



Pharmacovigilance Services
and Digitalisation

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)



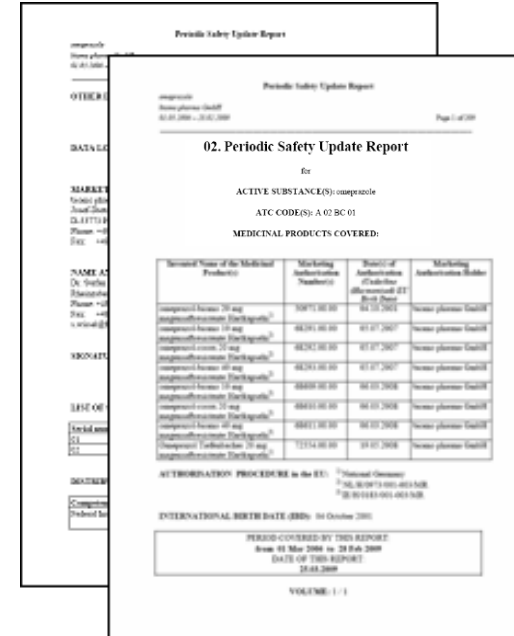
HWI services in Pharmacovigilance

- 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

02. Periodic Safety Update Report

for

ACTIVE SUBSTANCE(S): cospesolate

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 cospesolate/acetaminophen (Eurapharma)	10077.00.00	20.00/200.00	Novartis pharma GmbH
component active 10 mg cospesolate/acetaminophen (Eurapharma)	48261.00.00	10.00/200.00	Novartis pharma GmbH
component active 5 mg cospesolate/acetaminophen (Eurapharma)	48262.00.00	05.00/200.00	Novartis pharma GmbH
component active 40 mg cospesolate/acetaminophen (Eurapharma)	48263.00.00	40.00/200.00	Novartis pharma GmbH
component active 10 mg cospesolate/acetaminophen (Eurapharma)	48264.00.00	10.00/200.00	Novartis pharma GmbH
component active 20 mg cospesolate/acetaminophen (Eurapharma)	48265.00.00	20.00/200.00	Novartis pharma GmbH
component active 40 mg cospesolate/acetaminophen (Eurapharma)	48266.00.00	40.00/200.00	Novartis pharma GmbH
component active 10 mg cospesolate/acetaminophen (Eurapharma)	48267.00.00	10.00/200.00	Novartis pharma GmbH
component active 20 mg cospesolate/acetaminophen (Eurapharma)	11114.00.00	20.00/200.00	Novartis pharma GmbH

INTERNATIONAL HEADER Box 1E (2005) (30 October 2005)

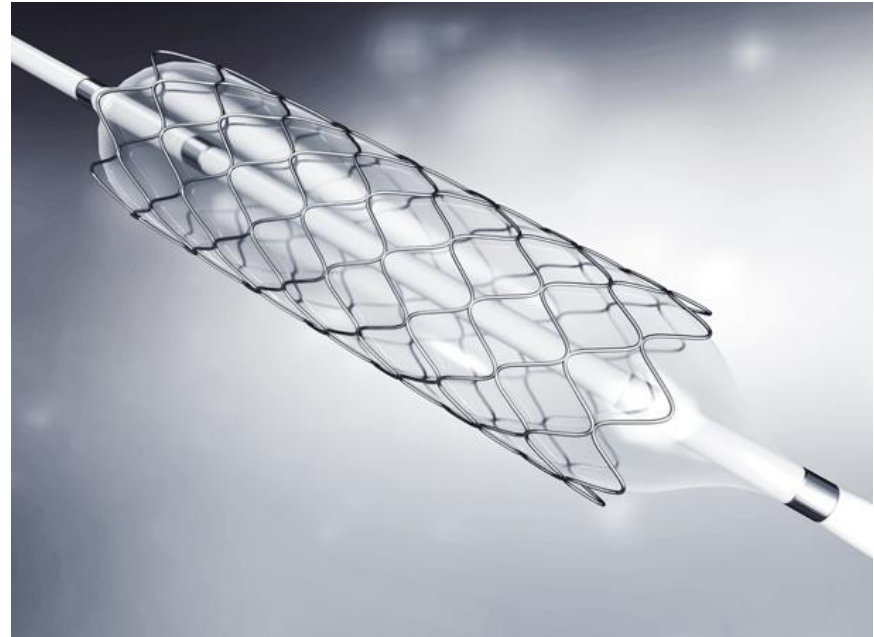
PERIOD COVERED BY THIS REPORT
From 01 Mar 2008 to 28 Feb 2009
DATE OF THIS REPORT
28.02.2009

