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CSMD 2024

Clinical Surveys in Post Market Phase

When, Why, How and Best Practices

ISO 9001:2015

ISO 14155

GDPR

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Introduction

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Types of Clinical Surveys

- Understanding User Needs
- Concept Evaluation
- Design Improvement
- Feasibility Assessment
- Usability Assessment
  Market Validation

- Real-World Performance Monitoring
- Early Detection of Adverse Events
- Improved Product Performance
- User Satisfaction and Experience
- Informed Decision Making

- Legacy Device/Well Establish Devices
- Limited Pre-Market Data
- Limited Patient Population
- Short-term safety Data
- Unforeseen Use Patterns

Why PMCF in Post Market Phase

PMCF Surveys can help cut cost, time, and generate EU-MDR compliant robust data especially for medical devices with limited clinical data

Key Considerations for legacy devices	Clinical Investigations	Registries	Clinical Literature	PMCF Surveys
Potential to focus PMCF study on collecting data from various patient population (e.g., pediatric, geriatric, etc.)	Yes	Yes	Likely	Yes
Potential to collect patient data at 3/6 months follow-up	Yes	Yes	Likely	Yes
Potential to collect for all indications and claims	Yes	Yes	Likely	Likely
Potential to collect data on clinical end points (Primary and secondary)	Yes	Yes	Yes	Yes
Potential to collect data on off-label use	No	Likely	Likely	Yes
Potential to collect data on adverse event and usability	Yes	Yes	Likely	Yes
Cost	$$$$	$$$	$	$
Timeline	>1 year	1 year for set up then ongoing	2-3 months	3 months
Level of data quality as per MDCG 2020-6	**1 or 2**	**3**	**4**	**4 or 8**

Legacy devices with limited clinical data struggle with traditional PMCF solutions (such as clinical trials, registries) as they are time, cost, and resource intensive – PMCF surveys may be best suited in such situations.

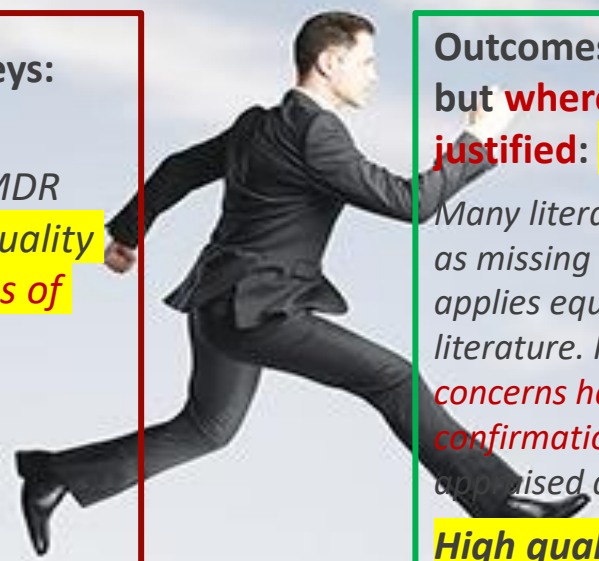
However, is the strength of the evidence generated by PMCF surveys sufficient?

Leveling Up Strategy to achieve Rank 4 for your clinical evidence

As per Appendix III – suggested hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the MDR, PMCF surveys may fall under rank 8 or rank 4.

Proactive PMS data, such as that derived from surveys: Rank 8

This falls within the definition of clinical data under MDR Article 2(48), but is not generally considered a high-quality source of data due limitations associated with sources of bias and quality of data collection.



Outcomes from studies with potential methodological flaws but where data can still be quantified, and acceptability justified: Rank 4

Many literature sources fall into this category, due to limitations such as missing information, publication bias, time lag bias, etc. This applies equally to publications in the peer-reviewed scientific literature. However, for legacy devices where no safety or performance concerns have been identified, these sources can be sufficient for confirmation of conformity to the relevant GSPRs if appropriately appraised and the gaps are identified and handled.

