Updates from EMA on scientific advice

15th Industry stakeholder platform on research and development support

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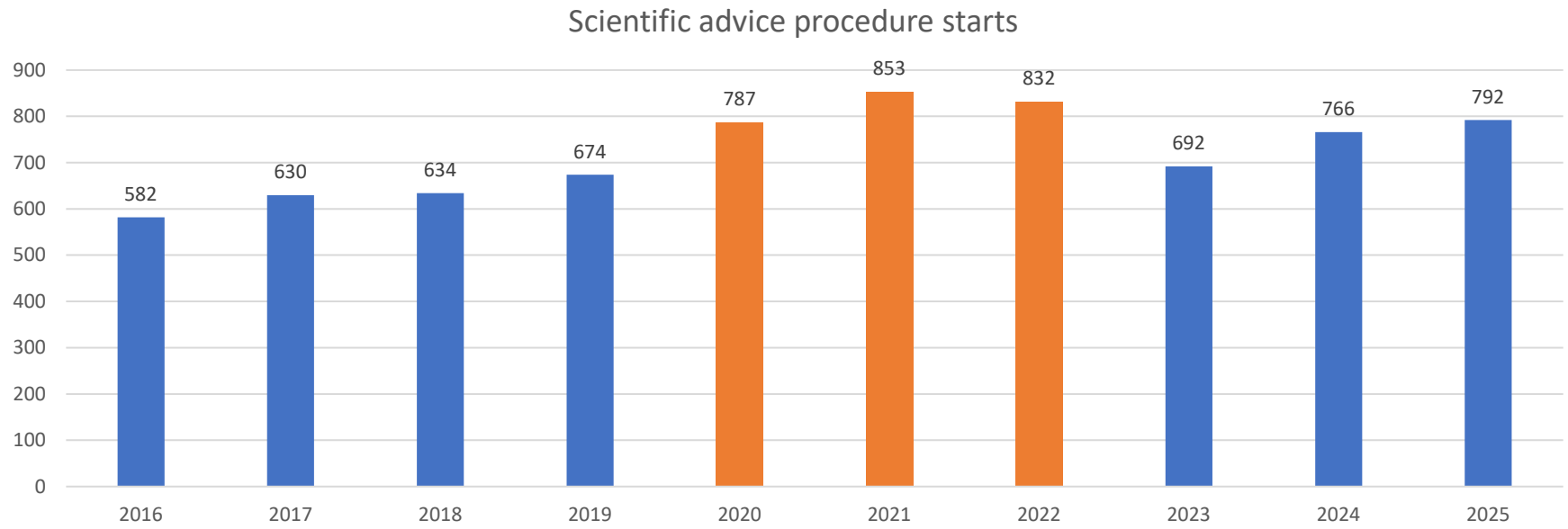
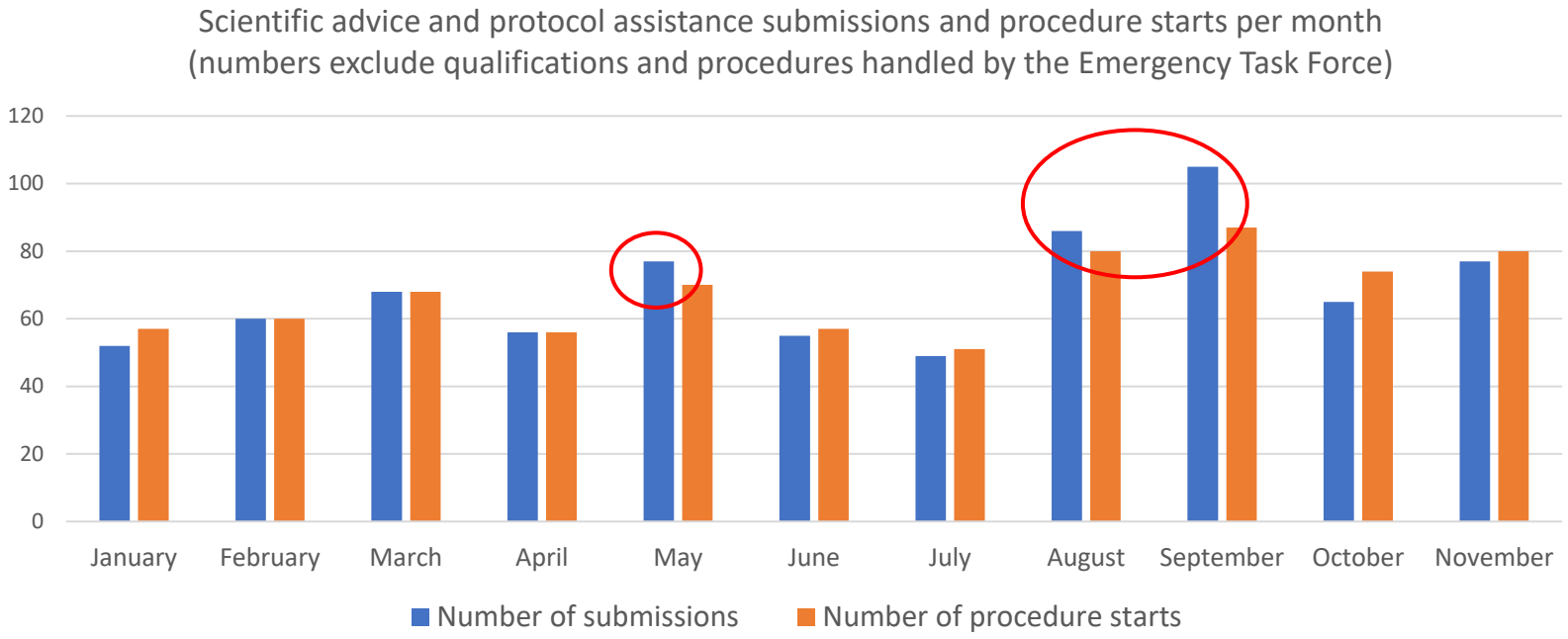
Outline

