Law No. 2017-541 of August 3, 2017, provides for penalties in the event of false or misleading statements regarding clinical trial applications. The penalties consist of imprisonment of two to ten months and/or a fine of 50,000,000 to 500,000,000 of West African Financial Community (CFA) francs for a natural person and a fine of 1,000,000,000 CFA francs for a legal person.

## 5. Clinical Trial Practice in Cote D'Ivoire

### 5.1 Work of the National Ethics and Research Committee (NEC) from 2015 to 2018

Among the 197 research projects reviewed by the NEC from 2015 to 2018, clinical trials represented 20 files, or 10.15% of the projects. Among the 20 files concerning clinical trials of medicinal products, three were at the review stage by the NEC following an unfavorable opinion, bringing the actual number of clinical trial files to 17.

#### 5.1.1 Clinical trial protocols reviewed by the ethics committee

Analysis of the NEC 's work reveals a decrease over time in the number of clinical trial applications, with 7 applications in 2015 and 2016, 4 applications in 2017, and 2 applications analyzed in 2018. Following the ethics committee's work on clinical trials, a "conditional approval" was issued for 12 applications, representing 60% of the clinical trial authorization requests. 4 applications (20%) received a favorable opinion, and 4 applications (20%) received an unfavorable opinion.

#### 5.1.2 Therapeutic classes subject to application for clinical trial authorization

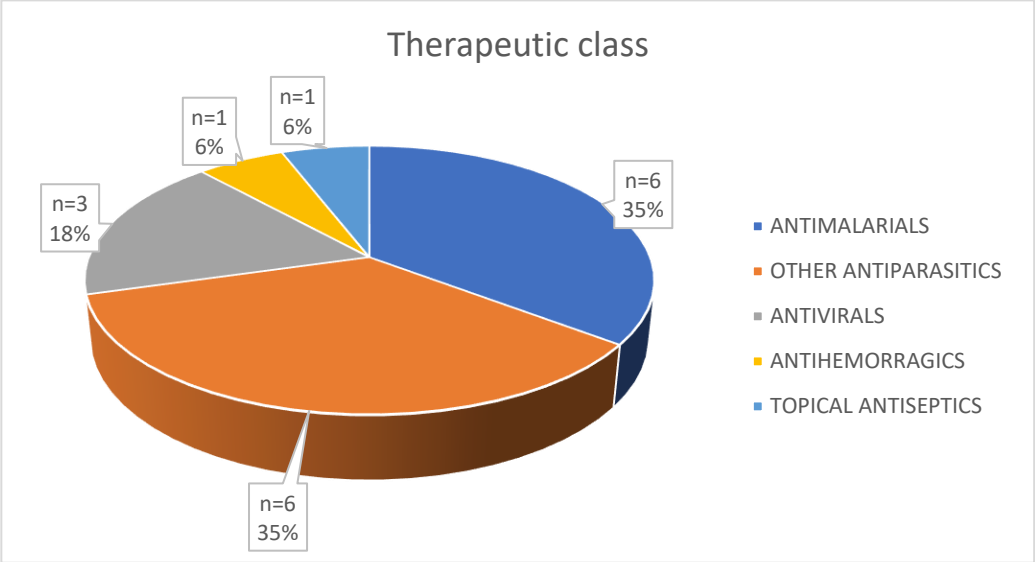


**Figure 1.** Molecules classes distribution therapeutic submitted for clinical trial authorization

Among the 17 clinical trial projects submitted to the NEC for review between 2015 and 2018, 65% (n=11) concerned antiparasitic drugs. Antimalarial drugs were the most common, representing 6 clinical trial projects, or 35% of all clinical trial projects submitted to the NEC for review.

### 5.2 National Pharmaceutical Regulatory Authority Work from 2017 to June 2025

#### 5.2.1 Directorate of Pharmacy Medicines and Laboratories (DPML) response to clinical trial authorization requests from 2017 to 2019

During the period from 2017 to 2018, the DPML, then known as the National Pharmaceutical Regulatory Authority (NPRA), reviewed eight applications for clinical trial authorization that had received a favorable opinion from the ethics committee. Of the eight applications reviewed, seven received NPRA approval (87.5%), while one application was deferred (12.5%). In 2019, eight clinical trials were approved by the DPML.

