N° 14
September 2024

Newsletter

Chagas Disease Clinical Research Platform

Guatemala: an exemplary experience of diagnosis and treatment of Chagas disease in primary care

The Chagas Clinical Research Platform was launched to address the research gaps of this neglected disease that causes thousands of deaths each year, especially in Latin America. Like other neglected diseases, the resources available to advance research are usually limited. Therefore, a space is needed to bring together different people to collectively identify barriers and strategies and pool knowledge, experience, and resources toward common goals.

The Chagas Platform is, above all, a network of people from around the world who share a commitment to improving the lives of people with Chagas disease while ensuring that the disease itself and those affected by it remain visible to the world. Coordinated by DNDi, the Platform is a broad network that includes more than 460 members from patient associations, government representatives, health professionals, and experts in all aspects of Chagas disease, from drug discovery to diagnosis, and from clinical research to social sciences, representing more than 150 organizations from various countries.

DNDi works to ensure that the most vulnerable people have access to the products of the best science. We are in a moment of reflection on the many lessons recently learned in global health, from the unprecedented acceleration of drug development processes, increased global awareness of the role of structural racism in health outcomes, to a renewed understanding of the critical importance of international cooperation to overcome public health challenges.

Progress is being made toward better diagnostic and therapeutic options, as well as greater visibility of people with Chagas disease, but many difficult challenges remain. The Chagas Platform will continue to provide a space for interdisciplinary, international, and multi-stakeholder cooperation.

Editorial

Progress and future directions in **the fight against Chagas disease**

Stéphane Hugonnet and **María-Jesús Pinazo** (DNDi)

In this new issue of the Chagas Platform Newsletter, we reflect on the significant strides made in the fight against Chagas disease. In May, our network reunited at the Plenary Meeting in Buenos Aires, bringing together global experts, researchers, and advocates to share insights, foster collaborations, and set strategic directions for combating this disease. This gathering reinforced our commitment and showcased the strength and quality of our collective research and advocacy efforts against Chagas disease.

A crucial research need for Chagas disease is still the inclusion of children in clinical trials for new drugs. Children, their unique physiological characteristics and differing drug metabolisms require specialized research. Conducting clinical studies tailored to children is essential to ensure they receive safe and effective treatments.

Another pressing issue is the reactivation of *Trypanosoma cruzi* infection in immunosuppressed patients. This underexplored area poses substantial risks to those with compromised immune systems. Delving into the mechanisms of reactivation and devising effective treatment strategies is vital to enhance outcomes for these vulnerable patients.

Access to healthcare for Chagas disease remains a formidable challenge, underscoring the need for accurate epidemiological data. The Chagas Observatory, a collaborative endeavor by DNDi, the Chagas Coalition, the World Heart Federation and Bayer, aims to provide current and accessible data on Chagas disease. This initiative is key to improving surveillance, shaping advocacy efforts, and ultimately enhancing healthcare access.

In 2024, DNDi continues its relentless pursuit of new treatments for Chagas disease. Through robust partnerships and collaborations, we are committed to improving the quality of life for those afflicted by this neglected tropical disease. Our involvement with the Chagas Platform unites researchers, clinicians, and patient advocates in the collective battle against Chagas disease. Together, we are poised to make a tangible difference, offering hope and progress to the millions impacted by this devastating condition.

In summary, the ongoing efforts and collaborations in 2024 signify a hopeful era in the fight against Chagas disease - we are forging a path towards better health outcomes with the dedication and synergy of our partners. Our network illuminates a promising future, one where neglected diseases receive the attention and resources they urgently require.

Summary

R&D Landscape

Pediatric formulations for the treatment of Chagas disease: **Why should children be included in clinical trials of new drugs?**

Jaime Altcheh (Multidisciplinary Institute for Research in Pediatric Pathologies - IMIPP-CONICET, Ricardo Gutierrez Children's Hospital)

Children are not small adults; they present differences in drug metabolism, which also varies between newborns and older children. Therefore, indicating treatment based on studies in adults or based on anecdotal reports of cases in children (off-label use) can be risky.

