

# Trainingspaket Arzneimittelinfo: Training Workbook + MiCAL



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Eine Alpenvereinskarte, ein GPS – in Köln?



**Höchste Erhebung:**  
Monte Troodelöh (118 Höhenmeter)  
im Vgl. Kölner Dom (157 Höhenmeter)

**... oder ist ...**

Eine Alpenvereinskarte, ein GPS – in Köln?



... Köln **alpin**er –  
als Sie dachten?

# Gliederung



1. Was ist das Trainingspaket?
  - Einführung
  - Ziele
2. Trainingseinheiten in Beispielen
  - Training Workbook
  - MiCAL
3. Umsetzung in Deutschland
  - Zielgruppe
  - Wegweisend? Ja, oder nein?
  - Trainingspaket „Must have“

# 1. Was ist das Trainingspaket? **Einführung**



# 1. Was ist das Trainingspaket? Einführung



UKM2  
UK Medicines Information

## Arzneimittelinformation Training Workbook

Angela Badiani & Simon Wills

Wessex Drug Medicines Information Centre - Southampton University Hospitals NHS Trust

adka-arznei.info



mi  
Medicines Information

# MiCAL V12

Medicines Information Computer Aided Learning (with MiDatabank Trainer)

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Navigating MiCAL

Core Skills Teaching

Core Skills Assessment

Enhanced Skills Teaching

Note: this section is under development and currently contains 'critical appraisal skills' teaching only.

Locations

Partners

# 1. Was ist das Trainingspaket? Einführung



## Arzneimittelinformation Training Workbook

Angela Badiani & Simon Wills  
Wessex Drug Medicines Information Centre - Southampton University Hospitals NHS Trust

UKMI  
UK Medicines Information

Mi  
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- *Training Workbook*: Printmedium (€)
- *MiCAL*: (Medicines Information Computer Aided Learning) internetbasierte Datenbank (€)
- Bestandteil der Weiterbildung in AM-Info in GB
- Herausgabe, regelmäßiges Update:  
AM-Info-Apotheker in GB (UKMI)

# 1. Was ist das Trainingspaket? **Einführung**



- Allgemeine Grundlagen zu Arzneimittelinformation u.a.
  - Prozess: Beantwortung von AM-Info-Anfragen
  - Kommunikation: Schreib- und Telefonkompetenz
  - Querverweise Standards (UKMI)
- Tutorien zu häufigen klinischen Themen u.a.
  - Interaktionen, unerwünschte Arzneimittelwirkung
  - Arzneimittel bei Nieren- und Leberinsuffizienz
  - Alternative Medizin
  - Kritische Bewertung
  - NEU: Arzneimittel und Kinder

