

Building a sarcoidosis biomarker roadmap: finding alignment and building consensus at the Foundation for Sarcoidosis Research’s 2025 Biomarker Summit

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INTRODUCTION

The Foundation for Sarcoidosis Research (FSR) 2024 Research Agenda identified biomarkers as critical enablers of progress in sarcoidosis diagnosis, multi-organ monitoring, and treatment. In October 2025, FSR convened a Sarcoidosis Biomarker Summit to draw on lessons from other disease areas and outline specific scientific and funding priorities for future strategic work.

MATERIALS AND METHODS

Clinicians, researchers, and patients were surveyed in advance on biomarker uses and priorities. Thirty-four expert clinicians and researchers representing 27 institutions attended the Summit. Attendees included specialists in pulmonary/critical care, cardiology, rheumatology, neurology, genetics, and biostatistics.

OBJECTIVE Develop a shared, patient-centered consensus biomarker roadmap to guide research investments, partnerships, and infrastructure over the coming decade.

RESULTS

Figure 1: FDA Biomarker Category Definitions that Served as the Foundation for Discussions of Biomarkers in Sarcoidosis

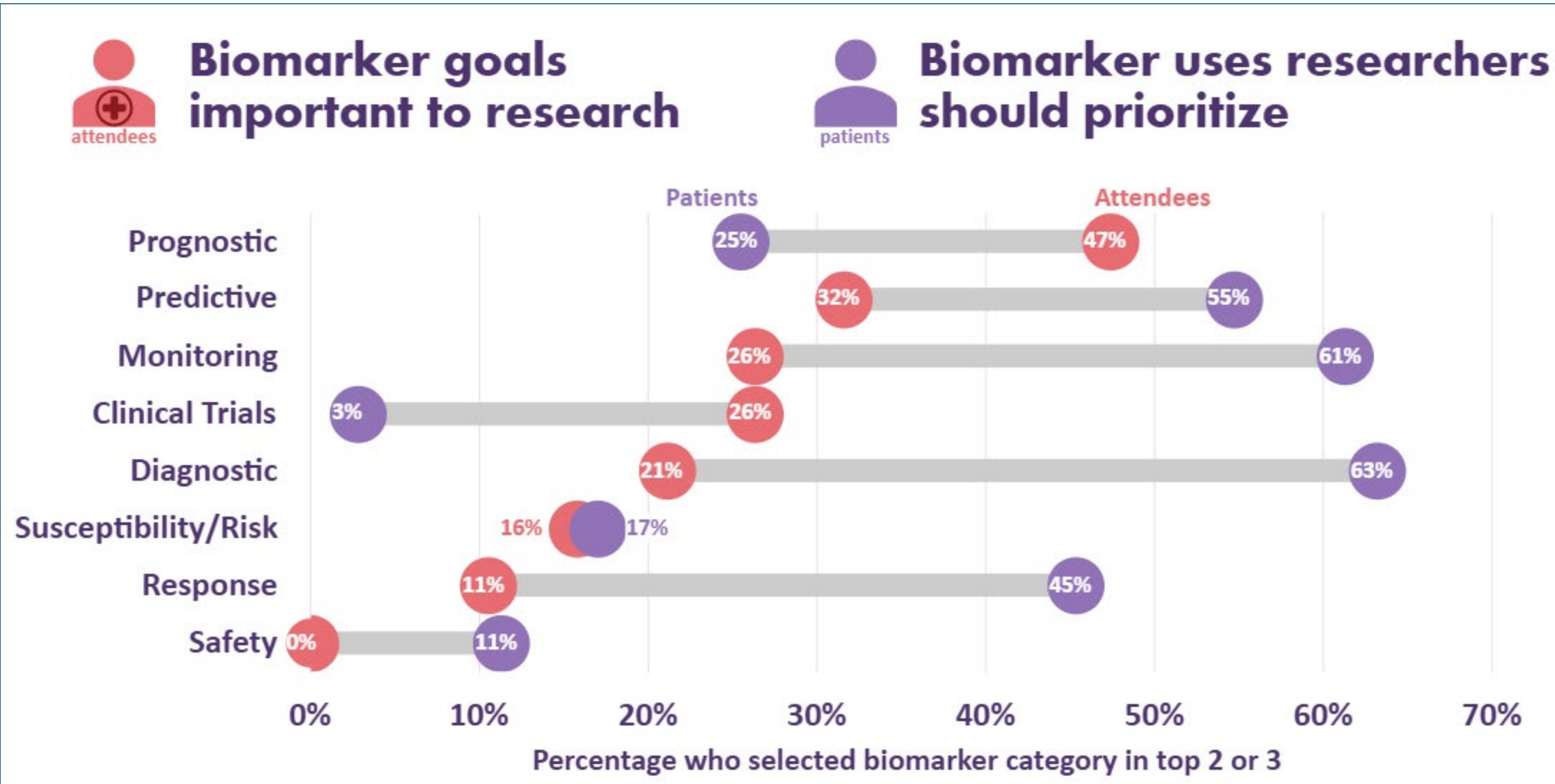
FDA Biomarker Category Definitions

1 Susceptibility/Risk	5 Predictive
2 Diagnostic	6 Response
3 Monitoring	7 Safety
4 Prognostic	8 Multicomponent

FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource [Internet]. Silver Spring (MD): US Food and Drug Administration. 2016 [Updated 2025 Jan 16]

