E2B(R3) - Reporting Scenarios

This document lists different scenarios for reporting Individual Case Safety Reports (ICSRs) to FAERS. These scenarios identify the key ICH and regional data elements that must be populated for the ICSRs to be accepted.

Scenario 1: Premarket report on an IND or IND-Exempt BA/BE study
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND or CDER_IND_EXEMPT_BA_BE
Type of Report (C.1.3) = 2 (Report from study)
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)
IND Number where AE Occurred (C.5.5a) = <IND Number> OR Pre-ANDA Number where AE Occurred (C.5.5b) = <Pre-ANDA Number>
FDA Additional Information on Drug (coded) (FDA.G.k.10a) * = 1 (Test) or 2(Reference)

**Must be used to describe the drug's role in the IND-Exempt BA/BE study. Use nullFlavor 'NA' for all other drugs or if information is not available.*

Scenario 2: Solicited reports or reports from Organized Data Collection System
Batch Receiver Identifier (N.1.4) = ZZFDA
Message Receiver Identifier (N.2.r.3) = CDER
Type of Report (C.1.3) = 2 (Report from study)
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 2 (Individual patient use) or 3 (Other studies)

Scenario 3: Premarket AGGREGRATE report
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
Type of Report (C.1.3) = 2 (Report from study)
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)
IND Number where AE Occurred (C.5.5a) = <IND Number> (Use parent IND*)
Patient (name or initials) (D.1) = AGGREGATE
Identification Number of the Report Which Is Linked to This Report (C.1.10.r) = <list of Sender's (case) Safety Report Unique Identifier (C.1.1)>

**The parent IND is the IND under which clinical trials were first initiated in the United States. If the drug is being evaluated in multiple INDs, the parent IND is generally the IND with the lowest number*

Scenario 4: Premarket report with cross referenced INDs
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
Type of Report (C.1.3) = 2 (Report from study)
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)
IND Number where AE Occurred (C.5.5a) = <IND Number>
IND number of cross reported IND (FDA.C.5.6.r) = <list the cross-referenced INDs>

Scenario 5: Premarket IND not approved and not marketed in US but is marketed outside US where AE occurred
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
Type of Report (C.1.3) = 1 (Spontaneous)
IND Number where AE Occurred (C.5.5a) = <IND Number>

Scenario 6: Postmarket study report - Must submit two (2) reports 1) on the IND and 2) on the NDA or BLA	
Report 1	Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
	Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
	Type of Report (C.1.3) = 2 (Report from study)
	Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)
	IND Number where AE Occurred (C.5.5a) = <IND Number>
Report 2	Batch Receiver Identifier (N.1.4) = ZZFDA
	Message Receiver Identifier (N.2.r.3) = CDER
	Type of Report (C.1.3) = 2 (Report from study)
	Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)

Scenario 7: Postmarket safety report
Batch Receiver Identifier (N.1.4) = ZZFDA
Message Receiver Identifier (N.2.r.3) = CDER
Type of Report (C.1.3) = 1 (Spontaneous)
IND Number where AE Occurred (C.5.5a) = empty

Scenario 8: Premarket IND not approved and not marketed both inside and outside US and AE occurred outside US
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
Type of Report (C.1.3) = 2 (Report from study)
IND Number where AE Occurred (C.5.5a) = <IND Number>
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)

Scenario 9: Premarket INDs not approved and not marketed both inside and outside US and AE occurred outside US
Batch Receiver Identifier (N.1.4) = ZZFDA_PREMKT
Message Receiver Identifier (N.2.r.3) = CDER_IND or CBER_IND
Type of Report (C.1.3) = 2 (Report from study)

IND Number where AE Occurred (C.5.5a) = <Parent IND Number>
Study Type Where Reaction(s) / Event(s) Were Observed (C.5.4) = 1 (Clinical trials)
IND number of cross reported IND (FDA.C.5.6.r) = <list of other cross-referenced INDs>