



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

Periodic Safety Update Report

02. Periodic Safety Update Report
for
ACTIVE SUBSTANCE(S): cimetidine
ATC CODE(S): A02 BC 01
MEDICINAL PRODUCTS COVERED:

International Name of the Medicinal Product(s)	Marketing Authorisation Number(s)	Start of Marketing Authorisation (EU)	Marketing Authorisation Holder
cimetidine 30 mg cimetidine (Eckaparis) ¹	50972.00.00	04.07.2002	Novartis Pharma GmbH
cimetidine 30 mg cimetidine (Eckaparis) ¹	48343.00.00	07.07.2002	Novartis Pharma GmbH
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cimetidine 30 mg cimetidine (Eckaparis) ¹	48343.00.00	06.07.2004	Novartis Pharma GmbH
cimetidine 30 mg cimetidine (Eckaparis) ¹	48343.00.00	06.07.2004	Novartis Pharma GmbH
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cimetidine 30 mg cimetidine (Eckaparis) ¹	48343.00.00	06.07.2004	Novartis Pharma GmbH
cimetidine 30 mg cimetidine (Eckaparis) ¹	12174.00.00	04.07.2004	Novartis Pharma GmbH

AUTHORISATION PROCEDURE in the EU: ¹ National Generic
² EU, 00/07/000-000-000
³ EU, 00/07/000-000-000

INTERNATIONAL BIRTH DATE (IBD): 04 October 2001

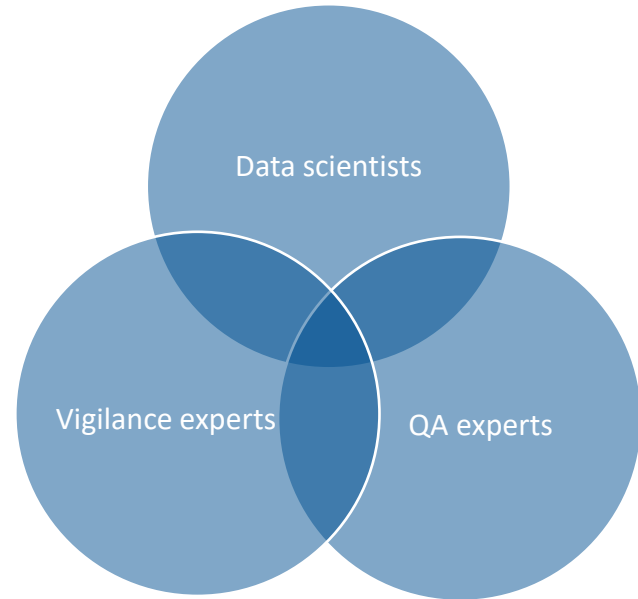
PERIOD COVERED BY THIS REPORT
From 01 Mar 2006 to 28 Feb 2009
DATE OF THIS REPORT
28.08.2009

VOLUME: 1 / 1

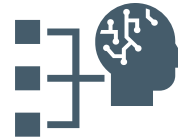
- Review and gap-analysis of your pharmacovigilance system
- Compilation and maintenance of the pharmacovigilance system master file (PSMF)
- Planning and performance of GVP-audits and self-inspections
- Performance of PV-trainings
- Submission of data to the Medicinal Product Dictionary (XEVPRM/XEVMPD)
- 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



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 / 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

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Search

Showing 1 to 50 of 106 rows rows per page

Action	Status	Name	PPR Group	Timeframe	Articles	Finalized	Pend. Clarif.	Pend. Final.	In Progress	Not Started	Created	Updated	Signed	Signer
View	ready			W19 (06.05.-12.05.2024)	47	0	0	0	0	-	2024-05-14T00:00:06.270000	2024-05-14T03:02:46.380000		
View	ready			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	
View	ready			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	
View	ready			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	
View	pending finalization			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	
View	ready			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	

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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