# 1. Was ist das Trainingspaket? Ziele



# 1. Was ist das Trainingspaket? Ziele

Korrekte  
Anfragerfassung

Effektive Recherche

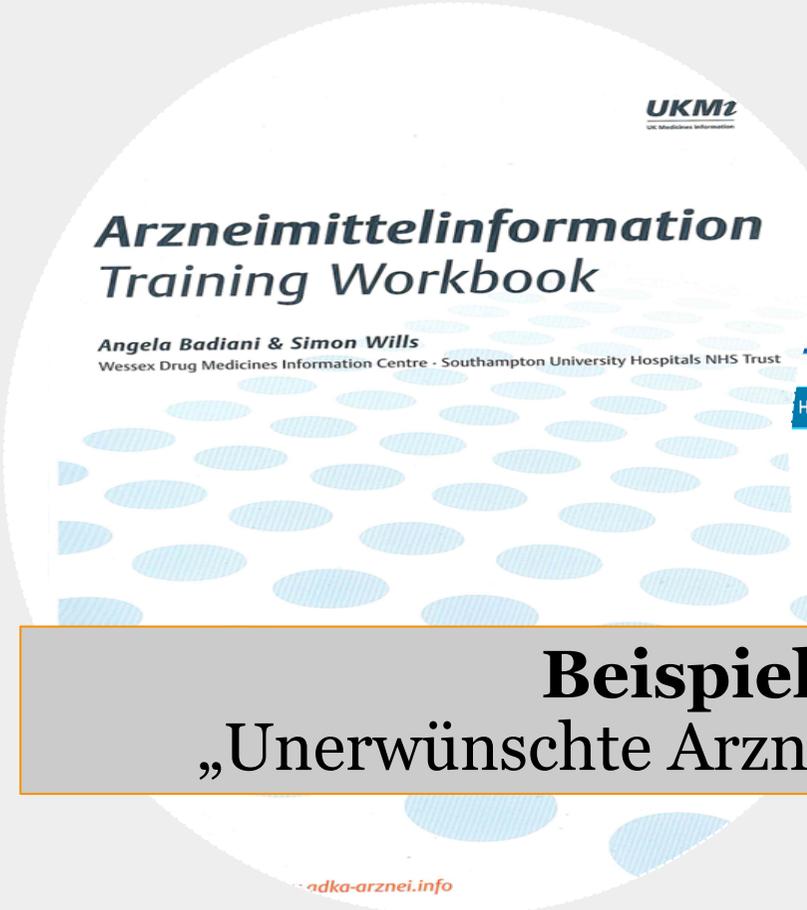
**Kompetenz AM-Info:**

- Qualität
- AMTS
- Stellenwert AM-Info-Service im Krankenhaus

Evaluation der  
Informationen

Klare Kommunikation  
der Antwort

## 2. Trainingseinheiten: In Beispielen



**UKM2**  
UK Medicines Information

### Arzneimittelinformation Training Workbook

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**Mi**  
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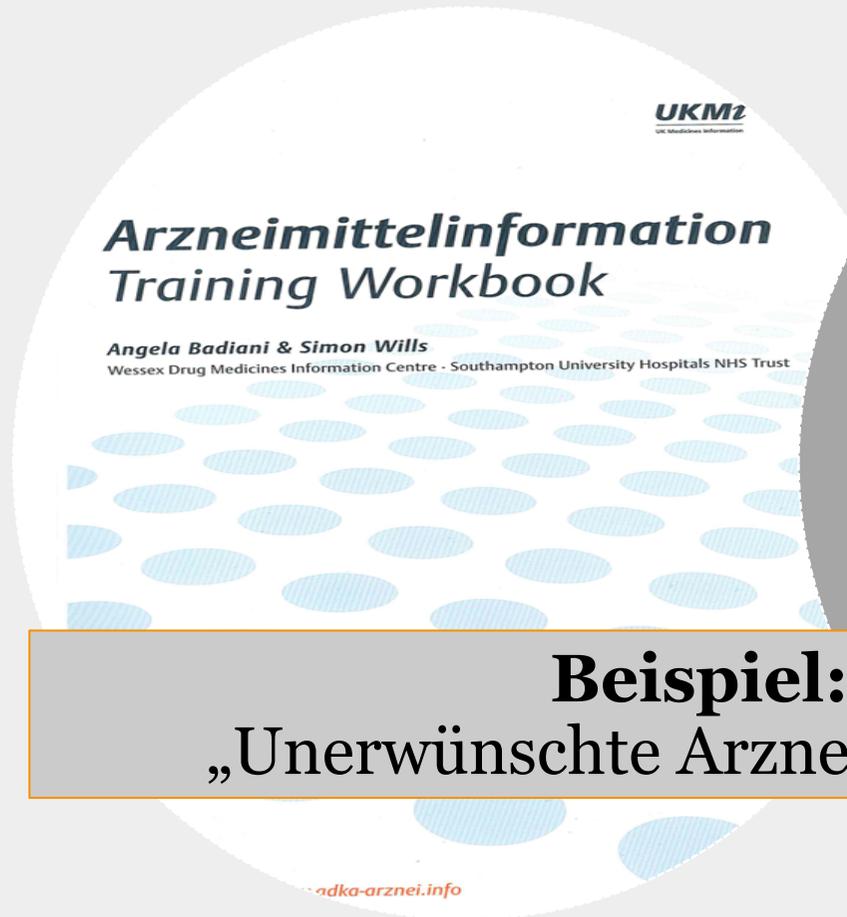
[Navigating MiCAL](#)

[Core Skills Teaching](#)

