Regional R2		Regional R3		
Element Number	Element Name	h: header e: entity	Element Number	Element Name
A.1.9	Does This Case Fulfill the Local Criteria for an Expedited Report?	e	FDA.C.1.7.1	Local Criteria Report Type
A.1.FDA.15	Combination Product Report Flag	e	FDA.C.1.12	Combination Product Flag
A.2.3.3	Study Type in Which the Reaction(s)/ Event(s) were Observed	e	FDA.C.5.4a	FDA Other Study Type Where Reaction(s) / Event(s) Were Observed
A.2.3.2	Sponsor Study Number	e	FDA.C.5.5a	IND Number where AE Occurred
		h	FDA.G.k.12.r	Device Information (repeat as necessary)
B.4.k.1	Characterization of drug role	e	FDA.G.k.1a	FDA Other Characterisation of Drug Role
B.4.k.20.FDA.17	Malfunction	e	FDA.G.k.12.r.1	Malfunction
B.4.k.20.FDA.18	Follow-Up Type			
B.4.k.20.FDA.18.1a	Correction	e	FDA.G.k.12.r.2.r.1	If follow-up, what type?
B.4.k.20.FDA.18.1b	Additional Information			
B.4.k.20.FDA.18.1c	Response to FDA Request			
B.4.k.20.FDA.18.1d	Device Evaluation			
B.4.k.20.FDA.14	Remedial Action Initiated Remedial Action Taken for the Product			
B.4.k.20.FDA.14.1a	Recall	e	FDA.G.k.12.r.11.r	Remedial Action Initiated
B.4.k.20.FDA.14.1b	Repair			
B.4.k.20.FDA.14.1c	Replace			
B.4.k.20.FDA.14.1d	Relabeling			
B.4.k.20.FDA.14.1e	Notification			
B.4.k.20.FDA.14.1f	Inspection			
B.4.k.20.FDA.14.1g	Patient Monitoring			
B.4.k.20.FDA.14.1h	Modification/Adjustment			
B.4.k.20.FDA.14.1i	Other	e	FDA.G.k.12.r.11.r	Remedial Action Initiated
B.4.k.20.FDA.19	Device Problem and Evaluation Codes			
B.4.k.20.FDA.19.1b	Evaluation Value	e	FDA.G.k.12.r.3.r.2	Device Problem Code
B.4.k.20.FDA.1	Brand Name	e	FDA.G.k.12.r.4	Device Brand Name
B.4.k.20.FDA.2	Common Device Name	e	FDA.G.k.12.r.5	Common Device Name
B.4.k.20.FDA.3	Product Code	e	FDA.G.k.12.r.6	Device Product Code
B.4.k.20.FDA.4	Manufacturer			

B.4.k.20.FDA.4a	Device Manufacturer Name	e	FDA.G.k.12.r.7.1a	Device Manufacturer Name
B.4.k.20.FDA.4b	Manufacturer Address	e	FDA.G.k.12.r.7.1b	Manufacturer Address
B.4.k.20.FDA.4c	Manufacturer City	e	FDA.G.k.12.r.7.1c	Device Manufacturer City
B.4.k.20.FDA.4d	Manufacturer State	e	FDA.G.k.12.r.7.1d	Device Manufacturer State
B.4.k.20.FDA.4e	Manufacturer Country	e	FDA.G.k.12.r.7.1e	Device Manufacturer Country
B.4.k.20.FDA.15	Device Usage	e	FDA.G.k.12.r.8	Device Usage
B.4.k.20.FDA.16	Device Lot Number	e	FDA.G.k.12.r.9	Device Lot Number
B.4.k.20.FDA.20	Operator of the Device	e	FDA.G.k.12.r.10a	Operator of the Device
		e	FDA.D.11.r.1	Patient Race Code
		e	FDA.D.12	Patient Ethnicity Code
		e	FDA.E.i.3.2h	Required Intervention

