

SERVICES

CLINICAL SAFETY

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Safety prevails efficacy

Being a full-fledged CRO, developmental safety is a natural progressive line for us. Our team has hands on talent to work in early and late phase clinical trials for ensuring safety monitoring.

Our service line for developmental safety includes following:



CT INITIATION SUPPORT

Safety Management
Plan (SMP)

Site training for AE/SAE
assessment and safety reporting

24x7 Clinical Site
Inquiry Support



EU CT Portal Management Support

RPEV

CTIS Portal
Management



CT AE/SAE Management

AE/SAE
Processing

SUSAR Processing
and submission

AOSE
Preparation



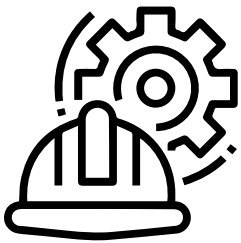
CT Medical Safety

Periodic Safety
Listing Review

SAR/SUSAR Line
Listing Report

Risk Management
Strategies

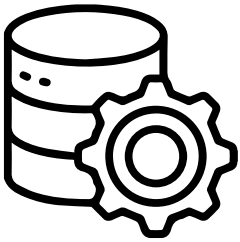
(DSUR) Development
Safety Update Report



**CT INITIATION
SUPPORT**

Our CT and PV Experts along with Medical Monitors develop a pragmatic Plan on safety management to foster correct safety information collection.

**EU CT PORTAL
MANAGEMENT SUPPORT**



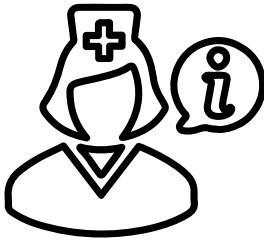
COD provides RPEV services for their European CT partners. COD has in-house RPEV, certified with EMA knowledge certification, having hands on experience to manage Eudravigilance.



**CT AE/SAE
MANAGEMENT**

Our team of safety CT physicians and Pharmacists manage AE/SAE right from case receipt to submission globally. With categorical experience in processing SUSAR with AOSE, trial compliance are in safe hands when CT Processing is considered. Team has experience working on 5 different safety databases, making them versatile to act as FSP experts as needed.

**CT MEDICAL
SAFETY**



COD considers itself expert when it comes to Medical Safety aspect, as we have collective experience of supporting DSUR/ASR/LLR/DRMP preparation, expert review and submission support.

Our experience ranges from drug, combination product, vaccines, biosimilar, biologics, nutraceuticals and cosmetic products.



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