

# Safety Reporting Services to Centralize Your Submission Process



PPD's central safety reporting team (CSRT) provides a **streamlined, systematic approach** to **safety submissions** for regulatory authorities, ethics committees and investigator sites.

## Services to meet your needs

Through our expert knowledge and global team of 120+ dedicated professionals, we consistently exceed 99.5% submission compliance. Our services range from individual case safety report submissions in the pre- and post-stages, aggregate report submissions, EudraVigilance services including Responsible Person/Trusted Deputy, EudraVigilance Medicinal Product Dictionary (xEVMPD) registration and regulatory intelligence monitoring. Our services also include:

- Web portal submissions to regulatory authorities (RAs) and ethics committees (ECs)
- EudraVigilance submissions via WebTrader
- Gateway submissions through safety databases
- Investigator submissions by electronic web portal
- Case reportability assessments
- Unblinding services for regulatory reporting
- Translation services
- Vendor management
- Safety reporting hubs in the U.S., U.K. and Philippines
- Local teams in Russia, China, India and Latin America

## Maintaining safety and compliance requirements

Centralized Regulatory Authority and Ethics Committee Tracking (CREST) is a proprietary technology built by PPD to facilitate the creation, tracking and documentation of regulatory report submissions. This innovative technology automates and centralizes the safety report submission process along with providing the following benefits:

- Automates the process for safety report submissions for RAs and ECs
- Integrates data from PPD's clinical trial management system (CTMS) and regulatory intelligence database to allow for real-time study data and regulatory intelligence
- Allows the CSRT to focus on the accuracy and timeliness of submissions
- Generates comprehensive compliance and metrics reports
- Increases oversight and awareness of submissions

**31,000+**  
Reports to  
**3.2 million**  
Recipients



**26,000+**  
Reports to  
**3.5 million**  
Recipients

