Identifying Opportunities and Overcoming Challenges in Conducting Alzheimer's Disease Trials in Low and Middle Income Countries

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In light of an aging population, the search for drugs that will delay or halt the progression of Alzheimer’s disease has intensified, leading to an increase in clinical trial programs in this challenging therapy area. With near saturation of traditional clinical trial markets, the focus has turned to emerging markets, which, if carefully navigated, offer an opportunity for efficient, cost-effective clinical trials in appropriate patient populations. In this article, Roza Hayduk, Lynne Hughes, and Amir Kalali discuss the opportunities and potential solutions to the challenges of conducting Alzheimer’s disease trials in low and middle income countries.

Introduction

Demographic aging is a global phenomenon that demonstrates the success of improved healthcare and better nutrition over the past century. Many are now living longer lives with the result that the world has a growing number of older people. Hand in hand with this “graying” of the population comes an escalation in diseases of aging, most notably Alzheimer’s disease (AD) and related dementias. It is estimated that a new case of dementia occurs somewhere in the world every 7 seconds, resulting in progressive deterioration in the sufferer’s memory, orientation, language, comprehension, and judgement.¹

Currently, there are no pharmacologic treatments that cure or even modify the progressive course of AD, although partially effective therapies are available for some core symptoms (e.g. cholinesterase inhibitors and N-methyl d-aspartate-receptor antagonists can lead to useful improvements in cognitive function). This high unmet need and growing population makes this a very promising field for drug development. An active, high-quality clinical trial program is needed to successfully identify interventions that will benefit patients.
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Introduction (continued)

This white paper discusses the opportunities and challenges of conducting new AD trials in low and middle income countries (LAMIC), including India, China, and Latin American countries – regions where, because of the size of their populations, nearly 60% of the world’s 36 million people with dementia live. LAMIC were defined by the World Bank as economies with less than U.S.$11,906 gross national income per capita in 2008 (Table 1).

Table 1. Definition of low and middle income countries

<table>
<thead>
<tr>
<th>Economies</th>
<th>Gross national income per capita (World Bank 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low income</td>
<td>$975 or less</td>
</tr>
<tr>
<td>Lower middle income</td>
<td>$976–3855</td>
</tr>
<tr>
<td>Upper middle income</td>
<td>$3856–11,905</td>
</tr>
<tr>
<td>High income</td>
<td>$11,906 or more</td>
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The global AD population is expected to nearly double every 20 years to 66 million by 2030 and to 115 million by 2050, with much sharper increases in LAMIC than in high income countries (Figures 1 and 2). By 2030 the proportion of the world’s AD population living in LAMIC is expected to be 63%, rising to 71% by 2050. This is almost entirely accounted for by a greater rate of increase in life expectancy in LAMIC through better healthcare and control of infectious diseases: in the 30 years up to 2020, the oldest sector of the population will have increased by 200% in LAMIC compared with 68% in the developed world.

Figure 1. Projected growth in dementia population in LAMIC versus non-LAMIC during 2010–2050 (reproduced from World Alzheimer Report 2009)
Despite the greater and more rapidly increasing numbers of people with dementia in LAMIC, these nations are vastly under-represented in AD clinical trial populations. Many developed countries are approaching “saturation,” in terms of site and patient recruitment, and the untapped potential of LAMIC for future trials is beginning to be explored.

**Why Consider Trials in Low and Middle Income Countries?**

There are many reasons why it is worthwhile to consider LAMIC as target sites for AD trials (Table 2).

**Table 2. Advantages of LAMIC for AD clinical trials**

- **Faster patient recruitment because of:**
  - large and increasing size of dementia population
  - relatively few ongoing trials, therefore little competition for patients
  - large pool of treatment-naïve patients
  - higher numbers of patients with dementia living with caregivers (who are “gatekeepers” for trial participation) rather than in institutions
  - higher patient-to-site ratio

- **More motivated clinical investigators**

- **Significant cost savings**

- **Conducive hospital infrastructure and healthcare systems**
**Faster patient recruitment of an appropriate trial population:** Rapid recruitment of a suitable patient population is one of the many key drivers for success of clinical trials. In high income countries, the availability of optimal care outside of the clinical trial setting, access to new drugs, and a high number of ongoing studies impacts the size and eligibility of the potential trial population. Conversely, in LAMIC there are large patient populations situated close to major urban centers, a growing number of patients with AD, and fewer ongoing trials. Limited access to currently available drugs results in a large pool of treatment-naïve patients who may benefit from access to novel agents. In combination, these factors promote fast recruitment of an appropriate trial population.

