Uppsala Monitoring Centre

A short introduction

Uppsala Monitoring Centre

– Building a global safety culture

Our vision

a world where all patients and health professionals make wise therapeutic decisions in their use of medicines

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We achieve this by

supporting and promoting patient safety through building sustainable and effective pharmacovigilance practices globally

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Pharmacovigilance
WHO definition

Science and activities related to

- detection, assessment, understanding, prevention of

adverse effects or any other possible drug-related problems

- scope also includes
  - *SSFFC (spurious, substandard, falsely labeled, falsified, counterfeit medicines)*
  - *Antimicrobial resistance*
  - *Medication errors*
  - *Misuse*

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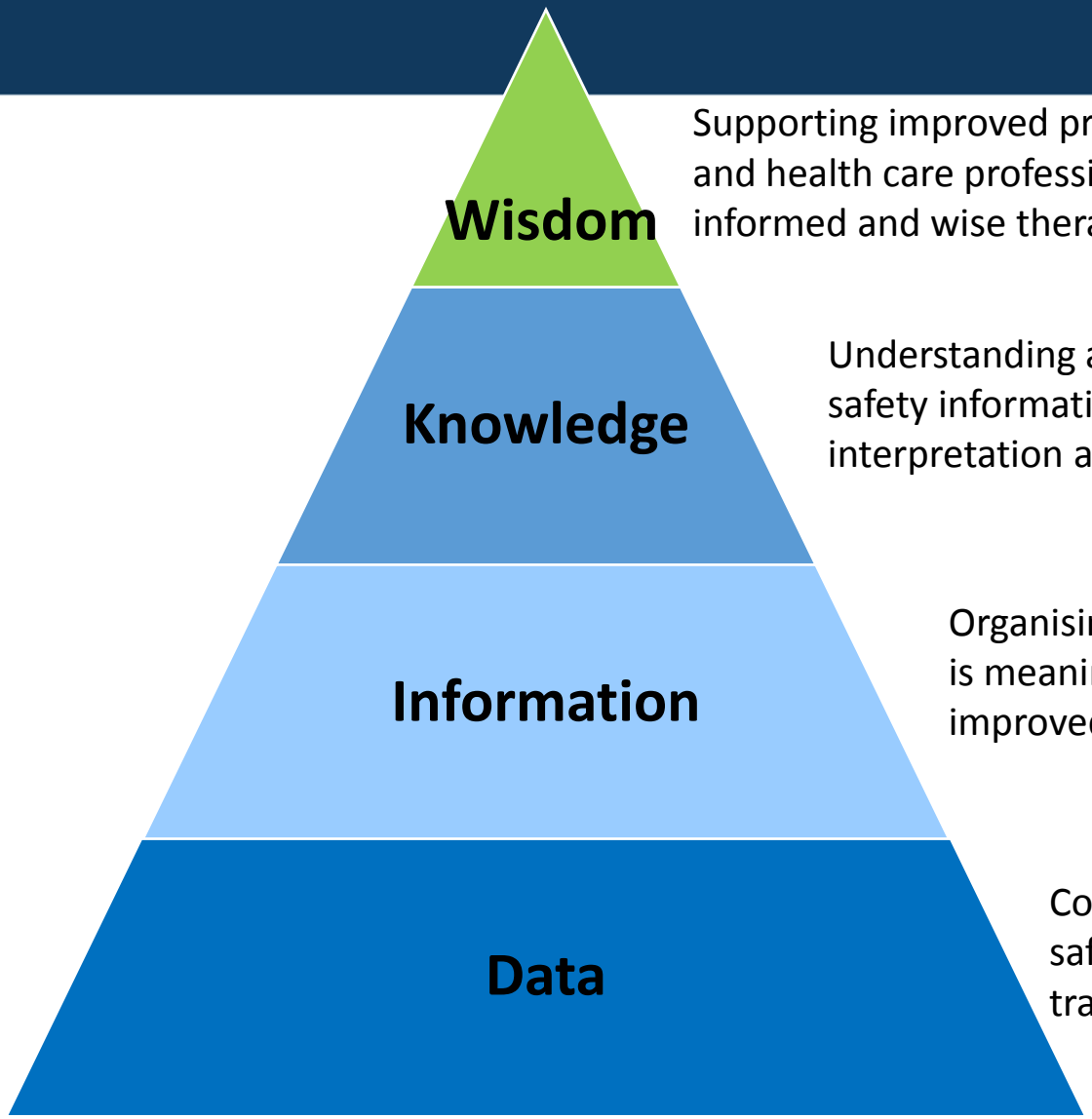
The pharmacovigilance value chain



