How to deal with ICSR Quality Issues in Pharmacovigilance?

Presented by

Global PLACO Solutions

An overview and approach for ICSR challenges and solutions!

Quality issues/Pain areas in PV:

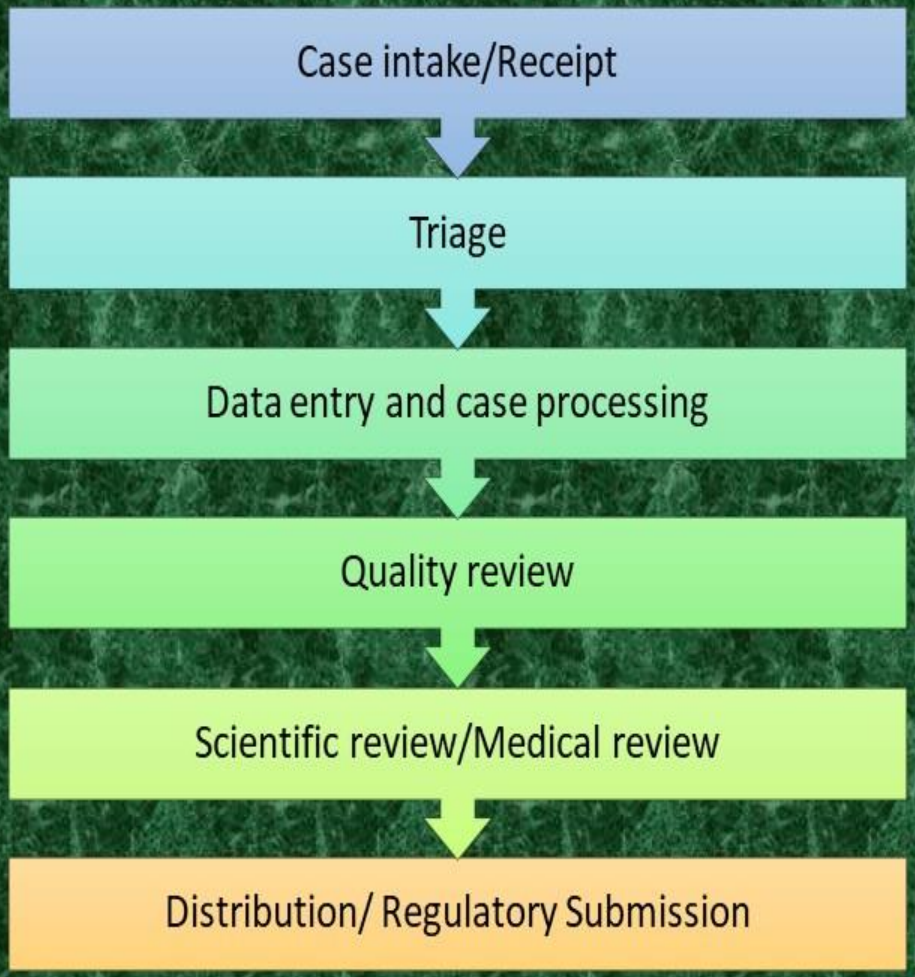
- **ICSR monitoring & processing**
- **Literature surveillance**
- **Periodic/Aggregate reports**
- **Signal detection & management**
- **Risk management plan (RMP)**

ICSR - highest Quality issues observed in PV:

ICSR monitoring & processing will be discussed in detail as it is one of the most outsourced activity and many organisations are performing this as a full scope activity.

ANTICIPATING THE CHALLENGES AND PLANNING SOLUTIONS BEFOREHAND IS THE KEY!!

