SSC Subcommittee Project/Collaborative Project

NAME OF PROJECT

Subcommittee Lupus anticoagulant/antiphospholipid antibodies

Harmonization of ELISA and non-ELISA Antiphospholipid Antibody Tests

Person responsible (Chair / Principal Investigator):

Chair: Hannah Cohen

Principal investigators:

Katrien Devreese, representative SSC Subcommittee

Pier Luigi Meroni, representative APS ACTION

Doruk Erkan, representative ACR/EULAR APS Classification Criteria Steering Committee

Working group members: Anne Tebo, Tatsuya Atsumi, Olga Amengual, Laura Bertolaccini, Orietta Borghi, Hannah Cohen, Claudia Grossi, Robert Roubey, Savino Sciascia, Rohan Willis

Description Abstract

The recently published 2023 ACR/EULAR Antiphospholipid Syndrome (APS) Classification Criteria include the detection of lupus anticoagulant (LA) with clot-based assays and enzyme-linked immunosorbent assays (ELISA) for anticardiolipin (aCL) and anti-β2-glycoprotein-I (aβ2GPI) antibodies. ELISA has been chosen as the sole solid-phase technology to ensure homogeneity. However, non-ELISA platforms for aCL and aβ2GPI are increasingly used in various countries, and thus the new APS Classification Criteria Steering Committee suggested further studying the moderate/high thresholds in non-ELISA platforms in association with clinical criteria from the new classification criteria. Indeed, determining “moderate” and “high” thresholds of non-ELISA aCL/aβ2GPI testing platforms was included in the final paper as one of the high-priority agenda items to guide the future updates of the criteria. Thus, a new international initiative, launched by the Laboratory Subcommittee of the 2023 ACR/EULAR APS Classification Criteria Steering Committee in collaboration with the ISTH-SSC LA/aPL Subcommittee and Antiphospholipid Syndrome Alliance for Clinical Trials and International Working (APS ACTION), is being developed.

Design and methodology

-A position paper describing the need for harmonization

-Collation of available data and published studies on efforts towards harmonization of aPL testing

-Use of available database of APS ACTION for data analysis on comparability of aPL and classification into low-medium-high titer ranges

-Use of international standard materials to compare quantitative (titer) results of different platforms

-Use of available previously collected patient samples to compare quantitative results of different platforms

-Investigation of the diagnostic usefulness of low-medium-high semiquantitative reporting and how this can be harmonized between different platforms

Study population

See study design

Expected timeline:

Project stage/set up: quartile 1 2024
Launch: quartile 2 2024
Duration: 2024-2026
Finalization/analysis 2026
Reporting 2025-2026

Expected outcomes (ie. publications)

A position paper, communication during SSC subcommittee session at the annual meetings of ISTH, guidance document on semiquantitative reporting

Publication type (SSC Communication, Guidance document or original article):

Guidance document on semiquantitative reporting of aPL

Description of project set/up and management, needed infrastructure and resources

The project is a collaborative initiative between three expert groups, with complementary expertise and strong collaborations, past and present. The infrastructure of the principal investigators and collaborators will be used to obtain the goals. Support of manufacturers will facilitate testing with different platforms on new cohorts of patients if needed.

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