**Beispiel: Tutorium**  
**„Unerwünschte Arzneimittelwirkung (UAW)“**

[adka-arznei.info](#)

## 2. Trainingseinheiten: **Training Workbook**



- Wichtige Grundlagen
- Hintergrundfragen
- Recherchequellen
- Übungen

**Beispiel: Tutorium**  
„Unerwünschte Arzneimittelwirkung (UAW)“

## 2. Trainingseinheiten: Training Workbook

### 2. Adverse Drug Reactions

#### Background

- Medicines Information Centres receive many reports of adverse drug reactions (ADRs), as well as a large number of enquiries about drug contraindications). Annual statistics collected from these centres show that on average about 15% of their enquiries fall into the category of ADRs. Patient helplines show that a high proportion of enquiries are about ADR effects.
- ADRs occur in 10-20% of hospitalised inpatients and are a major cause of deaths on medical wards. Studies in hospital wards have shown that up to 20% of ADRs are preventable. The epidemiology of ADRs in the community shows that 2% of GP consultations may be due to side effects of drugs.
- ADRs are great mimickers of disease, causing unnecessary referral and investigation.
- Certain disorders are commonly drug-induced. For example, drug-induced exposure is particularly important in the elderly. Common drug-induced disturbances, postural hypotension, confusion, and gastrointestinal haemorrhage. Less common drug-induced disturbances include

#### Wichtige Grundlagen

- Definition:
  - Wesentliche Merkmale...
- Kausalitätsbewertung:
  - zeitlicher Zusammenhang...
- Inzidenz:
  - EU-Klassifikation...
- Bewertung UAW in Studien:
  - klinische Studie vs. Fallbericht vs. epidemiologische Studie...

## 2. Trainingseinheiten: **Training Workbook**

### **Questions to Ask an Enquirer**

- ⊙ Establish patient's age if relevant
- ⊙ Ask about the diagnosis
- ⊙ List all current and recent medicines and potential
- ⊙ Ask about relevant bioch
- ⊙ Consider any history of
- ⊙ Ask for the details of the
- ⊙ Establish when the suspe (treatment) and whether t
- ⊙ Ask how the patient has

### **Hintergrundfragen**

- gezieltes Erfragen klinisch relevanter Informationen
- „Frage hinter der Frage“
  - Beginn der UAW vs. Therapiestart des verdächtigen AM?
  - Behandlung der UAW? ...

## 2. Trainingseinheiten: **Training Workbook**

### Example Sources to Use in Answering Enquiries

- ⊙ The Summary of Product Characteristics must include details of adverse events reported during clinical trials and their frequency.
- ⊙ Check MiDatabank for questions about (e.g. statins induced myopathy).
- ⊙ Meyler's Side Effects of Drugs is one of the best resources for ADRs. It's available online and as a hard copy. It's more than disease-by-disease which makes it easy to look up. As with all textbooks, new drugs are added regularly.

### Further Reading

- ⊙ Try the CKS on adverse drug reaction. Enter ADRs into the search box on the home page. On the hand side of the page to find the section on ADRs.
- ⊙ Chapter 5 on Adverse Drug Reactions and Whittlesea (Churchill Livingstone)

### **Recherchequellen**

- strukturiert, zeitökonomisch:  
Liste Printmedien/digitale Medien mit Bewertung z.B.
  - „neue AM selten aufgeführt“
  - „Fallberichte referenziert“
  - „Edition out-of-date“
  - „Tipps für Management der UAW“
- Querverweise auf Standards

## 2. Trainingseinheiten: Training Workbook

### Example Enquiry

Southampton **NHS**  
University Hospitals NHS Trust

Wessex Drug & M  
Sc

sir

Dr Timothy Sputum  
Respiratory Physician  
Southampton General Hospital

Dear Tim,

**re: Ivor Coff DoB 15/03/1964 25 Expectorations Close, Haw**

Thank you for your enquiry about a patient taking long-term ethambutol, who has developed paraesthesia in both legs. Drug-induced peripheral neuropathy is poorly documented in the medical literature and it can be difficult to come up with the most likely causative agent.

I cannot find anything suggesting a substantial link between rifampicin and paraesthesia, so I think it is the least likely cause.

