

Clinical Trials in least developed countries

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Abstract

Most of the conducted and organized clinical trials are ongoing in high income countries, but the number of organized clinical trials in countries with middle and low income is really low.

There are many reasons for this information, however in most of the cases the the sponsors and the producers of clinical trials at the end of the trail are expecting to have clean data with clear results which can be used for determination of the end result of the clinical trial. In countries with high and with middle income this is easier to be done, due to the fact that the hospitals, institutions, or organizations in which the clinical trials are conducted have better conditions so everything can be done according to the study protocols and according to the international ethical and scientific quality standards for designing, conducting recording and reporting the clinical trials. That is one of the reasons which leads the sponsors and the organizers of clinical trials to avoid countries with low income and poverty.

Key words: Clinical Trials, low income, high income, developing countries

Introduction

Almost entirely clinical trials have been organized in countries with high-income and high development. There are various of reasons for this, however in the past years the sponsors and the organizers of clinical trials are trying to include least developed countries and countries with low-income in the clinical trials. Primarily this is due to the growth in the number of trials and their increasing costs in high-income countries are combining with globalization to shift clinical trials to less wealthy countries (1). Another important reason nowadays is the conflict between the countries, like the one that is between Russia and Ukraine. This leads to lower number of patients from these two countries, and the sponsors and companies that are organizing clinical trials, make efforts to replace the number of patients who cannot be part of a clinical trial with patients

from other countries which have never been part of this industry in the past years, or the countries have only been part of not significant number of clinical trials. The fact that the number of clinical trials is increasing in least developed countries is positive because in this way the medicine that is part of the clinical trial is available for the patients from the country. Also, another beneficial fact is that knowledge for the disease can become higher in the country, and also another important fact is that the country can have some financial benefit due to this. This is also beneficial for the organizers of the clinical trials because in this way they will cut their planned costs.

Clinical trials in India, which is becoming a favored global destination for researches and clinical trials, was expected to have reached that country US\$1.5 billion of revenue by 2010. (2)

However, the possibility of growth in the number of organized clinical trials in countries with low income makes one really important question, Are the result of the clinical trial at the end be legit? The question is based on a possibility that can influence the organization and conduction of the clinical trial. It is said that the recent increase in the number of clinical trials being conducted in low-income and middle-income countries is not particularly benevolent or altruistic on the part of the pharmaceutical companies. There are various other considerations. (3)

It has been presented that proximately 15–25% of clinical studies conducted in a low-income country do not go through any institutional review boards nor any ethics committee, nor have the approval of the ministry of health. (4)

One of the most important parts of the clinical trials is to collect all the safety data, because with this data it can be considered if the new medication or the new procedure is working as it is planned at the beginning of the trial. The collected data at the end is one of the most important parts of the trial that is bringing the result of the trial. (5)

Materials and Methods

The number of all the organized clinical trials involving Achondroplasia is collected from <https://clinicaltrials.gov/> it is the biggest and the most reliable source for information for clinical trials. On this web page, privately and publicly funded clinical studies conducted all around the world are reported. (6) Additionally, a list available on the web page of the United Nations with least developed countries was used. Overall, there are 4 world regions in which there are countries in poverty. For reference we will take up to one country from region. From the region of Africa, Angola will be taken, from Asia, Afghanistan will be used, from Caribbean region Haiti will be used, and from the Pacific region, Kiribati will be used.

On [_https://clinicaltrials.gov/](https://clinicaltrials.gov/) the filter for location will be used and the four countries will be selected. After making the selection of the countries, we will get the exact number of reported organized clinical trials in these countries, also there will be information what was the main indication for the reported clinical trial and in which year it was organized.

Result & discussion

According to the available data on <https://clinicaltrials.gov/> in Angola reported and organized are 10 clinical trials, the first one was organized in 2001, and the last one is from 2024. 9 of the reported clinical trials are from interventional type, and 1 is observational. From all the 10 reported clinical trials, for 5 of them main indication is Sickle Cell Disease in children, for 1 clinical trial main indication is malnutrition in children, for 1 clinical trial indication is hypertension at adult population, for 1 of the clinical trials indication is ectopic pregnancy, for 1 of the clinical trials indication is bacterial meningitis and for 1, the indication is Trypanosomiasis.

The low number of organized clinical trials was expected, however it is positive that the number of organized clinical trials is getting higher after the year of 2020, prior to it only 3 clinical trials were organized, and the rest 7 clinical trials are after the year of 2020.