Supporting improved practice by patients and health care professionals and enabling informed and wise therapeutic decisions

Understanding and applying patient safety information through analysis, interpretation and communication

Organising and providing data so that it is meaningful, valuable and relevant to improved patient safety

Collecting and managing raw patient safety data (which needs transformation to be useful)

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Uppsala Monitoring Centre (UMC)

A foundation based in Uppsala, Sweden

- Not-for-profit, independent, self-financing

Set up in 1978 as the WHO Collaborating Centre for International Drug Monitoring

- by agreement between Swedish government and World Health Organization (WHO)

Providing scientific leadership and operational support to the WHO International Drug Monitoring Programme

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The WHO Programme for International Drug Monitoring

A global pharmacovigilance network

- Started in 1968 to prevent future drug disasters
  - *by pooling data from 10 countries with existing post-marketing reporting systems*
- Has 121 member countries and 29 associate members
- Supported by UMC since 1978, and now also by Collaborating Centres in Ghana, Morocco, Netherlands

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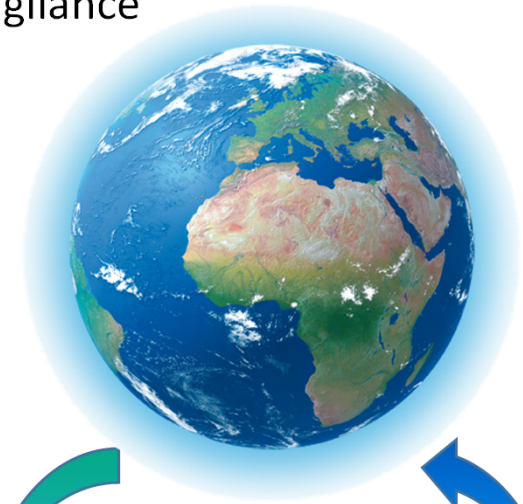
The WHO pharmacovigilance network

National pharmacovigilance systems



Norms and standards
Policy matters

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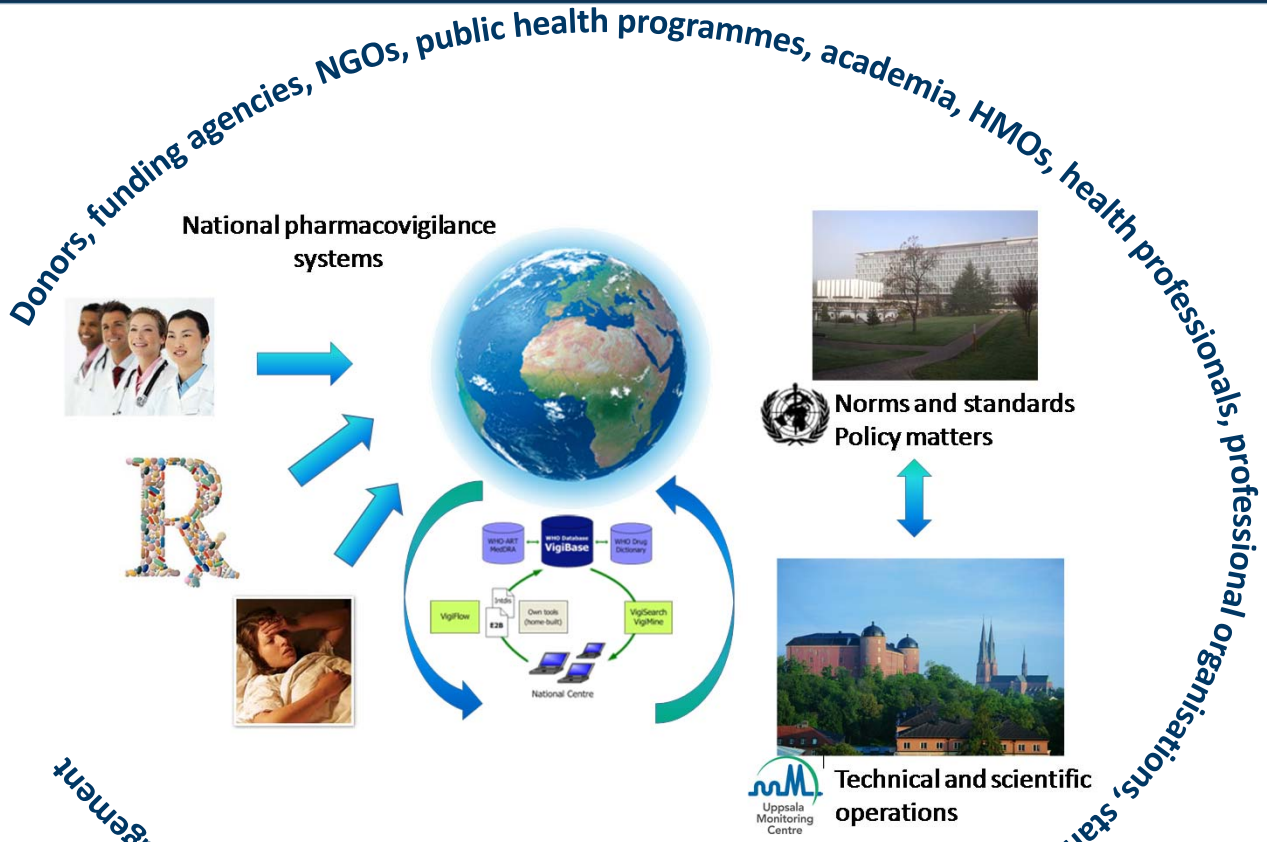
Technical and scientific operations