Excluding them from research denies access to potentially beneficial medications, which are not indicated because they have not been tested and approved in children. Likewise, the FDA Clinical Investigation of Medicinal Products in the Pediatric Population (2000) guideline E11 proposes that children should receive products that have been evaluated in children, and therefore new drug development programs should include clinical studies in children.

The use of adult formulations requires fractionation and dilution for children. This is risky since we cannot guarantee an adequate distribution of the active ingredient in each fractionated dose, and a patient may have different doses throughout the treatment. For this reason, it is necessary to have formulations adapted for use in the pediatric population. In addition, one should consider that the majority of *T. cruzi* infections occur in childhood, whether transmitted vertically or by vectors. We must remember that an infected adult probably was an untreated child.

Pediatric formulations of benznidazole and nifurtimox are currently available and have been tested in clinical trials involving children such as CHICO - SECURE (clinicaltrials.gov #NCT02625974). In turn, PK/PD studies have shown that lower blood drug levels were observed in children, but were safe and effective for the treatment of Chagas disease[1]. This prompted the development of clinical trials in adults using lower doses of these drugs changing the paradigm in adult Chagas disease care: BENDITA (clinicaltrials.gov #NCT03378661) and MULTIBENZ (clinicaltrials.gov #NCT03191162).

In order to guide the development of new pediatric formulations, a meeting was held in the city of Salvador (Brazil) under the coordination of DNDi with the main pediatric Chagas experts from Argentina and Bolivia to draft a TPP (Target Product Profile) of pediatric formulations for the population aged 0 to 18 years.

The TPP states the need to include children in the trials of new drugs and that the production of these drugs must be guaranteed for adequate availability in Latin American countries. The TPP is in the approval rounds and will be published shortly.

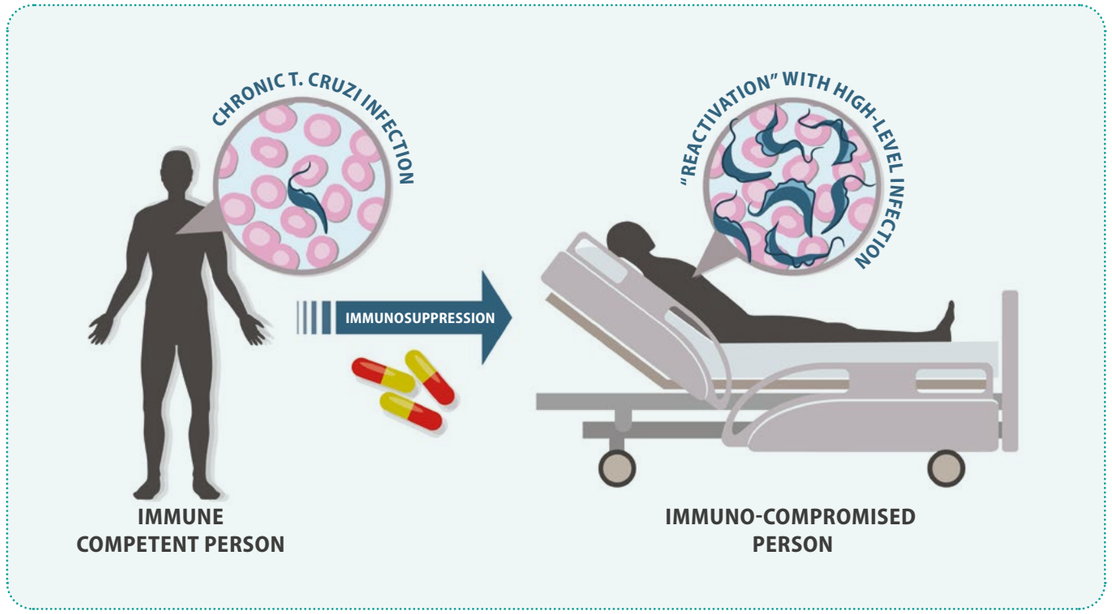
1 - Altcheh et al., 2014. PLoS Negl. Trop. Dis. 8:e2907. doi: 10.1371/journal.pntd.0002907

