Oracle Argus Safety Japan

PMDA PSR and ReSD Best Practices

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ORACLE

Oracle Argus Safety Japan PMDA PSR and ReSD Best Practices, Release 8.4

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Contents

Preface

Documentation accessibility v
Diversity and Inclusion v
Related resources v
Access to Oracle Support v

1 Introduction

2 Deprecated ReSD 7, 8, and 9

3 PSR and ReSD reports after the upgrade

4 Enhanced Event Counting Logic for P.S.R Form 3, 4 and ReSD Form 10, 11 Common Profile Switch

5 Inclusion of reactions sent by PMDA to the MAH

6 Listedness Assessment on Report-level Configuration Parameter

7 Inclusion Date Report-level Configuration Parameter

8 PT/LLT Count Level Form-level Configuration Parameter

9 Count Listed & Unlisted as Two Separate Events Form-level Configuration Parameter

Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

For information about Oracle Argus patches, see My Oracle Support.

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

On-premises customers receive support assistance through My Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

1 Introduction

MHLW (the parent agency of PMDA) made an announcement regarding changes to the PSR report, as well as the ReSD report, on November 28, 2017. As per the updated guidance, MAHs can submit the PSR/ReSD reports to PMDA in the updated format starting on the date of publication of the new guidance. The updated guidance makes it mandatory for MAHs to submit dossiers in the updated format starting in October 2019. As per the updated guidance, there are several updates to the ReSD report, which in turn impact several forms in the PSR report for which regulatory output overlaps with the ReSD reporting format.

ReSD Guidance Notification:

(PSEHB/ELD Notification No.1128-2 dated November 28, 2017)

PSR Guidance Notification:

(PSEHB/ELD Notification No.1128-5, PSEHB/SD Notification No.1128-4 dated November 28, 2017)

As a result of the updated guidance, the following areas of impact on Japan periodic reports have been identified, for which Oracle Argus Safety functionality for Japan periodic reports has been enhanced.

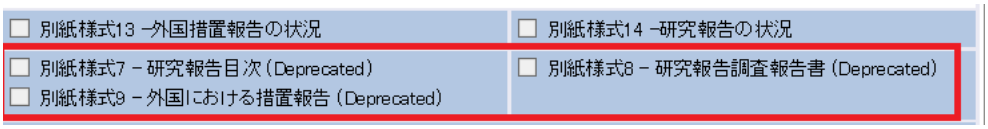
- Changes to ReSD Forms:
  - Updated ReSD Forms
    - ReSD Form 4 updated to ReSD Form 10 (Table)
    - ReSD Form 5 updated to ReSD Form 11 (Listing)
  - New ReSD Forms
    - Form 9 (Unlisted Events table)
    - Form 13 (Status of Overseas Measures Report)
    - Form 14 (Status of Study Report)
- Due to changes in ReSD, the following PSR Forms have been updated:
  - PSR Form 3 (Table)
  - PSR Form 4 (Listing)

This document lists recommendations on how to use the enhanced Japan periodic reports.

