PACTALS
Pan-Asian Consortium for Treatment and Research in ALS

Clinical Trial Readiness – A Survey On The Current State Of Play In Member Countries

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INTRODUCTION:

The Pan-Asian Consortium For Treatment And Research In ALS (PACTALS) was established to provide a platform for effective collaborations in achieving similar standards of care, treatment and research in the region. The current study aims to identify the clinical trial readiness of PACTALS member countries.

METHODS:

28 representatives from 13 member countries were invited to participate in an online survey to determine their existing research capabilities focusing on the establishment of ALS disease registers.

RESULTS:

Responses were received from 17/28 (61%) representatives with at least one response from every PACTALS member country. Of the 13 member countries, 10 (77%) had an ALS patient registry, 40% had national (Australia, China, Philippines, Japan) and 60% had institutional registries. The top two challenges in establishing a disease registry were limitations in technical infrastructure and trained personnel. Data quality and consistency, along with funding constraints were identified as the top challenges in maintaining a registry. All respondents were keen to collaborate, particularly in studies on disease management and disease stratification as well as participation in clinical trials. However, there were limitations in data sharing capabilities. The top barriers identified were local data protection laws and limited technical infrastructure for secure data transfer, with 35% also highlighting political or institutional resistance.

CONCLUSION:

There are variations in the clinical-trial readiness and availability of disease registers amongst the PACTALS member countries. Mentorship programmes and inclusive collaborative research are some of the measures that might help overcome the barriers in achieving equity in ALS care and research in the Asia-Pacific region.

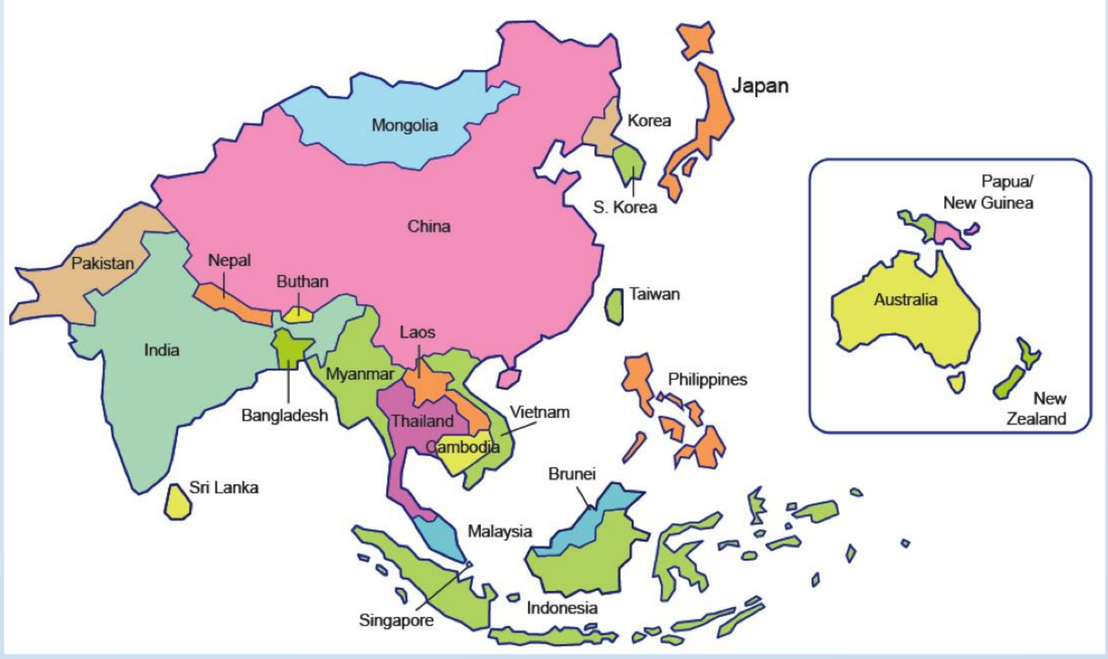

Figure 1. Overview of PACTALS Countries

Table 3. Regulatory Hurdles for International Research

Duration to obtain ethics approval for cross border data sharing:	Response, n (%)
1-3 months (China, Malaysia, South Korea, India, Thailand)	6 (35%)
3-6 months	9 (53%)
More than 6 months	2 (12%)
Policy restrictions that limit data sharing with international research:	Response, n (%)
Yes	6 (35%)
No (India, Malaysia, Philippines, Australia, South Korea, Taiwan)	6 (35%)
Not sure	5 (30%)
Regulatory challenges for sharing registry data internationally:	Countries, n
Lack of clear guidelines	8
Long ethical approval process	9
Data protection law restrictions	11
Limited infrastructure for secure data transfer	9
Political or institutional resistance	7
*41% respondents facing 3 or more hurdles	

Table 1. Registry Size in PACTALS Countries

Country	**Registry size**	**Number of sites**
Multi-site registry:		
China	500	60
Japan	2,600	40
Philippines	110	10
Australia	3,000	8
South Korea 1	3,000	4
Single-site registry:		
India	5,500	1
South Korea 2	4,000	1
South Korea 3	700	1
Malaysia	280	1
Singapore	50	1

Take Survey:

Table 2. ALS Registry Overview in PACTALS countries

Country	**Level**	**Number of sites**	**Platform used**	**Update Frequency**	**Funding, Collaborator**
Australia	National	8	Website	Real-time	Government agency
China	National	60	Website	3-monthly	Government agency, Research institution
Philippines	National	10	Website	Real-time	Private sector
Japan	National	40	Website	3-monthly	Government agency
Thailand	National	8	Redcap	Monthly	Research institution
Malaysia	Institutional	1	Redcap	3-monthly	Research Institution
South Korea	Institutional	4	Excel worksheet	3-monthly	Research Institution
India	Institutional	1	Excel worksheet	Real-time	Research Institution
Singapore	Institutional	1	Excel worksheet	Real-time	No funding

Table 4. Ranking Challenges in Building new registry

Most challenging	Technical Infrastructure limitations	5 votes
Least challenging	Language or cultural barriers	15 votes
	Geographical barrier	11 votes
Top 3 challenges	Technical Infrastructure limitations	10 votes
	Lack of trained personnel	10 votes
	Funding or financial constraints	12 votes

Table 5. Ranking Challenges in Maintaining registry

Most challenging	Data quality and consistency	11 votes
	Timely update of data	8 votes
	Sustaining funding	8 votes
Least challenging	Patient follow-up and retention	10 votes

REFERENCE:

1. Shahrizaila, N. et al., Amyotrophic lateral sclerosis and motor neuron syndromes in Asia. Journal of Neurology, Neurosurgery & Psychiatry 87.8 (2016) 821-830

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