High quality surveys may also fall into this category.

Data Collection Quality
Source of Bias

Process Quality – relevant Quality Standards
Data Quality – Endpoints accuracy, authenticity

PMCF Survey Tactics to achieve Rank 4 for your clinical evidence

Recommended Methodology

Capture real-world evidence using online surveys with data collection based on retrospective patient case form methodology that are back-checked for authenticity.

Why Online Surveys?

1. Quality processes compliance
   - GDPR/HIPAA compliance
   - ISO 20252
   - ISO 3534-4
2. Faster (~10 weeks vs. 12 months) and easier to audit, track, measure, follow-up, etc. vs. offline methods
3. Remove major sources of bias

Why Retrospective Patient Case Forms?

1. Mimics Patient **Case Record Forms (CRF)** to capture appropriate clinical end-points as per ISO 14155
2. Ensures accuracy and authenticity of the data vs. relying on memory of the respondent
3. Ensures faster results vs. prospective approach

Why back-checks?

1. Conducting telephonic or web-based back-checks ensures authenticity of the surveyed respondents as per ISO 20252 and 14155
2. Conducting telephonic or web-based back-checks ensures validation of the clinical evidence collected as per ISO 20252 and 14155

Relevant Quality Standards to be followed for Process Quality

Recommended Relevant Quality Standards to be followed for Process Quality

1 ISO 14155 – Clinical Investigations

- Good clinical practice (GCP) principles
- Improper influence or inducement
- Informed consent
- Monitoring plan
- Adverse events & device deficiencies
- Electronic data systems

2 GDPR/HIPAA Compliance – Data Security

- GDPR consent from respondents during recruitment
- Encrypt, pseudonymize, or anonymize personal patient data wherever possible
- Clear and transparent privacy policy
- Appropriate technical security measures for data protection

3 ISO 20252 – Market Research Process

- Planning, Delivery, and Reporting research project
- Sampling and access panels
- Sample authentication
- Fieldwork/Data collection
- Data validation and QC
- Validation reports
- Data Processing
- Data Analysis
- Compensation as per FMV (Fair Market Value)

4 ISO 3534-4 – Sampling Process

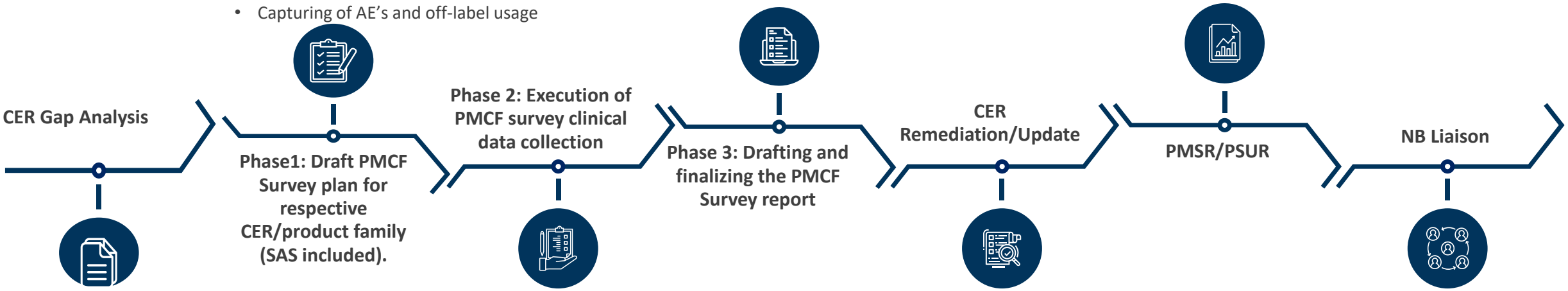
- Process of selecting a sample from population
- Methodology of survey sampling
- Cross-referencing
- Quality control during sampling

Ideal Approach for Executing PMCF Studies in Conjunction with CER Development

Phase 1: Expected outcome
- Define clinical outcome and sample size criteria in the PMCF survey plan.
- Finalize PMCF survey questionnaire and facilitate online survey execution

Phase 2: E**xpected outcome**
- Collect comprehensive raw clinical data including product indication, outcomes, adverse events, and off-label use.

