PSUR

Best Practice

Jenifer Hannon Post-market Surveillance Regulatory Lead
Andrew Butler Technical Team Manager Orthopaedics and Dental

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Disclaimer

- The information and interpretation presented today reflects the current EU medical device regulations and the interpretation of those regulations and any supporting guidance by BSI.

- The interpretation is subject to change including following publication of new (EU) MDCG or NBCG or other guidance and any amendments via Implementing or Delegating Acts.

Session objectives

- Understanding of how to ensure the PSUR meets requirements
- Awareness of PMS/PMCF requirements which if not adequately addressed in the PSUR may result in notified body action
- Tips on how to ensure a smooth submission and evaluation of the PSUR by BSI

PSUR challenges

MDCG 2022-21

Data Collection Period

Data analysis, presentation & justifications

Change Notification

Periodic Safety Update Report

- MDR Article 86
- Summary of results and conclusions and analysis of data gathered as a result of the PMS Plan

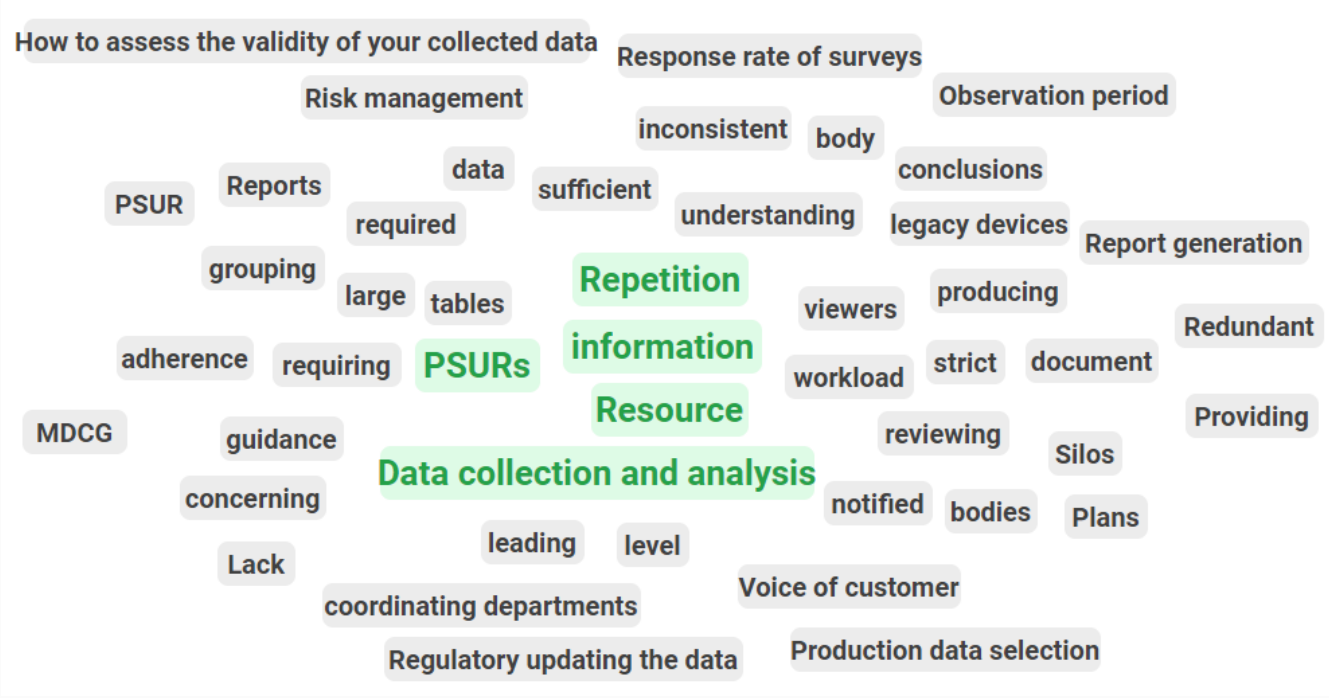
- MDCG 2022-21 Guidance on PSUR according to regulation (EU) 2017/745 (MDR)

Sales and usage data
complaints, device deficiencies,
user or patient feedback

Clinical study results,
scientific literature analysis,
registry data

CAPA:
rationale and description

What is challenging about PSURs?



