Alternatives to PMCF Clinical Investigations

LIVE

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Presenters

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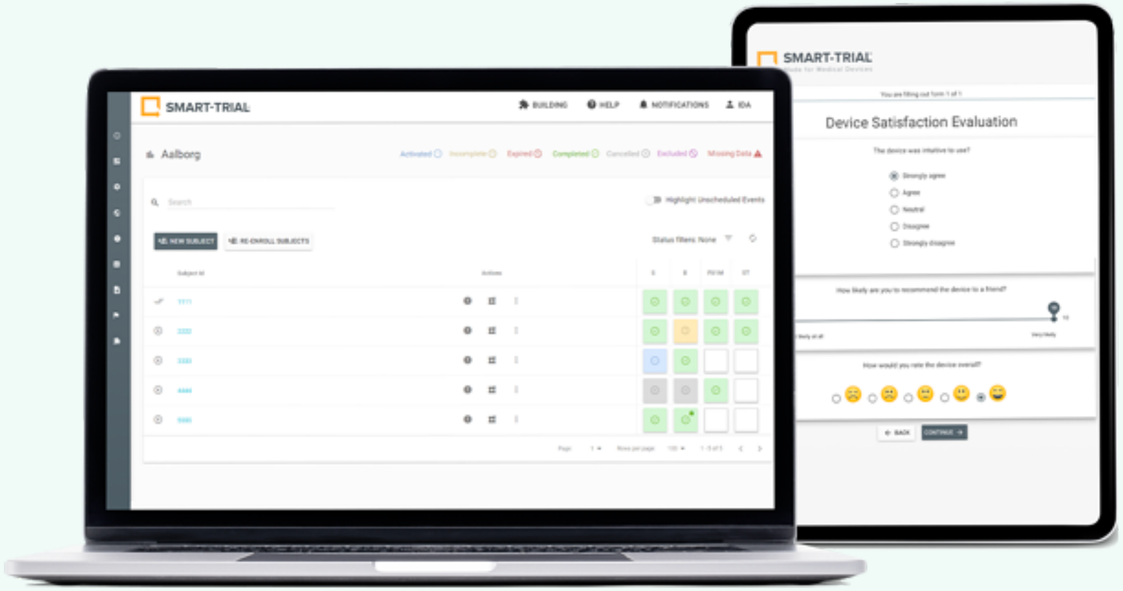

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Qserve is the largest consultant company in the EU that is 100% focused on medical devices and in-vitro diagnostics.

Why This Topic?

PMCF under the EU MDR is of higher importance (than under MDD)

Manufacturers are looking for ways to accomplish PMCF effectively

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What Is The Role of PMCF?

How does PMCF fit with the rest of the EU MDR requirements?

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EU MDR

EU MDR DEVICE CLASS	CE Report	PMS Plan	PMS Report	PMCF Plan	PMCF Report	PSUR	SSCP
EU MDR References	*Article 61 & Annex XIV PartA*	*Article 84*	*Article 85*	*Annex XIV, Part B*	*Annex XIV, Part B*	*Article 86*	*Article 32*
I	✓	✓	✓	✓	✓	⊘	⊘
IIa	✓	✓	⊘	✓	✓	✓ …	✓ →
IIb	✓ ↻	✓	⊘	✓	✓	✓ ↻	✓ →
III	✓ ↻	✓	⊘	✓	✓	✓ ↻	✓

↻ Update annually … Update at least every two years → Only implantable

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Continuous Effort

Clinical Evaluation

VS

Reality

Post-Market Clinical Follow-Up (PMCF)

PMCF plan - methods and activities

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Generic vs. Specific Methods

Generic

- Literature and publications
- Market feedback
- Public sources of information

Specific

- Clinical Investigations (observational and interventional)
- Case Series and Surveys
- Investigator Initiated Study

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Does the new EU MDR timeline impact PMCF?

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NOPE

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New EU MDR Timeline & PMCF

Sign a written agreement for conformity assessment before expiration of MDD certificate or before Sep. 26 2024

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Planning Ahead

What factors decide your choice of activity for PMCF?