Paraesthesia is a known side effect of azithromycin and the manufacturer's Product Characteristics ("data sheet") together with other reactions classed as "adverse effects" might be more common when azithromycin is given long term since resistance to azithromycin administration to prevent malaria (250mg daily for 20 weeks) was reported in about 2% [2]. Unfortunately the authors present little clinical detail in the paper. Paraesthesia developed slowly over a period of weeks. I enclose a full copy of the paper.

### Übung: Beispielanfrage mit Antwort

➤ nach dem Motto „So geht's!“ bzw.

➤ „Wie hätte ich geantwortet?“

- z.B. Paraesthesien in beiden Beinen unter derzeitiger Medikation?

## 2. Trainingseinheiten: **Training Workbook**



### Adverse Drug Reactions



#### Test Yourself!

1. A GP telephones you to ask whether you need to give further information do you need to find out more?

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---

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2. Where would you look to find out how to manage the discontinuation of paroxetine?

---

### Übung: „Test Yourself“!

- nach Durcharbeiten der Grundlagen
- Lösungsvorschläge (NEU!)
  - z.B. Hintergrundinformationen zu „Auftreten von Pulmonaler Fibrose unter derzeitiger Medikation.“

## 2. Trainingseinheiten: **Training Workbook**

### Real Enquiries

This section helps you to think about the enquiry answering process. Below are given the details of three real enquiries, as received by a regional MI centre. Decide with your tutor which of these enquiries to do. Then for each enquiry:

- (a) Any further questions you would like to ask
- (b) The top sources that you would use to answer the enquiry

Your tutor will go through these with you and you will then answer using the MiDatabank Trainer on the computer. Discuss your answers with your tutor first.

#### 1. Drug-induced hyponatraemia

A junior pharmacist drops into your clinic and asks you if amlodipine or ramipril can cause hyponatraemia. You check the literature and find that for an elderly female patient who currently takes amlodipine 5 mg daily and ramipril 10 mg daily, the following symptoms are reported:

Further questions for enquiry

### Übung: Fragen aus Praxis

➤ zum Selbsterarbeiten  
bzw. mit Tutor

➤ Lösungsvorschläge  
(Tutor's Guide)

- z.B. „Welches Antidepressivum bei Epilepsiepatient?“

## 2. Trainingseinheiten: **Training Workbook**



### Exercises

- ⊙ If you have the MiCAL programme, have a go at question nos. 4 or 10.

### **Querverweise in Training Workbook zu MICAL:**

- Ergänzen sich

## 2. Trainingseinheiten: MiCAL

UAW unter Sulfasalazin:

- Anfrageerfassung
- Recherche
- Evaluation
- Kommunikation



mi  
Medicines Information

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Navigating MiCAL  
Core Skills Teaching  
Core Skills Assessment

**Beispiel: Tutorium**  
„Unerwünschte Arzneimittelwirkung (UAW)“

## 2. Trainingseinheiten: MiCAL



*Input: Gathering The Initial Information For The Enquiry*

**TR** Hello, how can I help?

**EN** Hi, I wonder if you could help me with the following symptoms could be:  
Feeling sick, headaches, a temperature and a slight rash.

Go to MiDatabank, open a new enquiry and enter the symptoms in the Question field. *Note: If you put the symptoms in the Question field, they will automatically appear in the Title box when you save the enquiry.*

When you are happy with your document, click on the 'Save' button.

- Vorteil MiCAL: Beantwortung von Anfragen aus der Praxis
  - „blended learning“
  - interaktiv z.B. als Telefondialog
  - „Learner“ – „Assessor“ (Berechtigungen, Monitoring Lernerfolg)
  - vernetzt mit Dokumentationsdatenbank
- ❖ Gelenkschmerzen, Fieber Ausschlag unter Sulfasalazin?

## 2. Trainingseinheiten: MiCAL

*Input: Gathering The Initial Information For The Enquiry*

You now know that the enquiry relates to the enquirer herself.  
Considering sulfasalazine only for the moment, what further questions should you be asking?

Reshow Enquirer's Question

Type in your suggestions below and then click on the Check Answer button.

