What are the latest news about Sjögren with a special highlight on the European project NeceSSity

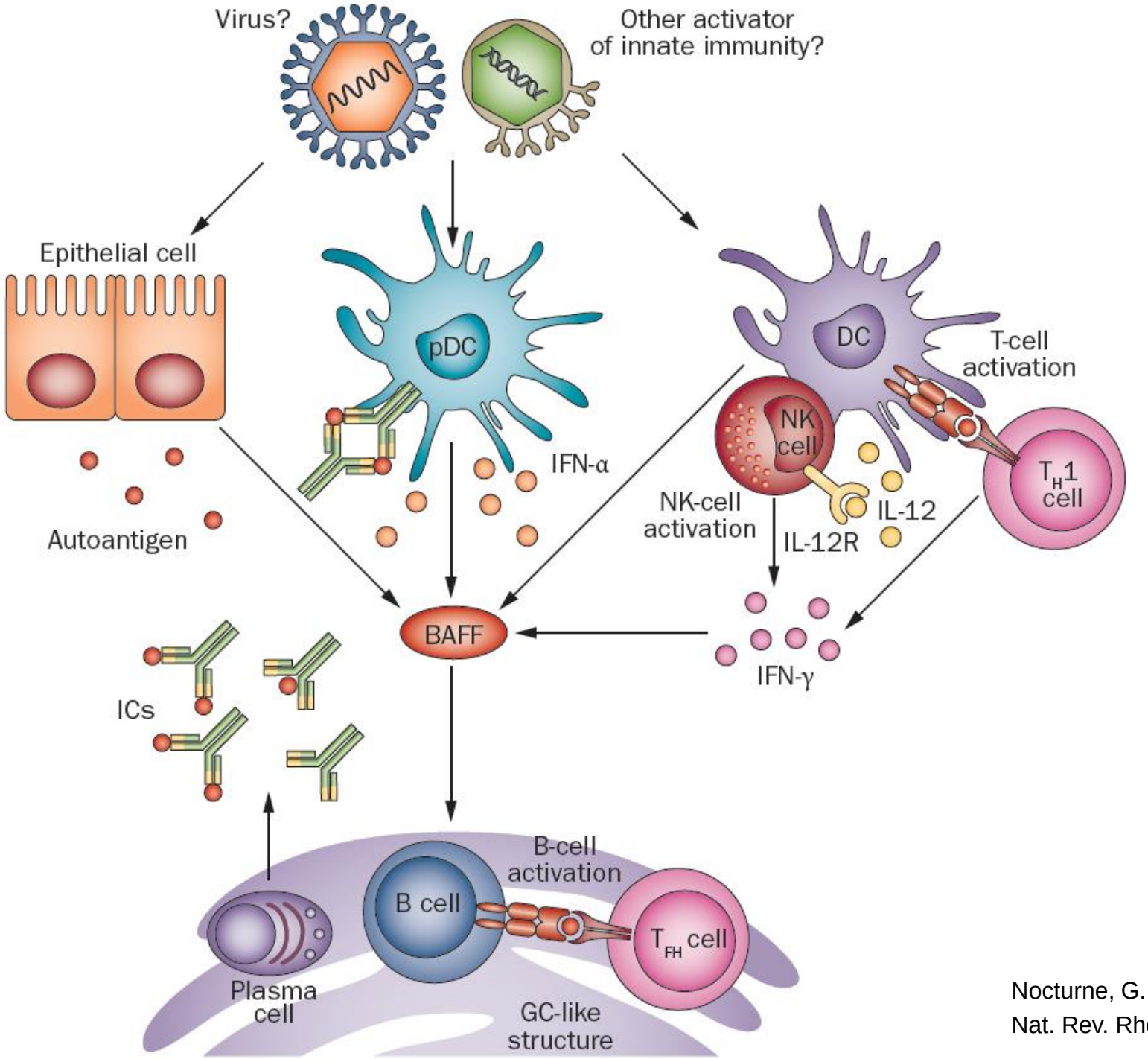
Sjögren Europe webinar April 28, 2022

Xavier Mariette
Hôpital Bicêtre, Assistance Publique-Hôpitaux de Paris,
Center for Immunology of Viral Infections and
Autoimmune Diseases INSERM U1184,
Université Paris-Saclay

- The mechanism of the disease is probably different in different subgroups of patients
  - Necessity of Stratifying the patients
- New promising drugs
- The NECESSITY project

- **The mechanism of the disease is probably different in different subgroups of patients**
  - **Necessity of Stratifying the patients**
- New promising drugs
- The NECESSITY project

Pathophysiology



Nocturne, G. & Mariette, X.
Nat. Rev. Rheumatol. 2013;9:544–556

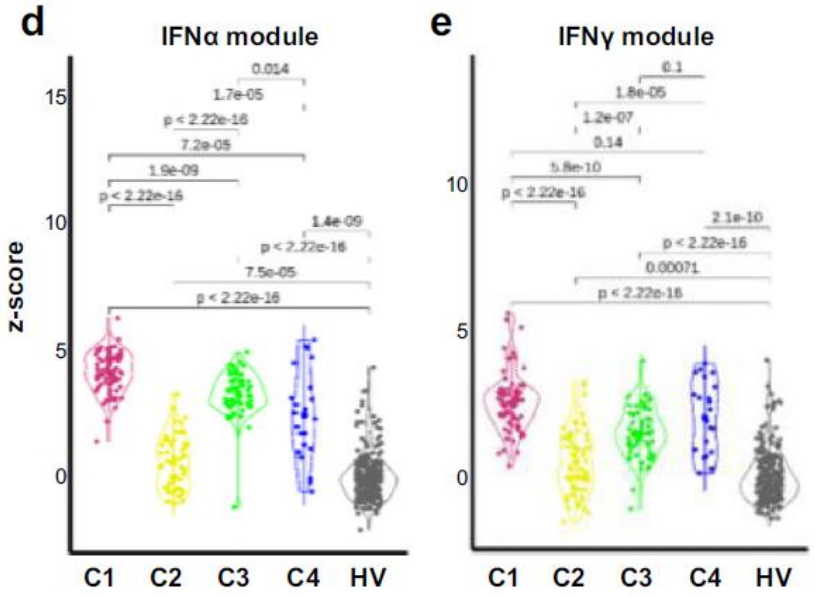
nature COMMUNICATIONS

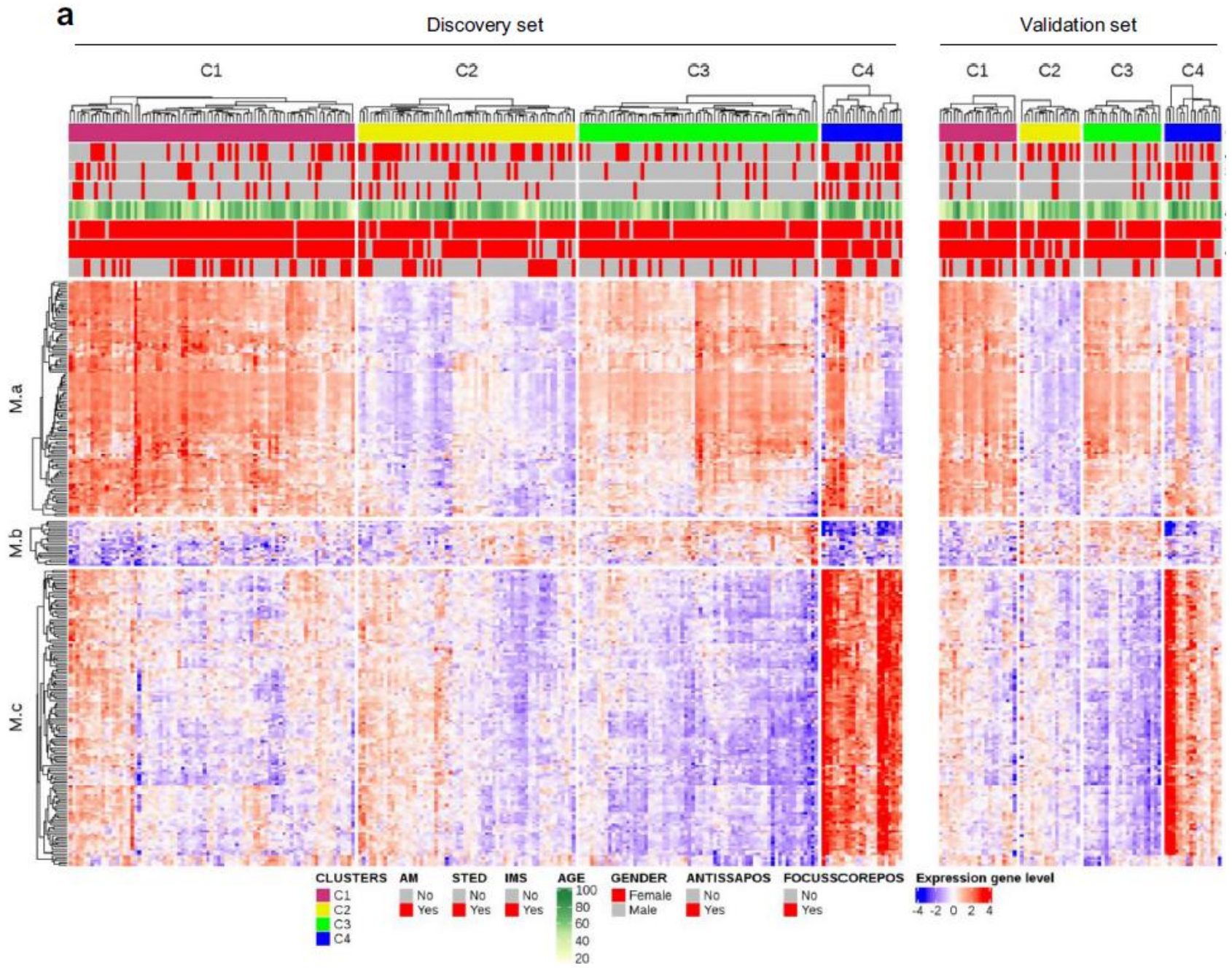
ARTICLE

https://doi.org/10.1038/s41467-021-23472-7 OPEN

A new molecular classification to drive precision treatment strategies in primary Sjögren's syndrome

Perrine Soret[1,29], Christelle Le Dantec[2,29], Emiko Desvaux[1,2], Nathan Foulquier[2], Bastien Chassagnol[1], Sandra Hubert[1], Christophe Jamin[2,3], Guillermo Barturen[4], Guillaume Desachy[1], Valérie Devauchelle-Pensec[2,3], Cheïma Boudjeniba[1], Divi Cornec[2,3], Alain Saraux[2,3], Sandrine Jousse-Joulin[2,3], Nuria Barbarroja[5], Ignasi Rodríguez-Pintó[6], Ellen De Langhe[7], Lorenzo Beretta[8], Carlo Chizzolini[9], László Kovács[10], Torsten Witte[11], PRECISESADS Clinical Consortium*, PRECISESADS Flow Cytometry Consortium*, Eléonore Bettacchioli[3], Anne Buttgereit[12], Zuzanna Makowska[12], Ralf Lesche[12], Maria Orietta Borghi[13], Javier Martin[14], Sophie Courtade-Gaiani[1], Laura Xuereb[1], Mickaël Guedj[1], Philippe Moingeon[1], Marta E. Alarcón-Riquelme[4], Laurence Laigle[1] & Jacques-Olivier Pers[2,3]✉