#### 5.2.2 Evaluation of Clinical Trial Authorization Applications by AIRP from 2020 to 2024

During the period from 2020 to 2022, AIRP, which is now the new NPRA, after receiving a favorable opinion from the CNESVS, evaluated 12 initial clinical trial authorization applications, which were subsequently authorized. It also authorized 10 clinical trial amendments, including 3 substantial modifications. From 2023 to 2024, 10 clinical trials were registered with AIRP.

**Table 4.** Clinical trial authorization applications evaluated by AIRP

| Parameter | 2020 | 2021 | 2022 |
|---|---|---|---|
| Number of initial clinical trial applications | 5 on products used in the context of COVID | 5 | 1 + 1 of 2021 evaluated in 2022 |
| Number of authorized clinical trials | 5 | 3 | 4 including 2 from initial applications in 2021 |
| Authorized clinical trial amendments | 0 | 8, including 3 substantial modifications | 2 |

### 5.2.3 Review of the NPRA's Clinical Trial Regulation Function

From 2017 to June 2025, the NPRA of Côte d'Ivoire registered 41 clinical trials, of which Phase III and Phase II trials represented 46.34% (n=19) and 31.71% (n=13), respectively. The tested molecules were intended to treat malaria in 19.52% of cases (n=8) and COVID-19 in 14.63% of cases (n=6). Overall, antiparasitic drugs represented 53.66% of the molecules (n=22).

## 6. Clinical Trials Legislative and Regulatory Aspects

### 6.1 Clinical trial regulations gradual implementation in Côte d'Ivoire

In Côte d'Ivoire, the need to regulate clinical trials was addressed as early as 1987 with the signing of Ministerial Decree No. 317/SP/DSPH of July 14, 1987. (8) This decree established prior authorization for conducting clinical trials, issued by the Minister of Health through the Director of Pharmaceutical Services, which later became the Directorate of Pharmacy and Medicines, and then the Directorate of Pharmacy, Medicines, and Laboratories. In 2001, the Presidential decree organizing the Ministry of Health, (9) created the National Ethics and Research Committee (NEC), tasked with providing advisory opinions on applications for clinical trial authorization, while designating the National Pharmaceutical Regulatory Authority, namely the Directorate of Pharmacy, Medicines, and Laboratories (DPML), as the authority responsible for managing clinical trials.

Thus, the DPML, like the structures that preceded it, evaluated applications for authorization of clinical trials but had few resources to ensure adequate control of trials conducted in the territory. (10)

### 6.2 Consideration of the need to adapt national regulations on clinical trials

### 6.2.1 Changes in the bodies responsible for clinical trials

The year 2017 was marked by a change in the organization of the pharmaceutical sector in Côte d'Ivoire with the creation of the Ivorian Pharmaceutical Regulatory Authority (AIRP). (11) The AIRP 's autonomy, unlike that of the former DPML, is conducive to adequate oversight in the granting of authorizations and the conduct of clinical trials in Côte d'Ivoire. Furthermore, the operation of the National Ethics and Research Committee (NEC) was modified by Ministerial Decree No. 871 MSHP of May 17, 2018, (12) which transformed it into the National Ethics Committee for Life Sciences and Health (CNESVS) to emphasize its role in public health. In the context of clinical trials, it is responsible for issuing opinions on applications for clinical trials undertaken in Côte d'Ivoire.

The same applies in France, where the sponsor of a clinical trial must obtain a favorable opinion from the Ethics Committee as well as authorization from the National Agency for the Safety of Medicines and Health Products (ANSM) in order to begin clinical trials. (13)

### 6.2.2 The advent of new national regulations for clinical trials

In 2020, more than 30 years after the first legislation specifically addressing clinical trials was drafted, Côte d'Ivoire adopted a Presidential Decree regulating clinical trials. (14) This new Decree, unlike the 1987 Order, extends to phase IV clinical trials and also applies to bioequivalence studies required for marketing authorization applications for generic drugs. It ensures better protection for participants by making free and informed consent mandatory. Trials of pediatric drugs are included, thanks to minor participation framework, which is permitted only under very restrictive conditions.

