ICSR – Case Processing

Revisions and Approval

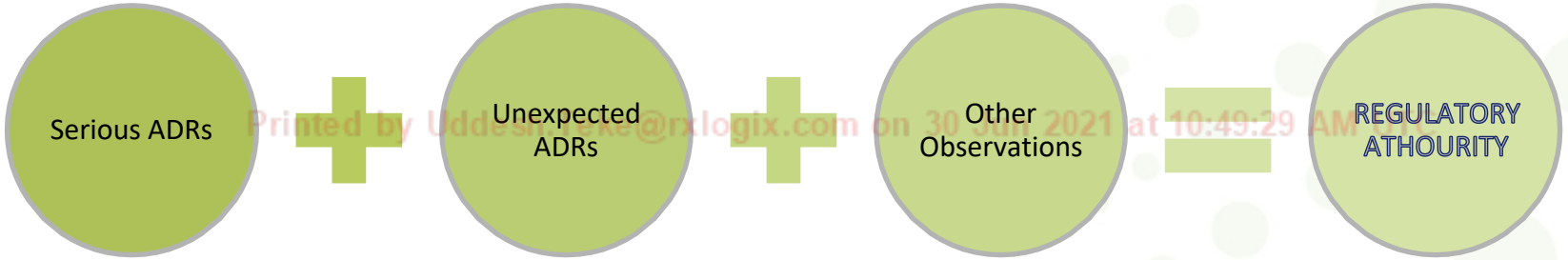
Author	Document ID	Version	Date	Change description
Bhavana Pant	RX-TRN-BUS-003	Version 1.0	13-Jun-2016	N/A

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

What should be reported?



