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| User Requirements for  CIOMS Export Template Report  (LSMV 10.x) v2 |
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| Document Version 1.0 |
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| **Required Signatures** | | | | |
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# Purpose

The purpose of this document is to list the user requirements for the development of below mentioned CIOMS Export Template Report which shall be implemented in LSMV 10.x.

# Scope

This URS is limited to above mentioned line listing report in LSMV 10.x. The report shall be generated from LSMV QBE or directly in LSRA (based on pre-defined QBE selection criteria or based on a list of cases/case versions generated in QBE and imported in LSRA).

# Definition

The following key describes the methodology used to assign criticality in section 5.

| Criticality | Description |
| --- | --- |
| Critical | The requirement is functionality the business must have to adhere to regulations. The requirement will be explicitly tested through performance qualification testing. The system cannot be implemented without meeting this requirement. |
| Major | The requirement is functionality that impacts the business workflow. If the functionality is not available in the purchased solution, an appropriate workaround must be implemented. Functionality that was tested through vendor functional testing may only be implicitly tested through installation and operational qualification or through performance qualification testing. |
| Deferred | The requirement is nice-to-having functionality identified by the business that is not available in the purchased solution or will not be implemented at this time. Deferred requirements may or may not be implemented in a future release. |

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# Reference











# User Requirements

The requirements documented in the following sections are presented in a tabular format indicating a Requirement Number (URS #), criticality, activity associated and a description of the requirement.

The requirements are segmented into categories of functionality for clarity. Requirement categories or modules are represented by section codes. Requirements are grouped and identified by codes X\_1 through X\_n. For example:

CET – code for main section CIOMS Export Template Report

CET \_01 – code for individual requirement

## CIOMS Export Template Report

| **URS #** | **Criticality** |  | |
| --- | --- | --- | --- |
|  |  | **Description** | **Condition** |
| CET\_01 | Major | The report shall be available in LSRA and in LSMV (To be confirmed if report can be called from QBE). | A new report link “CIOMS Export Template Report” shall be available in LSRA (LSMV to be confirmed). |
| CET\_02 | Critical | Selection criteria | User shall have the option to retrieve a list of cases/case versions by querying a set of fields available in LSMV and to generate the report based on the selected cases/case versions   * Report is generated from LSRA using predefined parameters. See section 6. |
| CET\_03 | Major | Header of the report | Header of the report with name “CIOMS Export Template Report” shall be printed with refreshed date of the report time stamp below the Header in the top right corner report page. |
| CET\_04 | Critical | Format | * 1 row is printed per Product – AE association (if a case has 2 suspect products and 3 events, 6 rows shall be printed) * Report is generated in the excel format. * No blank rows are printed in the report. * All dates shall be in date format: DD-MMM-YYYY |
| CET\_05 | Critical | Blinded/Unblinded | The user shall be able to generate the report in a blinded / unblinded manner or include both blinded and unblinded values in the report. |
| CET\_06 | Critical | The report should comply with the format specified. | The report will be in the form of an excel file with 54 columns as indicated in the sample file. |
| CET\_07 | Critical | The report shall display columns headers | All the 54 columns headers shall be as follows  - AER No.  - Initial Received Date  - Latest Received Date  - Report classification  - Country of Detection  - Weight and unit  - Height and unit  - Date of Birth  - Age and unit  - Gender  - Death?  - Life Threatening?  - Caused or prolonged hospitalization  - Required Intervention  - Disability or Permanent Damage?  - Congenital Anomaly or Birth Defect  - Other Serious Important Medical Event?  - Event Seriousness  - Suspect Products  - Indication  - Reactions  - AE additional information  - SOC  - PT  - Reaction Rank  - LLT  - Labeling  - Labeling country  - Event Outcome  - Onset Date  - Cessation Date  - Duration  - Reporter Causality  - Company Causality  - Dechallenge  - Rechallenge  - Concomitant Drug  - Risk factors  - Other Relevant History  - Primary Source  - All Sources  - Medically Confirmed  - Narrative  - Subject ID  - Protocol No  - Case Level Seriousness  - Literature data  - Therapy Start Date  - Therapy End Date  - Unit Dose  - Daily Dose  - Test Name (PT)  - Test Result  - Test Result (additional data) |
| CET\_08 | Critical | Data under Column 1 | AER No. – Case number with version Number.  e.g. VIT-2020-00200 (1) |
| CET\_09 | Critical | Data under Column 2 | Initial Received Date shall be printed in date format (DD-MMM-YYY) |
| CET\_10 | Critical | Data under Column 3 | Latest Received Date shall be printed in date format (DD-MMM-YYY) |
| CET\_11 | Critical | Data under Column 4 | Report classification shall be printed |
| CET\_12 | Critical | Data under Column 5 | Country of Detection shall be printed |
| CET\_13 | Critical | Data under Column 6 | Weight(B.1.3/D.3) and unit of the patient shall be printed |
| CET\_14 | Critical | Data under Column 7 | Height[B.1.4][D.4] and unit of the patient shall be printed |
| CET\_15 | Critical | Data under Column 8 | Patient Date Of Birth [ B.1.2.1b ][ D.2.1 ] shall be printed |
| CET\_16 | Critical | Data under Column 9 | Age at the Time of Event[ B.1.2.2a ][ D.2.2a ] and unit (Patient) shall be printed |
| CET\_17 | Critical | Data under Column 10 | Gender[B.1.5][D.5] of the patient shall be printed |
| CET\_18 | Critical | Data under Column 11 | Death? [E.i.3.2a] (event seriousness criteria Y/N shall be printed) |
| CET\_19 | Critical | Data under Column 12 | Life Threatening? [E.i.3.2b] (event seriousness criteria Y/N shall be printed) |
| CET\_20 | Critical | Data under Column 13 | Caused/prolonged hospitalization [E.i.3.2c] (event seriousness criteria Y/N shall be printed) |
| CET\_21 | Critical | Data under Column 14 | Required Intervention (event seriousness criteria Y/N shall be printed) |
| CET\_22 | Critical | Data under Column 15 | Disability/Permanent Damage? [E.i.3.2d] (event seriousness criteria Y/N shall be printed) |
| CET\_23 | Critical | Data under Column 16 | Congenital Anomaly/Birth Defect? [E.i.3.2e] (event seriousness criteria Y/N shall be printed) |
