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Analysis of registered cancer clinical trials in Latin America and the Caribbean, 2007–2013

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ABSTRACT

Objective. *To characterize cancer clinical trials in Latin America and the Caribbean (LAC), with a focus on registration and enrollment trends.*

Methods. *Data were collected from 1 285 active cancer clinical trials registered up until 31 May 2014 in the World Health Organization's International Clinical Trial Registry Platform (ICTRP). The trials were categorized by six characteristics of the continuum of cancer control and care: 1) control and planning, 2) prevention, 3) detection and screening, 4) diagnosis, 5) treatment, and 6) survivorship and palliative care. The search strategy protocol included the use of optimized keywords combined with the names of the 43 countries selected for a descriptive analysis.*

Results. *A total of 973 registered and 972 enrolled cancer clinical trials between January 2007 and December 2013 were identified. Trends of growth were observed for both registration and enrollment of cancer treatment clinical trials; for other types of cancer clinical trials, trends for registration and enrollment varied in direction.*

Conclusions. *Growth trends in the registration of cancer treatment clinical trials indicate incremental adherence to cancer research reporting and improvements in cancer research transparency. The higher proportion of cancer treatment trials versus other types of cancer clinical trials indicates an imbalance in cancer research in the LAC region and suggests the need for more funding and incentives for other areas of research in order to achieve a more comprehensive approach to gaining knowledge on cancer issues.*

Key words Neoplasms; clinical trial; health research policy; health research evaluation; Caribbean region; Latin America.

Cancer prevention and control is a high priority for public health research worldwide, including the countries of Latin America and the Caribbean (LAC), and is rather well defined with specialized cancer registries, research resources, networks, and dedicated institutions. However, there is no organized repository or systematic analysis of cancer clinical trials in LAC countries that provides up-to-date information to guide decisions, policies, and collaborations in the field. This limited access to cancer clinical trial information hinders efforts for research collaboration and the effective use of data for policy-making. Attempts have been made to identify related resources (1, 2), but they are not part of an integrated effort and are not regularly updated.

Providing actionable data and information on the characteristics of cancer clinical trials allows for the identification of areas that 1) need to be strengthened and 2) need additional resources (3, 4). This in turn facilitates the ability of cancer researchers to network with colleagues and access data and other resources, in order to conduct relevant, good-quality research and strengthen local and regional capacities. This analysis of cancer clinical trials in LAC countries focuses on trends in registration (calendar date on which the clinical trial was officially registered into the registry) and enrollment (anticipated or actual calendar date of first study

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participant recruitment) from 2007 to 2013. The results reveal existing elements of LAC cancer clinical trial research as well as those that are missing. Educating researchers about clinical trial characteristics, such as exposing these gaps and trends in cancer clinical trials, could lead to more balanced cancer research agendas and thus a more well-rounded knowledge base.

MATERIALS AND METHODS

The research team reviewed cancer clinical trials registered in the World Health Organization (WHO) International Clinical Trial Registry Platform (ICTRP) (5). This platform is a meta-register fed by information from 16 certified data providers that update their contributions regularly (at least every four weeks), generating an internationally agreed-upon dataset that provides information on 20 variables related to the design, conduct, and administration of cancer clinical trials (6, 7). A search strategy protocol for the ICTRP database was developed and included optimized keywords and the names of the 43 countries selected for the analysis (Supplementary Material Annex 1).

The inclusion criteria for the clinical trials were as follows: 1) "identified by searching the ICTRP using the keywords"; 2) "registration form completed in English"; 3) "recruited adult and/or children participants from any of the 43 LAC countries selected for the study"; 4) "date of registration (calendar date on which the clinical trial was officially registered) or date of first enrollment (anticipated or actual calendar date of first study participant recruitment) between 1 January 2007 and 31 December 2013"; 5) "could be categorized under any of the six characteristics (control and planning, prevention, detection and screening, diagnosis, treatment, and survivorship and palliative care) of the continuum of cancer control and care (8, 9) selected for study"; and 6) "designed as a controlled study, as defined by WHO's ICTRP (i.e., 'for the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes')" (5). The exclusion criteria were as follows: 1) "duplicate study (as identified by the system, intervention, comparator, participating sites, and/or outcomes)" and 2) "main focus is not directly related to cancer and/or does not fall into any of the six characteristic areas of the continuum of cancer control and care selected for the study."