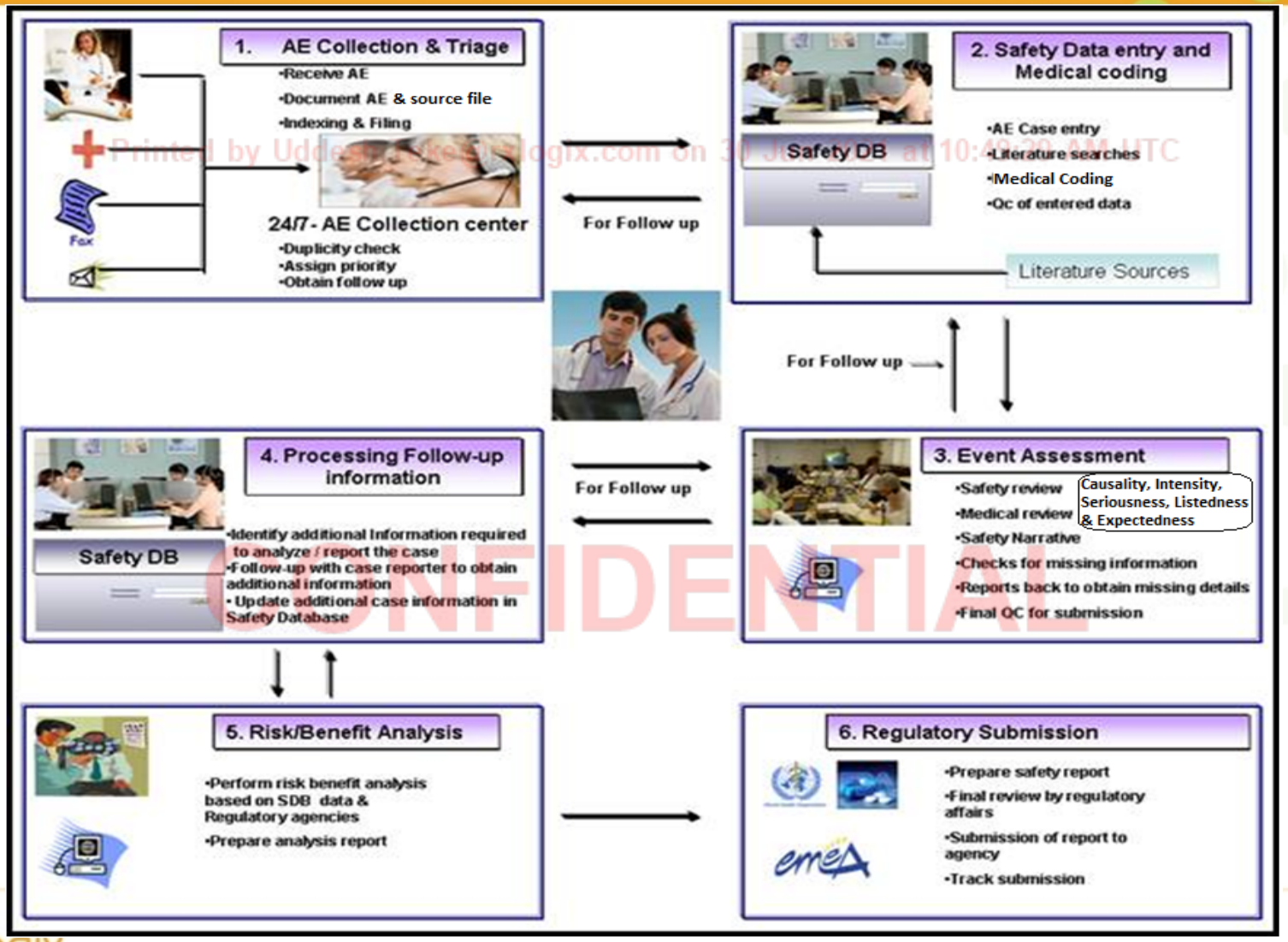
MINIMUM CRITERIA FOR REPORTING

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



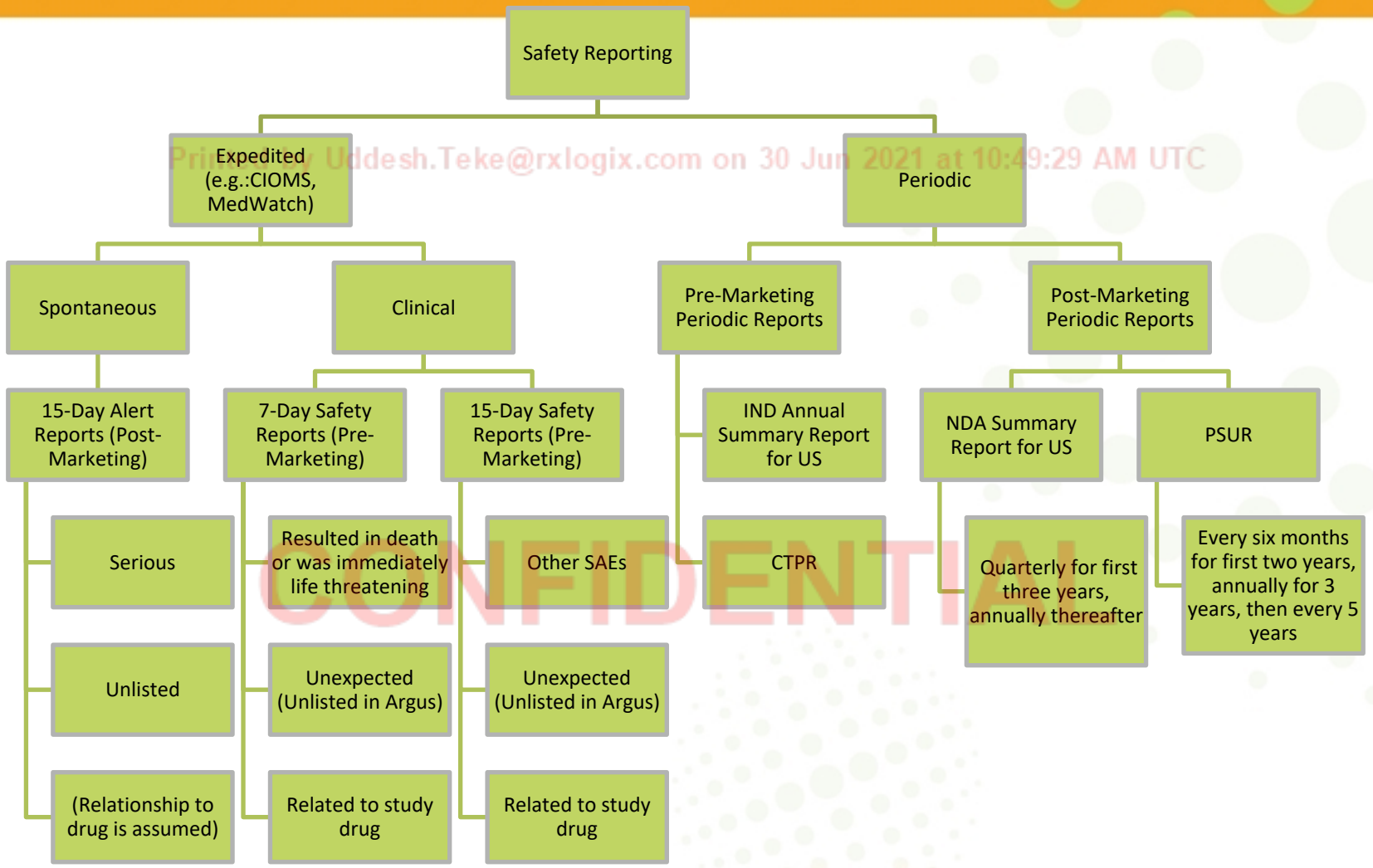
Adverse Event Assessment

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

Reporting Time Frames



ICSR examples

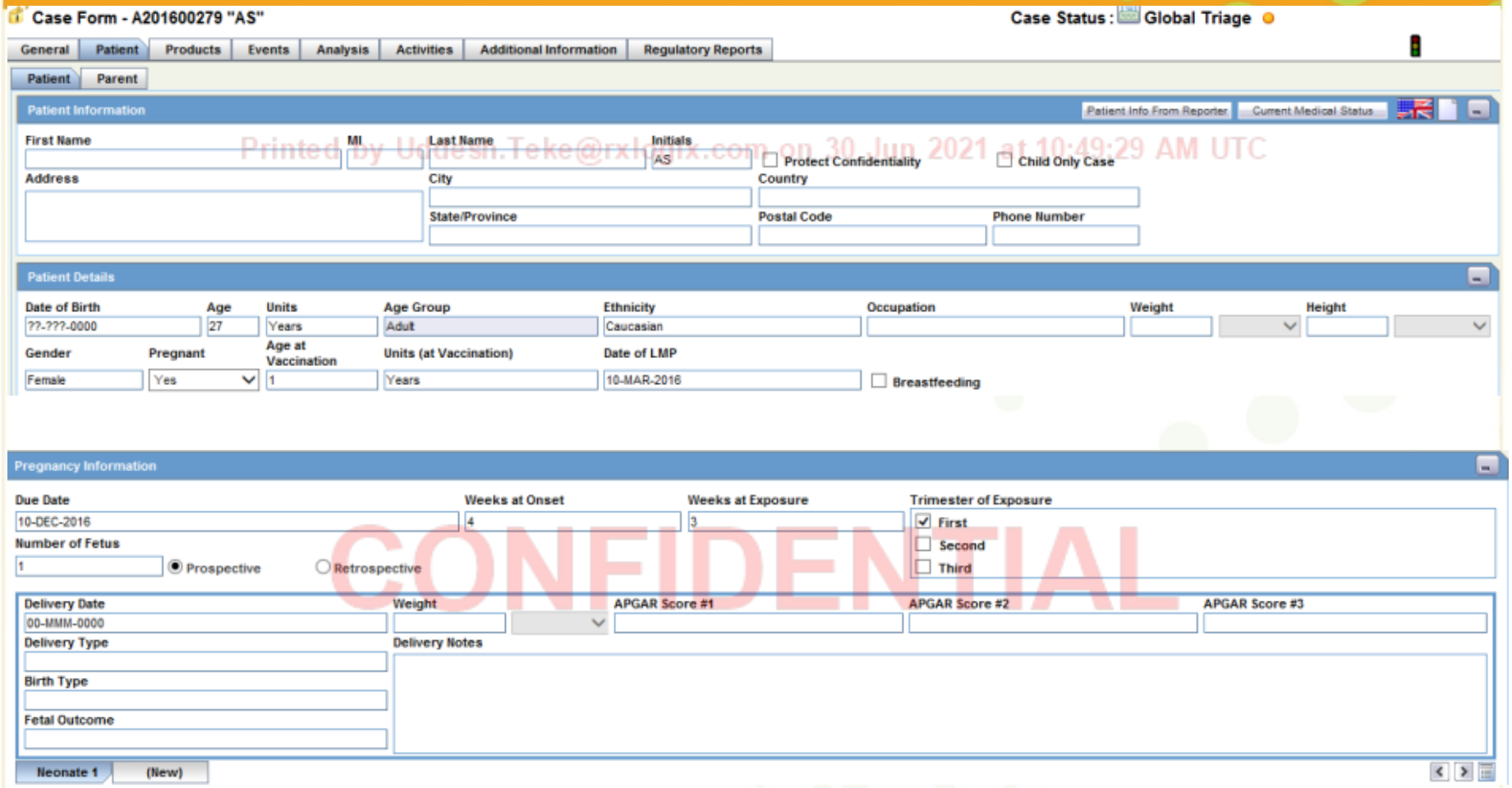
License type	Event Seriousness	Event description	Event Intensity	Event Causality	Event Expected	Event Origin
Marketed	NS Event	Pregnancy/ skin rash	Mild	Related	E	Local
	Death	death	Severe	Related	UE	local
	Hospitalisation	Heart Attack	Severe	Related	UE	Foreign
	congenital anomaly	blindness	Severe	Related	UE	Local
