EMA Priority Medicines Scheme (PRIME)

EIC – EMA Info Day 31 January 2023

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Outline

- PRIME – from inception to implementation
- PRIME entry points, criteria, and eligibility assessment
- Benefits of PRIME support to medicine developers
- How to prepare and submit your PRIME application

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PRIME inception and implementation

2014 Recognition of the scientific and regulatory challenges to develop promising medicines, and need to need to further reinforce support to foster development of new medicines addressing major public health needs

2015 Draft reflection paper on Priority Medicines scheme published October 2015

2016 Enhanced early dialogue to facilitate accelerated assessment of PRIority MEdicines (PRIME) adopted by the CHMP

2018 Review of first two years of PRIME 2016-2018

2021 Analysis of first five years of PRIME 2016-2021 published

PRIME scheme - Goal & Scope

To foster the development of ***medicines with major public health interest.***

Reinforce scientific and regulatory advice

- Foster and facilitate early interaction
- Raise awareness of requirements earlier in development

Optimise development for robust data generation

- Focus 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

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Eligibility to PRIME scheme

Based on Accelerated Assessment criteria

Medicinal products of major public health interest and in particular from the viewpoint of therapeutic innovation.

- **Potential** to address to a significant extent **an unmet medical need**
- Scientific justification, based on data available from nonclinical and clinical development

No satisfactory method or if method exists, bring a major therapeutic advantage

e.g. introducing new methods or improving existing ones

Meaningful improvement of efficacy (impact on onset, duration, improving morbidity, mortality)

Justification for eligibility to PRIME

For products under development yet to be placed on the EU market

Unmet medical need

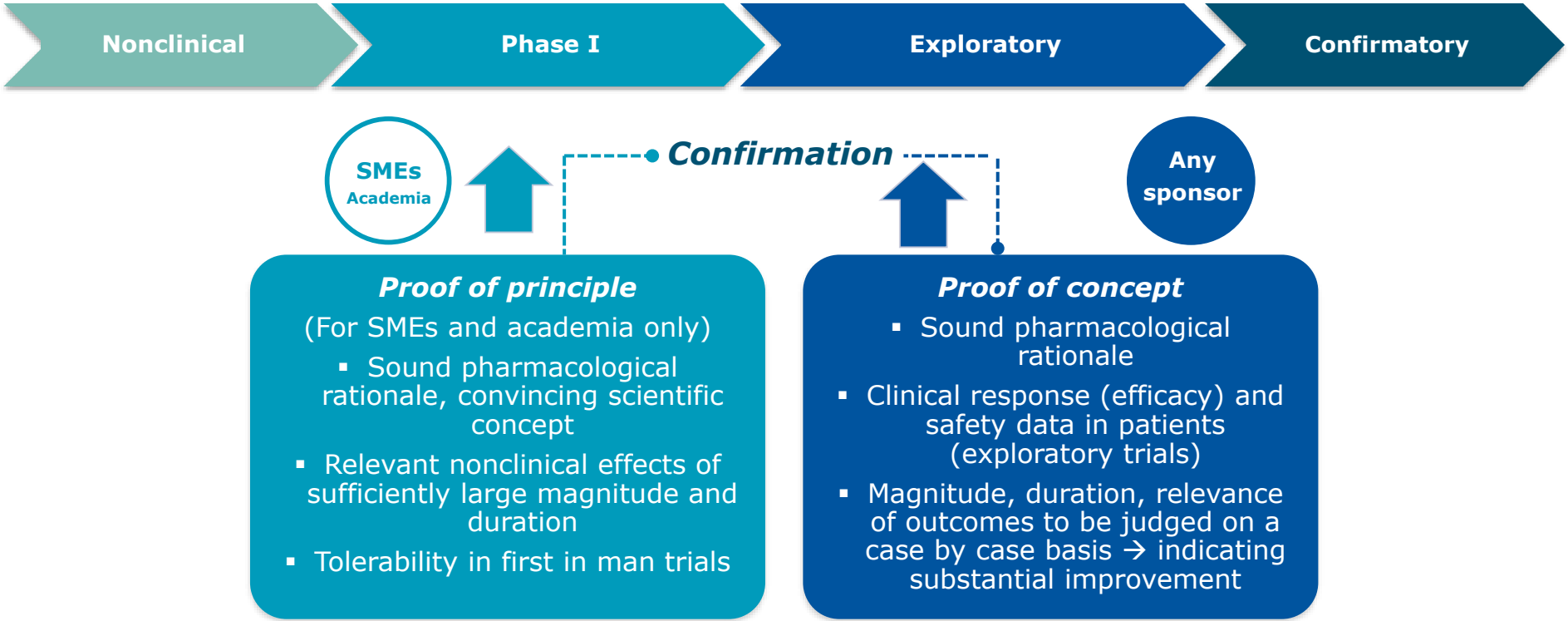
- Epidemiological data about the disease
- Description of available diagnostic, prevention and treatment options/standard of care (SOC), their effect and how medical need is not fulfilled