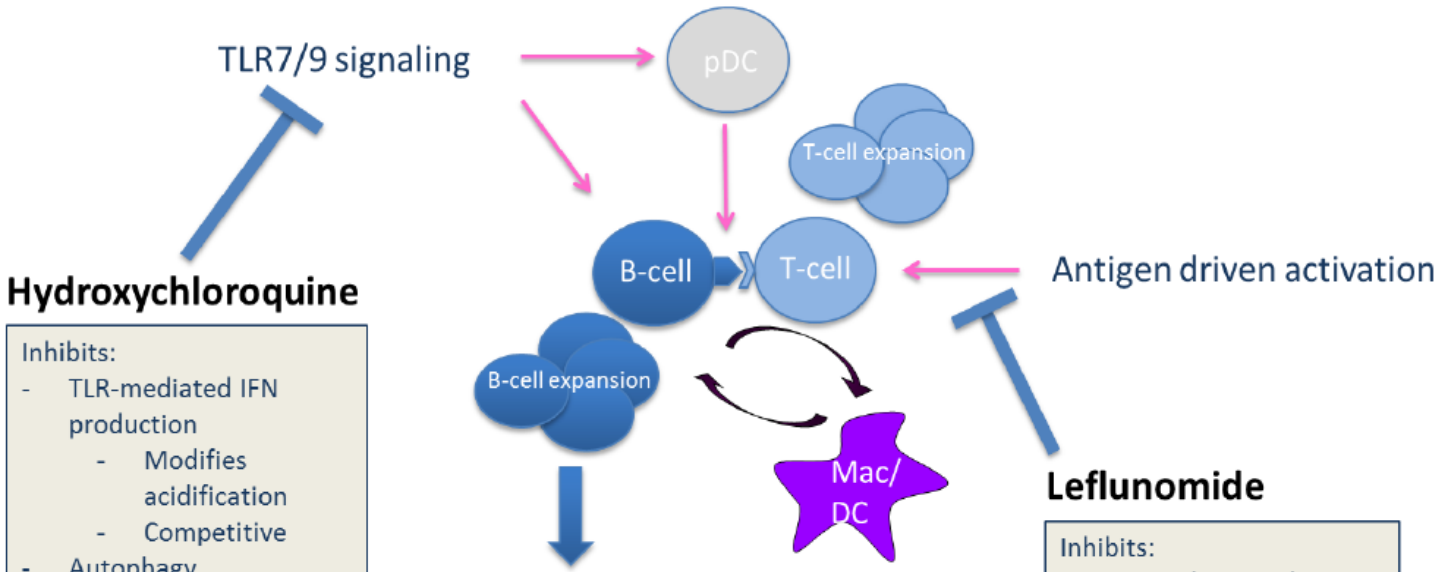




- The mechanism of the disease is probably different in different subgroups of patients
  - Necessity of Stratifying the patients
- **New promising drugs**
- The NECESSITY project

Combination of classical drugs targeting both B and T cells: HCQ + Leflunomide

Concept



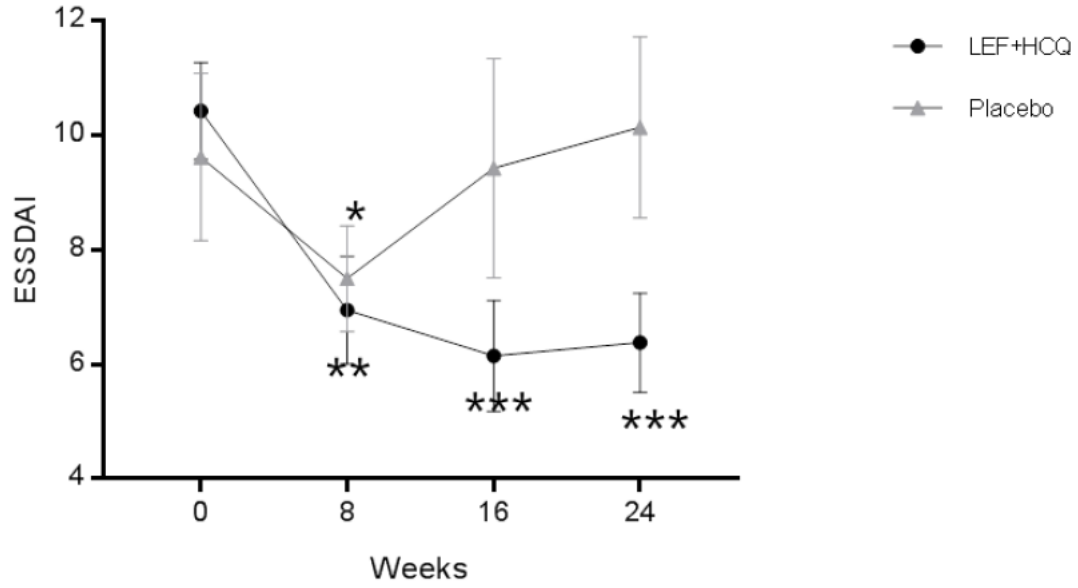
Hydroxychloroquine

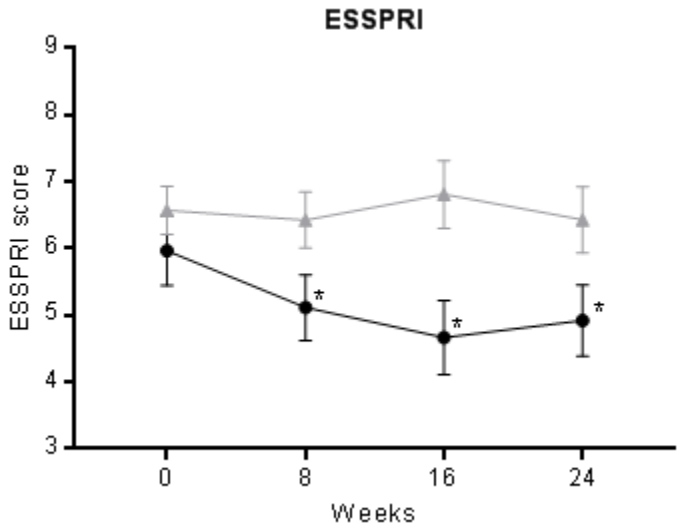
Inhibits:
- TLR-mediated IFN production
  - Modifies acidification
  - Competitive
- Autophagy
- IL-6 production
- B cell activation

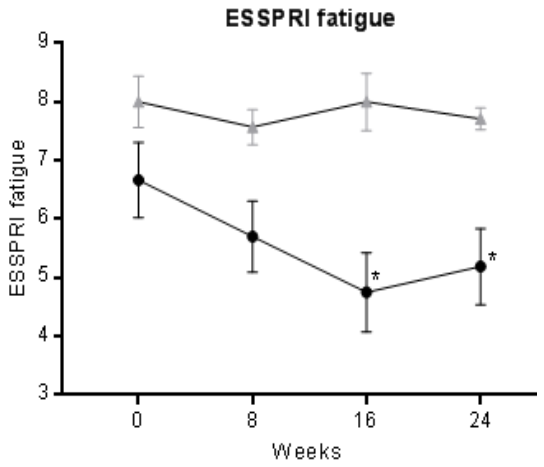
Leflunomide

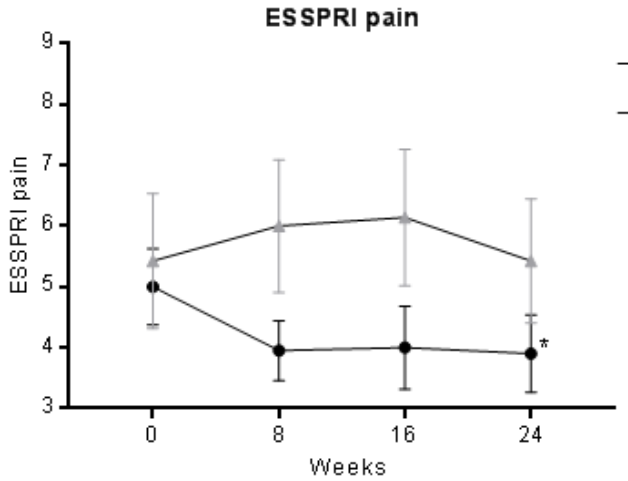
Inhibits:
- Pyrimidine synthesis (proliferation
- NF-kB/jakstat pathway
- Th1/Th17 activity
- B-cell activity

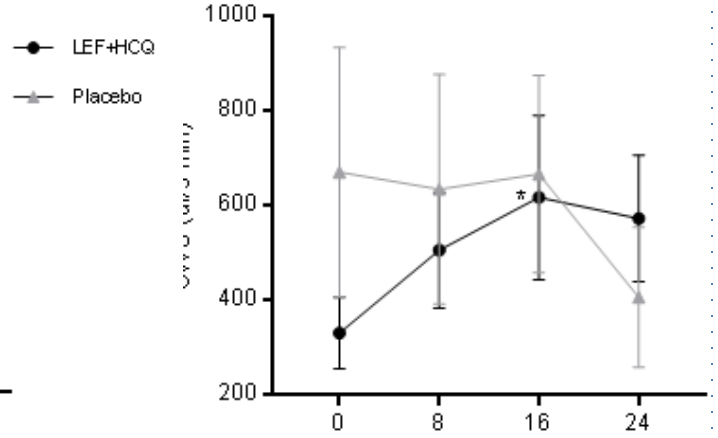
The main results of the LEF/HCQ RepurpSS-I study









