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ICSR – Case Processing

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Revisions and Approval

Author	Document ID	Version	Date	Change description
Bhavana Pant	RX-TRN-BUS-003	Version 1.0	13-Jun-2016	N/A

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Approver	Approval Date
Ram Patalapati	14-Jun-2016



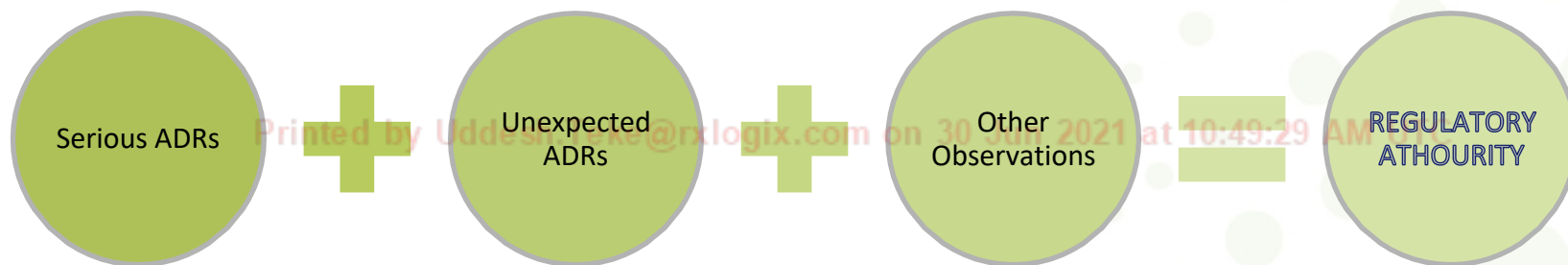
Agenda

- What should be reported?
- PV – General Business Process
- AE Assessment
- Case Processing
- ICSR Case Processing Exercise
- Periodic and Expedited Reports
- Reporting timelines

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What should be reported?



MINIMUM CRITERIA FOR REPORTING

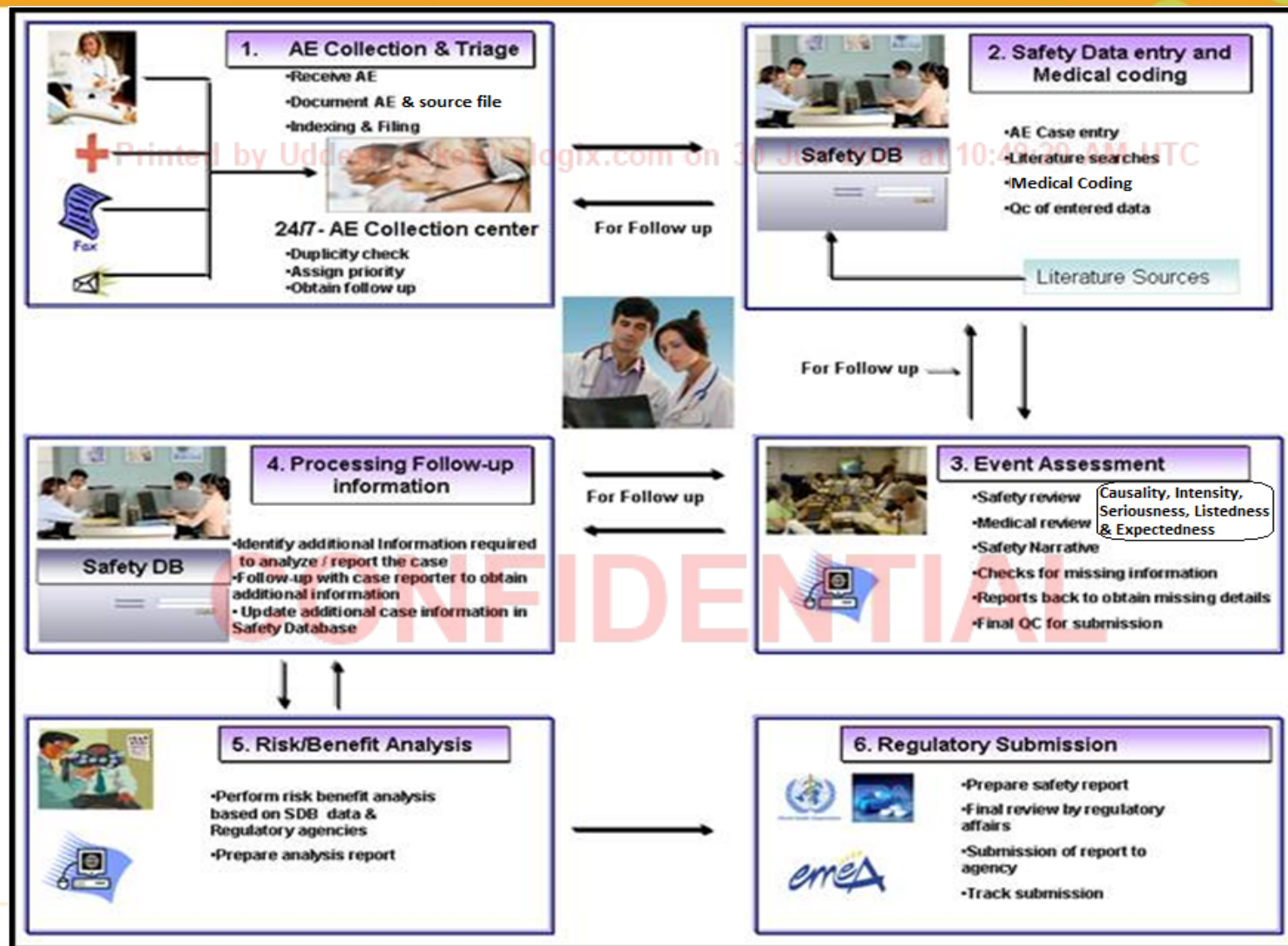
For regulatory purposes, initial reports should be submitted within the prescribed time as long as the following minimum criteria are met:

- an identifiable **patient**;
- a **suspect product**;
- an identifiable **reporting source**;
- and an **event** or outcome that can be identified as serious and unexpected, and for which, in clinical investigation cases, there is a reasonable suspected causal relationship.

Follow-up information should be actively sought and submitted as it becomes available.

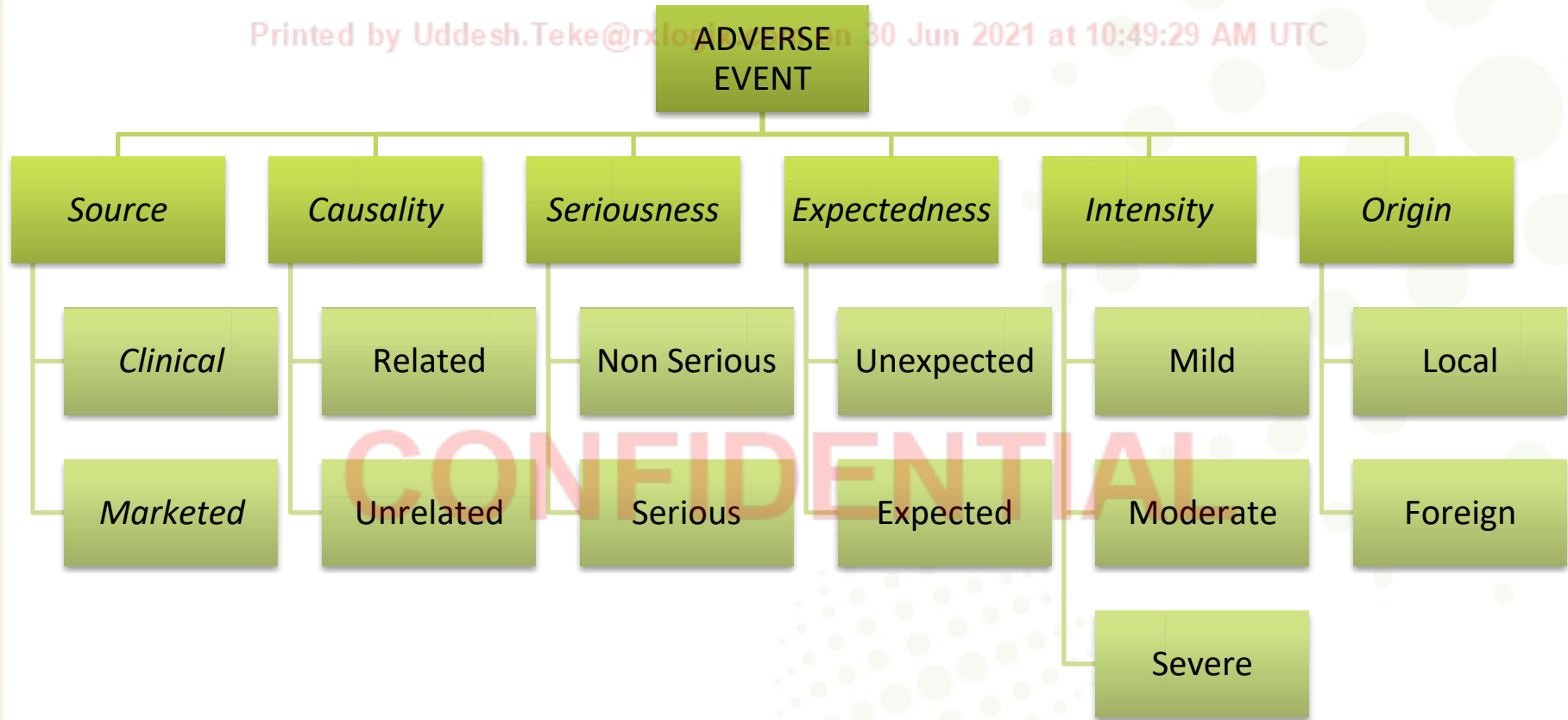


PV – General Business Process



Adverse Event Assessment

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Case Processing – Points to consider