Element	Regional R2			Regional R3			Rule	Conversion R2->R3
Does This Case Fulfil the Local Criteria for an Expedited Report?	A.1.9	0..1	1N (2)	FDA.C.1.7.1	1..1	1N (3)	FDA-01	Same 5 values: okay
Combination Product Report Flag	A.1.FDA.15	0..1	1N (2)	FDA.C.1.12	1..1	Bool (3)	FDA-02	Mapping yes-true and no-false If not set in R2, use nullFlavor: NI in R3

Element	Regional R2			Regional R3			Rule	Conversion R2->R3
Study Type Where Reaction(s) / Event(s) Were Observed	A.2.3.3	0..1	1N (3)	FDA.C.5.4a	0..1	1N (3)	FDA-03	Map 1, 2 and 3 to 1, 2 and 3. If value of A.2.3.3 = 4, then set FDA.C.5.4a = 1 and set D.1 (Patient (name or initials) to "AGGREGATE" If value is 5, then copy only the numeric part of A.2.3.2 (Sponsor Study Number) to FDA.C.5.r.6 (IND number of cross reported IND)
Sponsor Study Number	A.2.3.2	0..1	35AN	FDA.C.5.5a	0..1	10N	FDA-04	Copy only the numeric part of A.2.3.2 (Sponsor Study Number) to FDA.C.5.5a (IND Number where AE Occurred) where A.2.3.3 (Study Type Where Reaction(s) / Event(s) Were Observed) is not equal to 5
				FDA.C.5.r.6	0..N	10N	FDA-05	Copy only the numeric part of A.2.3.2 (Sponsor Study Number) to FDA.C.5.r.6 (IND number of cross reported IND) where A.2.3.3 (Study Type Where Reaction(s) / Event(s) Were Observed) is equal to 5

Element	Regional R2			Regional R3			Rule	Conversion R2->R3
Malfunction	B.4.k.20.FDA.17	0..1	1N (3)	FDA.G.k.12.r.1	1..1	Bool (3)	FDA-06	Mapping yes-true and no-false If not set in R2, set field to value "false" in R3
Correction	B.4.k.20.FDA.18.1a	0..1	1N (3)	FDA.G.k.12.r.2.r.1	0..N	1N (4)	FDA-07	For each FDA.G.k.12.r (Device Information) repeat FDA.G.k.12.r.2.r.1 where any of the R2 data values for the four fields is 1.
Additional Information	B.4.k.20.FDA.18.1b	0..1	1N (3)					
Response to FDA Request	B.4.k.20.FDA.18.1c	0..1	1N (3)					