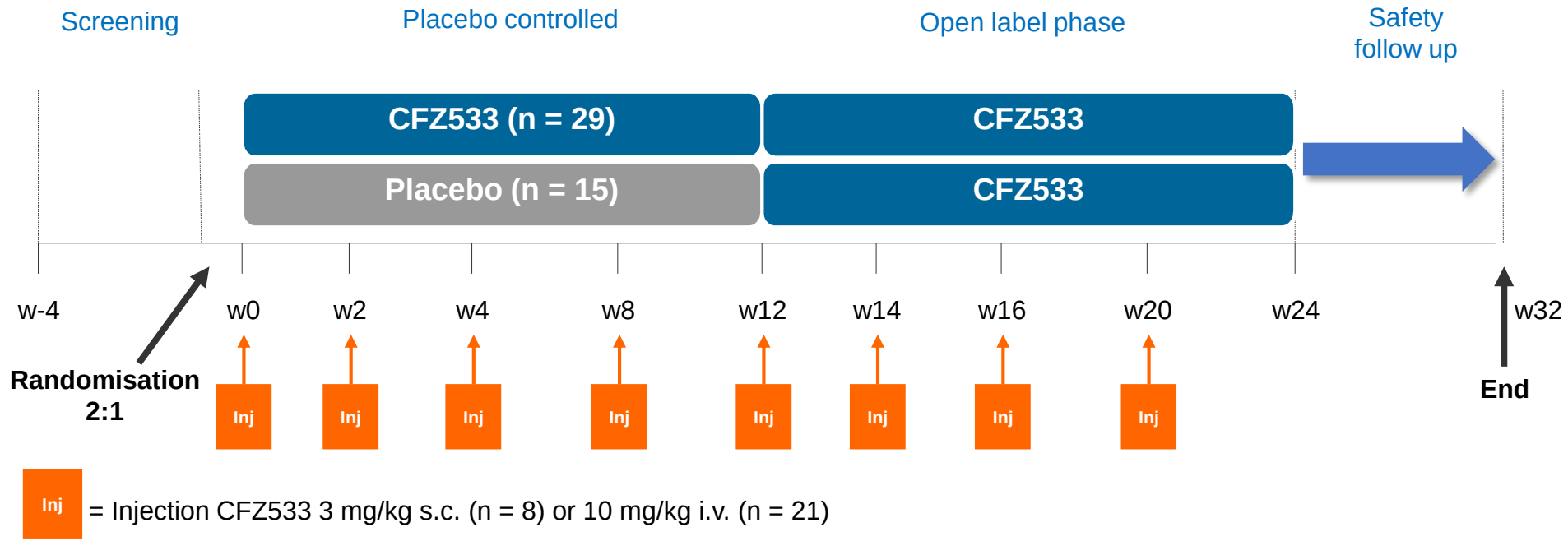


van der Heijden HM et al. Lancet Rheum, 2021

Iscalumab, anti-CD40 Ab, in primary Sjögren's syndrome

Phase IIa trial

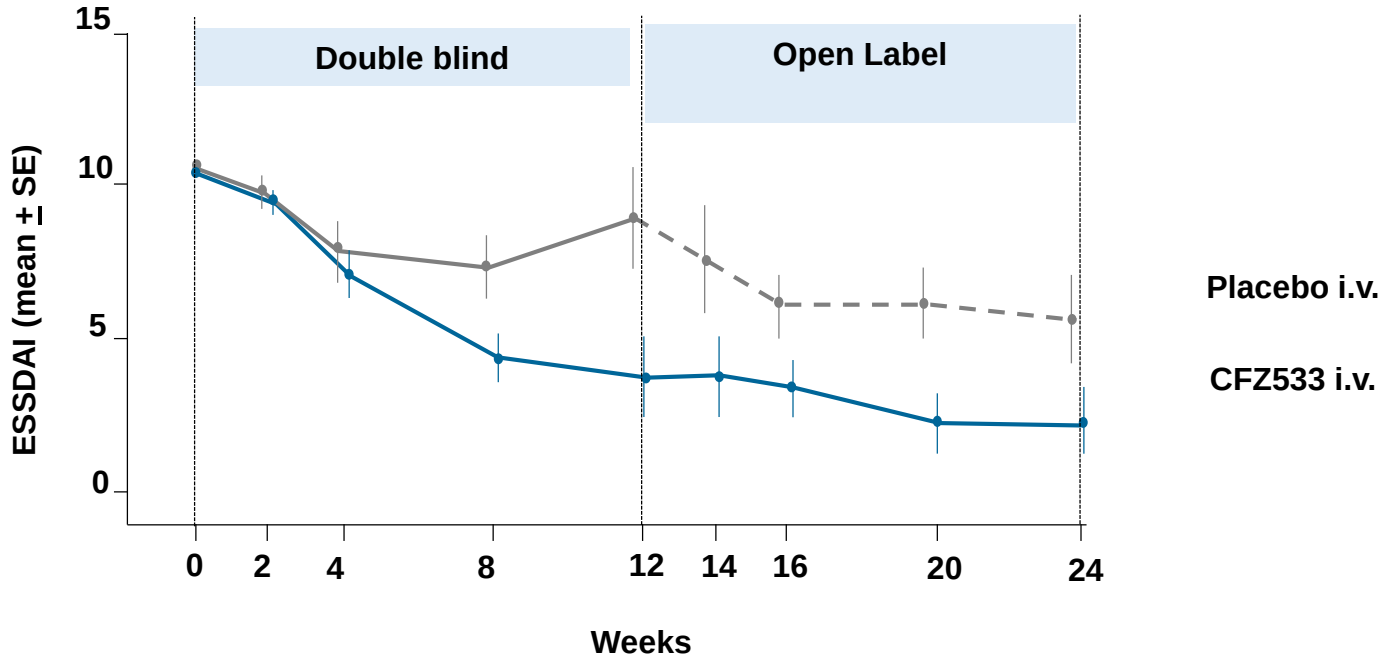
- CFZ533 monoclonal Ab against CD40 (costimulation – germinal centers)
- Inclusion Criteria : ESSDAI ≥ 6
  - age : 51 yrs ; women : 94 %
  - Mean ESSDAI = 10,7 (± 4,6) ; mean ESSPRI = 6,9 (± 1,6)
- Ouctome : change in ESSDAI score at W 12



Fisher B et al. Lancet Rheum, 2021

Iscalumab, anti-CD40 Ab, in primary Sjögren's syndrome

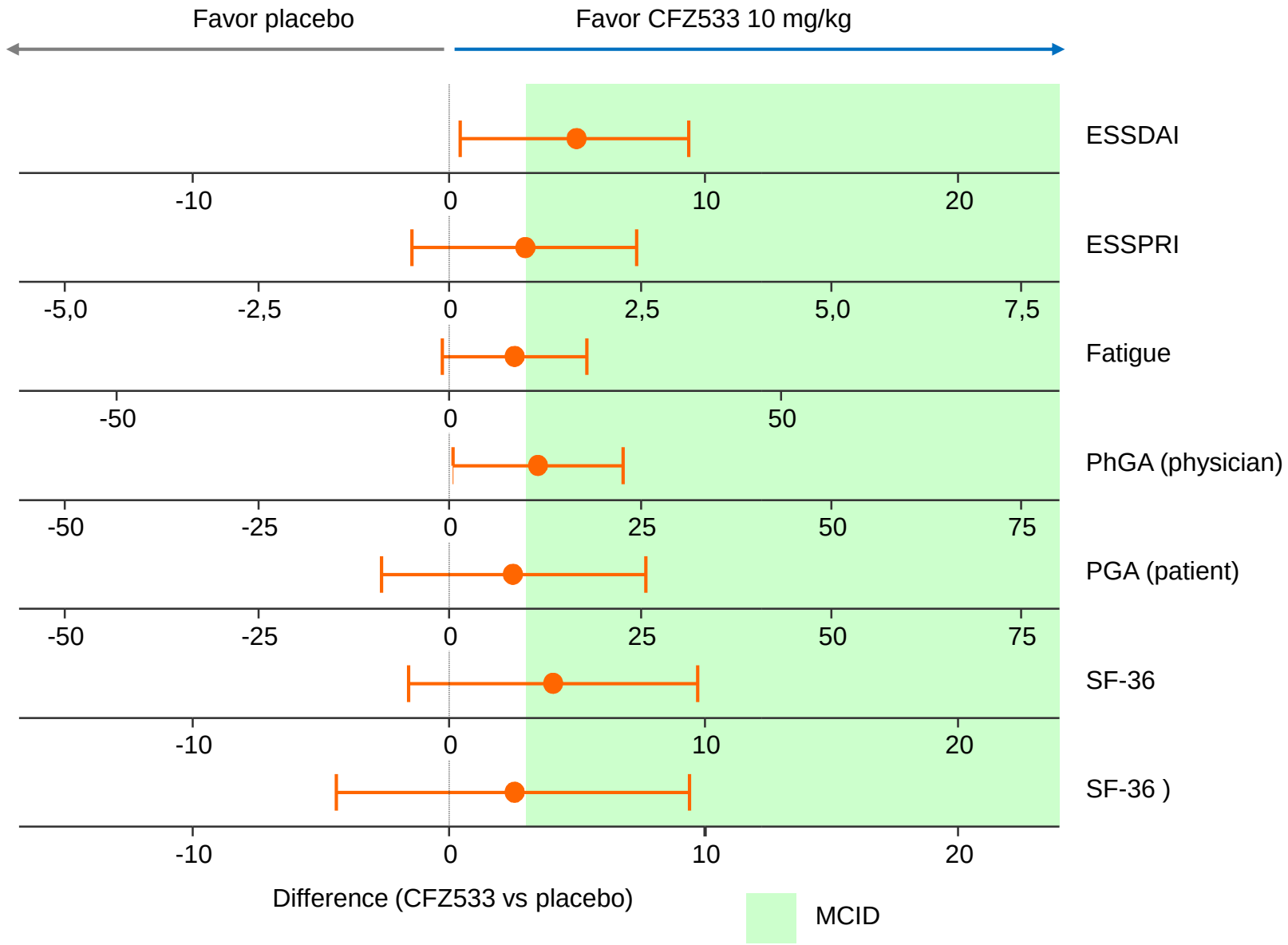
- Significant improvement of ESSDAI in the 10 mg/kg i.v. groups
- **ΔESSDAI = 5,64 à S12 (IC_{95} : 1,02-10,58)**



- Insufficient effect in the 3 mg/kg s.c.
  - ΔESSDAI = 0,68 ; IC_{95} : -4,71 ; -6,46)
- Good safety profile: 1 SAE (atrial fibrillation)

Fisher B et al. Lancet Rheum, 2021

Iscalumab, anti-CD40 Ab, in primary Sjögren's syndrome



Fisher B et al. Lancet Rheum, 2021

Safety and Efficacy of Subcutaneous Belimumab and Intravenous Rituximab Combination in Patients With Primary Sjögren's Syndrome: A Phase 2, Randomised, Placebo-Controlled 68-Week Study

OP0135

Xavier Mariette[1], Chiara Baldini[2], Francesca Barone[3], Hendrika Bootsma[4], Kenneth L Clark[5], Salvatore DeVita[6], Karoline Lerang[7], Prafull Mistry[8], Frederic Morin[9], Raj Punwaney[10], Raphaele Seror[1], Paul L A van Daele[11], André van Maurik[12], Nicolas Wisniacki[13], David A Roth[14]

[1]Department of Rheumatology, Université Paris-Saclay, Paris, France; [2]Centro Farmacologia Clinica AOUP, Rheumatology Unit, Department of Clinical and Experimental Medicine, University of Pisa, Pisa, Italy; [3]College of Medical and Dental Sciences, Department of Rheumatology, University of Birmingham, Birmingham, UK; [4]University Medical Center Groningen, Department of Rheumatology and Clinical Immunology, University of Groningen, Groningen, The Netherlands; [5]GlaxoSmithKline, Clinical Science, Stevenage, Hertfordshire, UK; [6]Azienda Ospedaliera Universitaria di Udine, Rheumatology Clinic, Department of Medical Area, Udine, Italy; [7]Oslo University Hospital, Department of Rheumatology, Oslo, Norway; [8]GlaxoSmithKline, R&D Biostatistics, Stevenage, Hertfordshire, UK; [9]Centre de Recherche Musculo-Squelettique, Trois Rivieres, QC, Canada; [10]GlaxoSmithKline, Pharmaceutical Research and Development, Philadelphia, PA, USA; [11]Erasmus Medical Center, Department of Internal Medicine and Department of Immunology, Rotterdam, The Netherlands; [12]GlaxoSmithKline, Clinical Pharmacology and Experimental Medicine, Stevenage, Hertfordshire, UK; [13]GlaxoSmithKline, Discovery Medicine, Stevenage, Hertfordshire, UK; [14]GlaxoSmithKline, Research and Development, Collegeville, PA, USA

