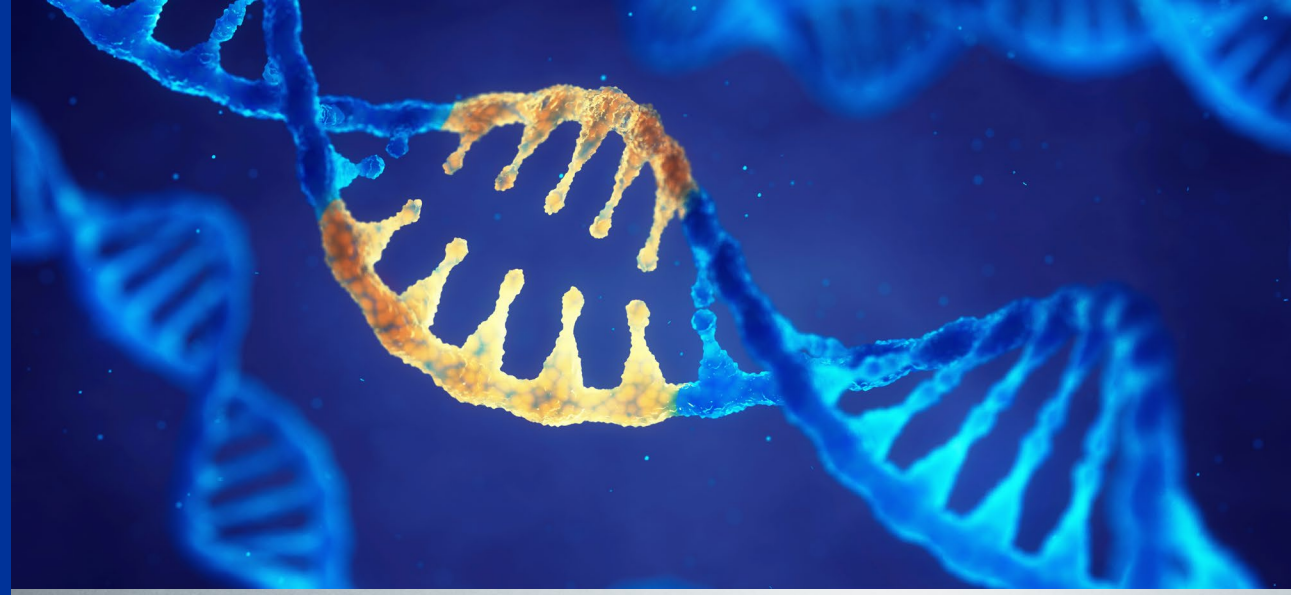
EMA
EUROPEAN MEDICINES AGENCY

Implementation of pilot initiatives based on first 5 years' experience of PRIME: - Analysis

14th Industry stakeholder platform on research and development support

Kevin Cunningham – EMA PRIME Scientific Coordinator

03 July 2025



PRIME: inception, implementation, evolution

Reinforce scientific and regulatory advice
- Foster and facilitate early interaction
- Raise awareness of requirements earlier in development

Optimise development for robust data generation
- Focus on efficient development
- Promote generation of robust and high-quality data

Enable accelerated assessment
- Promote generation of high quality data
- Facilitated by knowledge gained throughout development

2015

Draft reflection paper on Priority Medicines scheme

2016

2018

2021

2023

EMA launches new PRIME features

Pilot analysis/ refinement

2025

POLAND25.EU

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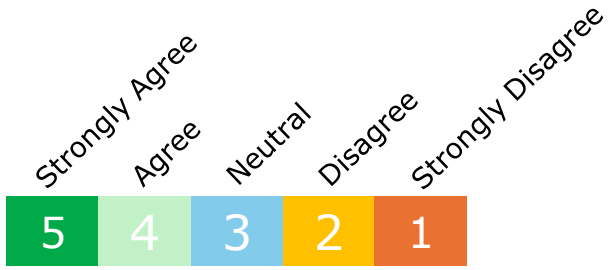
PRIME Pilot Analysis – SRM, Expedited SA, Development Tracker

- March 2023 EMA established:
  - Regulatory roadmap & development tracker for each PRIME development
  - expedited Scientific Advice to address development questions in shorter timeframe
  - Submission readiness meeting to ensure robust MAA dossier, facilitate AA
- Pilot experience gathered over 2 years April 2023-March 2025

Pilot survey: w/c March 29th – May 9th



- Applicable to existing and new PRIME product developer
- Format: EU Survey statements with 5 point scale + free text
- Industry: PRIME developers with active product since March 2023-March 2025 with one survey per product
  - 36 individual responses
  - 100% SRM participants (10), 73% of Expedited SA participants (8/11)
- Network: Primary targets Rapporteur, Rapporteur's team, SAWP coordinators, Committee members, key SRM attendees.
  - 20 individual responses
  - 80% of SRM Rapporteur team (8/10), 100% of Expedited SA Rapporteur teams (11)

Roadmap & Development tracker

Pilot implementation: Word document, Gantt Chart, tracker template table

Submission via IRIS, accessed/disseminated via Sharepoint

64 **development tracker submissions**

- 31 periodic updates; 23 KOM submissions, 10 SRM submissions
- Supported all KOM and SRM preparatory discussions and meetings

Developer Survey: 31/36 respondents submitted tracker

Assessor Survey: Tracker reviewed in the context of:

KOM	66%
SRM	50%
Periodic update	50%

New in this update:	Area	Summary of the topic (brief description)	Milestones	Impact on evidence generation Low Med High	Company observations	SA planned/advised (target date if known)	IRIS case number of previous SA/PIP/OD/ ITF on the topic
	I. QUALITY						
	Stability						
	Specifications						
	Manufacturing issues and process controls						
	Comparability (changes to manufacturing process/site)						
	GMP Issues						
	Other (specify)						
	II. NON-CLINICAL						
	Carcinogenicity						
	Reprotox/Germ line integration						
	Animal model adequacy						

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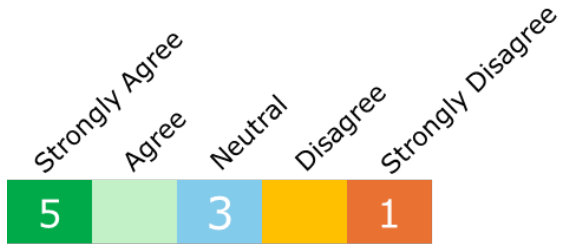
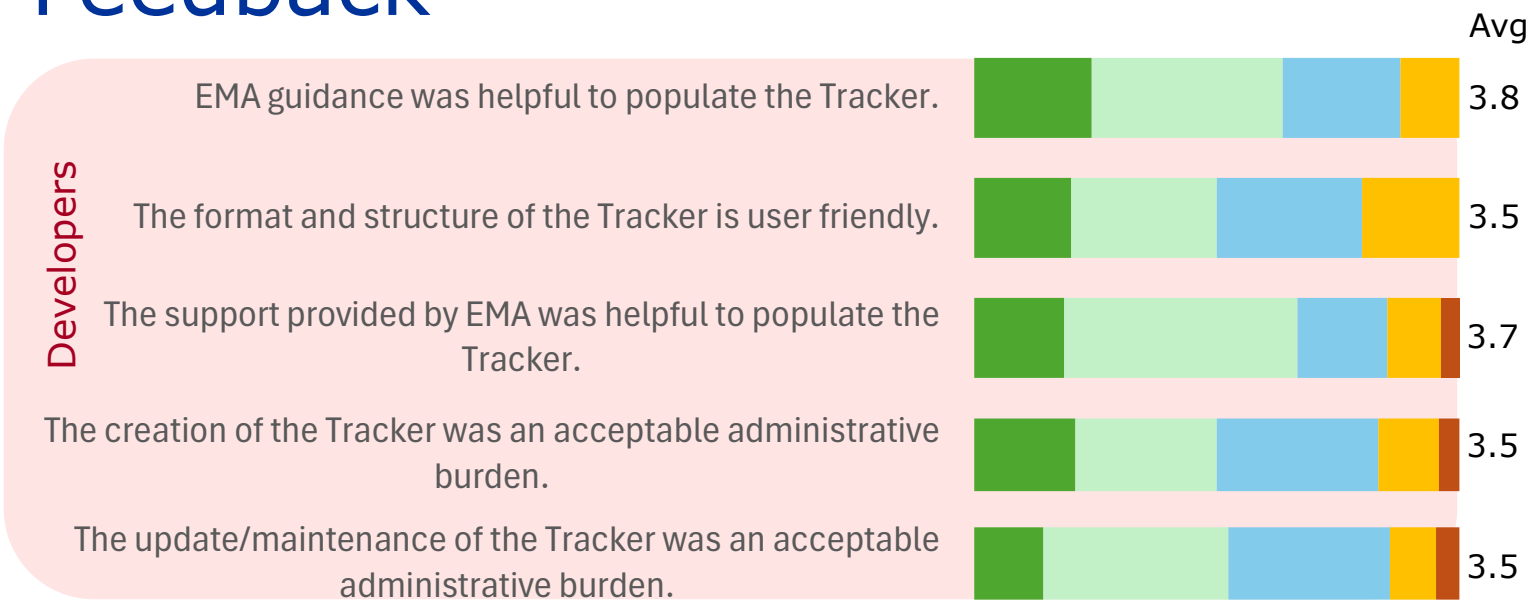
Roadmap & Development tracker: Developer Feedback