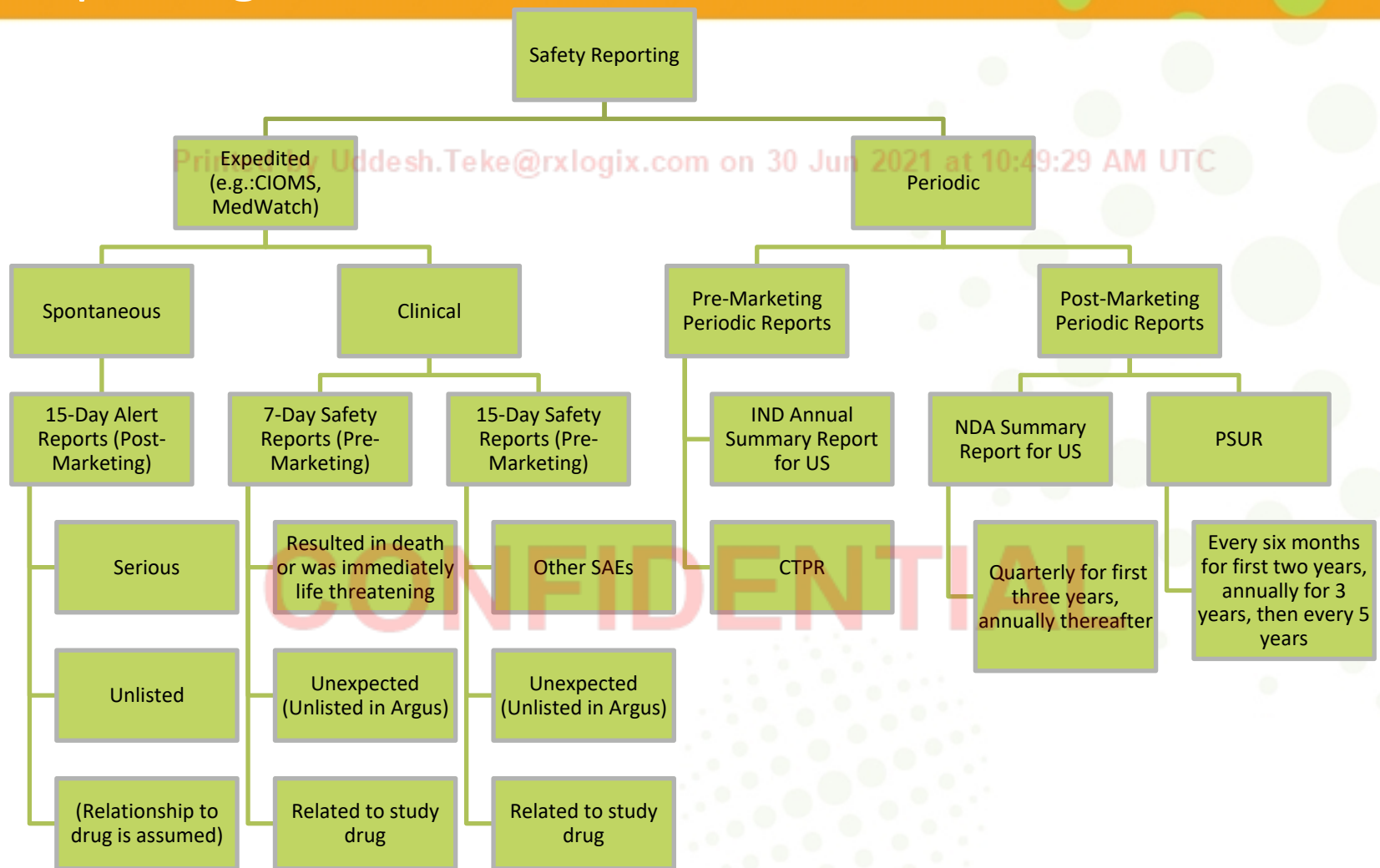
- Step 1 – Create case with existing information
- Step 2 - asses Case Priority by initial AE Assessment and License Type
- Step 3 – verify existing information and initiate process of FU (gathering complete information required for analyzing the case)
- Step 4 – Perform Medical review
- Step 5 – Initiate Expedited reporting based on regulatory obligations
- Step 6 – Complete Case processing (data gathering, FU completion and Expedited reporting completion) and Archive it
- Step 7 – Signal Detection

