



NEWSLETTER NO. 9

CHAGAS DISEASE CLINICAL RESEARCH PLATFORM



ANNIVERSARY EDITION: 10 YEARS OF THE CHAGAS PLATFORM AND 110 YEARS SINCE THE DISCOVERY OF CHAGAS DISEASE

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The Chagas Clinical Research Platform was created in 2009, the centennial anniversary of the discovery of the disease, to support the overcoming of Research and Development (R&D) challenges for Chagas disease. As a flexible network, the Platform focuses on tackling unmet needs of people affected by Chagas disease and facilitating diagnosis and treatment of *Trypanosoma cruzi* infection. By creating an open, innovative and collaborative environment, the Platform promotes meetings, training, standardization of protocols, regulatory matters, and the integration of ethical principles. Additionally, the Platform provides a forum for technical discussions and an exchange of information about Chagas disease, while supporting efficient use of resources by avoiding duplication of efforts.

Currently, the network gathers over 460 members from 23 endemic and nonendemic countries. Representing more than 150 institutions, these individuals come from diverse backgrounds including research, academia, government, international and national organizations, and patient associations. The increase in research and initiatives for Chagas disease provides renewed optimism and underlines the importance of open collaboration and a fluid exchange of information. To encourage cooperation among R&D initiatives, the Chagas Platform continues to facilitate clinical research, promote professional development, and strengthen institutional structures and capacities, while seeking accessible and simple treatments as well as new tools for diagnosis and follow-up.

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EDITORIAL

CHAGAS PLATFORM: A DECADE OF PROGRESS

SERGIO SOSA-ESTANI, DNDi LATIN AMERICA

The two current therapies against *Trypanosoma cruzi* – nifurtimox and benznidazole – were registered in the late 1960s and 1970s, respectively. Ever since, they have demonstrated key advantages, including the individual benefit of treating the infection and preventing morbimortality. Furthermore, they are important tools for stopping congenital transmission when women of childbearing age are treated before they get pregnant, positively impacting public health.

For several decades, national governments from endemic countries, acting through regional organizations (INCOSUR, IPA, IPCAM) and following WHO/PAHO guidelines, have concentrated their efforts on preventing the occurrence of new cases of Chagas disease, especially through vector elimination. More recently, activities related to care for infected persons were formally implemented through early diagnosis and proper treatment. While those actions have been established, acknowledged and agreed upon, they occur far too infrequently in relation to the magnitude of the affected population, which is estimated to be around 6 million people.

Moreover, in recent years, nongovernmental organizations, academic institutions, governments and supranational entities have made progress in advancing basic, preclinical, clinical and implementation research activities, seeking to optimize healthcare tools for patients. In order to

draw attention to this neglected disease and keep it on the public health agenda, there are also communication campaigns and awareness-raising actions.

