The next safety database upgrade – assessing impacts of E2b(R3)

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Quick summary

Pharmaceutical companies will be forced to upgrade their safety database to comply with E2b(R3) or face a major compliance risk. The new standard triggers a lot of changes and the impact and complexities can be difficult to assess for companies. As a consequence, many businesses are not able to accurately lock down the cost and resources for the required upgrade activities. Therefore, Navitas Life Sciences has constructed a "rapid assessment" framework, in order to quickly orient towards what is really necessary and save time and money on the implementation work.

Exactly what is E2b(R3)?

E2b(R3) is a new messaging protocol to carry safety information in a more interoperable and robust form than its predecessor E2b(R2). It is a representation of the ISO ICSR standard. The current E2b(R2) format was, already in 2005 when it was mandated, clearly limited and issues have been piling up. E2b(R3) is more contemporary and based on HL7 / ISO ICSR - and will allow for additional and more correct safety information to be transferred.

E2b(R3) represents the biggest pharmacovigilance technology challenge of the decade

Regulatory changes are constantly impacting pharmacovigilance (PV) and equally so the technology supporting it. The rate of changes has increased during the past years and been made more complex by heterogenous global requirements, despite efforts to build ISO and ICH standards. E2b(R3) is in itself a relatively simple technology advancement, comparing to the technology progressions across industries that are happening these years. That being said, E2b(R3) is a key component in an effort to bring data quality and interoperability to a level where health agencies can more accurately assess risk to patients. The European Medicines Agency (EMA) have been spearheading this and aim to bring their safety system / database, EudraVigilance, to a new level, using E2b(R3) as a vehicle for receiving safety cases from industry – and being able to identify medicinal products better with the addition of the upcoming IDMP standards. EMA will also be delivering safety information to industry using E2b(R3) formatted messages e.g. from EMA MLM (Medical Literature Monitoring), from NCAs or other MAHs, or by identified cases from EVDAS signal detection. The EMA are not alone in adapting to the new format, in Japan the PMDA will also be mandating submissions in this format by 2019. The US FDA is more open to an extended overlap of standards, but will have capability to receive both the old and new formats. There will be many local agencies that will still require E2b(R2) for a long time to come, therefore the coming years will be a complex mix of two messaging standards.

The next safety database upgrade is imminent – and complex

All pharmaceutical companies at **pvtech** are targeting to perform an upgrade of their Safety Database (SDB) in order to meet the challenges of E2b(R3). Based on discussions with a large number of companies, we have concluded that 2017-2019 will be the biggest years in history in terms of SDB investments. The complexity of implementation for the next upgrade is perceived as high. Unfortunately, many companies have not been upgrading a while, leading to general uncertainty about impact, i.e. having difficulties assessing where exactly the complexities issues will materialise on their upcoming upgrade project. A high percentage of companies have also built interfacing solutions on the E2b(R2) as well as a number of customisations, and are now considering if a major SDB upgrade will impair already established technological capabilities – all things are likely to drive the cost up.

The outlook for the SDB functionality longevity seems to be that not only one upgrade will be needed, but two over the course of the next 5 years, as IDMP standards will require new product dictionary and coding functionalities. This understanding suggests a different approach, to conserve as many resources as possible and create a lean entry angle on SDB upgrades, as PV departments typically are heavily strained by upgrade activities.

New processes and new challenges

The new messaging format and revised EudraVigilance system is not purely going to end up becoming a technology challenge: Many parts of the PV organisation will need to have procedural updates, to accommodate new data points for data entry and coding options, to ensure EudraVigilance monitoring and to ensure the right format to the right destination. At **pvtech**, members who have analysed the impact of case handling reported a workload increase of between 15-40% across functions.