Reactivation of *Trypanosoma cruzi* infection in immunosuppressed patients: an understudied problem

Frederick S. Buckner (University of Washington)

The *Trypanosoma cruzi* parasite causes a smoldering infection that persists for the lifetime of the host. A quarter of chronically infected individuals will develop symptomatic damage to the heart or gut (Chagas disease), but most people never know they have the infection. This standoff between parasite and host can be upended if the host's immune system becomes compromised. The quiescent infection can quickly rage out of control with life-threatening consequences. "Reactivation" of *T. cruzi* is commonly seen in patients co-infected with HIV or in patients receiving immunosuppressive therapy for cancer, autoimmune disorders, or solid organ transplantation (SOT). Patients with reactivation can experience aggressive myocarditis and sometimes invasion of the brain. If not quickly diagnosed and treated, the unchecked infection has a high mortality rate.

The number of immunosuppressed patients in the general population is growing rapidly, so clinicians need to be aware of the risk of *T. cruzi* reactivation. In addition to reactivation, *de novo* infections can occur in immunosuppressed patients from various modes of exposure. Many questions need to be answered, such as what forms of immunosuppression create the highest risk of reactivation, how can patients be monitored for an early diagnosis, should antiparasitic treatment (with all its side effects and limitations) be given prophylactically or after reactivation, what is the best dose and duration of treatment, and many more. Experts in the field have created clinical guidelines to help physicians manage transplant patients, but the guidelines are mostly based on retrospective experience and opinion (see references). Ideally, the questions should be addressed using prospective clinical trials.



Artwork by Z. M. Herbst

Where are the best opportunities to find patients with immunosuppression to research these questions? Centers that perform solid organ transplants on patients with chronic *T. cruzi* infection immediately come to mind. SOT patients receive strong immunosuppression to block transplant organ rejection. A study published in 2018 reported the *T. cruzi* reactivation rate was 61% following orthotopic heart transplant. Patients followed in clinics specializing in oncology, rheumatology, or HIV/AIDS represent other potential cohorts for research. Some likely advantages to studying SOT patients are: 1) *T. cruzi* infections can be diagnosed before immunosuppression is started, 2) the type and degree of immunosuppressive therapy are usually well "protocolized", and 3) the patients are deeply embedded in the medical system, thus facilitating close monitoring and prompt treatment. Of course, studies would need to be done at centers that handle significant numbers of patients with chronic *T. cruzi* infection, suggesting the involvement of busy centers in Latin America (and possibly some centers in North America with high volumes of Latin immigrants). On May 9, 2024, DNDi supported a workshop at the Chagas Platform in Buenos Aires to bring together interested clinician-investigators to consider the best approaches to study the topic. The Chagas community will greatly benefit from the research to better manage immunosuppressed patients with *T. cruzi* infection.

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R&D Landscape

Towards a tool for early prediction of parasitological cure in adult Chagas patients

Ursula Saade (InfYnity Biomarkers, Swiss Tropical and Public Health Institute and University of Basel), **Jasper de Boer** (KU Leuven), **Ivan Scandale** (DNDi), **Jaime Altcheh** (National Scientific and Technical Research Council - CONICET, Ricardo Gutierrez Children's Hospital), **Hans Pottel** (KULAK), **Maan Zrein** (InfYnity Biomarkers) and **Eric Chatelain** (DNDi).

One of the major issues in the development of new drugs for Chagas disease is the lack of reliable tools and adequate markers of treatment efficacy to assess parasitological cure in a timely manner. This hampers the assessment of drug efficacy and the development of more effective drugs.

So far, seroreversion following treatment, i.e., absence of antibodies/IgG against the parasite, is the only marker of parasitological cure (*T. cruzi* parasite clearance) in chronic Chagas disease accepted by health authorities. Serology clearly has value for monitoring parasitological cure, as waning antibodies is associated with parasite clearance.