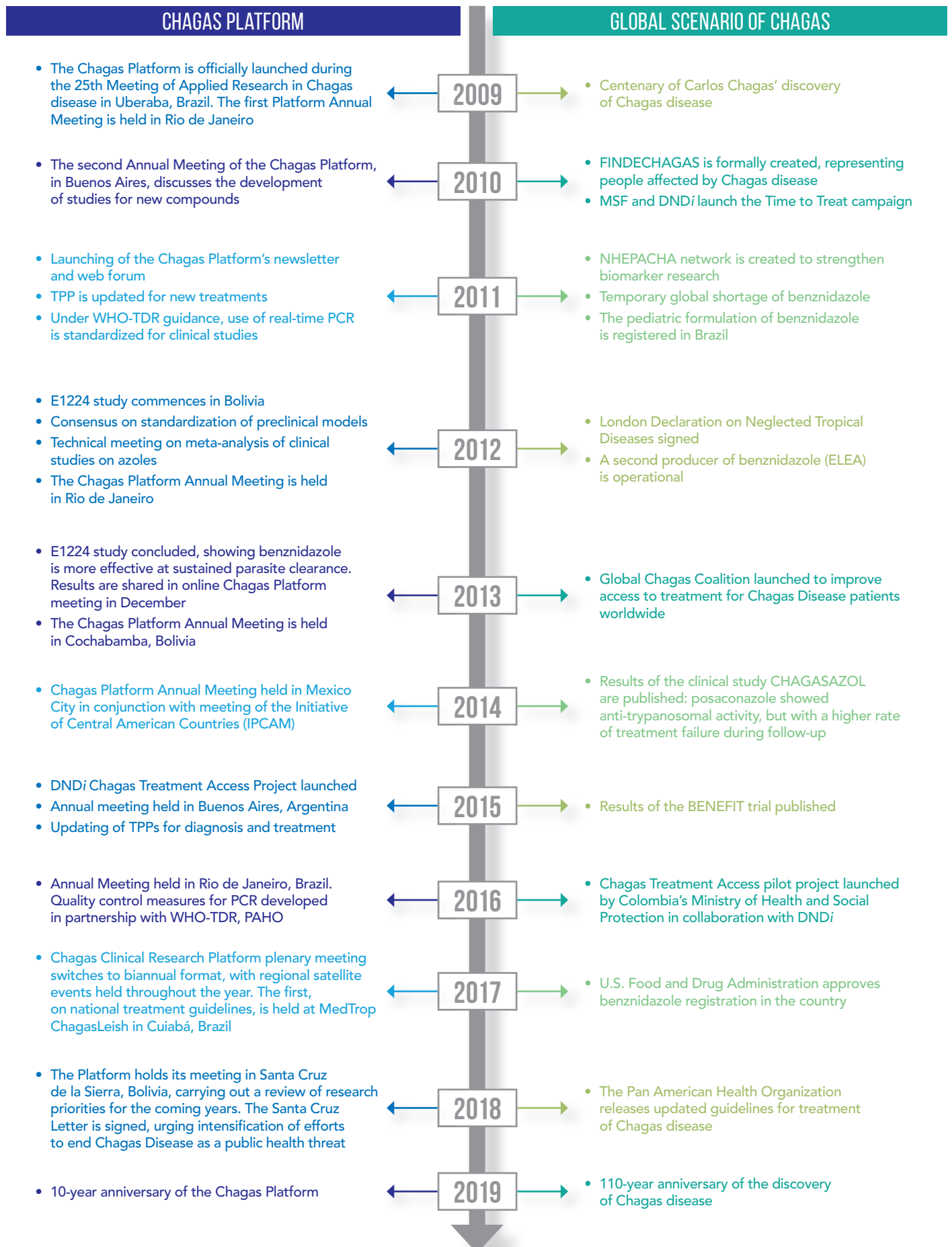
It is in this context that the Chagas Clinical Research Platform, coordinated by DNDi, is celebrating 10 years since it first opened up a space for discussion and strategic articulation in relation to research and access, advocacy, and communication with associations of people affected by the disease. Throughout these years, the Platform also played an important role in developing the rationale for new clinical trial schemes of current trypanocidal drugs, both alone and in combination, and in outlining guidelines for current clinical trial designs. In addition, the network has contributed to developing methodological laboratory definitions for measuring therapeutic response, discussing the harmonization of preclinical trial models, and integrating therapeutic strategies such as chemotherapy and immunotherapies/therapeutic vaccines, among others. It has been a forum for discussing and proposing strategies to eliminate barriers to diagnosis and treatment access using the tools currently available. It has also served as a venue for reflection and understanding among the scientific community, decision-makers in control programs, and people affected by the disease.

Throughout these 10 years of Platform activities, there has been much progress. However, we know there is still a lot to do. Our goal is that these contributions bring new hope of creating better tools to improve care for the people affected, and continue to generate new ideas that are feasible and available to the people who need them. We believe that we can continue to actively contribute to the elimination of Chagas disease as a public health problem. ◀



Participants of the 2018 Chagas Platform Meeting, held in Santa Cruz de la Sierra, Bolivia.

THE CHAGAS PLATFORM AND KEY MILESTONES FOR CHAGAS DISEASE: 2009-2019





The Santa Cruz Letter was approved by participants during the plenary session of the 2018 Chagas Platform meeting.

THE SANTA CRUZ LETTER

On November 15, 2018, members of the Chagas Clinical Research Platform and the Global Chagas Coalition, participating in the VIII Chagas Platform Meeting in Santa Cruz de la Sierra, Bolivia, signed the Santa Cruz Letter, addressed to governments, organizations and donors, requesting an intensification in the efforts to control and eliminate Chagas disease as a public health problem and demanding the following urgent measures:

1. Expand access to diagnosis and treatment of the disease within the framework of health systems.

This should include measures to reduce congenital transmission, such as systematic screening of pregnant women and babies, and improve access to diagnosis and treatment for women of reproductive age, with the active participation of affected communities. National guidelines should also ensure that diagnosis and treatment based on the most recent clinical evidence is available in primary healthcare facilities in or near affected communities, integrated into a well-defined referral system.

2. Increase investment in research and development, in alignment with the SDGs, to obtain new, safer and more effective therapeutic tools.

This includes undertaking research to optimize the current treatment; identifying and evaluating new chemical entities (NEQs) to be used in monotherapy or in combination; creating formulations adapted to newborns and children with adequate pharmacokinetic studies that allow adjusting dosage in an appropriate way; advancing new preventive or therapeutic vaccines to complement these strategies; generating better diagnostic tests; developing biomarkers to more accurately assess cure

after treatment as well as predict disease progression; and **designing and implementing a multi-country, multi-site, collaborative, long-term cohort to validate these biomarkers, and thus assist in informing and guiding research priorities.**

3. Improve the surveillance of Chagas disease by establishing compulsory reporting of chronic cases and their complications in the general population.