A further key consideration for patient recruitment in LAMIC is the higher proportion of patients with AD living at home in extended families rather than in nursing homes or other institutions. This is demonstrated by the cost of informal (family) care for people with dementia, which accounts for 56% of costs in low income countries, 42% in middle income countries, and just 31% in high income countries where there is far more formal health and social care services available. In high income countries there may be no primary caregiver who can serve as the “enabler” or “gatekeeper” of clinical trial participation. Conversely, patients who are being cared for by the family may be more easily accessed for clinical trial recruitment in LAMIC.

**More motivated clinical investigators:** The ability to recruit motivated clinical trial investigators is also a critical issue for the progress of clinical trial programs. Investigators in LAMIC may lack the degree of clinical trial experience of their non-LAMIC counterparts but are highly motivated and keen to:

- *obtain first-hand experience with the most recent drugs*
- *achieve global recognition through working on the same platform as other international experts*
- *improve their personal prospects through working with multinational corporations*

As such, it has become easier to recruit clinical investigators who are motivated to recruit patients and comply with clinical trial protocols.

**Significant cost savings:** Conducting trials in LAMIC involves significantly lower costs than for trials in the USA and Western Europe. The costs associated with medications, travel expenses, and pass-through expenses are lower, contributing to a reduction in the overall trial program budget. Cost savings can be significant, primarily due to more rapid recruitment of patients and shorter duration of the trial.

**Conducive hospital infrastructure and healthcare systems:** As the economic situation improves in LAMIC, there are associated improvements in the hospital infrastructure and healthcare systems. Large hospitals situated in major urban centers effectively treat large patient populations, offering an environment that is suitable for clinical trials. Increasingly, these centers have access to the latest diagnostic equipment, certified and accredited central laboratories, and skilled staff who can effectively contribute to the trial process.

In LAMIC there are large patient populations situated close to major urban centers, a growing number of patients with AD, and fewer ongoing trials. Limited access to currently available drugs results in a large pool of treatment-naïve patients who may benefit from access to novel agents.

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Large hospitals situated in major urban centers effectively treat large patient populations, offering an environment that is suitable for clinical trials.
Key Challenges of Conducting Trials in Low and Middle Income Countries

While there are many advantages to pursuing clinical trials in LAMIC, there remain a number of potential challenges (Table 3). Awareness of these potential barriers by the sponsor or partnering organization in conjunction with appropriate pre-planning means that they can be successfully navigated.

Table 3. Key barriers to conducting AD clinical trials in LAMIC

| > Less experience in conducting clinical trials |
| > Poor societal awareness of dementia resulting in delayed diagnosis |
| > Caregiver pressures |
| > Language/cultural barriers |
| > Need for neuroimaging facilities |
| > Issues with validity and global acceptance of clinical trial data |
| > Issues with local regulatory requirements |
| > Clinical trial logistics hurdles |
| > Long regulatory timelines in some countries: 8–12 months |

Less experience in conducting clinical trials: Investigators in LAMIC have, on the whole, had less exposure to the rigors and regulations of clinical trial conduct than their non-LAMIC counterparts. While expertise may be present in some centers, knowledge of and adherence to the required standard may differ between sites within and between LAMIC. Additional support, education, and training are therefore required to ensure understanding and compliance with global requirements and to support the collection of high-quality data.

Poor societal awareness of dementia and delayed diagnosis: The focus of many dementia trials is patients with mild-to-moderate disease – or even the earlier prodromal phase (mild cognitive impairment) – where intervention may be more useful. There is a clear need, therefore, to detect and diagnose AD early in its course, which poses a particular challenge for LAMIC. In many of these countries, societal awareness of dementia is poor. The typical features of dementia are widely recognized; however, awareness of dementia as an organic brain syndrome or as any kind of medical condition is limited. Rather, it is perceived as a normal, anticipated part of aging. Research in China showed that 49% of patients with dementia had been classified as normally aging compared with 20% in Europe, and only 21% of patients in China had adequate access to diagnostic assessment compared with more than 70% in Europe. This general lack of awareness means that help from formal medical care services is not sought and the diagnosis is often not made until much later.