	Serious Literature	Nausea in Multiple patient	Moderate	Related	E	Foreign
Clinical	Death	death	Severe	Related	UE	Foreign
	disability	Vaccine/ paralysis	Severe	Related	UE	Local
	Life Threatening	renal failure	Moderate	Unrelated	UE	Foreign
	Req. Intervention	Device/ irregular heartbeat	Moderate	Related	UE	Foreign
	Non Serious Literature	fever	Moderate	Related	E	Foreign

ICSR CASE PROCESSING EXERCISE- Spontaneous- Non-serious-Related-Expected

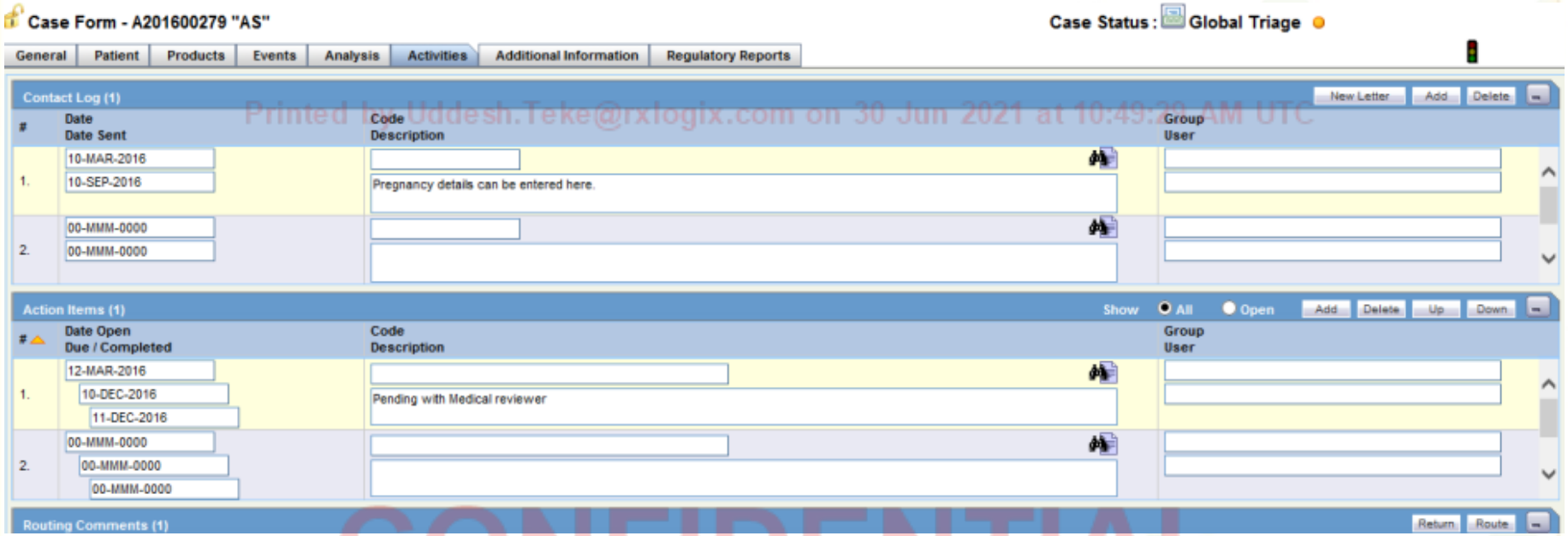
Event description	Pregnancy/ skin rash
Event Intensity	Mild
Event Causality	Related
Event Expected	E
Event Origin	Local