Phase 3: Expected outcome
- In-depth analysis of clinical data with respective graphs and conclusions.
- Accurate mapping of indication and clinical outcomes against the individual products with a graphical representation.
- Capturing of AE's and off-label usage



- Review CER to check any potential gaps in clinical data
- Identification of clinical endpoint (Primary & secondary)
- Literature review in case of inadequacy found in clinical endpoint for the subject device
- Review of SOTA for better understanding and analysis of stand of care and benchmark device
- Review/Map reference data source for clinical data
- Mapping of indication/claim against clinical data
- mapping of adverse events as per IFU
- Identification of off-label use

- Prepare updated CER for submission
- Prepare updated PMSR/PSUR for submission
- Ensure compliance with regulations
- Provide supporting documentation as needed
- Continuously monitor device performance
- Collect additional data through PMCF activities
- Update CER periodically
- Ensure ongoing compliance with regulation

PMCF Questionnaire Drafting – Best Practices

Identify and Manage Your Stakeholders' Expectations

Notified Body

Expectations from the survey to:
Fulfil the study objectives, make their decision easy, fit their standards/style, be comparable

They need to see inputs to/output of CERs:
Question type: screening, consent, procedures, indications, endpoints, AE, side-effects

Aim to get their cooperation and ensure maximum relevant information is collected

- Avoid ambiguity, bias / leading, over generalization, misunderstanding, drop out, fatigue

Expectations from the survey to:
Easy to follow (knowing how to answer), short, not difficult, interesting, not asking confidential info

HCPs

Medical Writers

Expectations from the survey to:
Answer research objectives, yield as much information as possible, with no errors

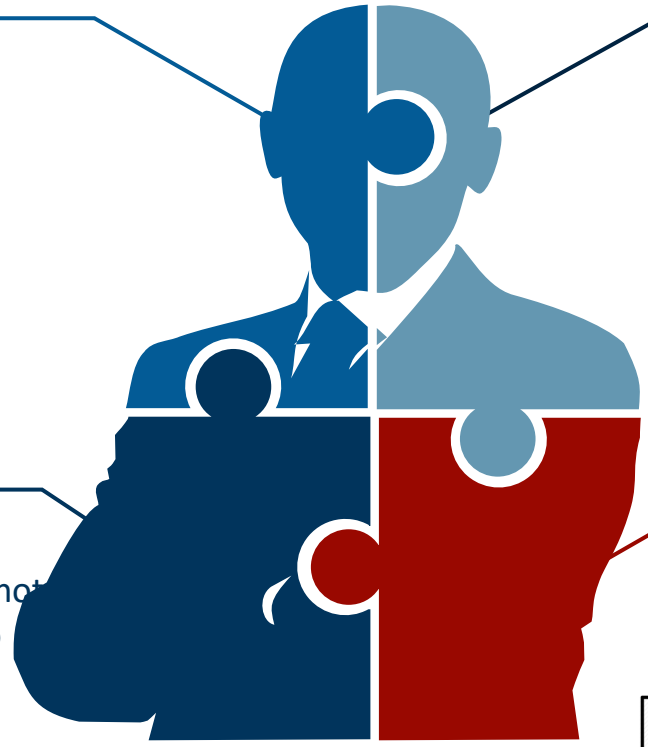
Ensure reliable analysis to provide the expected output - needs to uncover information AND balance the needs of other three groups of people.