When did her symptoms first start?  
How long has she been taking Sulfazalasin?  
What dose of Sulfasalazin is she taking?

You need to find out the following:

1. Has she seen her doctor?
2. Why is she taking sulfasalazine?
3. What dose of sulfasalazine is she taking?
4. How long has she been taking sulfasalazine?
5. When did her symptoms first start?

### Hintergrundfragen

- Querverweis: Standards UKMI  
z.B. Quick Question Guide
- ❖ Seit wann Einnahme von Sulfasalazin und in welcher Dosis?

## 2. Trainingseinheiten: MiCAL

*Input: Gathering The Initial Information For The Enquiry*

Do you need to know anything else about the enquirer in order to answer the enquiry effectively?

A I Need **Further** Information

B I Have **Sufficient** Information

No, you are wrong - you still need further information about the enquirer.

What further information do you need to find out about the enquirer?  
Type in your ideas below then click on the Check Answer button.

medical history

You need to find out further information about the enquirer's medical history and drug history.

You ask the lady for further information.

Show Dialogue

### Hintergrundfragen

- Nachhaken: Fehlen noch wesentliche Infos?
- ❖ Anamnese inkl. Arzneimittel

## 2. Trainingseinheiten: MiCAL

Research: Planning And Researching The Enquiry

From the choices below, indicate which information sources you would suggest using to research the enquirer's question. *When you have selected all your choices, click on the Check Answer button.*

Issues To Research

- AHFS Drug Information
- British National Formulary
- Clinical Pharmacy And Therapeutics
- Commission On Human Medicines (CHM)
- Drug Tariff
- Drugdex Database
- Electronic Medicines Compendium
- EMBASE
- LexiComp
- Martindale: The Complete Drug
- Medicines, Ethics And Practice
- Merck Manual Of Diagnosis And
- Meyler's Side Effects Of Drugs
- MIMS

The main information sources recommended for researching the three areas are shown below. How does your selection compare?

- Electronic Medicines Compendium ([www.emc.medicines.org.uk](http://www.emc.medicines.org.uk))
- British National Formulary
- Martindale: The Complete Drug Reference
- AHFS Drug Information OR Drugdex

### Recherche planen

- Querverweis u.a.: Linkliste UKMI
- apothekeninterne Linkliste
- ❖ BNF, Martindale

Drugs

Medicines

NOTE

therapeutics

## 2. Trainingseinheiten: MiCAL

Research: Planning And Researching The Enquiry

### Example Results

**Results For First Two Issues: What are the side effects of sulfasalazine?  
How do you manage early onset side effects of sulfasalazine?**

\*\*\*\*\*

[Electronic Medicines Compendium \(www.emc.medicines.org.uk\)](http://www.emc.medicines.org.uk)

*Salazopyrin® En-Tabs SPC*

Overall, about 75% of ADRs occur within 3 months of starting therapy, and over 90% by 6 months. Some undesirable effects are dose-dependent and symptoms can often be alleviated by reduction of the dose.

The most commonly encountered ADRs are nausea, vomiting, diarrhoea, and raised temperature. Patients with slow acetylator phenotype experience side effects due to sulphonamides.

Joint pain is not listed as a side effect.

\*\*\*\*\*

### Recherche/Evaluation

- Beispielergebnisse
- ❖ Dosisabhängig: Reduktion der Dosis, Gelenkschmerzen nicht in Fachinfo aufgeführt

## 2. Trainingseinheiten: MiCAL

*Answer: Devising An Answer To The Enquiry*

What points do you think you should consider when constructing your answer?

Show Example Results

Are the symptoms caused by sulfasalazine?  
How could these side effects be managed?

### Kommunikation

- Strukturieren der Antwort
- ❖ Empfehlungen zum Management der UAWs?

*You should consider the following points. Turn to the next page when ready.*

- ◆ You need to make sure that you answer the enquirer's initial question - ie are the lady's symptoms caused by sulfasalazine?
- ◆ You need to offer advice on how these side effects could be managed.
- ◆ You need to mention that alternatives may be available which may give fewer side effects.

Points To Consider

Points To Consider

Points To Consider

## 2. Trainingseinheiten: MiCAL

*Answer: Devising An Answer To The Enquiry*

What points do you think you should consider when constructing your answer?