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Reporting Time Frames



ICSR examples

License type **Event Seriousness** **Event description** **Event Intensity** **Event Causality** **Event Expected** **Event Origin**

Marketed

<u>NS Event</u>	Pregnancy/ skin rash	Mild	Related	E	Local
<u>Death</u>	death	Severe	Related	UE	local
<u>Hospitalisation</u>	Heart Attack	Severe	Related	UE	Foreign
<u>congenital anomaly</u>	blindness	Severe	Related	UE	Local
<u>Serious Literature</u>	Nausea in Multiple patient	Moderate	Related	E	Foreign

Clinical

<u>Death</u>	death	Severe	Related	UE	Foreign
<u>disability</u>	Vaccine/ paralysis	Severe	Related	UE	Local
<u>Life Threatening</u>	renal failure	Moderate	Unrelated	UE	Foreign
<u>Reg. Intervention</u>	Device/ irregular heartbeat	Moderate	Related	UE	Foreign
<u>Non Serious Literature</u>	fever	Moderate	Related	E	Foreign



ICSR CASE PROCESSING EXERCISE-

Spontaneous- Non-serious-Related-Expected

<u>Event description</u>	Pregnancy/ skin rash
<u>Event Intensity</u>	Mild
<u>Event Causality</u>	Related
<u>Event Expected</u>	E
<u>Event Origin</u>	Local

Workflow	Case Specifications
<i>Data Entry</i>	-Case details - Pregnancy Details
<i>Quality Control</i>	- Pregnancy Details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	-Product and Event Assessment - Coding and Narrative - FU consolidation and request * (specifically for Case seriousness post birth)
<i>Reporting</i>	- No Expedited report



Pregnancy Details

Case Form - A201600279 "AS" Case Status: Global Triage

General | **Patient** | Products | Events | Analysis | Activities | Additional Information | Regulatory Reports

Patient | Parent

Patient Information Patient Info From Reporter | Current Medical Status

First Name MI Last Name Initials ☐ Protect Confidentiality ☐ Child Only Case

Address City Country

State/Province Postal Code Phone Number

Patient Details

Date of Birth Age Units Age Group Ethnicity Occupation Weight Height

Gender Pregnant Age at Vaccination Units (at Vaccination) Date of LMP ☐ Breastfeeding

Pregnancy Information

Due Date Weeks at Onset Weeks at Exposure Trimester of Exposure ☒ First ☐ Second ☐ Third

Number of Fetus ☒ Prospective ☐ Retrospective

Delivery Date Weight APGAR Score #1 APGAR Score #2 APGAR Score #3

Delivery Type Delivery Notes

Birth Type

Fetal Outcome

Neonate 1 (New)



Activities Tab

Case Form - A201600279 "AS"

Case Status: Global Triage

General Patient Products Events Analysis **Activities** Additional Information Regulatory Reports

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Contact Log (1) New Letter Add Delete