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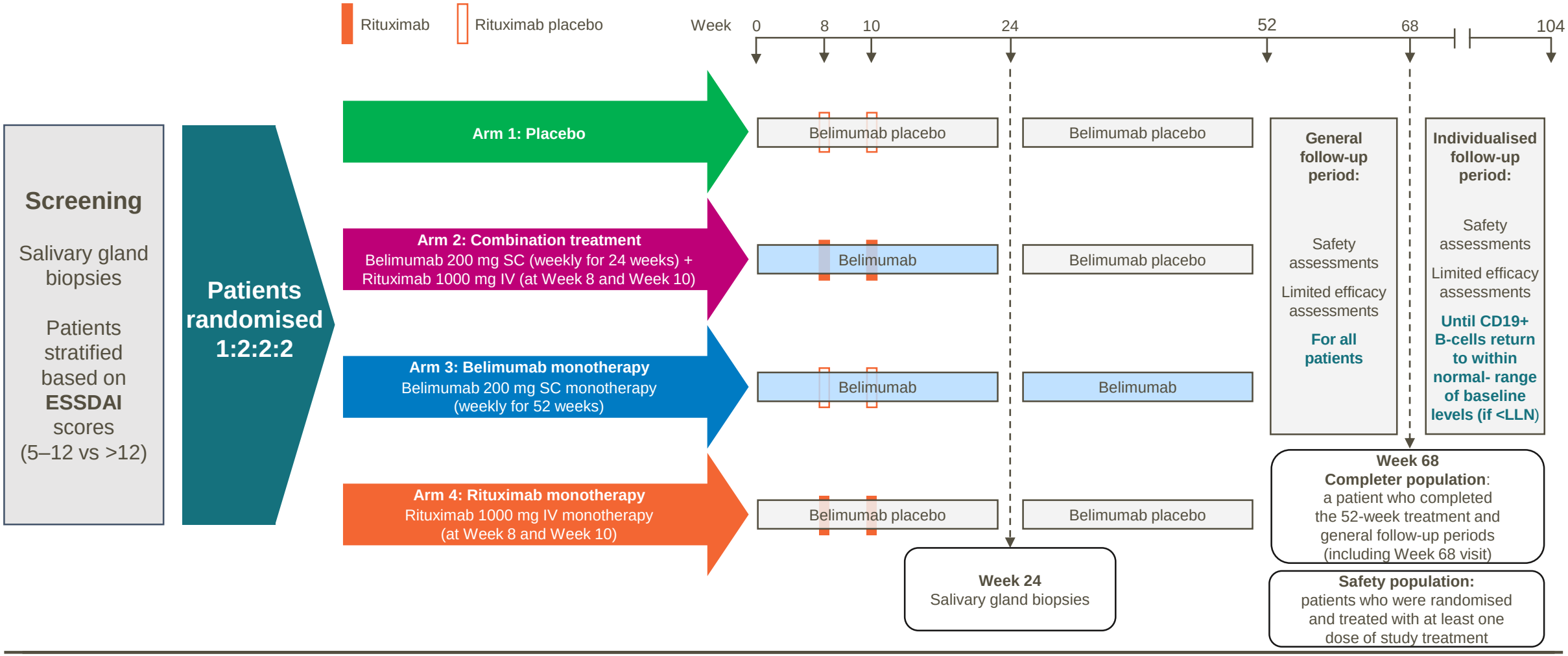
Study Design



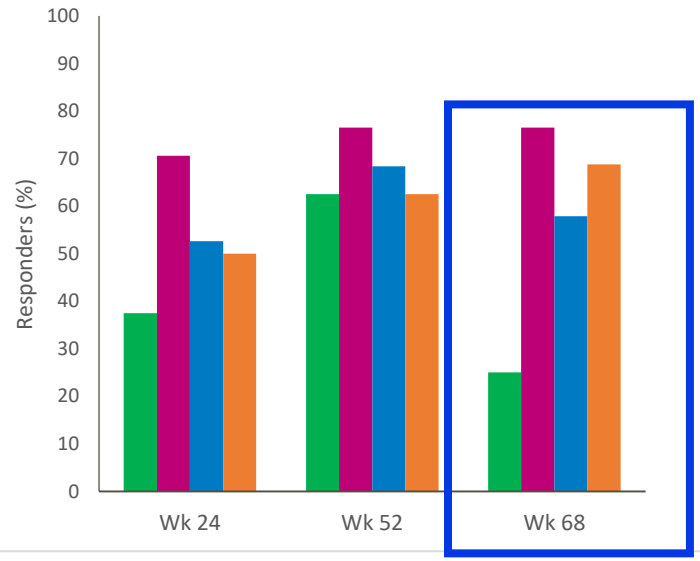
ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; EULAR, European League Against Rheumatism; IV, intravenous; LLN, lower limit of normal; SC, subcutaneous

Efficacy: ESSDAI Responder Analysis (Completer Population)

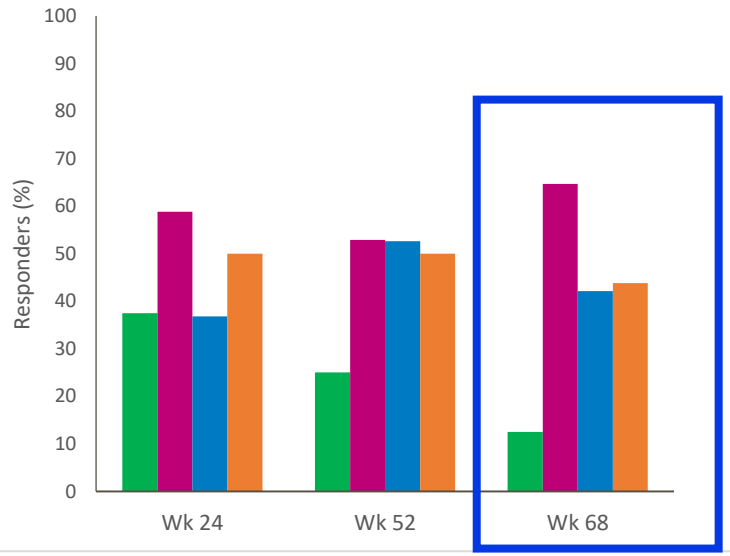
At Week 52, there was a **numerically higher proportion** of responders in the **belimumab/rituximab** group than in the placebo group; this trend was sustained to Week 68

This trend was also observed for the belimumab and rituximab groups versus the placebo group

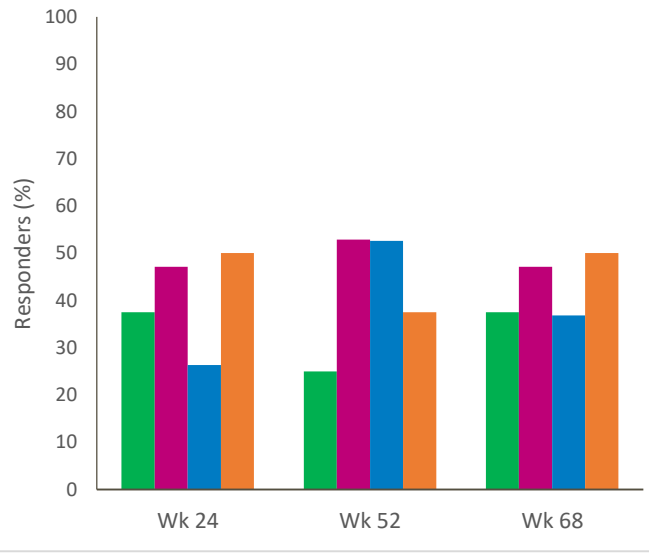
Percentage of ESSDAI responders (≥3-point improvement vs. baseline)



Percentage of ESSDAI responders (≥5-point improvement vs. baseline)



Percentage of ESSDAI responders (total score <5)

