

PMCF Data Collection for Lower Class **Medical Devices & WETs**

Broadcast starts at
15:00 CET, Dec. 2nd

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Today's Hosts



Dr. Efstathios Vassiliadis

CEO

Evnia



Jón I. Bergsteinsson

VP of Global Business Development

SMART-TRIAL

What is the Role of Post-Market Clinical Follow-up?



Continuous Effort



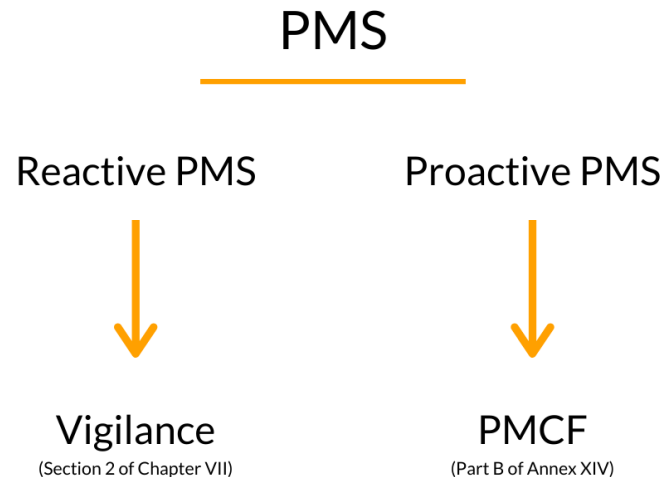
Clinical
Evaluation

VS

Reality

The Role of PMCF

- Post-Market Clinical Follow-Up is a part of the Post-Market Surveillance
- Continuous and proactive process to update the Clinical Evaluation
- PMCF plan specifies *how* you will collect and evaluate data



What are Lower Class Devices & Well-Established Technologies (WETs)?

Lower Class Medical Devices

Under the EU MDR

- Low risk Class 1 & 2a devices
- “Point of Care”
- No need for long-term follow-up data



Well-Established Technologies

As defined in the MDCG 2020 6

- Simple, common and stable design
- Well-known safety profile
- Well-known clinical performance characteristics