#	Date Sent	Code Description	Group User
1.	10-MAR-2016 10-SEP-2016	Pregnancy details can be entered here.	
2.	00-MMM-0000 00-MMM-0000		

Action Items (1) Show ☒ All ☐ Open Add Delete Up Down

#	Date Open Due / Completed	Code Description	Group User
1.	12-MAR-2016 10-DEC-2016 11-DEC-2016	Pending with Medical reviewer	
2.	00-MMM-0000 00-MMM-0000 00-MMM-0000		

Routing Comments (1) Return Route

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ICSR CASE PROCESSING EXERCISE- Spontaneous-SUSAR- Death

<u>Event description</u>	Death
<u>Event Intensity</u>	SEVERE
<u>Event Causality</u>	RELATED
<u>Event Expected</u>	UE
<u>Event Origin</u>	Local

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Death and Autopsy details
<i>Quality Control</i>	<ul style="list-style-type: none"> - Death and Autopsy details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> -Product and Event Assessment - Coding and Narrative - FU consolidation and request
<i>Reporting</i>	<ul style="list-style-type: none"> - 15 Day Expedited report



Death Details

Event Death Details

Death Date: 05-MAR-2016 Autopsy Done?: Yes Autopsy Results Available?: Yes

Cause of Death and Autopsy Results (1)

#	Term Type	Verbatim / Coded Term PT (LLT)
1.	Cause of Death	Description as Reported: renal failure Renal failure
2.	Cause of Death	Description as Reported:

Other Relevant History (0)

#	Start / Stop Date	Condition Type / Verbatim / Indication / Reaction	Coded PT / Description of condition LLT / Indication PT / Reaction	Notes
1.	01-FEB-2016 10-FEB-2016 <input type="checkbox"/> Ongoing	Allergy Allergy 	Hypersensitivity L Allergy	Available information can be entered here.

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ICSR CASE PROCESSING EXERCISE- Spontaneous-SUSAR- Hospitalisation

<u>Event description</u>	Heart Attack
<u>Event Intensity</u>	Severe
<u>Event Causality</u>	Related
<u>Event Expected</u>	UE
<u>Event Origin</u>	Foreign

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Hospitalisation details
<i>Quality Control</i>	<ul style="list-style-type: none"> - Hospitalisation details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> -Product and Event Assessment - Coding and Narrative - FU consolidation and request
<i>Reporting</i>	<ul style="list-style-type: none"> - 15 Day Expedited report



Seriousness Criteria

- | | |
|--|---|
| <input type="checkbox"/> Death | <input checked="" type="checkbox"/> Medically Significant |
| <input checked="" type="checkbox"/> Hospitalized Details | <input type="checkbox"/> Life-threatening |
| <input type="checkbox"/> Disability | <input type="checkbox"/> Intervention Required |
| <input type="checkbox"/> Other: | <input type="checkbox"/> Congenital Anomaly |

Details

Related

Event Hospitalization -- Webpage Dialog

Hospitalization Details

Hospitalization Start Date	<input type="text" value="01-JAN-2016"/>	<input type="button" value="X"/>
Hospitalization End Date	<input type="text" value="20-JAN-2016"/>	
Duration of Hospitalization	<input type="text" value="20"/>	Day

☒ Event Caused Hospitalization
☐ Hospitalization Prolonged
☐ Hospital Discharge Summary Available

Lab Data (0)

Lab Data Test as Reported	<input type="button" value="Add Test"/>	Results / Units	<input type="button" value="Add Date"/>
Test Name		Assessment	
Units	<input type="button" value="Select Lab Test Group"/>	Notes	
Norm Low / Norm High			
		Date	<input type="text" value="04-JAN-2016"/>
		<input type="button" value="Encode"/>	

Blood Test	<input type="text"/>	<input type="button" value="X"/>
Blood test	<input type="text"/>	<input checked="" type="button" value="✓"/>
g/dL	<input type="text"/>	
80	<input type="text" value="120"/>	



ICSR CASE PROCESSING EXERCISE- Spontaneous-SUSAR- congenital anomaly

<u>Event description</u>	blindness
<u>Event Intensity</u>	Severe
<u>Event Causality</u>	Related
<u>Event Expected</u>	UE
<u>Event Origin</u>	Local