Show Example Results

Are the symptoms caused by sulfasalazine?  
How could these side effects be managed?

### Kommunikation

- An welche Punkte muss gedacht werden?
- ❖ Dosisabhängige UAW: Reduktion der UAW durch Dosisreduktion?

*Points To Consider*

*You should*

You need to consider the following point:

- ◆ You need to consider the following point:
  - ◆ Side effects can be dose related and a reduction in dose may alleviate them.
- ◆ You need to offer advice on how these side effects could be managed.
- ◆ You need to mention that alternatives may be available which may give fewer side effects.

*Click to remove information.*

*When ready.*

Consider

Points To Consider

Points To Consider

## 2. Trainingseinheiten: MiCAL

*Answer: Devising An Answer To The Enquiry*

Bearing the major points in mind, now do

- Go to your MiDatabank enquiry and  
(The Research Summary box allows you

### *Example Answer*

You can confirm that these side effects are likely to be caused by the sulfasalazine. Some people are particularly susceptible to the effects of sulfasalazine and she could be one of these people. Sometimes these side effects can be managed by reducing the dose but a reduction in dose would need to be done in conjunction with her doctor.

There are also other similar drugs in this class that can be used to treat ulcerative colitis and which may not cause these side effects in her.

*Click to remove information.*

### **Kommunikation**

- Schriftliche Beispielantwort
- ❖ UAWs durch Sulfasalazin möglich, ggf. Dosisreduktion, Hinweis auf alternative AM

### 3. Umsetzung in D: Zielgruppe



### 3. Umsetzung in D: Zielgruppe



- Für alle, die sich auf dem Gebiet Arzneimittel-information weiterentwickeln möchten:
  - Apotheker
  - Pharmazeuten im Praktikum (PhiP)
  - PTA
- Zum
  - Einsteigen
  - Auffrischen
  - Lehren

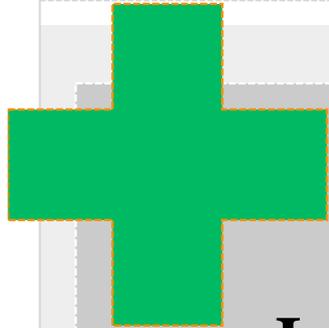
### 3. Umsetzung in D: Wegweisend? Ja, oder...



### 3. Umsetzung in D: ... nein?



### 3. Umsetzung in D: **Wegweisend? Ja oder nein?**



- **Lernen**
  - strukturiert
  - praxisnah
  - spricht verschiedene Lerntypen an
- **regelmäßige Updates**
- **Kosten**
  - Training Workbook



- **Zeit**
- **Kosten**
  - MiCAL
- **Unterschiede GB-D**
  - Wirkstoffe
  - Recherchequellen
  - Recht
  - Strukturen/Ausbildung

### 3. Umsetzung in D: **Wegweisend? Ja oder nein?**



#### **Erfahrungen in Deutschland: Training Workbook**

##### ➤ **Villingen-Schwenningen, Konstanz:**

- Treffen (ca. alle 4-6 Wochen): 1-2 Kapitel/Treffen
- Apotheker
- (+) „total begeistert, sehr viel Spaß, viel in netter Runde gearbeitet, viel profitiert, kein Problem der mangelnden Übertragbarkeit
- (-) „sehr viel Eigeninitiative: neben der Routine schafft man als betreuender Apotheker nicht richtig viel in 6 Monaten“