PMCF Requirements

**What do
Manufacturers Need
to Achieve?**

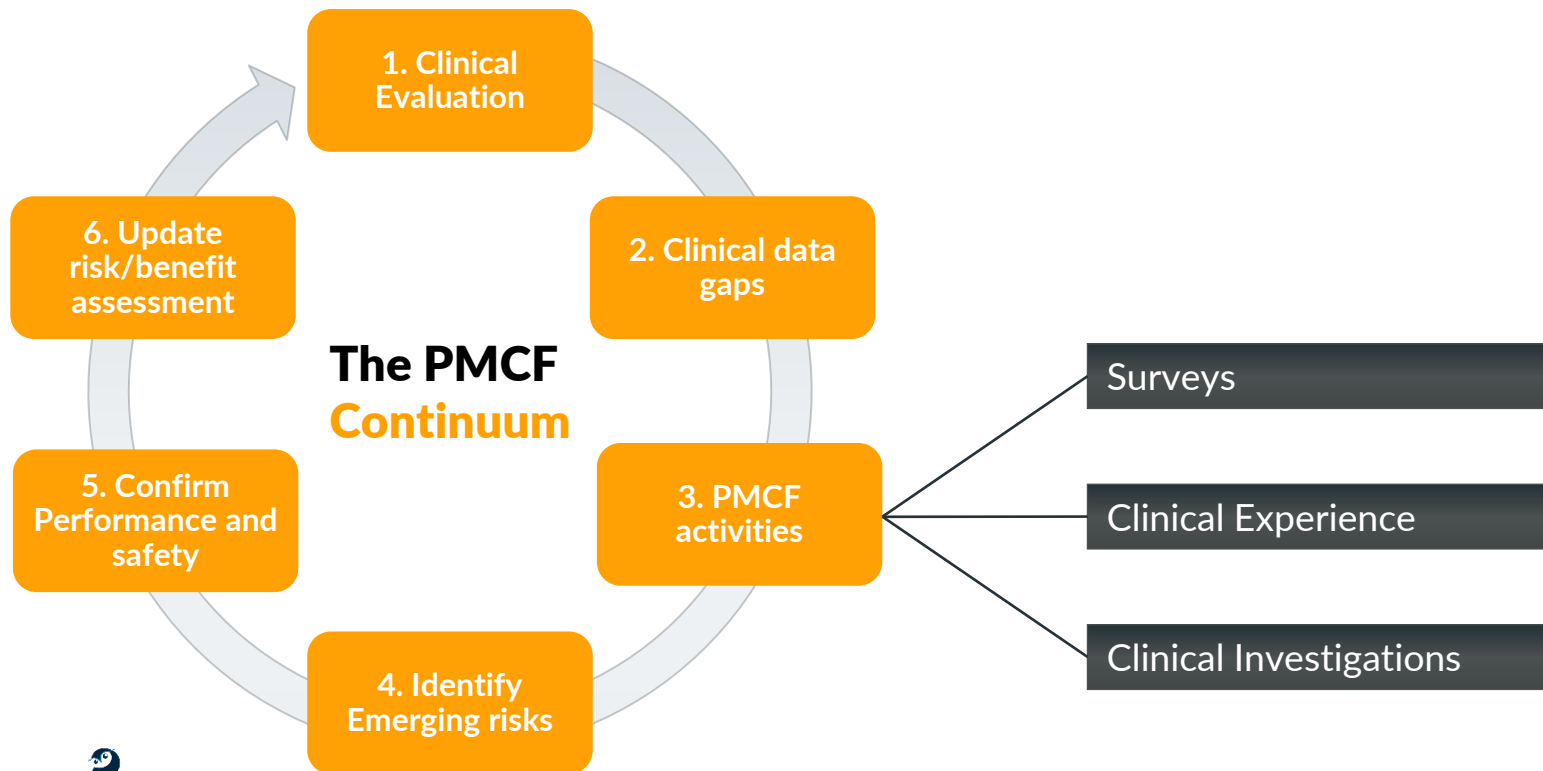
PMCF Goals

What do manufacturers need to achieve

- Proactively identify emerging risks
- Confirm MD performance and safety
- Update clinical performance / benefits



PMCF - What Needs to be Achieved?



PMCF - What Needs to be Achieved?

Surveys (90%)

Cost: €

Time: 🕒

Clinical Experience (10%)

