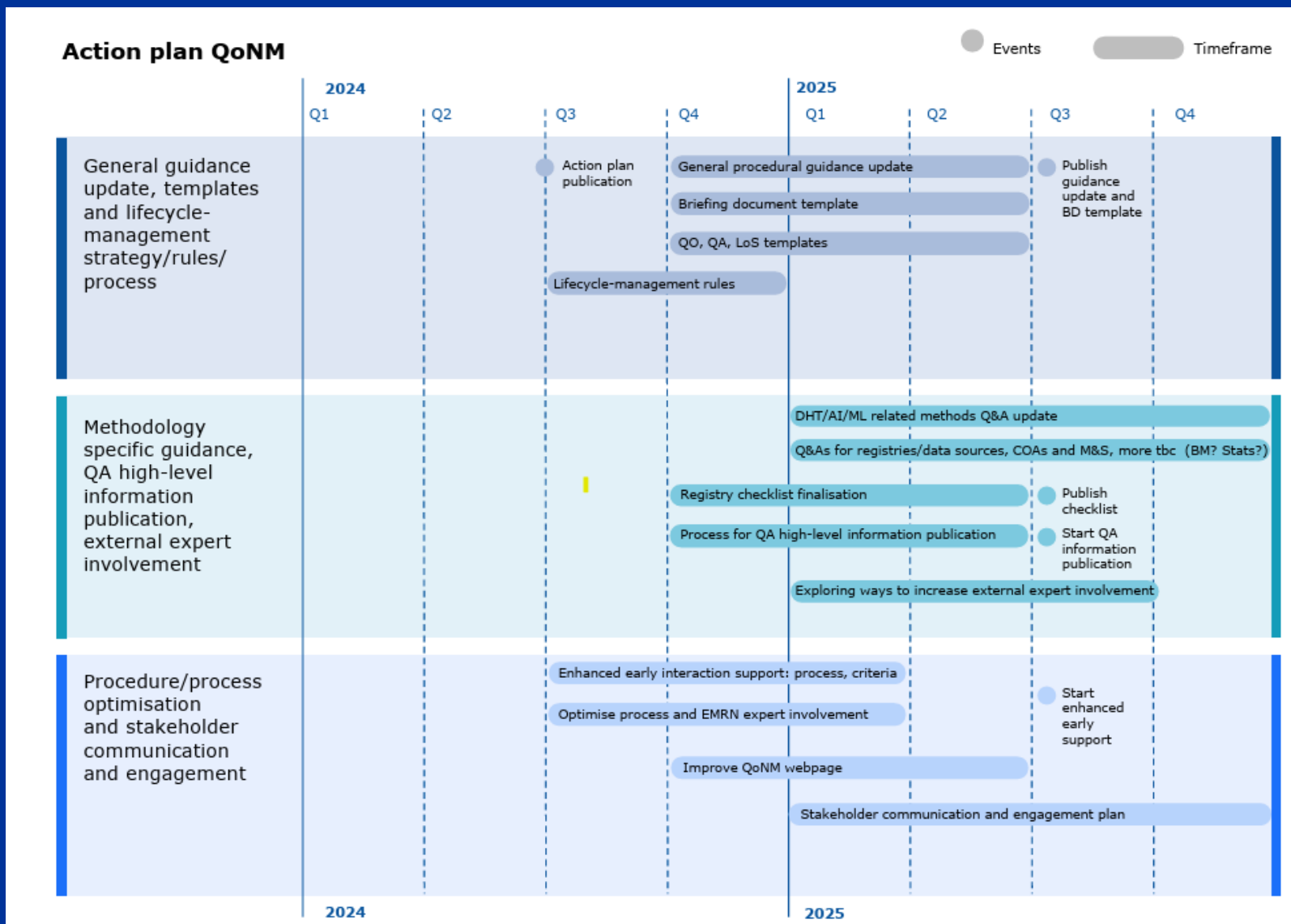


Future-proofing Qualification of Novel Methodologies (QoNM)

Update on delivery of the
action plan

Industry Stakeholder Platform July 2025





- Industry sounding board has been updated in detail on 25 June 2025

- **QoNM core group** has met monthly and progressed discussions on
 - QoNM scope
 - Lifecycle management
 - Early-interaction support and process improvement
 - External expert input during review for highly innovative methodologies
 - Ways to increase EMRN expert awareness/involvement

General procedural guidance, BD templates, webpage

- Core group discussions inform ongoing drafting of
 - General procedural guidance update,
 - General briefing document template and
 - QA/QO/LoS templates
 - 'Registry Checklist' will become a briefing document template
- Work with EMA Webteam has started to improve QoNM webpage presentation including publication of high-level Qualification Advice information, delivery with implementation of procedural guidance (beginning 2026)

General procedural guidance, BD templates

- Due to high EMRN workload, there is some delay vs. the timelines mentioned in the action plan
 - SAWP consultation is planned in September 2025 for
 - General procedural guidance
 - General Briefing Document template
 - Registry Briefing Document template
 - Industry Sounding Board consultation during October 2025
 - Aim to finalise and publish these elements of the action plan by end 2025 with implementation of new elements after publication

Q&A's

- Update of Q&A on Qualification of methods related to DHT/AI/ML
 - Drafting group has been convened
 - Update will focus on DHT related methodologies, given the limited experience with QoNM of AI/ML based methodologies
 - Consultation with sounding board in Q4 2025 and publication in Q1 2026

Q&A's

- Q&A on Qualification of registries/data sources
 - Drafting group is being set up, led by TDA-RWE
 - QoNM aspects may become part of a general Q&A on RWD/RWE generation to support regulatory decision making led by MWP, tbc
 - Drafting group is aiming for draft by end of 2025
 - Consultation in Q1 2026, tbc

Q&A's

- Q&A on Qualification of Clinical Outcome Assessments
 - Drafting group is being set up
 - First draft by end of 2025
 - Consultation in Q1/2 of 2026, tbc

Q&A's

- Q&A on Qualification of modelling & simulation related methods
 - Drafting will start after [WS 8/9 October 2025](#)
 - Timelines tbc, likely drafting until Q2 2026, consultation Q3 2026

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

Further actions

- Stakeholder communication and engagement plan will be developed together with Stakeholder Department and Academia Office by end of 2025
 - Training/webinar on QoNM platform in 2026, potentially in collaboration with PPPs
- Core group to consider utility/need of additional Q&A's on biomarkers/statistical methods
- Options for HTA involvement, liaison with colleagues implementing HTAR
- Monitoring and reporting of evidence generated by qualified methodologies that has informed regulatory decisions (potential use case for SE/AI tool development)



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Thank you

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