Potential to significantly address the unmet medical need

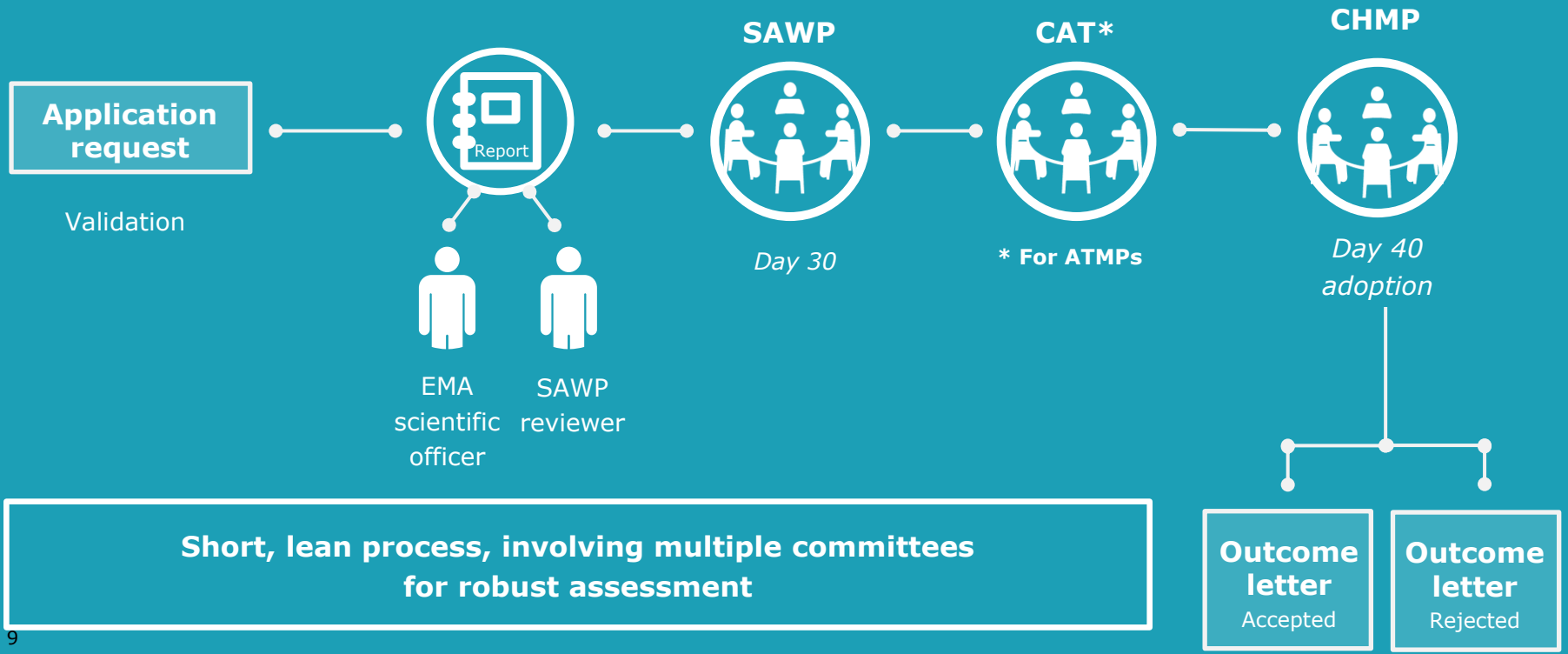
- Description of observed and predicted effects, clinical relevance, added value and impact
- If applicable, expected improvement over existing treatments

