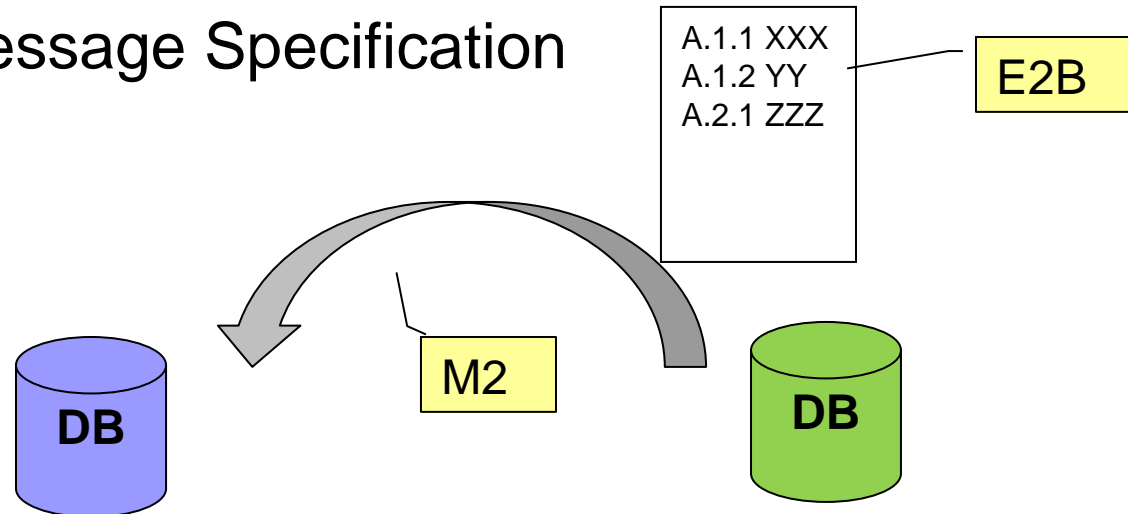


Data Elements for Transmission of Individual Case Safety Reports (ICSRs)

E2B (R3)

Background

- **E2B (R3)** : Data Elements for Transmission of Individual Case Safety Reports (ICSRs)
- **M2** : Electronic Transmission of Individual Case Safety Reports Message Specification



