



When you need
to be sure

Automating your safety data reconciliation: An approach towards reliable and efficient SAE reconciliation process

SGS Pharma, Clinical Research

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Agenda

- Introduction
- Advantages
- Practical aspects
- SDTM Database
- Automatic Reconciliation Flow
- Conclusion

Introduction



Important for Patient Safety

- Correct reporting is critical



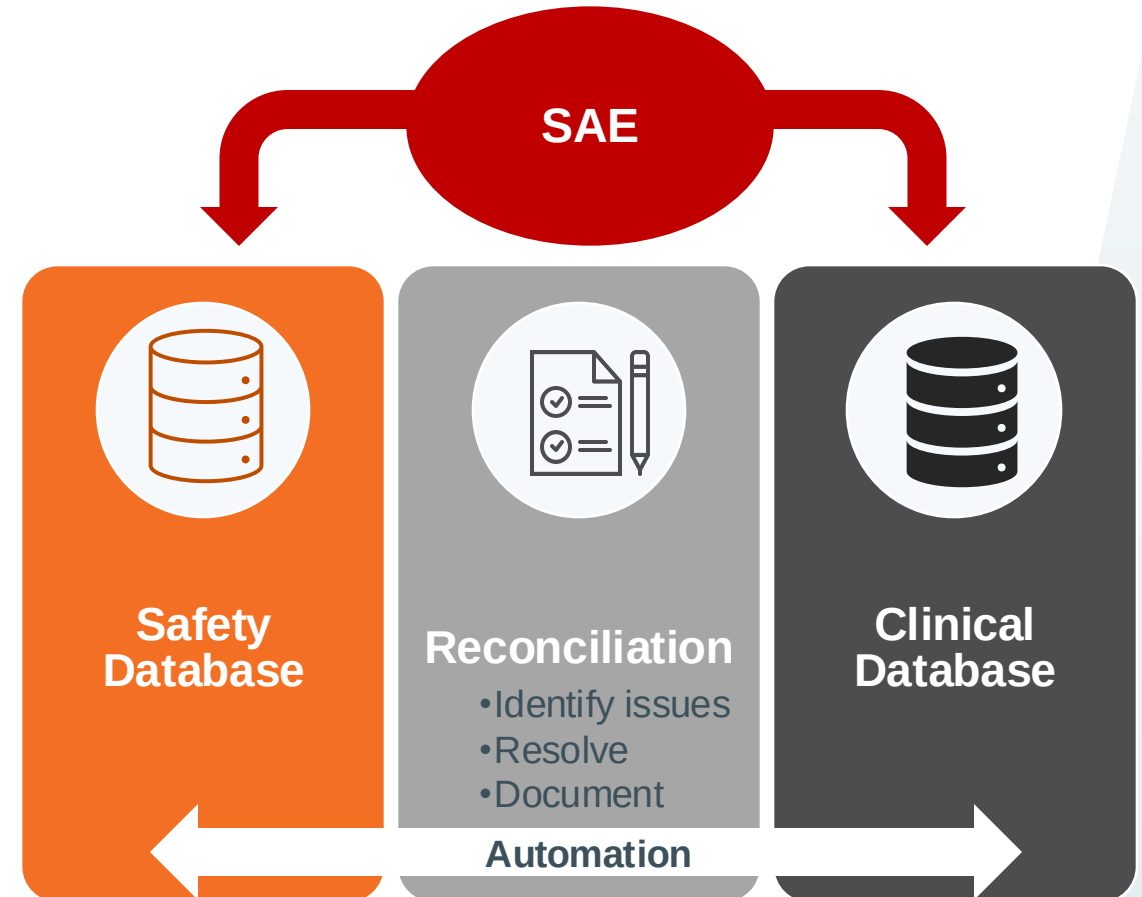
Accuracy is Essential

- Reporting to Health Authorities



Need for a process

- Reliable and efficient



Advantages of Automatic SAE reconciliation



Reduced Errors

- Minimal manual inputs



Scalability

- Handle large volumes of data



Improved Efficiency

- Streamlines and speeds up