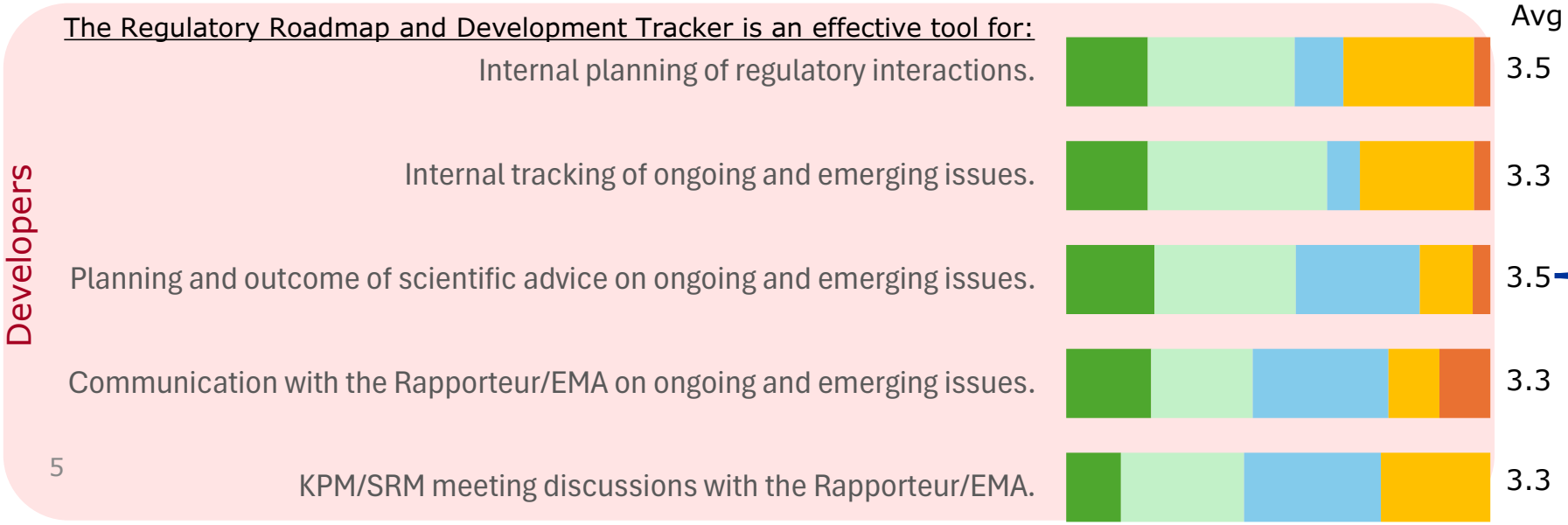




Changes to Development Tracker? (Free text)

More detailed instructions on level of detail, formatting, update frequency

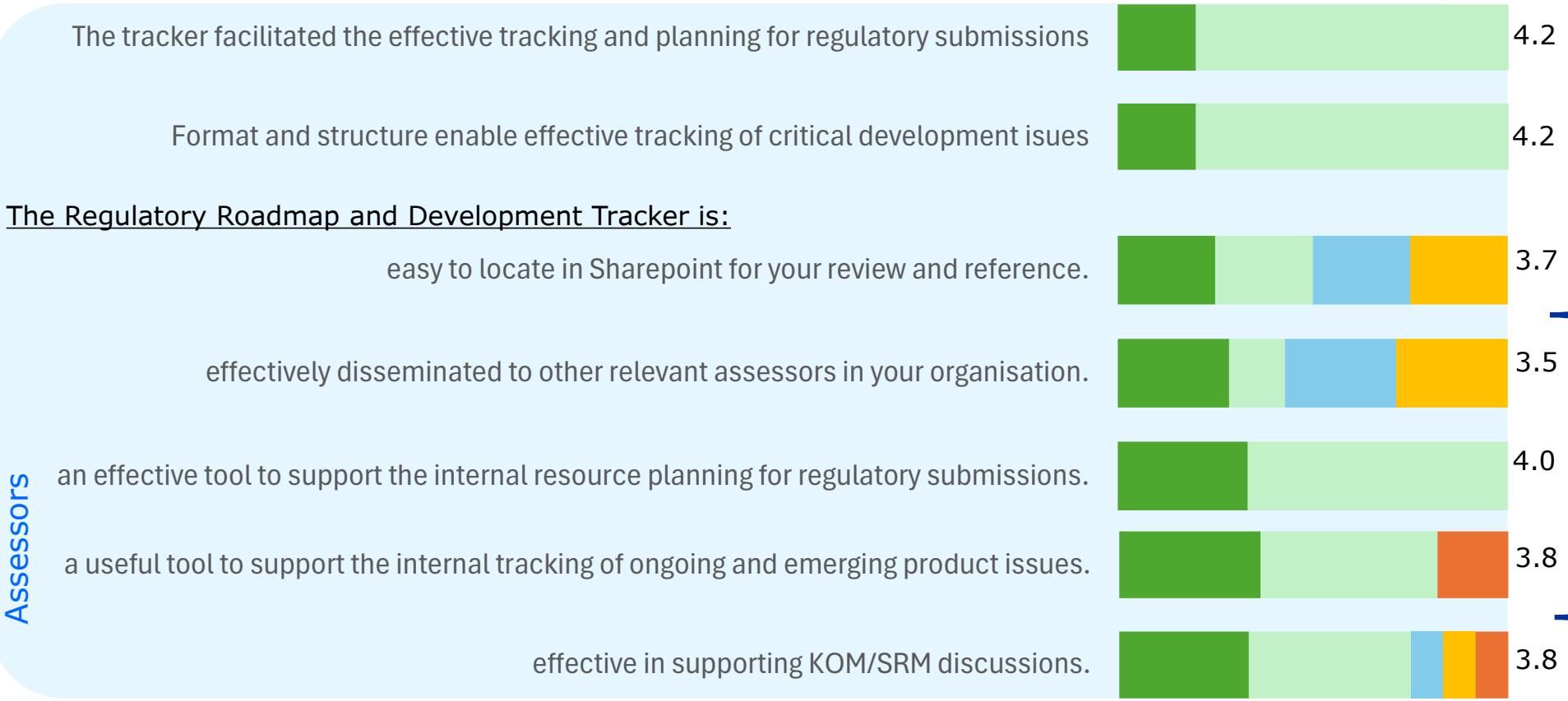
Online tool for up-to-date tracking of planned SA; live risk-log for identified risks/impact on milestones/mitigation



More feedback upon submission: Impact level; use as basis for discussion, feedback to address emerging issues

Frequent/Annual update may be justified for regulatory milestones, etc

Roadmap & Development tracker: Assessor Feedback



Changes to Development Tracker? (Free text)