ICSR workflow process

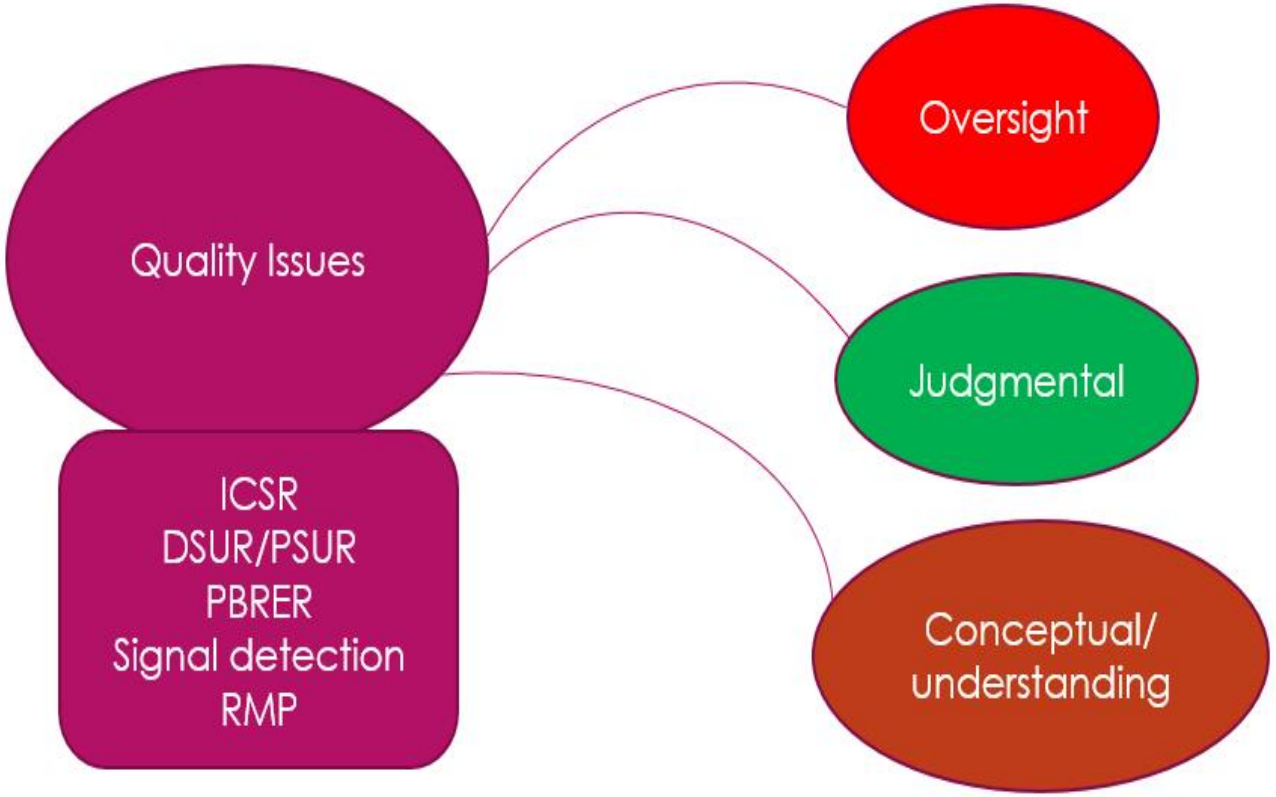


Errors observed in each step are categorized and provided with tried and tested solutions:

ICSR monitoring and reporting process

- **Case intake/receipt/Triage**
- **Data entry**
- **Quality review**
- **Scientific/medical review**
- **Distribution/Reporting/Submission**

PV Quality Issues
Categorization



Case intake/receipt & triaging

- Missing the “validity criteria”
- Missing the seriousness and causality assessment
- Not assessing the complete data of the case
- Not queried in the initial step for more information
- Querying for causality in the spontaneous report

SOLUTION 1

The following approaches can be implemented to reduce the errors:

- ✓ **Error category :**
  - **Oversight**
  - **knowledge gap**

- ✓ **Solution:**
  - **Improvement in the quality review process**
  - **Training**

Date entry/Case processing:

Errors observed

- Missing out on fields – Lab, history, conmeds
- Incorrect/wrong entry – age, history etc
- Improper MedDRA coding
- Incorrect Seriousness, Causality, labelling assessment
- Missing queries related to significant information
- Incomplete narrative and not followed chronology

SOLUTION - 2

The following if implemented and practiced will achieve better results:

✓ **Error category :**

- **Oversight**
- **Judgmental**
- **Conceptual/understanding/knowledge gap**

✓ **Solution:**

- **Automation of the database/customization**
- **Improvement in the quality review process**
- **Training**

SOLUTION - 2

✓ **Methods to identify errors:**

- **Trend and pattern analysis – to identify the type of errors**
- **Analysis of number of defects opportunities**
- **Accuracy levels – based on fields**
- **Automation of the certain tabs to reduce errors**
- **Trainings: General PV, project related, weekly assessment, refreshers and one-one training/mentoring**

Quality review:

- Missing out entries on fields – Lab data, history, conmeds
- Incorrect/wrong entry – age, history etc
- Improper MedDRA coding
- Incorrect Seriousness, Causality, labelling assessment
- Missing queries related to significant information
- Incomplete narrative and not followed chronology

SOLUTION - 3

The following if implemented and practiced will achieve better results:

✓ **Error category :**

- **Oversight**
- **Judgmental**
- **Conceptual/understanding/knowledge gap**

✓ **Solution:**

- **Automation of the database/customization**
- **Improvement in the quality review process**
- **Training**

Scientific/Medical review:

Medical/scientific reviewers must complete the assessment of overall case/event including the field entry especially the below as it will be the reporting in the next step:

- **Event terms**
- **MedDRA coding**
- **Seriousness criteria**
- **causality assessment**
- **Labelling**

Medical narrative and judgment to ensure that the narrative makes the medical sense for the case.