- Quicker discrepancy identification



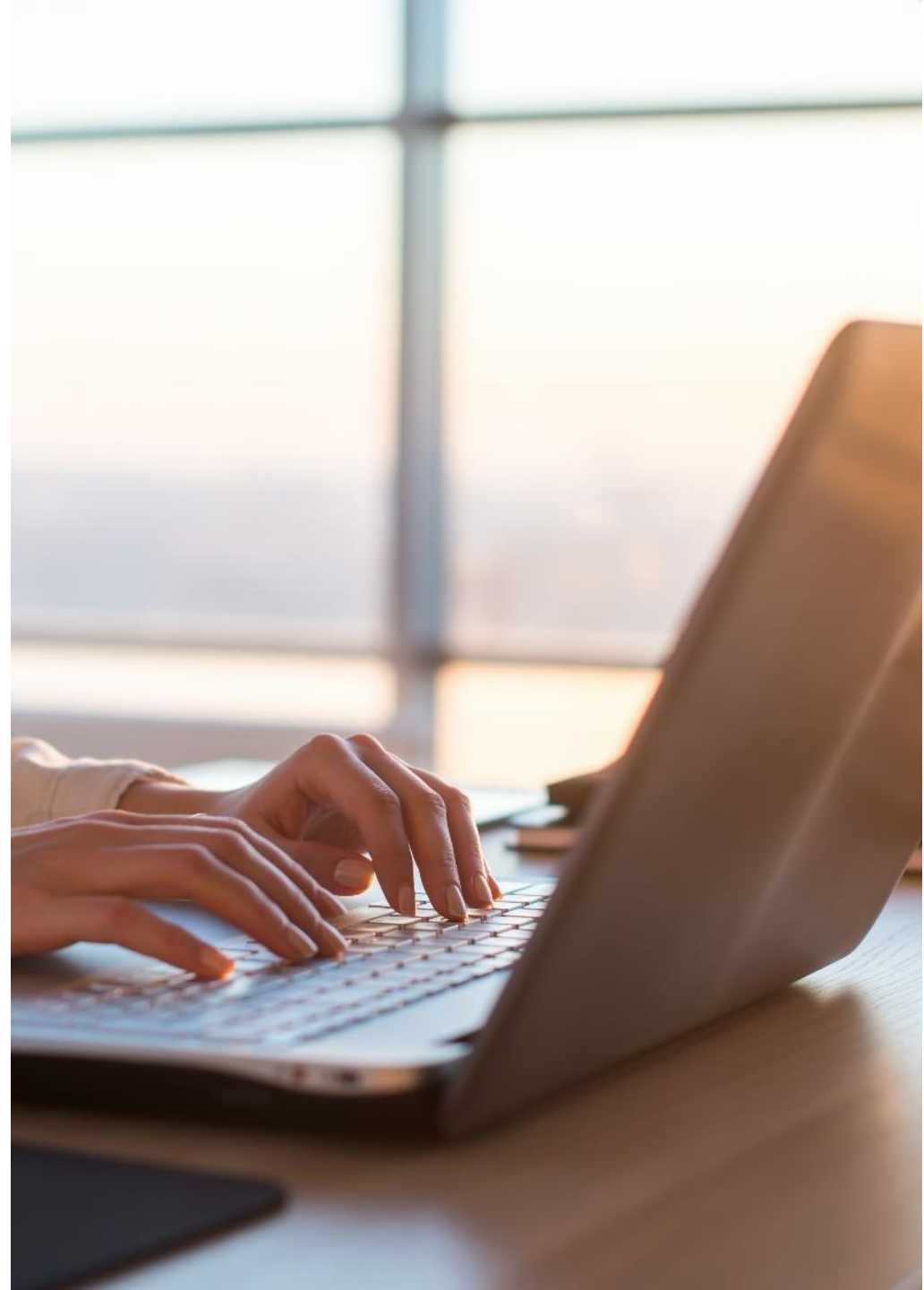
Clear Reporting

- Quick generation
- Comprehensive reports



Practical Aspects

- Different trials
 - EDC systems
 - Safety database extract formats:
 - SAS file, excel file, etc.
- Review by Clinical Data Managers
 - Only new and changed records
 - Tracking reconciliation status
- Customised reports



SDTM Database

SDTM: Standardized data format by CDISC

- Uniform structure across different studies
- Suitable for automated processes



EDC system goes live



SDTM Database available



Reconciliation/Data cleaning

Automated Reconciliation Flow

1

Safety Database Extract

- Received from safety database owner
- Upload extract in a help table (fixed structure)

