Pharmacovigilance Services

Your Trusted Partner in Pharmacovigilance

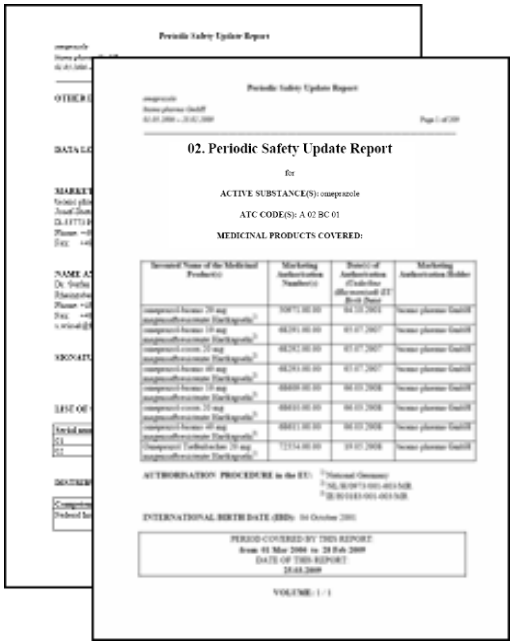
- HWI provides pharmacovigilance services since 2002
- The vigilance department is located at the HWI headquarter in Ruelzheim
- Personal: 6 QPPVs and GPOs, 13 experts, administrative staff
- Maintenance of 500 marketing authorisations with 250 active substances

Our Pharmacovigilance Services

We provide complete pharmacovigilance services or selected modules, including:

- Assumption of the EU-QPPV, Graduated Plan Officer and Information Officer roles by internal staff
- Individual Case Safety Report (ICSR) management
- Follow-up activities and MedDRA coding
- Signal detection, validation and evaluation
- Global and local literature screening
- Risk Management Plans (RMPs)
- Periodic Safety Update Reports (PSURs)

Our Pharmacovigilance Services



02. Periodic Safety Update Report

for

ACTIVE SUBSTANCE(S): esomeprazole

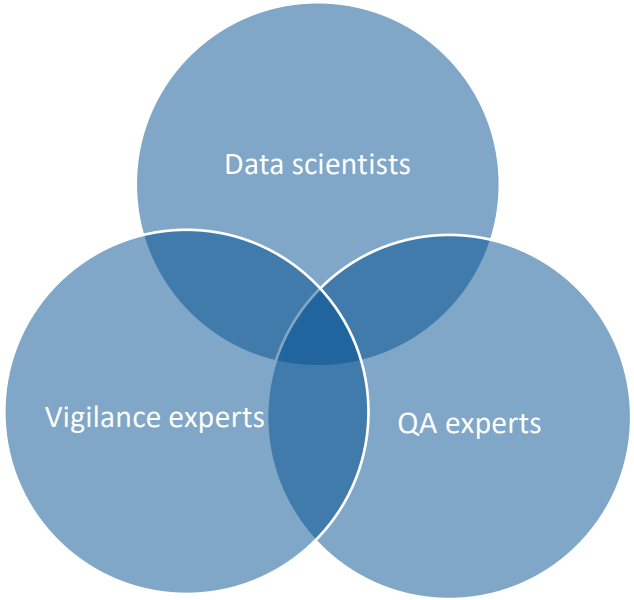
ATC CODE(S): A 02 BC 01

MEDICINAL PRODUCTS COVERED:

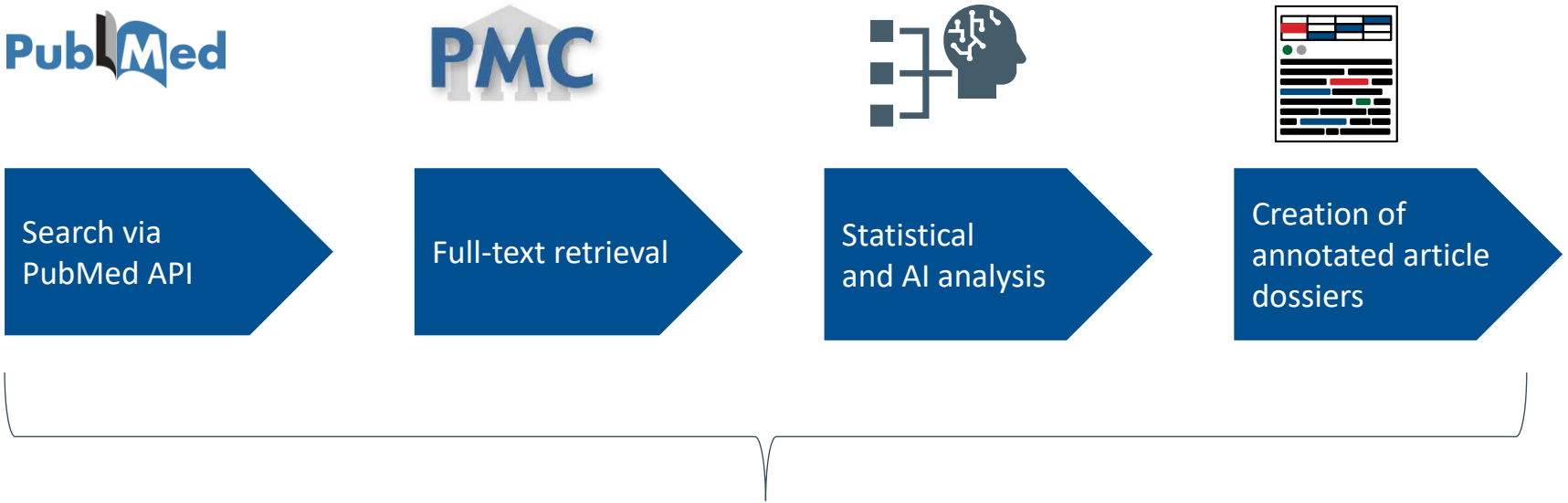
- Review and gap-analysis of your pharmacovigilance system
- Compilation and maintenance of the pharmacovigilance system master file (PSMF)
- Planning and performance of GVP-audits and self-inspections
- Performance of PV-trainings
- Submission of data to the Medicinal Product Dictionary (XEVPRM/XEVMPD)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