Device Evaluation	B.4.k.20.FDA.18.1d	0..1	1N (3)					
Recall	B.4.k.20.FDA.14.1a	0..1	1N (3)	FDA.G.k.12.r.11.r	0..N	1N (9)	FDA-08	Repeat FDA.G.k.12.r.11.r where any of the R2 data values for the eight fields is 1.
Repair	B.4.k.20.FDA.14.1b	0..1	1N (3)					
Replace	B.4.k.20.FDA.14.1c	0..1	1N (3)					
Relabeling	B.4.k.20.FDA.14.1d	0..1	1N (3)					
Notification	B.4.k.20.FDA.14.1e	0..1	1N (3)					
Inspection	B.4.k.20.FDA.14.1f	0..1	1N (3)					
Patient Monitoring	B.4.k.20.FDA.14.1g	0..1	1N (3)					
Modification/Adjustment	B.4.k.20.FDA.14.1h	0..1	1N (3)					
Other	B.4.k.20.FDA.14.1i	0..1	75AN	FDA.G.k.12.r.11.r	0..N	1N (9)	FDA-09	Set FDA.G.k.12.r.11.r = 9 (Other), if the R2 value is not null.
Evaluation Value	B.4.k.20.FDA.19.1b	0..N	6AN	FDA.G.k.12.r.3.r.2	0..N	6AN	FDA-10	Device Problem Code
Brand Name	B.4.k.20.FDA.1	0..N	80AN	FDA.G.k.12.r.4	0..N	80AN	FDA-11	Device Brand Name
Common Device Name	B.4.k.20.FDA.2	0..N	80AN	FDA.G.k.12.r.5	0..N	80AN		Common Device Name
Product Code	B.4.k.20.FDA.3	0..N	3AN	FDA.G.k.12.r.6	0..N	10AN		Device Product Code
Device Manufacturer Name	B.4.k.20.FDA.4a	0..N	100AN	FDA.G.k.12.r.7.1a	0..1	100AN	FDA-12	Device Manufacturer Name
Manufacturer Address	B.4.k.20.FDA.4b	0..N	100AN	FDA.G.k.12.r.7.1b	0..1	100AN		Manufacturer Address
Manufacturer City	B.4.k.20.FDA.4c	0..N	35AN	FDA.G.k.12.r.7.1c	0..1	35AN		Device Manufacturer City
Manufacturer State	B.4.k.20.FDA.4d	0..N	40AN	FDA.G.k.12.r.7.1d	0..1	40AN		Device Manufacturer State
Manufacturer Country	B.4.k.20.FDA.4e	0..N	2AN	FDA.G.k.12.r.7.1e	0..1	2AN		Device Manufacturer Country
Device Usage	B.4.k.20.FDA.15	0..1	1N (3)	FDA.G.k.12.r.8	0..1	1N (3)	FDA-13	Device Usage
Device Lot Number	B.4.k.20.FDA.16	0..1	100AN	FDA.G.k.12.r.9	0..1	100AN	FDA-14	Device Lot Number
Operator of the Device	B.4.k.20.FDA.20	0..1	100AN	FDA.G.k.12.r.10a	0..1	1N (3)	FDA-15	Operator of the Device