Different formats:
SAS file, excel file, etc

Challenge:
No changes to the safety database
extract structure

Automated Reconciliation Flow

1

Safety Database Extract

- Received form safety database owner
- Upload extract in a help table (fixed structure)

2

AEREFIDs in clinical database

- Automatic Completion of AEREFIDs
- Linking between USUBJID, AESTDTC and AEDECOD

Automatic completion of AEREFIDs

Help table/
Safety database
extract

USUBJID	SAENO	AETERM	AEDECOD	AESTDTC
92-1108	3-003193	DECOMPENSATED HEART FAILURE	Cardiac failure	2023-07-03
92-1108	3-002294	ACUTE ON CHRONIC CONGESTIVE HEART FAILURE	Cardiac failure acute	2023-05-05
92-1109	1-002578	RIGHT KNEE PAIN	Arthralgia	2021-10-08
92-1109	2-002093	TRANSIENT ALTERED CONSCIOUS STATE	Altered state of consciousness	2022-06-08
92-1109	2-001853	WORSENING CELLULITIS R) LOWER LEG	Cellulitis	2022-05-13
01-1101	4-002524	ACUTE LITHIASIC CHOLECYSTITIS	Cholecystitis acute	2024-04-15

Clinical
database

USUBJID $\uparrow \pm 1$	AEREFID $\uparrow \pm 2$	AEGR	AESPI	AETERM	AEDECOD	AESTDTC
92-1108	3-003620	18		PULMONARY HYPERTENSION	Pulmonary hypertension	2023-07-25
92-1108	3-004232	20		DECOMPENSATED HEART FAILURE	Cardiac failure	2023-08-23
92-1109	1-002578			RIGHT KNEE PAIN	Arthralgia	2021-10-08T14:30
92-1109	2-001853	23		WORSENING CELLULITIS R) LOWER LEG	Cellulitis	2022-05-13
92-1109	2-002093	29		TRANSIENT ALTERED CONSCIOUS STATE	Altered state of consciousness	2022-06-08
92-1109	2-003168	35		HYPOGLYCAEMIA	Hypoglycaemia	2022-08-28
92-1109	2-003168	38		HOSPITAL ACQUIRED PNEUMONIA	Pneumonia	2022-09-03

Automated Reconciliation Flow

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AEREFIDs in clinical database

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Challenge:
No exact match between databases

Manual completion of AEREFIDs

Help table/
Safety database
extract

USUBJID	SAENO	AETERM	AEDECOD	AESTDTC
06-1101	3-003407	ANAEMIA	Anaemia	2023-07-12
92-1108	3-002294	ACUTE ON CHRONIC CONGESTIVE HEART FAILURE	Cardiac failure acute	2023-05-05
89-1108	3-002455	CARDIOGENIC SHOCK	Cardiogenic shock	2023-05-15
80-1124	3-003266	WORSENING OF CHRONIC HEART FAILURE	Cardiac failure chronic	2023-06-30
80-1108	3-003349	HEMORRHAGIC SHOCK (POST-OP)	Procedural shock	2023-04-04
80-1108	3-003349	R GROIN/THIGH INFECTION	Groin infection	2022-09-16
59-1109	3-002275	PANCREATIC TUMOR	Pancreatic neoplasm	2023-04-26

Clinical
database

USUBJID	AEREFID	AEGR	AESP	AETERM	AEDECOD	AESTDTC
44-1104	3-003373	16		FALLING FROM YOUR OWN HEIGHT	Fall	2023-06-22T02:00
80-1124		35		WORSENING OF CHRONIC HEART FAILURE	Cardiac failure	2023-06-30
80-1108	3-003349	13		HEMORRHAGIC SHOCK (POST-OP)	Procedural shock	2023-04-04
10-1104	3-001950	4		PNEUMONIA	Pneumonia	2023-06-11T10:00
01-1104	3-003141	14		WORSENING HEART FAILURE	Cardiac failure	2023-06-16T08:00
86-1103	3-003489	8		WORSENING DIASTOLIC HEART FAILURE	Left ventricular failure	2023-07-16T20:30
06-1101	3-003407	25		ANAEMIA	Anaemia	2023-07-12T10:23

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AEREFIDs in clinical database