However, following infection with *T. cruzi*, whether post-treatment or due to spontaneous parasitological resolution, it may require years to decades for antibodies to completely diminish from the bloodstream in adults. Consequently, conventional ELISA tests currently in use are inadequate for confirming parasite clearance. Additionally, clinical trials adhere to standard drug development timelines, which cannot extend over decades. There is an immediate requirement for serology tests capable of promptly evaluating drug efficacy.

MultiCruzi is a multiplex *in vitro* Enzyme-Linked Immunosorbent Assay (ELISA) test composed of 15 different *Trypanosoma cruzi* antigens with three derived from discrete typing unit (DTU) specific antigens, from the TcI, TcII, and TcVI protein regions of the *T.cruzi* DTU, all printed in duplicate in each well of 96-well microtiter plates (Figure 1).

This test has demonstrated efficacy in confirming the presence of Chagas disease and forecasting parasitological recovery in infants and children with acute or early chronic Chagas disease, surpassing the capabilities of traditional serology tests. This technique has been recently adapted to measure the gradual decrease in antibodies over time in adults, making it the first test capable of predicting cure in this category of patients. This quantitative aspect facilitates the anticipation of future seroreversion, serving as an indicator for the parasite clearance.

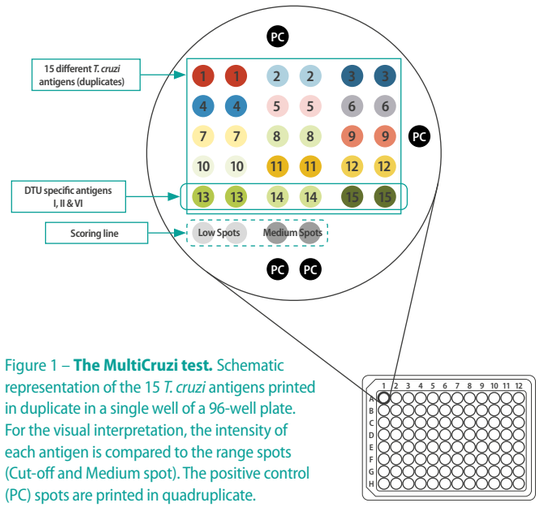


Figure 1 – **The MultiCruzi test.** Schematic representation of the 15 *T. cruzi* antigens printed in duplicate in a single well of a 96-well plate. For the visual interpretation, the intensity of each antigen is compared to the range spots (Cut-off and Medium spot). The positive control (PC) spots are printed in quadruplicate.

By carefully monitoring the dynamic of selected specific antibodies in this multiplexed serology immunoassay and by applying statistical methods, we could address the issue of time needed for seroversion in adult patients. This is the first time it has been possible to predict seroreversion in an adult population much earlier than using conventional serology.

This new method shows the antibody signatures and their dynamic decline in reactivity for treated patients, allowing for the prediction of future cure. This new methodology may be useful for Phase II trials as a decision point before moving forward to Phase III and could be integrated into future Chagas clinical trials as a primary endpoint instead of, or in addition to, PCR tests.

Chronic indeterminate Chagas: a case report form template

Caitlin Naylor (Infectious Diseases Data Observatory, University of Oxford)

The IDDO - Infectious Diseases Data Observatory, DNDi - Drugs for Neglected Diseases initiative, and the Chagas disease research community have collaborated to develop a freely available case report form (CRF) template for chronic indeterminate Chagas disease, annotated using CDISC standards.

Data heterogeneity presents a challenge for the development of new treatments. Differences in methods of recording, storing, and reporting data lead to difficulties when comparing treatment efficacy between different studies, as well as combining and comparing data across studies.

The intent of this CRF template is to provide a tool for researchers to use when collecting data for their studies. The CRF provides a standardised method for data collection, making comparison between studies easier and enabling data combination across studies.

