CTIS in 2026: What EU Trial Sponsors Need to Know

CTIS is now the mandatory portal for EU/EEA interventional medicinal-product trials.
The next major change is the new Annual Safety Report (ASR) module.

31 JAN 2025

Full CTR/CTIS Operation

All ongoing EU/EEA trials must be governed under the Clinical Trials Regulation and managed in CTIS.

UNTIL 27 NOV 2026

Prepare Safety Reporting

Explore the CTIS ASR training environment. Confirm ASR Submitter acess. Align sponsor, CRO and pharmacovigilance responsibilities.

28 SEP 2026

New Safety Module Goes Live

All new ASRs must be created and submitted in the new module. The legacy workflow will no longer accept new ASRs.

30 NOV 2026

Transition Ends

Finalize ongoing ASRs in the legacy workflow and download needed records. Sponsor access to legacy workflow ASRs ends.

SPONSOR ACTION CHECKLIST

- ☑ Submit one annual report for each IMP other than placebo.
- ☑ Choose a clinical-trial-centric or substance-group-centric ASR.
- ☑ Monitor notices and alerts daily; ASR RFI deadlines default to 14 days and may be shortened.
- ☑ Maintain your own compliant archive; CTIS is not a clinical trial management system.
- ☑ Continue submitting SUSARs through EudraVigilance.
- ☑ Redact confidential information and anonymize personal data before publication.

MAKE THE CUTOVER EASIER.

QPS aligns CTIS roles, ASR/DSUR preparation, submission timelines, RFI responses and cross-functional safety workflows.