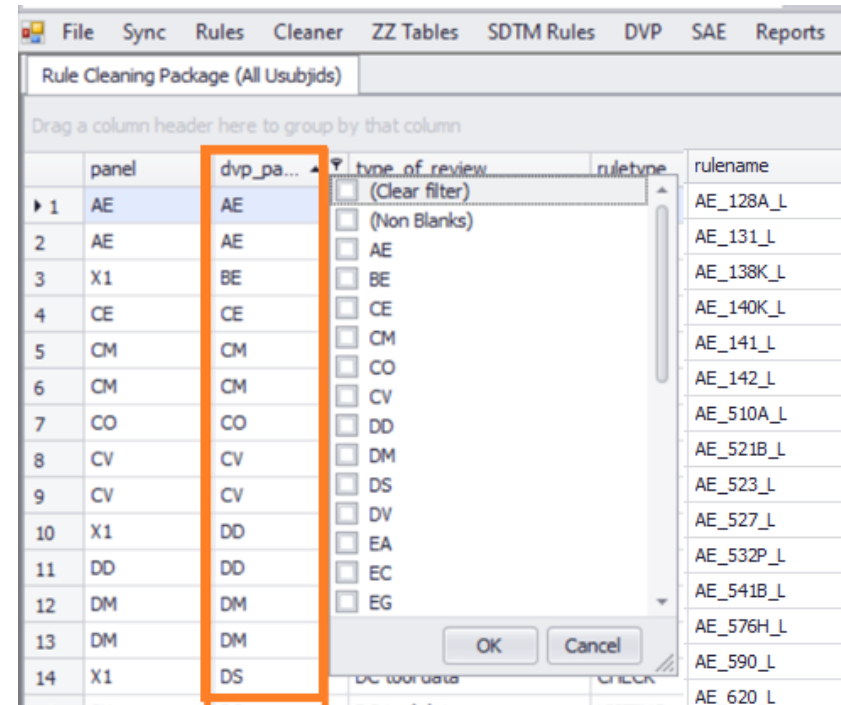
- Automatic Completion of AEREFIDs
- Linking between USUBJID, AESTDTC and AEDECOD

3

SAE Reconciliation

- Automatic checks comparing both databases
 - SDTM/Clinical database
 - Helptable/Safety database
- Taking appropriate action

In-house data cleaning tool:
Reviewing/tracking reconciliation
output



Discrepancy check

1. For each SAE in clinical database a corresponding SAE is present in safety database and vice versa
2. Discrepancies between clinical and safety database (AESTDTC, AETERM, AEDECOD, SAE criteria etc.)
3. If an AE is serious, AEREFID should be completed and vice versa

aedecod#crf	aedecod#sae	aestdtc#crf	aestdtc#sae	aesdisab#crf	aesdisab#sae	aesdth#crf	aesdth#sae	aeshosp#crf	aeshosp#sae	diff#all	state
Pneumonia	Pneumonia	2024-12-27T09:00	2024-12-27	N	N	N	N	Y	Y	AETERM - AEOUT - AESM...	QUERIED TO PROVIDER ▼
Arrhythmia	Arrhythmia	2022-12-11	2022-12-11	N	N	N	N	Y	Y	AEREL	NO ACTION NEEDED ▼
Confusional state	Confusional state	2024-09-20	2024-09-20	N	N	N	N	Y	Y	AEOUT	CREATED IN EDC ▼
Confusional state	Confusional state	2024-09-24	2024-09-24	N	Y	N	N	N	N	AESDISAB	QUERIED TO PROVIDER ▼
Urinary tract infection	Urinary tract infection	2024-11-01	2024-11-01	N	N	N	N	Y	Y	AESMIE	QUERIED TO PROVIDER ▼
Bundle branch block left	Bundle branch block left	2022-12-03	2022-12-03	Y	Y	N	N	Y	Y	AETERM - AEACN	NO ACTION NEEDED ▼
Septic shock	Septic shock	2024-07-29T23:08	2024-07-29	Y	Y	Y	Y	Y	Y	AEACN - AEOUT	QUERIED TO PROVIDER ▼
Hypovolaemic shock	Hypovolaemic shock	2022-03-13	2022-03-13	N	N	N	Y	Y	Y	AEACN - AEOUT - AESDTH	NO ACTION NEEDED ▼
Cardiac failure	Cardiac failure	2024-12-04	2024-12-04	N	N	N	N	Y	Y	AESEV	CREATED IN EDC ▼
Acute kidney injury	Acute kidney injury	2024-12-25	2024-12-25	N	N	N	N	Y	Y	AEOUT	QUERIED TO PROVIDER ▼