Cost: €€€

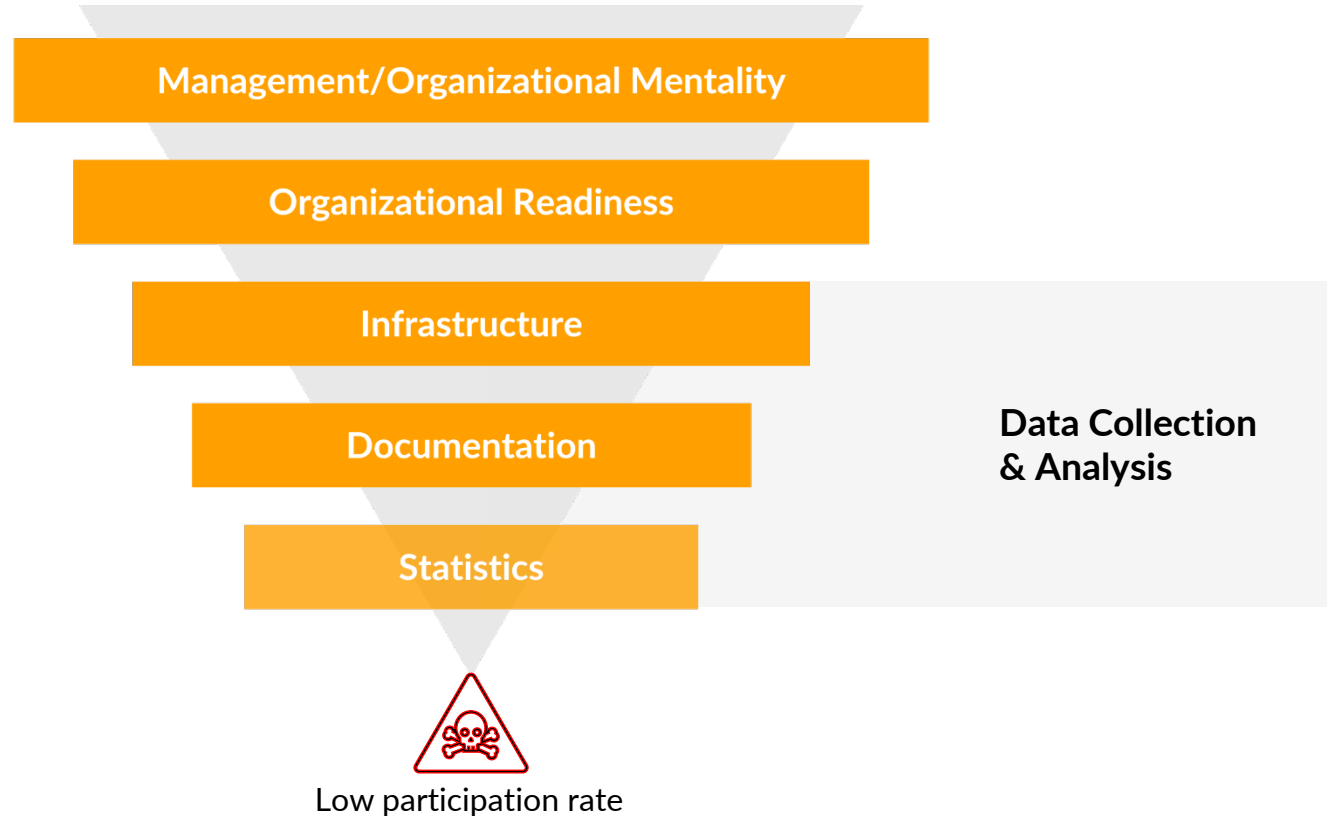
Time: 🕒

Clinical Investigations

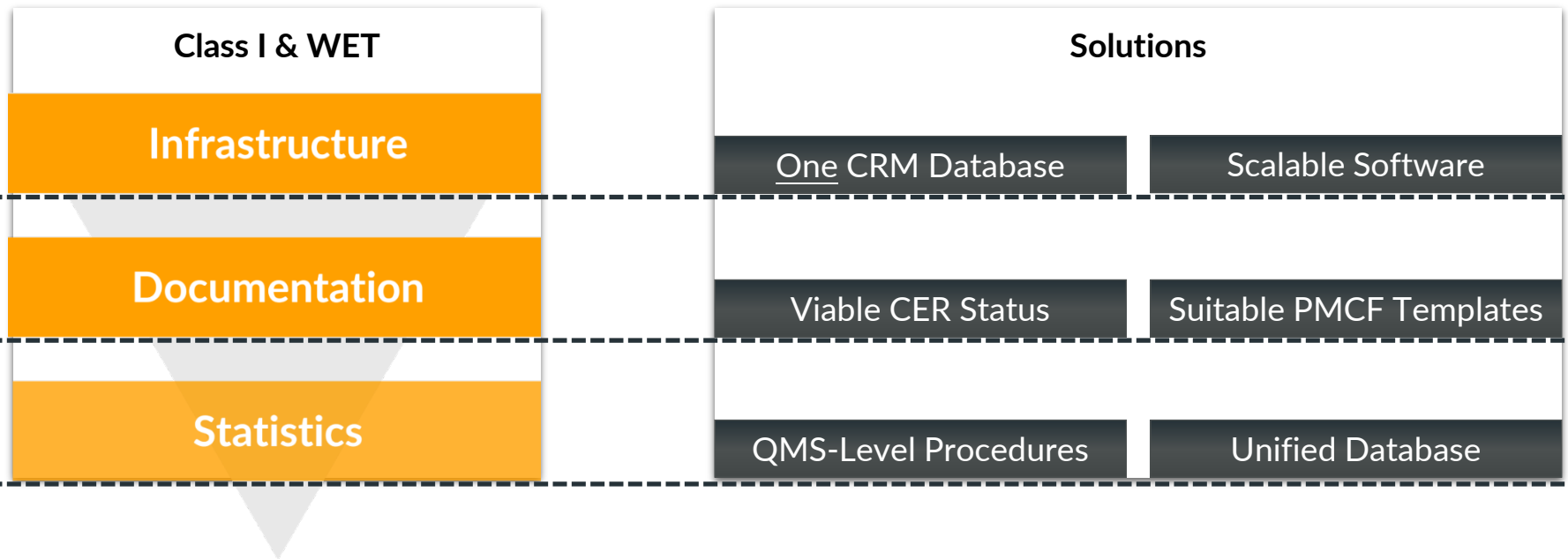
Cost: €€€€€

Time: ●●

Existing Challenges with **PMCF Data Collection**



Solutions for Data Analysis



Real PMCF