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

Pregnancy Details



Activities Tab

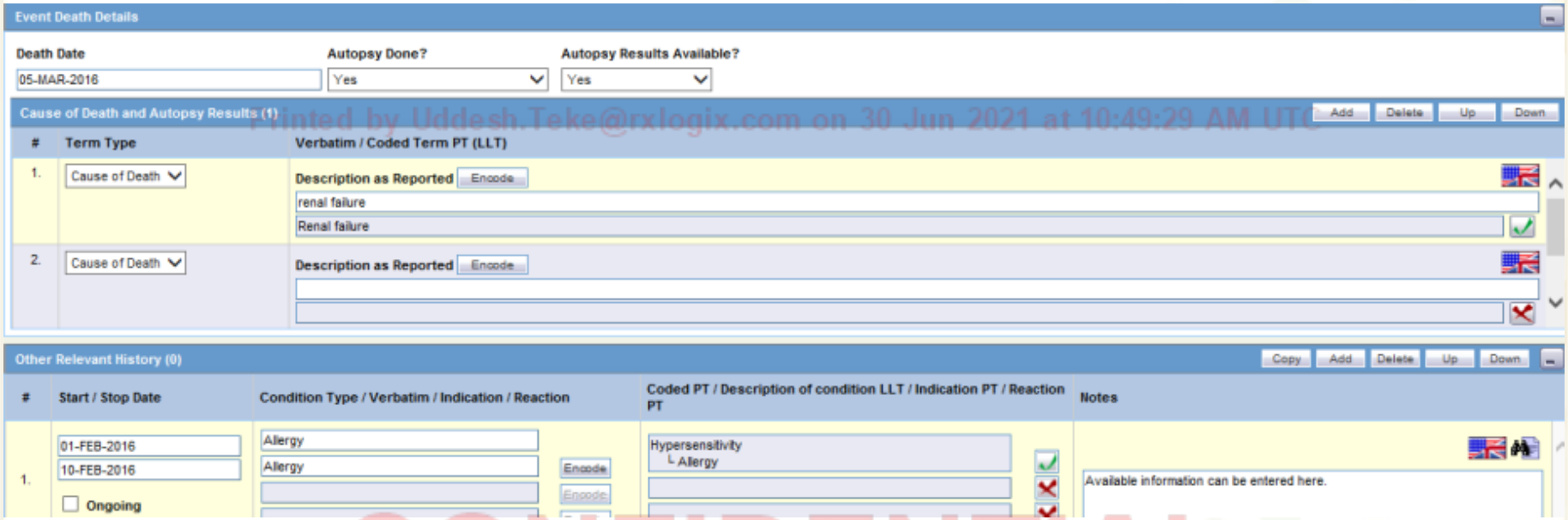


ICSR CASE PROCESSING EXERCISE- Spontaneous- SUSAR- Death

Event description	Death
Event Intensity	SEVERE
Event Causality	RELATED
Event Expected	UE
Event Origin	Local

Workflow	Case Specifications
Data Entry	- Case details - **Death and Autopsy details**
Quality Control	- Death and Autopsy details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	-Product and Event Assessment - Coding and Narrative - FU consolidation and request
Reporting	- 15 Day Expedited report

Death Details



ICSR CASE PROCESSING EXERCISE- Spontaneous- SUSAR- Hospitalisation

Event description	Heart Attack
Event Intensity	Severe
Event Causality	Related
Event Expected	UE
Event Origin	Foreign