The categorization of the ICTRP search output into the six selected areas of research on cancer control and care was evaluated independently by two researchers (BL and PRF). In cases where the categorization was not unanimous, a third researcher (LGC) assisted in determining inclusion or exclusion. In addition, inter-rater agreement was measured to ensure the reproducibility and accuracy of data categorization. Concordance between the independent reviewers was rated as "good," based on a Cohen's kappa coefficient value of 0.797 (10).

Data analysis focused on registration and enrollment trends of active LAC cancer clinical trials. Terminated clinical trials that were registered in ICTRP and had enrolled participants within the window of analysis were initially omitted from the analysis but later re-added in order to report registration and enrollment trends more accurately. An additional descriptive analysis of terminated clinical trials was conducted to examine reported reasons for termination (Supplementary Material Annex 2).

Registration and enrollment trends were analyzed using the interactive Motion Chart application from Google (Google Visualization API, Mountain View, California, United States), an online tool that allows users to input data and create animated statistics for interactive visualization (11).

RESULTS

A total of 1 285 cancer clinical trials were identified using the ICTRP and categorized into the six characteristics of cancer control and care. After applying selection criteria, 973 and 972 clinical trials were analyzed for trends in registration and enrollment, respectively (Figure 1). Examples of the types of study topics identified in the ICTRP search, listed by each of the six selected categories, are as follows: 1) control and planning: cancer biology, cancer bio banking, intervention strategies and programs, management and evaluation, and registries; 2) prevention: lifestyle (behavior, diet, and exercise), vaccines, and cancer risk factors; 3) detection and screening: biomarker, genetic, Papanicolaou (Pap) test, prostatic acid phosphatase (PAP) and prostate specific antigen (PSA) tests, mammography, and colonoscopy; 4) diagnosis: confirmatory tests and methods, and medical and/or invasive procedures (CT scans, biopsies); 5) treatment: drug therapy, chemotherapy, drug pharmokinetics, efficiency and/or effectiveness, and neoadjuvant and adjuvant therapy; and 6) survivorship and palliative care: quality of life, coping mechanisms, treatment of adverse effects (fatigue, pain), and chemotherapy induced vomiting and/or diarrhea.

Registration trends

Registration trends were analyzed using 973 characterized clinical trials. Absolute values and proportions of registered trials that fell into each of the six categories are summarized in Table 1, with a supplemental representation of the total number of clinical trials registered by year over the observed period of analysis (Figure 2).

