E2B R3 Deep Dive Workshop

Its time to get ready for R3. EMA and FDA have started finalizing the guidance. The first to implement date for organizations to be in compliance is expected to be as early as Q4 2015 for FDA CBER. Vitrana consultants are on a mission to help its clients prepare for the imminent challenge to be E2B (R3) Ready.

Agenda

- ✓ E2B(R3) Highlights
- ✓ Understanding IDMP(M5)
- ✓ FDA Regional Requirements
- ✓ Hands-on session
- ✓ Assess Readiness
- ✓ Next Steps

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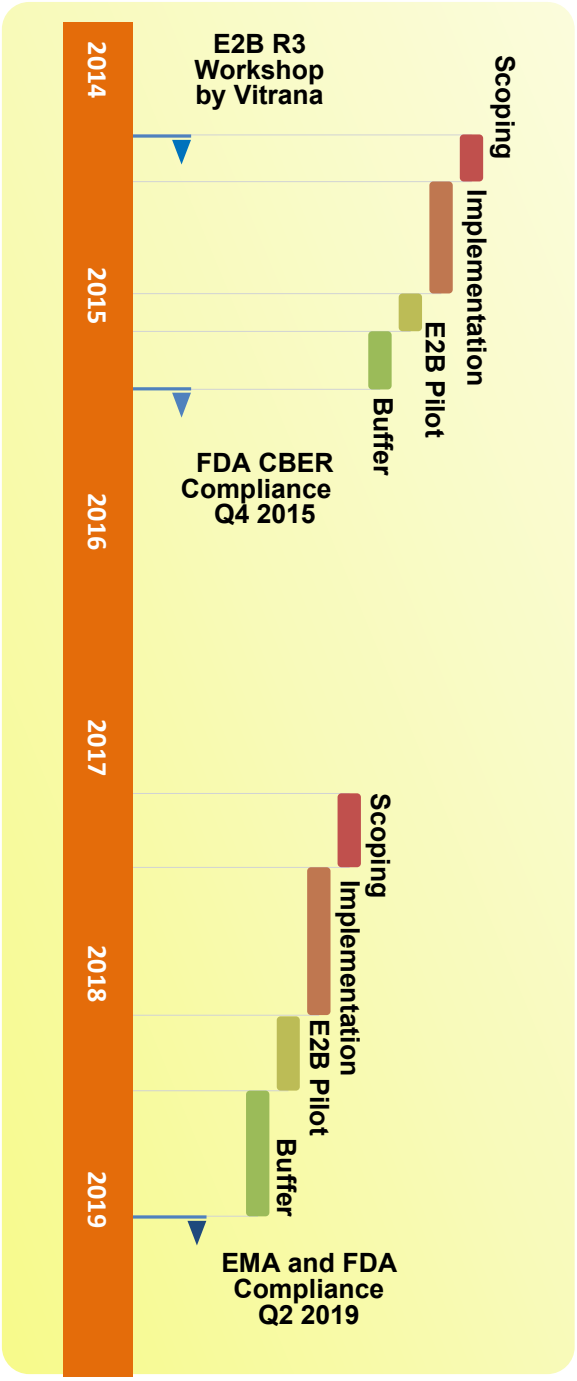
E2B R3 Readiness

In November 2012, ICH E2B (R3) was signed off based on the ISO ICSR standard, enabling the worldwide implementation replacing progressively the current E2B (R2) version. Regional guidance are being provided by the FDA and EMA, with the final rule for Vaccines already issued by FDA. 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 of PLS in line with IDMP requirements
- Review of business process
- Regional Requirements

Project Plan

- Aligned with compliance dates
- E2b Pilot Planning
- Ready to implement detailed project plan

Automation

- Transformation tool utilizing Backward Forward Compatibility(BFC) Adapter
- Web based UI for easy configuration and front end based validation

Validation Strategy

- Comprehensive validation strategy aligning with regulatory requirements
- Accelerator based validation assets

E2B Pilot

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