HWI group

Pharmacovigilance Services and Digitalisation

www.hwi-group.de

HWI Pharmacovigilance & Vigilance for Medical devices

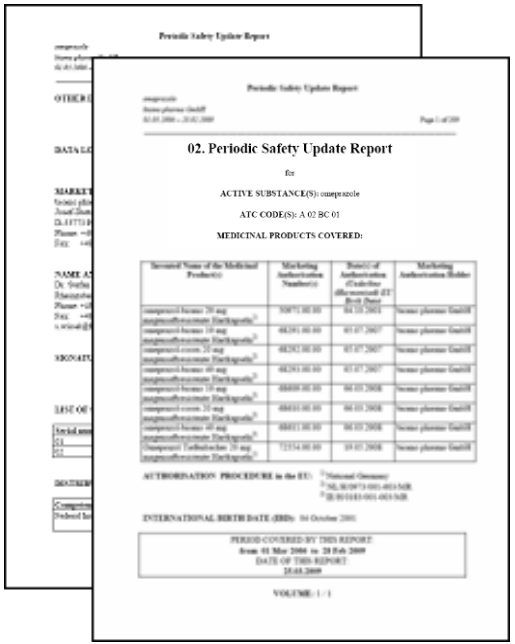
- HWI provides vigilance services since 2002
- The vigilance department is located at the HWI headquarter in Ruelzheim
- Personal: 4 QPPVs, 16 experts, administrative staff
- Maintenance of 350 marketing authorisations with 250 active substances
- Member of ecosystem AIQNET (Medical Data Ecosystem)

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

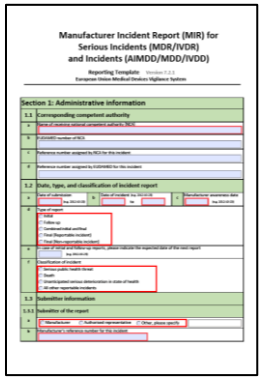
HWI services in Pharmacovigilance

- 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).



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/MDD/IVDD)

Reporting Template

Section 1: Administrative information

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:
Federal Ministry for Economic Affairs and Climate Action
on the basis of a decision by the German Bundestag