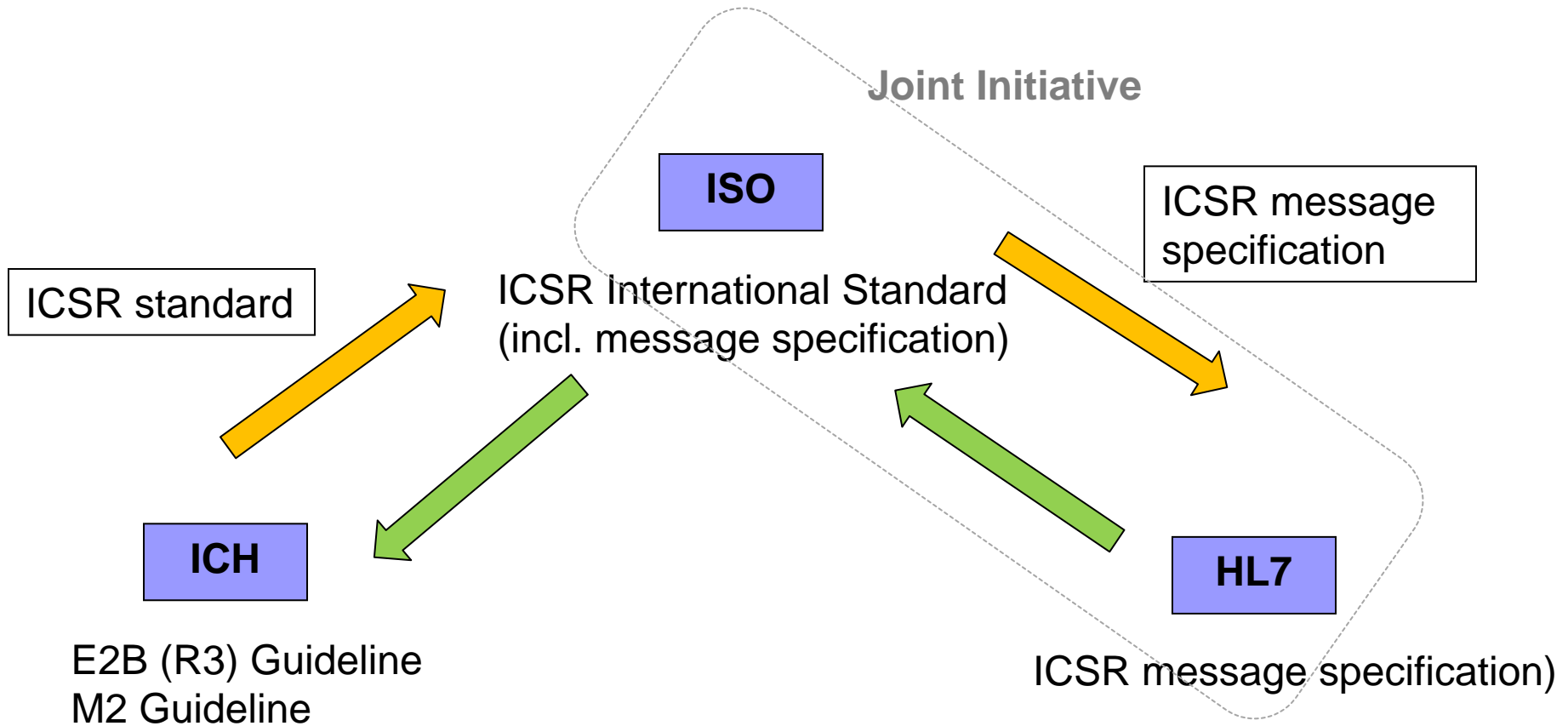
- Deliverable of E2B(R3) EWG
 - E2B(R3) guideline

History of E2B

- July 1997 E2B step4
- Nov 2000 E2B (M) step4
- Feb 2003 E2B (M) IWG
- Nov 2003 E2B (R3) EWG start
- May 2005 Step2
- July 2005 Step3
- Mar 2007 ISO New Work Item Proposal

Move to SDO Process

SDO Process for E2B



ISO / TC215 / WG6 / ICSR TF

- TC215 (Healthcare information) / WG6 (Drug)
- ICSR Task Force :
 - Leader : Nick Halsey (E2B expert, EMEA)
 - Experts : ICH member and non-ICH member
 - Objective : Developing international standard for pharmaceutical products for human use
- Balloting step
 - National member body (1 voting / country)
 - CD → DIS → FDIS → IS

HL7 / Pharmacy SIG

- Developing standard for message of broad ICSR (pharmaceutical products, veterinary products, cosmetics and foods)
- Balloting step
 - HL7 member (1 voting / member)
 - Normative standard, Informative standard and Draft Standard for Trial Use

Scope of ICSR

HL7

ISO req./ISO conform./ISO schema

regional extended requirements

ICH requirements

ICH E2B / M2 (1)

- Implementation guide
 - Constrain ISO ICSR message for the purpose of ICH E2B use (constrained message specification and rules for implementation)
 - Explain how to use the message (user guidance)