Efficient programming and data processing with minimum error

- Programming Instructions,
- Skip logics, pre-codes,
- Efficient layout

Expectations from the survey to:
Well laid out, clearly coded, efficient data mapping, clear skip patterns, unambiguous, unchanged to allow high quality raw data

Biostatisticians



7 Steps of PMCF Questionnaire Design

Step 1 Decide what information is required

Step 2 Make sections of the questions

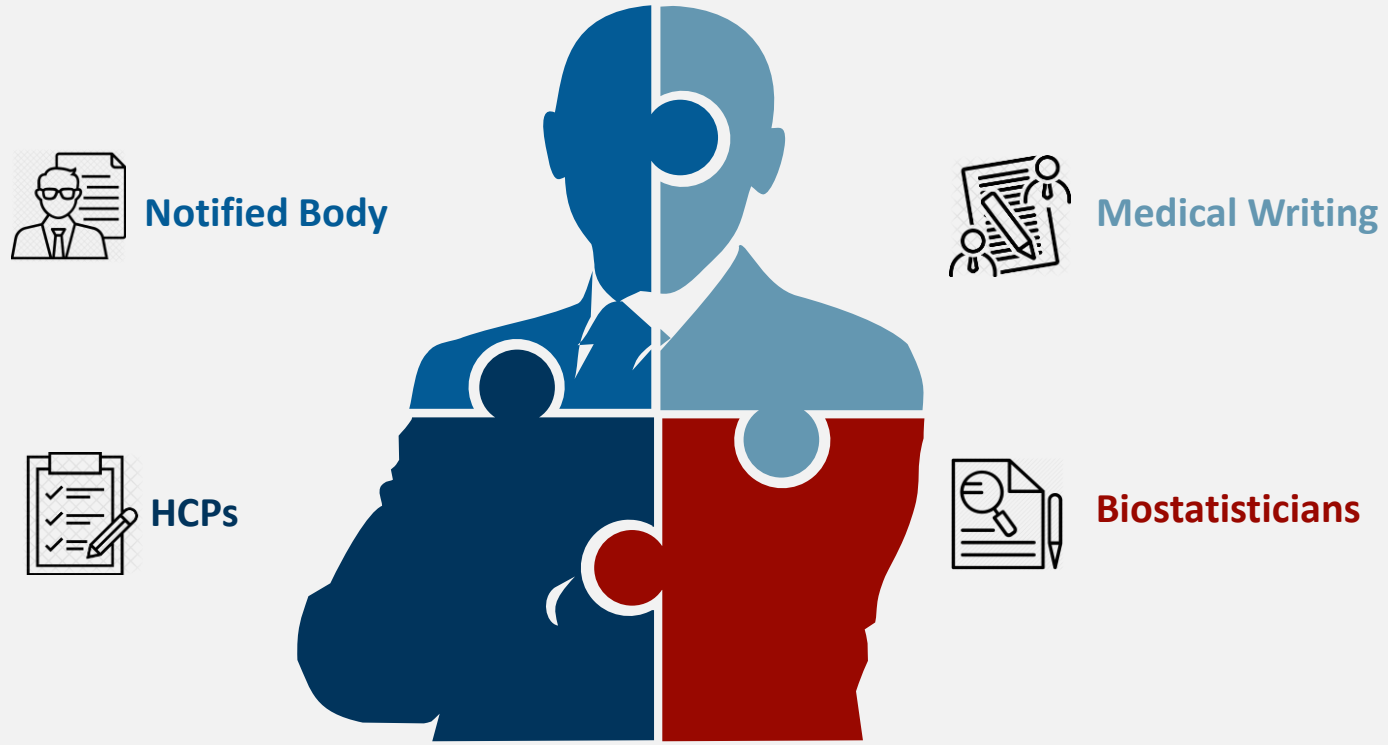
Step 3 Refine the question phrasing

Step 4 Develop the response format

Step 5 Put questions in appropriate sequence

Step 6 Finalize the layout of the questionnaire

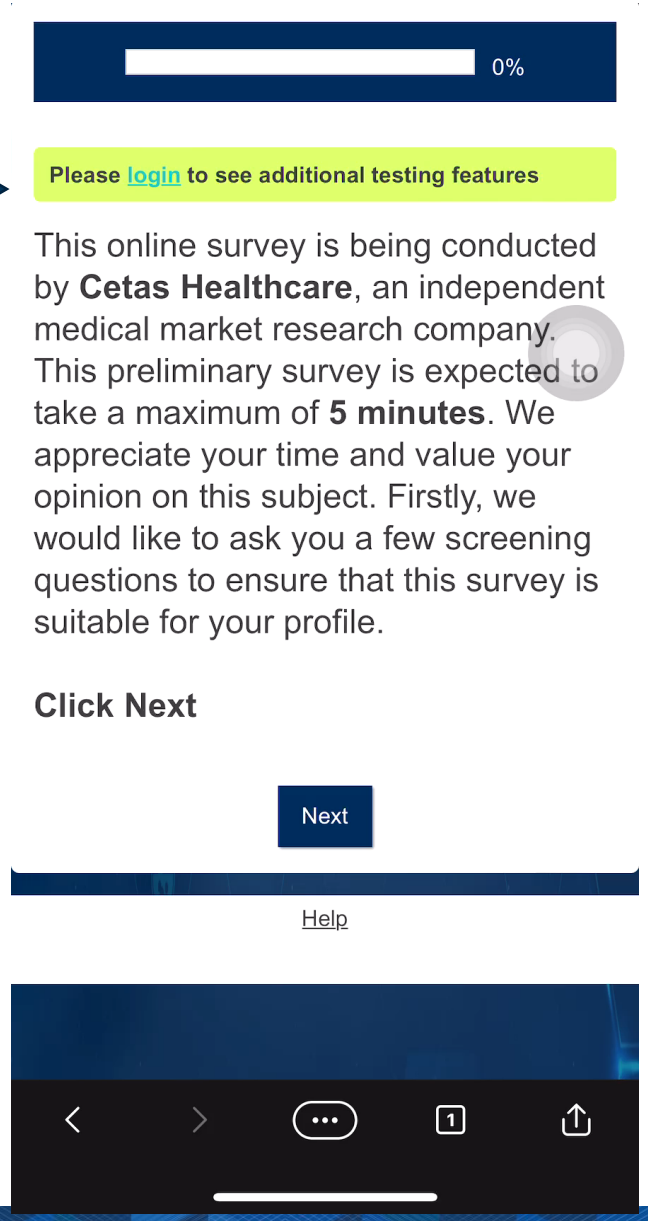
Step 7 Pretest and revise



Typical Online Survey Deployment

Sample video of on online survey

Mobile phone version:



Pro Tips (1): Getting HCPs to Participate

How to maximize the participation rate in PMCF surveys

The Introduction to Survey

- Give a full and frank disclosure to put respondent at ease - first impressions count
- Keep it as short as possible, while still allowing for rapport
- A hook - we are very interested in the opinions of experts, like yourself
- It’s a good idea to include an indication of time
- Show them what is required (pen & paper or online platform-based survey approach)

The Incentive to participate in PMCF Survey

- Work with your compliance department for FMV based incentivization
- Think of other non-monetary incentive options to engage HCPs (CME?)
- Explore ‘community’ approach to ensure long term engagement (portfolio dependent)

Pro Tips (2)- Authentication of Respondents

How to weed out unsuitable respondents from PMCF Surveys

QC Steps

Pre-launch

- ✓ Database vetted with:
  - Desk research and validated via NPI for US, GMC for EU, etc.
  - Contextual data validation (publications, news, SM, etc.)
- ✓ Recruitment via authentic, certified, and verified sources

In-survey

Survey terminations based on:

- ✓ Strict screening criteria
- ✓ Cheater check questions
- ✓ IP checks vs. location
- ✓ DFP (Digital Finger Printing) based checks

Post-survey

- ✓ Demographic data checks (e.g., name/location of the hospital) mentioned in the survey vs. database
- ✓ Telephonic or web-based back-checks among random respondents who have completed the survey is one of the most critical steps to validate the authenticity of the survey respondents and their data

Consult with our PMCF Surveys Experts

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