

## Post-Market Clinical Follow-Up (PMCF) Services

Strengthen Clinical Evidence. Stay Audit-Ready. Maintain Market Access.

Ensure your medical devices meet clinical evidence requirements under EU MDR with a structured, compliant, and real-world evidence-driven PMCF approach.

Celegence combines regulatory expertise, AI-assisted medical writing, and efficient survey execution to deliver PMCF strategies aligned with Notified Body expectations.



### ARE YOU?

Facing challenges with sufficient clinical evidence for legacy devices?

Addressing NB non-conformities on safety & performance?

Struggling with PMCF plans or HCP survey design?

Experiencing low HCP survey response rates?

Unsure how to collect patient record data?

Managing multiple devices with limited bandwidth?

### PMCF Services

**PMCF Strategy & Planning**

- ✓ Identify existing clinical evaluation
- ✓ Define PMCF strategy (Annex XIV Part B)
- ✓ Develop PMCF Plans (MDCG 2020-7)

**PMCF Execution**

- ✓ HCP survey design & execution
- ✓ Global respondent recruitment
- ✓ Survey management

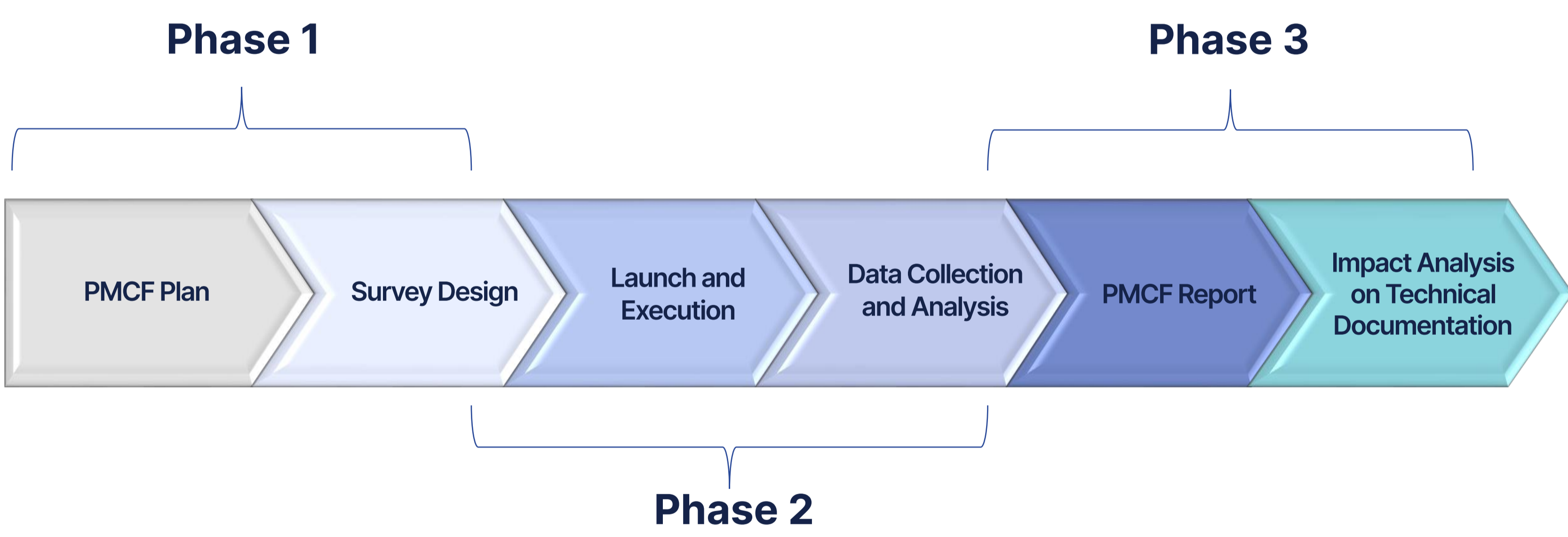
**Documentation & Reporting**

- ✓ PMCF data analysis & Evaluation Reports
- ✓ Benefit-risk impact assessment
- ✓ Integration with CER, PMS, PSUR

**Regulatory & NB Readiness**

- ✓ NB observation responses
- ✓ Methodology justification
- ✓ Submission-ready documentation

### PMCF Survey - Process Flow



### PROVEN OUTCOMES

- NB non-conformances successfully closed.
- PMCF strategies accepted by Notified Bodies.
- High survey response rates.
- Faster turnaround with structured execution.

### WHY CELEGENCE

**Experience**

Deep expertise in clinical evaluation, PMS, and PMCF

**Efficiency**

Minimal lead time with seasoned SMEs and AI-assisted writing

**Cost Optimization**

At least 20% savings with CAPTIS® and blended model

**Integrated Execution**

All-in-one support for strategy, design, analysis, and reporting

**Flexibility & Trust**

Trusted by small, mid-sized, and top 20 life sciences companies

**Compliance-Based Approach**

Driven by NB feedback trends and evolving expectations