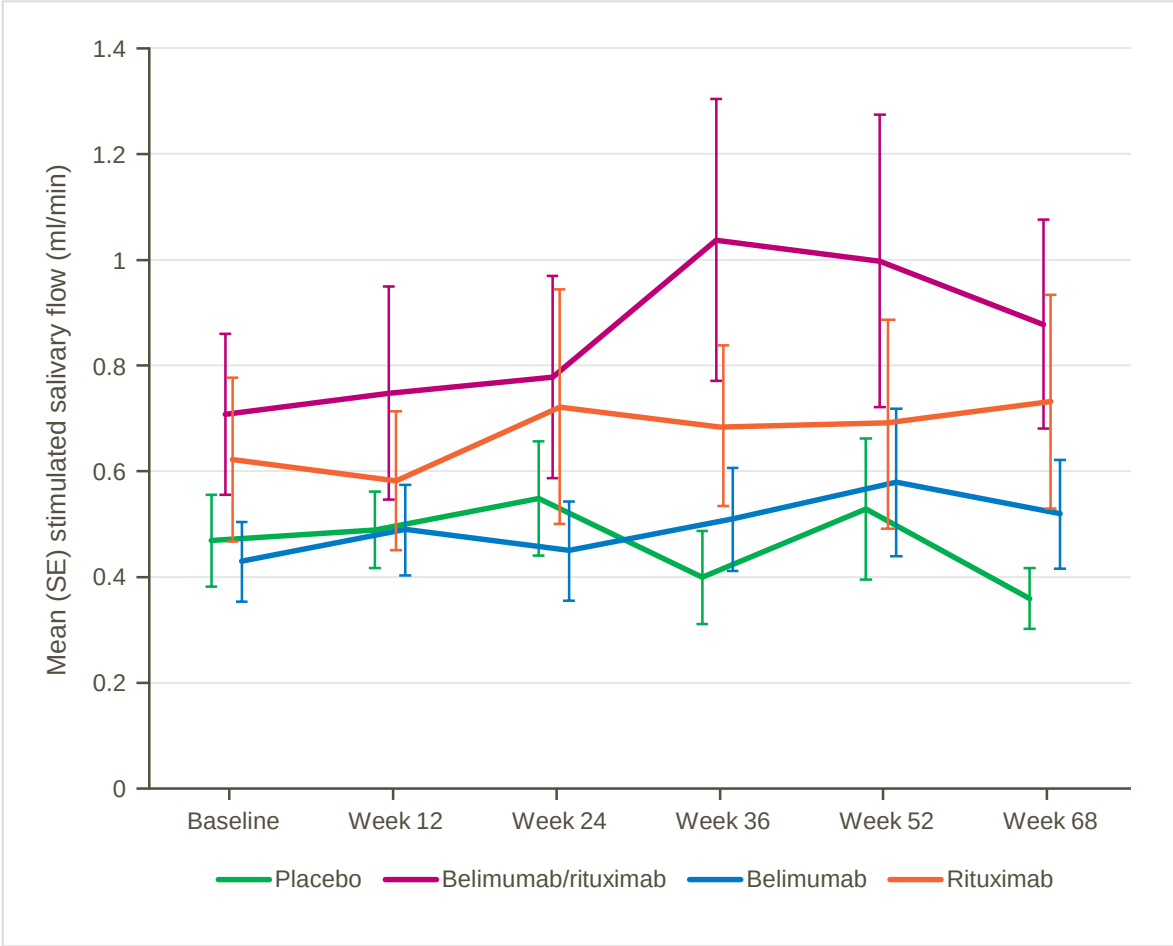


Placebo | Belimumab/rituximab | Belimumab | Rituximab

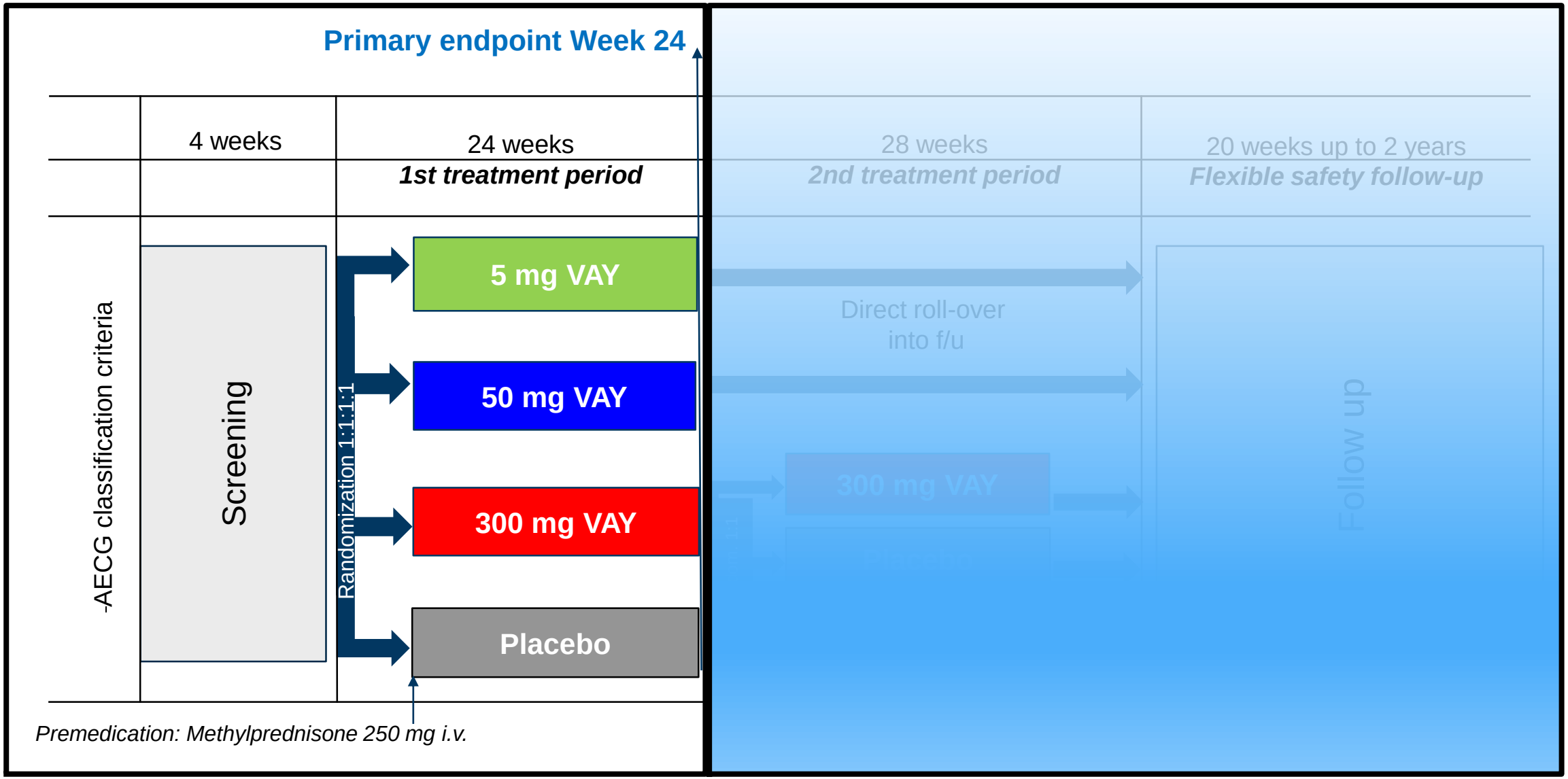
Efficacy: Stimulated Salivary Flow (Completer Population)

At Weeks 36, 52 and 68, the **stimulated salivary flow rate** showed a trend for numerically **greater increases** in the **belimumab/rituximab group** compared with the placebo group

Changes in stimulated salivary flow rate throughout the study were similar between the placebo and monotherapy groups



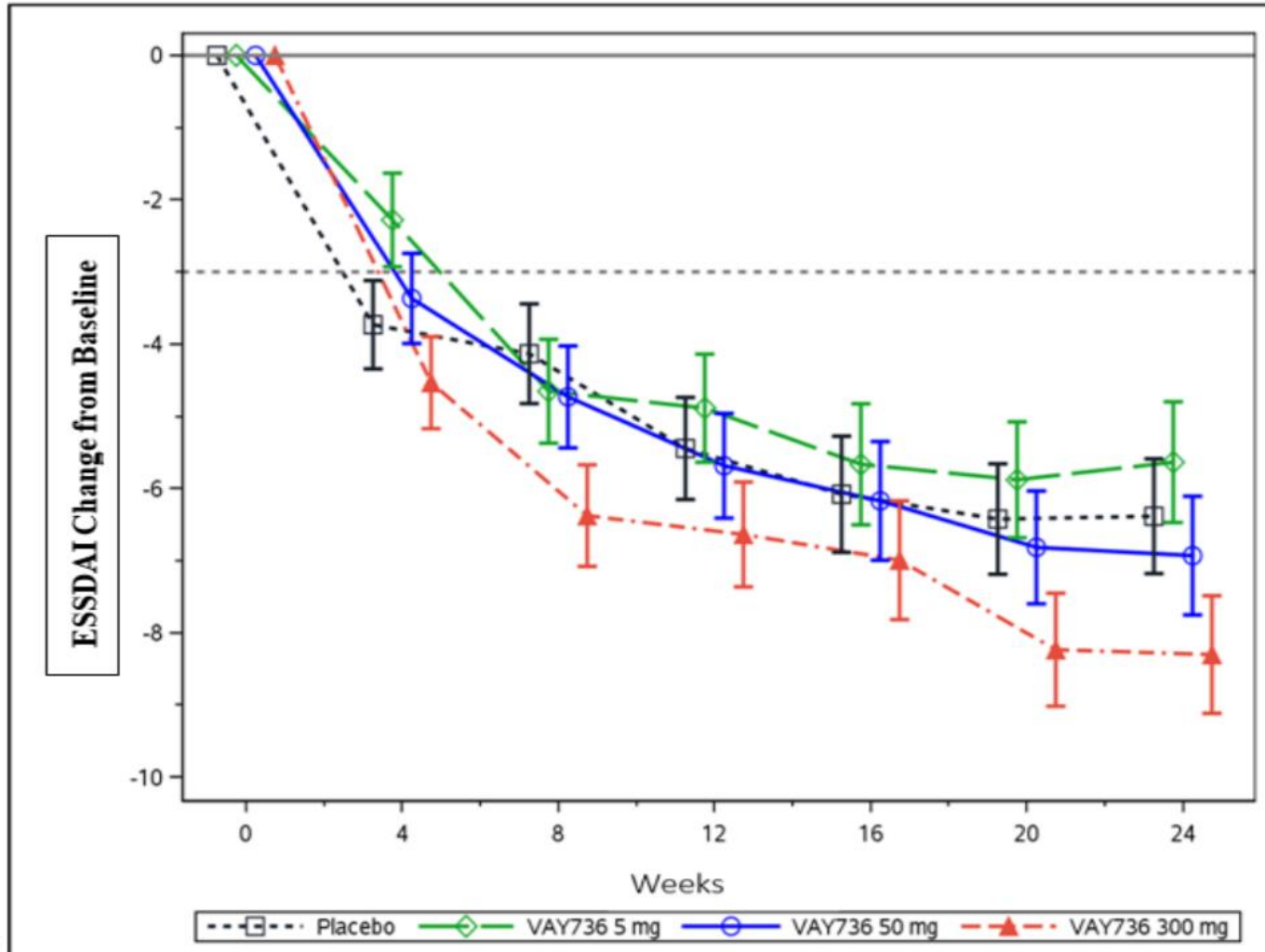
Ianalumab (anti-BAFF-R receptor) - Study design

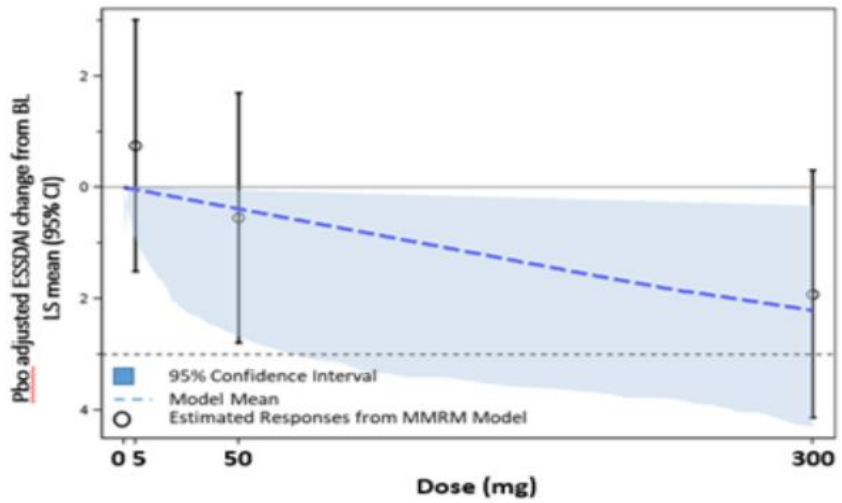


AECG, American European Consensus Group

Bowman S et al. The Lancet 30 Nov 2021

ESSDAI Change from Baseline over Time up to Week 24 Reveals a Statistically Significant Dose Response Relationship*





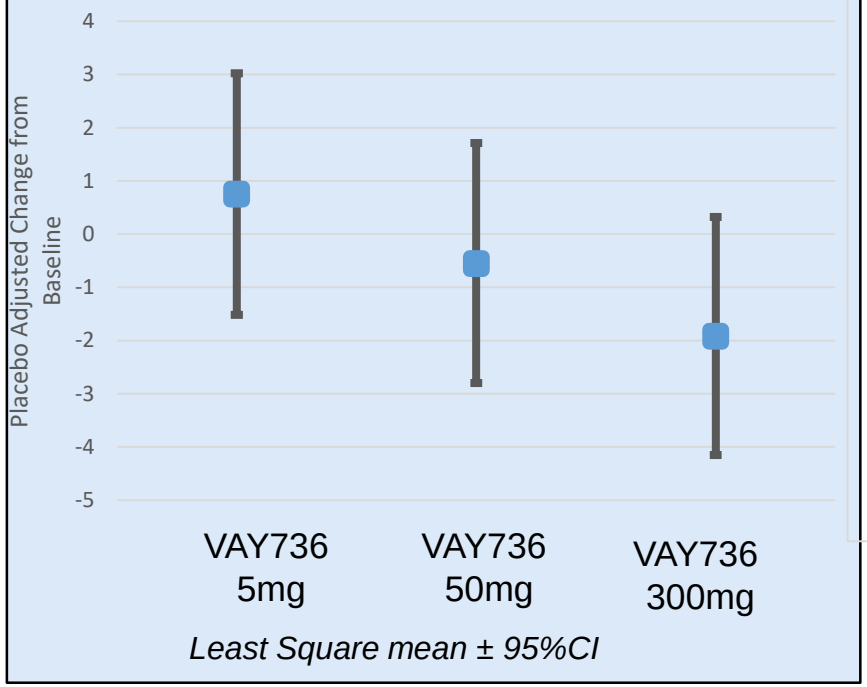
Model	T-Statistics	Adjusted P-Value
Emax1 (ED50=10)	1.816	0.0598
Emax2 (ED50=50)	2.204	**0.0249**
Linear	2.232	**0.0231**
sigEmax1 (ED50=50, h=5)	2.294	**0.0205**
sigEmax2 (ED50=100, h=3)	2.214	**0.0244**

***The simulated dose response is based on model average method through bootstrapping technique.**
ESSDAI, EULAR Sjogren's Syndrome Disease Activity

