

4-digit Session #: 4250



Establishing consensus understanding of the barriers to drug development in lupus

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MAIN FINDINGS

The study identified lupus **heterogeneity as the primary barrier impeding drug development, clinical care and access.**

Additionally, experts agreed upon the following as the top barriers to improving outcomes in lupus:

- Lack of diagnostic, predictive and prognostic biomarkers for lupus and lack of biomarkers to predict drug response in clinical trials
- Flawed clinical trial design
- Lack of access to clinicians familiar with lupus/limited awareness of lupus among non-expert medical professionals
- Barriers to effective management of lupus due to social determinants of care in predominantly lower socioeconomic status areas
- Lack of treatment adherence

BACKGROUND

The Addressing Lupus Pillars for Health Advancement (ALPHA) Project is a global consensus initiative convened by the Lupus Foundation of America and the Tufts Center for the Study of Drug Development

Objectives:

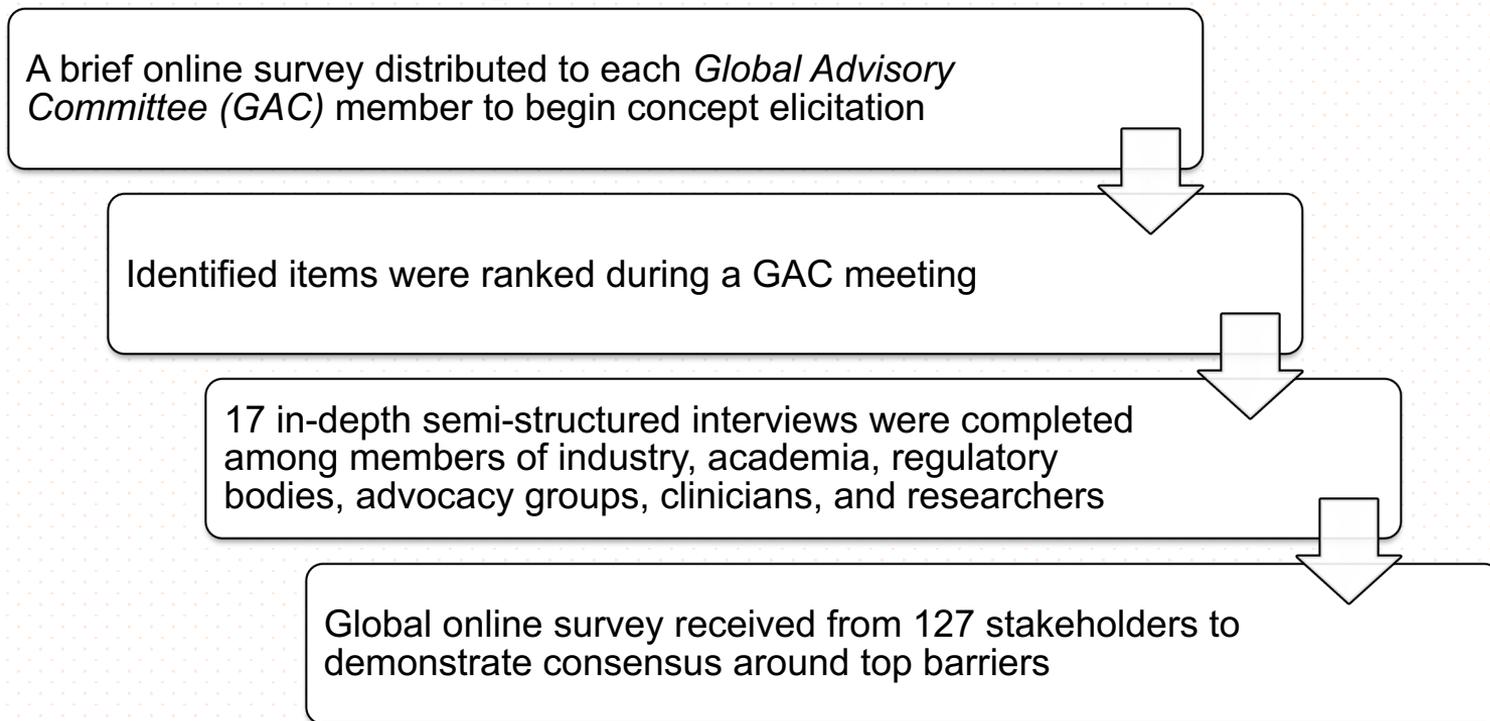
- Identify and prioritize top barriers in lupus impacting diagnosis, care, treatment and research.

Goals:

- Improve rates of accurate and timely diagnosis
- Increase access to care
- Improve short and long-term patient outcomes

METHODS

A mixed methods approach was used to elicit concepts seen as major barriers in lupus diagnosis, care, treatment and research, then consolidate and confirm those selected as most urgent.



RESULTS *Ranked Barriers by Category*

Drug Development	Clinical Care	Access & Value
Lack of biomarkers to predict response to drug in clinical trials	Lack of diagnostic, predictive and prognostic biomarkers for lupus	Barriers to effective management of lupus due to social determinants of care in predominantly lower socioeconomic status areas
Lack of user-friendly, sensitive and accurate outcome measures	Lack of treatment adherence	Lack of access to clinicians familiar with lupus
Flawed clinical trial design	Limited awareness of lupus among non-expert medical professionals	Lack of access to medications (due to lack of coverage or cost to patients)
Challenges with collecting patient-reported and clinician-reported outcomes	Lack of clear risk factors that trigger lupus and lupus-like diseases (onset and flares)	Lack of understanding by government payers/insurers about lupus and the medications needed to treat the disease
Lack of alignment between patients, providers and regulatory	Inadequate understanding of benefit-risk tradeoffs between physicians and patients	Lack of tools for collecting real world evidence (RWE)
Challenges with attracting underrepresented study populations	Lack of attention to pediatric issues	
Limited awareness of lupus among non-expert medical professionals	Lack of diagnostic criteria	
Lack of attention to R&D pediatric issues		
Lack of classification criteria		



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Related Publications

Peña, Y., Tse, K., Hanrahan, L.M. *et al.* Establishing Consensus Understanding of the Barriers to Drug Development in Lupus. *Ther Innov Regul Sci* **54**, 1159–1165 (2020). doi.org/10.1007/s43441-020-00134-2

Manzi, S., Raymond, S., Tse, K., Peña, Y., et al. Global consensus building and prioritisation of fundamental lupus challenges: the ALPHA project. *Lupus science & medicine*, 6(1), e000342 (2019). doi.org/10.1136/lupus-2019-000342

Website

<https://www.lupus.org/partnerships-and-collaborations/the-alpha-project>