| CET\_24 | Critical | Data under Column 17 | Other Serious Important Medical Event? [E.i.3.2f] (event seriousness criteria Y/N shall be printed) |
| CET\_25 | Critical | Data under Column 18 | Event Seriousness (event level) shall be printed |
| CET\_26 | Critical | Data under Column 19 | All suspect products shall be printed (one row per suspect product) |
| CET\_27 | Critical | Data under Column 20 | Indication Term[B.4.k.11b ][G.k.7.r.1] shall be printed for each suspect product |
| CET\_28 | Critical | Data under Column 21 | Reported Term [B.2.i.0][E.i.1.2] - All reported terms shall be printed - one row per event |
| CET\_29 | Critical | Data under Column 22 | AE additional information (TBC if prints reaction/co-manifestation) shall be printed |
| CET\_30 | Critical | Data under Column 23 | Primary MedDRA SOC decode of each event shall be printed (to be aligned with the reported term – one row per event) |
| CET\_31 | Critical | Data under Column 24 | Event MedDRA PT decode of each event shall be printed (to be aligned with the reported term – one row per event) |
| CET\_32 | Critical | Data under Column 25 | Rank (Event) shall be printed |
| CET\_33 | Critical | Data under Column 26 | Event MedDRA LLT decode of each event shall be printed (to be aligned with the reported term – one row per event) |
| CET\_34 | Critical | Data under Column 27 | Labeling (print all labeling values for each event: data shall be presented in order to match each labeling country per event) |
| CET\_35 | Critical | Data under Column 28 | Labeling Country (print all labeling countries for each event: data shall be presented in order to match each labeling value per event) |
| CET\_36 | Critical | Data under Column 29 | Outcome [B.2.i.8][E.i.7] shall be printed for each event |
| CET\_37 | Critical | Data under Column 30 | Onset date [B.2.i.4b][E.i.4] shall be printed for each event |
| CET\_38 | Critical | Data under Column 31 | Cessation date [B.2.i.5b][E.i.5] shall be printed for each event |
| CET\_39 | Critical | Data under Column 32 | Duration [B.2.i.6b][E.i.6a/b] and unit shall be printed for each event |
| CET\_40 | Critical | Data under Column 33 | Reporter Causality shall be printed for each event |
| CET\_41 | Critical | Data under Column 34 | Company Causality shall be printed for each event |
| CET\_42 | Critical | Data under Column 35 | Dechallenge shall be printed |
| CET\_43 | Critical | Data under Column 36 | Rechallenge shall be printed |
| CET\_44 | Critical | Data under Column 37 | Print all the product descriptions of all products marked as concomitant (product characterization = concomitant) for the case |
| CET\_45 | Critical | Data under Column 38 | All risk factors of the patient shall be printed |
| CET\_46 | Critical | Data under Column 39 | For each disease the following data shall be printed: Disease Term[ B.1.7.1a.2 ] + Continuing[ B.1.7.1d ][ D.7.1.r.3 ] + Start Date[ B.1.7.1c ][ D.7.1.r.2 ]  This information shall be printed for each disease (grouped) |
| CET\_47 | Critical | Data under Column 40 | Primary Source (marked as primary shall be printed) |
| CET\_48 | Critical | Data under Column 41 | All sources shall be printed |
| CET\_49 | Critical | Data under Column 42 | Medically Confirmed (case specific information) shall be printed |
| CET\_50 | Critical | Data under Column 43 | The full narrative shall be printed:  Event Description[B.5.1][H.1]  -  Evaluation Summary |
| CET\_51 | Critical | Data under Column 44 | Subject ID shall be printed (Study) |
| CET\_52 | Critical | Data under Column 45 | Protocol No[A.2.3.2][C.5.3] shall be printed |
| CET\_53 | Critical | Data under Column 46 | Seriousness[ A.1.5.1 ] (case level) shall be printed |
| CET\_54 | Critical | Data under Column 47 | Article title(s) shall be printed |
| CET\_55 | Critical | Data under Column 48 | Therapy Start date[B.4.k.12b][G.k.4.r.4] (all shall be printed for each suspect product) |
| CET\_56 | Critical | Data under Column 49 | Therapy End date[B.4.k.14b][G.k.4.r.5] (all shall be printed for each suspect product) |
| CET\_57 | Critical | Data under Column 50 | Unit dose[B.4.k.5.1/2] and unit shall be printed |
| CET\_58 | Critical | Data under Column 51 | Daily dose and unit shall be printed |
| CET\_59 | Critical | Data under Column 52 | Test name PT decode (lab data) - all tests shall be printed |
| CET\_60 | Critical | Data under Column 53 | Test Result Value[B.3.1d/e][F.r.3.2/3] and unit (all test results shall be printed - to be aligned with test name - same order) |
| CET\_61 | Critical | Data under Column 54 | Result Unstructured Data (Free Text) [F.r.3.4] - (all test results to be printed - to be aligned with test name - same order) |

