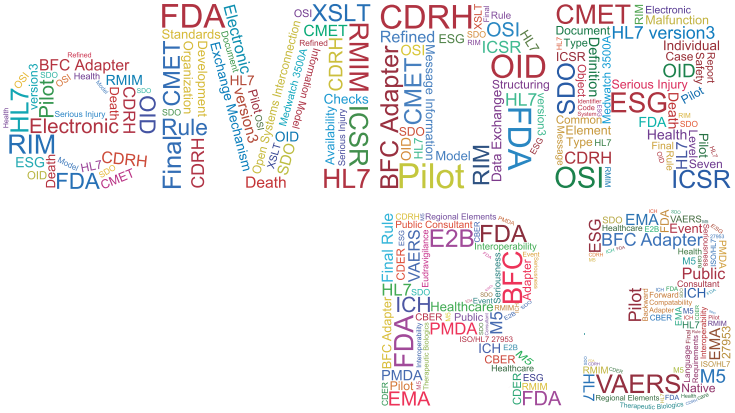
eMDR Deep Dive Workshop



Its time to get ready for Electronic Medical Device Reporting (eMDR). The Food and Drug Administration (FDA) has started to accept E2B pilots for eMDR and is expecting organizations to be in compliance by August 2015. Vitrana consultants are on a mission to help its clients prepare for the imminent challenge to be eMDR Ready.

Agenda

- ✓ eMDR Highlights
- ✓ E2B(R3) Overview for Drugs and Vaccines
- ✓ FDA Regional Requirements
- ✓ Hands-on session
- ✓ Assess Readiness
- ✓ Next Steps

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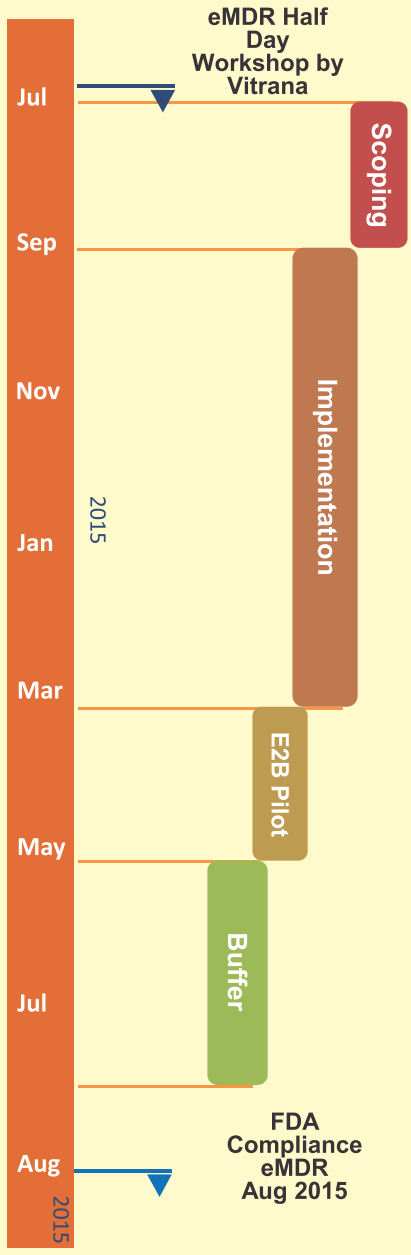
eMDR Readiness

On Feb. 13, 2014, the FDA published a final rule on Electronic Medical Device Reporting (eMDR) that requires submission of MDRs to the FDA in an electronic format. Post August 13th 2015, manufacturers must provide an evidence of ongoing efforts toward eMDR. Now is the time to perform an organizational R3 compliance readiness assessment to determine how best to meet these changing regulatory requirements, and to minimize any impact on the existing systems



Scoping

- Fit gap analysis
- Review of business process
- Prepare validation plan

Project Plan

- Aligned with compliance dates
- E2b pilot planning
- Ready to implement detailed project plan

Automation

- Transformation tool for eMDR conversion
- Web based UI for easy configuration and front end based validation

Validation Strategy

- Comprehensive validation strategy aligned with regulatory requirements
- Accelerator based validation assets
- Apply best practices from past integration implementations

E2B Pilot

- Experienced consultants with strong experience in working with EMA and FDA
- Sufficient buffer for back and forth with regulator for data validation