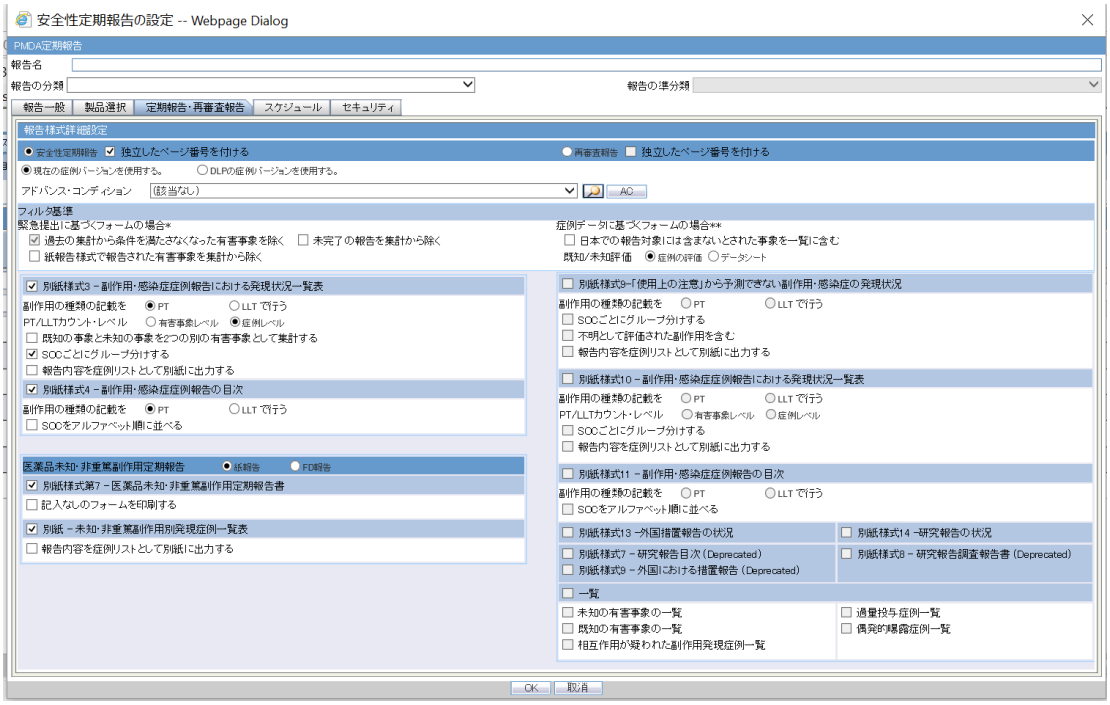
2

Deprecated ReSD 7, 8, and 9

Existing ReSD Forms 7, 8, 9 are marked as deprecated in the PSR/ReSD configuration window, so that customers know they cannot generate any new report thereafter. The old forms will be completely removed from the UI in a future release.



The updated PSR/ReSD Configuration tab for reference:



If any new PSR or ReSD report is created or copied from an existing report, it is recommended to uncheck the checkbox for ReSD Forms 7,8, 9. This ensures that the deprecated forms are not printed in the report output.

Note:

- If there are existing ReSD Form 7, 8, 9 reports in a Submitted state, users can still open them without errors.
- If there are existing ReSD Forms 7, 8, 9 reports in any state other than Submitted, they are validated to ensure they will not fail generation after the upgrade. Data printed in the report output is not verified for correctness, since the reports are marked as deprecated.

3

PSR and ReSD reports after the upgrade

All the existing PSR and ReSD reports that were generated before the 8.1.3 upgrade are retained in the old format.

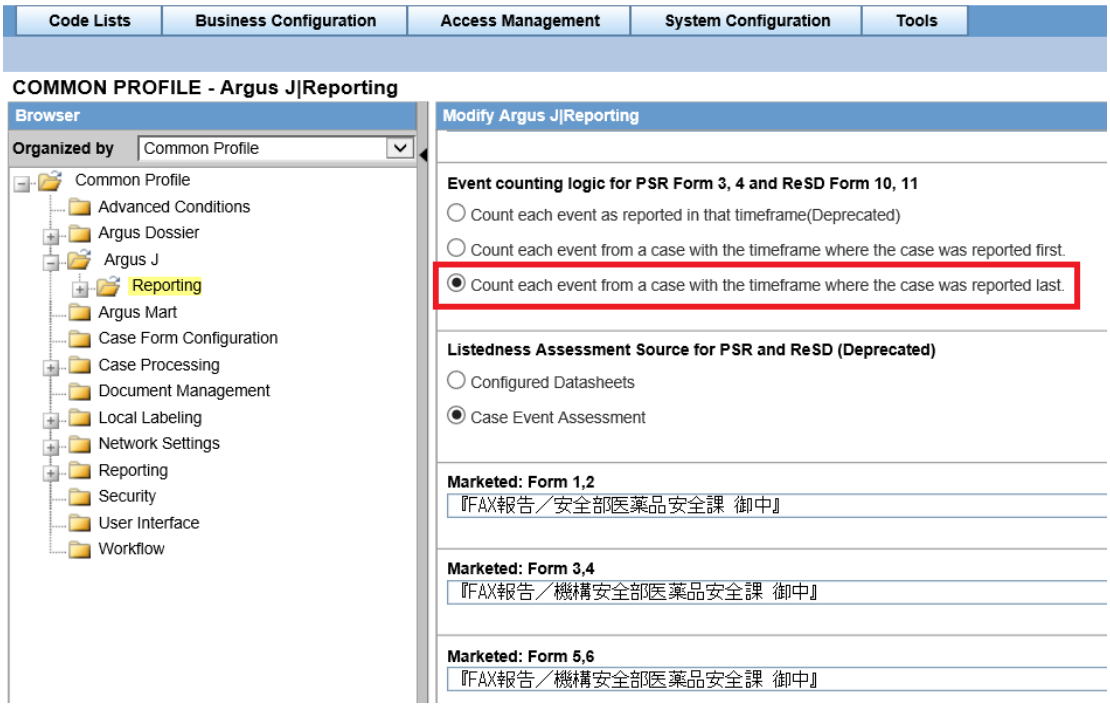
All the reports that are generated or re-generated after the upgrade are generated in the updated format/layout, as mentioned for individual forms.