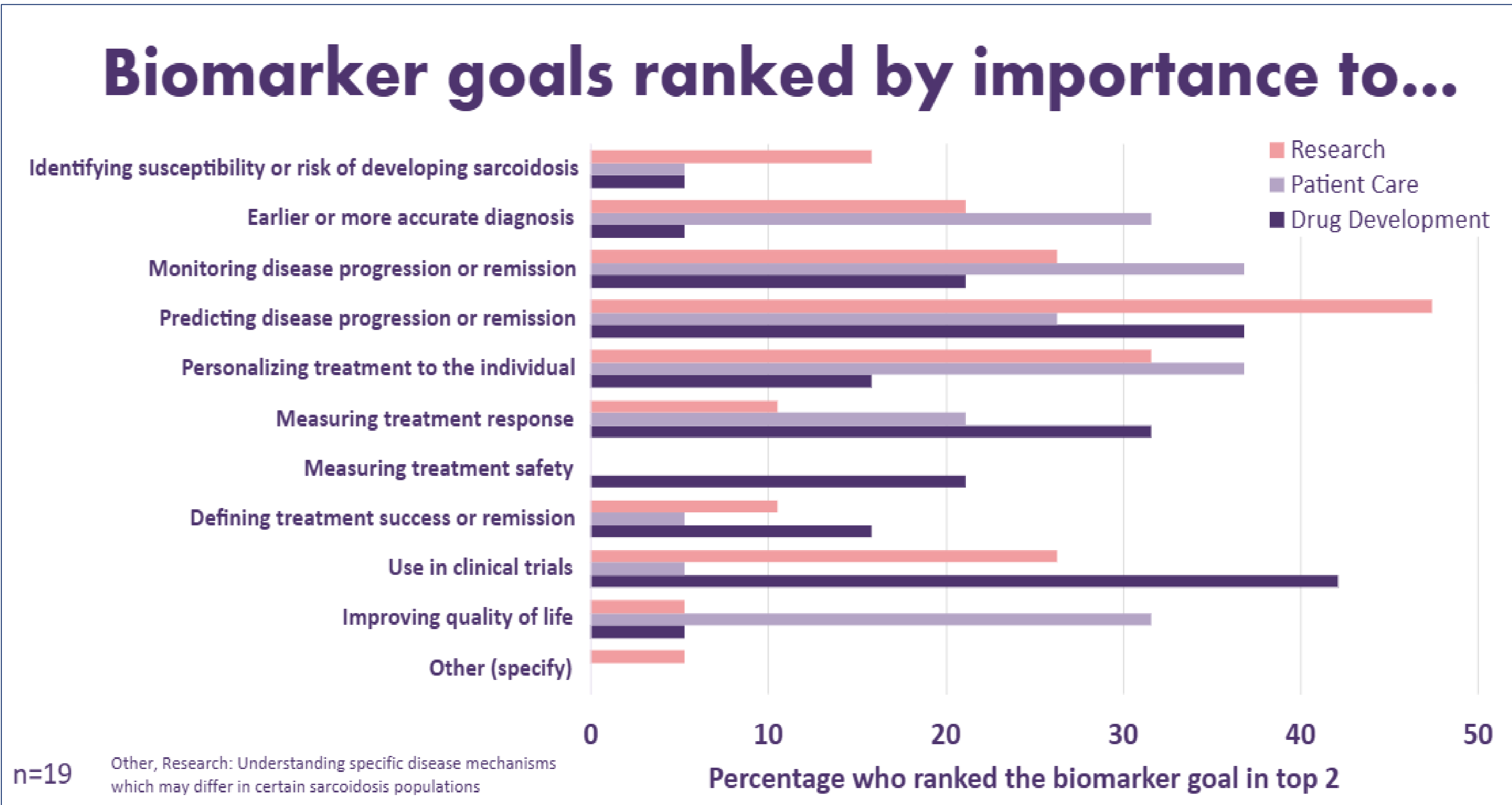
Many clinicians/researchers noted that FDA definitions may need to be modified or expanded for sarcoidosis, particularly in the category of predictive and response biomarkers.

Figure 2: Biomarker Prioritizations from both the Clinician/ Researcher and Patient Perspectives



Surveys revealed both clinicians and patients prioritized biomarkers for disease monitoring, with clinicians also prioritizing progression/remission prediction, and patients emphasizing a broader set of needs spanning diagnosis, treatment decision-making, and quality-of-life outcomes.

