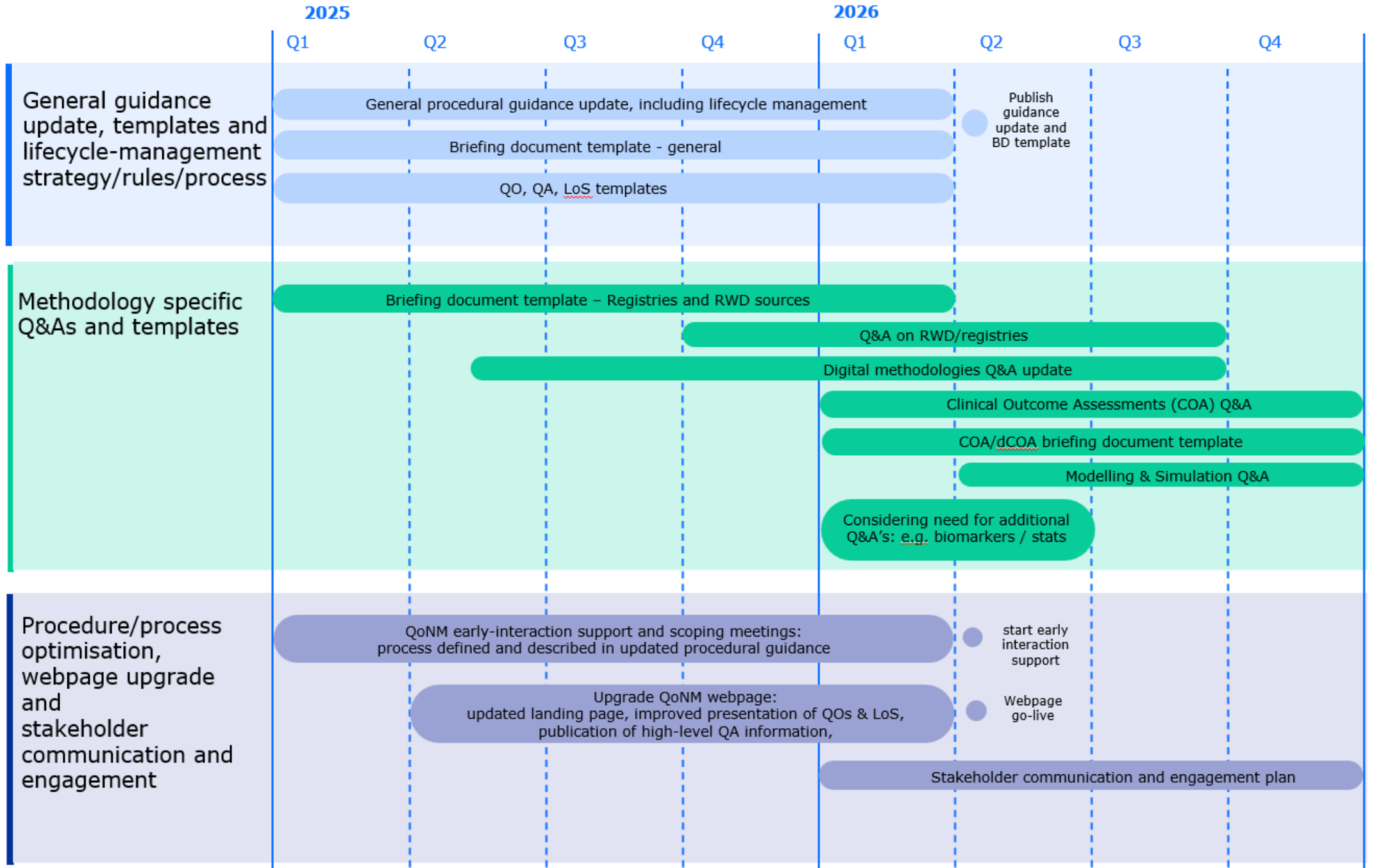
EMA
EUROPEAN MEDICINES AGENCY

Future-proofing Qualification of Novel Methodologies (QoNM)