When the reports are created (copied and saved after modification) using the submitted report, the **Inclusion Date Report-level Configuration** parameter is automatically set to Aware Date for all the reports. This allows the users to continue to generate the reports correctly, including the PMDA feedback cases, without the need to create a new report (with no historical schedule).

4

Enhanced Event Counting Logic for P.S.R Form 3, 4 and ReSD Form 10, 11 Common Profile Switch

An additional option, **Count each event from a case with the timeframe where the case was reported last**, has been added to the common profile switch, along with **Count each event from a case with the timeframe where the case was reported first**. It is recommended to set this option as per the business process.



Note:

Count each event as reported in that timeframe (deprecated) has been retained in the console, but the application logic has not been updated for changes made to PSR and ReSD reports when the switch is set to **Count each event as reported in that timeframe (deprecated)**. It is recommended that this deprecated option is not used. It will be completely removed from the UI in a future release.

5

Inclusion of reactions sent by PMDA to the MAH

As per the updated guidance, it is necessary to include the reactions reported to MHLW directly (PMDA/MHLW sends back such cases to the MAH).
In order to include such reactions sent by PMDA/MHLW to the MAH, follow the steps below:

1. Define a case classification in **Codelist** > **Flexible Re-Categorization** > **CASE_CLASSIFICATION** to define PMDA to MAH cases.