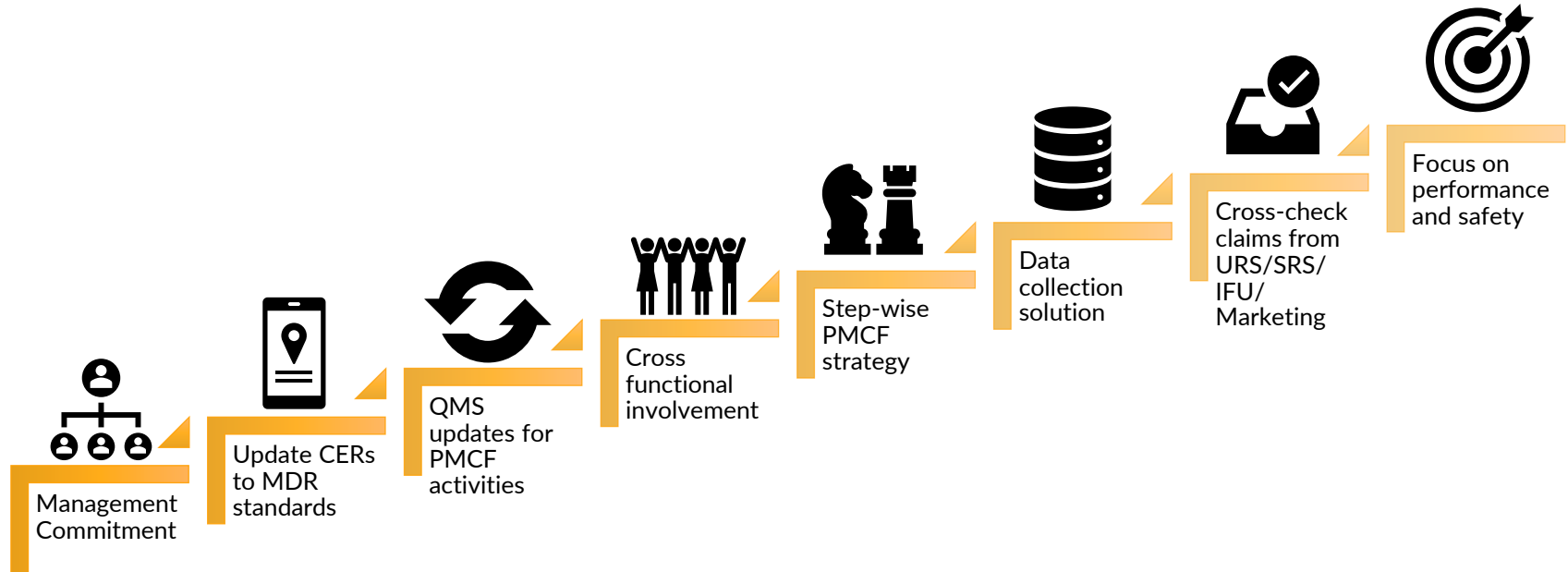
Use Cases and Solutions



Use Case #1

- WET medical device with 20+ years in market
- No experience with PMCF and no data ever produced
- Low quality of MDD CERs to drive decisions
- Establish PMCF process and obtain PMCF Data