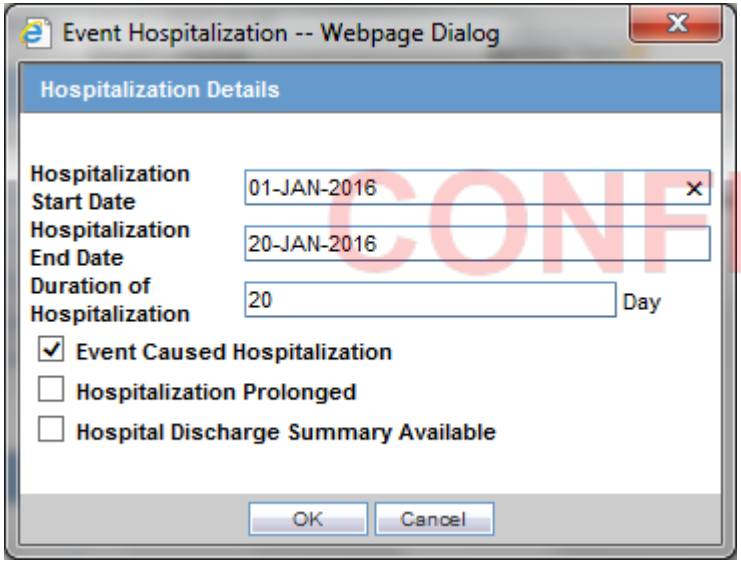
Workflow	Case Specifications
Data Entry	- Case details - **Hospitalisation details**
Quality Control	- Hospitalisation details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	-Product and Event Assessment - Coding and Narrative - FU consolidation and request
Reporting	- 15 Day Expedited report

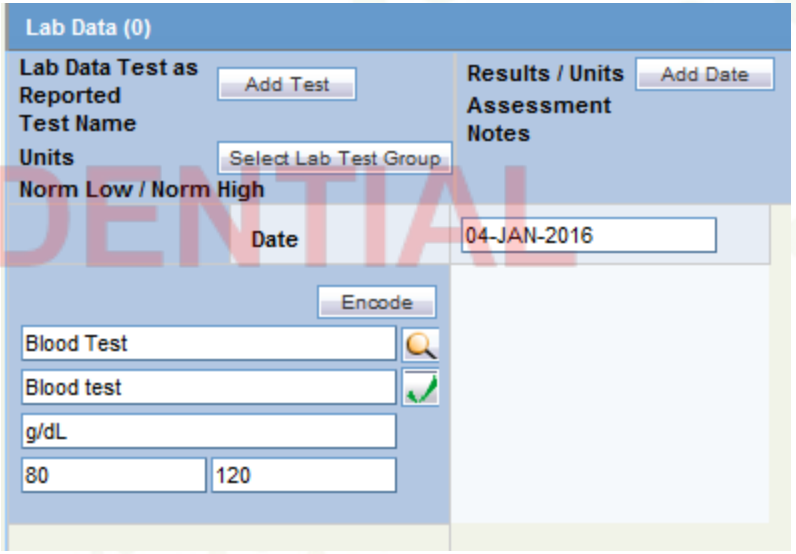
Seriousness Criteria

- [ ] Death
- [x] Hospitalized — Details
- [ ] Disability
- [ ] Other:
- [x] Medically Significant
- [ ] Life-threatening
- [ ] Intervention Required
- [ ] Congenital Anomaly