The signing of the draft Order establishing the conditions for authorizing a clinical trial in Côte d'Ivoire should strengthen regulation by introducing regulatory procedures for issuing authorizations to undertake clinical trials, which, in the meantime, are governed by guidelines developed by AIRP. (15) In France, new measures governing clinical trials were announced on May 23, 2016, by the Minister of Health following the death of a participant in the trial of the analgesic molecule BIA 10-2474 from the Portuguese laboratory Bial. (13) These measures considered the provisions of Regulation (EU) No 536/2014 on clinical trials of medicinal products for human use, which repealed Directive 2001/20/EC on this matter. (16)

### 6.2.3 Ambiguity surrounding certain responsibilities of the CNESVS regarding clinical trials

Among the missions of the CNESVS is the supervision and inspection of trials, (12) which can lead to ambiguity with Law No. 2017-541 of August 3, 2017, which, in Article 7, designates the AIRP as the authority responsible for implementing pharmaceutical inspection, especially since clinical trials constitute a pharmaceutical regulatory function. Given the primacy of Law over Ministerial Decree, it appears necessary to redefine the responsibilities of the CNESVS in order to avoid a kind of dual leadership in the practical management of clinical trials and to prevent potential conflicts between the AIRP and the CNESVS.

### 6.2.4 Consolidation of the ethics committee's opinion

The requirement for an advisory opinion has shifted to a binding opinion from the Ethics Committee before the AIRP grants authorization to undertake the clinical trial, in accordance with the provisions of Article 7 of Law No. 2017-541 of August 3, 2017, concerning AIRP. These provisions are confirmed by Article 13 of the 2018 Presidential Decree, (17) which specifies that this opinion must be favorable, making it essential for granting authorization to undertake a clinical trial.

However, a number of developing countries where clinical trials are conducted do not yet have ethics committees, or these committees are not sufficiently independent. (18)

### 6.3 Inclusion of Clinical Trials in WAEMU Community Law

Within the WAEMU region, despite the initiation of the pharmaceutical regulation harmonization process in 2005, (19) it was not until the adoption of Directive No. 06/2020/CM/WAEMU concerning the status of Pharmaceutical Regulatory Authorities (PRA), (20) that clinical trials were included among the responsibilities of

the PRA. Furthermore, Regulation No. 01/2022/CM/ WAEMU concerning pharmaceutical regulations harmonization in WAEMU member states, (21) includes clinical trials among its areas of interest. This long delay could be explained by the low rate of development of new molecules or new drugs in the West African sub-region, which impacts the number of clinical trials conducted. Furthermore, the promotion of generic drugs in West Africa has impacted the existing pharmaceutical industry, whose production has shifted primarily towards generics, with little to no investment in research and development of new therapeutic molecules. This is the case in Côte d'Ivoire, where, between 2012 and 2014, generic production accounted for over 90% of local drug manufacturing. (10) This solution is not sustainable, as the majority of generic drugs sold on the market are produced outside West Africa. Thus, pending the adoption of specific legislation on clinical trials in the WAEMU zone, the European Union has maintained its lead in this area by adopting Regulation (EC) No 536/2014 on clinical trials of medicinal products for human use, which establishes a single European portal with a database that collects all information related to clinical trials. (22) Before submitting an application for biomedical research authorization, the sponsor must obtain a registration number for the research in the European clinical trials database of medicinal products for human use called EudraCT. This European database contains all information relating to the start, conduct and completion of clinical trials. This data is confidential and is accessible only to the competent authorities of the Member States, the European Medicines Agency and the Commission. (2)

## 7. Clinical Trials Practical Aspects

### 7.1 Specific nature of clinical trial projects

The low representation of clinical trial projects involving drugs among the files analyzed by the ethics committee is explained by the committee's versatility. Its responsibilities extend to all health research projects and are not limited to the strict framework of clinical trials. Indeed, the national ethics committee uses international standards and certain general national rules to evaluate research projects planned in Côte d'Ivoire. (12) The fluctuating number of files submitted over time could be explained by the prolonged absence of a well-defined regulatory framework that considers all aspects related to conducting clinical trials, resulting in sponsors' reluctance to undertake clinical trials in an insufficiently regulated environment. The predominance of antimalarial drug clinical trial projects is explained by the high prevalence of malaria, which in 2010 ranked as the 7th leading cause of death in Côte d'Ivoire. (10) In Dakar (Senegal), the disease most targeted in clinical trials conducted from 2003 to 2007 was malaria, which accounted for 60% of the cases (n=20). (23) The fact that all clinical trial proposals submitted to the AIRP in 2020 concerned drugs for COVID-19 is explained by the particular context of that year, marked by the pandemic. In France, the opinions of the High Council for Public Health (HCSP) of March 5 and 23, 2020, served as the basis for the publication of Presidential Decree No. 2020-314 of March 25, 2020, authorizing, under certain conditions, the off-label use of several drugs while encouraging the continuation of clinical trials; (24) medicines examples are Xevudy® (sotrovimab), Ronapreve® (casirivimab / imdevimab).