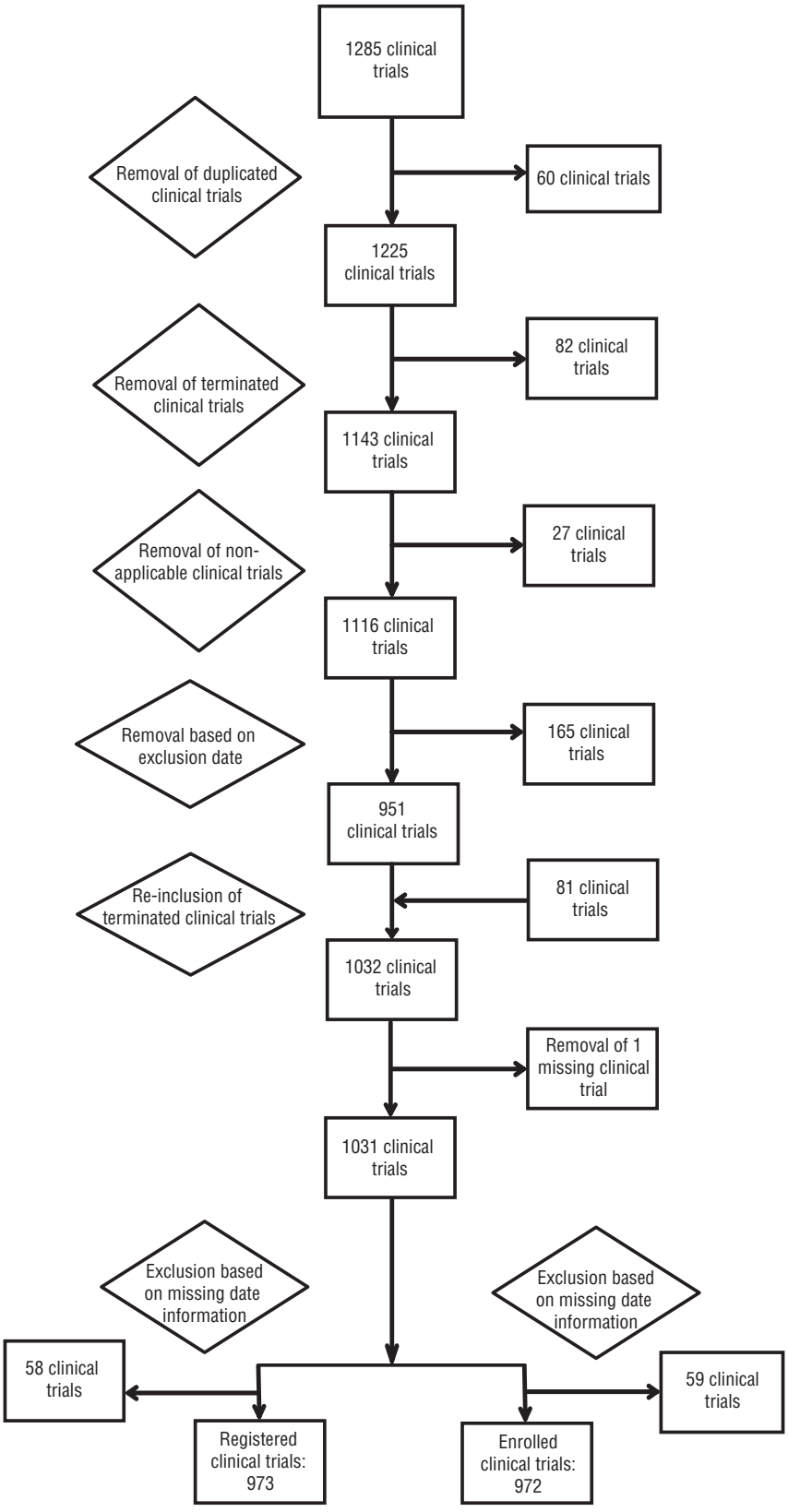
There was a considerable increase in the total number of registered treatment trials over the study period (from 22 registered clinical trials in 2003 to 78 by the end of 2013), with a peak registration of 83 clinical trials in 2011. This nearly fourfold increase included a sustained registration of at least 62 clinical trials each year since 2006. For survivorship and palliative care trials, the number of registered trials rose from three (in 2004) to 24 (by the end of 2013), with a peak registration of 26 clinical trials in 2012. Growth was not as impressive or sustained for other categories, as shown in Figure 2. There were no registered trials for the cancer detection and screening or cancer diagnosis categories for several years of the study period.

Enrollment trends

Enrollment trends were analyzed using 972 characterized clinical trials. Absolute values and proportions of enrolled trials that fell into each of the six categories are summarized in Table 2, with a supplemental representation of the number of clinical trials enrolled by year over the observed period of analysis shown in Figure 3.

For the treatment category, the research team observed sustained growth in trial enrollment (from two clinical trials in 1995 to 76 in 2013). Trial enrollment was sustained at above 69 clinical trials per year beginning in 2006. In the remaining

FIGURE 1. Flowchart diagram of cancer clinical trials in Latin America and the Caribbean registered in the World Health Organization's International Clinical Trial Registry Platform (ICTRP), 1999–2013



Source: prepared by the authors based on the study results.

categories, there was an observed maximum of six enrolled clinical trials per year (as in the detection and screening category), with observed growth trends that had either slow increases or no observed growth (as in the diagnosis category).

Additional information on the dynamics of these registration[2] and enrollment[3] trends for all six categories analyzed over the study period is available from interactive graphs at Google.com.

Terminated trials

Terminated clinical trials are clinical trials that were discontinued at any point during their implementation (12). A total of 82 trials from the initial data set were reported as "terminated" in the ICTRP. A total of 81 of the 82 trials were re-added to the analysis to improve the accuracy of the registration and enrollment numbers over the study period. The one trial that was not re-added had missing information in the ICTRP when the database was re-accessed. Of the 81 clinical trials re-added to the analysis, 49 (60.5%) included the principal reasons for the trial termination in their ICTRP entry, and 16 of those (32.7%) reported issues with recruitment (Supplementary Material Annex 2).