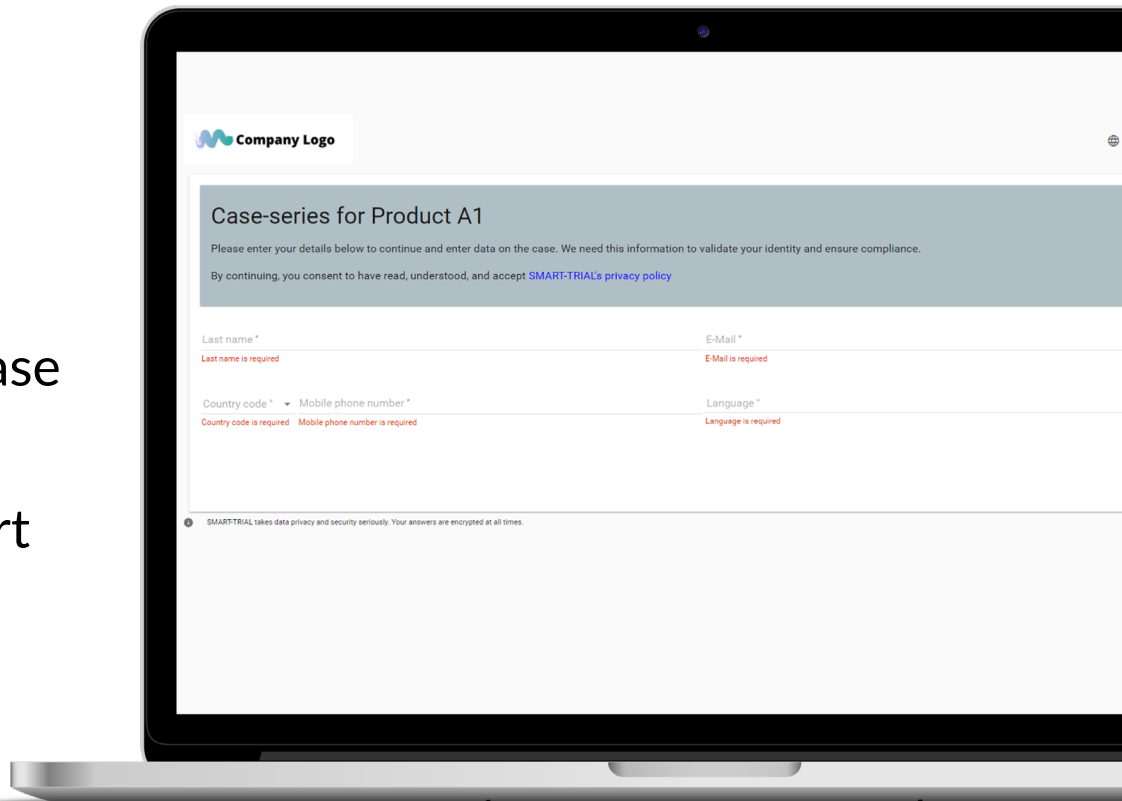
Use Case #1 – Finding the Solution



Use Case #1 - Solution



- Ad-hoc case reporting
- Clinicians complete a questionnaire for each case
- Ease of use through smart interfaces



