

Editorial

Latin America has been under-represented in dementia clinical trials, we must turn the corner...

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The world's population is aging, life expectancy is increasing in the past century as result of the improvements in healthcare and the people arrive to live longer and healthier. However, this has also resulted in increase the number of people with age-related diseases like most of dementia etiologies (fundamentally Alzheimer and Vascular dementia). The growth of people with dementia in the next 20 years will be exponential around the world but even more in those countries with Low and Medium Incomes (LMIC) due to the recently and future improve in health care and quality of life.

In 2012, the World Health Organization-WHO and Alzheimer Disease International-ADI launched a report which makes a major contribution to our understanding of dementia and its impact on individuals, family, and society around the world; the report calls on all governments, policymakers, and stakeholders to define dementia as a public health priority (WHO & ADI, 2012).

Latin America (LA) is comprised by Low— and Middle-Income Countries (LMIC). Ethnic, cultural, educational, and economic diversity and disparity are the hallmark of the region. From the linguistic point of view, Spanish language is predominant, followed by Portuguese in Brazil. Even within the different Spanish-speaking countries, the language has evolved differently and for cognitive assessment or intervention, we need local adaptations and standards.

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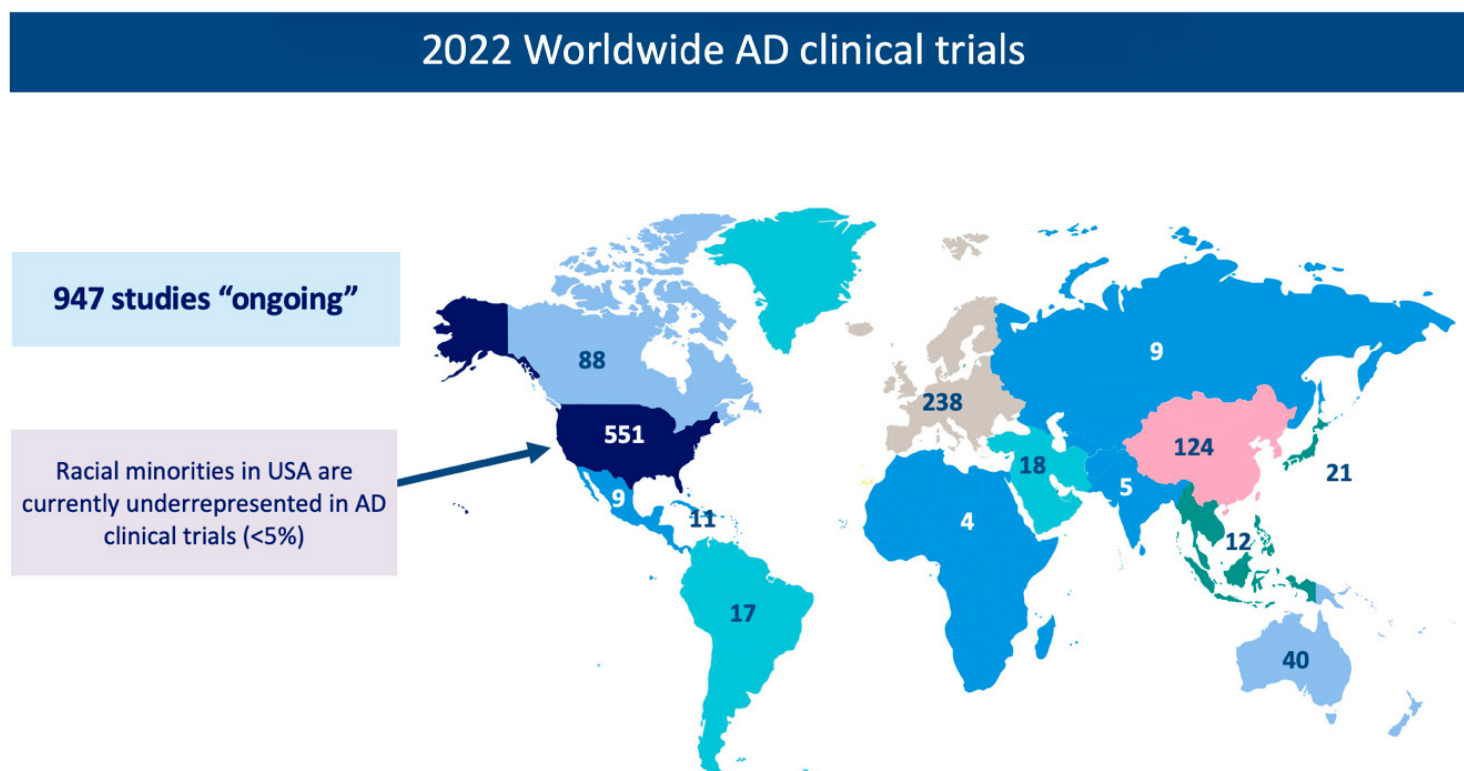
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Grants for Clinical trials are growing because of considering dementia as an epidemic disease in the coming years. However, we are in an exceptional moment, after almost 20 years without a new medication for Alzheimer’s disease, last year (2021) the FDA (Food and Drugs Administration) approved in accelerated manner the first monoclonal antibody against the amyloid (Aducanumab). It was highly controversial because it showed that erased amyloid but did not clearly improve the clinical evolution. However, three other anti-amyloids that show better clinical prospects and less side effects are currently in Phase 3 (lecanemab, donanemab, and gantenerumab).