This situation is changing, however, and teams from the 10/66 Dementia Research Group (an Alzheimer’s disease international collective of researchers carrying out population-based research into dementia and aging in LAMIC) have succeeded recently in raising awareness of AD through newspapers, TV, and radio outlets in India, Argentina, Venezuela, Peru, and the Dominican Republic. The Times of India published 15 articles on dementia in the past 18 months alone (compared with no articles in 1999). The media in LAMIC are highly receptive to these stories as
part of their role is informing the public and stimulating debate. They are responsive to efforts to alert them to the importance of aging and dementia, and to build their capacity to report research and understand its local relevance. To complete the picture, primary-care teams also need educating to detect early signs of dementia in elderly patients when consulted for this reason or for other health issues.

Caregiver pressures: As mentioned previously, caregivers play a vital role in facilitating the participation of patients with AD in clinical trials. However, caregivers in LAMIC are often also the primary breadwinners for their extended multi-generation families and may also be caring for other dependents. Their numerous responsibilities and pressures may make it difficult for them to engage in supervising trial participation, particularly if the protocol demands regular and frequent clinic visits. Where conflicting commitments from work and family – and even the risk of loss of earnings through absences – are an issue, consideration could be given to running a community-based rather than a centralized trial where possible.

Language/cultural barriers: The successful implementation of any clinical trial requires an understanding of local culture and language.

Clinical trial documents must be provided in appropriate languages and local dialects, and in a format that is easily understandable for patients and caregivers with differing educational and literacy levels. They must also be sensitive to the cultural environment of the country that they are prepared for and appropriate for different genders.

The patient–physician relationship in many cultures in LAMIC, particularly China, differs from that in other countries. There may be a reluctance to disclose a patient’s diagnosis. Furthermore, a high level of respect for physicians may prevent a patient from questioning the suggestion that they join a clinical trial program and fully understanding the reasons and implications. Therefore, the informed consent process must be rigorously adhered to and additional patient/investigator tools may be required to support this.

Need for neuroimaging: Many AD trials involve neuroimaging for confirmation of early stage disease and as a biomarker for measuring response to therapies. Major institutions within LAMIC generally have relatively easy access to MRI and many also have access to additional imaging modalities such as PET. However, community-based hospitals in LAMIC may not have access to neuroimaging so, when this is mandated as part of the trial protocol, judicious site selection is important.

Issues with validity and global acceptance of clinical trial data: To maintain credibility within the scientific community, it is of key importance that trials conducted in LAMIC enforce rigorous standards and provide high-quality data that is acceptable and applicable to regulatory authorities in other regions. This is particularly important in protecting the patient, for example gaining informed consent and the recognition and appropriate reporting of adverse events that may be related to the study drug.

Issues with local regulatory requirements: Although there have been improvements in reducing the time taken to obtain local approval for clinical trials in a number of emerging markets, regulatory approval processes for clinical trials are typically slow in LAMIC in comparison with the USA and Western Europe. For example, in China the regulatory approval process for clinical trials may take up to a year.7 Thorough understanding of the local regulatory requirements in LAMIC is necessary to ensure that dossiers are correctly assembled and to reduce the potential for delays.

Clinical trial logistics hurdles: An efficient logistics process is key to ensuring a steady flow of medications. The navigation of local import regulations can be challenging and lead to delays. It is imperative, therefore, to obtain local knowledge of the systems and to implement strategies to avoid these issues.
The following section focuses on three specific geographic areas: India, China, and Latin America. These regions do not cover all LAMIC but many of the advantages they offer for clinical trials and many of the issues they present are representative of those in LAMIC as a whole.

**Focus on India**

South Asia (including India) has a large, genetically diverse population and is currently home to 4.48 million people with dementia, many of whom are treatment-naive. This number is projected to increase to 9.31 million in 2030 and to 18.12 million by 2050. As well as a large patient pool, official reports indicate that the number of clinical trials is on the rise with a concurrent increase in the value of the clinical trials market, which is predicted to reach $2bn by 2012.