This will allow for the real burden and distribution of the disease to be known so that appropriate public health strategies can be structured.

4. Finally, to help reverse the silence and negligence that has marked Chagas disease since its discovery in 1909, the signing members of the Chagas Clinical Research Platform and Chagas Global Coalition support the request of **the International Federation of Associations of People Affected by Chagas Disease (FINDECHAGAS) for the official establishment of the International Day of People Affected by Chagas Disease on April 14.** On this day, every year, governments, organizations, donors, patients and all those who are involved in the fight against Chagas should join their efforts in raising awareness of the disease and commemorating those individuals and families who have suffered in silence.

The Santa Cruz Letter was approved by the 95 researchers present at the plenary meeting of the Chagas Platform, representing 12 countries, and so far it counts with the institutional support of more than 17 organizations.

You can read the full text of the Letter of Santa Cruz on: <http://bit.ly/santa-cruz-letter>.

CHAGAS DISEASE: AN END TO THE NEGLECT

JAVIER SANCHO, GLOBAL CHAGAS COALITION

The Santa Cruz Letter records the objectives and the shared dream of the Global Chagas Coalition for better access to diagnosis and treatment, as well as for more research and development of new tools. The letter is essentially a summary of the Chagas community's roadmap. The fourth item requested in the letter, regarding International Chagas Day, is closer to becoming a reality in the next World Health Assembly in 2019. Ten years after the Chagas Platform started functioning and 110 years after Dr. Chagas discovered the disease, the Santa Cruz Letter, jointly written by the Coalition and the Chagas Platform, outlines in practical terms how to continue the fight to stop neglecting the many thousands of people affected by this illness. ◀

THE RIO CHAGAS ASSOCIATION'S FIGHT AGAINST 110 YEARS OF SILENCE

NANCY DOMINGA DA COSTA AND TANIA C. ARAÚJO-JORGE
ASSOCIAÇÃO RIO CHAGAS (RIO CHAGAS ASSOCIATION)

The World Health Organization estimates the number of people infected with *Trypanosoma cruzi* worldwide to be around 6 million. Chagas disease has been around for a very long time; the parasite's DNA has been found in 9000-year-old human mummies in the Andes region. Its discovery as a pathology is far more recent; Carlos Chagas identified it in 1909. Even more recent is the organization of associations of people living with the disease around the world, which has brought new strength to the fight for diagnosis and treatment rights for the affected populations. Organized around the International Federation of Associations of People Affected by Chagas Disease – FINDECHAGAS – the associations have taken a leading role in this fight.

In Rio de Janeiro, our association has a very unique story: it was conceived in a space for monthly meetings provided by an extended learning course from the Oswaldo Cruz Institute (IOC) called "Falamos de Chagas com CienciArte", meaning "We talk about Chagas with science/art". One of the course's outcomes was the Rio Chagas Collective, which later decided to organize itself as the Rio Chagas Association, with a board of directors, fiscal and scientific boards, and business registration.

Early on, the meetings only took place on class days. Gradually, the association started to develop autonomy. Today, the association and the course feed one another in an ongoing partnership. The course offers classes on Mondays and Fridays, providing hands-on



workshops in science/art which are open to the public. In 2018, the Rio Chagas Association's actions started to stand out, showcasing its strength and its members' eagerness: 1) visits to the University Hospital at Fundão to share information about the association with other specialized services involved in the treatment of Chagas disease; 2) participation in a media campaign with Doctors Without Borders; 3) two arts and crafts courses, on porcelain and sandal customization; 4) participation in Fiocruz events such as a FioChagas program meeting, Carlos Chagas talks, and Talent Fair; 5) setting up a tent to sell arts and crafts in cultural festivities of IOC students and the Fiocruz Labor Union; 6) participation in the Brazilian Conference on Tropical Medicine in Recife and in the Science, Art and Citizens' Rights Symposium in Rio de Janeiro; and 7) participation in the FINDECHAGAS Meeting in Mexico. In 2019, Rio Chagas promoted awareness actions with vendors from the traditional northeastern fair in São Cristóvão, Rio de Janeiro.