Details

Related



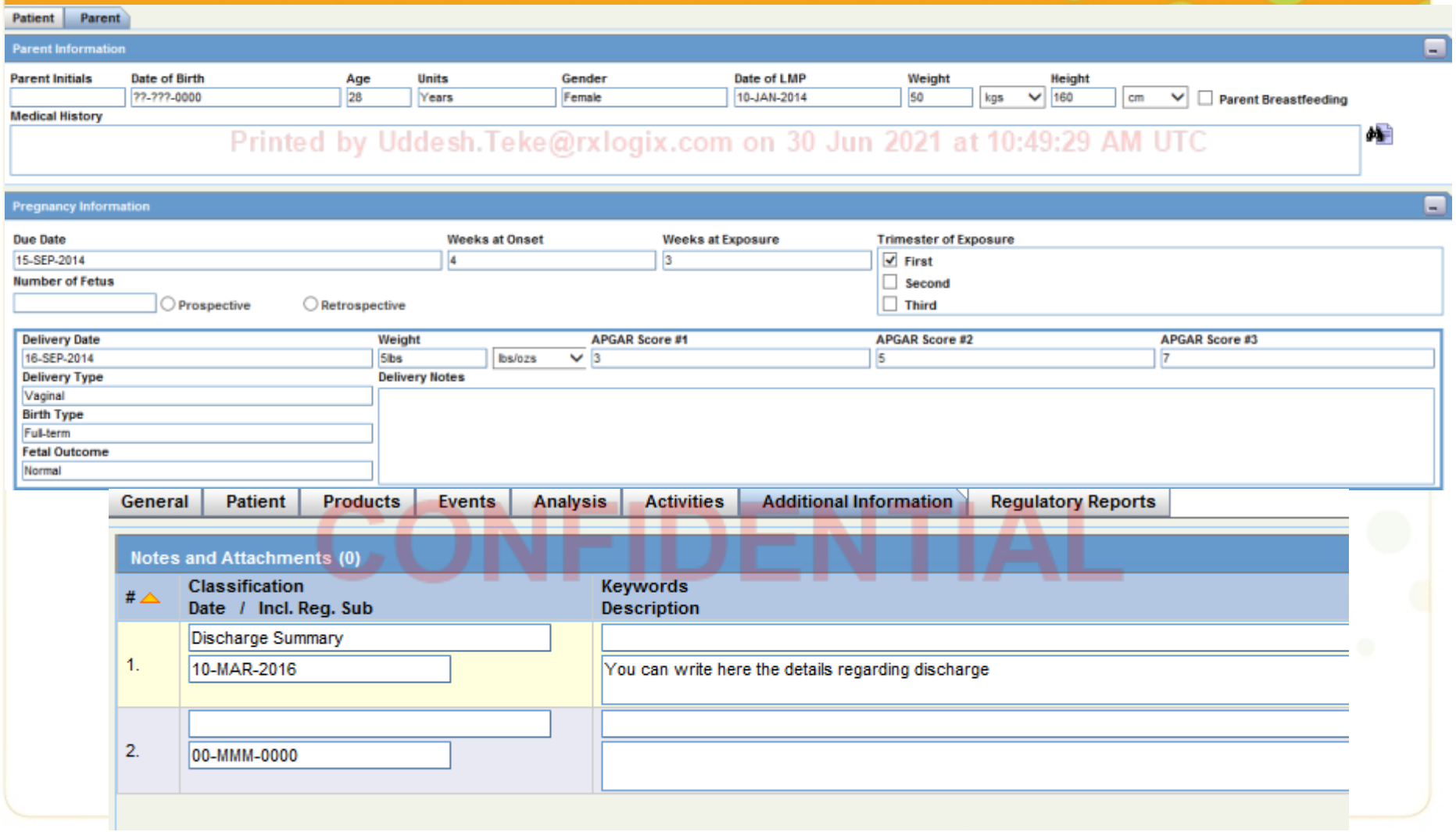


ICSR CASE PROCESSING EXERCISE- Spontaneous- SUSAR- congenital anomaly

Event description	blindness
Event Intensity	Severe
Event Causality	Related
Event Expected	UE
Event Origin	Local

Workflow	Case Specifications
Data Entry	- Case details -**Child details** -**Parent details**
Quality Control	- Child details -Parent details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	-Product and Event Assessment – of parent and child - Coding and Narrative - – of parent and child details - FU consolidation and request – of parent and child
Reporting	- 15 Day Expedited report

Parent & Patient Details



ICSR CASE PROCESSING EXERCISE- Clinical- SUSAR- Death

Event description	death
Event Intensity	Severe
Event Causality	Related
Event Expected	UE
Event Origin	Foreign

Workflow	Case Specifications
Data Entry	- Case details - **Death and Autopsy details**
Quality Control	- Death and Autopsy details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	- *Unblinding of study product* -Product and Event Assessment - Coding and Narrative - FU consolidation and request
Reporting	- 7 Day Expedited report

