EMA
EUROPEAN MEDICINES AGENCY

Future-proofing Qualification of Novel Methodologies (QoNM)

Update on delivery of the action plan

R&D Stakeholder Platform July 2026

QoNM procedural guidance update

- Industry sounding board (ISB) reviewed, provided helpful comments and supported the final draft
- After consultation involving Methodology Working Party (MWP) and Nonclinical Working Party (NCWP) and 3Rs Working Party (3RsWP), SAWP and CHMP have adopted the revised procedural guidance
- Publication July 2026

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Key new elements

- Detailed chapter defining the **Scope of QoNM**
- '**QoNM early-interaction support**' with **scoping meetings** before submission of a formal request which will help clarifying the best available regulatory support for methodology developments and improving the quality of briefing packages
- Optional **stakeholder consultation** if external expertise is needed (e.g. for highly innovative methodologies) but external experts cannot be involved as QT members due to CoI considerations
- **Publication of high-level information on Qualification Advices**
    - descriptive title, targeted context(s) of use, applicant name, methodology type, contact
    - Aim: facilitate collaboration, data sharing and avoid duplication of development efforts
- **Periodic informal dialogue/trialogue** (QO holder, MP developer, EMA), possible upon request

Key new elements

- **Considerations on generating evidence for qualification**
  - Question of interest
  - Planning evidence generation for qualification
  - Context of Use (detailed discussion of elements to be considered)
  - Risk-based assessment
  - Planning stage, learn/confirm paradigm
- **Lifecycle management (LCM) considerations**
  - LCM plan to be proposed and included in QO request, case-by-case consideration
  - Overview on available regulatory guidance and standards to consider when drafting LCM plan
  - Process: emphasis that monitoring of performance is responsibility of any stakeholder applying qualified methodology; justification usually needed at time of regulatory submission of evidence generated applying qualified methodologies; new QoNM request only voluntarily to update a QO for major changes, or to extend CoU

Briefing document templates

- **Registry briefing document template** is being finalised, publication along with updated procedural guidance
- **General briefing document template** is being finalised; to be shared with ISB in July, publication targeted by September 2026
- **(digital)COA briefing document template** will be drafted in parallel with Q&A, consultation targeted for Q4 2026
- **Modelling & Simulation briefing document template** will be drafted in parallel with Q&A, consultation targeted for Q1 2027

QA/QO/LoS templates

- Drafting ongoing, expected availability for EMRN experts in Q3 2026

Q&A on RWD sources/registries

- Guidance on use of real-world data: questions and answers have been made available on the EMA real-world-evidence webpage in May 2026
- Intended to be a living resource with frequent update cycles
- During drafting, it was considered to focus Q&As first on facilitating understanding of regulatory aspects addressed in existing EMA guidance on the use of real-world data
- Inclusion of aspects related to RWE data sources/registry qualification in this Q&A resource will be considered in 2027

Q&A on (digital) Clinical Outcome Assessments

- Drafting group is starting work
- ISB consultation planned for Q4 2026

Q&A on Modelling & Simulation based methodologies

- Successful workshop on the qualification of mechanistic models in Oct 2025
- adoption of ICH M15 on MIDD
- new pilot program for Scientific Advice on Model-Informed Drug Development (MIDD)
- drafting group is starting work on Q&A
- ISB consultation expected for Q4 2026