The wider circle



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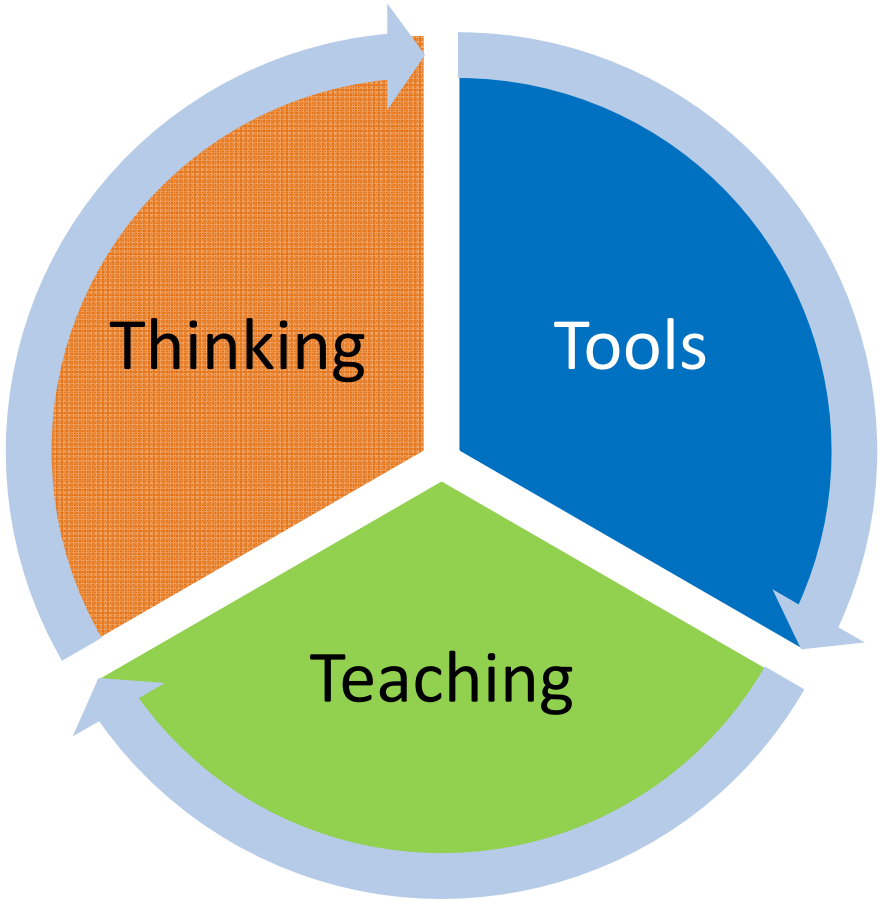
We build pharmacovigilance capacity by providing