SOLUTION - 4

✓ **Error category :**

- **Judgmental**
- **Conceptual/understanding/knowledge gap**

✓ **Solution:**

- **Training on medical coding and judgment concepts**

Reporting/Submission:

Issues with reporting submission

- **Failure to send it to the concerned authority**
- **Failure codes not recorded/understood**

SOLUTION - 5

✓ **Error category :**

- **Technical**
- **knowledge gap**

✓ **Solution:**

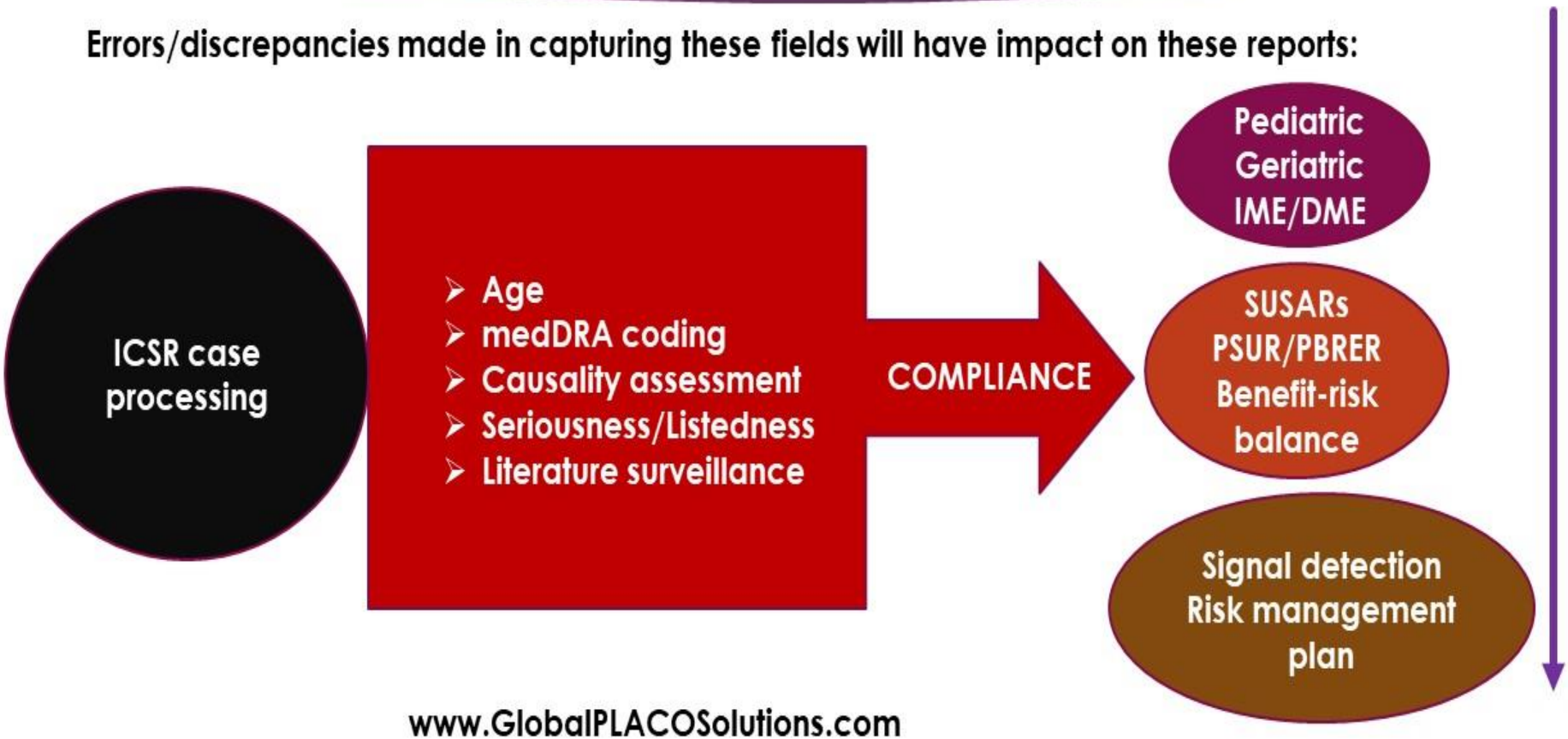
- **Automation of the database/customization**
- **Training on reporting/submission**

Your quality improvement plan (QIP) entirely depends on the analysis and categorization of errors. So, analysis must be done carefully and implement the one's mentioned above and monitor the results.

IT IS A STEP BY STEP PROCESS AND NOT AN OVERNIGHT SUCCESS!!

Why PV "Quality" is extremely important?

Errors/discrepancies made in capturing these fields will have impact on these reports:



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Check your overall ICSR quality scores?

If the monthly scores are fluctuating between:

- **<85% - Poor quality**
- **85% to 90% - Average quality**
- **90% to 94% - Good quality**
- **>95% to 98% - Excellent quality**

Handling PV activities?

- ICSR monitoring and reporting
- Literature surveillance
- Periodic/Aggregate reporting – DSUR/PSUR/PBRER, PADER
- Signal detection & management
- Risk management plan (RMP)
- PSMF

GPLACO SOLUTIONS
INTELLIGENT INFUSIONS

Good and basic training on Pharmacovigilance concepts, case scenarios and presentation with well documented WIs, will reduce numerous errors!

Most conceptual and judgmental errors are basically due to lack of understanding and guidance/reference documents.

Need help?

- **ICSR and periodic/aggregate reports process set-up and operations**
- **Selection and customizations of cost effective safety databases with great features**
- **Forecasting, case allocation tracking and PM tools**
- **Guaranteed compliance with a quality score of >95%**

Contact us:

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