Implementation Success Story

Vitrana’s TransformPV, the preferred solution for meeting R3 requirements recently went live at biggest Pharma organization in the world. Despite the significant complexities the implementation went very smoothly and implementation went live on time and within the project budget. In current scenario with a defined FDA Guidelines and no major updates expected, the TransformPV implementation can be managed through an accelerated approach and can be accomplished in as little as 2-3 months.

TransformPV is the only solution in the market to have successfully gone live with both Vaccine R3 and Device HL7 reporting.

Since the go-live there have been thousands of successful submissions to FDA VAERS and eMDR.

During the course of the project there were significant updates introduced in the guidance, but due to design of TransformPV platform there was minimal impact of these updates and we were to able turnaround with updated solution within weeks instead of months.

As we look back at this significant milestone, there are few critical success factors we would like to share for organizations who are planning or in process of implementing an R3 capable solution:

**Detailed requirements Assessment**

- To Identify impact to company’s system and processes
- How to manage new data in R3 e.g. Amendment, EU Causality Assessment, Vaccine fields, nullflavors
- Manage organization specific customization
- Prepare the business for upcoming regulatory changes and R3 framework
- Additional data needs and business process updates required
- Identify upstream/downstream implications
Close coordination with regulatory agency

- Multiple discussions with FDA resulted in significant updates in VAERS regional guidance in July/Aug 2016 (the updates prevented one of top 5 pharma organization to roll back their R3 solution)

Here’s some interesting details from the last implementation:

- First solution to successfully go-live on Vaccine R3 and eMDR HL7 format
- Before the formal pilot with FDA, approx 200 R3 and HL7 were submitted to FDA as part of informal pilot
- Feedback from project team to FDA resulted in major updates to VAERS guidance
- Agency acknowledged the positive impact by the project on the final guidance

TransformPV platform allows organization to manage their R3 compliance needs without significant investments and allows them to focus on more pressing needs. The platform is scalable to meet future requirements and comes with features like R3 only viewer, R2-R3 view for transmissions, Integration with LDAP and Documentum.

For more details about the solution please reach us at sales@vitrana.com or www.vitrana.com/products/transformpv