



Pharmacovigilance Services
and Digitalisation

Our Services



Laboratory Services



Pharmacovigilance



Drug Development



QP services



HWI Pharmacovigilance & Vigilance for Medical devices

- HWI provides vigilance services since 2002
- The vigilance department is located at the HWI headquarter in Ruelzheim
- Personal: 4 QPPVs, 16 experts, administrative staff
- Maintenance of 350 marketing authorisations with 250 active substances
- Member of ecosystem AIQNET (Medical Data Ecosystem)



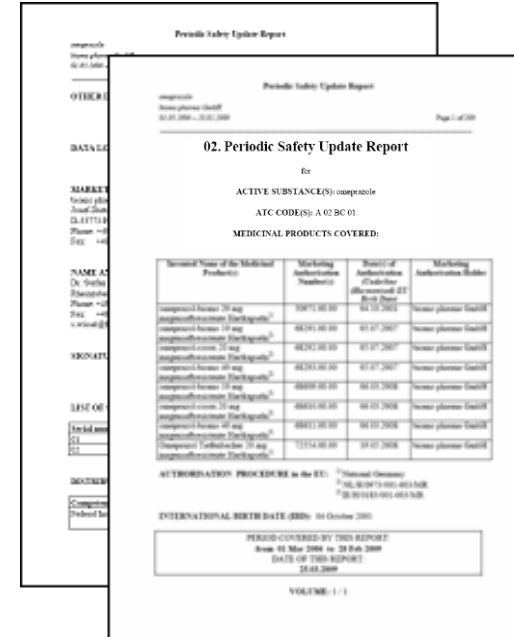
HWI services in Pharmacovigilance

- Adoption of responsibility as EU-QPPV and graduated plan officer (“Stufenplanbeauftragter”) by our own staff
- Case processing
- Periodic reports
- Risk management plans
- Continuous monitoring of the risk-benefit balance
- Signal management



HWI services in Pharmacovigilance

- Review and gap-analysis of your pharmacovigilance system
- Compilation and maintenance of the pharmacovigilance system master file (PSMF)
- Planning and performance of GVP-audits and self-inspections
- Performance of PV-trainings
- Submission of data to the Medicinal Product Dictionary (XEVPRM/XEVMPD)
- We have our own comprehensive GVP-compliant pharmacovigilance system (incl. CTD Module 1.8.1).



Periodic Safety Update Report

OTHER INFORMATION

DATE

MARKET INFORMATION

NAME AND ADDRESS

LIST OF

02. Periodic Safety Update Report

for

ACTIVE SUBSTANCE(S): omperzone

ATC CODE(S): A 02 BC 01

MEDICINAL PRODUCTS COVERED:

General Name of the Medicinal Product(s)	Marketing Authorisation Number(s)	Strength of Active Substance (Active Ingredient)	Marketing Authorisation Holder
component active 20 mg omperzone (Eurymed)	10077.00.00	20 mg/200 mg	Novartis Pharma GmbH
component active 10 mg omperzone (Eurymed)	48261.00.00	10 mg/200 mg	Novartis Pharma GmbH
component active 10 mg omperzone (Eurymed)	48262.00.00	10 mg/200 mg	Novartis Pharma GmbH
component active 40 mg omperzone (Eurymed)	48263.00.00	40 mg/200 mg	Novartis Pharma GmbH
component active 10 mg omperzone (Eurymed)	48264.00.00	10 mg/200 mg	Novartis Pharma GmbH
component active 20 mg omperzone (Eurymed)	48265.00.00	20 mg/200 mg	Novartis Pharma GmbH
component active 40 mg omperzone (Eurymed)	48266.00.00	40 mg/200 mg	Novartis Pharma GmbH
component active 10 mg omperzone (Eurymed)	11114.00.00	10 mg/200 mg	Novartis Pharma GmbH

AUTHORISATION PROCEDURE in the EU: ^{(1) National Generic}
EU, ^{(2) EU} 48261-48266, 11114
^{(3) EU} 48261-48266, 11114


INTERNATIONAL BIRTH DATE (IBD): 04 October 2000

PERIOD COVERED BY THIS REPORT
from 01 Mar 2008 to 28 Feb 2009
DATE OF THIS REPORT
28.02.2009

VOLUME: 1 - 1

HWI services in Vigilance for medical devices

- Analysis of serious incidents and field safety corrective actions (Art. 89)
- Reporting of serious incidents (MIR form) and field safety corrective actions (MDR Art. 87)
- Trend reporting (MDR Art. 88)
- Periodic safety update reports (MDR Art. 86)