Automated Reconciliation Flow

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Completion of AEREFIDs

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- Taking appropriate action

4

Automatic Report Generation

- Comprehensible
- Customised

Automatic SAE report generation

Subject Id	SAE Refno	AE Verbatim	AE Preferred Term	Discrepancy Detected	Action Taken CDM	Print Row	Decisi...	High Light Color
4-1103	001826	LEFT SHOULDER PAIN	Arthralgia	Event reported in safety database but missing in clinical database.	NO ACTION NEEDED: ok, acceptable discrepancy RC14aug2024	☒		
4-1101	000682	LIGHTHEADEDNESS	Dizziness	Reported Term for the Adverse Event Safety database = LIGHT HEADED DUE TO 2:1 HIGH DEGREE AV BLOCK Clinical database = LIGHTHEADEDNESS Severity/Intensity Safety database = SEVERE	UPDATE REQUEST SAFETY DATABASE SENT: SAE reconciliation DEC2024	☒		
4-1103	001826	LEFT SHOULDER PAIN	Musculoskeletal pain	Event reported in clinical database but missing in safety database.	NO ACTION NEEDED: ok, acceptable discrepancy RC14aug2024	☒		
4-1103	001826	LEFT SHOULDER PAIN	Musculoskeletal pain	Study Identifier Safety database = Clinical database = Unique Subject Identifier Safety database = Clinical database = 04-1103	NO ACTION NEEDED: ok, acceptable discrepancy RC14aug2024	☒		
1-1105	001304	SEPSIC SHOCK	Septic shock	Reported Term for the Adverse Event Safety database = SEPTIC SHOCK Clinical database = SEPSIC SHOCK	NO ACTION NEEDED: Ok, AETERM consistent(Wrong spelling in EDC)	☒		

Automatic

Theme Colors

Standard Colors

More Colors...

Export To Excel

Refresh

Close

Automatic SAE report generation

Protocol Reference:							Version: Draft
SGS Internal Reference:							Date: 13/Dec/2024
Subject ID	SAE refno	Discrepancies Y/N	AE Verbatim	AE Preferred Term	Discrepancy detected	Decision Safety database owner/Sponsor	Action taken CDM
AA-BB-CC	AA-BB-CC	Y	LIGHTHEADEDNESS	Dizziness	<u>Reported Term for the Adverse Event</u> Safety database = LIGHT HEADED DUE TO 2:1 HIGH DEGREE AV BLOCK Clinical database = LIGHTHEADEDNESS <u>Severity/Intensity</u> Safety database = SEVERE Clinical database = MILD <u>Serious Event</u> Safety database = Y Clinical database = N		UPDATE REQUEST SAFETY DATABASE SENT: SAE reconciliation DEC2024
AA-BB-CC	AA-BB-CC	Y	ATRIAL FIBRILLATION	Atrial fibrillation	<u>Reported Term for the Adverse Event</u> Safety database = ATRIAL FIBRILLATION WITH HEART BLOCK Clinical database = ATRIAL FIBRILLATION		UPDATE REQUEST SAFETY DATABASE SENT: SAE reconciliation DEC2024
AA-BB-CC	AA-BB-CC	Y	LEFT SHOULDER PAIN	Arthralgia	Event reported in safety database but missing in clinical database.		NO ACTION NEEDED: ok, acceptable discrepancy RC14aug2024
AA-BB-CC	AA-BB-CC	Y	SEPSIC SHOCK	Septic shock	<u>Reported Term for the Adverse Event</u> Safety database = SEPTIC SHOCK Clinical database = SEPSIC SHOCK		NO ACTION NEEDED: Ok, AETERM consistent(Wrong spelling in EDC)



Conclusion

Implement automation at each step of SAE reconciliation process:

- Uniform structure
 - Safety database: Helptable
 - Clinical database: SDTM
- AEREFIDs completion in the same tool
 - Automatically populated via linking
 - Plan B if needed for manual input
- Discrepancy management
 - Validated automatic checks
 - Reconciliation status tracking throughout the trial
- Automatic report generation

Questions?



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Contact us

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