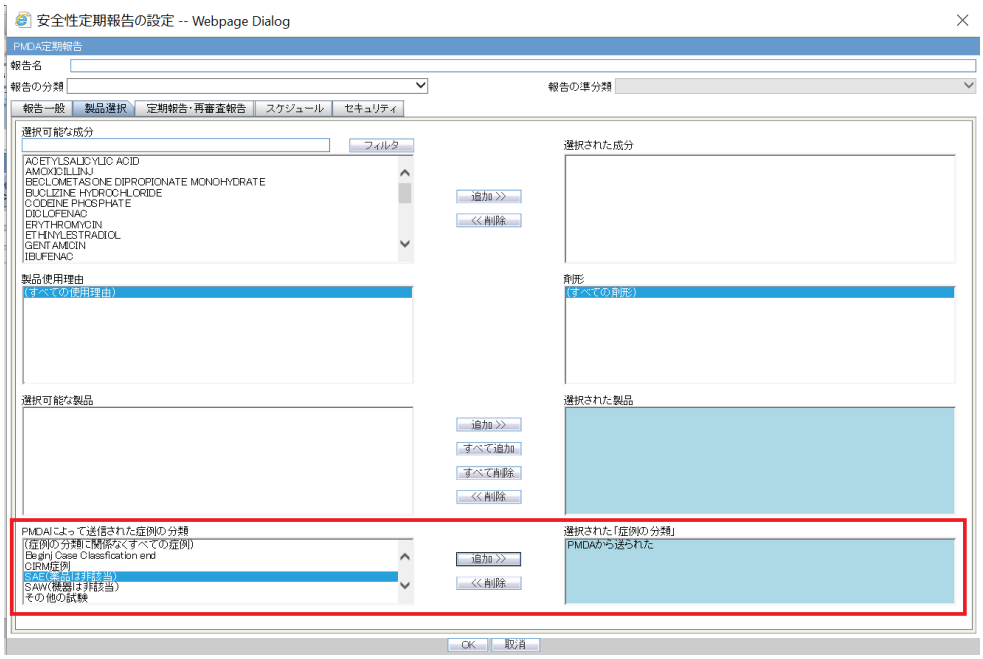
   For example, **PMDA から送られた**

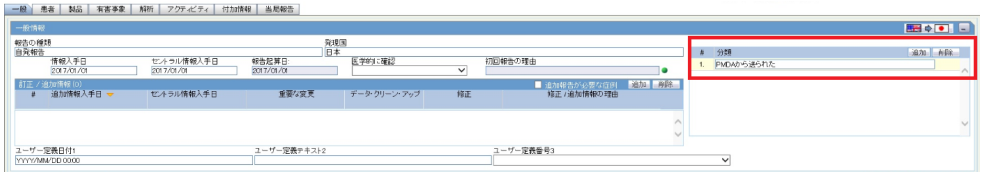
2. When PMDA/MHLW sends a case to the MAH, create the case and add the case classification in the **Case form** > **General tab** > **Classification** (分類) window.

3. Select the classification defined in step a above in the configuration screen.

   The PSR/ReSD configuration screen has been enhanced to provide an option to configure the case classification using the list box **Classification for cases sent by PMDA** (PMDA によって送信された症例の分類).

> **Note:**
>
> If the option **All cases irrespective of Case Classifications** (症例の分類に関係なくすべての症例) is selected, then all the cases, irrespective of the case classification set in the case, are considered for inclusion in the report. Even cases where there is no case classification set are considered. Depending on the volume of cases, this may impact the performance of report generation. Hence, it is recommended to select case classification(s) in the PSR/ReSD configuration screen.


安全性定期報告の設定 -- Webpage Dialog
PMDA定期報告
報告名
報告の分類
報告の重分類
報告一般
製品選択
定期報告・再審査報告
スケジュール
セキュリティ
選択可能な成分
フィルタ
ACETYLSALICYLIC ACID
AMOXICILLINJ
BECLOMETASONE DIPROPIONATE MONOHYDRATE
BUCLIZINE HYDROCHLORIDE
CODEINE PHOSPHATE
DICLOFENAC
ERYTHROMYCIN
ETHINYLESTRADIOL
GENTAMICIN
IBUFENAC
追加 >>
<< 削除
選択された成分
製品使用理由
(すべての使用理由)
剤形
(すべての剤形)
選択可能な製品
追加 >>
すべて追加
すべて削除
<< 削除
選択された製品
PMDAによって送信された症例の分類
(症例の分類に関係なくすべての症例)
Begin Case Classification end
CIRM症例
SAE(薬品は非該当)
SAW(機器は非該当)
その他の試験
追加 >>
<< 削除
選択された「症例の分類」
PMDAから送られた
OK
取消