Becoming faster and better at assessing what to do

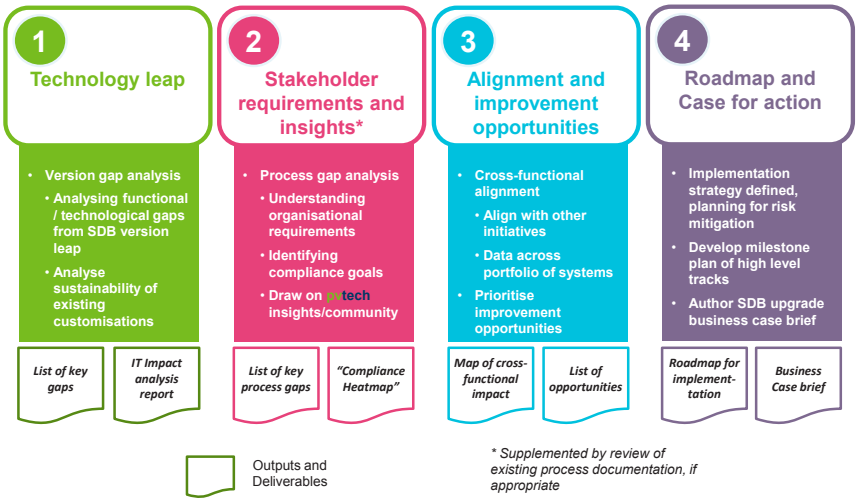
Realising that companies will be struggling to meet regulatory requirements, while conserving resources and keeping costs at a reasonable level, Navitas Life Sciences has developed a framework for assessing SDB upgrades. The aim is to help companies quickly assess their next upgrade in order to uncover all the significant uncertainties, holistically, from technology, process and organisation, across all the PV processes - and at the same time to build a business case and implementation plan. We call this a "SDB rapid assessment".

Why Navitas Life Sciences is uniquely positioned to help assessing impact

- Contextual understanding and expertise; Extensive experience in the Safety function (business and technology) and having worked in many small, medium and large global life science organizations on similar engagements
- Unique industry insight; Our expertise and insights gained from running the industry leading networks of pvnet®, pvconnect®, pvtech®, labelnet® and rimnet® ensure we understand industry challenges and the approaches to address them
- Capable and experienced global team; Efficient and flexible resourcing model driven by our combined US, EU and India based team of highly skilled and knowledgeable consultants
- Depth and breadth of experience; Navitas Life Sciences experts work as a cohesive and well connected project team calling upon years of diverse skillsets
- Argus experience and an Oracle Gold Partnership; Navitas Life Sciences have been successfully delivering Argus upgrades, implementations (traditional and cloud based) and support for several years – Navitas Life Sciences has over 15 successful implementations of Argus to its credit
  - We work in close alignment with the Oracle Product Strategy Team which provides us with an insight into future versions of Oracle Argus

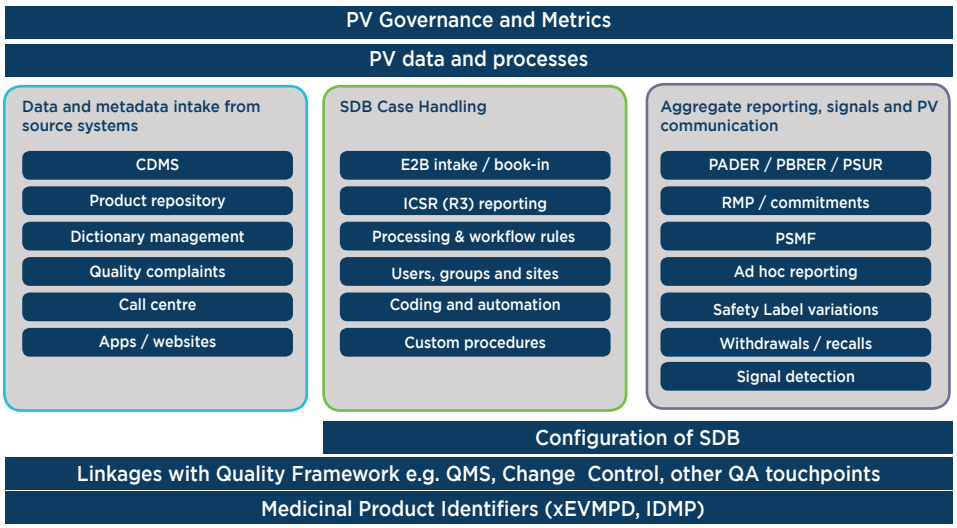
- The SDB rapid assessment provides:
  - Cost reductions for the implementation phase, through accurately describing/streamlining activities; driving an informed RFP
  - Increased efficiency and delivery of implementation to project timelines; risks are understood through proactive analysis of complexities
  - Technical best practices are built into implementations from the outset; driven by our industry insights and SDB experience
  - Allows for alignment between operational excellence initiatives and the upgrade project, to ensure best practice, integrated processes
  - You get the most from your upgrade, by mapping the latest SDB improvements against organisational needs

The Navitas Life Sciences Rapid Assessment framework is a 4-step model



It is all designed to happen within a span of intense 4-8 weeks, depending on company specific needs and availability of key stakeholders. Any assessment will be tailored to the company and take into account specific angles of interest. The discussions on scope is driven by the figure below.

SDB Rapid assessment components of potential focus in a company



If you are interested in learning more about the SDB rapid assessment framework, please contact Navitas Life Sciences at contact@navitaslifesciences.com

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