Simplify the table to improve interpretability

Increase broader awareness of tracker for assessment teams

Mandatory submission per year to increase use

Clearly identify critical issues and whether they were solved/mitigated

Include recommendation of iterative SA, and whether advice was implemented

Expedited Scientific Advice - Overview

12 requests for Expedited Scientific Advice received

11 requests agreed expedited timeline submission (91%)

9 requests maintained expedited timeline (75%)

Expedited SA topics:

Quality: Comparability, Potency Assay, Analytical Methods, manufacturing process validation

Non-clinical: Comparability, package to support MAA

Clinical: Statistical aspects/SAP, data to support CMA, trial design (endpoints, population, interim analysis), comparability

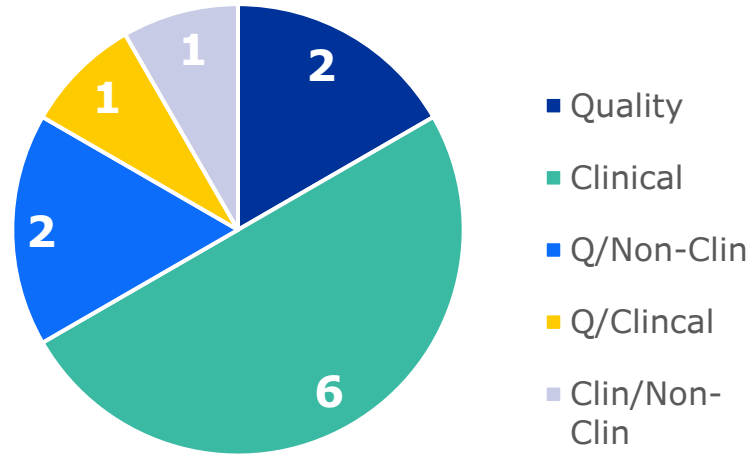
Procedural Aspects

High flexibility w.r.t. submission deadlines

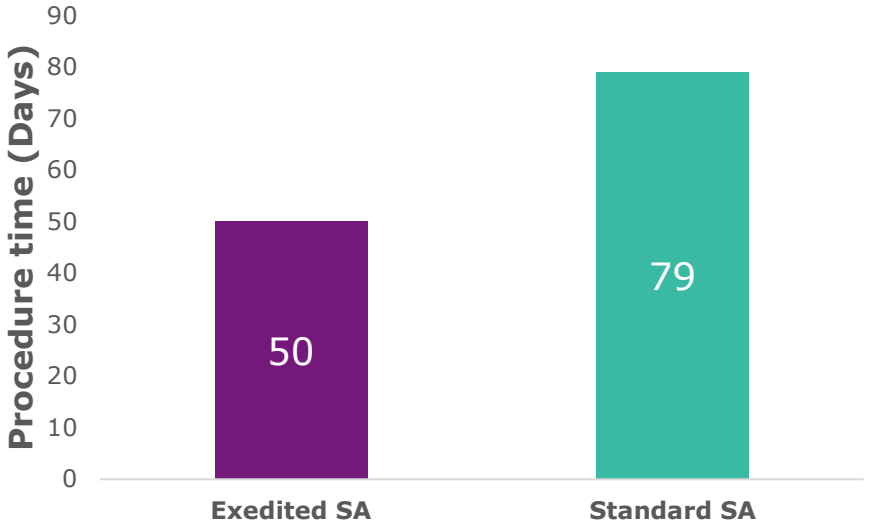
SAWP Assessment time preserved

Reduced overall timeline from submission to final Advice letter Vs standard timeframe

