Updates from EMA on scientific advice, PRIME and Joint Scientific Consultations with HTA bodies

12th Industry stakeholder platform on research and development support

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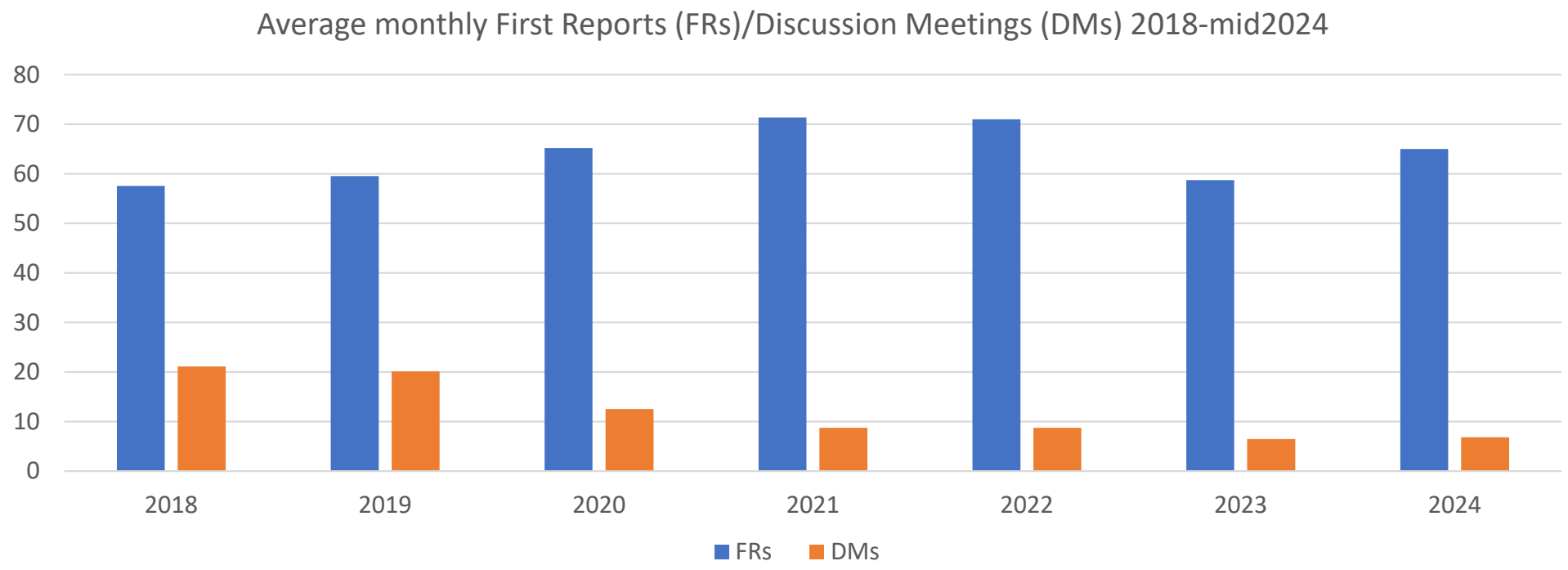
Outline

- Current practices and future proposals regarding discussion meetings in scientific advice
- Progress with the implementation of PRIME recommendations
- Use of transitional arrangements for Parallel Consultation with HTA bodies

Scientific advice discussion meetings

Discussion meeting volumes in recent years



Proposals for improving discussion meetings

- DMs provide opportunity for more interactive exchange and clarifications of discussion points
- Shorter DMs focused on a small number of issues may allow an increase in DM numbers considering the limitations with SAWP plenary meeting duration
- Would applicants consider an extension of the procedure by one month, should a draft FAL be issued at D40 and used as starting point for decision to hold a DM?

Progress with the implementation of PRIME recommendations

PRIME pilot initiatives: Experience to date

- Experience of 8 **Expedited Scientific Advice requests**:

Request	Scope	Question(s)	Expedited criteria met	Outcome	Reason	Conclusion day	Submission to outcome
1	Clinical	Statistical aspects	Yes	Expedited SA		Day 34	6 weeks
2	Clinical	Statistical aspects	Yes	Expedited SA		Day 35	6 weeks
3	Quality/Non-clinical	Comparability programme	Yes	Standard SA	Rapporteur team capacity to initiate review	Day 40	15 weeks (summer break)
4	Quality	Potency Assay	Yes	Expedited SA		Day 40	7 weeks
5	Clinical	CMA/Statistical aspects	Yes	Expedited SA		Day 40	7 weeks
6	Quality	Manuf. process validation	Yes	Expedited SA		Day 40	7 weeks
7	Quality/Clinical	Comparability programme	Yes	Expedited SA		pending	tbd
8	Clinical	Interim analysis	tbd	tbd		tbd	tbd

- 38 **development tracker submissions** until mid-2024:
  - High level of quality, detail, comprehensiveness
  - Ad hoc PRIME team support provided for population and submission of tracker
  - Increasingly used to support KOM
- 5 **submission readiness meetings** held until mid-2024 (2 more in planning until end of 2024)
  - High quality of submission and level of engagement from Applicant/Rapporteur
  - Discussion on data package/maturity, CMA/MAA under EC, accelerated assessment request
  - EMA PRIME team coordinating with MAA Forecasting; proactive planning for SRM

PRIME pilot initiatives – Planned analyses

- Pilots Launched March 2023 and will conclude at **24 month (March 2025)**
- Planned analyses based on IRIS submissions**:**
  - number of **expedited SA requests**, scope, duration, outcome (clarification/expedited/standard)
  - number of **development trackers** submitted, number of updates submitted, metrics compared to previous annual update
  - number of **SRM**, number of subsequent pre-sub meetings held, analysis of AA outcome and maintenance, MAA duration and outcome
- Focused questionnaire to PRIME product developers/Rapporteurs/regulators at conclusion of pilot:
  - Experience of the **expedited SA** procedure, effectiveness
  - Company experience populating/maintaining the **development tracker**, user-friendliness, effectiveness to support internal processes, and EMA PRIME meetings and interactions
  - effectiveness of **SRM** (strengthened engagement, identification of outstanding issues, AA/MAA preparedness), utility of the meeting versus pre-submission activities
- EMA will initiate preparations with industry on survey content and approach through PRIME sounding board in Q4 2024

Use of transitional arrangements for Parallel Consultation with HTA bodies

Parallel EMA/HTA Scientific Advice for the 'interim period'

- Developers can request the involvement of HTA bodies when applying for EMA scientific advice (Sept 2023-Dec 2024)
- 7 applications received
- 4 have been accepted as parallel HTA/EMA scientific advices (3 rejected)
- Of the successful applications: 3 oncology products; 3 applications from big pharma, 1 from an SME-company
- Active HTA-participants per procedure: 3-4
- HTA observers per procedure: 6-8

Let’s discuss!