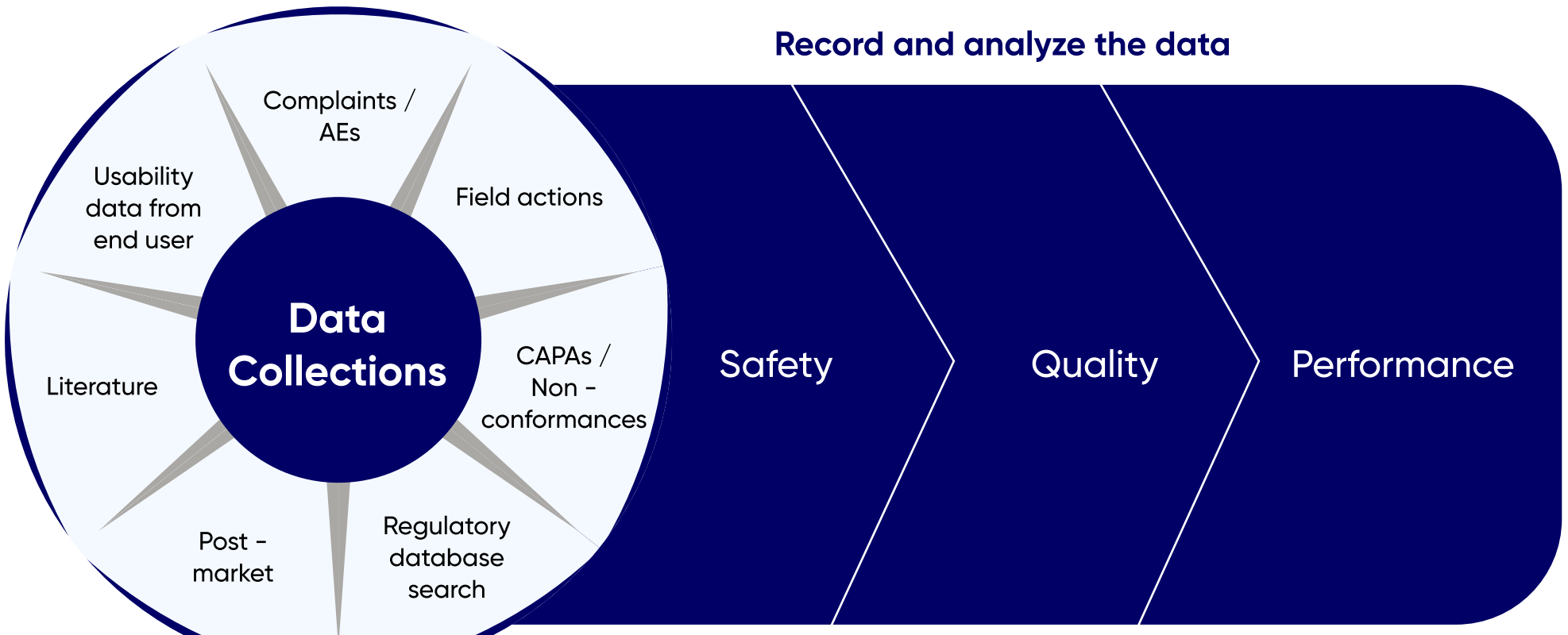
Post-Market Surveillance

Monitoring Today. Protecting Tomorrow

PMS ensures your medical device continues to deliver safety, quality, and performance long after launch. By tracking real-world use, PMS provides actionable insights that help anticipate risks, strengthen compliance, and enhance patient trust.



Proactive Surveillance

- Benefit-risk determination update
- Improve the risk management
- Instructions for use and labelling update
- Clinical evaluation update

- Design and manufacturing information update
- Identify needs for preventive, corrective or field safety corrective action

- Identify options to improve the usability
- Improve performance of the device

Continues entire Life cycle of the Device

POST-MARKET SURVEILLANCE

Our Services

Planning:

- Post-Market Surveillance Plan
- Post-market clinical follow-up plan

Data Collection:

- Complaints/ Vigilance reporting
- Medical Information Management System (Call Centre)