It is beautiful to look back and see how much we have accomplished. This is a group of ordinary people, most of them elderly and with various physical limitations caused by the progression of this chronic illness, but who are beginning to realize their role as protagonists in the fight against the invisibility of Chagas disease. We are positive that this is the path to take, and we will continue firmly along it. ◀

THE LAST DECADE OF CHAGAS DISEASE RESEARCH

ISRAEL MOLINA, VALL D'HEBRON UNIVERSITY HOSPITAL

More than 100 years have passed since the discovery of Chagas disease. The first sketches Dr. Carlos Chagas drew by hand in the early 20th century have given way to hyper-realistic electronic microscope images or the colorful shapes generated by bioluminescent microscopy.

Fortunately, neglected tropical diseases or NTDs have also benefited from the latest technological advances, albeit not in an equitable way. There is no doubt that technology has brought about an exponential increase in knowledge generation, to the point that more papers have been published in the last two decades than in the 90 years prior. The impact is unquestionable, and many recent advances are helping clinicians understand one of the most challenging tropical diseases.

New drug discovery platforms have culminated in the selection of possible drug candidates, which through considerable financial and human effort were able to be assessed in clinical trials with patients. Ergosterol synthesis inhibitors deserve special attention as the first drug candidates to draw the interest of basic researchers. Even though the results were not as positive as originally thought, they have paved the

way for an interesting line of research to assess promising combinations.

Also worth mentioning are new candidates such as fexinidazole, which apart from being the first drug to reach an advanced development stage against sleeping sickness in the past 30 years, is also being studied for Chagas disease.

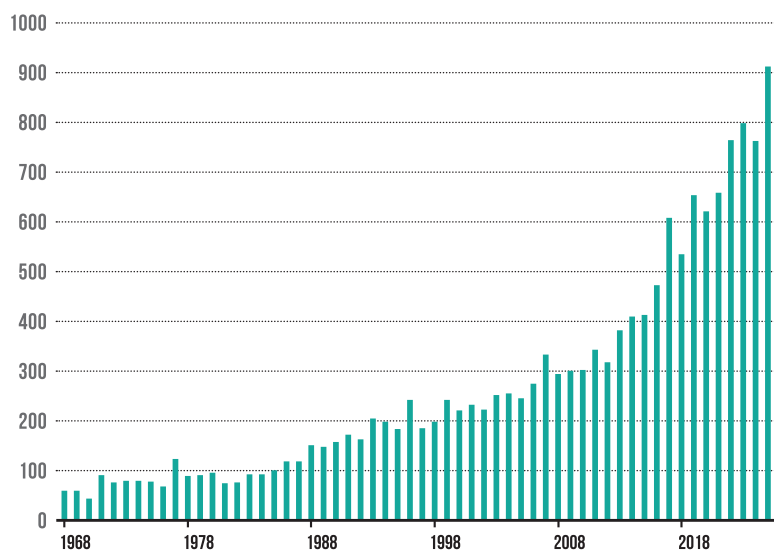
Moreover, and while we wait for new compounds currently in the preclinical phase, new therapeutic approaches are being studied, with interesting changes in the dosage and posology of old trypanocidal agents. Preclinical animal models have not proven entirely reliable when it comes to predicting the therapeutic response in subsequent clinical trials with humans. Novel image diagnostic techniques such as bioluminescence and confocal microscopy have arrived to fill this gap, or at least mitigate it

until we are able to decisively shift the paradigm with regard to evaluating the trypanocidal activity of new candidate compounds.

At the same time, implementing these new diagnostic techniques has allowed us to understand the physiopathogenesis of Chagas disease, demonstrating the existence of latent parasitic forms that force us to rethink therapeutic approaches for this infection.

In the 21st century, Chagas disease has fully entered the fourth industrial revolution, in which the most advanced technologies are put at the service of those who need them the most. Still, it is up to us to not be blinded by the glitter of new things when we still need to understand the principles of this disease, and especially when we still need to make sure all patients have access to diagnosis. We have a long and difficult road ahead, but with technology on our side, it can certainly become more manageable. ◀

ARTICLES PUBLISHED ON CHAGAS DISEASE



Source: <https://www.ncbi.nlm.nih.gov/pubmed/>

WORKSHOP DISCUSSES RESEARCH PRIORITIES TO END THE NEGLECT OF CHAGAS DISEASE

COLIN FORSYTH, DNDi

On November 14-15, 2018, the Chagas Clinical Research Platform held its plenary meeting in Santa Cruz, Bolivia, bringing together 95 participants from 12 countries to discuss priorities for Chagas disease research. On the first day, a workshop was held in which participants divided into three groups: 1) preclinical research (including drug discovery and biomarkers); 2) clinical research; and 3) implementation research. Each group discussed the main barriers, needs, and opportunities specific to their area. Key conclusions are summarized in the table below.

