

## Pharmacovigilance – Acronyms

Im den letzten Jahren nahm der Einsatz von Abkürzungen drastisch zu, so dass auch ein Experte die Übersicht leicht verliert. Allein im Bereich der Pharmakovigilance werden zahlreiche neue Abkürzungen verwendet.

Die folgende Liste soll eine Hilfestellung für die Praxis sein.

<b>ADR</b>	Adverse Drug Reaction
<b>ADSL</b>	Asymmetric Digital Subscriber Line
<b>CHMP</b>	Committee for Medicinal Products for Human Use
<b>CVMP</b>	Committee for Veterinary Medicinal Products
<b>DBMS</b>	Database Management System
<b>DIA</b>	Drug Information Association
<b>DTD</b>	Data Type Definition
<b>E2B</b>	Clinical Safety Data Management: Data Elements for Transmission of ICSRs
<b>EC</b>	European Commission
<b>EDI</b>	Electronic Data Interchange
<b>EEA</b>	European Economic Area
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Associations
<b>EMA</b>	European Medicines Agency
<b>ESTRI</b>	Electronic Transfer of Regulatory Information Gateway
<b>EU</b>	European Union
<b>EV</b>	EudraVigilance
<b>EVCTM</b>	EudraVigilance Clinical Trials Module
<b>EVMPD</b>	EudraVigilance Medical Product Dictionary
<b>EV PM</b>	EudraVigilance Post-Authorisation Module
<b>EWG</b>	Expert Working Group <b>oder</b> Europäische Wirtschaftsgemeinschaft
<b>ICH</b>	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
<b>ICSRs</b>	Individual Case Safety Reports
<b>ICT</b>	Information and Communications Technologies
<b>IDA</b>	Interchange of Data between Administrations

<b>IMP</b>	Investigational Medicinal Product
<b>JIG</b>	The Joint Implementation Group
<b>M2</b>	Electronic Standards for Transmission of Regulatory Information (ESTRI)
<b>MAH</b>	Marketing Authorisation Holder
<b>MedDRA</b>	Medical Dictionary for Regulatory Activities
<b>MedDRA MSSO</b>	MedDRA Maintenance and Support Services Organization
<b>MR</b>	Mutual Recognition
<b>MS</b>	EU Member State
<b>NCS</b>	Non Commercial Sponsor of clinical trials
<b>PASS</b>	Post-authorisation Safety Study
<b>PMS study</b>	Post-Marketing Safety study
<b>PSUR</b>	Periodic Safety Update Report
<b>RAS</b>	Rapid Alert System
<b>SAR</b>	Serious Adverse Drug Reaction
<b>SGML</b>	Standard Generalised Markup Language
<b>SMEs</b>	Small and Medium Size Enterprises
<b>SPC</b>	Summary of Product Characteristics
<b>SUSAR</b>	Suspected Serious Unexpected Adverse Reactions
<b>TIG</b>	Telematic Implementation Groups
<b>TMC</b>	Telematic Management Committee
<b>TSC</b>	Telematic Steering Committee
<b>VICH</b>	International Co-operation on Harmonization of Technical Requirements of Veterinary Medicinal products
<b>XML</b>	Extensible Markup Language