The content of the CRF was guided by the expertise and input of the Chagas research community, including researchers, clinicians, and study sponsors. The content is broad and aims to be as comprehensive as possible, with modular design to allow each visit day to be constructed as needed.

Above all, the CRF template is meant to be flexible: researchers choose what they wish to include for their study, remove what they do not need, and add anything not already included.

Data is precious, particularly for a neglected tropical disease like Chagas. Sparse funding, challenging environments, and complex disease characteristics mean that it is critical to make the most of available data. The CRF aims to help in this space, providing a convenient method and format for data collection, but not restricting or directing content, focus, or interpretation.

Find the CRF and its user guide on the IDDO website: **https://www.iddo.org/chagas/crf**.
Both are living documents, so feedback and suggestions are always welcome (**chagas@iddo.org**).

Access

Chagas in Florida: taking a *One Health* approach

Norman L. Beatty (University of Florida)

Chagas disease in Florida needs attention, and taking a *One Health* approach to tackling this neglected tropical disease is a strategy Dr. Norman Beatty has envisioned since 2019 when he started at the University of Florida.

An interesting fact about Chagas in Florida is that there are two different populations at risk for this potentially deadly infection: those living with chronic Chagas disease who have immigrated from endemic regions of Latin America, and populations residing in Florida with exposure to local kissing bugs which invade homes and may be infected with *Trypanosoma cruzi*.

Dr. Beatty is working to address the many gaps in our understanding of Chagas by constructing and working with a multidisciplinary team. Working to understand the dynamics of Chagas disease can be challenging, but connecting with partners like DNDi and Mundo Sano is key to the success of the Chagas research which is being conducted in Florida. Developing a model to simplify screening, diagnosis and treatment is the one vital objective of the team. Learning more about how *T. cruzi* circulates naturally in Florida and the behavior of the kissing bug is another important aspect of the work they are doing. This will ultimately help mitigate autochthonous risk to humans and companion animals in the state.

The story of Chagas is no different in Florida than what we see in other endemic regions of Latin America. Chagas primarily impacts vulnerable populations which tend to live in rural settings and with limited resources. Bringing awareness to Chagas disease in the Unites States is imperative, and developing models which can reach at-risk populations as we move forward is the goal as we tackle this neglected disease worldwide.

Access

Testing and treating patients with Chagas disease in primary care: **a story of success**

Rafael Herazo and **Marianela Menes** (DNDi)

Nurse Esdras wakes up very early and, before the sun begins to scorch the air in the municipality of Comapa, he gets ready without losing sight of the hands of the clock. Motivated by those waiting for him, he gets on his motorcycle to go to the Permanent Health Care Center (CAP), where he has dedicated eight hours of his life every day for the last five years. To get there, you must cross the vaccination area, where, if you're lucky, you might see an undaunted newborn baby, born at home, standing fearlessly in front of the needle that promises to protect him from some diseases.

The doctor's office or clinic, as it's called in the region, is a space adapted to treat people. It used to be a laundry room. The space is divided in two, and when you pass through the entrance door and leave the blue walls, you arrive at the smaller part with beige walls that evoke tranquillity, where patients are welcomed, some alone and others accompanied by relatives or neighbours seeking help against the disease that afflicts many people in the region, Chagas disease.

After being registered on the computer, they move on to another space, a little larger and with a couple of strange apparatuses that indicate to the patient that their heart will be examined. The nurse explains that Chagas could affect their health, that at the beginning the patient may not feel any symptoms and that it is important to see how the electricity travels through the heart, because sometimes, between blockages and slow pulses, it may be necessary to be treated in the capital.

As in most cases, Esdras can identify that the electrocardiogram at that moment is within normal parameters. He has been trained like almost no other counterpart in the sector, and is able to recognize normality and abnormality, although the latter is not extensively detailed. In addition to the absence of symptoms and clinical signs, it was decided, with the approval of the medical epidemiologist of the health area who remotely oriented the case, to prescribe nifurtimox, an antiparasitic from the 60's, which is still in use and that, along with another medicine similarly of around the same age, is the only thing available.