Update on delivery of the action plan

R&D Stakeholder Platform December 2025

Updated action plan QoNM



Guidance revision – key new elements

- Detailed discussion on the scope of QoNM
  - Categories of methodologies in scope and out of scope for QoNM
- Early interaction support
- Operational and procedural aspects
- Considerations on generating evidence for qualification
- Life-cycle management considerations
- Glossary, reference documents and QoNM-relevant publications

Preparing QoNM and early interaction support

- Dedicated chapter, recommending early, stepwise and iterative approach:
    - ITF (*methodology/research without/before Context-of-Use concept*)
    - Early interaction support preparing QoNM – scoping meetings (*CoU can be envisaged*)
    - Qualification Advice (*methodology in development*)
    - Qualification Opinion (*methodology for regulatory qualification*)

Early interaction support

- Free of charge
- Dedicated contact inbox for inquiries
- Introduction of virtual scoping meetings:
  - Clarify whether methodology and CoU are in scope for QoNM
  - Address procedural questions
  - Advise on optimal briefing documentation to achieve efficient process

Publication of high-level Qualification Advice information

including:

- Descriptive title
- Context of Use
- Applicant name
- Methodology type
- Public enquiry contact

Information intended to support pre-competitive collaboration and will be subject to applicant agreement prior to publication

- Intended to provide high-level principle considerations for methodology developers when developing a qualification plan
- Detailed recommendations for drafting meaningful Context of Use have been included as advised by Industry Sounding Board

- Lifecycle management is critical for certain categories of methodologies:
  - data sources towards adaptation to needs of intended study context and research questions ➔ possibility for trialogue between data source holder, medicinal product developers and EMA
  - AI/ML and other constantly evolving tools ➔ concept of lifecycle management plan
- It also includes extensions to novel contexts of use

Briefing document (BD) templates

- General BD template planned to be shared with sounding board in the next two weeks
- Registry checklist will become a registry/data source-specific BD template
- COA and digital COA (dCOA) BD templates will be drafted in parallel with Q&A, consultation targeted for Q3 2026

Q&A documents

Name	Status; comments	SB consultation	Intended publication
Q&A on Qualification of methods related to DHT/AI/ML	Drafting; focus on DHTs given limited experience with AI/ML-based methodologies	Q2 2026	Q3 2026
Q&A on RWD in medicines development	Drafting; dedicated chapter on Qualification of registries/data sources	Q2 2026	Q3 2026
Q&A on Clinical Outcome Assessments	Drafting group being convened	Q3 2026	Q4 2026?
Q&A on modelling & simulation	Not started	Q3 2026	2027?

Webpage upgrade

- Work with EMA Webteam ongoing
- Go-live at the time of publication/implementation of procedural guidance
    - Introduction of subpages for QA high-level information / LoS / Qualification Opinions
    - Topical ordering as per categories of methodologies
    - Search Engine Optimisation (SEO) of content will increase ability to find content via EMA external webpage search tool and general search engines
    - Introduction of expanding panels to improve usability

Further actions

- Stakeholder communication and engagement plan will be developed together with Stakeholder Department and Academia Office in Q1 2026
    - Training/webinar on QoNM platform later in 2026, potentially in collaboration with public-private-partnerships
- Core group to consider utility/need of additional Q&A’s on other types of methodologies, e.g. biomarkers/statistical methods
- Monitoring and reporting of evidence generated by qualified methodologies that has informed regulatory decisions: potential use case for AI tool development, currently limited by available resources

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

thorsten.vetter@ema.europa.eu

Follow us

General procedural guidance revision

Table of contents

General procedural guidance revision

Qualification Advice high-level information publication

How

Ensure applicant gets involved in review of high-level QA information prior to publication

- the information to be made public should be phrased in a way that IP and CCI is sufficiently protected.
- Furthermore, the applicant should actively participate to shape the content to be made public.
- There should be clear guidance to the Applicant on the EMA qualification advice disclosure process so that internal procedures can be implemented to protect IP and CCI

What

Industry proposal for content of high-level QA information for publication

Proposed descriptive Qualification Advice title elements:

- <method>
- <target population>
- <tool>

Industry proposed format for high-level QA information for publication
Descriptive Qualification Advice title
Context of Use
Applicant
Type of Novel Methodology
Contact for public enquiries

Industry trade organisations agreed to Qualification Advice high-level information publication