



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 Date>
2 <Document reference number>
3 <Name of the office>
4 Human Medicines Division
5 dd/mm/yyyy
6 EMA/400811/2024

7 Draft 3-year rolling work plan for the Rheumatology and 8 Immunology Working Party (RIWP)

9 - **Draft for public consultation** -

10
11

Chair: Caroline Auriche

Vice-Chair: Karolina Törneke

12

13 Work plan period: January 2025 – December 2027 (with a first review point after one year)

14

15

16

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



17 **Table of contents**

18 **1. Strategic goals 3**

19 **2. Tactical goals..... 3**

20 2.1. Guidance activities 3

21 2.2. Training and workshop activities..... 5

22 2.3. Communication and Stakeholder activities 5

23 2.4. Multidisciplinary collaboration 5

24 **3. Operational goals 5**

25 **4. List of Abbreviations..... 6**

26

27

28

29 1. Strategic goals

30 The strategic goal of the Rheumatology/Immunology WP is the support of medicines development and
31 evaluation of products in internal medicine, including auto-immune diseases, diseases of the bones and
32 joints and diseases from areas of gastroenterology, respiratory system and nephrology. Thus, its
33 strategic goals are mainly related to the Strategic Focus Area "Availability and Accessibility of
34 Medicines" of the "European medicines agencies network strategy to 2025".

35 2. Tactical goals

36 2.1. Guidance activities

- 37 • Revision of the Guideline on clinical investigation of medicinal products for the treatment of
38 Psoriatic Arthritis
- 39 • Drafting of Guidance on the investigation of medicinal products in Systemic Sclerosis
- 40 • Drafting of Guidance on development strategies for allergen products intended for allergies with
41 low prevalence.
- 42 • Revision of the Guideline on therapeutic equivalence of orally inhaled products
- 43 • Drafting guidance on therapeutic equivalence for nasal products
- 44 • Revision of the Guideline on clinical investigation of medicinal products for the treatment of cystic
45 fibrosis
- 46 • Revision of the guideline on clinical investigation of medicinal products for the treatment of acute
47 respiratory distress syndrome
- 48 • Revision of the guideline on the investigations of medicinal products in the term and preterm
49 neonates
- 50 • Review of existing guidelines in the remit of RIWP and horizon scanning to identify the need for
51 guideline updates.

52 (A) Activities ongoing/to be finalised in 2025

53 *Action: Lead*

54 Guideline on the clinical investigation of medicinal products for the treatment of psoriatic arthritis

Target date Draft revised Guideline to be published for public consultation by Q4 2025

Comments Revision of an [existing guideline](#)

55 *Action: Lead*

56 Guideline on the clinical investigation of medicinal products in the term and preterm neonates

Target date Draft revised guideline to be published for public consultation by Q1 2025.

Comments Revision of [existing guideline](#).

57 **Action: Lead**

58 Guideline on allergen products development for immunotherapy and allergy diagnoses in moderate to
59 low-sized study populations

Target date Final guideline to be published by Q2 2025.

Comments New guideline. Public consultation on the [draft guideline](#) ended 31/05/2024

60 **Action: Lead**

61 Guideline on requirements for clinical documentation for orally inhaled products (**OIP**) including the
62 requirements for demonstration of therapeutic equivalence between two inhaled products for use in the
63 treatment of asthma and chronic obstructive pulmonary diseases

Target date Final updated guideline to be published for by Q2 2025

Comments Revision of [existing Guideline](#). Public consultation on the [draft updated Guideline](#) ended 30/10/2024

64 **Action: Lead**

65 Guideline on requirements for clinical documentation for demonstration of therapeutic equivalence for
66 nasal products

Target date Draft Guideline to be published for public consultation by Q4 2025

Comments New Guideline.

67 **Action: Lead**

68 Guideline on the clinical development of medicinal products for the treatment of cystic fibrosis

Target date Draft updated Guideline to be published for public consultation by Q2 2025

Comments Revision of existing [Guideline](#).

69 **Action: Lead**

70 Guideline on clinical investigation of medicinal products in the treatment of patients with acute
71 respiratory distress syndrome

Target date Draft updated Guideline to be released for public consultation by Q1 2025

Comments Revision of the [existing Guideline](#).

72 **Action: Lead**

73 Guidance document on the clinical investigation of medicinal products for the treatment of Systemic
74 sclerosis

Target date Concept paper to be published for public consultation by Q2 2025

75 **(B) Activities to be started in 2025**

76 Drafting a paediatric addendum to the guidelines on the clinical investigation of medicinal products in
77 ulcerative colitis and Crohn's disease.

78 **(C) Activities to be started in 2026-2027**

79 Drafting guidance on the clinical investigation of medicinal products for the treatment of Idiopathic
80 Pulmonary Fibrosis (IPF)

81

82 **2.2. Training and workshop activities**

83 The RIWP will be providing trainings to the network to be organised as needed (e.g., when guidelines
84 are finalised or updated) and workshops as needed to support the drafting of Guidelines.

85 **2.3. Communication and Stakeholder activities**

86 Participation in stakeholder activities will be decided on a case-by-case basis.

87 **2.4. Multidisciplinary collaboration**

- 88 • On the Guideline on therapeutic similarity of orally inhaled products (OIP): Quality Working Party
89 (QWP) and Methodological Working Party (MWP) will be consulted before a final Guideline will be
90 released.
- 91 • On the new Guideline on therapeutic equivalence for nasal products QWP and MWP will be
92 consulted before a final Guideline will be released.
- 93 • On the Guideline on the clinical development of medicinal products for the treatment of cystic
94 fibrosis: Infectious Disease Working Party (IDWP), MWP and PDCO will be consulted before a draft
95 updated Guideline for public consultation is released.
- 96 • On the Guideline on the investigation of medicinal products in the term and preterm neonates:
97 multidisciplinary consultations are planned including PDCO.
- 98 • On the guideline on acute respiratory distress syndrome with regular consultations with Emergency
99 Task Force (ETF) and planned discussion with PDCO and MWP.

100

101 **3. Operational goals**

102 RIWP will provide product related support upon request from Committees and SAWP.

103

104 **4. List of Abbreviations**

105 N/A, abbreviations are spelled out where mentioned first in the document