Characterization of drug role	B.4.k.1	0..1	1N (3)	FDA.G.k.1a	0..1	1N (3)	FDA-19	If B.4.k.1 = 4 (Similar Device) then set G.k.1 = 4 and FDA Other Characterisation of Drug Role (FDA.G.k.1a) = 1 (Similar Device)

Element	Regional R2			Regional R3			Rule	Conversion R2->R3
Patient Race Code				FDA.D.11.r.1	1..N	10AN	FDA-16	Since R2 does not have Patient Race Code data element, to convert from R2 to R3 use nullFlavor: UNK
Patient Ethnicity Code				FDA.D.12	1..1	10AN	FDA-17	Since R2 does not have Patient Ethnicity Code data element, to convert from R2 to R3 use nullFlavor: UNK

Element	Regional R2			Regional R3			Rule	Conversion R2->R3
Required Intervention				FDA.E.i.3.2h	1..1	Boolean	FDA-18	Since R2 does not haveRequired Intervention data element, to convert from R2 to R3 use nullFlavor: NI

Rule	Regional Field(R2)	Description(R2)	R2	Regional Field(R3)	Description(R3)	R3	Comment
FDA-01	A.1.9	Does this case fulfill the local criteria for an expedited report?	1=15-Day 2=Periodic 4=5-Day 5=30-Day 6=7-Day	FDA.C.1.7.1	Local Criteria Report Type	1=15-Day 2=Periodic 4=5-Day 5=30-Day 6=7-Day	Mapping 1, 2, 4, 5 and 6 to 1, 2, 4, 5 and 6.
FDA-02	A.1.FDA.15	Combination Product Report Flag	- Yes - No - <not set>	FDA.C.1.12	Combination Product Flag	- true - false - nullFlavor: NI	Mapping yes-true and no-false If not set in R2, use nullFlavor: NI in R3
FDA-03	A.2.3.3	Study Type Where Reaction(s) / Event(s) Were Observed	1= Clinical Trials 2= Individual Patient Use 3= Other Studies 4= Report from Aggregate Analysis or for Several Events Submitted if a Narrative Summary Report is Provided 5= Cross-Reported IND Safety Report	C.5.4	Study Type Where Reaction(s) / Event(s) Were Observed	1= Clinical Trials 2= Individual Patient Use 3= Other Studies	Mapping 1, 2 and 3 to 1, 2 and 3. If value is 4, then set: - the value of D.1 (Patient (name or initials)) to "AGGREGATE“ - FDA.C.5.4a (FDA Other Study Type Where Reaction(s) / Event(s) Were Observed) to 1=Aggregate If value is 5, then copy only the numeric part of A.2.3.2 (Sponsor Study Number) recoeds to FDA.C.5.r.6 (IND number of cross reported IND)
FDA-04	A.2.3.2	Sponsor Study Number	IND 123456	FDA.C.5.5a	IND Number where AE Occurred	123456	If A.2.3.3 (Study Type Where Reaction(s) / Event(s) Were Observed) is not equal to 5, then copy only the numeric part of A.2.3.2 (Sponsor Study Number) to FDA.C.5.5a (IND Number where AE Occurred)
FDA-05	A.2.3.2	Sponsor Study Number	IND 123456	FDA.C.5.r.6	IND number of cross reported IND	123456	If A.2.3.3 (Study Type Where Reaction(s) / Event(s) Were Observed) is equal to 5, then copy only the numeric part of A.2.3.2 (Sponsor Study Number) to FDA.C.5.r.6 (IND number of cross reported IND)
FDA-06	B.4.k.20.FDA.17	Malfunction	- Yes - No - <not set>	FDA.G.k.12.r.1	Malfunction	- true - false	Mapping yes-true and no-false If not set in R2, set field to value "false" in R3
FDA-07	B.4.k.20.FDA.18.1a	Correction	- Yes - No - <not set>	FDA.G.k.12.r.2.r.1	If follow-up, what type?	1=correction 2=additional informaton 3=response to FDA request 4= device evaluation	If B.4.k.20.FDA.18.1a is Yes, then FDA.G.k.12.r.2.r.1=1. If B.4.k.20.FDA.18.1b is Yes, then FDA.G.k.12.r.2.r.1=2 If B.4.k.20.FDA.18.1c is Yes, then FDA.G.k.12.r.2.r.1=3 If B.4.k.20.FDA.18.1d is Yes, then FDA.G.k.12.r.2.r.1=4 Since this is a repeating entity there could be multiple values Each R2 tag value is setup as a repeatble value with in the R3 entity. If the values of the R2 fields is No or <no set> then don't include them.
	B.4.k.20.FDA.18.1b	Additional Information	- Yes - No - <not set>				
	B.4.k.20.FDA.18.1c	Response to FDA Request	- Yes - No - <not set>				
	B.4.k.20.FDA.18.1d	Device Evaluation	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1a	Recall	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1b	Repair	- Yes - No - <not set>				