Data required at different stages of development

Entry points PRIME eligibility and required evidence



Assessment of Eligibility: 40-day procedure



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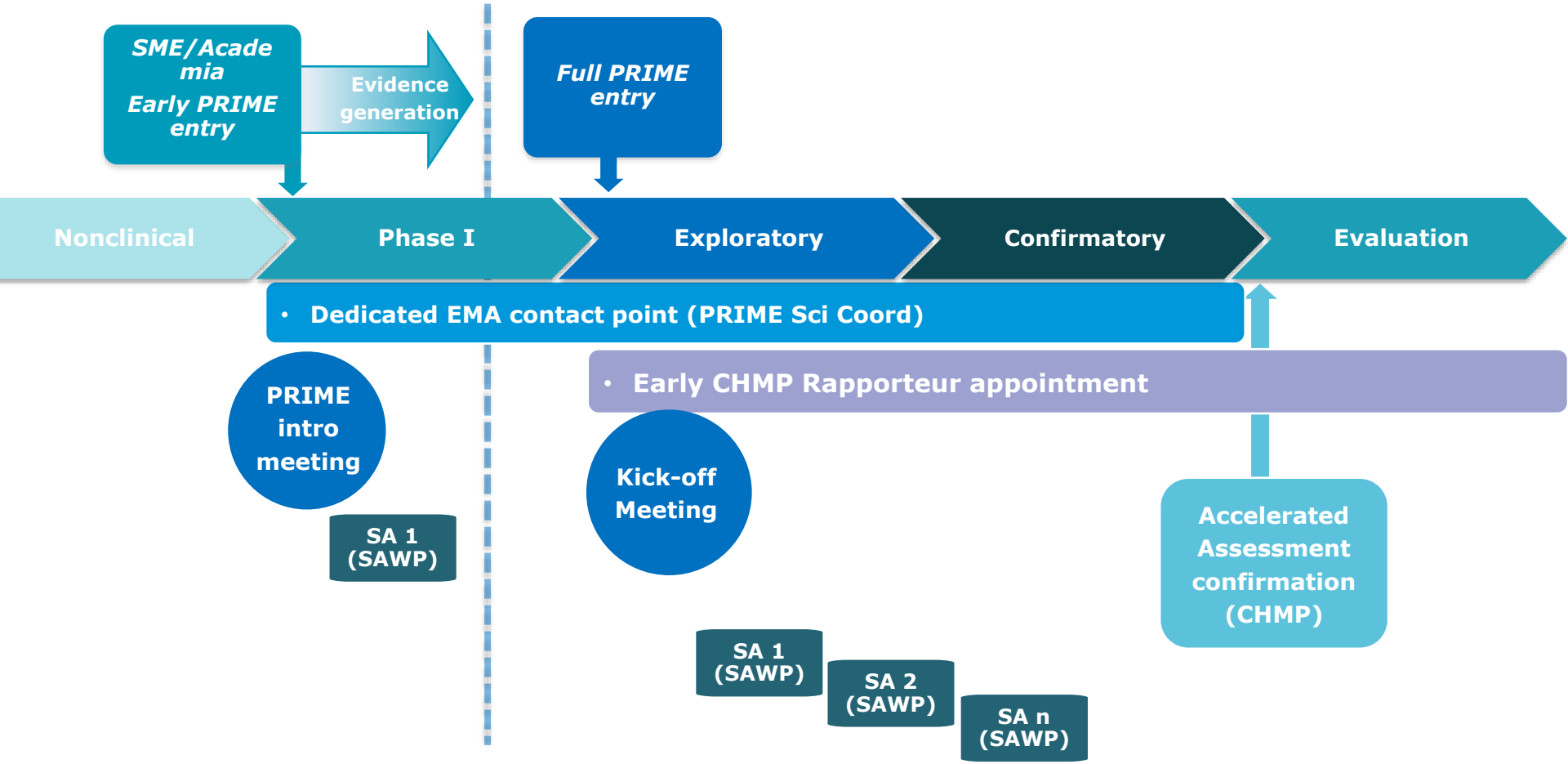
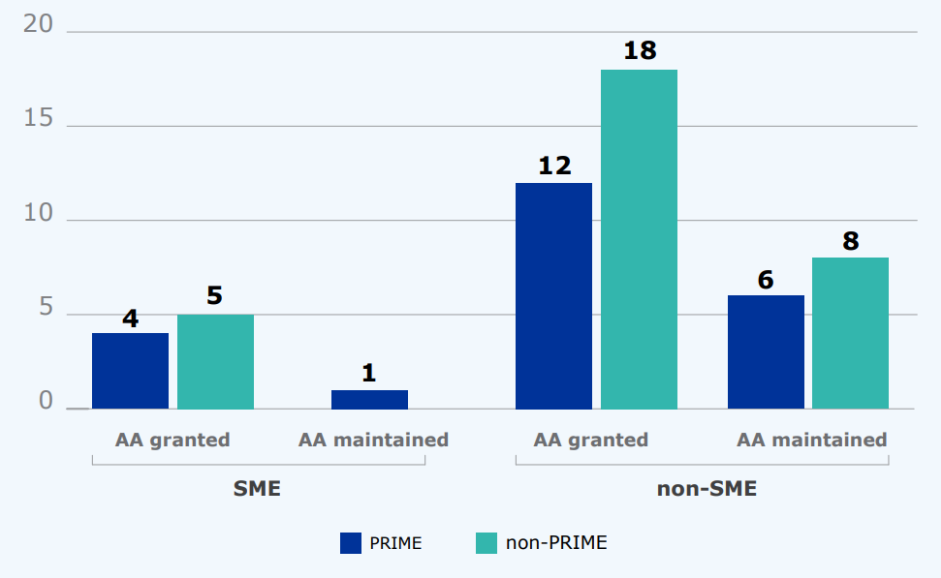
PRIME – Benefits and Enhanced Support