For two months, the patient is periodically monitored, tolerance to the medication is evaluated and, in the event of any intolerance, the nurse will know what to do, as he is trained for it. Most of the patients successfully complete the 60 days and are registered in the database, documenting another success story. They are expected to continue their health check-ups every year, re-encountering the device that registers the heart's energy and knowing that they must stay away from the relatives of the insect that infected them and which may still be around.

The Chagas clinic's capacity to resolve the problem, staffed by a nursing professional, is reflected in the successful indicators recorded. Seventy-two percent of the people that are seen start treatment; another 12% of the cases are postponed because they are pregnant or breastfeeding. More than 90% complete the treatment.

Guatemala is consolidating an exemplary experience for the world.

Chagas Observatory: a tool for consultation, communication and advocacy

Diogo Galvão (DNDi) and **Javier Sancho** (Chagas Coalition)

If you have ever attempted to access up-to-date epidemiological data or even general information on Chagas disease, you have likely encountered difficulties. The data you found were probably broad estimates, possibly outdated, and required considerable time spent searching and consulting, leaving you dissatisfied.

Chagas programs themselves struggle to access information related to the disease and progresses made in healthcare accessibility. Due to these challenges and the advocacy efforts of associations representing those affected by Chagas — who in 2022 adopted the motto for World Chagas Day "Help us know how many we are and where we are"— the Chagas Observatory project was launched.

Through a highly productive process of collaboration and data collection with various countries, which has led to significant learning and future improvements, the Chagas Observatory makes its debut in this first edition of 2024. This initiative includes the participation of seven countries: Argentina, Brazil, Colombia, Guatemala, Paraguay, the United Kingdom (London), and Switzerland (Geneva). The Observatory aims to provide current data (as of 2021) in an accessible and educational format. In addition to quantitative data such as the number of people tested, diagnosed, and treated—broken down by age, gender, and pregnancy status—the initiative also offers qualitative information on the availability and registration of medicines, the use of rapid diagnostic tests, the existence of patient associations, and other valuable insights. This comprehensive data helps paint a clearer picture of the progress made by countries in terms of access to healthcare for Chagas disease.

The official estimates we currently rely on were provided by the World Health Organization (WHO) and the Pan American Health Organization (PAHO) in 2010. These figures have practically become a mantra we frequently repeat: 6-7 million people affected worldwide by Chagas disease; only 10% of people living with Chagas know they have the disease; around 30,000 new cases and 10,000 deaths in Latin America each year[1]. To better align our efforts with the goals outlined in the Road Map for Neglected Tropical Diseases for 2021-2030, it is crucial to enhance surveillance, generate accurate data, and make it accessible. Achieving this requires collaboration among various stakeholders, including researchers and civil society organizations.

In 2024, PAHO and WHO will update their estimates of the epidemiological data for Chagas disease. At the same time, prevalence studies by country/region, such as the RAISE study - The Burden of Chagas Disease in the Contemporary World, will contribute to more accurate estimates. Initiatives such as the Chagas Observatory, led by civil society organizations such as the Chagas Coalition, the Drugs for Neglected Diseases initiative (DNDi) and the World Heart Federation (WHF), are important for generating discussion and providing an easy-to-consult platform for qualitative and quantitative data on Chagas, as well as being an advocacy tool.

We invite you to visit the Observatory at **www.observatoriochagas.com** and share it widely to generate greater visibility, foster discussion, and engage new partners in contributing.

1 - https://www.paho.org/en/news/13-4-2023-less-10-people-chagas-receive-diagnosis

The **Brazilian National Movement** for Neglected Diseases

João Victor Pacheco Fós Kersul de Carvalho and **Josefa de Oliveira**
(National Movement for Neglected Diseases – MNDN)

On January 30, 2024, during the World Neglected Tropical Diseases Day Seminar held by the Ministry of Health at the headquarters of the Pan American Health Organization (PAHO) in Brazil's Federal District, the National Movement for Neglected Diseases (MNDN, from of the Portuguese acronym) was created. This movement was established with the aim of uniting leaders and patients to improve the quality of life and ensure access to dignified and equitable treatments for those affected by neglected diseases such as leprosy, tuberculosis, hepatitis, Chagas disease, leishmaniasis, and schistosomiasis. The MNDN emerged from discussions at the 8th Brazilian Social Forum on Neglected Diseases in Salvador, reflecting the need for a collective effort to combat neglect and improve patients' living conditions.