Regarding the clinical trials registered with AIRP for the period from 2017 to June 2025, 46.34% (n=19) were Phase III trials, followed by 31.71% (n=13) for Phase II trials.

The same profile was observed in Dakar's university hospitals from 2003 to 2007, with 57.57% for Phase III trials and 24.25% for Phase II trials. (23)

### 7.2 Challenges in obtaining informed consent from clinical trial participants in Côte d'Ivoire

Following its deliberations, the ethics committee often issued observations to the sponsor, which explains the predominance of "conditional approvals" issued by the committee. These observations concerned several aspects, including the methods and conditions for obtaining consent.

Even though Presidential Decree No. 2020-407 of April 22, 2020, includes provisions regarding the free and informed consent of participants in clinical trials, in practice, obtaining informed consent can prove difficult due to potential misunderstandings regarding the conduct of the clinical trial, particularly concerning Improved Traditional Medicines for malaria.

A study conducted in Abidjan in 2023 showed that 18.50% of survey participants (n=63) had prior knowledge of clinical trials, but 42% of participants (n=143) did not trust clinical trials conducted in Côte d'Ivoire. (25) This situation can raise the issue of obtaining informed consent, which requires prior understanding from the participant. In France, a study revealed that 40% of patients (n=322) would refuse to participate in clinical trials proposed by their general practitioner or had no opinion, as in most cases they simply stated that they wanted to be treated primarily by going to their general practitioner.

They felt they were not sufficiently informed about the research. (26) Another difficulty relates to understanding information given to the patient to obtain their informed consent, since a clinical trial may involve participants who do not understand French. This raises the problem of translation into local dialects, with the risk that such translation may not consider all aspects related to conducting a clinical trial and may not ensure an efficient understanding of the information provided to the participant. In this context, it is difficult to verify the translation and therefore the correct understanding of the information conveyed due to the lack of recognized official translators of traditional languages. Although the participation of minors in clinical trials is limited by Presidential Decree No. 2020-407 of Côte d'Ivoire, there is currently no specific regulation on the matter.

In France, obtaining the free, informed, and explicit consent of the individual concerned is a legal obligation, the non-compliance is punishable by three years' imprisonment and a fine of €45,000. (27) The same penalties apply when biomedical research is carried out after consent has been withdrawn. (2) In addition, obtaining informed consent from patients and being over 18 years of age are among the inclusion criteria, allowing for the most homogeneous population possible for a

clinical trial. (3) For under 18 years patients, there has been specific regulation for pediatric clinical trials in France and the European Union since 2006. (28)

## 8. Conclusion

Given the Ivorian government's commitment to developing the local pharmaceutical industry and the need to protect the population, the regulation of clinical trials in Côte d'Ivoire, like that of other countries and regions worldwide, is of paramount importance. The first specific legislation governing clinical trials dates back to 1987, and this area saw little development for approximately thirty years. Therefore, the enactment of Presidential Decree No. 2020-407 of April 22, 2020, regulating clinical trials in Côte d'Ivoire, is a welcome development, in addition to the restructuring of regulatory bodies. This decree reaffirms the role of the Ivorian Pharmaceutical Regulatory Authority not only in authorizing clinical trials but also in monitoring them, while considering the mandatory opinion of the National Ethics Committee and the free and informed consent of the participants. Recent regulatory developments present an opportunity to strengthen the regulatory framework for clinical trials, addressing the challenges of developing the local pharmaceutical industry and improving access to safe, effective, and quality medicines. The draft regulation on this subject at the WAEMU level could facilitate the creation of a platform for data collection and information exchange on clinical trials in West Africa.

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## Conflict of Interest

he author declares that there is no conflict of interest regarding the publication of this article.

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