Manufacturer Incident Report (MIR) for
Serious Incidents (MDR/IVDR)
and Incidents (AIMDD/MDO/IVDD)

Reporting template

Section 2: Administrative information

2.1 Corresponding competent authority

2.2 Manufacturer name

2.3 Product name

2.4 Device type

2.5 Incident type

2.6 Incident date

2.7 Incident location

2.8 Incident description

2.9 Incident classification

2.10 Incident status

2.11 Incident severity

2.12 Incident impact

2.13 Incident cause

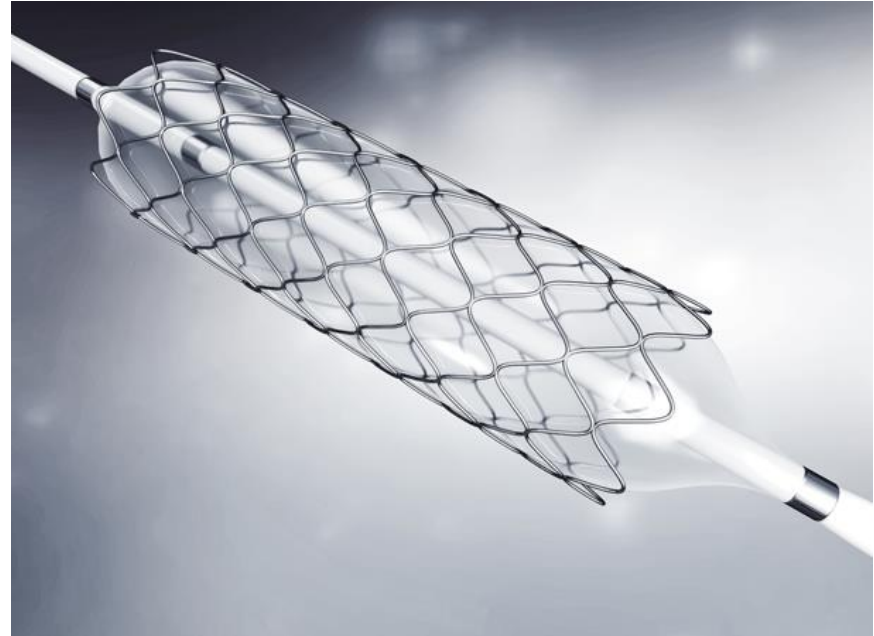
2.14 Incident consequences

2.15 Incident mitigation

2.16 Incident prevention

2.17 Incident follow-up

2.18 Incident closure



AIQNET

- HWI group is one of the winners of the BMWK AI Innovation Competition 2019
- HWI group is part of the consortium of 16 partners from the medical device industry, technology providers, and university hospitals
- Shared goal of the project is the intelligent use of medical data - with the HWI group focussing on vigilance processes
- Project launch: January 2020
- End of Project: June 2023
- Project volume: 15.7 million Euro

Supported by:



on the basis of a decision
by the German Bundestag



Software Made by Experts for Experts

In 2020, HWI founded a Digital Services department to create tailor-made apps for the pharmaceutical value chain.



Apps are created in **close collaboration** between data scientists, pharmacovigilance experts, and QA experts to ensure **regulatory compliance** and adherence to best practices (**GxP**).

Design Thinking methodology & modern software development methods are used to fuel **innovation** and create **modular, easy-to-use** apps.

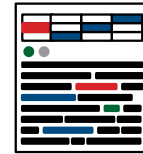
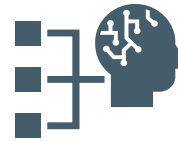
Document Retrieval & Augmentation Pipeline



PubMed



PMC



Search via
PubMed API

Full-text
retrieval

Statistical
and AI analysis

Creation of
annotated
article dossiers

fully automated process

Literature Assessment & Search Profile Management in the Vigilance App

Home • EKnow • PV Pubmed Research • Literature • References • Audit Trail • Links

Home / Research Assignments

Status:

Year: Week: Name: PPR Group:

Updated from: 01.01.2020 Updated to: 14.05.2024 Created from: 01.01.2020 Created to: 14.05.2024

[View](#) [Sign](#)