DISCUSSION

Categorization

The large majority of the cancer clinical trials registered in the ICTRP addressed the issue of treatment. While this was not surprising, given that the ICTRP is a clinical trial database, the research team was expecting to find a more balanced representation of survivorship and palliative care studies. This finding was one of the most important gaps in cancer clinical trial research in LAC countries identified in the study.

Trends

With its launch in 2007, the ICTRP database met its goal of providing "a network of international clinical trials registers to ensure a single point of access and the unambiguous identification of trials with a

[2] https://docs.google.com/spreadsheets/d/1VYQXPrdH6ZP5vZ4VIpyP8qZdEeaNWj2NLv0lzZoc7SU/pubhtml?gid=1774624104&single=true

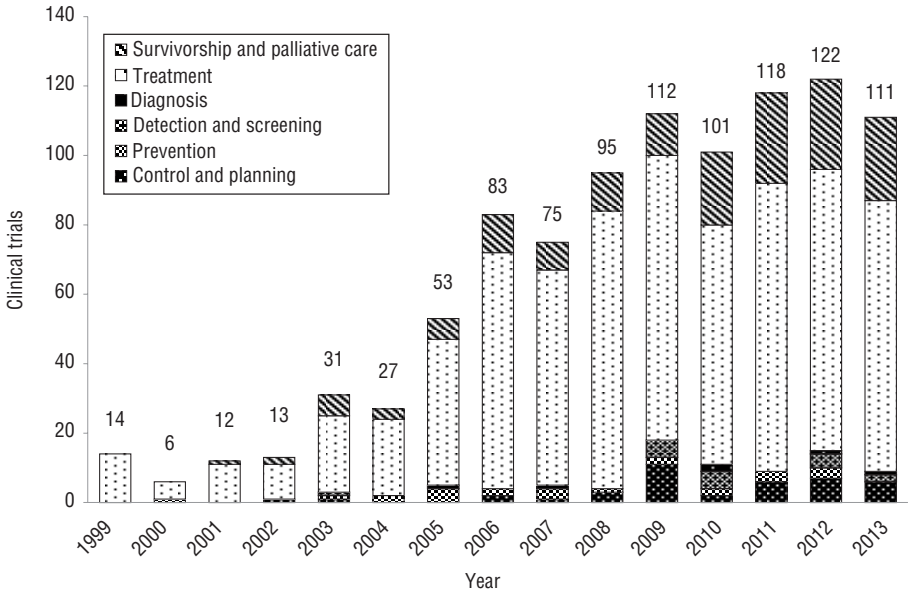
[3] https://docs.google.com/spreadsheets/d/1VYQXPrdH6ZP5vZ4VIpyP8qZdEeaNWj2NLv0lzZoc7SU/pubhtml?gid=986815410&single=true

TABLE 1. Distribution of clinical trials registered in the World Health Organization's International Clinical Trial Registry Platform (ICTRP), categorized by type of cancer research, Latin America and the Caribbean, 1999–2013

Type of cancer research	No.	%
Control and planning	40	4
Prevention	24	3
Detection and screening	17	2
Diagnosis	6	1
Treatment	729	75
Survivorship and palliative care	157	16
Total	973	100

Source: prepared by the authors based on the study results.

FIGURE 2. Distribution of cancer clinical trials in Latin America and the Caribbean by year of registration in the World Health Organization's International Clinical Trial Registry Platform (ICTRP), 1999–2013



Source: prepared by the authors based on the study results.

TABLE 2. Distribution of clinical trials enrolled in the World Health Organization's International Clinical Trial Registry Platform (ICTRP), categorized by type of cancer research, Latin America and the Caribbean, 1993–2013

Type of cancer research	No.	%
Control and planning	41	4
Prevention	24	3
Detection and screening	17	2
Diagnosis	6	1
Treatment	725	75
Survivorship and palliative care	159	16
Total	972	100

Source: prepared by the authors based on the study results.

view to enhancing access to information by patients, families, patient groups and others" (13). As clinical trials were conducted long before 2007, the increases seen in the registration and enrollment for some cancer research categories in the first few years after the ICTRP's launch could be the result of back registration.[4] An analysis of clinical trials registered a few years after the initial launch of ICTRP in 2007 might show smoother and steadier trends in registration and enrollment. Hence, the decreased registration and enrollment observed in this study for 2010 may be explained by this decrease in back registration after the first three years of ICTRP operations. These concerns can be prevented in future reviews by looking only at prospective clinical trials.