Death Details

Event Information

Description as Reported

rash

Description to be Coded

rash

Encode

Diagnosis

○ Diagnosis ◉ Symptoms

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

Action Taken with Study Treatment

Seriousness Criteria

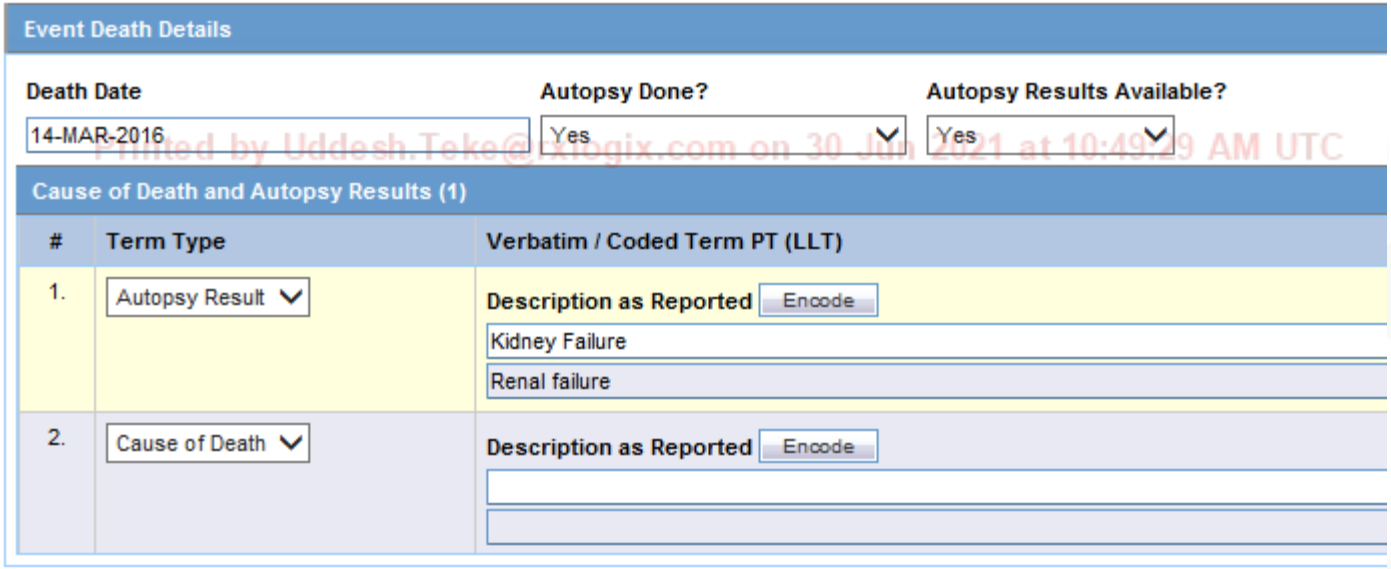
☑ Death

☐ Hospitalized

☐ Medically Significant

☐ Life-threatening

Autopsy Details

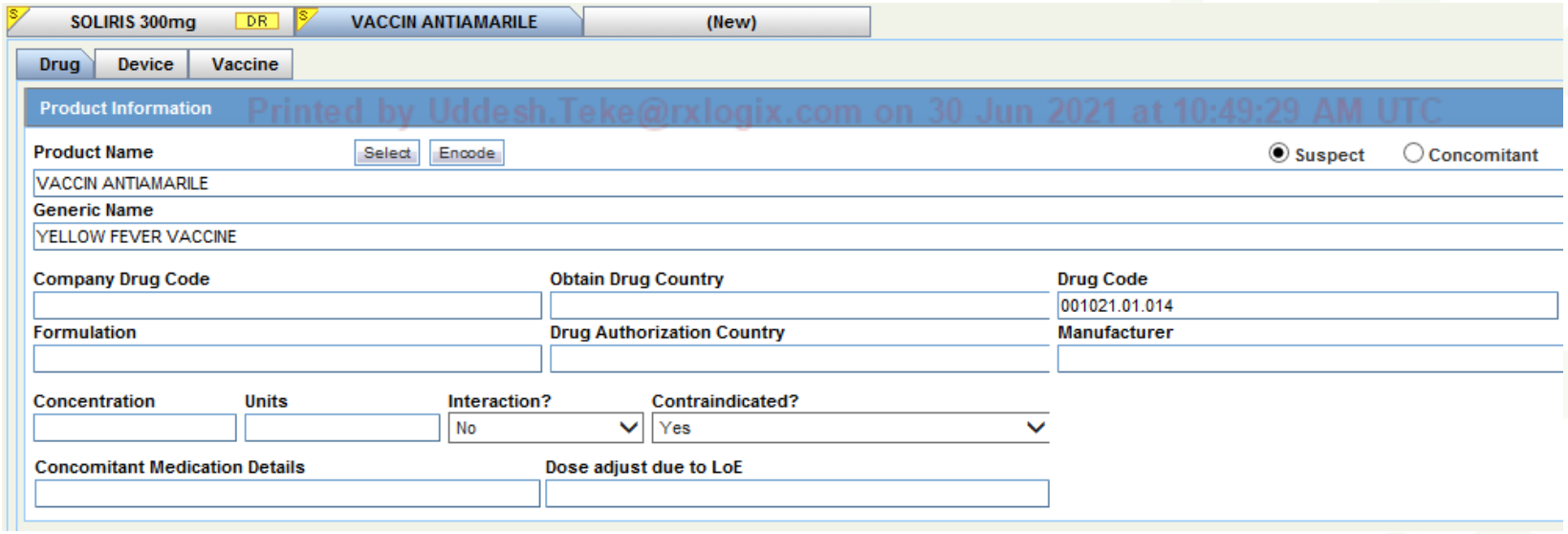


ICSR CASE PROCESSING EXERCISE- Clinical- SUSAR- Disability

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

Workflow	Case Specifications
Data Entry	- Case details -**Vaccine details**
Quality Control	- Vaccine details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	- *Unblinding of study product (as specified in study protocol)* -Product and Event Assessment - Coding and Narrative - FU consolidation and request
Reporting	- 15 Day Expedited report