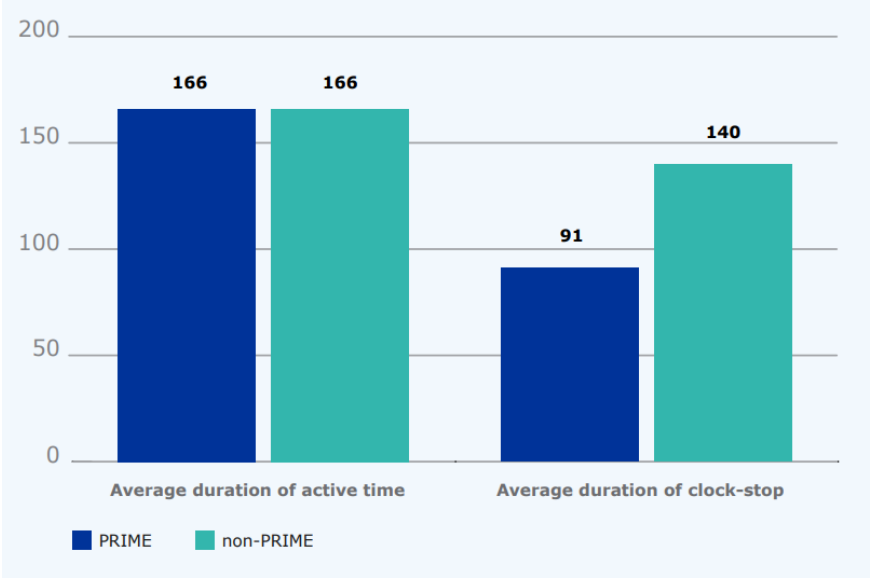


Benefits of the PRIME scheme – 5 year review

Accelerated assessment per type of applicant for PRIME and non-PRIME products



Evaluation times for products started under AA: active time and clock stop (in days)



Recommendations from PRIME 5 year review – evolution and improvements

Scope and timing of the PRIME eligibility requests

Under discussion

Flexibility of scientific advice for PRIME

Expedited Scientific advice for PRIME products: shortened time lines to submit and receive formal CHMP advice **NEW 2023**

Knowledge building to support accelerated assessment.