The indications are also expected, in most of the clinical trials, in 6 of them the targeted indications are diseases during child ages. This is expected since it is known that in this not developed countries the conditions for raising a child are much more difficult compared to the more developed countries.

According to the available data on <https://clinicaltrials.gov/> in Afghanistan, reported and organized are 30 clinical trials, the first one was organized in 2004, and the last one was organized in 2025. From all the 30 clinical trials, 20 are from interventional type, 8 are from observational type and 2 are expanded access clinical trials, organized by the US military present in Afghanistan, these are clinical trials for patients in critical condition.

For 8 of the organized clinical trials main indication is associated with Malaria. 5 are associated with injuries on different locations of body and healing of wounds, 3 are associated with depression and mental health, 2 are associated with Pneumonia, 2 are associated with COVID 19, 2 are associated with child malnutrition, 1 is associated with high blood pressure, 1 is associated with inguinal hernia, 1 is associated with parenting, , 1 is associated with Hepatitis B, 1 is associated with Postpartum Hemorrhage, 1 is associated with diarrhea, 1 is associated with acute abdomen symptoms, and 1 is associated with Prevalence of Cervical Extension of the Thymus.

The results from Afghanistan are expected, most of the clinical trials are organized in the period prior to 2010, however it is positive that 2 from the reported clinical trials are organized in 2025, so it is giving positive signals that in future there will be more possibilities for new clinical trials. In regards with the indications, in most of the cases the indications are expected.

According to the available data on <https://clinicaltrials.gov/> in Haiti reported and organized are 77 clinical trials.

The first reported clinical trial is organized in 2001, and the last one is in 2025.

From all the reported clinical trials 57 are from the interventional type, and 20 are from the observational type.

In most of the reported clinical trial the indication is associated with HIV infection, overall, 37 clinical trials. 8 of the clinical trials are associated with Tuberculosis. 5 of the clinical trials are associated with malnutrition, 3 of the clinical trials are associated with mental health and depression, 2 of the clinical trials are associated with surgical site infections. 2 of the clinical trials are associated with iron deficiency anemia, 2 of the clinical trials are associated with Lymphatic Filariasis, 2 of the clinical trials are associated with diarrhea, 2 of the clinical trials are associated with vision problems, 1 of the clinical trials is associated with telemedicine in pediatrics patients. 1 is associated with iodine deficiency, 1 is associated with heart failure, 1 is associated with teachers' violence, 1 is associated with diabetes mellitus, 1 is associated with peritonitis, 1 is associated with Soil-transmitted Helminth Infections, 1 is associated with gynecological surgery, 1 is associated with hypertension, 1 is associated with Chikungunya Virus Infection, 1 is associated with HPV infection, 1 is associated with vitamin d deficiency, 1 is associated with wounds and injuries, and 1 of the clinical trials is associated with lymphedema. For one of the clinical trials the indication is not reported.

The number of organized clinical trials in Haiti is not low, since it is considered as country with low income, however most of the reported organized clinical trials are in the period between 2010 and 2020. There are not positive signals for new clinical trials. Regarding the indication, since it is known that the prevalence of HIV was high in this country, also the number of organized clinical trials with main indication HIV infection was expected.

According to the available data on <https://clinicaltrials.gov/> in Kiribati, reported is only 1 clinical trial from 2018, the main indication is Type 2 Diabetes, and it is from interventional type.

This is showing that in this country clinical trials are almost not organized at all, which is negative. However, the country is not that big with less than 150 000 citizens, so that is the main reason why the sponsors are not considering Kiribati as good location for conducting clinical trials.

Conclusion

The study is based on available data for reported clinical trials on <https://clinicaltrials.gov/> and from available data on the web page of the United Nations for least developed countries.

From the available data we can see that the number of the least developed countries is low. There are various of factors about this, however in most of the cases the sponsors are not considering these regions to be good for organization of their trials. In some of the trials in these regions clinical trials are organized because of the spread of the targeted indication, as it is in Haiti with HIV infection. Organizing clinical trials can be beneficial for both of the sides, the organizations and also the countries, and the researchers in the countries. Since in these countries diseases that are not that common in developed countries can be found. The countries should work more on organization of their laws, if the countries got good laws, it could attract the organizations to organize clinical trials and the countries will have financial benefit to organize their health care system, and also the patients will have the medications available.

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