GROUP	KEY BARRIER	HIGH-PRIORITY ACTION
DRUG DISCOVERY	Lack of understanding of the physiopathology of Chagas disease prevents drug discovery and development from advancing with improved translation to the clinical setting.	Continue drug discovery projects in parallel with a large-scale collective effort to answer basic questions such as “What is the cure for Chagas disease?” and “What is the impact of parasite subpopulations in the field?”
BIOMARKERS	To validate biomarkers, serological cure is currently the only surrogate available, but this entails a lengthy and costly process.	Plan and assess feasibility and regulatory acceptance of performing a well-designed retrospective study within a Chagas Biomarker Consortium, learning and expanding from previous experiences such as NHEPACHA.
CLINICAL RESEARCH	Ensuring study designs account for variation (geographic and genetic) in the disease and are capable of effectively measuring the effects of drug therapy.	Create a working group to plan and begin carrying out a multicentric cohort study to confirm effects of drug therapy, validate biomarkers, and better define risk factors for clinical progression.
IMPLEMENTATION RESEARCH	Models of care are not always adapted to the contexts/needs of each country/setting.	Simplify diagnostic algorithms to increase availability of testing and reduce barriers for patients.

The groups agreed that collaborative, multicentric initiatives represent the best way to address the main research needs. Large-scale longitudinal studies can enhance understanding of biomarkers and the impact of drug therapy on clinical outcomes. All groups stressed the need for greater coordination both within and between different research areas. A comprehensive research plan, which clearly outlines benefits for affected people and other stakeholders, would improve coordination between groups and strengthen efforts to secure funding. Sustainable sources of funding and strong political commitment from governments are crucial for addressing Chagas disease’s main research needs. ◀

NEW REGIMENS FOR THE TREATMENT OF CHAGAS DISEASE: BENDITA, A RANDOMIZED TRIAL

FABIANA BARREIRA AND BETHANIA BLUM, DND, LATINA AMERICA

Chagas disease ranks amongst the world's most neglected diseases. Benznidazole (BZN), a nitro-heterocyclic drug, is the most commonly prescribed treatment. The BENDITA trial evaluated new regimens of BZN as a monotherapy and in combination with fosravuconazole, a broad-spectrum antifungal triazole. BENDITA, the acronym for Benznidazole New Doses Improved Treatment and Associations, was a double-blind, Phase II, randomized, placebo-controlled trial conducted in Bolivia between 2016 and 2018. The objective of the study was to determine the efficacy and safety of different regimens of BZN as a monotherapy or in combination with fosravuconazole E1224 in reducing and clearing *Trypanosoma cruzi* parasitemia in adults with chronic indeterminate Chagas disease.

The sites that participated in the trial were part of the

Bolivian Chagas Platform for comprehensive care of patients with Chagas disease in Cochabamba (Principal Investigator [PI]: Faustino Torrico), Tarija (PI: Lourdes Ortiz) and Sucre (PI: Wilson García). The primary efficacy endpoint was parasitological response by serial qualitative polymerase chain reaction (PCR) at end of treatment (EOT) and sustained for 6 months. Secondary efficacy analyses were done at 12 months. The study was approved by the Ethics Committee of CEADES in Bolivia, the Ethics Committee of the School of Medicine, Universidad Mayor de San Simon in Bolivia, and the Ethics Committee of the Hospital Clinic in Barcelona, Spain (ClinicalTrials.gov number, NCT03378661).

A total of 210 adult patients with chronic indeterminate Chagas disease participated in the study, randomized to one of the following six treatment regimens or to placebo: BZN 300 mg daily, given for a) 8 weeks, b) 4 weeks or c) 2 weeks; d) BZN 150 mg daily for 4 weeks; e) BZN 150 mg daily for 4 weeks in combination with E1224 300 mg weekly; f) BZN 300 mg weekly for 8 weeks in combination with E1224 300 mg weekly; and g) matching placebos. 202 patients completed the study, and demographic and baseline characteristics were comparable between treatments.

The two-week treatment arm is particularly promising – in addition to being significantly shorter than the standard treatment, no patient discontinued treatment because of adverse effects. The study had a limited sample of participants in each arm and was compared against placebo. Confirmatory studies are important to prove the efficacy over the standard BZN regimen. The adoption of a shorter regimen of BZN could potentially

impact the clinical and public health landscapes for Chagas disease, supporting the elimination of one of the barriers to expanding access to treatment for Chagas disease in the region.

Details will be published very soon. ◀



The Chagas Platform clinic in Cochabamba, one of the clinical research centers of the BENDITA study.

TRYPANOSOMA CRUZI AND HIV COINFECTION

ANDREA SILVESTRE, INI/FIOCRUZ AND UFRJ; EROS ALMEIDA, UNICAMP

In the chronic phase, when Chagas disease is usually diagnosed, *Trypanosoma cruzi* is in its latent form due to actions of the host's immune system.