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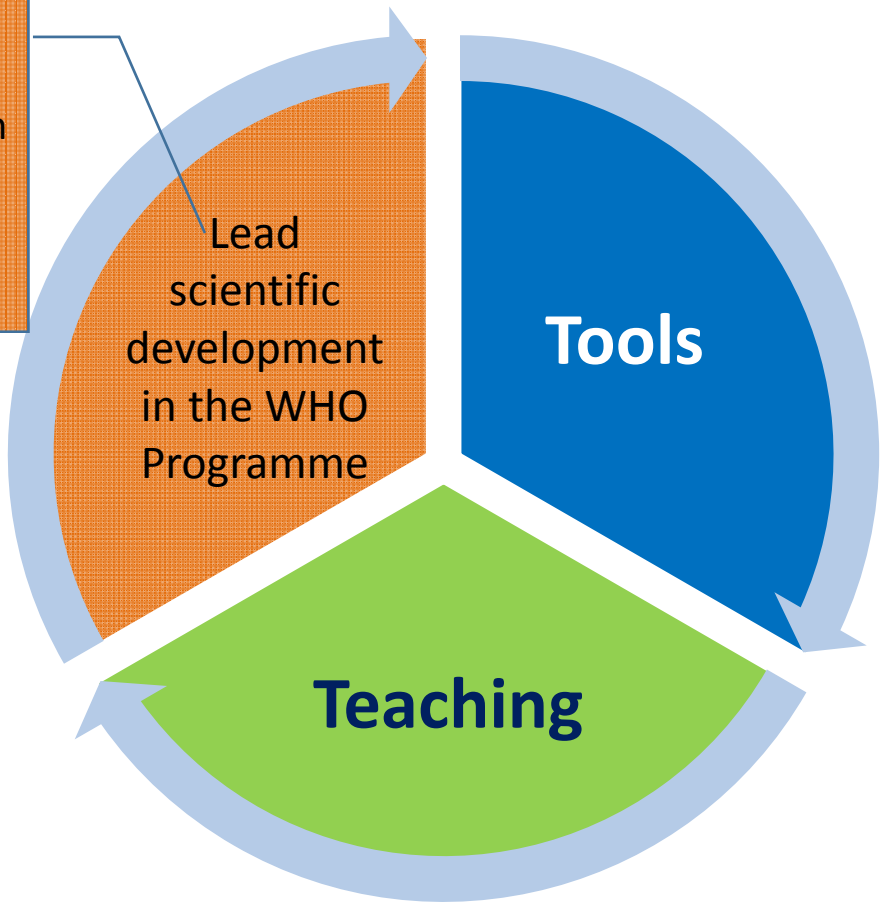
UMC's goals

- ✓ Find and explain important signals
- ✓ Develop best practices in pharmacovigilance
- ✓ Improve PV visibility and status



