Benefit-risk Assessment

Balancing risks for Patient Safety

We support you in navigating benefit-risk assessments by balancing product benefits and risks to align with regulatory expectations, reimbursement needs, and healthcare provider priorities.

At COD Research, we provide a comprehensive suite of services for Medical Devices, ensuring compliance with applicable laws and regulations while supporting manufacturers in meeting the highest quality and safety standards.

With our expertise, you gain a reliable partner to ensure your CERs includes risk-benefit analysis as per the appropriate methodologies and regulatory standards.

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.

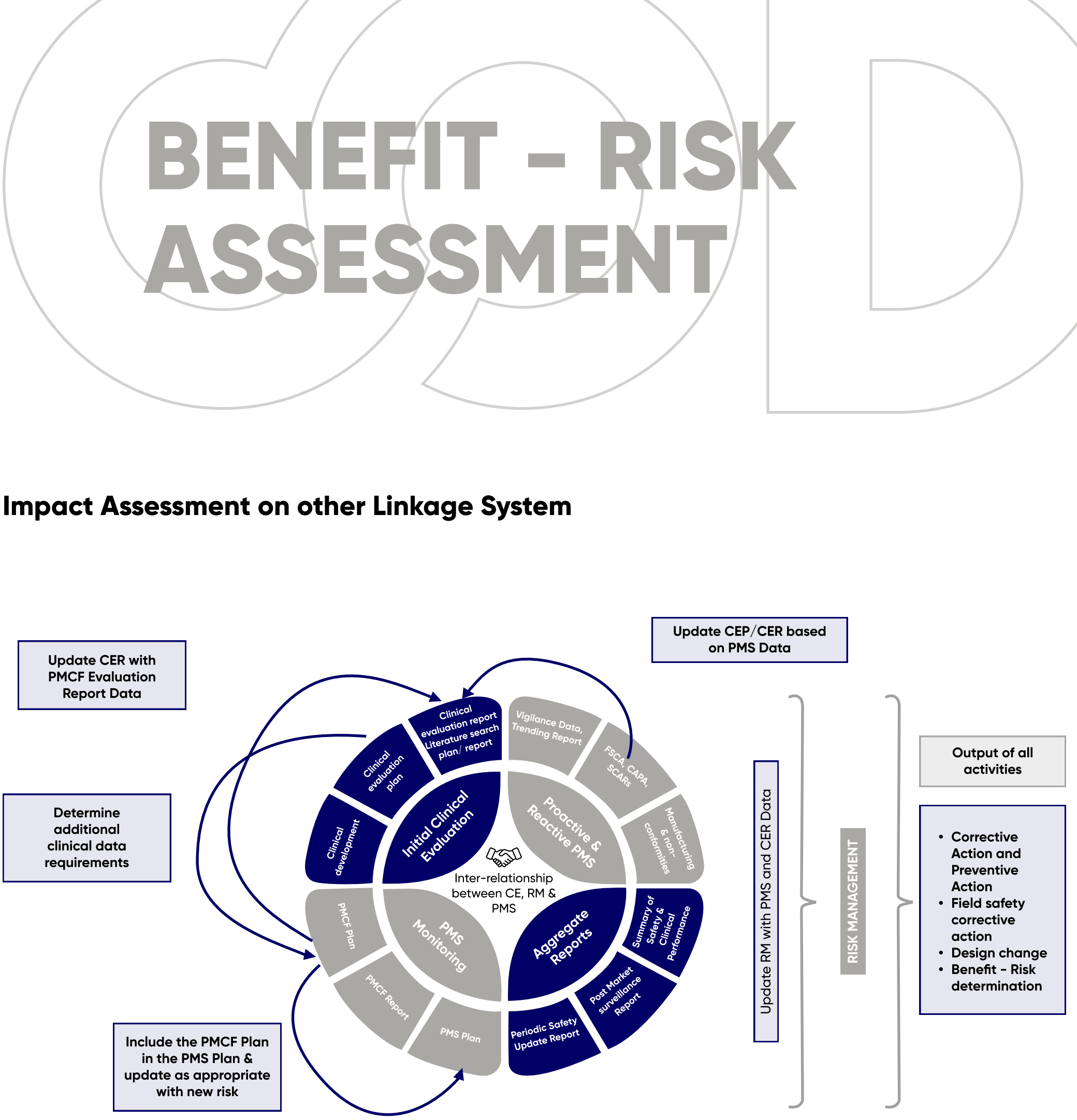
Our services include:

Preparation of Benefit Risk Assessment Document (BRAD) which includes following activities:

- Support in Structured approach for evidence generation
- Incorporating patient and/or User preferences
- Implementing Risk controls/ design change (Device) OR additional risk minimization measures, and studies to evaluate their effectiveness (Drug)
- Initiating post marketing safety studies and/or comparative effectiveness studies

BENEFIT - RISK ASSESSMENT

Impact Assessment on other Linkage System



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