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details -Child details -Parent details
<i>Quality Control</i>	<ul style="list-style-type: none"> - Child details -Parent details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> -Product and Event Assessment – of parent and child - Coding and Narrative - – of parent and child details - FU consolidation and request – of parent and child
<i>Reporting</i>	<ul style="list-style-type: none"> - 15 Day Expedited report



Parent & Patient Details

Patient **Parent**

Parent Information

Parent Initials: Date of Birth: 77-??-0000 Age: 28 Units: Years Gender: Female Date of LMP: 10-JAN-2014 Weight: 50 kgs Height: 160 cm ☐ Parent Breastfeeding

Medical History

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Pregnancy Information

Due Date: 15-SEP-2014 Weeks at Onset: 4 Weeks at Exposure: 3 Trimester of Exposure: ☒ First ☐ Second ☐ Third

Number of Fetus: ☐ Prospective ☐ Retrospective

Delivery Date: 16-SEP-2014 Weight: 5lbs lbs/ozs APGAR Score #1: 3 APGAR Score #2: 5 APGAR Score #3: 7

Delivery Type: Vaginal Birth Type: Full-term Fetal Outcome: Normal

Delivery Notes

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

Notes and Attachments (0)

#	Classification Date / Incl. Reg. Sub	Keywords Description
1.	Discharge Summary 10-MAR-2016	You can write here the details regarding discharge
2.	 00-MMM-0000	



ICSR CASE PROCESSING EXERCISE-

Clinical- SUSAR- Death

<u>Event description</u>	death
<u>Event Intensity</u>	Severe
<u>Event Causality</u>	Related
<u>Event Expected</u>	UE
<u>Event Origin</u>	Foreign

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Death and Autopsy details
<i>Quality Control</i>	<ul style="list-style-type: none"> - Death and Autopsy details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> - <i>Unblinding of study product</i> - Product and Event Assessment - Coding and Narrative - FU consolidation and request
<i>Reporting</i>	<ul style="list-style-type: none"> - 7 Day Expedited report



Death Details

Event Information

Description as Reported

rash



Diagnosis

☐ Diagnosis

☒ Symptoms

Description to be Coded

rash

Encode

Onset Date/Time

??-??-0000 00:00

Onset Latency

Intensity

Severe

☐ Lack of Efficacy

☐ Infection

Event Coding



System Organ Class (SOC) (Code) Skin and subcutaneous tissue disorders (10040785)

High Level Group Term (Code) Epidermal and dermal conditions (10014982)

High Level Term (Code) Rashes, eruptions and exanthems NEC (10052566)

☒ Preferred Term (Code) Rash (10037844)

Lower Level Term (Code) Rash (10037844)

Synonym (Code)

Action Taken with Study Treatment

Seriousness Criteria

☒ Death

☐ Hospitalized

☐ Medically Significant

☐ Life-threatening



Autopsy Details

Event Death Details		
Death Date	Autopsy Done?	Autopsy Results Available?
14-MAR-2016	Yes	Yes
Cause of Death and Autopsy Results (1)		
#	Term Type	Verbatim / Coded Term PT (LLT)
1.	Autopsy Result	<div>Description as Reported</div> <div>Kidney Failure</div> <div>Renal failure</div>
2.	Cause of Death	<div>Description as Reported</div> <div></div> <div></div>

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ICSR CASE PROCESSING EXERCISE-

Clinical- SUSAR- Disability

<u>Event description</u>	Vaccine/ paralysis
<u>Event Intensity</u>	Severe
<u>Event Causality</u>	Related
<u>Event Expected</u>	UE
<u>Event Origin</u>	Local

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Vaccine details
<i>Quality Control</i>	<ul style="list-style-type: none"> - Vaccine details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> - <i>Unblinding of study product (as specified in study protocol)</i> - Product and Event Assessment - Coding and Narrative - FU consolidation and request
<i>Reporting</i>	<ul style="list-style-type: none"> - 15 Day Expedited report



Vaccine Details

SOLIRIS 300mg		DR	VACCIN ANTIAMARILE		(New)
Drug Device Vaccine					
Product Information Printed by Uddesh.Teke@rxlogix.com on 30 Jun 2021 at 10:49:29 AM UTC					
Product Name		Select Encode		<input checked="" type="radio"/> Suspect <input type="radio"/> Concomitant	
VACCIN ANTIAMARILE					
Generic Name					
YELLOW FEVER VACCINE					
Company Drug Code		Obtain Drug Country		Drug Code	
				001021.01.014	
Formulation		Drug Authorization Country		Manufacturer	
Concentration	Units	Interaction?	Contraindicated?		
		No Yes	Yes No		
Concomitant Medication Details		Dose adjust due to LoE			