Figure 3: Clinicians and Researcher Biomarker Goals Ranked by Importance to Research, Patient Care and Drug Development

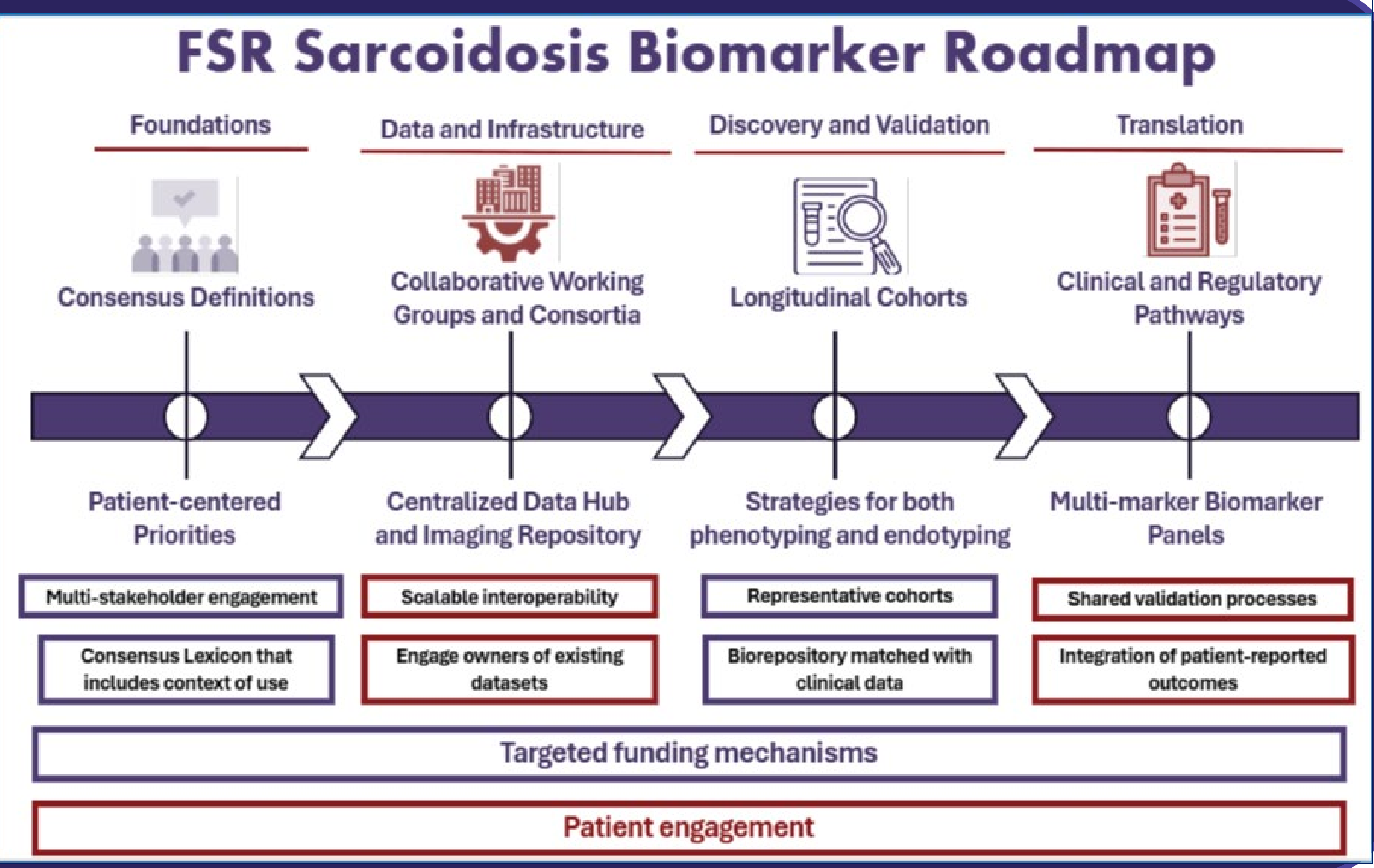


“The reason we all have different terms for progression is because those definitions are meaningful to our unique clinical practices. We shouldn’t lose them – instead how can we combine them so we can untangle them together?” – Biomarker Summit panelist

Summit attendees identified adaptable lessons from FSR-invited case studies by the Crohn’s & Colitis Foundation and the Michael J. Fox Foundation, including clear context-of-use definitions, harmonized data and assay protocols, longitudinal cohorts, and standardized shared datasets. Discussions emphasized leveraging heterogeneous real-world data while balancing organ-specific insights with phenotype-driven precision medicine

CONCLUSIONS AND VISION

Differences in emphasis on priorities for biomarker development underscore the need for a strategy that explicitly links biomarkers to patient-reported outcomes and prioritizes consensus where possible, flexibility where necessary, and sustained collaboration across stakeholders. The FSR Biomarker Summit culminated in a practical roadmap built on shared foundations, intentional infrastructure, longitudinal validation strategies, and a patient-centered path to clinical translation.



RESOURCES



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FSR Research Agenda

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