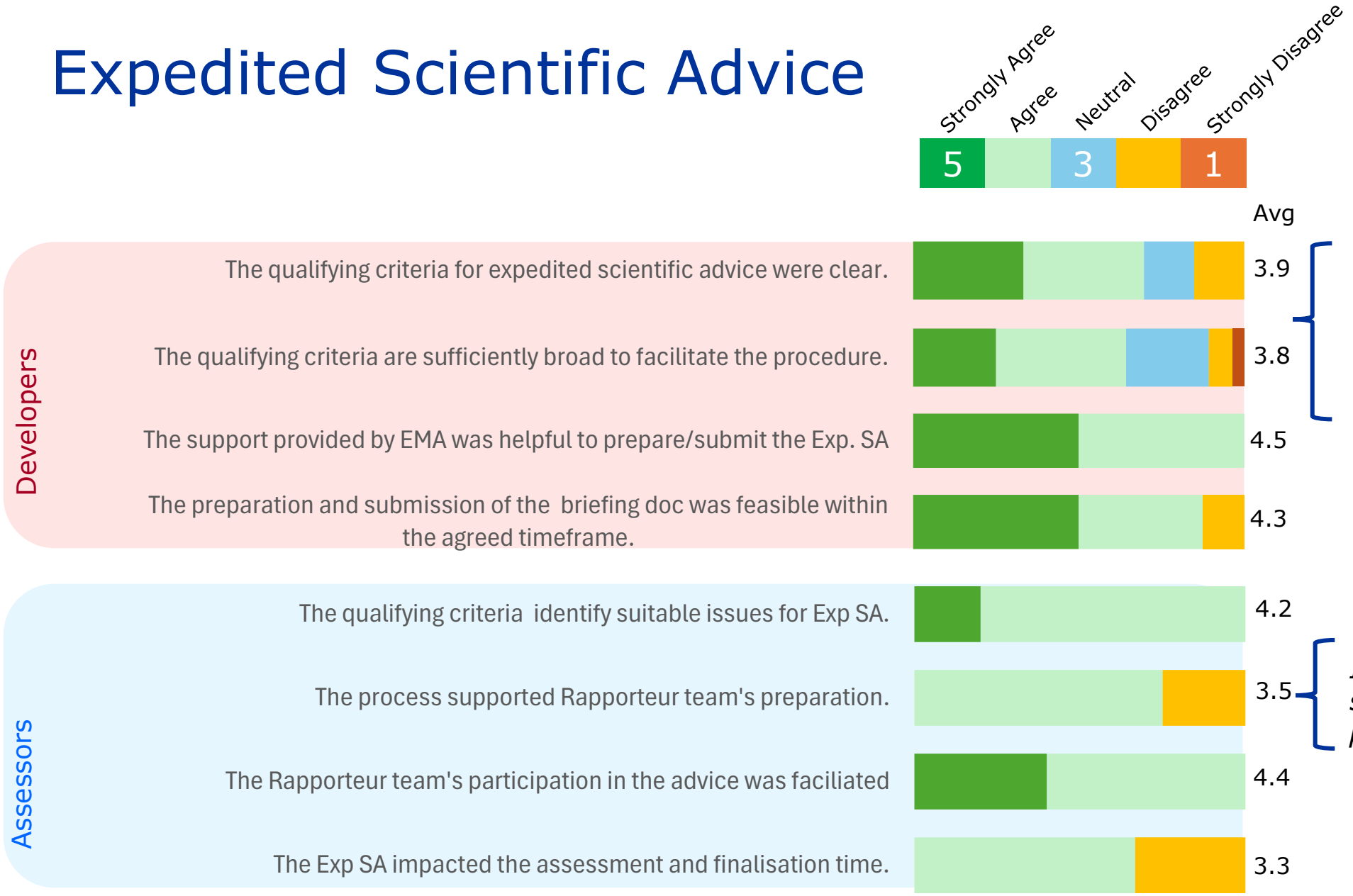
Expedited Scientific Advice request - scope



Duration (days): Scientific doc submission to final JR



Expedited Scientific Advice



Changes to expedited SA? Developers (Free text):

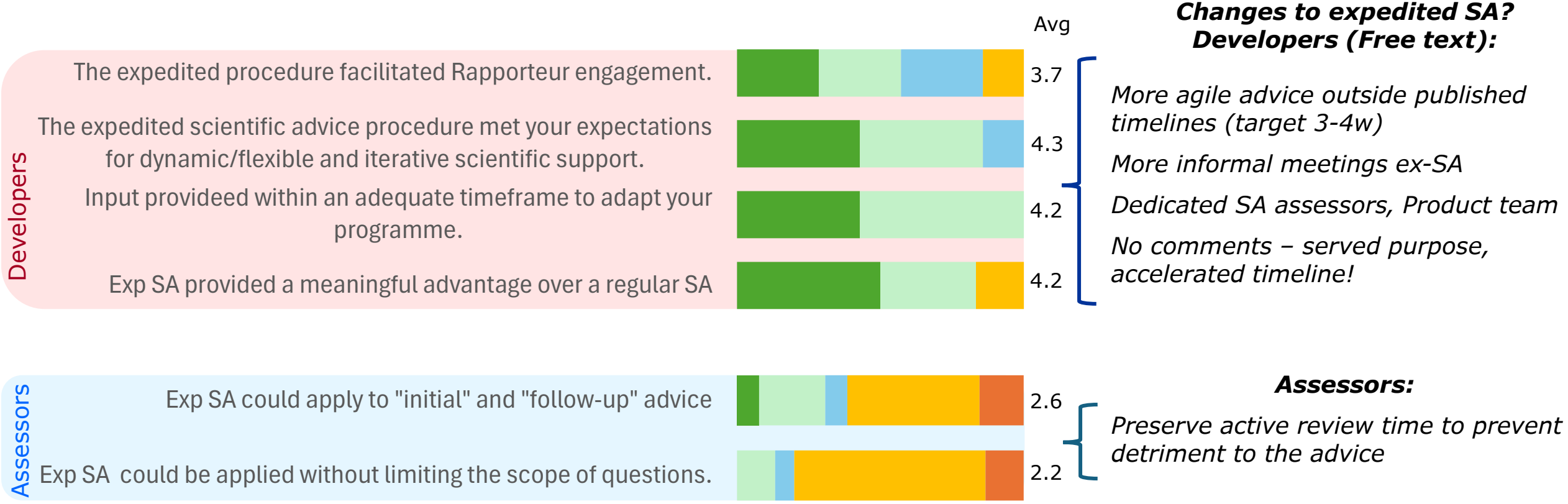
Detailed guidance on criteria/ timelines

Apply Exp SA to: initial advice, all KOM/SRM topics

Assessors:

Increase Predictability: current submissions limit ability to participate

Expedited Scientific Advice (ii)



Changes to expedited SA? Developers (Free text):

More agile advice outside published timelines (target 3-4w)

More informal meetings ex-SA

Dedicated SA assessors, Product team

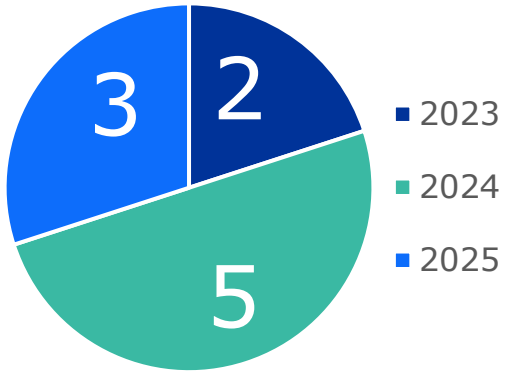
No comments – served purpose, accelerated timeline!