The PSUR challenge

Notified Body perspective:

1. When is the PSUR due?
2. Who do we have available to review it?
3. Did it arrive when expected?
4. On receipt of PSUR: Is it compliant? Can we assess this PSUR? Does it “stand alone?”
5. During the review: Are there PMS or PMCF activities that haven’t been progressed?
6. Does the evidence included align to the conclusions drawn?
7. What action, if any, do we need to take?

Key principles for producing a PSUR

Summarising, not duplication

The PSUR should standalone: can be assessed independently

Consistency & readability by using the MDCG 2022-21 template as far as practical

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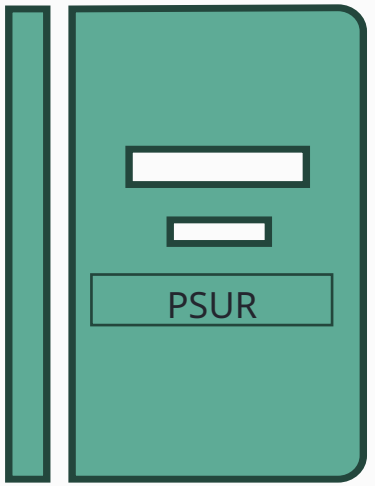


MDCG 2022-21, Annex I: Template for PSUR

Periodic safety Update Report

Manufacturer Information	Joints R Us Unit 5 Runnymead Way Beacon Industrial Estate Brecon Beacons Wales BB23 8ST UK
Medical device(s) covered by the PSUR	Hip 1 Hip 2 Hip 3
Notified body name and organization numbe;	BSI/NB2797
PSUR reference number assigned by the manufacturer	JOINT123/REF4567
Version Number	1
The data collection period covered	1 January 2022 – 31 December 2022

Table of Contents:

PSUR content

01
Executive Summary

02
Device description and intended use

03
Device grouping

04
Volume of sales

05
Size and other characteristics of population using the device

06
PMS – vigilance and CAPA

07
PMS – General PMCF

08
PMS – Specific PMCF

09
Summary of findings and conclusions

Data Collection Period (DCP)

- No gaps from previous PSUR DCP
- Justify any DCP +/- 12 or 24 months
- Grouping devices

Deviation from MDR certification date as the start point for data collection to be agreed with Notified Body

Schedule over certificate lifecycle

- Remains consistent throughout
- Predictability => Efficiency

Submit/upload

- Separate document file
- Follow the Notified Body's instructions

Communication is key!

Resource and Content

- Coordinating input from across the organisation
- How long a report is a PSUR?

Data Analysis

- Level 2 IMDRF codes
- Refer to methods, thresholds and indicators in PMS Plan
- Compare data year to year and State of the Art

Results and Conclusions

- Highlight limitations and any conflicting results
- Evidence-based conclusions on risk-benefit

Multiple factors influence the length of a PSUR, therefore there is no “ideal” length/size of the report

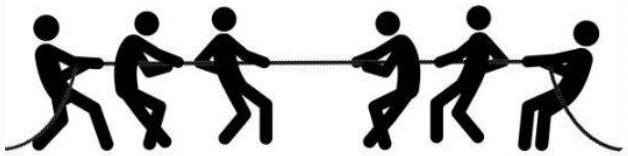
Considerations to ensure a compliant PSUR which can be reviewed efficiently

Data summary…when is more information required?..

- Clear device descriptions, variant information, indications, intended use information per BUDI. (if not clear unable to determine scope)
- Clear and concise summary of S&P data linked to each BUDI (from each appropriate source of data)
- Consideration on device compatibility (like initial CER review expectations)
- Consideration to summarize data between sub-variants if the clinical data outcomes are expected to be different. *(note: we have seen BUDI generation at a high level i.e. clear differences in design, material etc that can impact the clinical outcome)*
- If manufacturer is aware of any NB concerns at MDR initial, please address at PSUR

Images are from Google Domain; not from NB database
For explanation purposes only