Vaccine Details

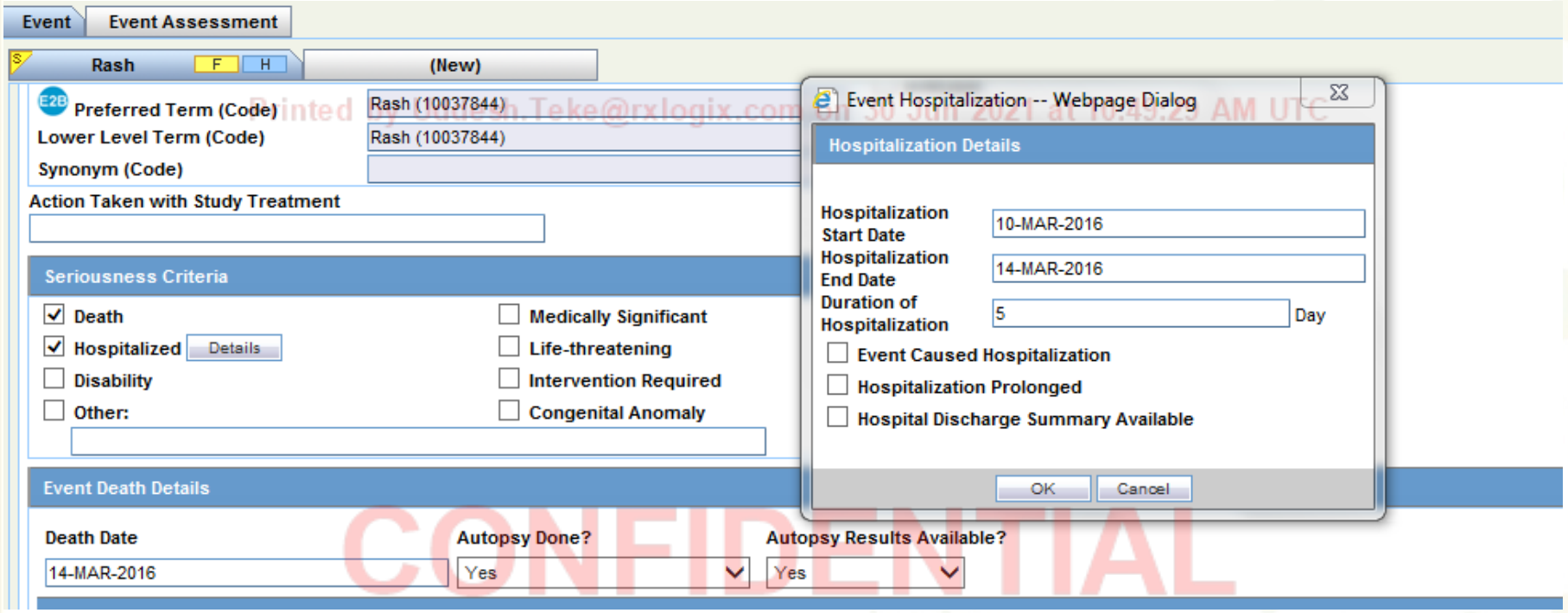


ICSR CASE PROCESSING EXERCISE- Clinical- SUSAR- Life threatening

Event description	renal failure
Event Intensity	Moderate
Event Causality	Unrelated
Event Expected	UE
Event Origin	Foreign

Workflow	Case Specifications
Data Entry	- Case details - **Hospitalisation details**
Quality Control	- hospitalisation details - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	- *Unblinding of study product* -Product and Event Assessment - Coding and Narrative - FU consolidation and request by comparator manufacturer* - intimation to comparator drug manufacturer
Reporting	- 7 Day Expedited report

Hospitalisation Details

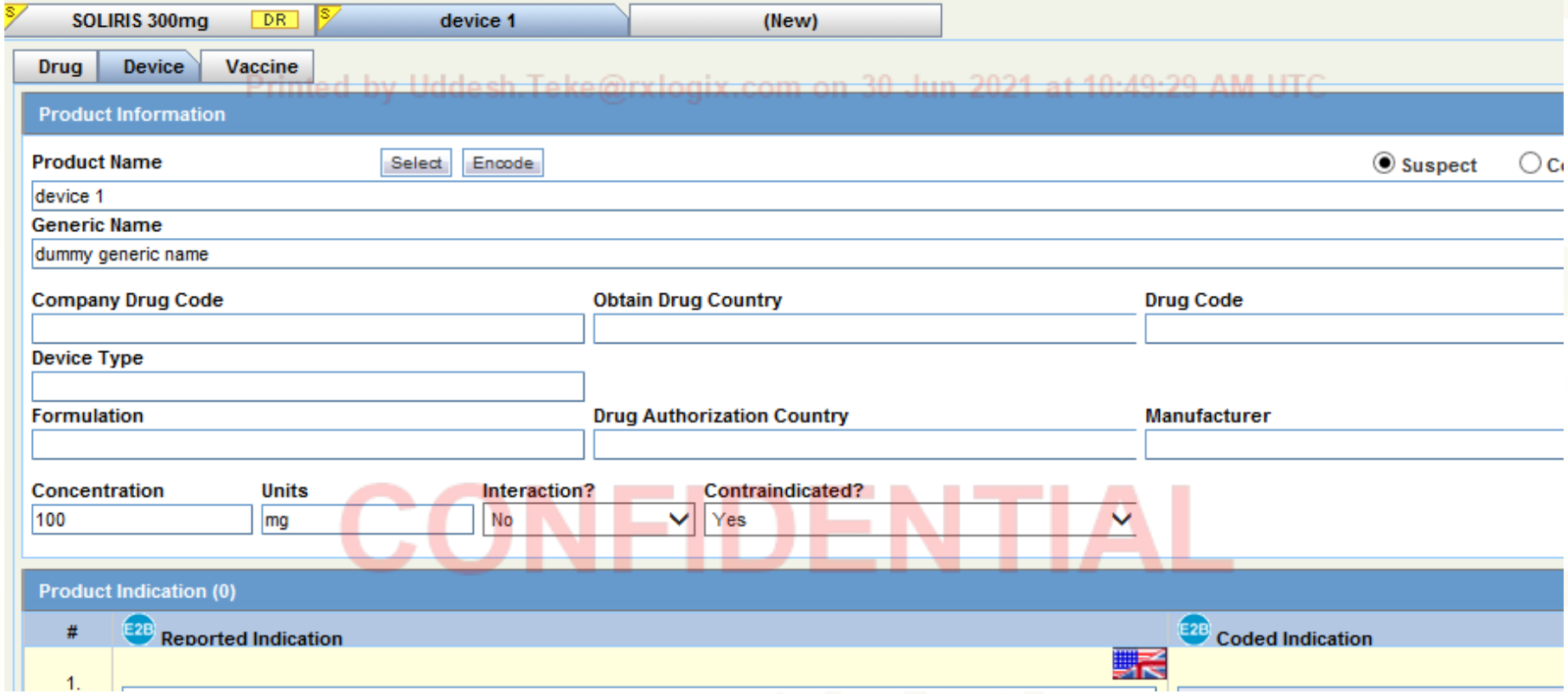


ICSR CASE PROCESSING EXERCISE-
Clinical- SUSAR- Requires Intervention

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

Workflow	Case Specifications
Data Entry	- Case details - **Device details and patient medical history**
Quality Control	-Device details - *Dechallenge/ Rechallenge for causality* - Essential case fields (Patient, Product, Event and Reporter fields for reporter completion and signal detection)
Medical Review	- no unblinding till End of study (unless specified in the protocol) -Product and Event Assessment – *refer IB* - Coding and Narrative - FU consolidation and request
Reporting	- 15 Day Expedited report

Device Details



Periodic and Expedited Reports

Criterions	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

The End

REVISION HISTORY

Version 01 Effective on 30-Sep-2019
Initial Version

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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