Use Case #1 - Solution

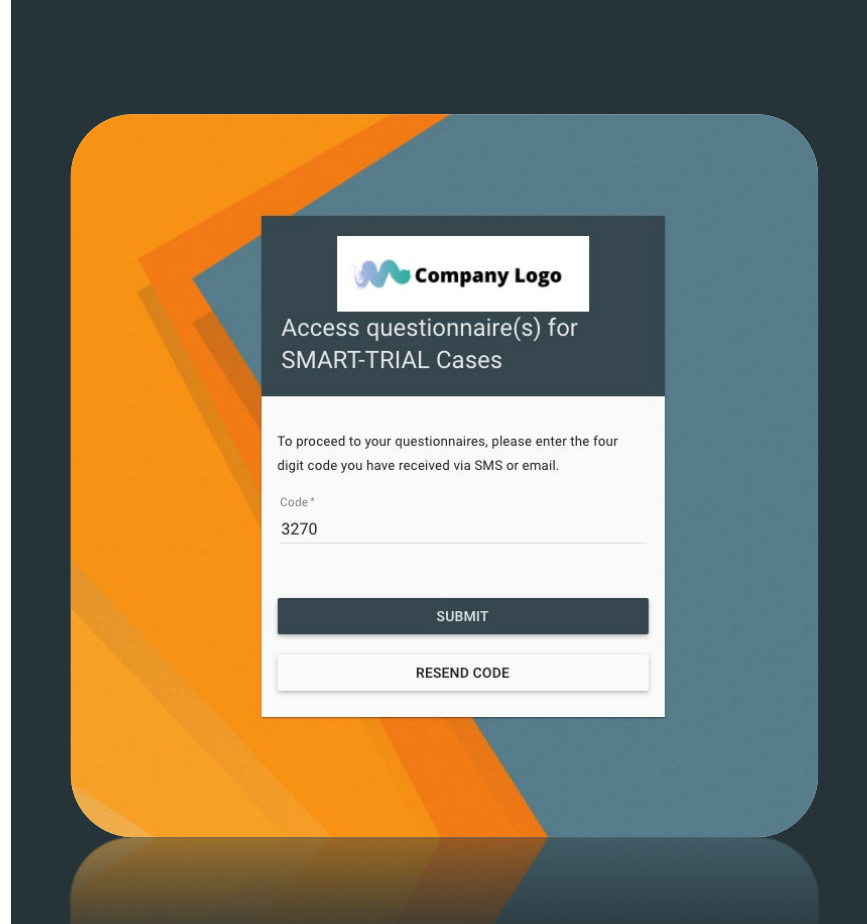
- Collect data on multiple devices in same family
- Full flexibility in endpoint design and structure



The image shows a tablet with a digital form interface. At the top left is a 'Company Logo' with a blue and green wave icon. Below it, a progress bar indicates 'You are filling out form 1 of 2'. The main title of the form is 'Case Information'. The first section is 'Select clinical application', which has a dropdown menu and a red prompt 'Please answer this question'. The second section is 'Please specify the type of product used', featuring three radio button options: 'Product 1A', 'Product 2A', and 'Product 3'. Below these options is another red prompt 'Please answer this question'. At the bottom of the form, a red warning triangle icon is followed by the text 'You have not answered all required questions in this form. Please review missing answers to continue.' and a 'CONTINUE →' button.

Use Case #1 - Solution

- Data authenticity achieved through end-user validation
- Full traceability of data origin