Bowman S et al. The Lancet 30 Nov 2021

ESSDAI – Efficacy at Week 24 (Secondary analysis)

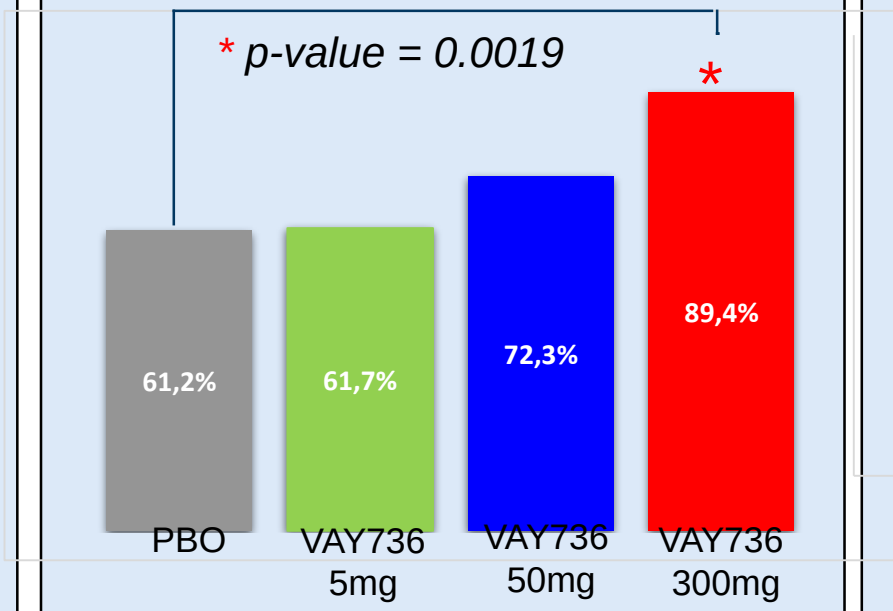
The largest treatment effect was minus 1.92 points with ianalumab 300 mg over Pbo



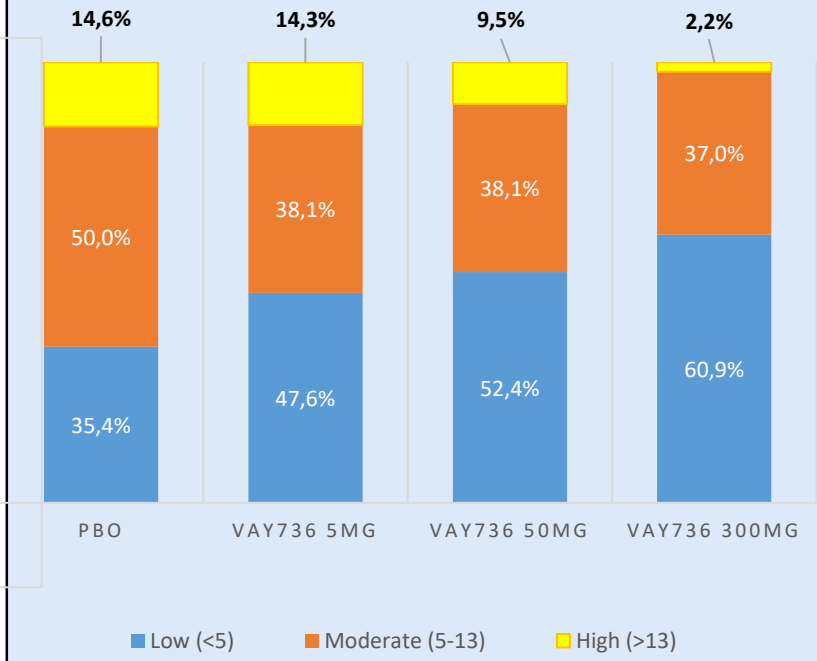
Least Square mean ± 95%CI

Responder Analysis: Statistically significant difference for ianalumab 300 mg vs Pbo

Responders are defined as follows: ≥ 3 points reduction from baseline for ESSDAI



More patients achieved low disease activity on ianalumab



ESSDAI, EULAR Sjogren's Syndrome Disease Activity; Pbo, placebo

Bowman S et al. The Lancet 30 Nov 2021

The recent RCT in Sjögren's

Study	Drug	Sponsor	N	Inclusion criteria	Primary endpoint	Estimated completion
NCT02291029	**anti-CD40** Ab Phase 2	Novartis	44	**ESSDAI ≥ 6**	**ESSDAI change W12**	**Completed and positive**
NCT02334306	**anti-ICOS-L** mAb Phase 2	MedImmune /Amgen	32	**ESSDAI ≥ 6.** Anti-SSA/SSB and IgG> 16 g/L or RF +	**ESSDAI change D99**	**Completed and negative**
NCT01782235 ETAP	**Tocilizumab** Phase 2	Strasbourg University	110	**ESSDAI ≥ 5** Anti-SSA/SSB	**Improvement ESSDAI ≥3**	**Completed and negative**
NCT02149420	**anti-BAFF-R** m Ab Phase 2B	Novartis	70	**ESSDAI ≥ 6** Anti-SSA/SSB Sal. flow>0	**ESSDAI change W12**	**Completed and positive**
NCT	**HCQ + LEF** Phase 2	Utrecht University	29	**ESSDAI ≥ 5**	**ESSDAI W24**	**Completed and positive**
NCT02915159	**Abatacept** Phase 3	BMS	172	**ESSDAI ≥ 5** Anti-SSA	**ESSDAI D169**	**Completed and negative**
EUCTR2014-004523-51-GB	**Pi3 kinase inhibitor** Phase 2	UCB	58	**ESSDAI ≥ 5** Anti-SSA/SSB Sal. flow>0	**ESSDAI change W12**	**Completed and negative**
NCT02631538	**belimumab and rituximab co-administration** Ph2	GlaxoSmith-Kline	70	**ESSDAI ≥ 5** Anti-SSA/SSB Sal. flow>0	**SAEs at W104**	**Completed and positive**
NCT03100942	**Filgotinib (Jak-i) Lanraplenib (Syk-i) Tirabrutinib (Btk-i)**	Gilead Galapagos	152	**ESSDAI ≥ 5** Anti-SSA/SSB	**composite improvement of biologic and PRO**	**Completed and negative**

Conclusion REVIEWS

Check for updates

Current and future therapies for primary Sjögren syndrome

Raphaèle Seror[1,2], Gaetane Nocturne[1,2] and Xavier Mariette[1] ✉

Classification based on the immunophenotype of the disease has improved

- Interferon type 1 or type 2
- T cells
- B cells
- Plasma cells

We have drugs dedicated to each of these pathways

The challenge:

- To get reliable biomarkers of each of these phenotypes
- To design stratified trials based on these biomarkers with specific drugs

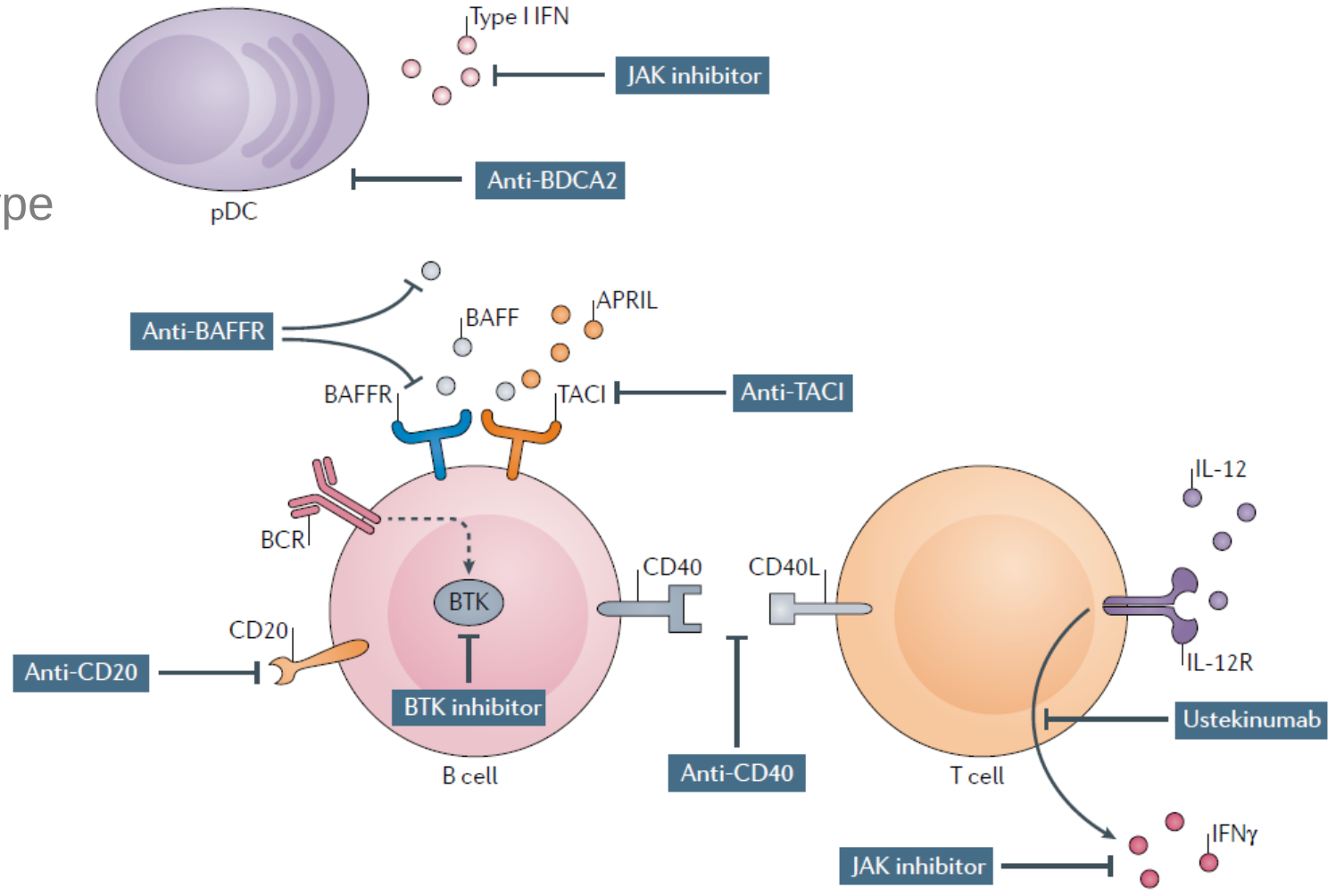


Fig. 1 | **New therapeutic targets in primary Sjögren syndrome.** Advances in understanding the pathogenic processes

Seror R at al, Nat Rev Rheumatol. 2021 Aug;17(8):475-486.

- The mechanism of the disease is probably different in different subgroups of patients
  - Necessity of Stratifying the patients
- New promising drugs
- **The NECESSITY project**

Title: NEw Clinical Endpoints in primary Sjögren's Syndrome: an Interventional Trial based on stratifYing patients

Acronym: NECESSITY

Funded by IMI (European Commission) and EFPIA (Consortium of pharma industries)

Leader: Novartis: P Gergely Coordinator: INSERM: X Mariette

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 806975. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA. The present communication reflects only the author's view and the JU is not responsible for any use that may be made of the information it contains. www.imi.europa.eu

The vision

Sjögren's: burden for patients and associated direct and indirect costs for society are considerable

High unmet need: still no disease-modifying therapies licensed for pSS patients

Why?