Example

Different 4 styles of airplane can be created under HL7



- ICH E2B needs only one style

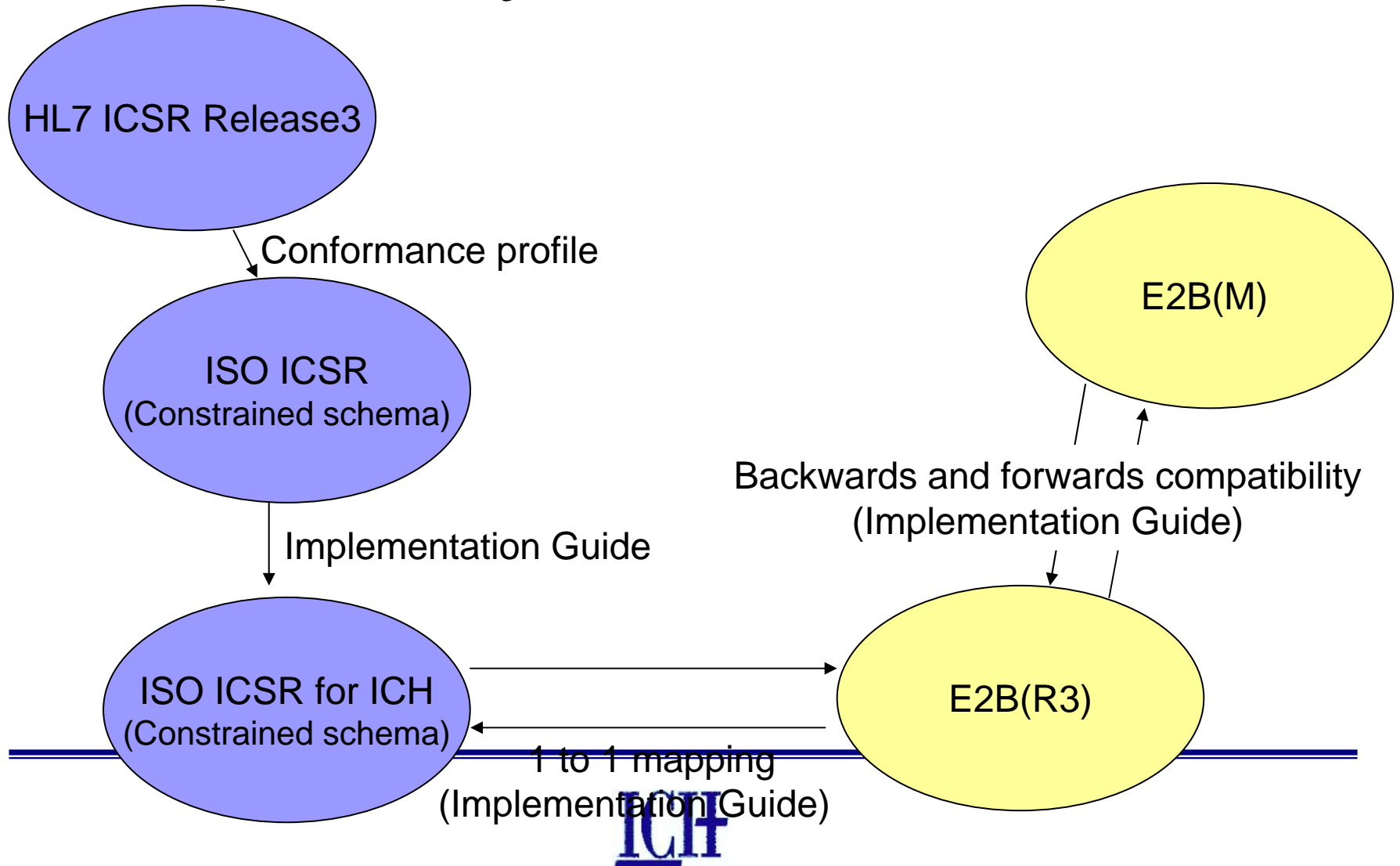


What is the airplane?
ICH Definition is;
Airplane have to have Wings, Cockpits,
and Engines.