India is able to offer significant cost savings compared with conducting clinical trials in the USA and Western Europe. In addition, changes to the regulatory and administrative structure within the office of the Drugs Controller General of India have significantly improved the ease and efficiency of conducting clinical trials in India.

There are, however, a number of barriers that must be negotiated. These include varying levels of literacy and education, cultural sensitivities including a paternalistic physician–patient relationship that may hamper the informed consent processes, and the influence of the extended family in making a decision on whether or not a patient should enroll in a clinical trial. While the official language of India is Hindi, there are a number of languages in use. As a result, documentation and recruitment tools may need to be translated into a number of different languages (usually six at the minimum) including Bengali, Gujarati, Urdu, and Kannada.

**Focus on China**

China is currently home to one-fifth of the world’s population. The country’s population is expected to reach 1.484 billion by the year 2050. Currently there are 5.49 million people with dementia in China, Hong Kong, and Taiwan, a figure projected to rise to 11.93 million by 2030 and to 22.54 million by 2050.

The number of clinical trials has recently increased in China. The Chinese CRO market – originally established in the 1990s – was estimated to be worth $250m in 2008 and is predicted to be worth $791m by 2012. As in India, a large pool of treatment-naïve patients, significant cost savings, and principal investigators with extensive experience with Western pharmaceutical companies offer significant advantages.

In 2003 the Chinese State Food and Drug Administration (SFDA) was formed. The development of this single drug regulatory authority eliminated conflicting standards between provincial government agencies, and resulted in a centralized Chinese healthcare regulatory system with increased transparency. Despite the advantages that this move provided, there remains a long clinical trial approval regulatory process that can easily take 1 year. The requirement to obtain import and export licenses may extend the time before starting a trial even further. Furthermore, although the Chinese SFDA Good Clinical Practice (GCP) closely resembles the International Conference on Harmonisation (ICH) GCP, it is not identical. Clinical trials conducted under SFDA GCP regulations may not fully comply with the ICH GCP, and it is important, therefore, for companies to ensure that standards are maintained through careful selection of their development partners.
Focus on Latin America

Latin America comprises the 13 countries of South America as well as Central America and the countries of the Caribbean. The number of people with dementia in Latin America is currently 3.1 million and is predicted to rise to 7.04 million by 2030 and to 15.03 million by 2050.4

The countries representing the most important clinical trial markets are Argentina, Brazil, and Mexico, where there has been a dramatic increase recently in the number of clinical trials conducted (Figure 3).

**Figure 3. Accumulative number of clinical trials in key Latin American countries**

<table>
<thead>
<tr>
<th>Number of trials in 2000</th>
<th>Number of trials in 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Brazil</td>
</tr>
<tr>
<td>6</td>
<td>1177</td>
</tr>
</tbody>
</table>

There are a number of advantages in conducting clinical trials in Latin America. These include the large treatment-naïve population, rapid patient enrollment and associated high compliance and retention rates among clinical trial patients, cost savings, and, with the exception of Brazil, a common Spanish language. Many investigators are U.S.-trained and compliant with ICH GCP regulations.

Challenges do exist for companies conducting trials in Latin America. Concerns over intellectual property protection, differences in the rules governing clinical trial conduct, and cultural issues may present barriers to a successful clinical trial program. While Argentina, Brazil, and Mexico comply and adhere to GCP, the regulations governing ethics committees in some of the other Latin American countries do not fully comply with the ICH guideline. In these instances an independent review board that meets ICH standards is recommended. Furthermore, in light of the evolving regulatory environment, it is important for sponsors to access local knowledge of the regulations in each country and how changes may impact the approval process.

Significant cultural differences exist between the individual countries in Latin America, and they should not be treated as a single entity. It is essential that sponsors are aware of, and sympathetic to, these differences. Local knowledge and awareness of cultural issues are essential in navigating the trial process successfully and in fostering good communication and mutual respect.

Conducting clinical trials in Latin America offers a number of advantages including access to a large treatment-naïve population, rapid patient enrollment, high compliance and retention rates, and cost-savings.

A local knowledge of the regulations in each country and awareness of cultural issues are essential to navigate the clinical trial process successfully.
Conducting AD trials in LAMIC offers numerous and far-reaching benefits to sponsors. Awareness of cultural and ethical considerations, well-trained investigator sites, and measures to support investigators and facilitate patient recruitment and retention can pave the way for a successful trial program.