- 2025 scientific advice final volumes
- Discussion meetings update
- Experience with the SAWP/CTCG scientific advice pilot
- Latest experience with new pre-payment requirements
- Survey on parallel EMA-FDA development support

2025 scientific advice final volumes

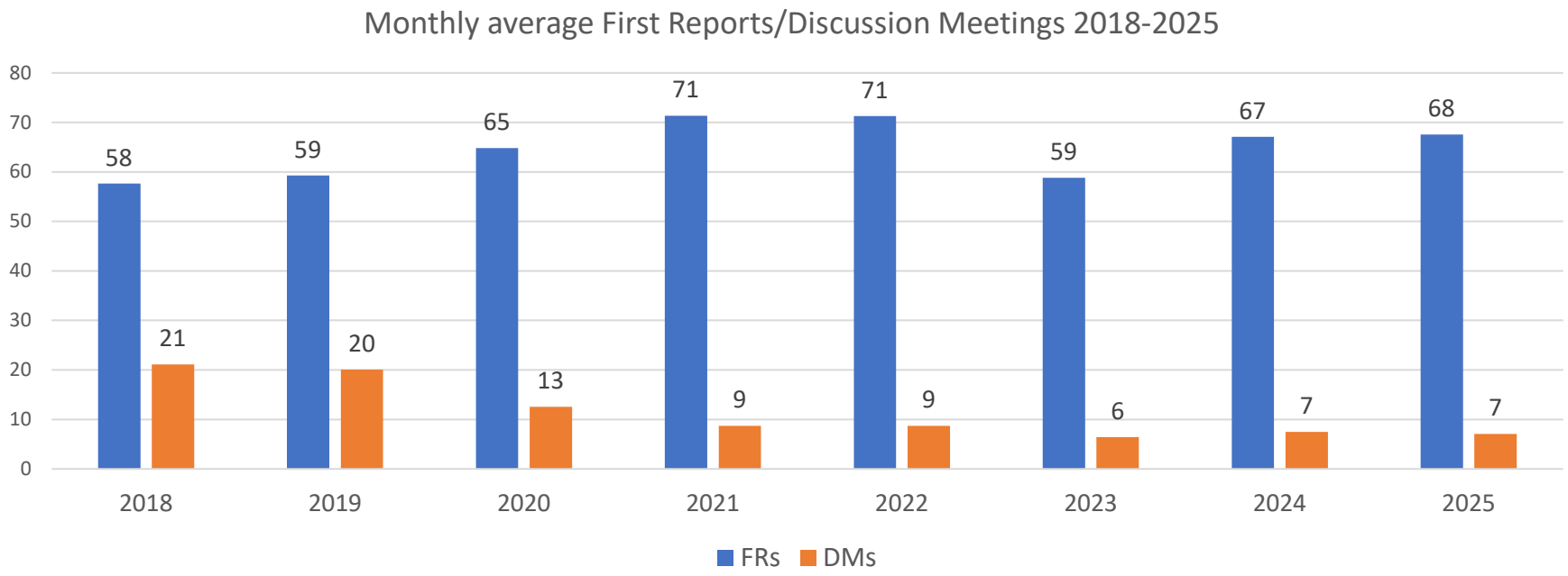


2025 scientific advice volumes per month



Low submissions in first half of the year; Red circles indicate usual submission peaks in May and September

Discussion meetings update



SAWP/CTCG pilot update

- Launched in June 2024, 11 applications (latest from July 2025) successfully completed
- Applicant and EMRN feedback collected via dedicated surveys
  - Expectations of consolidated advice and smoother CTA process
  - Cross-fertilisation between SA/MAA and CT assessors in regulatory discussions but concerns about workload
  - Concerns about MSC engagement and implications for subsequent CTA
  - Concerns about lack of involvement of Ethics Committees and about combined studies* being out of scope

* Combined studies are clinical trials for medicinal products combined with clinical investigations of medical devices or performance studies of in vitro diagnostics, SAWP: Scientific Advice Working Party, CTCG: Clinical Trials Coordination Group, EMRN: EU Medicines Regulatory Network, CT(A): clinical trial (application), SA: scientific advice, MAA: marketing authorisation application, MSC: Member State Concerned,

Next steps

- The pilot remains open, also for previous applicants
- Feedback on the subsequent clinical trial application (if submitted) will be collected and analysed
- Publication of a final report expected now in 2026
- Involvement of Ethics Committees and extension of scope to combined studies is being considered

Latest experience with pre-payment requirements

- Implementation problems with scientific advice advance payment at time of validation as mandated by Regulation (EU) 2024/568 ('new' EMA fee regulation)
  - Constraints on validation time
  - Confusion from separate deadlines for 'financial' validation and submission of final documents/content validation
  - Confusion from legally mandated invoice deadlines extending beyond procedure start date
  - Issues with invoice communication to relevant applicant financial contact point
- EMA plans to move payment at time of initial submission with invoice adjustment at time of procedure start without time pressure
- EMA is developing IT infrastructure to allow direct debit for payment of invoices

EMA survey on parallel EMA/FDA development support

- Low numbers of Parallel Scientific Advice (PSA) procedures prompted EMA to develop a survey in an attempt to understand reasons/opportunities for improvement and to reflect on other forms of EMA/FDA interaction
- Industry associations prepared in parallel a similar survey
- To avoid survey fatigue, the decision was made to conduct a single survey
- Industry proposal informed EMA survey development and the proposed text will be shared with the industry scientific advice sounding board in early 2026 towards finalisation and conduct of the survey
- Discussions to follow in the sounding board after survey conduct to discuss possible improvement possibilities

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Thank you

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