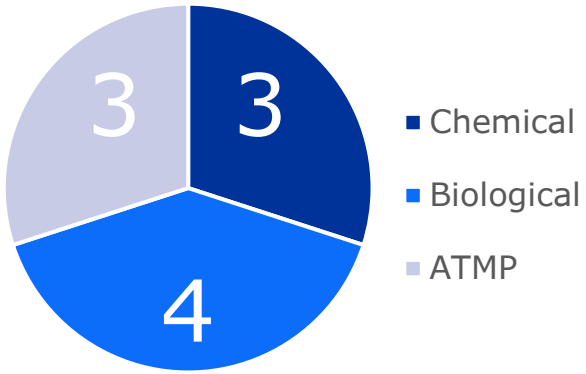
Assessors:

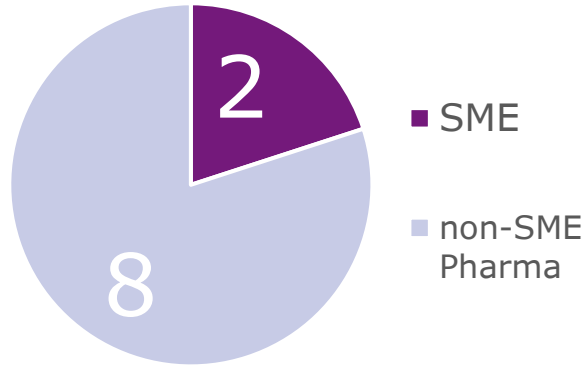
Preserve active review time to prevent detriment to the advice

Submission readiness meeting - Overview

10 SRMs included in the pilot







MAA status:

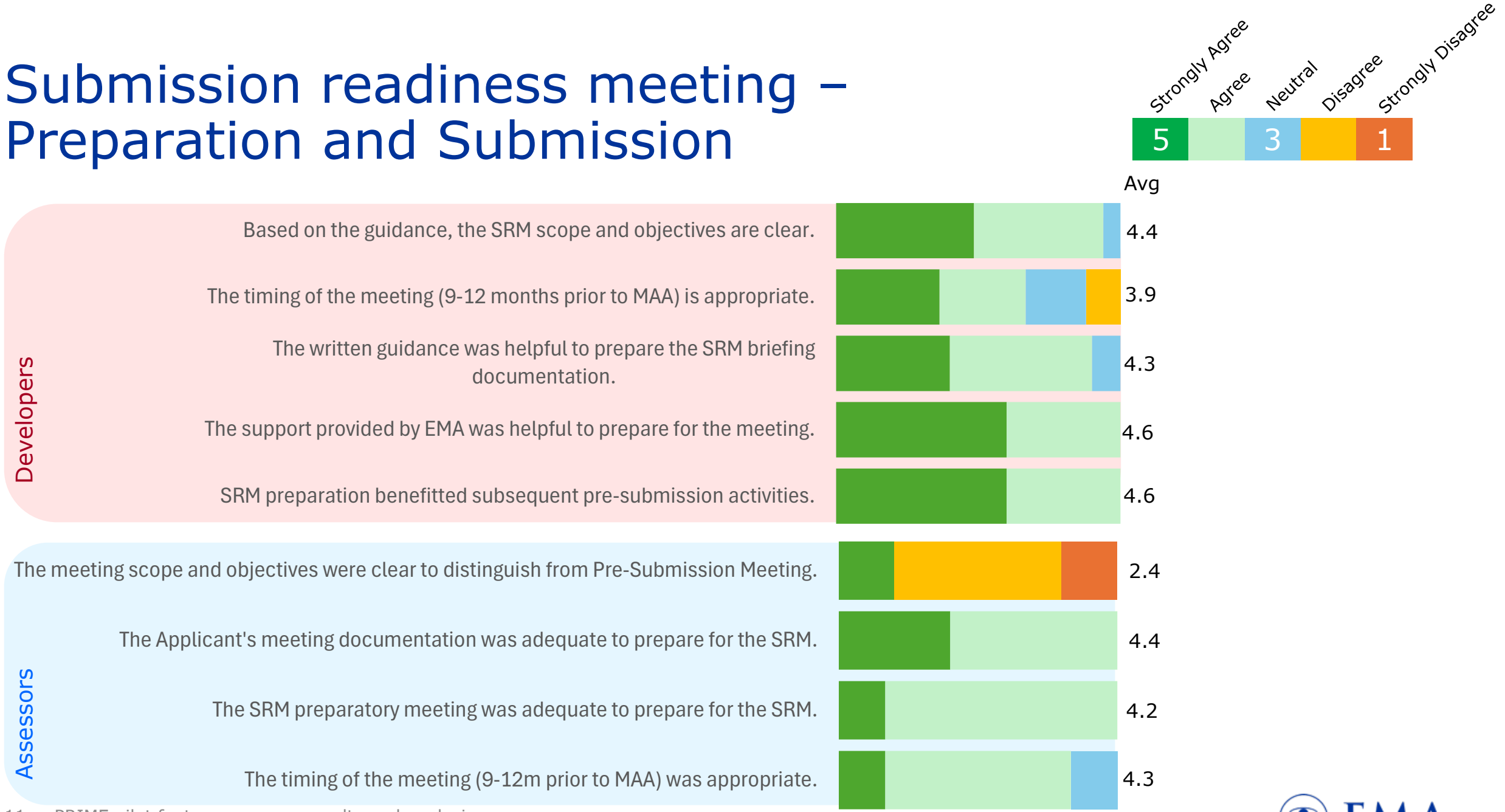
1 product authorised (Vimkunya): Accelerated Assessment granted, and maintained