The disease can be reactivated in low-immunity scenarios, with an increase in parasitemia. In advanced cases of immunosuppression, serums can become negative, and the reactivation is diagnosed through direct or histopathological parasitological testing. The clinical scenario is usually more serious than that of acute infection, frequently with meningoencephalitis or myocarditis. Hence, early diagnosis and treatment are critical to reduce the high lethality of the chronic phase. Chagas disease remains endemic in Latin America, where recent migration processes brought the disease to urban areas and globalized it to non-endemic areas. Exposure to low-immunity conditions has become more frequent, including neoplasia, autoimmune disease, transplant-related immunosuppression, and especially the risk of HIV coinfection, when *T. cruzi* can present opportunistic behavior. According to estimates by the World Health Organization (WHO), cases of *T. cruzi*-HIV coinfection have been diagnosed and published in most American and European countries, as well as in Australia and Japan.

Brazil was a pioneer when it acknowledged, in 2004, the reactivation of Chagas disease as an AIDS-defining condition. WHO/PAHO reaffirmed this fact in 2005. At the time, the diagnosis of HIV/AIDS was done late, often based on symptoms, and antiretroviral therapy (ART) was established only with a reduced CD4 (<350 cells/mm³) or with AIDS-defining conditions. The frequent reactivations manifest especially as meningoencephalitis or brain abscesses, which

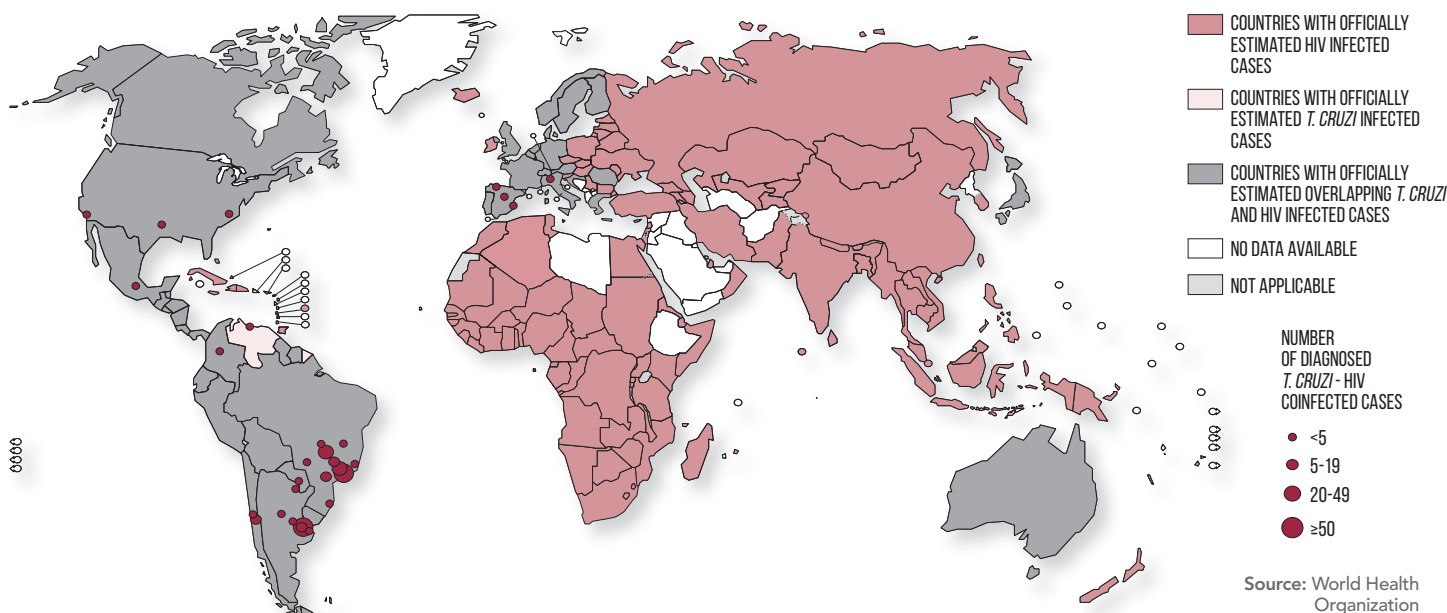
require immediate antiparasitic treatment after the diagnosis, for 60 days. Secondary prophylaxis can be provided while low-immunity conditions persist (CD4<200 cells/mm³).

Lymphocyte levels of CD4<200 cells/mm³ were identified in more than 80% of reactivation cases, and a higher viral load is also often observed. Higher parasitemia was present in 50% of the cases with a less evident association of risk. The participation of different subpopulations of *T. cruzi* in the genesis of clinical reactivation manifestations has also been discussed.