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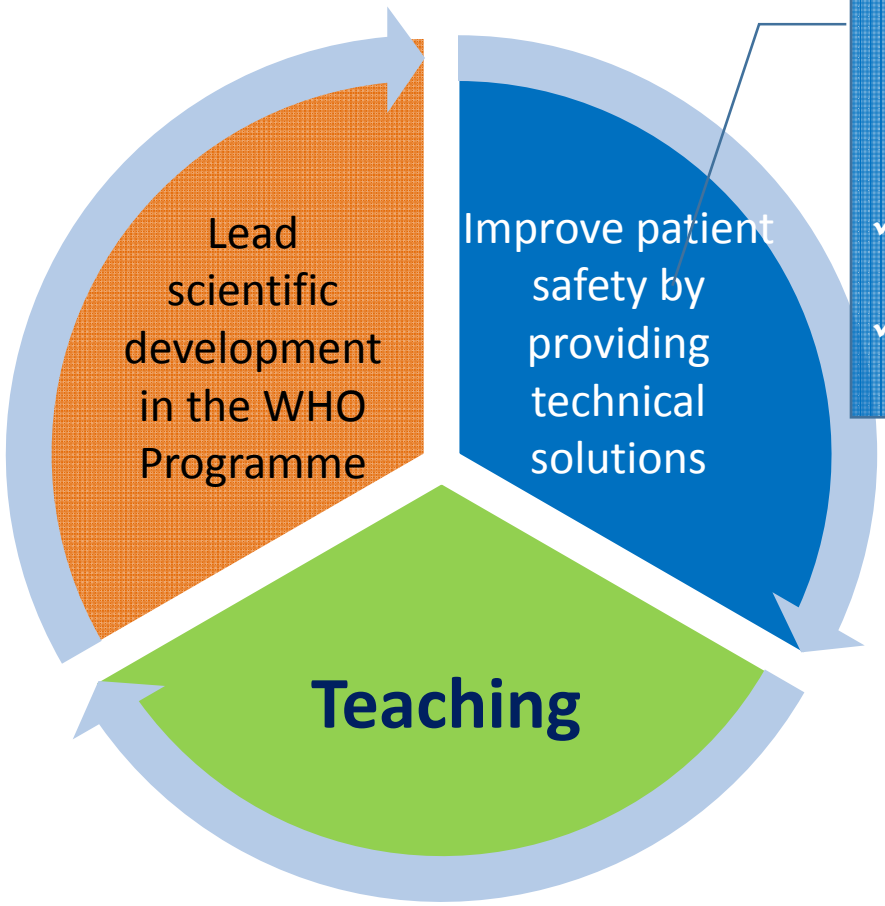
UMC's goals



- ✓ Provide technical solutions & tools that are
  - ✓ Useful
  - ✓ High quality
  - ✓ Cost-effective
- ✓ Global coverage and local applicability
- ✓ Funding to sustain the WHO Programme

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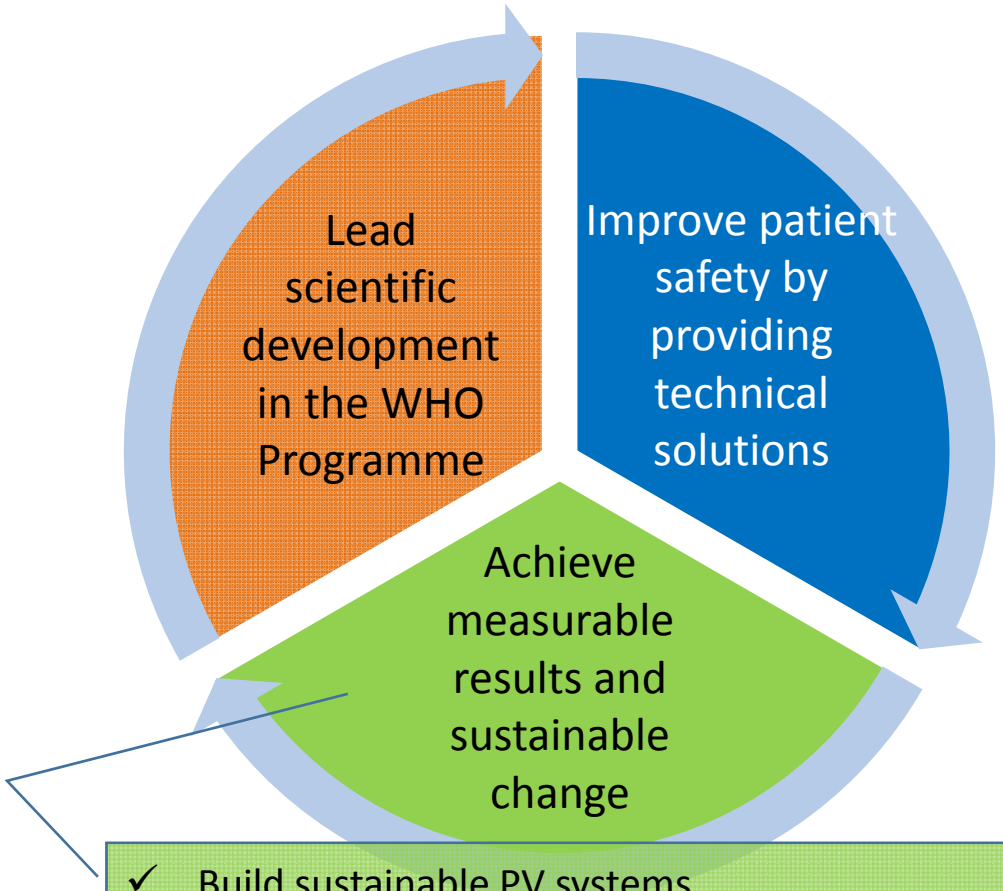
UMC's goals