FDA-08	B.4.k.20.FDA.14.1c	Replace	- Yes - No - <not set>	FDA.G.k.12.r.11.r	Remedial Action Initiated	1=Recall 2=Repair 3=Replacement 4=Relabeling 5=Notification 6=Inspection 7=Patient Monitoring 8=Modification or Adjustment 9=Other	If B.4.k.20.FDA.14.1a is Yes, then FDA.G.k.12.r.11.r=1 If B.4.k.20.FDA.14.1b is Yes, then FDA.G.k.12.r.11.r=2 If B.4.k.20.FDA.14.1c is Yes, then FDA.G.k.12.r.11.r=3 If B.4.k.20.FDA.14.1d is Yes, then FDA.G.k.12.r.11.r=4 If B.4.k.20.FDA.14.1e is Yes, then FDA.G.k.12.r.11.r=5 If B.4.k.20.FDA.14.1f is Yes, then FDA.G.k.12.r.11.r=6 If B.4.k.20.FDA.14.1g is Yes, then FDA.G.k.12.r.11.r=7 If B.4.k.20.FDA.14.1h is Yes, then FDA.G.k.12.r.11.r=8 Since this is a repeating entity there could be multiple values. Each R2 tag value is setup as a repeatble value with in the R3 entity. If the values of the R2 fields is No or <no set> then don't include them.
	B.4.k.20.FDA.14.1d	Relabeling	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1e	Notification	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1f	Inspection	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1g	Patient Monitoring	- Yes - No - <not set>				
	B.4.k.20.FDA.14.1h	Modification/Adjustment	- Yes - No - <not set>				
FDA-09	B.4.k.20.FDA.14.1i	Other	Free Text	FDA.G.k.12.r.11.r	Remedial Action Initiated	9=Other	If value present in R2 then include 9=Other in R3 for the tag FDA.G.k.12.r.11.r (Remedial Action Initiated). Do not include the R2 value.
FDA-10	B.4.k.20.FDA.19.1b	Evaluation Value		FDA.G.k.12.r.3.r.2	Device Problem Code		Copy Evaluation Value to Device Problem Code, where the R2 tag B.4.k.20.FDA.19.1a (Evaluation Type) is 01=Device Problem.
FDA-11	B.4.k.20.FDA.1	Brand Name	Free Text	FDA.G.k.12.r.4	Device Brand Name	Free Text	Copy R2 value as is to R3.
	B.4.k.20.FDA.2	Common Device Name	Free Text	FDA.G.k.12.r.5	Common Device Name	Free Text	
	B.4.k.20.FDA.3	Product Code	FDA Device Component Code	FDA.G.k.12.r.6	Device Product Code	FDA Device Component Code	
FDA-12	B.4.k.20.FDA.4a	Device Manufacturer Name	Free Text	FDA.G.k.12.r.7.1a	Device Manufacturer Name	Free Text	Copy R2 value to R3 as is.
	B.4.k.20.FDA.4b	Manufacturer Address	Free Text	FDA.G.k.12.r.7.1b	Manufacturer Address	Free Text	
	B.4.k.20.FDA.4c	Manufacturer City	Free Text	FDA.G.k.12.r.7.1c	Device Manufacturer City	Free Text	
	B.4.k.20.FDA.4d	Manufacturer State	Free Text	FDA.G.k.12.r.7.1d	Device Manufacturer State	Free Text	
	B.4.k.20.FDA.4e	Manufacturer Country	ISO3166	FDA.G.k.12.r.7.1e	Device Manufacturer Country	ISO3166	
FDA-13	B.4.k.20.FDA.15	Device Usage	1=Initial Use of Device 2=Reuse 3=Unknown <not set>	FDA.G.k.12.r.8	Device Usage	1=Initial Use of Device 2=Reuse 3=Unknown <not set>	Copy R2 value to R3 as is.
FDA-14	B.4.k.20.FDA.16	Device Lot Number	Free Text	FDA.G.k.12.r.9	Device Lot Number	Free Text	Copy R2 value to R3 as is.
FDA-15	B.4.k.20.FDA.20	Operator of the Device	Free Text	FDA.G.k.12.r.10a	Operator of the Device	1= Health Professional 2= Lay User/Patient 3 = Other	Map R2 value of “Health Professional” to 1 in R3; “Lay User/Patient” to 2 in R3. If the R2 value is not “Health Professional” or “Lay User/Patient” then set R3 value to 3.

FDA-16				FDA.D.11.r.1	Patient Race Code	C16352=African American C41259=American Indian or Alaska Native C41260=Asian C41219=Native Hawaiian or Other Pacific Islander C41261=White nullFlavor: UNK, MSK, OTH, NA	Since R2 does not have Patient Race Code data element, to convert from R2 to R3 use nullFlavor: UNK
FDA-17				FDA.D.12	Patient Ethnicity Code	C17459=Hispanic or Latino C41222=Non Hispanic or Latino nullFlavor: UNK, MSK, NI, NA	Since R2 does not have Patient Ethnicity Code data element, to convert from R2 to R3 use nullFlavor: UNK
FDA-18				FDA.E.i.3.2h	Required Intervention	true, nullFlavor: NI	Since R2 does not have Required Intervention data element, to convert from R2 to R3 use nullFlavor: NI
FDA-19	B.4.k.1	Characterization of drug role	1=Suspect 2=Interacting 3=Concomitant 4=Similar Device	FDA.G.k.1a	FDA Other Characterisation of Drug Role	1=Similar Device	Map R2 value of Similar Device to 1 in R3 and since G.k.1 is required, set the value to 4=Drug not Administered.