Bianca Lutters
PhD & Head of Clinical Operations &
Principal Consultant

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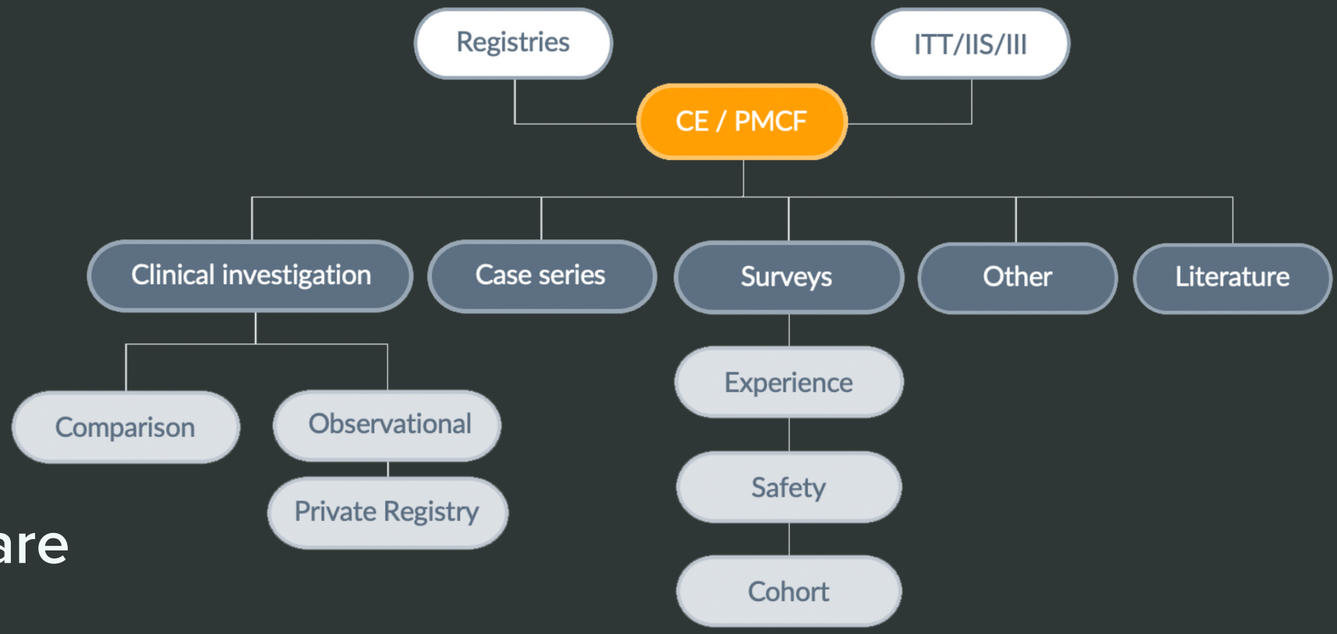
Considerations for Selecting a PMCF Activity

- Need/Goal
- Device and lifetime
- Gaps in clinical data
- Sales volume and market share
- Timelines



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Diving In

What is your need?

- Sufficient clinical data - MDR
- PMCF / real-world data regulatory requirements
- Based on PMS data / PMCF data / risk management
- Reimbursement

New device or longer on the market?

- Clinical study data available vs. lots of clinical data available

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Medical Device and Lifetime

- High-risk vs. lower-risk
- Implantable
- HCP vs. lay-user
- Long lifetime vs. short

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Factors at Play

Gaps in clinical data

- Variants
- Use
- Lifetime not covered
- Patient group
- Off-label use

Sales volume and market share

Timelines

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Alternative Options

to Clinical Investigations with focus on collecting patient-specific data

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Survey of HCP - prospective, retrospective

- Direct contact with HCP is needed
- Mainly works if you have gaps in clinical data on variants, uses, patient groups
- Gather information on off-label use
- Only works in some cases, for long lifetime devices

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Healthcare Panel Questionnaires/Surveys

- Sufficient sales and no. of devices in market
- Mainly works if you have gaps in clinical data on variants, uses, patient groups
- Gather information on off-label use
- Only works in some cases, for long lifetime devices

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Data Collected by Device

Devices with software components that collect data

If information collected supports safety and performance

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Scraping Healthcare Records

- Sufficient sales
- Mainly works if you have gaps in clinical data on variants, uses, patient groups
- Only works in some cases, for long lifetime devices
- Depending on what is documented in healthcare records

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Retrospective Case Series

Full use of device

- Direct contact with HCP
- Patients can be selected
- Patient visits HCP during full use
- Long lifetime in some cases

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Lay User Cohorts

- Sufficient sales
- Simple questionnaire
- Patients can be reached with marketing

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Literature Search for Your Own Device

Are you sure you have all papers for your device?

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Key Takeaways

Design your PMCF activity well !

- Suitable for your need
- Endpoints and acceptance criteria
- Statistically sound sample size
- Well-designed questionnaire

Don't wait !
The time is NOW

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Time for

Q&A

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Access our 'Ultimate Guide to Selecting the Ideal PMCF Activity', for free
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