EMA
EUROPEAN MEDICINES AGENCY

Progress update on the launch of the Voluntary Data Submissions (VDS) pilot

16th Industry Stakeholder Platform on R&D Support

2 July 2026

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Problem statement - VDS framework

Identified issues

No NAMs qualified yet*, and no data seen in MAA dossiers using the safe harbour approach

*One draft qualification opinion

Sometimes industry may fear NAM data will be negatively considered in regulatory decisions (EFPIA presentation at EPAA meeting)

By the time of MAA some NAMs could be outdated – not latest advancements

Regulators struggle developing regulatory acceptance criteria for a CoU without having access to the data

Reframing the VDS procedure

Independent procedure from MAA and product specific procedures

Specific call for data to address particular contexts of use and regulatory applicability areas

Confidential data only used for supporting regulatory acceptance of NAMs.
No impact on regulatory decision making

Operational expert group (OEG) composed of non-clinical assessors from the EU regulatory network and EMA staff will review the data

Objectives

- Gain **knowledge** and build **confidence** in NAMs data
- Discuss and review **NAMs** within predefined **CoUs** and broader **RAAs**
- Identify **challenges** and **opportunities** for regulatory use
- Provide scientific feedback for **fitness-for-purpose**
- **Harmonise** EU assessment approaches and support training
- Facilitate **regulatory uptake** of NAMs across the network

Previous stakeholders' interactions

Initial engagement with companies and trade associations

- Introduce the VDS concept
- Assess willingness to share NAM-related data via VDS
- Be informed on NAMs in development and intended Contexts of Use

Pilot Co-Creation Kick off meeting with industry stakeholders (Dec 2025)

- Presentation of the proposed VDS pilot
- Refinement of regulatory applicability areas (RAAs) was considered necessary

Stakeholder survey (Jan 2026)

- Gather input to redefine and prioritise RAAs for VDS pilot calls
- Understand expected outcomes of the pilot

Webinar with Industry (30 June 2026)

- Informe on the official launch of the VDS pilot
- Describe the VDS scope and details of the procedure
- Discuss estimated time to complete a full VDS pilot briefing package submission

VDS pilot - scope and eligibility

Scope NAMs data within predefined contexts of use (CoUs) and regulatory applicability areas (RAAs)

RAAs defines a broader regulatory scenario encompassing multiple specific contexts of use, within which methods or combinations of methods may contribute to regulatory decision-making

RAA 1	RAA 2	RAA 3	RAA 4
Biologics risk assessment	**DART risk assessment**	**Safety pharmacology**	**Hepatotoxicity and DILI**
Biologics with no pharmacologically relevant species, or partial response in non-clinical test species	Developmental and reproductive toxicity risk assessment in accordance with ICH S5(R3)	NAMs as part of WoE approaches to support safety pharmacology evaluation	NAM data integrated within a WoE approach to assess the risk of hepatotoxicity/drug-induced liver injury (DILI) for small molecules and biological products

Eligible participants Companies, CROs, method developers, NGOs, consortia and other stakeholders

VDS pilot – Outcome

Submission-specific insights

- Individual, informal written feedback on
  - the readiness of the overall approach or NAM
  - regulatory considerations on the adequacy of the data
  - recommendations on next steps (e.g. ITF, Scientific Advice, Qualification)

Strategic Outputs

- Lessons learned report
  - Support outreach and stakeholders' dissemination
  - Contribute to global alignment (e.g. IMRWG3Rs, ICH activities)
- Impact on NC domain activities and workplan
- Support the drafting of CoU-based acceptance criteria (Annex EMA guideline on 3Rs)

VDS pilot – Process for data submission

1

Step 1

Submission of the **application form** via e-mail **or** EudraLink to the dedicated VDS inbox (VDS@ema.europa.eu)

2

Step 2

EMA **application validation** and **prioritisation**

3

Step 3

Selected applicants invited to submit a **full briefing package**

4

Step 4

Set up required **access**, as needed

- EMA account
- EudraLink

5

Step 5

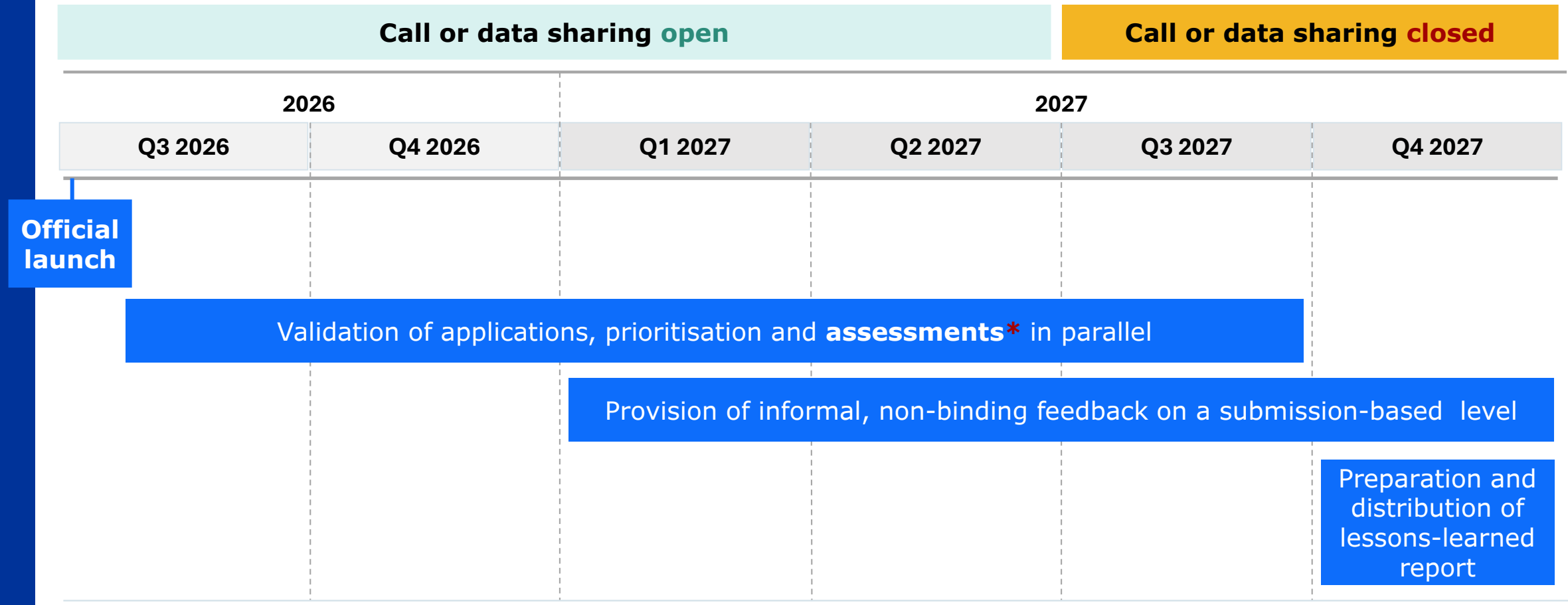
Submission of briefing package via EudraLink

6

Step 6

Secure storage and handling through EMA SharePoint. Data accessible only by OEG members and EMA staff

VDS pilot – Proposed timeline



* The assessment of briefing packages is expected to follow a specific timeline, similar to the SA procedure. However, this may vary depending on the number, prioritisation and complexity of the submissions as well as OEG availability

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Thank you

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