Data Element	R2 Title	R2 Description
B.4.k.2.4.FDA.1a	Expiration date format	Product Expiration Date
B.4.k.2.4.FDA.1b	Expiration date	Product Expiration Date
B.4.k.2.FDA.5	Product available for evaluation	Indicate whether product is available for evaluation
B.4.k.2.6.FDA.1a	Product return date format	Date Format
B.4.k.2.6.FDA.1b	Product return date	Date when Product was returned
B.4.k.20.FDA.5	Model Number	Model number of the device constituent part
B.4.k.20.FDA.6	Catalog Number	Catalog number of the device constituent part
B.4.k.20.FDA.7	Serial Number	Serial number of the device constituent part
B.4.k.20.FDA.8	Unique Identifier UDI#	Unique identifier of the device constituent part
B.4.k.20.FDA.9a	Implanted Date Format	Date format of implanted in the patient
B.4.k.20.FDA.9b	Implanted Date	Date implanted in the patient
B.4.k.20.FDA.10a	Explanted Date Format	Date format of explanted from the patient
B.4.k.20.FDA.10b	Explanted Date	Date explanted from the patient
B.4.k.20.FDA.11a	Approximate age of device/product	Age of device constituent part
B.4.k.20.FDA.11b	Approximate age unit of device/product	Age unit of device constituent part
B.4.k.20.FDA.12	Single Use Device	Indicate whether the device constituent part was labeled for single use or not.
B.4.k.20.FDA.13a	Device Manufacture Date Format	Device Manufacture Date format
B.4.k.20.FDA.13b	Device Manufacture Date	Device Manufacture Date
B.4.k.20.FDA.14.1i	Other	Other Remedial Action Initiated Remedial Action Taken for the Product
B.4.k.20.FDA.19.1a	Evaluation Type	Type of problem and/or the evaluation

Draft Conventions for FDA E2B(R2) regional requirement – FDA E2B(R3) regional requirement Compatibility

Purpose

This spreadsheet is the source of an appendix to the draft *'FDA Regional Implementation Specification'* .

This spreadsheet is intended to assist reporters and recipients (including pharmaceutical companies, authorities and non-commercial sponsors) in implementing systems with special focus on the recommendations for conversion forth between the previous regional elements, i.e., FDA E2B(R2) regional requirements and these regional elements, i.e., FDA E2B(R3) regional requirements.

Background

The current pharmacovigilance databases are operating largely based on the FDA E2B(R2) regional requirements. Whilst it is envisaged the FDA E2B(R3) regional requirements will improve the current requirements, it is obvious that there will be a time of transition until all stakeholders (regulators, pharmaceutical industry and other parties in the pharmaceutical business sector) have implemented the new regional requirements and have their pharmacovigilance databases adapted to these new regional requirements.

This implies that pharmacovigilance databases operating FDA E2B(R2) regional requirements and/or FDA E2B(R3) regional requirements will have to coexist and mapping procedures must be in place to ensure a coherent and harmonized exchange of ICSRs among all stakeholders at the regional level. This is even more important since the exchange of ICSRs takes place between multiple senders and receivers and therefore depends on the implementation status (FDA E2B(R2) regional requirements) or (FDA E2B(R3) regional requirements) of each party in each transmission.

As a result, it is of major importance to address the compatibility between the two regional requirements and the relevant message specifications and to provide a mapping rules that will ensure a smooth transition phase.

The present spreadsheet intends to

- Categorize the compatibility issues
- Define the mapping rules for the FDA E2B(R2) regional elements and the FDA E2B(R3) regional elements