Software Made by Experts for Experts

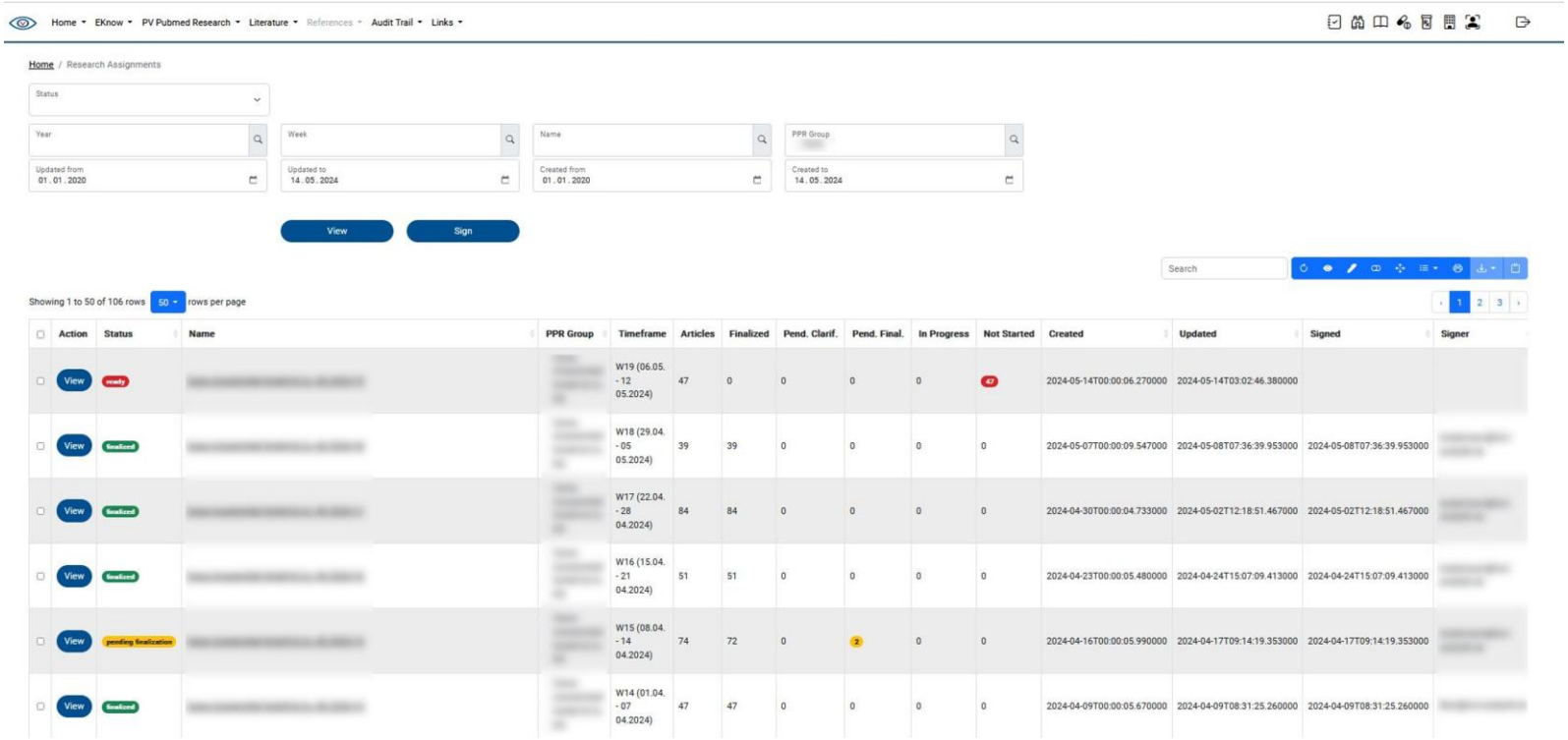
- In 2020, HWI founded a Digital Services department to create tailormade apps for the pharmaceutical services.
- Apps are created in **close collaboration** between data scientists, pharmacovigilance experts, and QA experts to ensure **regulatory compliance** and adherence to best practices (**GxP**).
- **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 in the Vigilance App



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	47	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 finalization	[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**

Thank you for your attention.

Lilia Selinger | Head of Sales
Mobil: +49 172 2113128 | Email: sales@hwi-group.de

Silvia Öttl | Sales Manager
Phone: +49 7272 7767-2561 | Email: sales@hwi-group.de