QoNM webpage upgrade

- Work ongoing with EMA Webteam

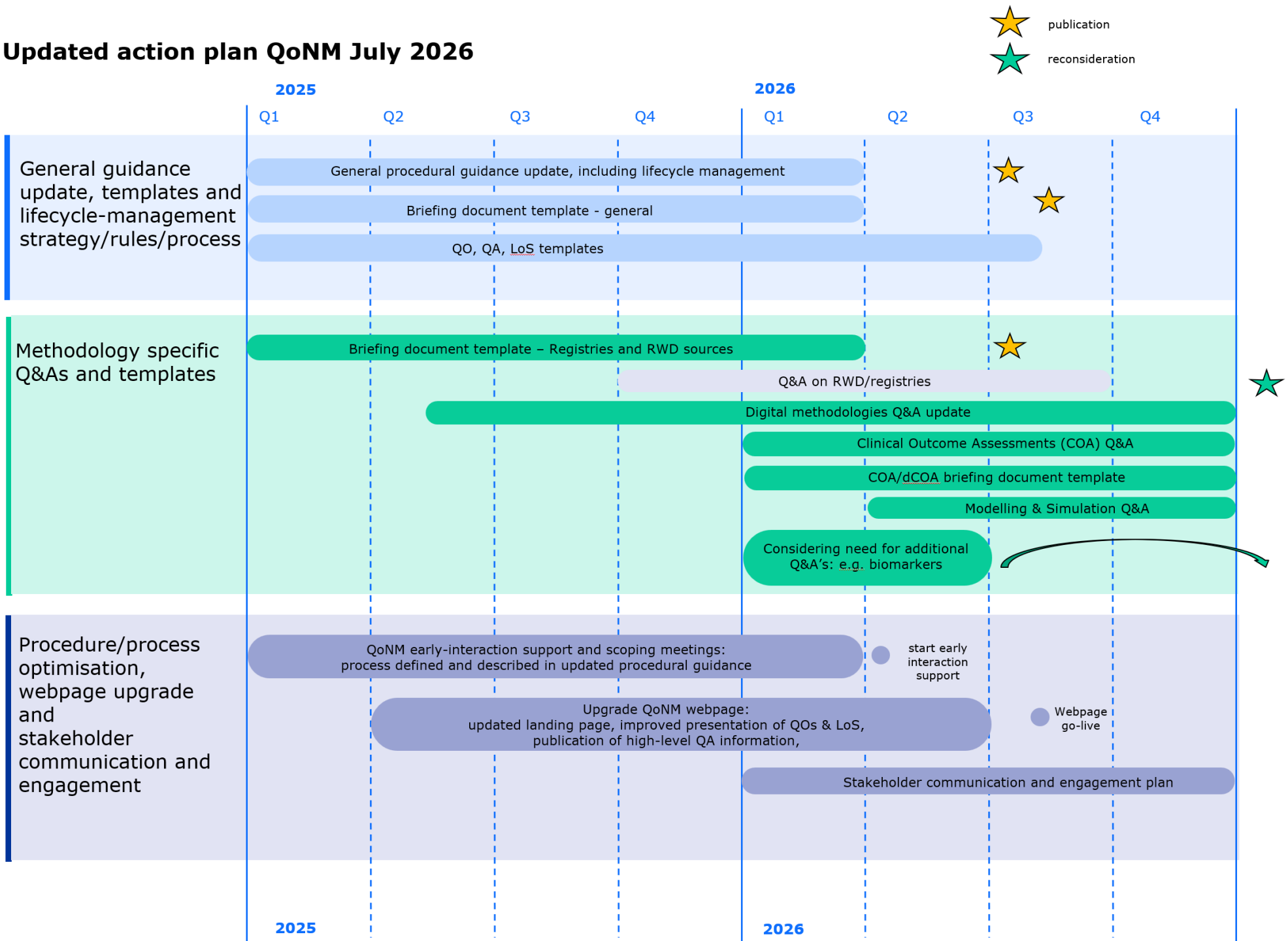
- Concise landing page, explains procedure and presents new procedural guidance
    - Linking to three outcome pages (high-level QA information, QO, LoS)
        - Outcomes structured along the 5 categories of methodologies defined in guidance
    - Linking to html Q&As subpage for upcoming Q&As, to allow frequent updates

- Optimisation of structure and documents based on SEO considerations
- Cross-links to and from other EMA R&D support pages

Further actions

- Stakeholder communication and engagement plan is being developed together with EMA Stakeholder Department and Academia Office and will be shared with the ISB for input
    - Key elements will be a webinar on QoNM platform later in 2026, potentially in collaboration with public-private-partnerships, and reach-out to different stakeholder groups to provide information on the new elements of the QoNM procedure
- EMRN QoNM Core group will consider utility/need of additional Q&A's on other types of methodologies, e.g. biomarker qualification in the beginning of 2027 and liaise with ISB
- Monitoring and reporting of evidence generated by qualified methodologies that has informed regulatory decisions: EMA is developing AI based knowledge management tools, feasibility of automated or periodic manual monitoring will be explored

Updated action plan QoNM July 2026



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Thank you

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