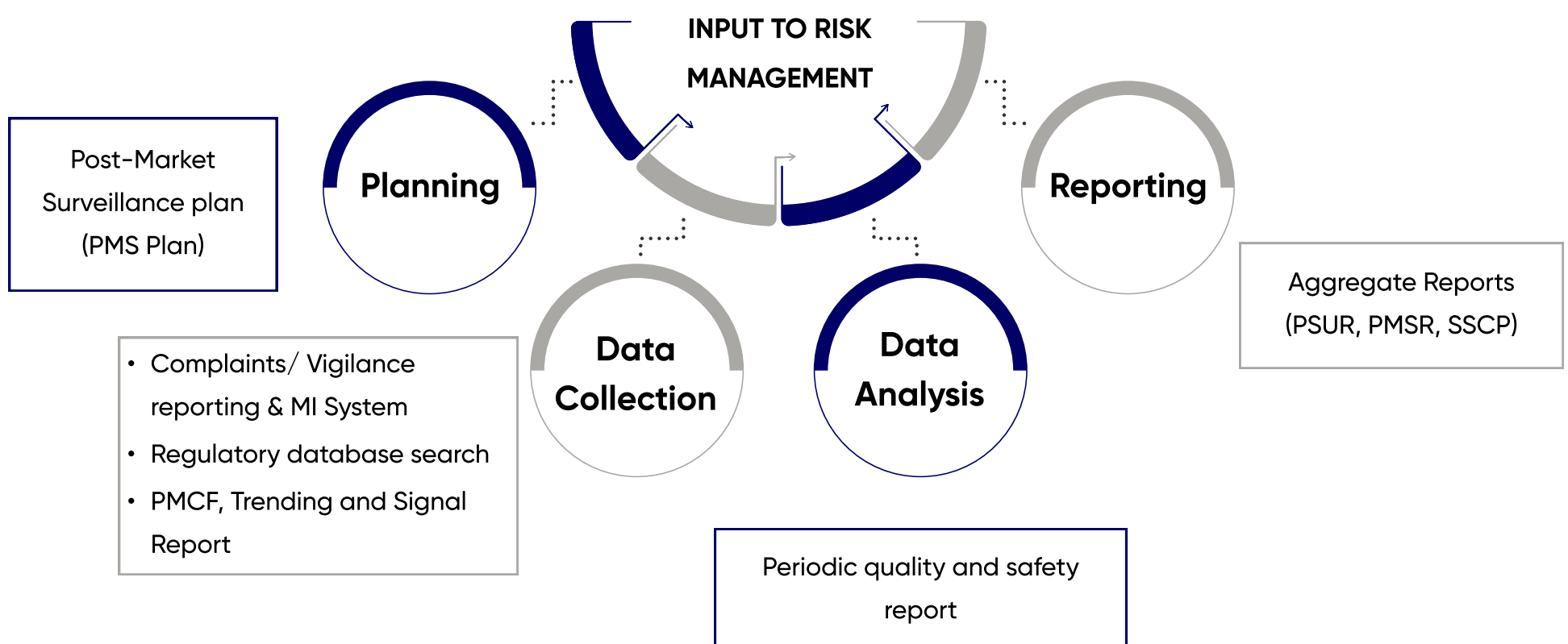


# Global Risk Management

**Risk Managed, Success Assured**

At **COD Research**, we provide **end-to-end risk management support** – from risk analysis and evaluation to post-production monitoring, ensuring your devices meet the highest standards of safety and compliance.



## Risk Management File

ISO 14971 sets the global benchmark for managing risks throughout the entire lifecycle of a medical device, from design and development to production and post-market use. A robust risk management framework goes beyond compliance. It enables you to design safer devices, protect patients, and strengthen trust in every market you serve.

Manufacturers are required to establish and maintain a documented, ongoing process that ensures potential hazards are identified early, risks are effectively controlled, and safety measures remain reliable throughout the device's lifecycle.

We partner with you to embed risk management into every stage of your product lifecycle, delivering confidence in both regulatory approval and long-term success.