### 3. Umsetzung in D: **Wegweisend? Ja oder nein?**

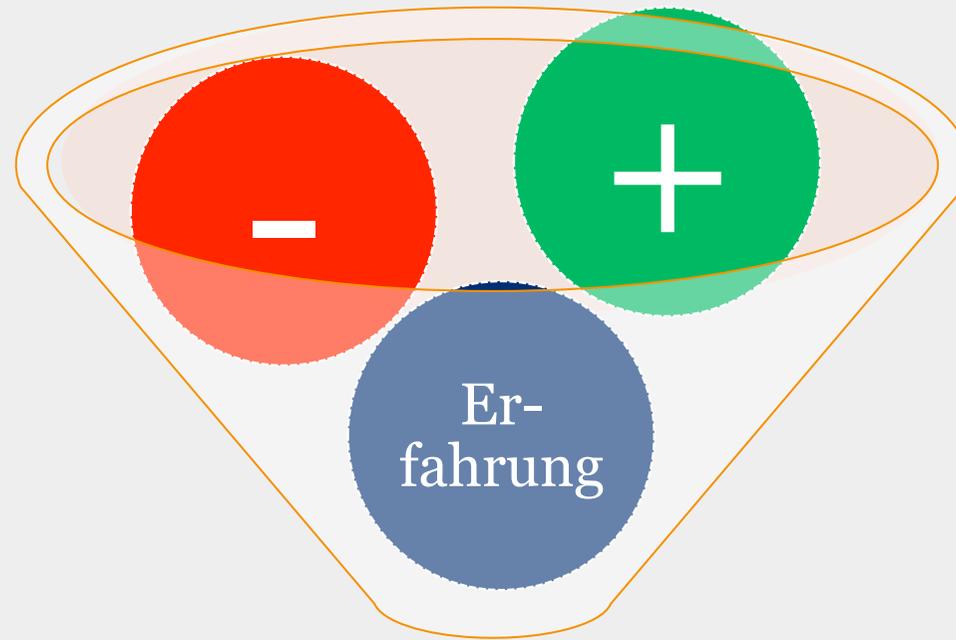


#### **Erfahrungen in Deutschland: Training Workbook**

##### **➤ München:**

- strukturierte Aufarbeitung eigener Anfragen aus der Praxis z.B. Interaktion, Schwangerschaft (Basis: Training Workbook, apothekeneigene Linkliste)
- angepasst an dt. Gegebenheiten
- Apotheker, PhiP

### 3. Umsetzung in D: *Wegweisend? Ja oder nein?*



**Trainingspaket  
„Must have“**

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have

Nice to have

Kosten ca.

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have	Nice to have	Kosten ca.
✓ Training Workbook		30€/2 J
	<i>MiCAL</i>	300€/J

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have	Nice to have	Kosten ca.
✓ Training Workbook		30€/2 J
	<i>MiCAL</i>	300€/J
✓ Treffen/QM: <ul style="list-style-type: none"><li>• Workbook, Standards: UKMI/ADKA</li><li>• eigene Linkliste/Anfragen aus Praxis</li></ul>		<b>Zeit</b>

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have	Nice to have	Kosten ca.
✓ Training Workbook		30€/2 J
	<i>MiCAL</i>	<del>300€/J</del>
✓ Treffen/QM: <ul style="list-style-type: none"><li>• Workbook, Standards: UKMI/ADKA</li><li>• eigene Linkliste/Anfragen aus Praxis</li></ul>		<b>Zeit</b>

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have	Nice to have	Kosten ca.
✓ Training Workbook		30€/2 J
	(MiCAL	300€/J)
✓ Treffen/QM: <ul style="list-style-type: none"><li>• Workbook, Standards: UKMI/ADKA</li><li>• eigene Linkliste/Anfragen aus Praxis</li></ul>		<b>Zeit</b>
✓ Kongress AM-Information		250€/Ps/2 J (Poster, ÜN, RK)

### 3. Umsetzung in D: Trainingspaket „Must have“



Must have	Nice to have	Kosten ca.
✓ Training Workbook		30€/2 J
	(MiCAL	300€/J)
✓ Treffen/QM: <ul style="list-style-type: none"> <li>• Workbook, Standards: UKMI/ADKA</li> <li>• eigene Linkliste/Anfragen aus Praxis</li> </ul>		<b>Zeit</b>
✓ Kongress AM-Information		250€/Ps/2 J
<b>Trainingspaket „Must have“</b>		<b>150€/J</b>

### 3. Umsetzung in Deutschland: O-Ton



„Das macht  
richtig  
Spaß!“



# Quellen



- Badiani A, Wills Simon. Arzneimittelinformation Training Workbook. Wessex Drug Medicines Information Centre Southampton University Hospitals NHS Trust. Siebte Auflage 2011
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- <http://www.ukmi.nhs.uk/>