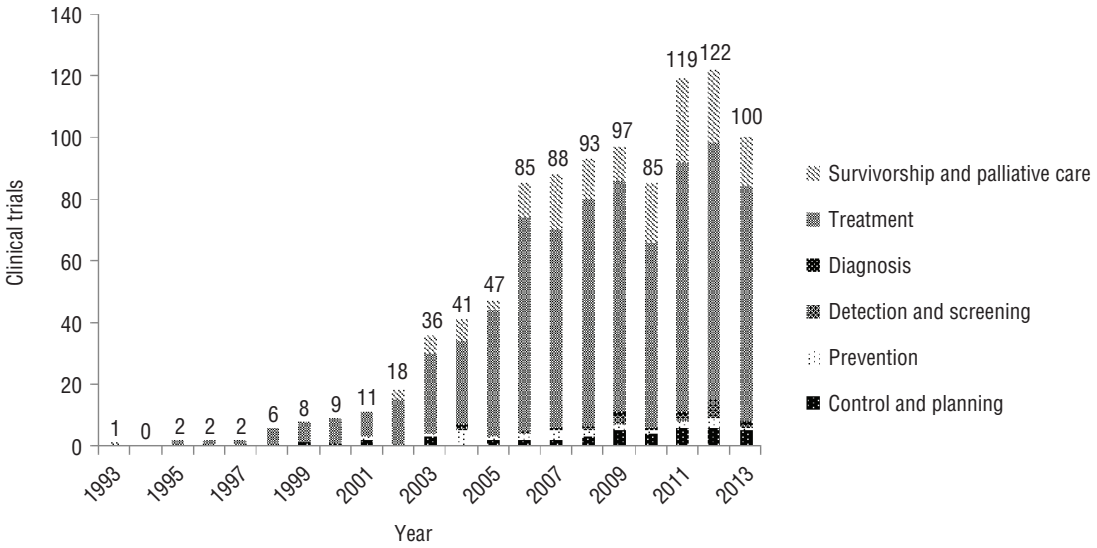
The fluctuations in registration and enrollment observed in the analysis might also be at least partly attributable to various initiatives and interventions occurring during the study period that may have, at some points, increased awareness of clinical trial registration and/or the ICTRP database, and/or affected the development of clinical trials, such as the moratorium Costa Rica's constitutional court placed in 2010 and lifted in 2014 (14).

Transparency

Transparency of reporting for terminated cancer clinical trials was observed to be no more than satisfactory. In addition to the observed number of terminated clinical trials that did not provide reasons for termination (32 or 39.5%), several studies provided vague reasons for termination, including overly simplified explanations such as "toxicity," "business issues," "corporate reasons," "safety issues," "side effects," and "regulatory requirements." The study observations reported here imply a need for 1) standardization in the nomenclature and in categorization; 2) facilitation and promotion of adherence to guidelines for reporting key variables outlined in WHO's list of 20 clinical trial registration criteria (6), and 3) use of additional standardized reporting guidelines, such as those collated by the EQUATOR Network (15–17). For example, Harm Reporting guidelines can be used to steer a shift toward increased transparency in terminated clinical trial reporting by following recommended guidelines and adhering to various provisions; providing 1) definitions for each side effect and the corresponding absolute risk and reoccurrence statistics for each adverse event, 2) conditions for and explanations of how termination was decided, including harm monitoring and analysis methodology, and 3) descriptions for all participants who withdrew from the clinical trial due

[4] Although the registration and enrollment trends reported in this study correspond to the specific window of analysis (1 January 2007–31 December 2013) for all clinical trials (active and terminated), when the ICTRP was launched in 2007, back registration allowed researchers to report active trials begun prior to that date.

FIGURE 3. Distribution of cancer clinical trials in Latin American and the Caribbean by year of enrollment in the World Health Organization's International Clinical Trial Registry Platform (ICTRP), 1993–2013



Source: prepared by the authors based on the study results.

to harms acquired during the study are specific recommendations for components that should be required for terminated clinical trial reporting (18–20). Overall, the lack of detail in terminated clinical trial reporting observed in this analysis indicates the need for researchers and their funders to be more transparent and to improve standards for reporting more detailed information about their clinical trials.

