

We offer...

- **Hosted E2B-compliant web-based database solution** for electronic transmission and management of adverse reaction reports (ICSRs/SUSARs)
- **Transmission via gateway**
- **Autonomous case management and electronic transmission by users** within their own secure account
- **Retention and administration of non-reportable case reports**
- **Fully validated system – according to GAMP-Standards**
- **System owned by German Pharmaceutical Industry Association (BPI e.V.)** – independent of commercial provider
- **Helpdesk** with personal telephone support

For more information, please visit www.psur.de or www.bpi-service.de

Pooling Project Pharmacovigilance

BPI-Pheda Pharmacovigilance
Database

Our Clients

- **Small and medium sized pharmaceutical companies** with a small number of reportable adverse reaction reports seeking cost-efficient pharmacovigilance solutions
- **Small and medium sized CROs** who wish to offer their clients low-cost SUSAR reporting and user-friendly data management

Modular service

- **Hosted database solution (BPI-Pheda)**
- **Optional MedDRA Group License** for companies with small case load and low turnover
- **Optional data entry** for companies with very small case load

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Or send us an email or call us at:

info@bpi-service.de +49 30 27909 - 136

Key features

- **Hosted E2B-compliant software solution** – no software installation by user
- **Gateway transmission**
- **Online access**
- **User-friendly** user interface
- **Data queries**
- **Generation of CIOMS**
- **Generation of tables for reports** (PSURs, Annual Safety Reports)
- **Fully validated system** (GAMP)
- **Integrated MedDRA Browser**
- **Updates and MedDRA Dictionary managed centrally**
- **Support for EudraVigilance registration & other European authorities**