Use Case

#2

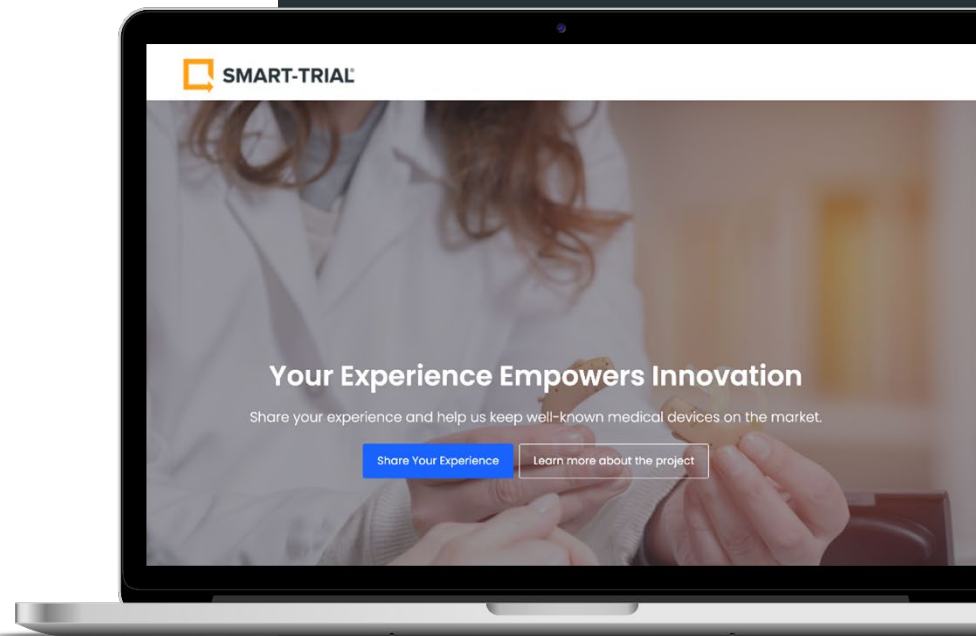
- Top 3 global leader in hearing aid technology
- Required end-user input for PMCF clinical performance
- Little interest in "study-like" data collection programs
- Access to end-users through distributors

Use Case #2 – Finding the Solution

1. Identifying distributors
2. Contracting and present the value
3. Cross functional involvement
4. Cross-check claims from URS/SRS/IFU/Marketing
5. Translate questionnaires
6. Understand the workflow
7. Adapt data capture process to workflow
8. Monitor recruitment and provide support

Use Case #2 - Solution

- Prospective cohort-based survey questionnaires
- Recruiting locally, collecting data globally
- “Public enrolment” through SMART-TRIAL Landing Page

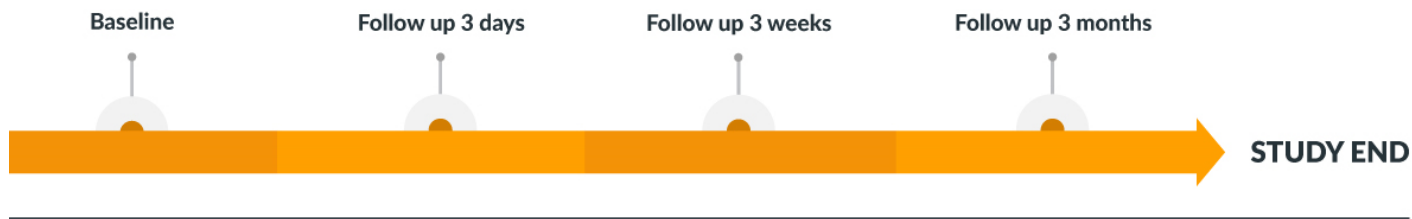


Use Case #2 - Solution



End-users register

Questionnaire follow-ups with endpoints focused on claims



Facilitating Compliance

- 👍 Pre-validated (PIC/S guideline & IEC62304)
- 👍 ISO 14155:2020, ISO 20916:2019, ICH GCP, FDA CFR 21 Part11, EU GDPR & HIPAA
- 👍 Ready to use compliance document templates & system reports



QUESTIONS & ANSWERS

Key Takeaways



01

Have a CER at an MDR level

Before creating a PMCF plan, ensure that you have your CER updated to an MDR level, especially for Class 1

02

Align data with claims

Design quantitative questionnaires and forms that capture your clinical claims

03

Centralized database

Ensure that you have a centralized database registry that allows for a thorough data analysis in large cohorts

04

Ensure that your QMS is PMCF ready

Define the processes and quality files needed to document your PMCF process and plan

05

Data collect is not just done in studies

PMCF data collection is not limited to clinical studies or simple surveys. Select a tool that opens new possibilities

Thank you for today!



Electronic Data Capture for PMCF
Data Collection

smart-trial.com/pmcf



PMCF Planning & Implementation.
S&P Clinical Data / CER

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