



Bayer HealthCare
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Electronic Transfer of Serious Adverse Events to Global Pharmacovigilance

PhUSE, Berlin, October 2010

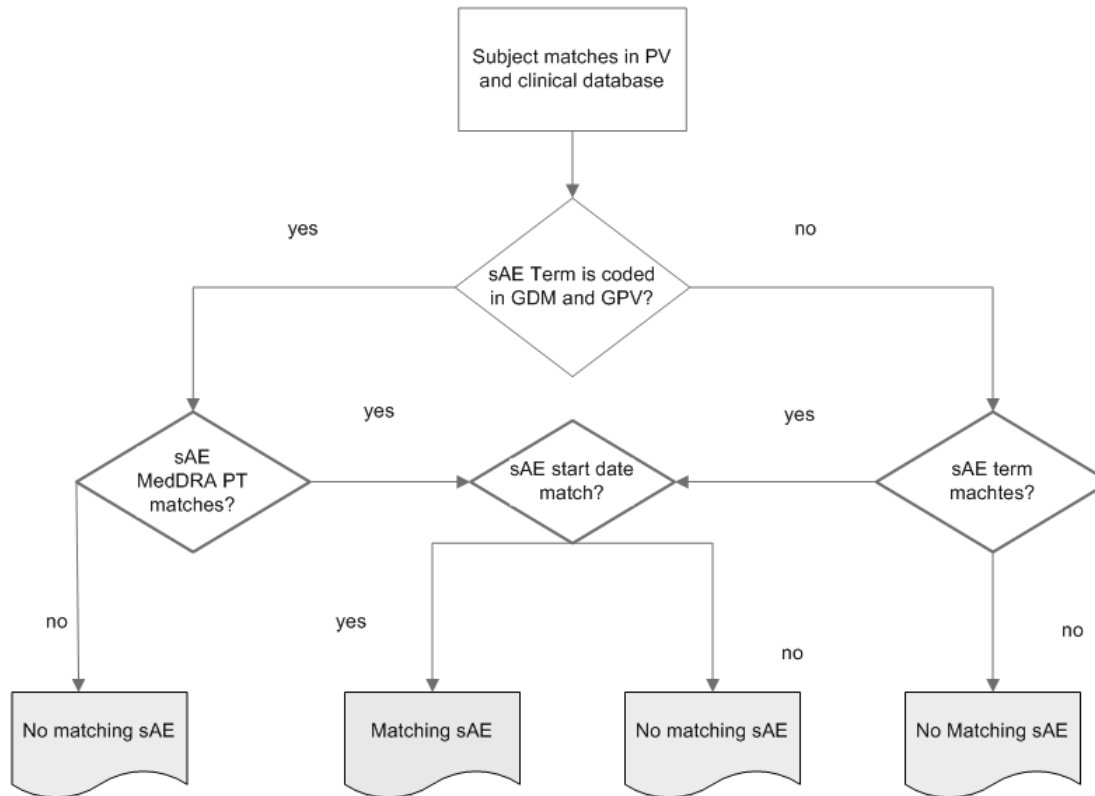
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- Introduction
- Paper-Based SAE Reporting
- Electronic SAE Reporting
- Implementation

- Reconciliation of Serious Adverse Events (SAE) is done between
 - Clinical Database (GDM) and
 - Global Pharmacovigilance Database (PV)
- Regular SAEs reporting via fax to PV (manual process)
- SAS macro used to compare GDM and PV databases
 - Creation of three different integrated reports
- Implementation of electronic process currently in pilot phase

Matching of Subjects/SAEs



SAE Report-Subject Match

- Subject Match

Country	Trial unit	Clinical DB Random number	Safety DB Random number	Clinical DB Patient number	Safety DB Patient number	Birth Date	Death Date	Gender
C1	1	100	100	100	100	01FEB1940	-	Female [Male]
C1	1	200	200	200	200	23MAY1942	-	Female
C2	2	300	300	300	300	01DEC1931 [26DEC1931]	-	Female
C2	2	400	400	400	400	01NOV1937	-	Female
C2	2	500	501	501	501	01JAN1935	-	Female
C3	3	600	600	600	600	01AUG1934 [13AUG1934]	-	Female
C4	1	700	700	700	700	14DEC1942	12JAN2010	Female

SAE Reports-SAE Match

- SAE match

Country	Trial unit	Patient/ random number	SOURCE	MedDRA preferred term	Adverse event	Start date of adverse event	
C1a	1a	301a	GDMe	Headache unspecified	Headache	07JAN2009a	21
C1a	1a	301a	GPVa	Headache unspecified	Headache, nose	07JAN2009a	21
C2a	6a	600a	GDMe	Atrial flutter	ATRIAL FLUTTER, LEFT	22MAY2008	21
C2a	6a	600	GPVa	Atrial flutter	ATRIAL FLUTTER	20APR2008a	21
C3a	5a	200a	GDMe	Humerus fracture	FRACTURE OF THE LEFT ARM BONE	20JAN2007a	??
C3a	5a	200a	GPVa	Upper limb fracture	FRACTURE OF THE LEFT ARM BONE	20JAN2007a	??

} match

} non match

- Other important item comparison

Country	Trial unit	Patient/ random number	Start date of adverse event	MedDRA preferred term	Adverse event	VARIABLE NAME	Safety databases	Clinical databases
C1a	1a	200a	19JANV2007a	Pneumonia	ACUTE PNEUMONIA	Action taken	93=Unknown	1=None
C1a	1a	200a	10NOV2007a	Syncope	SYNCOPE	Action taken	93=Unknown	1=None

Limitations of Current Process

- Manual process via fax and data entry into PV database needed
- More discrepancies, because of two sources for SAE information (Complementary page and EDC CRF)
- Reconciliation between PV and Clinical Databases
 - Time-consuming
 - Manual work

- Study must be setup and conducted in EDC
- All relevant data must be available electronically
(i.e. the information that is now documented on the paper complementary page)
- Transfer gateway required, which can be implemented either as
 - Module / Interface of EDC system to PV Systemor as
 - SAS-based program interface between EDC & PV database

- Investigator must indicate that the SAE should be sent to GPV by selecting a check-box in EDC

Check this box if you want to **transfer an initial or follow-up report concerning this SAE** to Global Pharmacovigilance.



Date and time of last transfer

- Last transfer date stored, if tick box is checked
- Identifier to send the data to PV
→ Investigator decision



- E2B (E2B Plus = enhanced E2B)
 - XML based Format
 - Standardized exchange format
 - Data exchange format between Pharmacovigilance and Regulatory Authorities
- SAS macro
 - Executed on daily basis
 - XML files sent to exchange directory and imported into PV system
 - Investigator gets pdf version of SAE report per email for the site file
 - Copy of mail sent to monitor

Cons

- Still need extra reconciliation to show discrepancies between GDM and PV items

Pros

- Investigator only needs to document SAE once
- Reduction of discrepancies to a minimum
- Less time-consuming for investigator, DM and PV
- SAE reaches PV more quickly (although depends frequency DB replication)

Thank you for your attention!