# Parameters

The report parameters are defined in the attachment below:

|  |  |  |  |
| --- | --- | --- | --- |
| FRS ID | Parameter | Field | Description |
| FRP01 | Initial Received Date | Initial Received Date[A.1.6b][C.1.4] | There should be an option to choose IRD or LRD. -Start Date Default value: Null -End Date Default value: Null -Mandatory parameter (either IRD or LRD is Mandatory parameter)  -The format shall be “DD/MMM/YYYY”. |
| FRP02 | Latest Received Date | Latest Received Date[A.1.7b][C.1.5] | There should be an option to choose IRD or LRD. -Start Date Default value: Null -End Date Default value: Null -Mandatory parameter (either IRD or LRD is Mandatory parameter)  -The format shall be “DD/MMM/YYYY”. |
| FRP03 | Primary Source Country | Primary Source Country[A.1.1] | The report shall have a look up prompt with multi-select option. - Optional parameter |
| FRP04 | Preferred Product Description | Preferred Product Description | The report shall have a look up prompt with multi-select option for preferred product description  -Optional parameter -System shall consider all products (suspect)  -System shall consider product type: Drug or Vaccine or device or cosmetic or combination. |
| FRP05 | Case Approval Status | Case status | The report shall have a dropdown prompt with multi-select option to select: - Approved cases / Approved and Unapproved / Unapproved cases - Optional parameter |
| FRP06 | Case Deleted | Case Deleted | The report shall have a dropdown prompt with multi-select option to select: - Deleted / Not Deleted / Deleted and Not Deleted - Optional parameter |
| FRP07 | Invalid | Report classification | The report shall have a radiobutton to select valid or invalid cases - By default no values shall be selected, all invalid and valid cases are considered - Optional parameter |
| FRP08 | Primary Source | Primary source | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP09 | All sources | All sources | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP10 | Latest version or all versions |  | The report shall have a radiobutton to select all versions or the latest version of the cases - By default latest version shall be selected, all invalid and valid cases are considered - Mandatory parameter |
| FRP11 | Blinded / Unblinded |  | The report shall have a dropdown prompt with multi-select option to print in the report:  - Blinded information / Unblinded information / Blinded and Unblinded - Mandatory parameter |
| FRP12 | SMQ (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP13 | SOC (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP14 | HLGT (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP15 | HLT (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP16 | PT (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP17 | LLT (event) | Event | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP18 | SMQ (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP19 | SOC (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP20 | HLGT (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP21 | HLT (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP22 | PT (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP23 | LLT (disease) | Patient Medical History | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP24 | SUSAR | SUSAR (General screen) | The report shall have a checkbox - Optional parameter |
| FRP25 | Company causality OR Reporter causality | Company causality OR Reporter causality | The report shall have a look up prompt with multi-select option, the report shall consider the company or reporter causality - Optional parameter - If one event has a selected value, the case shall be retrieved |
| FRP26 | Protocol number | Protocol No[A.2.3.2][C.5.3] | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP27 | Age group | Age Group[B.1.2.3][D.2.3] | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP28 | Patient Age | Age at the Time of Event[ B.1.2.2a ][ D.2.2a ] and unit | The report shall have a prompt to select an age range and units (multiple age ranges - at least 5, and units shall be available for selection) - Optional parameter |
| FRP29 | Date of Birth | Patient DOB[ B.1.2.1b ][ D.2.1 ] | The report shall have a prompt to select a DOB range (multiple DOB - at least 5, and units shall be available for selection) - Optional parameter |
| FRP30 | Patient Age | Age at the Time of Event[ B.1.2.2a ][ D.2.2a ] and unit | The report shall have a prompt to exclude an age range and units (multiple age ranges - at least 3, and units shall be available for exclusion) - Optional parameter |
| FRP31 | Date of Birth | Patient DOB[ B.1.2.1b ][ D.2.1 ] | The report shall have a prompt to exclude a DOB range (multiple DOB - at least 3, and units shall be available for exclusion) - Optional parameter |
| FRP32 | Sender Organization Name | Sender Organization Name | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP33 | Search scenarios |  | The report shall have the option to select one of the 47 search scenarios defined in the below attached file: **Search scenarios\_LSRA\_09MAR2021**: - 33 risks and special situations searches - Pregnancy - Fatal - 4 TQs - 4 Medication error - 4 Other  - Optional parameter |
| FRP34 | List of cases |  | The report shall have a prompt to enter a list of cases on which the report shall be generated - Optional parameter |
| FRP35 | Seriousness | Seriousness[ A.1.5.1 ] (case level) | The report shall have a prompt to select serious / non serious or both serious and non-serious cases - Optional parameter |
| FRP36 | Medically Confirmed | Medically Confirmed (case specific information) | The report shall have a prompt to select MC / non MC or both cases - Optional parameter |
| FRP37 | Labeling | Labeling | The report shall have a look up prompt with multi-select option - Optional parameter |
| FRP38 | Labeling Country | Labeling Country | The report shall have a look up prompt with multi-select option - Optional parameter |

In addition, the search scenarios to be configured as additional parameters of this report (as defined in FRP33) are detailed in below attachment:



# Report Layouts

## CIOMS Export Template Report

See section 4.

# Definitions, Acronyms, and Abbreviations

This section presents the definitions for acronyms, abbreviations, and terms specific to this document.

| Term / Acronym | Definition |
| --- | --- |
| URS | **U**ser **R**equirements **S**pecification. This document defines clearly and precisely what the customer wants the system to do. |
| QBE | **Q**uery **B**y **E**xample |
| LSMV | **L**ife**S**phere **M**ulti**V**igilance |