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Action	Status	Name	PPR Group	Timeframe	Articles	Finalized	Pend. Clarif.	Pend. Final.	In Progress	Not Started	Created	Updated	Signed	Signer
View	ready	[REDACTED]	[REDACTED]	W19 (06.05.-12.05.2024)	47	0	0	0	0	0	2024-05-14T00:00:06.270000	2024-05-14T03:02:46.380000		
View	finalized	[REDACTED]	[REDACTED]	W18 (29.04.-05.05.2024)	39	39	0	0	0	0	2024-05-07T00:00:09.547000	2024-05-08T07:36:39.953000	2024-05-08T07:36:39.953000	[REDACTED]
View	finalized	[REDACTED]	[REDACTED]	W17 (22.04.-28.04.2024)	84	84	0	0	0	0	2024-04-30T00:00:04.733000	2024-05-02T12:18:51.467000	2024-05-02T12:18:51.467000	[REDACTED]
View	finalized	[REDACTED]	[REDACTED]	W16 (15.04.-21.04.2024)	51	51	0	0	0	0	2024-04-23T00:00:05.480000	2024-04-24T15:07:09.413000	2024-04-24T15:07:09.413000	[REDACTED]
View	pending finalisation	[REDACTED]	[REDACTED]	W15 (08.04.-14.04.2024)	74	72	0	2	0	0	2024-04-16T00:00:05.990000	2024-04-17T09:14:19.353000	2024-04-17T09:14:19.353000	[REDACTED]
View	finalized	[REDACTED]	[REDACTED]	W14 (01.04.-07.04.2024)	47	47	0	0	0	0	2024-04-09T00:00:05.670000	2024-04-09T08:31:25.260000	2024-04-09T08:31:25.260000	[REDACTED]

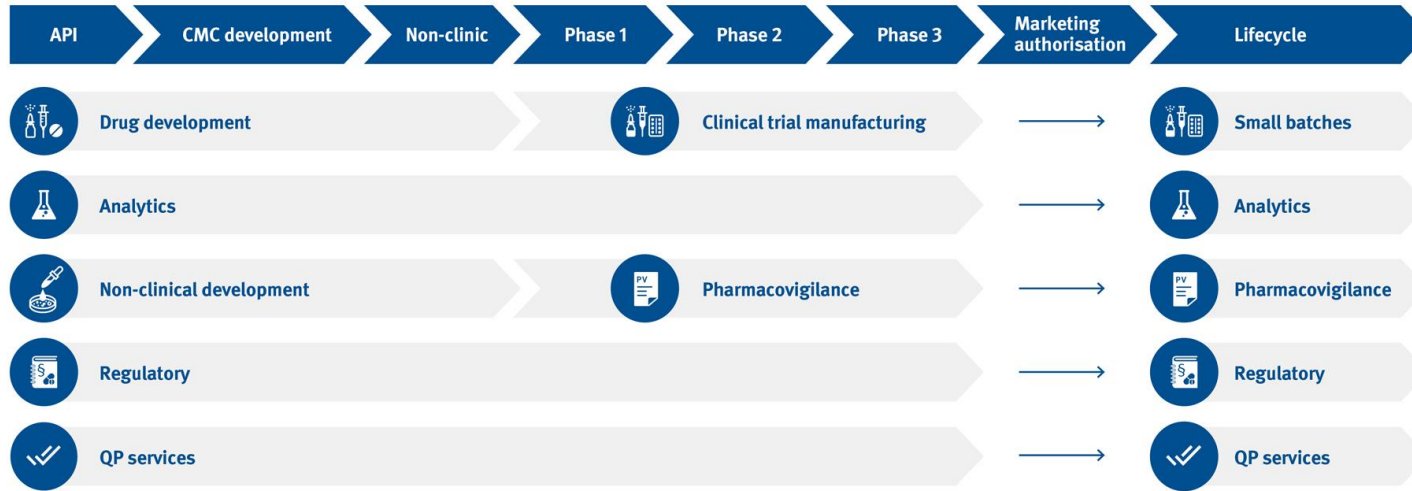
Key Benefits of App-driven Literature Assessment

- End-to-end documentation with detailed **audit trails**
- Experts **assisted by AI-based suggestions & smart highlights**
- Guided **workflows & data validation** reduce risk of errors
- Digital connections to other pharmacovigilance processes can leverage synergies to create a **360° approach to drug safety**



End-to-end service concept

Our services cover all phases of a pharmaceutical value chain



Technologies

Micro- and Nanotechnology | HSA-Carrier system | Highly flexible isolators & filling lines

Integrated Services

Development | Analytics | Regulatory strategy | Quality | Production & Packaging | Batch release

Digital Capabilities

Active ingredient data bases | Artificial intelligence | Specific algorithms for text recognition and literature research

Thank you for your attention.

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