- **Primary endpoints used in pSS studies have limitations**
  - ESSDAI (measuring disease activity) lacks specificity (high placebo response rates)
  - Several important clinical features are not (well) captured in the ESSDAI score
    - Oral and ocular function, markers for autoimmunity and B cell hyperactivity
  - ESSDAI lacks meaningfulness to patients
    - Symptoms are assessed in ESSPRI and not in ESSDAI
    - Improvement in ESSDAI does not translate to symptom improvement measured by ESSPRI

  ⇒ *Need for a validated composite endpoint to assess all facets of pSS*

- **Targeted biological therapies may work on a subset rather than the entire population**
  - Clinical heterogeneity is high in pSS, design of studies is difficult

  ⇒ *Need for biomarkers for stratification of patients*
  - No validated surrogate clinical endpoint available for clinical studies

  ⇒ *Need for biomarkers predictive of response to treatment*

necessity

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The Consortium

20 ACADEMIC PARTNERS

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Karolinska Institutet

Newcastle University

Les Hôpitaux Universitaires de STRASBOURG

UMC Utrecht

UBO Université de Bretagne Occidentale

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NOVARTIS

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imi innovative medicines initiative efpia

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Objectives

Objective 2: **To identify and evaluate discriminative biomarkers for stratification** of pSS patients predictive of drug response (and thus available for inclusion in clinical trials),

Objective 1: **To develop and assess sensitive clinical endpoints for use in future clinical trials** to evaluate response to drug treatments in patients with primary Sjögren's syndrome (pSS) with high disease burden and/or systemic involvement,

Objective 3: **To set-up and perform** an original multi-arm multi-stage (MAMS) **clinical trial to validate the newly defined pSS endpoints and the identified biomarkers**, by maximizing the chance of finding a difference between the placebo arm and the treated arm.

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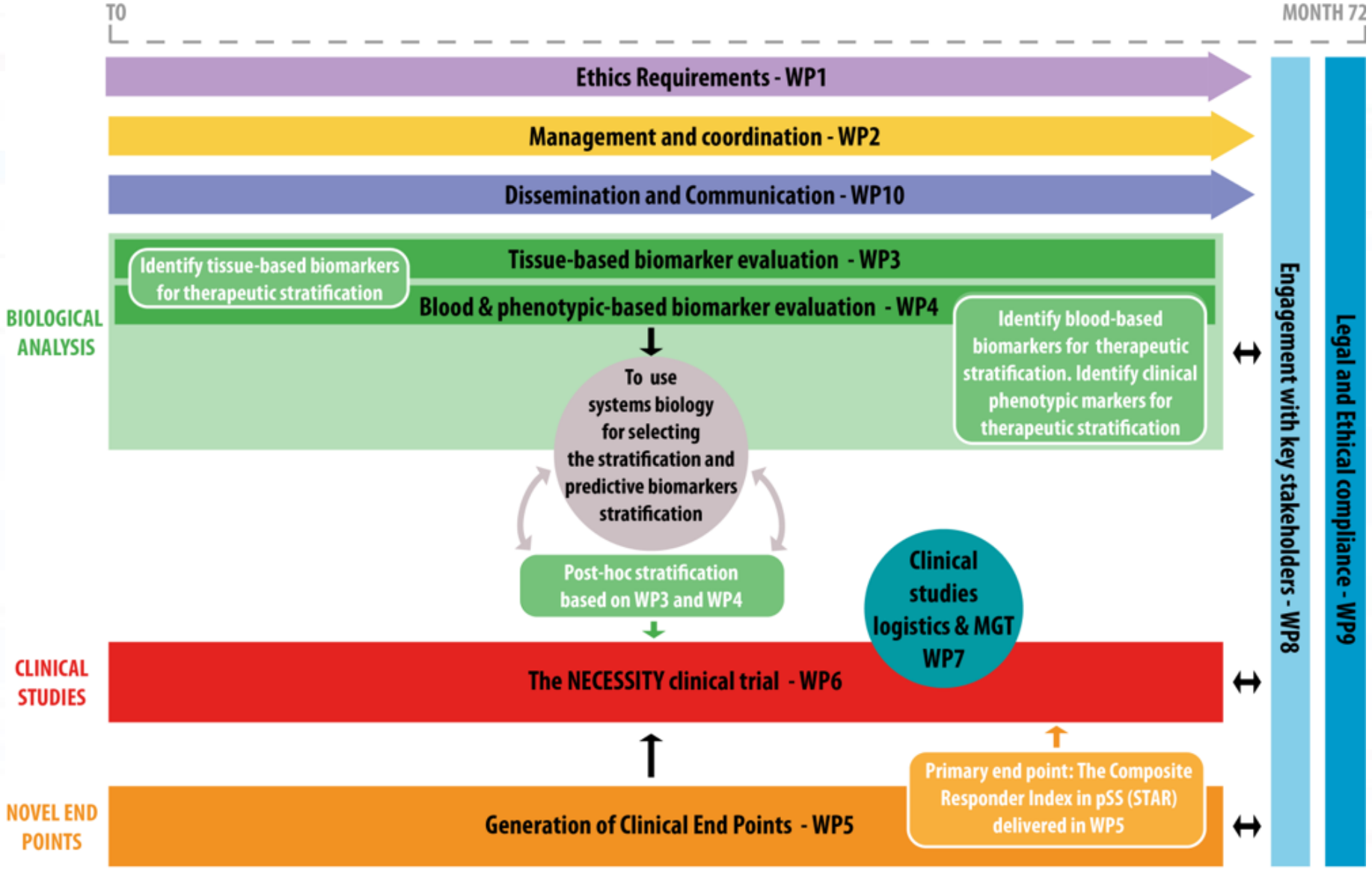
The project

72 months
Jan 2019 – Dec 2024
10 Work packages
15.4M€
8.2M€ EU
7.2M€ EFPIA



necessity

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Progress towards objective 1: novel biomarkers

The NECESSITY data warehouse on tranSMART was set up (D4.1).
A preliminary list of tissue biomarkers was identified (D3.1).
A preliminary list of blood biomarkers was identified (D4.3).

- Successful sharing of samples and data
  - Datasets: 9 academic and 1 industry studies (1 more pending)
  - Samples: 6 academic and 2 industry studies
- 3 publications, 1 manuscript in preparation

Issue/concern:

- Delays due to COVID-19 pandemic (more on this in WP2)

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Progress towards objective 2: novel endpoint STAR

The candidate STAR is ready (D5.1).

- Data sharing
  - 9 datasets: 7 academic and 3 industry studies
- Scientific contribution
  - 53 academic and 11 industry partners
  - Regulatory and payers' through WP8 activities
- Patients contribution
  - 20 patients
- Agreement from the European Medicines Agency for a Letter of support
- Manuscript has been published on April 7 in The Annals of Rheumatic Diseases (top 1 Rheumatology journal)
- On-going discussion with OMERACT for a possible endorsement of STAR

Objective 1 is met.

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ADDRESSING THE CHALLENGES IN DRUG DEVELOPMENT

Primary endpoint

ESSDAI and ESSPRI: current measures selected as primary endpoint :

- Consensually developed and validated
- MCID available

Limitations of ESSDAI:

- Promising recent trials, however many trials failed due to lack of sensitivity
- Does not measure symptomatic improvement
- Only relevant for patients with moderate to high systemic activity disease

Limitations of ESSPRI:

- No clear effect detected to date on ESSPRI in most of current clinical trials

Need for a unique score to measure both systemic and symptoms and include important but not well captured features (i.e. glandular function)

Patient stratification

- Heterogeneous patient population
- Recent work showed 4 subgroups of patients based on symptoms
- Could respond differently to treatment

Need for stratification biomarkers to optimize design of clinical trials

Evaluation of all features of pSS

- Symptoms are very variable from day to day
- No objective measure of fatigue, one of the three mots important symptoms of pSS
- Lack of validated procedures for evaluating improvement of glandular function

Need for more assessment procedures validated in pSS

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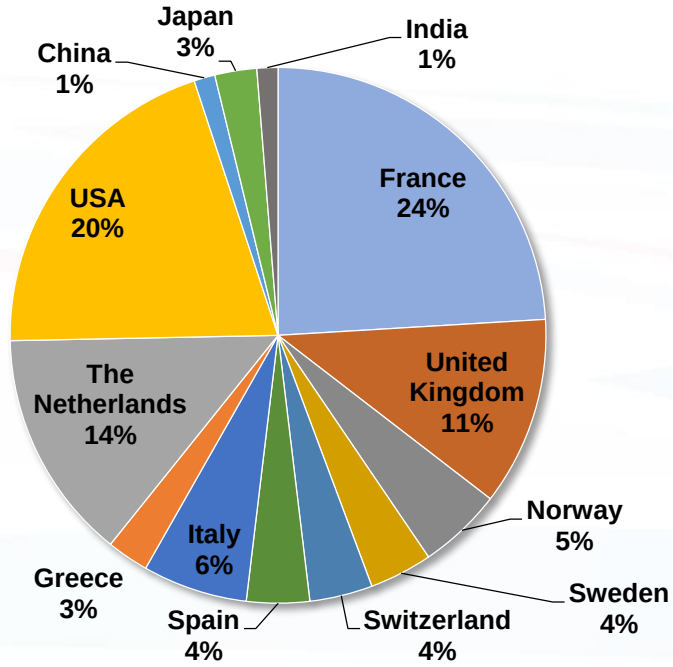
NEW CLINICAL OUTCOME:
SJÖGREN'S TOOL FOR ASSESSING RESPONSE TO TREATMENT (STAR)

Methodology

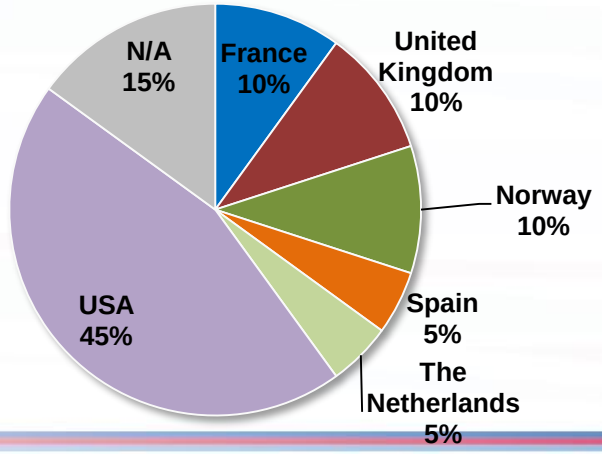
- **Data, patient, and expert driven**
  - Analysis on dataset from **9 clinical trials**
  - Consensual building through iterative rounds of **Delphi process**

Trial	Arms	N patients
TEARS	RTX/Placebo	120 (1:1)
TRACTISS	RTX/Placebo	133 (1:1)
ETAP	Toci/placebo	110 (1:1)
JOQUER	HCQ/Placebo	120 (1:1)
ASAP-III	ABA/Placebo	88 (1:1)
Baminercept	Baminercept/Placebo	52 (2:1)
Anti-CD40 PoC Novartis	Anti-CD40/PBO Cohort 1 and 2	69 (2:1)
Anti-BAFFR PoC Novartis	Anti-BAFFR/PBO Cohort 1 and 2	25 (1:1)
RepurpSS-I	HCQ+LEF/PBO	29 (2:1)