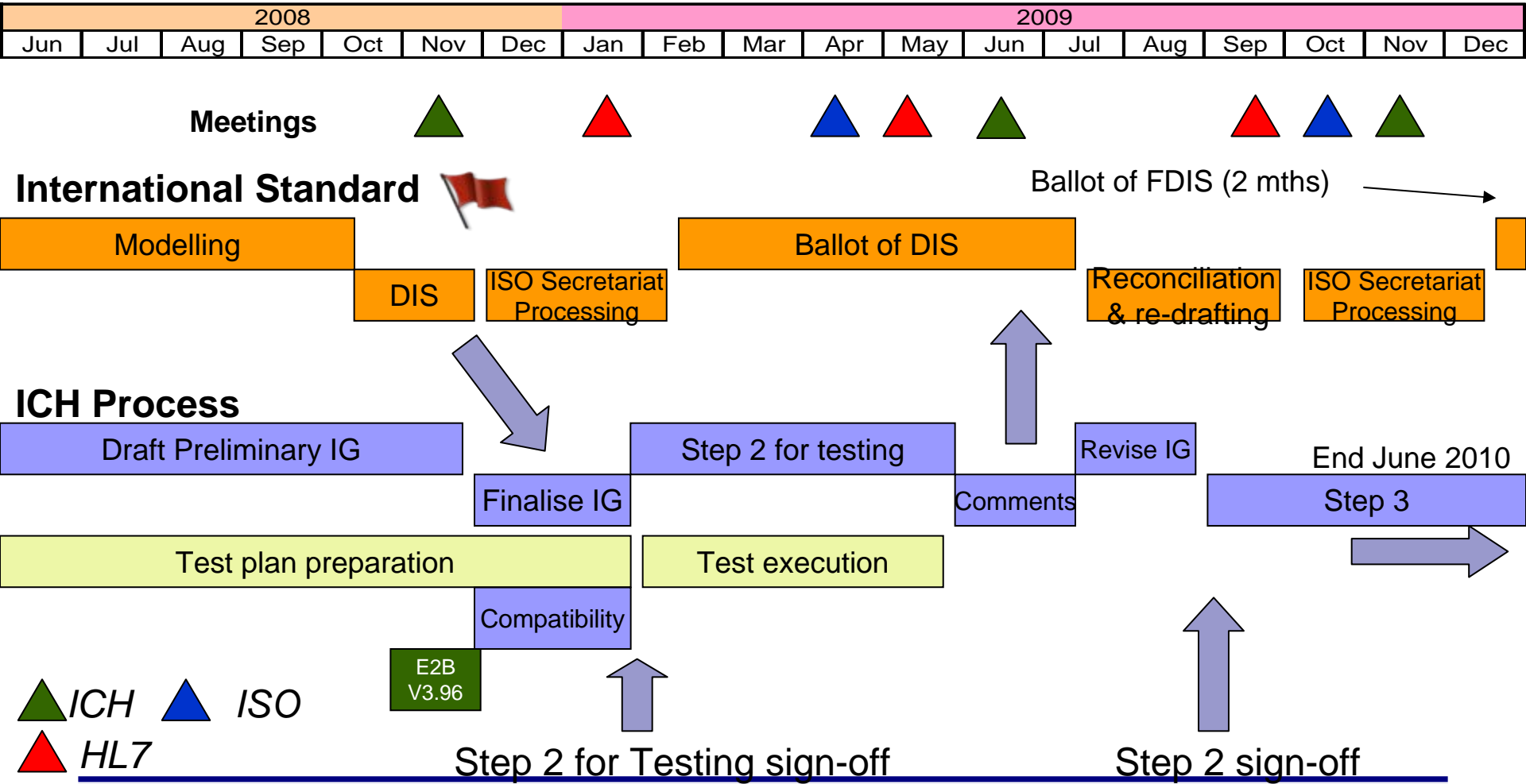
ICH E2B / M2 (2)

- Test for ISO ICSR message
 - Validate the message
 - Confirm the message whether it meets ICH requirements
- Confirm compatibility between E2B (M) and E2B (R3)

Compatibility



Timeline



Future Plan

- Implication is that Step 4 will be published later than anticipated but International Standard is on the timeline
- FDIS ballot ends – March 2010
- Publish IS – April 2010
- Step 3 ends – June 2010
- Produce Step 4 – November 2010?

Thank you