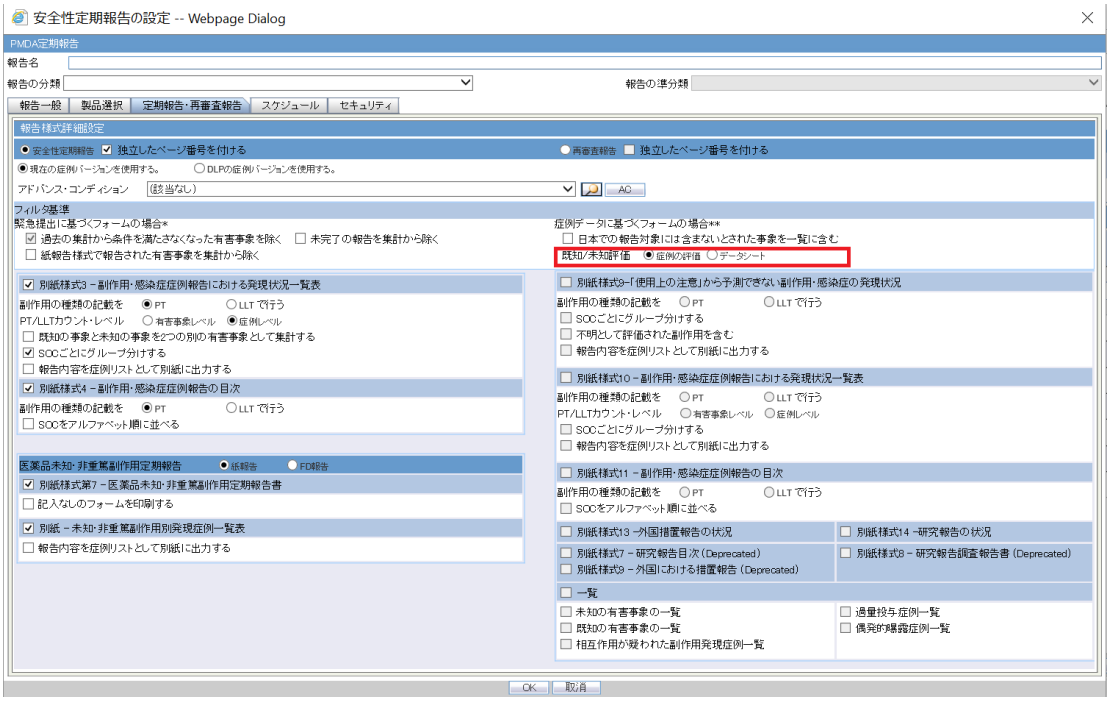


6

Listedness Assessment on Report-level Configuration Parameter

A new report-level parameter has been added as **Listedness Assessed on (既知/未知評価)** for configuring the assessment parameter for the reaction, with the following options:

- Option 1: Case Assessment (症例の評価) (Default option set in new reports)
- Option 2: Datasheet (データシート)



The **Listedness Assessment Source for PSR and ReSD** common profile switch is marked as deprecated.

PSR and ReSD reports considering this common profile switch will henceforth consider the new report-level configuration for newly created reports or for copied reports.

For reports created prior to the upgrade, the option for **Listedness Assessed on** is set based on the value set in the Common profile switch **Listedness Assessment Source for PSR and ReSD** during upgrade.

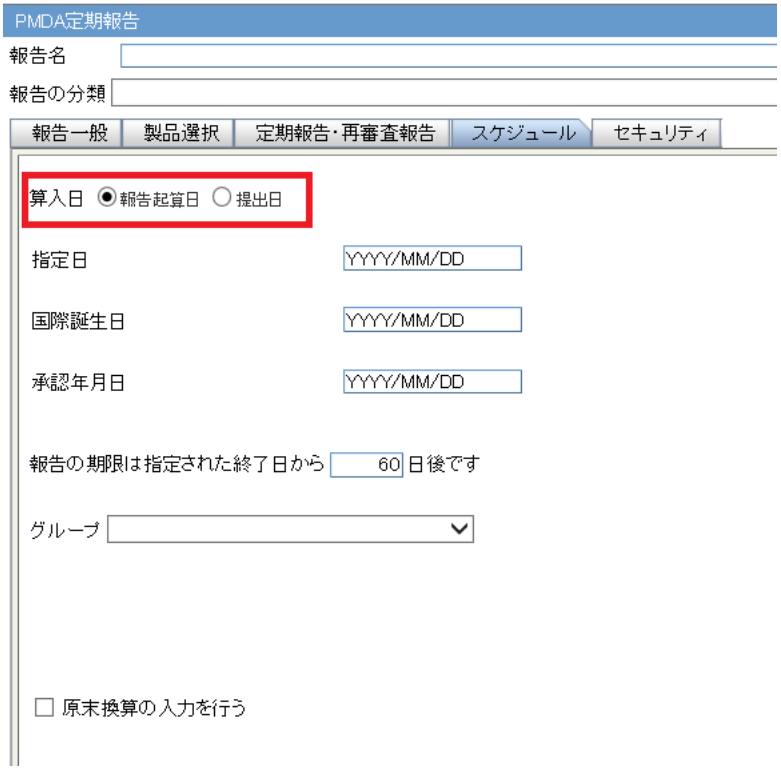
It is recommended to set this option for every report configuration as per the business process.