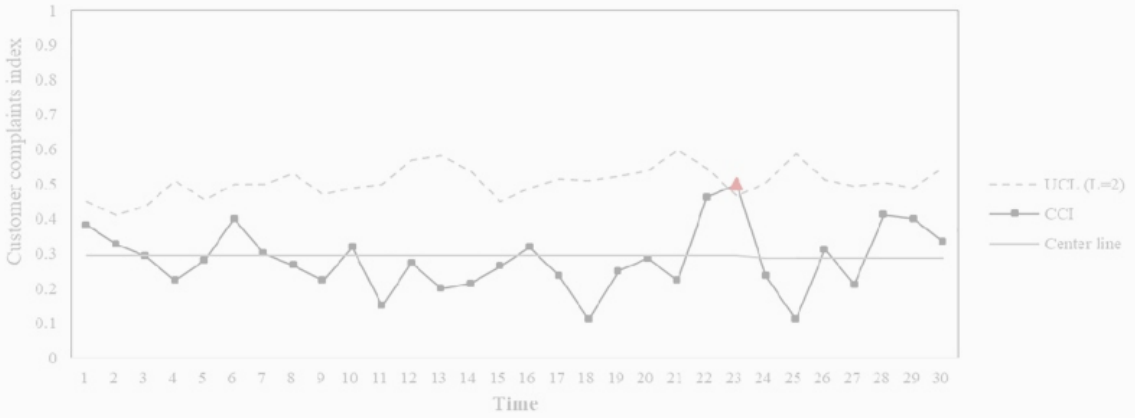
Article 86: manufacturer RB Summary



NB to verify RB conclusions

Data presentation….analysis

- Confirmation that PMCF data is being collected per specific PMCF plan (and it's to plan/explanation of deviations)
- BSI will check: BUDI/device data conclusions to State of the Art (safety and performance data). Possible to Consider adding KM plots from registry data (clear, compare to SoA)
- If the PSUR communicates unfavorable data, important for NB to see data trending over reporting periods to help determine next actions from PSUR (i.e. wait for next PSUR or earlier actions).
- Generally, we are seeing transparent data but not seeing concise/targeted justifications to that BUDI/device to demonstrate its still within its RB profile (or not).



This information helps BSI decide what we do next

Actions BSI may take if Risk Benefit conclusions are not accepted/aligned

Please ensure that observations are clearly addressed/considered at the next PSUR update for that PSUR. (BSI will check)

BSI will need to consider taking appropriate action if safety related observations are not actioned appropriately (per article 86)

BSI has not encountered severe situations to date. Guidance is to support

- More Observations raised
- Request earlier data analysis (<12 months)
- Review CER in special review outside of PSUR process
- Increased Control (Entropy)
- More?..(e.g. additional surveillance activities)

PMCF & PMPF change notifications

PMCF & PMPF change notifications

Please be aware that it is **not** appropriate to notify BSI of **substantial changes** to the PMCF / PMPF plan solely within the PSUR document.

- Timely
- Supporting documentation
- Assessment of acceptability

PMCF/PMPF change notification

Examples of Substantial Changes requiring separate notification (not exhaustive):

- The need for conducting PMCF / PMPF has changed (e.g. PMCF / PMPF plans are changed in response to issues identified in the CER/PER, risk management, safety related concerns, etc.)
- Removal or ceasing of any ongoing or planned specific / proactive activities
- Delays or deviations (protocol, timelines, etc.) from the plan
- Changes to specific methods and procedures that could impact the overall quantity and quality of clinical data:
    - Reduction in sample sizes, the number of sites or number of respondents
    - Changes to objectives or endpoints
    - Changes to statistical analysis plans
- PMCF / PMPF activities determined to be insufficient to fulfil the specific objectives set out.

PMCF/PMPF change notification

Examples of non-substantial changes (not exhaustive):

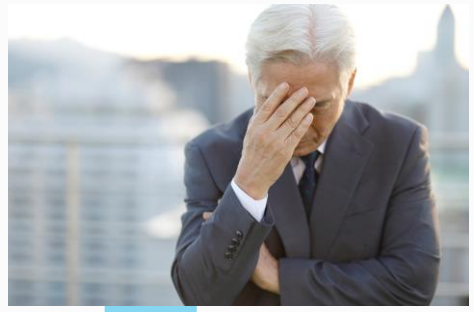
- Administrative changes to the PMCF / PMPF plan that impact legal manufacturer name, addresses, etc. that do not require further clinical evaluation.
- Changes to general methods such as screening of scientific literature, complaint trending, etc.
- New activities are added based on marketing interests, investigator-initiated studies, etc. which are supplemental and not meant to replace current activities.

Key messages

YES

1. **Communicate** with your Notified Body
2. **Read** and **follow** MDCG 2022-21
3. **Address BSI observations** in the next PSUR

1. Do not present data without findings and justification for decisions taken
2. Do not make substantial changes to PMCF before informing your Notified Body



NO

Questions

Thank you for listening

BSI Group

389 Chiswick High Road

London, W4 4AL

+44 345 080 9000

bsigroup.com