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 - Version 2.0.0 European Union Medical Device Vigilance System	
Section 1: Administrative information	
1.1 Corresponding competent authority	<input type="text"/>
1.2 Reporting authority	<input type="text"/>
1.3 Reporting authority address, POC for the incident	<input type="text"/>
1.4 Reporting authority telephone number for the incident	<input type="text"/>
Section 2: Public type, and classification of incident report	
2.1 Public type	<input type="text"/>
2.2 Classification of incident report	<input type="text"/>
2.3 Submitter information	<input type="text"/>
2.4 Submitter of the report	<input type="text"/>
2.5 Submitter contact information	<input type="text"/>
2.6 Submitter telephone number for the incident	<input type="text"/>



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

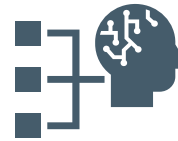
In 2020, HWI founded a Digital Services department to create tailor-made apps for the pharmaceutical value chain.



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



Search via
PubMed API

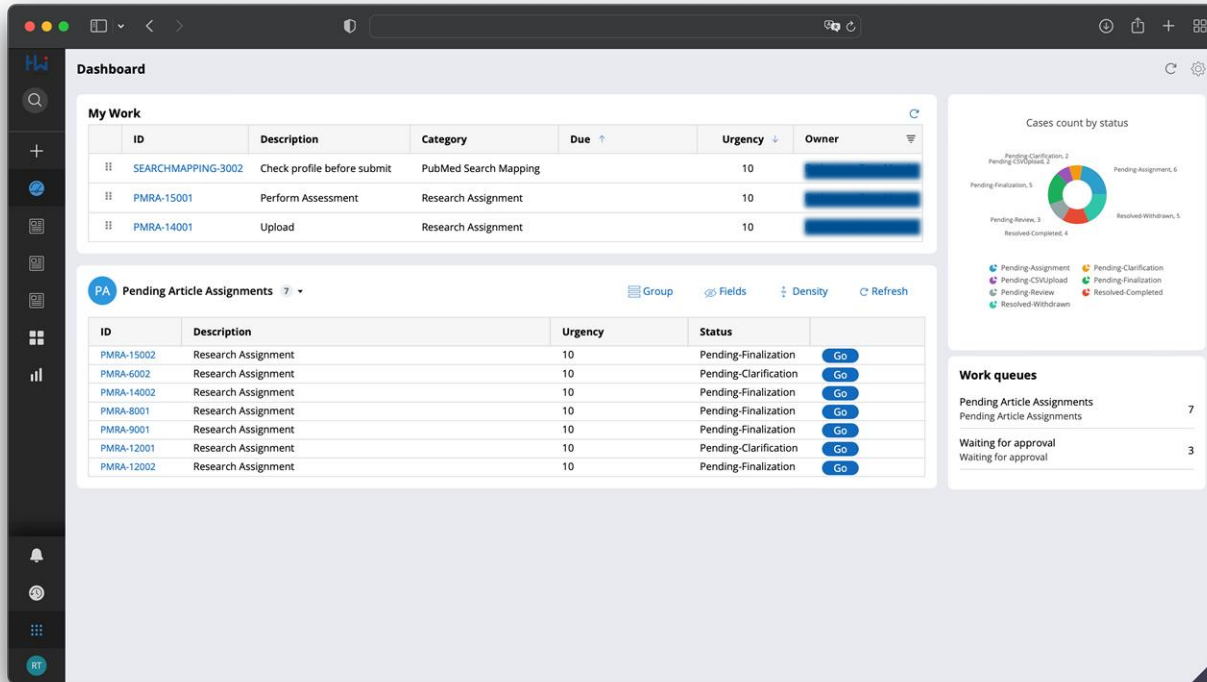
Full-text
Retrieval

Artificial
Intelligence
Microservices

Creation of
HTML-based
Dossiers

fully automated process

Literature Assessment & Search Profile Management App



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**



Thank you for your attention.

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