EMA
EUROPEAN MEDICINES AGENCY

Safety MVP: Progress update, ASR key changes & upcoming events

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Status update: New Safety Module

- The new Safety Module is composed of two key components
  - saMS module
  - ASR module
- **April 2025:** Technical prototype completed
- **June- September 2025:** Consultation sessions conducted and completed
- **January 2026:** saMS module successfully completed User Acceptance Testing (UAT)
- **Today:** the ASR Module is in the final stages of development
- **June 2026:** EMA internal testing is planned
- **July 2026**: ASR UAT planned
- **Go live:** End of September 2026

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ASR: Key changes 1/2

Draft ASR management: Sponsors can save, edit and delete draft ASR

Correct saMS display

The system will display the correct saMS for each ASR

ASR submission

Sponsors will be able to submit ASR per substance group (IR 2022/20)

Multiple sponsor collaboration

Not a sponsor-centric system, multiple sponsors can join and submit one ASR after the correct roles are assigned

-Applicant, when ASR is submitted on behalf of the sponsor(s)

- Invoice section

Structured Assessment Report: Includes default mandatory sections while providing flexibility to support in-depth assessment and upload documents where needed.

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ASR: Key changes 2/2

Optimised RFI process: New way of creating, submitting and responding to the RFIs

Clear outcomes: clear Summary & Conclusion and Recommendation for sponsors, including clear actions with deadlines for sponsors

Recommendation option: Clear recommendation for sponsors if there is any

Email notification for sponsors: Timely email notifications when an RFI is submitted, and ASR is finalised

Download: Download document, structured data and the outcome & conclusion

User interface improvements: Enhanced user experience for greater ease of use

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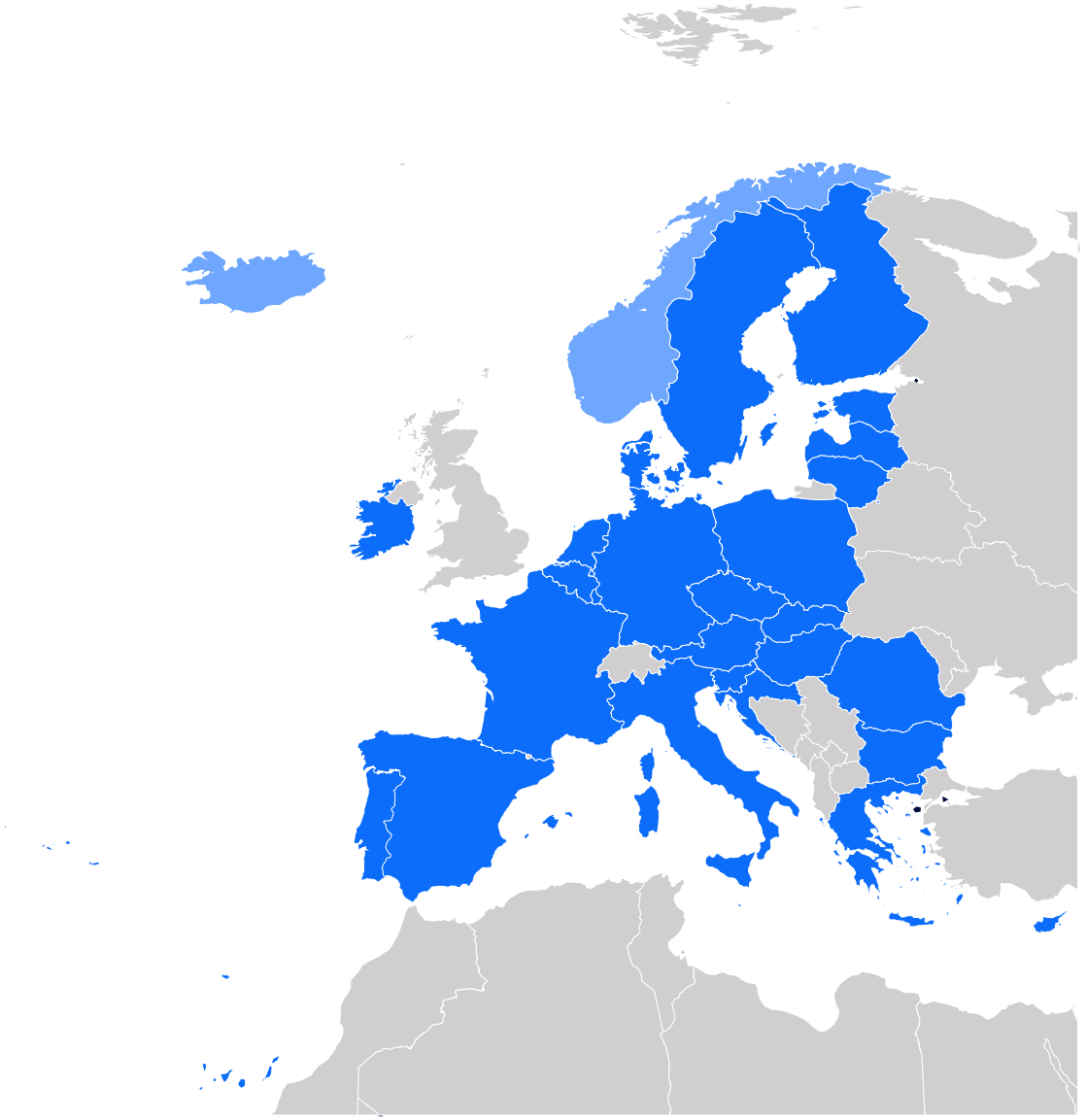
The New Safety- Go live

- The new Safety Module is scheduled to go live at the end of September 2026
- Once launched, all new ASRs will be submitted in the New Safety Module
- Already submitted ASRs in the current system will be managed in the current ASR module
- A training environment will be available in August for both sponsors and assessors
- Draft training materials will be released at the same time
- A Bitesize talk will take place in July, with the recording shared along with the training materials
- Additional Bitesize talk and walk-in clinic sessions will be organised after go-live, based on demand.



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Transition period

- A 2-month **transition period** will follow the go-live date

During this period:

- Member States can **finalise ongoing and already submitted ASRs** in the current system
- Sponsors can **receive notices and requests (RFIs) and respond to them** in the current system
- Sponsors **cannot create or submit new ASRs** in the current system

Important

- After the transition period ends, **completed ASRs will no longer be accessible** in the current system
- Member States are **strongly encouraged to complete all ASRs** before the end of the transition period

Data migration and archiving

- CT-specific information (e.g. authorised, halted, suspended) will be migrated based on the status of CTs in CTIS
- Information about the test IMPs and the substance group
- Completed ASRs will be archived during the transition period, with access restricted to NCA users

Not in scope for migration/archiving

- saMS history and Safety issue tracker (for MSs)
- Incomplete ASR after the end of the transition period

Important

- Ensure that all ASRs are finalised before the transition period
- Ensure that relevant copies are retained for archiving purposes (sponsors)

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Key takeaways

- The new Safety Module is scheduled to **go live at the end of September 2026**
- A 2-month **transition period** will follow the go-live date
- The new Safety Module **will fully align ASR and saMS processes in CTIS with the applicable regulatory framework.**
- **ASR UAT** on July 20-22
- A **Bitesize talk** will take place on July 23rd, with the recording shared along with the training materials
- A **training environment and training materials** will be available in August for both sponsors and assessors
- Key milestones and important information will be communicated regularly through the **CT Highlight newsletter**

The new Safety Module is modern, flexible, and it is designed to be user-centric

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Thank you.

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