Development Tracker and Regulatory Roadmap **NEW 2023**

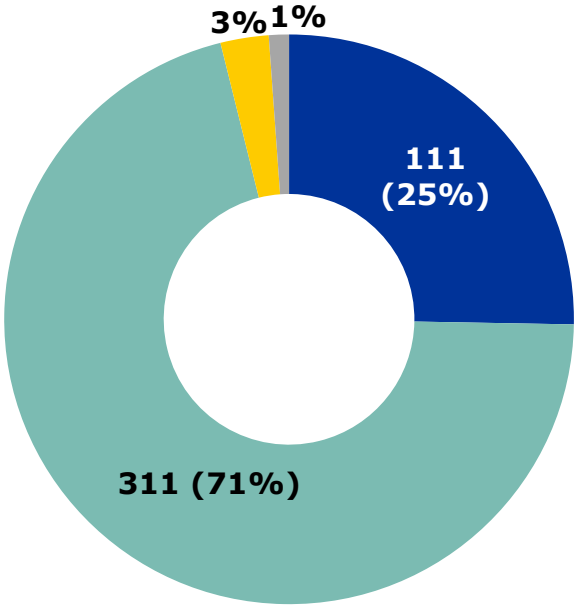
AIM: increase knowledge sharing and predictability of regulatory interactions to promote Rapporteur involvement

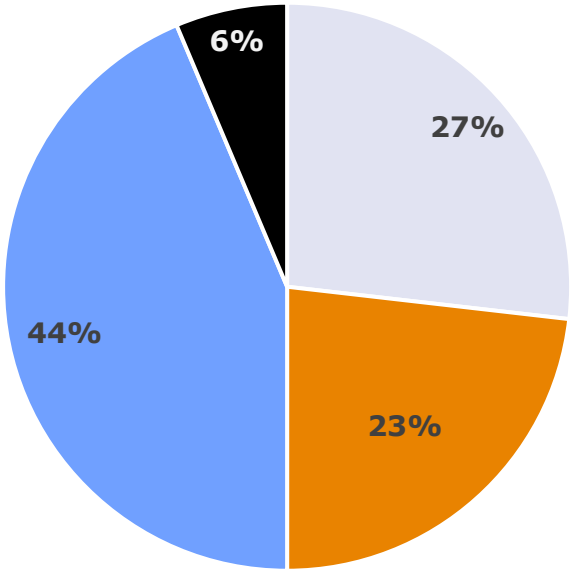
Submission Readiness Meeting prior to MAA **NEW 2023**

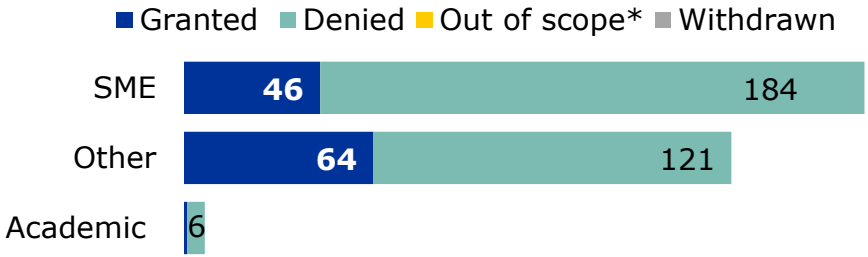
AIM: strengthen engagement in the period between KOM and MAA