7

Inclusion Date Report-level Configuration Parameter

A new report-level parameter has been added as **Inclusion date (算入日)**, with the following options:

- Option 1: Aware Date (報告起算日) (Default option set in new reports)
- Option 2: Date Submitted (提出日)



For reports created prior to the upgrade or for copied reports, this parameter is set to Date Submitted. For new reports, this parameter is set to Aware Date. As per the updated guidance, it is recommended to set to case-based counts. If the same PT/LLT code appears in the case/E2B more than once, then the application counts it as one. The infection count that is printed in the '()' also follows the same logic as PT/LLT if the event is marked as Infection for any of the entries.

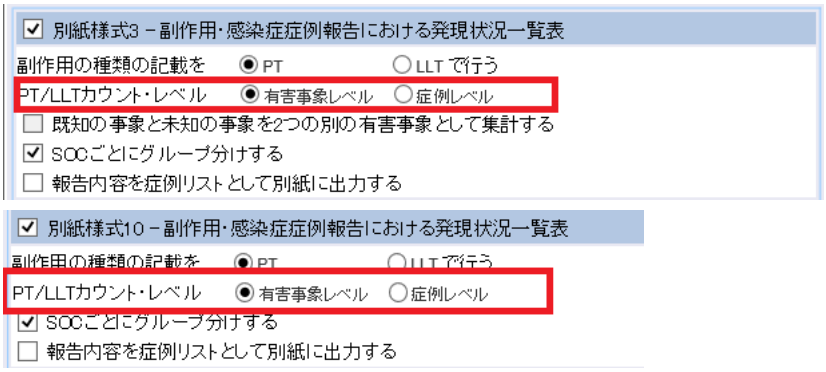
When the reports are created (copied and saved after modification) using the submitted report, the **Inclusion Date Report-level Configuration** parameter is automatically set to Aware Date for all the reports. This allows the users to continue to generate the reports correctly, including the PMDA feedback cases, without the need to create a new report (with no historical schedule).

8

PT/LLT Count Level Form-level Configuration Parameter

A new form-level parameter has been added as **PT/LLT Count Level (カウント･レベル)**, with the following options in PSR Form 3 and ReSD Form 10:

- Option 1: Case Level (症例レベル) (Default option set in new reports)
- Option 2: Event Level (症例レベル)

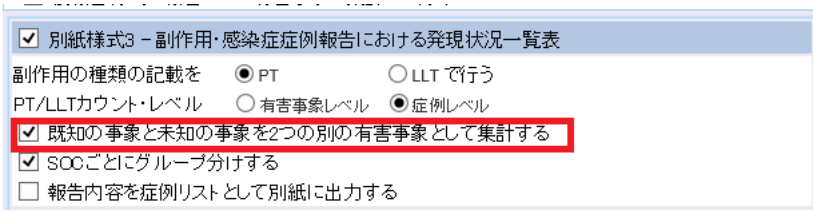


For reports created prior to the upgrade or for copied reports, this parameter is set to Event Level. For new reports, this parameter is set to Case Level. As per the updated guidance, it is recommended to set to case-based counts. If the same PT/LLT code appears in the case/E2B more than once, then the application counts it as one. The infection count that is printed in the '()' also follows the same logic as PT/LLT if the event is marked as Infection for any of the entries.

9

Count Listed & Unlisted as Two Separate Events Form-level Configuration Parameter

A new form-level checkbox has been added as **Count Listed & Unlisted as two separate events (既知の事象と未知の事象を 2 つの別の有害事象として集計する)** in PSR Form 3.



This checkbox is enabled only if the **PT/LLT Count Level** is set to **Case Level Count**. It is recommended to check the option **Count Listed & Unlisted as two separate events**, so that if the same reaction is marked as listed for one entry in the case and unlisted for the other entry, then it will be counted as two separate events.