- ✓ Build sustainable PV systems
- ✓ Support quality PV practices for all populations
- ✓ Evaluate PV systems performance

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How UMC supports the pharmacovigilance value chain

Research

VigiLyze™

Pushing boundaries

Analytical tools

Algorithms, methodology

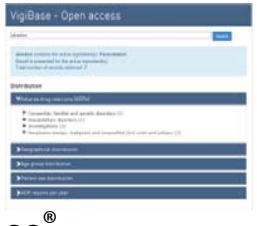
Terminologies, dictionaries for structured information

Data quality management tools

The global ICSR database, VigiBase

Reporting and data management tools, incl. patient/health professional reporting

Education & Training



vigiRank™

VigiAccess®

vigiMatch™

WHO-ART

WHO DDE

VigiFlow®

eReporting

WHO-ART

WHO DDE

VigiBase®

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The need for standards

- A drug dictionary and a medical event terminology were created in 1968 to enable efficient storage and analysis of the collected patient data
  - *WHODrug Dictionary (WHO-DD)*
  - *WHO Adverse Reaction Terminology (WHO-ART)*

  maintained and developed by UMC since 1978
- WHO International Nonproprietary Names used for all active pharmaceutical ingredients

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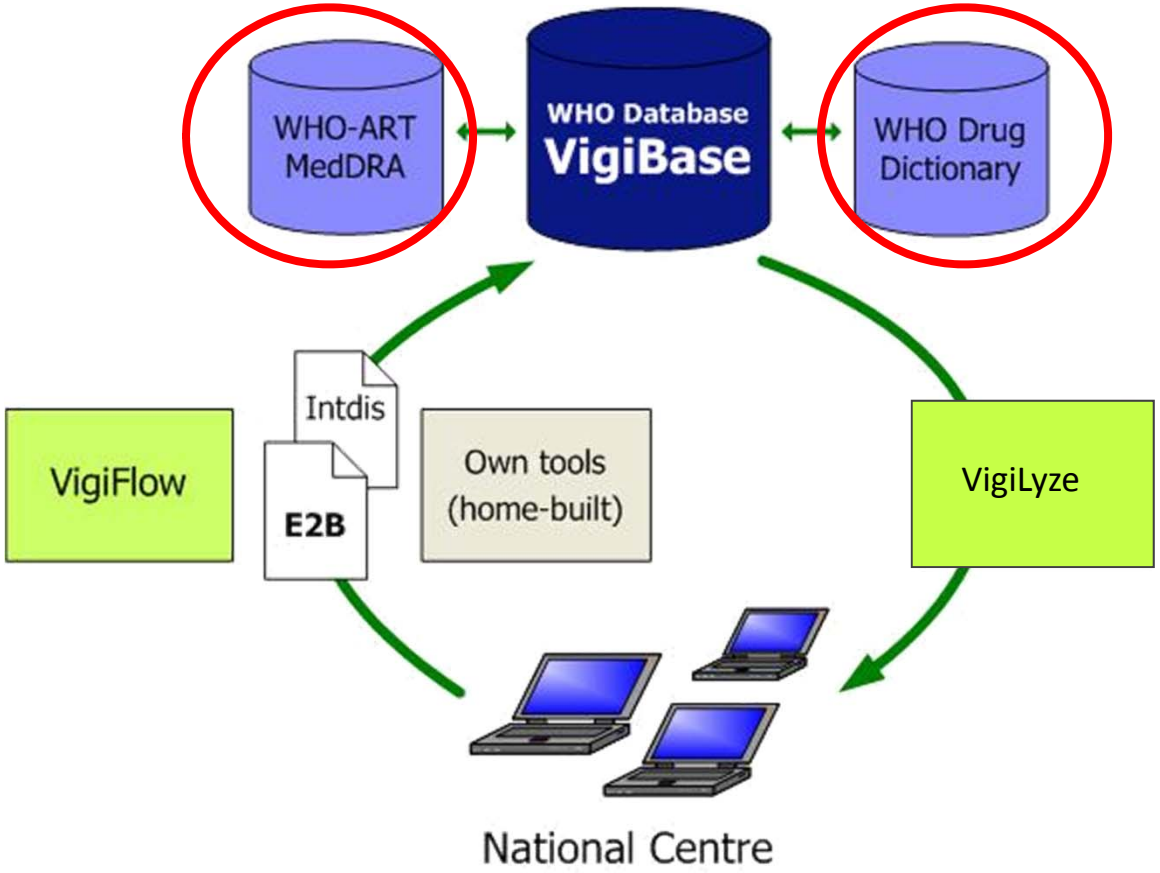
Standard terminologies