4 products under evaluation,

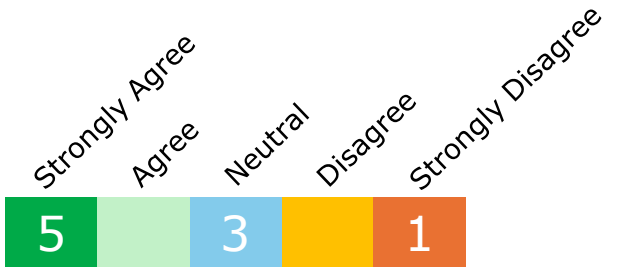
5 products in active development

Future analyses: time from SRM to MAA submission, AA request/outcome, MAA duration, MAA outcome

Submission readiness meeting – Preparation and Submission

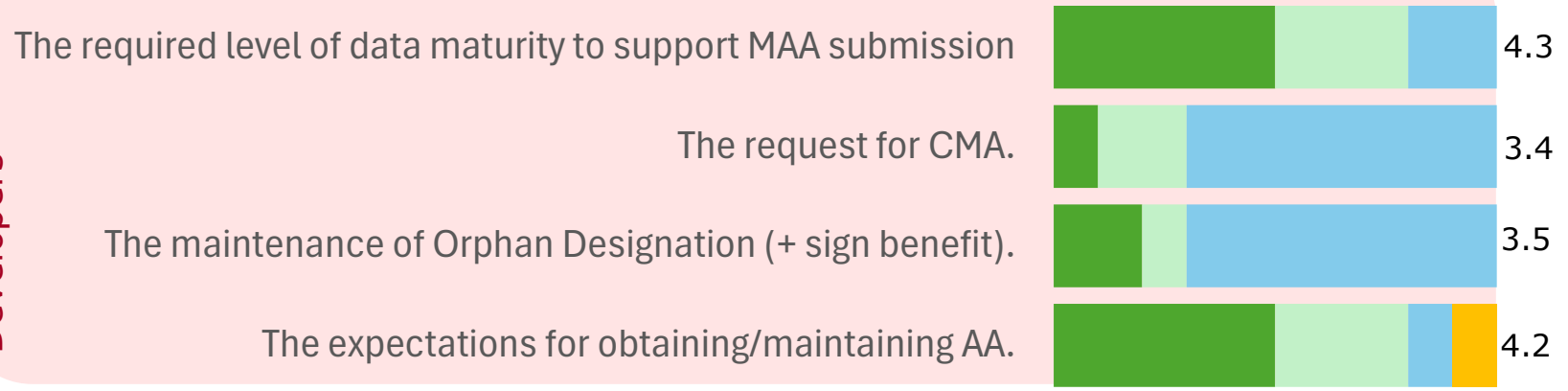


Submission readiness meeting – Meeting Scope

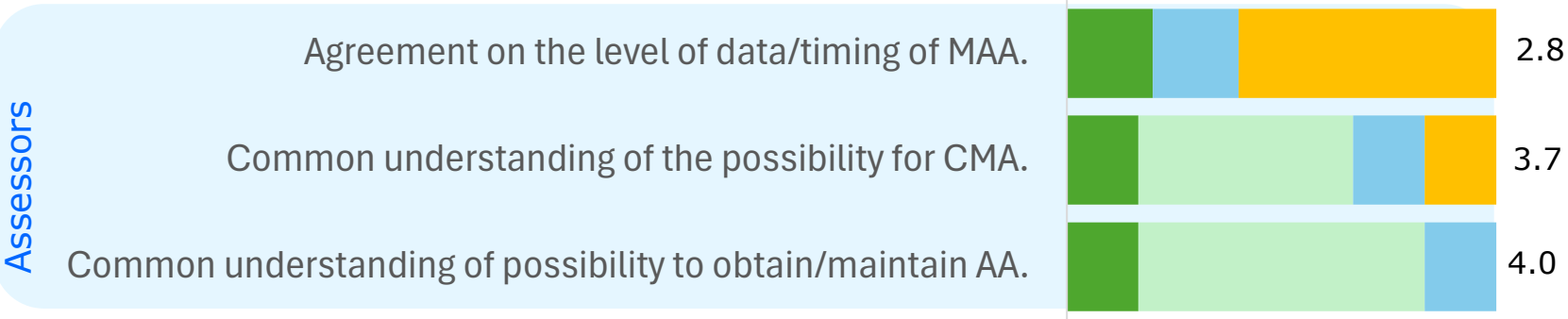


Please consider the extend to which the follows aspects were addressed:

Developers



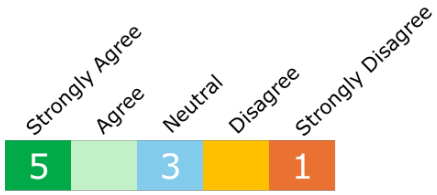
Assessors

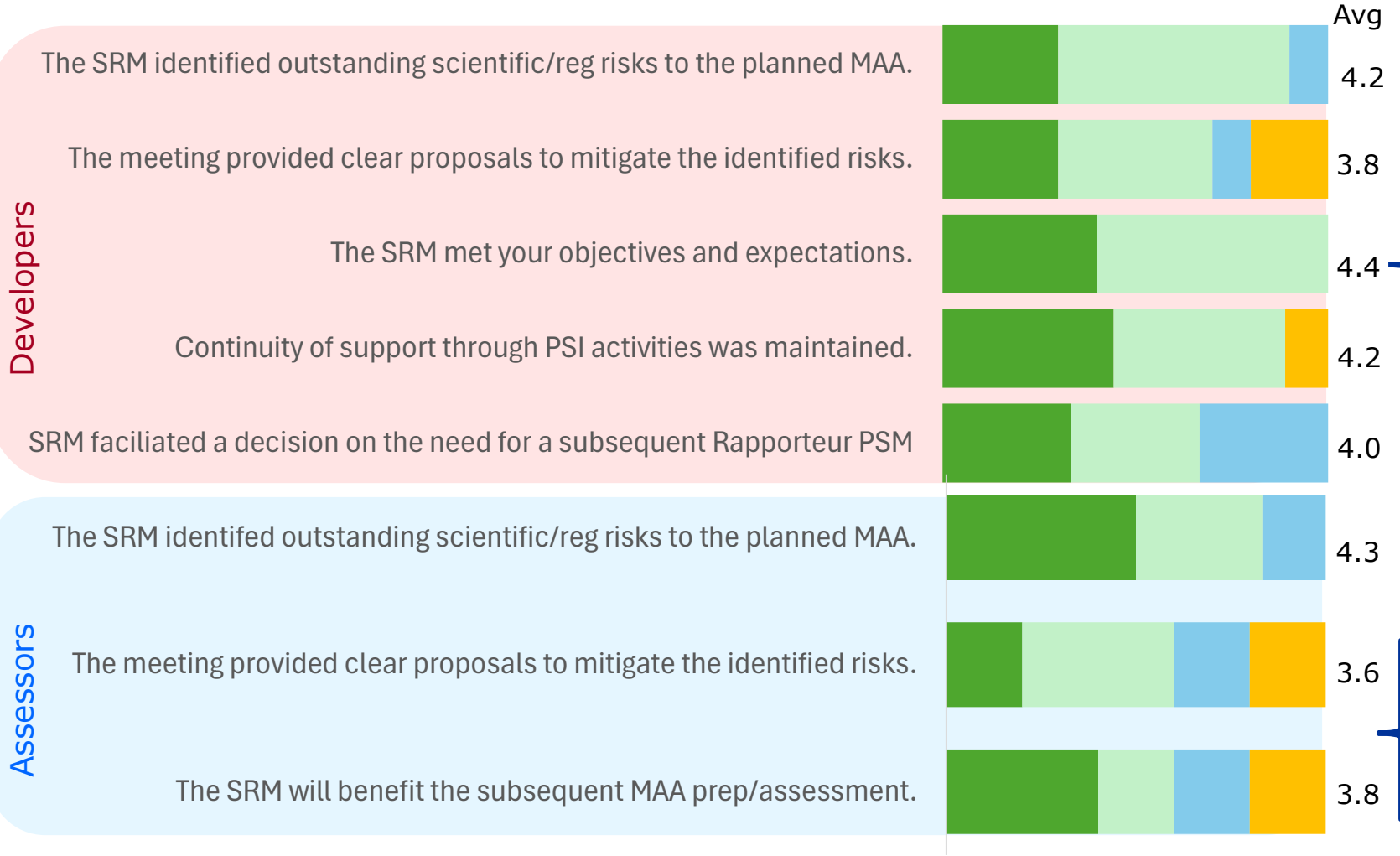


Most relevant discussion topics Assessors (Free text):

- Alignment with Scientific advice
- Presentation of Data Package
- Data Maturity/Comprehensiveness to support MAA
- GMP/GCP inspections
- Readiness re: PIP, OD
- Timelines

Submission readiness meeting: Outcomes, PSM, MAA





Changes to SRM? Developers (Free text):

- *More flexible timing (6-12m)*
- *Minimize further Scientific advice*
- *More Pre-sub Meeting questions*
- *Structured follow-up for outstanding risks*
- *Broaden involvement (PRAC Rapp, HTA, patients)*
- *Stronger link to MAA product team*

Changes to SRM? Regulators (free text):

- *Clear focus on SA issues/ deviations (utilising Dev Tracker),*
- *Agenda point on MAA basis (CMA, EC)*

PRIME Pilots: next steps and strengthened PRIME support

- EMA will continue to analyse pilot data and Industry/Network surveys to assess performance of Pilot Features
- PRIME scheme features will remain in place as standard features while review undertaken
- EMA will engage PRIME Industry Sounding board on surveys (EMA and Industry-led) to incorporate feedback, refine features and related guidance
- Strengthening support to PRIME applicants:

  Transparency and predictability of PRIME eligibility: EMA PRIME pre-submission support continues following launch to all (non-SME) developers in 2023
- Strengthening support to PRIME Developers:

  Enhanced PRIME support through launch dedicated **PRIME product development coordinator,** providing stewardship through scientific dialogue, specialized expertise

  Product development coordinator serves as point of contact for all PRIME product Developer questions

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SCIENCE MEDICINES HEALTH

Thank you

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