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LO-033 TOWARDS A NOVEL CLINICAL OUTCOME ASSESSMENT FOR SYSTEMIC LUPUS ERYTHEMATOSUS TRIALS – FIRST OUTCOMES OF AN INTERNATIONAL CONSENSUS PROCESS

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Background Measurement of treatment effects in systemic lupus erythematosus (SLE) randomised controlled trials (RCTs) remains challenging. Current RCT endpoints are not based on contemporary outcome assessment methodology. We report the current status of a global academic-industry-patient partnership aiming to develop a novel, patient-centred clinical outcome assessment (COA) for SLE RCTs: Treatment Response Measure for SLE (TRM-SLE).

Methods We convened a global Taskforce of clinical-academic, metrology and regulatory experts, patient representatives and experts from ten pharmaceutical companies. A study protocol outlining a structured process for COA development was drafted and refined by TRM-SLE Taskforce members (figure 1), with reference to updated regulatory guidance. We next defined the high-level measurement goals for TRM-SLE using formal consensus methods, first by generating a conceptual definition using the PICO-C framework then establishing the context of use. Taskforce members participated in moderated discussion and real-time voting via virtual platforms with a pre-defined consensus threshold of 70% agreement.

Results A panel of 45 Taskforce members representing key stakeholder groups formulated the conceptual definition and context of use for TRM-SLE. Moderated discussion and multiple rounds of voting resulted in high agreement (81–100%, table 1). The current project phase (Aim 1.3) will establish consensus on the domain-level concepts to be measured by TRM-SLE. To date, TRM-SLE Taskforce members, including patients, have nominated 64 concepts, which have been grouped into a core list of 34 candidate domains.

Conclusions A global academic-industry-patient partnership has completed the first steps towards developing a novel SLE COA that is a quantitative measure of treatment response. Subsequent steps will combine consensus techniques with evaluation of supporting evidence, to determine the final set of concepts and associated measurements to be included in TRM-SLE. These measures will be integrated as a multi-domain COA in an SLE RCT endpoint that will be validated in clinical trials.

Abstract LO-033 Table 1 High level measurement goals for the TRM-SLE COA

PICO-C	Consensus Definition	Agreement
Patients/Population	SLE defined by criteria, with active immune-mediated disease manifestations modifiable by therapy	81%
Intervention	Treatment to reduce or control disease activity	92%
Comparator	Placebo and/or active comparator	96%
Outcome	The impact of an intervention on the patient, as measured by change in the concepts of interest	100%
Context	Clinical trials assessing efficacy and satisfying requirements for registration	96%
Context of Use	**Consensus Description**	**Agreement**
Targeted disease and study subpopulation	Adult and adolescent patients with criteria-defined SLE, with active disease in ≥1 included domain despite standard of care therapy	100%
Targeted study design and study setting	Randomised clinical trial (RCT) conducted in an outpatient setting, with the TRM-SLE instrument being the main outcome assessment within a primary efficacy endpoint with landmark analysis comparing meaningful response.	100%