Since 2013, ART has been extended regardless of the presence of a defining illness and/or CD4 level, and since then the diagnosis of patients with seriously compromised immunity has become infrequent. In theory, this action has reduced the probability of Chagas disease reactivation in HIV-positive individuals, as long as they have been properly diagnosed. Moreover, the conditions for the superimposition of epidemiological risk for both infections might be diminishing: in Brazil, the age group with the most new cases of HIV/AIDS is 20-39 years of age, in which currently there are fewer cases of Chagas disease.

The reactivation rate for Chagas/HIV coinfection has been described as between 20-25% in studies of the pre- and post-ART period, with a lengthy follow-up time. Nevertheless, even in populations diagnosed since ART became more available and effective, and despite a shorter follow-up, the reactivation rate of 9.8-11% is still of concern. Therefore, considering the potential risk and ongoing changes in the epidemiological profile of both illnesses, we must remain vigilant about both conditions. ◀

GLOBAL DISTRIBUTION OF CASES DIAGNOSED AND PUBLISHED WITH *TRYPANOSOMA CRUZI* AND HIV COINFECTION, 2006 - 2010



Blood testing for patient evaluation in Bolivia: one of the major obstacles to the development of new drugs for the treatment of Chagas disease has been the lack of clear and timely biomarkers that correlate with the clinical treatment results.



EVALUATION OF BIOMARKERS FOR THE EARLY ASSESSMENT OF TREATMENT RESPONSE: THE NHEPACHA NETWORK EXPERIENCE

JULIO ALONSO-PADILLA AND MARIA JESUS PINAZO, IS GLOBAL, SPAIN.
M. CARMEN THOMAS, INSTITUTO DE PARASITOLOGÍA Y BIOMEDICINA LÓPEZ NEYRA, SPAIN

The absence of practical and reliable biomarkers (BMKs) for early assessment of response to treatment is still a major drawback in the clinical management of chronic Chagas disease. The use of currently available serological or molecular diagnostic tools is less than ideal, taking into account that: 1) serological reversion to a non-reactive immunological state may take decades; and 2) a negative molecular detection is not a definitive indicator of parasite clearance, as the parasite can be hidden deep in tissues so that its DNA presence is simply not picked up by the polymerase reaction from circulating blood. Besides, the complex interactions that exist between host and pathogen during the chronic phase of infection further complicate patient follow-up, which will probably require the use of several BMKs at a time.

The evaluation and validation of several combinations of BMKs has been the scope of the NHEPACHA network in the last few years. Its acronym (in Spanish) stands for “New tools for the diagnosis and evaluation of Chagas disease patients”. It is an Ibero-American network that encompasses a total of 13 groups of clinicians and researchers from 9 countries, who have agreed to share a battery of parasite antigens (to be evaluated as BMKs), patient serum samples, and clinical records in a blinded study with coded samples. As it progressed, the network evolved to include two more teams who showed keen interest in getting their sets of antigens evaluated as well. In the context of the network’s work, a retrospective study is being performed with the inclusion of 504 samples from 221 patients and 42 healthy control subjects coming from six different countries; samples that range from pre-treatment (baseline) to well over two years post-treatment. These samples were amicably shared between institutions within the framework of the collaborative nature of the network, and they were all tested against the different BMKs included in the study (KMP11- HSP70-PFR2-3973; F29; the α -galactosyl synthetic antigen KM24; and the InfYnity company set of BMKs). These tests relied on ELISA-type assays, either using colorimetric or chemiluminescent readouts. In total, as many as 21 antigens from four different laboratories were evaluated throughout the study.

At present we are about to reach a major milestone of the study, since the analysis of BMK results is now being processed by the team of statisticians at the Barcelona Institute for Global Health (ISGlobal), the institution that has coordinated the network. ◀

REMARKS ON CHAGAS DISEASE IN THE DEPARTMENT OF JUTIAPA, GUATEMALA

TESTIMONY OF **DR. ELSA BERGANZA**, FROM THE EPIDEMIOLOGY DEPARTMENT OF THE JUTIAPA HEALTH AREA

Since 2018, Guatemala has taken a leading role toward the elimination of Chagas disease, hosting the **Alliance Project for the Elimination of Chagas Disease as a Public Health Concern in Central America and Mexico**. The Drugs for Neglected Diseases initiative (DNDi), Mundo Sano Foundation, and the International Development Research Centre (IDRC, Canada) participate in the project under the leadership of the Ministry of Public Health and Social Assistance. The University of San Carlos (Guatemala) provides coordination, and other supporting organizations include the Association for Research and Social Studies, and the Guatemala offices of the Pan American Health Organization (PAHO) and the World Health Organization (WHO). From the onset, successful access models should ensure the feasibility of actions within allotted time frames. The strengthening of local capacity and healthcare services is a key pillar of the project. Therefore, in 2018, two physicians from Guatemala undertook an internship with the CEADES Foundation/Bolivian Chagas Platform to gain practical insight into clinical management of Chagas disease. **Dr. Elsa Berganza, from the Epidemiology Department of the Jutiapa Health Area**, was one of the participating health professionals and her testimony is presented below.