Overcoming the Challenges Through Effective Solutions

Conducting clinical trials in LAMIC – and AD trials in particular – clearly offers numerous and far-reaching benefits to sponsors. Challenges do exist and these can be navigated successfully in partnership with a Contract Research Organization (CRO) with an excellent understanding of the local regulations and approval process, and the experience to proactively manage any issues. A strong local presence and awareness of cultural and ethical considerations in conjunction with experience of AD trials is a key consideration. Furthermore, access to well-trained investigator sites that can provide data accepted by appropriate regulatory bodies including the FDA and EMA (formally the EMEA) is essential. In addition, there are specific measures that can support investigators and facilitate patient recruitment and retention in AD trials:

> Producing appropriate educational materials to raise awareness for physicians and patients/caregivers focused around their specific needs
> Visual aids to enhance diagnosis, recruitment, and retention in the trial
> Transportation for clinic visits
> Compensation for caregivers’ time
> Motivating investigators by providing additional educational meetings to support clinic site staff and those from surrounding clinics that may refer patients
> Educating investigators to ensure quality of processes and subsequent data.

Summary

LAMIC offer a significant opportunity for clinical trials programs in AD. Compared to non-LAMIC, patient recruitment can be speeded up considerably in light of the large and increasing size of the dementia population, much of which is treatment-naïve. In addition, LAMIC offer a pool of highly motivated investigators, a well developed hospital infrastructure in the major centers, and attractive cost savings. However, important barriers and challenges remain for sponsors venturing into LAMIC; it is essential to bear these in mind and seek CRO partners with extensive local knowledge, networks, and experience. With the appropriate support and advice, sponsors can steer a course into LAMIC with confidence and reap the undisputed benefits associated with these markets.
While there are many advantages to pursuing clinical trials in LAMIC, there remain a number of potential challenges (Table 3). Awareness of these potential barriers by the sponsor or partnering organization in conjunction with appropriate pre-planning means that they can be successfully navigated.

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References

About the Authors

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Dr. Roza Hayduk is a neurologist with subspecialties in epilepsy and sleep disorders. She has more than 25 years’ experience in clinical neurology and clinical research both in the USA and Europe. She has consulted and participated in drug development programs for neurological diseases through NIH and pharmaceutical company sponsored projects, especially for Alzheimer’s disease, and has served as Global Medical Monitor for international clinical trials on symptomatic and disease-modifying treatment of AD. Dr. Hayduk is a recipient of the renowned Fulbright Award for Medicine. For several years, she served as Adjunct Assistant Professor in the Department of Neuropharmacology at The Scripps Research Institute. She is a Fellow of various societies including the American Academy of Neurology, the American Epilepsy Society, and the American Academy of Sleep Medicine.

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Vice President and Global Head of Neurology, Global Project Management, Quintiles

Dr. Lynne Hughes has more than 23 years of experience working in the pharmaceutical industry in Europe and the USA. Before taking on her current role, she worked as a Project Director/Program Director for Quintiles leading large global and multi-national Phase III studies. She has significant experience working in the field of neurology, acute care, oncology (both diagnosis and treatment), and medical imaging. Dr. Hughes has played a part in the clinical trial development of all the current AD therapies on the market, is involved in a number of disease modification programs, and sits on a number of steering committees for clients with AD products in development. She also has responsibility for several consultancy programs for investment opportunities within all areas of neurology.

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Dr. Amir Kalali is globally responsible for the medical and scientific aspects of development programs in psychiatry and neurology. He is also Professor of Psychiatry at University of California, San Diego. He was the Founding Chairman of the Executive Committee of the International Society for CNS Drug Development (ISCDD), and currently the Executive Secretary. Dr. Kalali is also Chair of the Membership Committee of the International Society for CNS Clinical Trials and Methodology (ISCTM), as well as a member of the Scientific Committee. In these roles, he is active in facilitating scientific collaboration between academia, government, and pharmaceutical industry scientists. Dr. Kalali has been an academic investigator in more than 70 psycho-pharmacological clinical trials and at Quintiles has had medical and scientific responsibility for more than 200 clinical trials. He is an expert in CNS clinical trial methodology, including clinical rating scales, and has trained investigators from over forty countries.

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Introduction

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