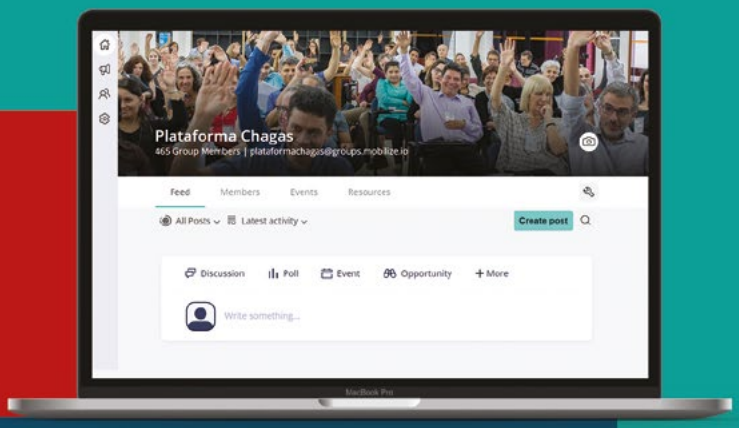
The MNDN emerged as a response to the injustices faced by communities affected by infectious and neglected tropical diseases. In a country where there are still breeding grounds for these diseases, people live with problems that go beyond the health system, such as houses without bathrooms, neighbourhoods with sewage, poorly structured landfills and unsuitable housing, which serves as a shelter for insects and mosquitoes.

Our movement goes beyond the fight against neglected diseases. It is driven by a collective dream: the dream of seeing our generation enjoying a full and healthy life, experiencing every aspect of health that exists. We want health that goes beyond the physical, that embraces the social, the mental and the spiritual, and that extends to the planet itself. We imagine a world where health is not just the absence of disease, but a state of complete physical, mental and social well-being. We dream of a society where everyone has equal access to quality health services, regardless of their socioeconomic status or place of residence. We also want to live in a more inclusive country, where every individual is valued and respected for their diversity. We want to build a nation where everyone has equal opportunities to access education, work and basic services, without discrimination or prejudice. Our dream is to live in harmony with the planet, recognizing the interconnection between our health and the environment. We believe that this dream is possible.

*** During the preparation of this publication, we were saddened by the unexpected news of the passing of our fellow advocate and president of the Rio Chagas Association, Josefa de Oliveira, who was also a co-author of this text.** Despite facing daily challenges, she used her experience to inspire and guide others affected by the disease, striving for full health and a better quality of life for everyone in the community. A strong fighter, joyful, tireless, friendly, wonderful, happy, caring, extraordinary, inspiring, and compassionate: these are some of the adjectives used by all those who admired her and who will deeply miss her.

Join the **Chagas Platform webforum!**

We migrated to a
new, more up-to-date
and **user-friendly system**



Access the online platform together with **experts from across the globe** and stay up to date **on the latest in Chagas disease research**

The forum works as a social network in which you can also receive updates sent to your email. Members can interact and post news, facilitating communication among collaborators. We encourage the sharing of documents and scientific papers, the promotion of events and debate, and the possibility of asking questions and making new contacts.

Register using the **link** or the **QR code**

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DNDi Latin America
Rua São José, 70, sala 601, Centro
20010-020 Rio de Janeiro, RJ, Brazil
+55 21 2529-0400
www.dndial.org

Global Headquarters
15 Chemin Camille-Vidart 1202
Geneva, Switzerland
+41 22 906 9230
www.dndi.org

Published by the Drugs for Neglected Diseases initiative (DNDi)

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