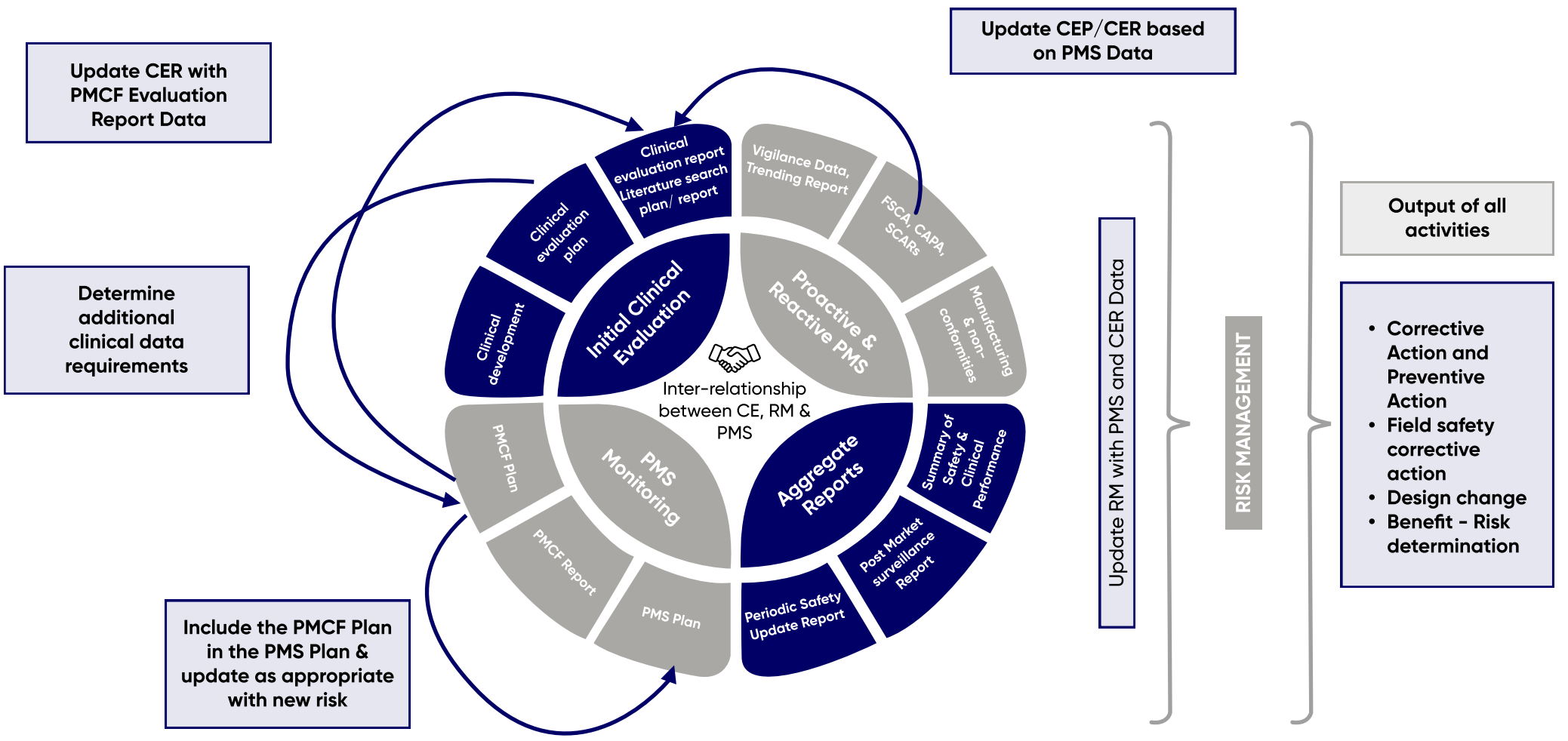
Data analysis

- Periodic monitoring of PMS activities – Quarterly/ half yearly Reports

Safety Reports

- Aggregate Reports
  - Periodic Safety Update Report (PSUR)
  - Post Market Surveillance Report (PMSR)
  - Summary of Safety and Clinical Performance (SSCP)
- Post-market clinical follow-up Report
- Trending and Signal Management reports
  - Statistical Analysis

Impact Assessment on other Linkage System



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