EXPERTS
N = 79
Mean years of experience = 18,9



PATIENTS
N = 20
Mean age (years) = 58,3



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NEW CLINICAL OUTCOME:
SJÖGREN'S TOOL FOR ASSESSING RESPONSE TO TREATMENT (STAR)

Development of preliminary STAR

Step 1: Identification of domains to include in STAR (core set)

Step 2: Construction of STAR options from different combinations of the core set

Step 3: Evaluation of sensitivity/specificity to change of STAR options and selection of the preliminary STAR

Validation and selection of final STAR

Step 4: Validation in the NECESSITY clinical trial and selection of the final STAR

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EPIDEMIOLOGICAL SCIENCE

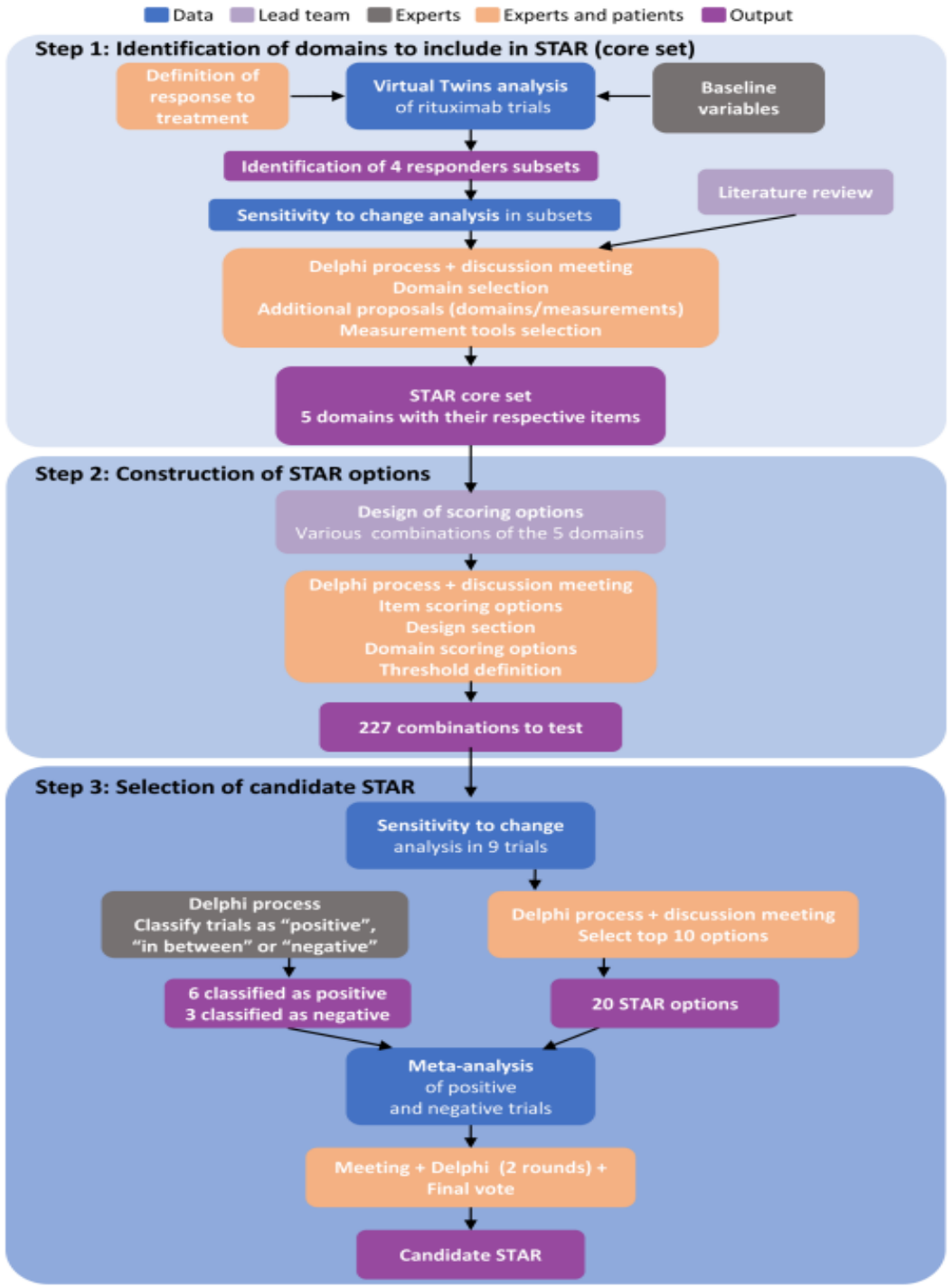
Development and preliminary validation of the Sjögren's Tool for Assessing Response (STAR): a consensual composite score for assessing treatment effect in primary Sjögren's syndrome

Raphaele Seror ,[1,2] Gabriel Baron,[3,4] Marine Camus,[1,2] Divi Cornec ,[5,6] Elodie Perrodeau,[3,4] Simon J Bowman,[7,8,9] Michele Bombardieri,[10] Hendrika Bootsma,[11] Jacques-Eric Gottenberg ,[12,13] Benjamin Fisher ,[14,15] Wolfgang Hueber,[16] Joel A van Roon,[17] Valérie Devauchelle-Pensec,[5,6] Peter Gergely,[18] Xavier Mariette ,[1,2] Raphael Porcher,[3,4] on behalf of the NECESSITY WP5 - STAR development working group

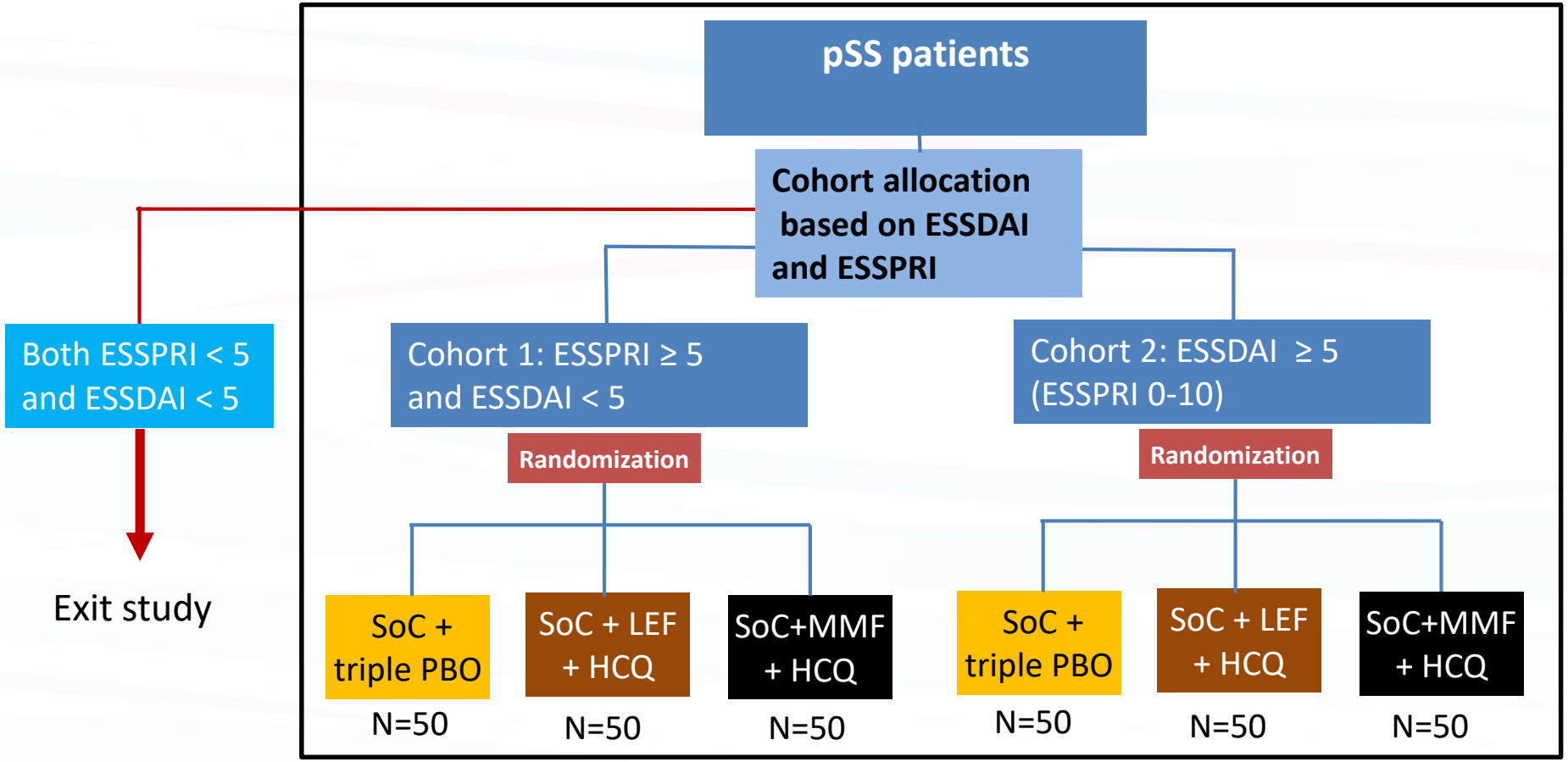
Seror R et al. Ann Rheum Dis, 7 April 2022

Table 3 Candidate STAR

Domain	Point	Definition of response
Systemic activity	3	Decrease of ≥3 in clinESSDAI.
Patient-reported outcome	3	Decrease of ≥1 point or ≥15% in ESSPRI.
Lachrymal gland function (assessed by Schirmer's test or ocular staining score)	1	Schirmer's test: If abnormal score at baseline: increase ≥5 mm from baseline. If normal score at baseline: no change to abnormal. *Or* Ocular staining score: If abnormal score at baseline: decrease of ≥2 points from baseline. If normal score at baseline: no change to abnormal.
Salivary gland function (assessed by unstimulated whole salivary flow or ultrasound)	1	Unstimulated whole salivary flow: If score is >0 at baseline: increase of ≥25% from baseline. If score is 0 at baseline: any increase from baseline. *Or* Ultrasound: Decrease of ≥25% in total Hocevar score from baseline.
Biological (assessed by serum IgG or RF level)	1	Serum IgG level: decrease of ≥10%. *Or* RF level: decrease of ≥25%.
Candidate STAR responder		≥5 points



Objective 3: validation of STAR in The NECESSITY clinical trial



SoC: Standard of Care (e.g. low dose steroid, methotrexate)
PBO: placebo
HCQ: hydroxychloroquine
LEF: leflunomide
MMF: mycophenolate

Treatment: 6 months
Follow-up: plus 3months (with any SOC)

Key endpoints at 6 months:
- Delta ESSPRI for Cohort 1
- Delta ESSDAI for Cohort 2
- Performance of the new endpoint(s)

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NEW NON INVASIVE ASSESSMENT PROCEDURES IN THE CLINICAL TRIAL

PEPSS

- Web application: secure website accessible from smartphone, computer
- Self-reporting of symptoms of dryness, pain and fatigue
- Daily reporting
- In the context of the patient's routine life

Biosensors

- Watch and patch
- Physical activity/rest and physiological date (ECG etc)
- Objective evaluation of fatigue

Ultrasound scoring

- Originally developed for diagnostic purposes
- Determine if could detect changes after therapy and avoid the need for biopsies

Ophthalmologic procedures

- Meibography and non-invasive tear break up time
- Shown value for objective evaluation of ocular dryness
- Not yet validated in pSS

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Merci
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Questions ?