Promote initiation and maintenance of AA

Prime Applications: 2016 - 2022







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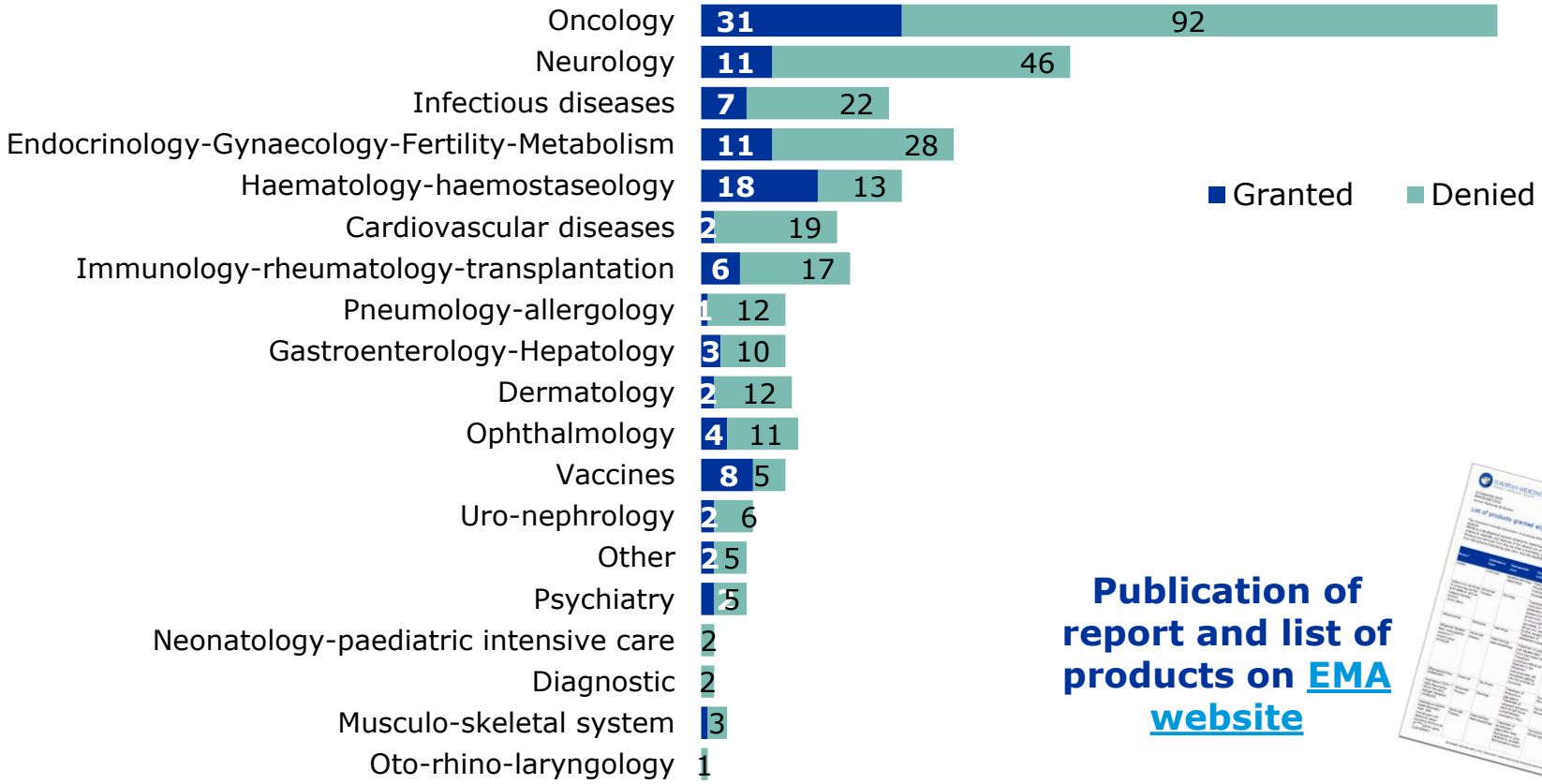

Publication of report and list of products on EMA website

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What does EMA expect to grant eligibility?

Unmet medical need

No treatment or clear limitations of existing therapies

- *Epidemiological data for disease and outcomes, for each subpopulation where relevant*
- *Clear description of SOC, all relevant modalities*
- *Effects of available treatments, the limitations which are aimed to be addressed*

Non-clinical data

Supporting convincing pharmacological rationale

- *Pharmacodynamic studies to support purported mechanism*
- *In vivo PD studies in relevant model of disease*
- *Sufficient magnitude of effect at exposures relevant and appropriate to early clinical studies*

What does EMA expect to grant eligibility?

Clinical data demonstrating promising activity to substantiate potential to address UMN to a significant extent

- *Typically based on clinical response and safety data indicating substantial improvement in patients in the targeted indication*
- *Promising exploratory efficacy clinical data on **relevant** endpoint of sufficient magnitude*
- *Indirect comparisons adequately substantiated (methodology, patient characteristics)*
- *Early entry: acceptable exposure, tolerability to support clinical development*

What does EMA expect to grant eligibility?

Overview of next steps and PRIME benefit

- *Planned non-clinical and clinical development*
- *Potential complexities and risks requiring enhanced dialogue*
- *Planned interaction with Reg authorities*

Dossier

- *PRIME Applicant's justification template*
- *Pre-submission request form*
- *Literature references cited in the justification*

Thank you for your attention

Questions, clarifications, experiences with PRIME?

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