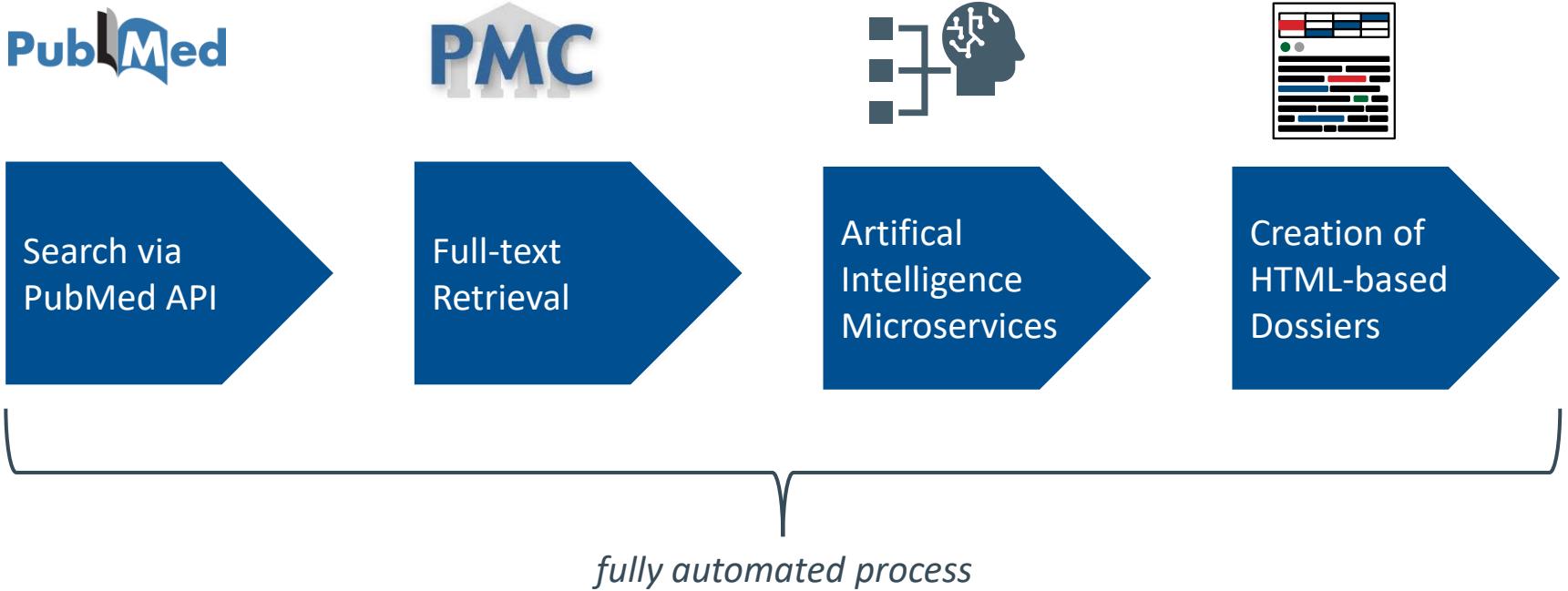
Software Made by Experts for Experts

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

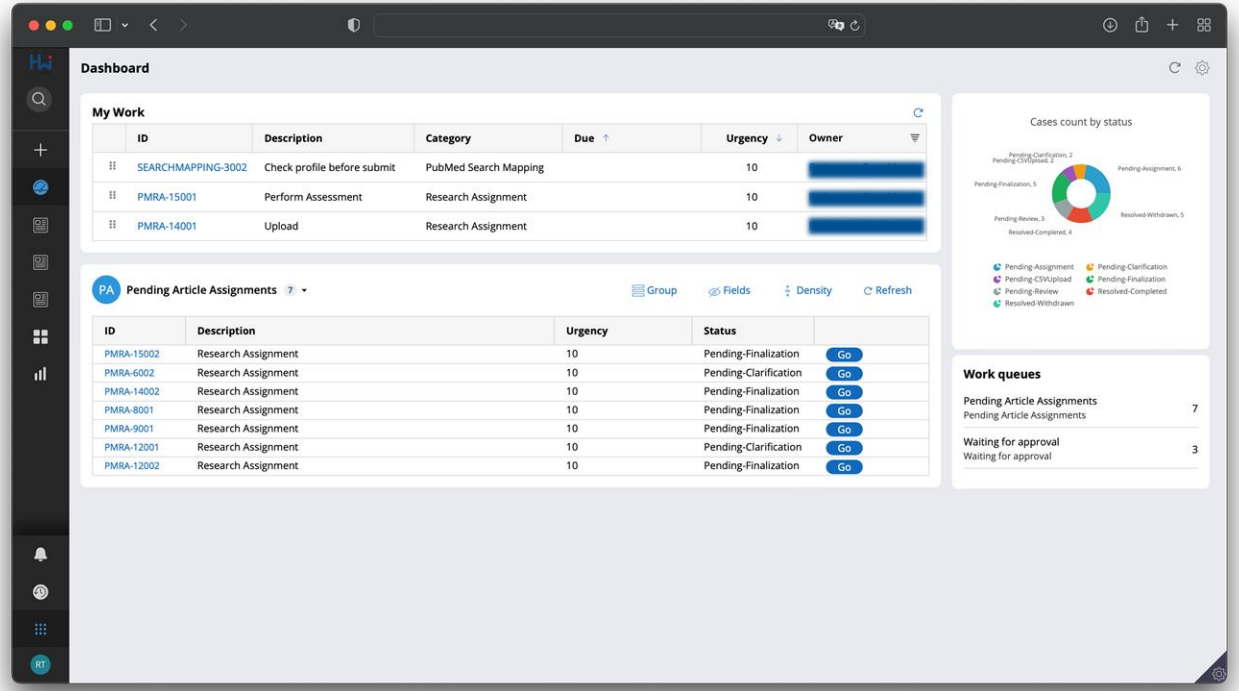
Apps are created in **close collaboration** between data scientists, pharmacovigilance experts, and QA experts to ensure **regulatory compliance** and adherence to best practices (**GxP**).

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

Document Retrieval & Augmentation Pipeline



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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