Implications

The increases in cancer clinical trial registration and enrollment observed in this analysis indicate overall growth in the number of cancer clinical trial studies. This could be caused in part by increased adherence to good research practice and ethical requirements and/or an increase in clinical trials conducted in the LAC region. Increased registration also brings transparency into clinical trials research and shows that the WHO-sponsored ICTRP is serving its purpose of increasing research transparency and contributing to the implementation of initiatives and policies, including the WHO Strategy on Research for Health and the Pan American Health Organization (PAHO) Policy on Research for Health (21, 22). The analysis also revealed the predominance of cancer treatment clinical trials, exposing the need to strengthen other areas of focus within this research field.

This analysis complements the Global Oncology Inc./NCI Global Cancer Project Map, an interactive online database of cancer research projects that 1) allows users to search for cancer research and initiate contact with principal investigators (23) and 2) supports the momentum of research and initiatives such as the Lancet five-report series on research (http://www.thelancet.com/series/research), the EQUATOR Network (http://www.equator-network.org/), the REWARD-EQUATOR Conference (http://researchwaste.net/research-wasteequator-conference), and +AllTrials (http://www.alltrials.net/), which all call for increasing the value of research by adopting and expanding recommendations, addressing research gaps, and reducing waste (24, 25).

Overall, this study identified progress in the development of a multifaceted research information map, where data are organized by the components of national health research systems described in the Healthy People Framework (26). Once fully established, this publically available research tool (which is designed to eventually include data on non-cancer clinical trials) should not only advance PAHO's Policy on Research for Health and other policies relevant to cancer research but also strengthen cancer research overall to improve people's health (3, 4, 21, 22, 27).

Conclusions

Growth trends in cancer clinical trial registration and enrollment observed in this analysis reveal overall increases in the number of cancer clinical trial studies, indicating increasing adherence to cancer research reporting and improvements in cancer research transparency. The analysis also revealed the predominance of cancer treatment clinical trials, showing the need to strengthen other areas of cancer research in the LAC region. Exposing such gaps in cancer research allow researchers the opportunity to advance current approaches to gaining knowledge within the field of cancer research.

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Análisis de los ensayos clínicos sobre el cáncer registrados en América Latina y el Caribe del 2007 al 2013

RESUMEN

Objetivo. Caracterizar los ensayos clínicos sobre el cáncer realizados en América Latina y el Caribe, con especial atención en las tendencias del registro y la incorporación de pacientes.

Métodos. Se recogieron datos de 1285 ensayos clínicos activos sobre cáncer, registrados del 1° de enero del 2007 al 31 de mayo del 2014 en la Plataforma de Registros Internacionales de Ensayos Clínicos (ICTRP) de la Organización Mundial de la Salud. Los ensayos se clasificaron según seis características del espectro continuo del control y la atención del cáncer, a saber: 1) control y planificación, 2) prevención, 3) detección y tamizaje, 4) diagnóstico, 5) tratamiento y 6) supervivencia y cuidados paliativos. El protocolo de la estrategia de búsqueda incluyó la utilización de palabras clave optimizadas, asociadas con los nombres de los 43 países seleccionados para un análisis descriptivo.

Resultados. Se encontraron 973 ensayos clínicos registrados y 972 ensayos con pacientes incorporados de enero del 2007 a diciembre del 2013. Se observó una tendencia creciente en el crecimiento del registro y la incorporación de pacientes en los ensayos clínicos de tratamiento; las tendencias del registro y la incorporación en los demás tipos de ensayos clínicos sobre cáncer revelaron direcciones diversas.

Conclusiones. La tendencia creciente del registro de los ensayos clínicos de tratamiento del cáncer indica un cumplimiento progresivo de la notificación de las investigaciones sobre este tema y un adelanto en materia de transparencia. La mayor proporción de ensayos sobre tratamiento, en comparación con los otros tipos de ensayos clínicos sobre cáncer, pone de manifiesto un desequilibrio de la investigación sobre el cáncer en América Latina y el Caribe y destaca la necesidad de aumentar el financiamiento y mejorar los incentivos en otras esferas de la investigación, a fin de lograr una estrategia más integral que permita ampliar los conocimientos sobre los diferentes aspectos del cáncer.

Palabras clave Neoplasias; ensayo clínico; política de investigación en salud; Región del Caribe; América Latina.