Q&A not addressed during the Pistoia Alliance **P**harmacovigilance **S**ystems and **P**rocesses **S**tandards (PS^2) webinar on 27th Aug 2025

Q: What KPIs should be tracked to measure the success of a unified ICSR intake solution?

A: We haven't yet defined those KPIs, but adherence to process and functional requirements, compliance with pharmacovigilance regulations, adherence to interoperability standards and the safe and ethical use of AI and NLP in line with regulatory expectations are certainly a few relevant KPIs to be tracked.

Q: With the emerging standards by different regulatory authorities on the use of AI in PV processes, especially on data privacy and security as the main concern, how hard is it to set the standards?

A: We are planning to engage with regulatory authorities and will be able to answer this question after our initial conversations.

Q: One point I would add is that clean intake data is not just a one way push into the safety system, it has to be a two way exchange. Would the standards also cover how this two way exchange should happen, so that we are solving the full problem and not just half of it

A: Clean intake data indeed depends on upstream systems' capabilities of providing structured and clean data to intake, which is often not the case (e.g. call center systems, PSP (**Patient Support Program**) platforms, etc...). Clear APIs to accept upstream data would allow PV teams to communicate their needs to these systems.

Q: If you use AI, why you have siloed functional modules since AI can present and evaluate data as current and as refined?

A: This question would require clarification before we can provide an accurate response.

Q: The industry already worked on data standards. What have we learned from the limits of those past efforts? (r3 was supposed to make things more efficient and less expensive but it does not)

A: We are going to leverage existing data standards and extend them where needed. If you see inefficiencies in those standards, we'd be happy to discuss them with you to avoid those pitfalls.

Q: how we are defining systematic plans to adapt AI to complement our tech transformation to be more efficient and complaint

A: We aren't going to produce any plans of adopting AI as part of PS². There's a separate and complementary Pistoia Alliance initiative that will explore opportunities to use AI in PV. (PA contact thierry.escudier@pistoiaalliancve.org). However, as part of PS², we will define requirements to ensure a safe and ethical use of AI and NLP in line with regulatory expectations.

Q: What are the aspects we can look at, when we say case intake?

A: This is a very broad and open question, which would need refinement to allow us to respond.