Guatemala is a developing country where various health issues stem from poverty, limited access to healthcare, and lack of work opportunities.

In Jutiapa, these same circumstances abound. Some health issues cannot be comprehensively addressed due to gaps and barriers in the health system. Chagas disease particularly affects the population living in poverty in rural areas of our country.

Because the impact of Chagas disease is hidden rather than glaringly or unavoidably noticeable, health policies for this disease are not a priority. Epidemiological surveillance, diagnosis, treatment and monitoring of Chagas disease in the official system are weak, and the actions that are executed do not represent a comprehensive approach. For this reason, Chagas is considered to be neglected.

Doing a practicum at the Chagas Platform in Cochabamba, Bolivia helped me realize that the disease must be addressed comprehensively, with close communication and follow-up with patients. Healthcare personnel should fully take charge of the patient's problem, which should not be treated as just another appointment without additional concern for the patient. There must be empathy between the healthcare provider and the patient, and the most important thing is that achieving good results does not require a huge investment, but rather effective use and management of the resources at hand.

One of the fruits of our experience in Bolivia was the decision to establish a clinic to care for Chagas patients in one of the municipalities in Jutiapa that is the most affected by the disease. We also

MAP OF
GUATEMALA



hope that local healthcare providers will be trained in the knowledge and skills to provide proper care for people with this disease. This way we can identify, gather, diagnose and treat patients in a timely manner, ensuring that patient follow-up is personalized, with complementary studies, and also expand vector surveillance by utilizing information reported by patients. The ultimate goal is to provide better care and ensure quality of life for patients living with this neglected disease.

Changes to some healthcare strategies for patients in Comapa, in the department of Jutiapa, are being planned by implementing a clinic as a pilot which, if successful, can become a model of care for Chagas disease for the other areas of the country where it is endemic. ◀

A PARTNERSHIP MODEL TO IMPROVE ACCESS

CAROLINA BATISTA, GLOBAL HEALTH CONSULTANT

Over six million people are infected by *T. cruzi*, the protozoan that causes Chagas disease. Treatment options are available, yet over 90% of estimated cases do not access diagnosis and treatment, despite significant progress achieved in vector control and blood safety in the last decades.

While DNDi continues its efforts to develop new treatment options, it also launched an access initiative to address these needs. An access strategy was developed in alignment with global experts and projects initiated in Colombia, the United States and Guatemala, as part of a multi-institutional approach. The goal of this initiative is not only to improve access to existing tools, but to pave the way for uptake of new tools coming out of the pipeline.

The partnership model that DNDi has successfully adopted for R&D serves as a foundation for its access initiative and ensures sustainability by acting as a catalyst for in-country stakeholders to lead the process.

This approach supports global access efforts for Chagas Disease. Strategies are developed in collaboration with the WHO, PAHO, the Chagas Coalition and others, but goals are driven by countries.

DNDi'S "4-D" ACCESS METHODOLOGY IS OUTLINED BELOW:

DIAGNOSE: The first step is to map stakeholders, epidemiological and policy data, barriers, political engagement and opportunities. Finally, local actors are engaged to generate momentum for the upcoming projects.

DESIGN: Once needs and priorities are identified, a plan is designed with national partners. This plan should be pragmatic, evidence-based, clearly outlining roles and responsibilities. It incorporates global targets adapted to local contexts. Indicators to measure impact are defined, as well as timeframes. Information, education, and communication (IEC) activities are designed.

DELIVER: The project is implemented and the IEC plan is launched. Capacity building is rolled out and data is collected. Adjustments in guidelines and policies are made, if needed. Ensuring the availability of drugs and diagnostics is required, so that efforts to scale up are not jeopardized by lack of tools.

DEMONSTRATE IMPACT: Monitoring and evaluation are key elements throughout the project. Evidence generated guides policy change and drives replication in similar contexts.

Access efforts go hand in hand with DNDi's R&D efforts for Chagas. DNDi's access initiative provides a model that facilitates the urgently needed increase in access to diagnosis and treatment. It also aims to ensure that the results of innovation successfully reach the neglected individuals who need them the most. ◀

Published by the Drugs for Neglected Diseases *initiative* (DNDi)

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DNDi

Drugs for Neglected Diseases *initiative*

Iniciativa Medicamentos para Enfermedades Olvidadas

Iniciativa Medicamentos para Doenças Negligenciadas