Urgent Safety Update: New Signal Raised by the FDA

The Situation

In April 2025, the FDA issued a safety labelling change notification for a product. They requested updates to the USPI across several sections, including Contraindications, Warnings and Precautions, and Adverse Reactions.

Following the FDAs request in parallel, the client's HQ clinical safety team assessed the signal for anaphylaxis and shared a proposal for a core data sheet (CDS) update and a Direct Healthcare Professional Communication (DHPC) to the Drug Safety Committee (DSC).

The DSC gave the team endorsement on 11 June 2025. This was deemed urgent and therefore followed urgent safety timelines [11 June + 3 months.] HQs had a timeline to dispatch by 25th July (so 6 weeks for HQ and 6 weeks for affiliates). DLRC realised that this would be one of the first CDS dispatches in the new system itself and we didn't really have a chance to get it wrong due to the high complexity around the system itself and the urgent safety timelines. We had to ensure the process went smoothly the first time round due the tight timelines. DLRC successfully dispatched this CDS 3 days earlier than the deadline!

Following the CDS dispatch. The team were planning a Type II variation to include this safety change in the EU Annex (which was due 11 September). Whilst the team prepared for this, in parallel there was a PBRER being submitted end of July. The EU PM informed EMA about the safety signal and the team's plans for submitting a Type II variation. The EMA asked for the safety updates to be included in the PBRER. We had to incorporate this safety signal in the EU Annex, review this with authors/experts, and send this off to publishing within 6 days.

DLRC's Solution

Task: DLRC was responsible for coordinating the CDS update and EU Annex. The main challenges were navigating tight regulatory timelines and working with a completely new system (RIM), which involved multiple cross-functional teams.

Action:

- We collaborated closely with clinical safety, EU PM and compliance colleagues to ensure accuracy and alignment.
- We took the initiative to be proactive by helping other functions who were unfamiliar with RIM and guide SMEs through finalizing reviews, and clarifying next steps in the process.
- The DLRC team managed reviews and submissions within very short timelines, while also troubleshooting RIM uncertainties as one of the first users for CDS dispatch in our new system, making the process both critical and complex.

The Outcome

DLRC successfully dispatched the CDS in July 2025, meeting urgent safety timelines despite system and process challenges. We delivered the EU Annex update and incorporated the safety signal into the PBRER submission within six days. This ensured on-time compliance with EMA's request.

This was the teams first experience managing a CDS and EU Annex update, and despite the steep learning curve, we contributed to a smooth, timely dispatch.

The team later shared the experience internally with the DLRC team as best practice. This will help streamline future RIM dispatches and submissions.

This project gave DLRC valuable experience in urgent safety labelling, cross-functional collaboration, and adapting quickly to new systems under pressure. Although it was a high-pressure situation, it demonstrated how teamwork, adaptability, and proactive problem-solving can lead to success.

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