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ICSR CASE PROCESSING EXERCISE-

Clinical- SUSAR- Life threatening

<u>Event description</u>	renal failure
<u>Event Intensity</u>	Moderate
<u>Event Causality</u>	Unrelated
<u>Event Expected</u>	UE
<u>Event Origin</u>	Foreign

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Hospitalisation details
<i>Quality Control</i>	<ul style="list-style-type: none"> - hospitalisation details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> - <i>Unblinding of study product</i> - Product and Event Assessment - Coding and Narrative - FU consolidation and request by comparator manufacturer* - intimation to comparator drug manufacturer
<i>Reporting</i>	<ul style="list-style-type: none"> - 7 Day Expedited report



Hospitalisation Details

Event Assessment

Rash F H (New)

E2B Preferred Term (Code) Rash (10037844)
Lower Level Term (Code) Rash (10037844)
Synonym (Code)

Action Taken with Study Treatment

Seriousness Criteria

<input checked="" type="checkbox"/> Death	<input type="checkbox"/> Medically Significant
<input checked="" type="checkbox"/> Hospitalized Details	<input type="checkbox"/> Life-threatening
<input type="checkbox"/> Disability	<input type="checkbox"/> Intervention Required
<input type="checkbox"/> Other:	<input type="checkbox"/> Congenital Anomaly

Event Death Details

Death Date 14-MAR-2016 Autopsy Done? Yes Autopsy Results Available? Yes

Event Hospitalization -- Webpage Dialog

Hospitalization Details

Hospitalization Start Date 10-MAR-2016
Hospitalization End Date 14-MAR-2016
Duration of Hospitalization 5 Day

☐ Event Caused Hospitalization
☐ Hospitalization Prolonged
☐ Hospital Discharge Summary Available

OK Cancel

ICSR CASE PROCESSING EXERCISE-

Clinical- SUSAR- Requires Intervention

<u>Event description</u>	Device/ irregular heartbeat
<u>Event Intensity</u>	Moderate
<u>Event Causality</u>	Related
<u>Event Expected</u>	UE
<u>Event Origin</u>	Foreign

Workflow	Case Specifications
<i>Data Entry</i>	<ul style="list-style-type: none"> - Case details - Device details and patient medical history
<i>Quality Control</i>	<ul style="list-style-type: none"> - Device details - <i>Dechallenge/ Rechallenge for causality</i> - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
<i>Medical Review</i>	<ul style="list-style-type: none"> - no unblinding till End of study (unless specified in the protocol) - Product and Event Assessment – <i>refer IB</i> - Coding and Narrative - FU consolidation and request
<i>Reporting</i>	<ul style="list-style-type: none"> - 15 Day Expedited report

Device Details

S SOLIRIS 300mg DR S device 1 (New)

Drug Device Vaccine

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Product Information

Product Name ☒ Suspect ☐ C

device 1

Generic Name

dummy generic name

Company Drug Code **Obtain Drug Country** **Drug Code**




Device Type

Formulation **Drug Authorization Country** **Manufacturer**

Concentration **Units** **Interaction?** **Contraindicated?**

100 mg No Yes

Product Indication (0)

#	 Reported Indication	 Coded Indication
1.		



Periodic and Expedited Reports

Criteria	Periodic	Expedited
	* Product specific	* Region Specific
Primary aim	-Product Profiling - Product profiling summary for a specified period - Line listings	- Event profiling for regulatory compliance
Expectedness	- Listedness	- Labeledness
Timeline	-2 months to 5 years -E.g. : ICH PSUR 0 to 2 years – Every quarter 2 to 5 years – Every year > 5 years - Every 5 years	7 day or 15 day
Types	- Clinical - CTPR and IND (for USA) - Spont – PSUR and NDA (for USA)	Region specific forms E.g.: MedWatch, MHRA, Spanish
Categories	- by therapeutic area -Sub category by ingredient	-By product type – drugs, vaccine, devices

References

- <http://www.fda.gov/RegulatoryInformation/Guidances/ucm129457.htm#3>
- <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARsandASRs/index.htm>

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The End

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Version 01 Effective on 30-Sep-2019

Initial Version

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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