# GLOBAL RISK MANAGEMENT

## Our Services

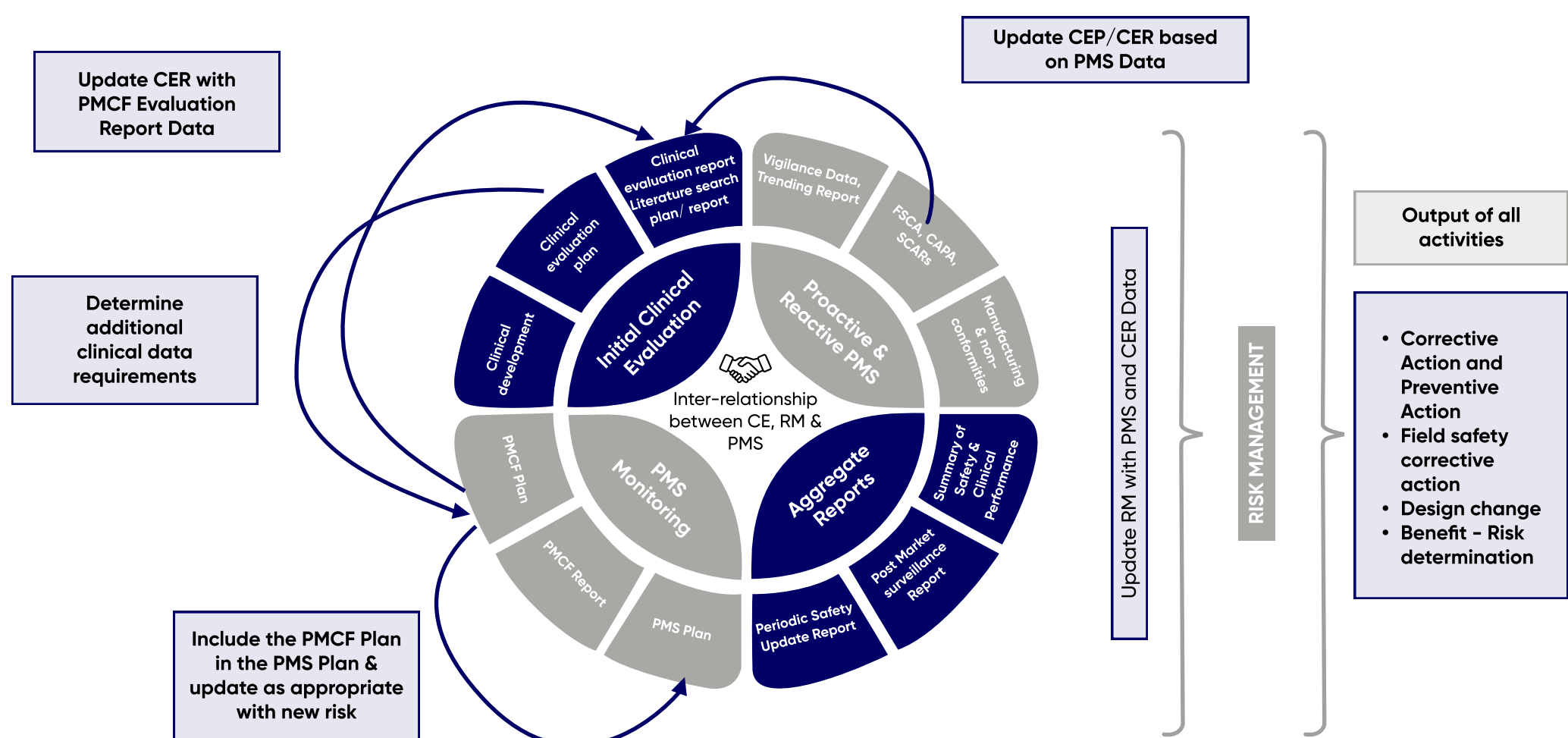
Pre & Post marketing Risk management services:

- Preliminary hazard analysis
- Risk Management Plan (RMP)
- Risk acceptability policy
- Risk management Matrix
- Benefit-risk determination
- Production & Post Production risk review
  - Risk Impact Assessment
  - Health Hazard evaluation
- Risk management review Report

We offer a full spectrum of services tailored to meet the unique needs of medical device safety. Our expertise includes:

- Drug-Device Combinations: Drug-Eluting Stents, Inhalers, Transdermal Patches etc
- Invasive Devices: Surgical Instruments, Implants etc.
- Non-Invasive Devices: Diagnostic Imaging Equipment, Therapeutic Devices etc

## Impact Assessment on other Linkage System



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