A worrying fact is that Latin America is underrepresented in those clinical trials. *ClinicalTrials.gov* (2022) showed that over 947 Alzheimer’s disease (AD) clinical trials ongoing worldwide only less than 2% are in Latin America. But this is not only a LA problem, even in USA racial minorities are less than 5% in clinical trials.

FIGURE 1. *Latin America has several opportunities and challenges.*



Source: AD, Alzheimer’s disease. <https://www.clinicaltrials.gov/>. Accessed September 2022.

1. Larger urban populations than other emerging regions that could provide high number of treatment-naïve patients for clinical trials. As example San Pablo (Brazil), Mexico City (Mexico) and Buenos Aires (Argentina) have approximately 15 million inhabitants each. This situation allows easier, bigger and faster recruitment.

2. Suitable conditions for conducting and developing clinical trials, incorporating particularities of diversity and disparity. Some countries as Argentina, Chile and Uruguay have more than 85% of the population European descendent, other as Peru more than 45% amerindians, and other as Mexico more than 60% Mestizos. But this is different even in the same country, as example in Argentina, the east predominance is European and the west and north mestizos or amerindians.
3. Resources and healthcare infrastructure are well suited for enabling global clinical trials. Most of the LA countries have renamed memory clinics and AD biomarkers availability as you can see in the paper of Parra et al. (2018).
4. Most of the principal researchers have completed their medical training in USA or Europe.
5. LA regulatory authorities employ GCP terminology and guidelines according to the Documents of America from Pan American Health Organization.
6. There is a great market for drugs to control and reverse dementia, mainly AD; developing countries will be the main source of aging people in the future.

Trials are becoming more complex and clinical trial designs are changing there are greater demands to meet requirements of the country's regulatory agencies. At the same time, the new paradigm to study mild cognitive impairment or mild dementia due to AD has increased the mandatory inclusion of biomarkers (CSF Abeta42 and Tau, FDG PET, MRI hippocampal volume) in most of the trials, which can limit the number of places that use that technology.

Our countries have large urban populations and high per site recruitment levels. There are well-equipped centers, memory clinics, and a great number of specialists in dementia, which is also proved by an increasing number of publications.

Finally, the results of the studies should be transferred to the general LA population with a more rational use of the treatments.

We hope that in the near future equity in scientific research between LMIC and HIC will be improved, and the distribution of clinical trials will be more homogeneous and equitable around the world. We must turn the corner.....

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