Trial SafetyXchange (TSX)

CTIS Expertise

30 years
of regulatory experience

Description

Cloud based SaaS solution to support pharmacovigilance and submitting of ICSRs in the new E2B R3 format, compliant to FDA standards, and scalable for international standards.

FDA MANDATE

Pharmacovigilance ICSRs submission in ICH E2B R3 format by **Apr. 2026,** expected to be adopted by other international authorities.

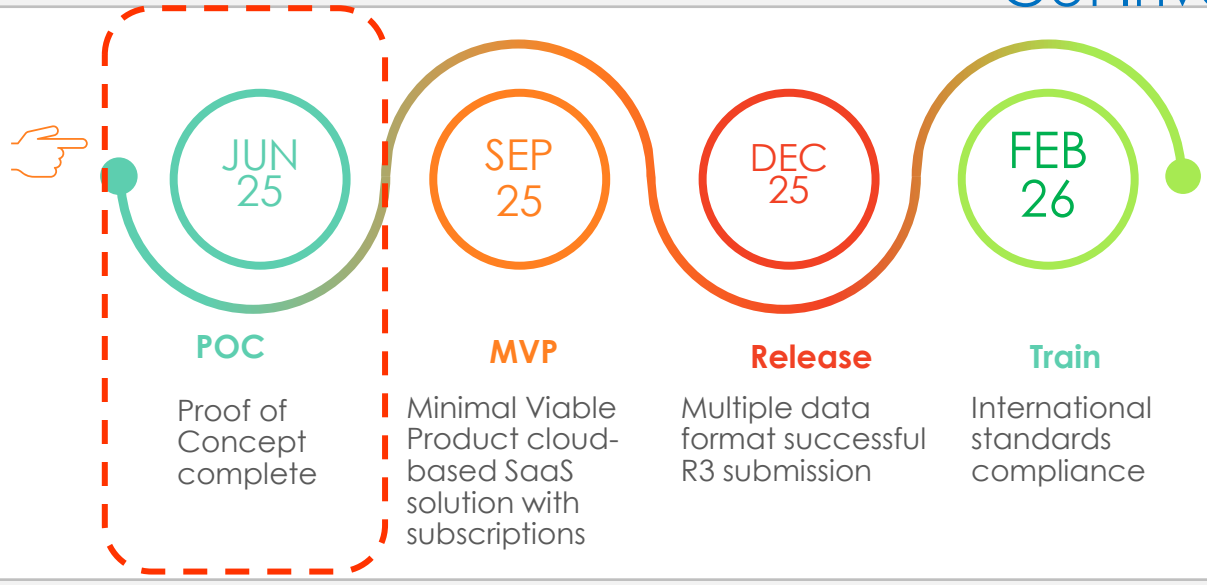
Challenges

- Budget constraints for pharmacovigilance systems upgrade.
- Limited IT and technical expertise.
- Adoption process and learning curve to the new standards
- Risk of regulatory penalties
- Higher cost of rework
- Delayed approvals

Key Features of TSX

- Saas Based product with tiered approach
- One size fits all, easy to use workflow
- Load current file formats in Excel or XML to the tool to see automated report in the new R3 format
- Drag and drop features to map fields with unique requirements
- Automatic Import of R2 files
- Auto validation feature that flags errors and provides actionable guidance for correction

Get Involved



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