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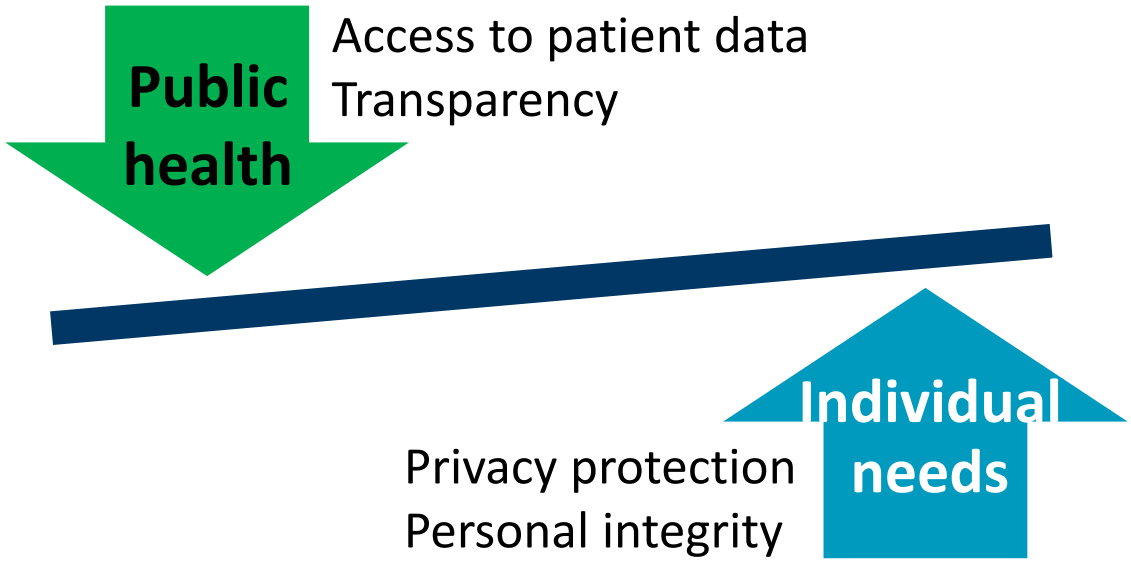
Integrity and data quality

Pharmacovigilance is about data



but above all about people!

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UMC protects integrity and data quality

Pharmacovigilance is about data

but above all about people!

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Quality parameters - general

- Security
- Confidentiality
- Timeliness
- User-friendliness
- Conformity to regulations, standards, good practice etc.

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Quality parameters – data values

Completeness	Are all critical items included? Are they filled in?
Consistency	No contradictions?
Currency	Is the information up to date?
Accuracy	Is the information represented correctly?
Precision	Is the output level of detail supported by input data?
Relevance	Is the data fit for purpose?
Understandability	Can it be interpreted correctly? No ambiguities?

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UMC's focus to help and support

resource-limited countries to get going

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UMC's focus to help and support

countries with big populations and relatively underdeveloped pharmacovigilance systems to improve

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UMC's focus to partner with

countries with mature PV systems to forward research and development of better science, methods and practices

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Priorities for the coming years

Support WHO and regional WHO CCs in safety activities

Increase capacity for signal detection and evaluation

Build a global safety culture

Develop and disseminate methods for risk-benefit assessment and decision support

Provide dictionaries and terminologies that meet user needs

Assess impact and improve communication

Engage with partners for active and productive collaborations

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