HEIDELBERG UNIVERSITY HOSPITAL

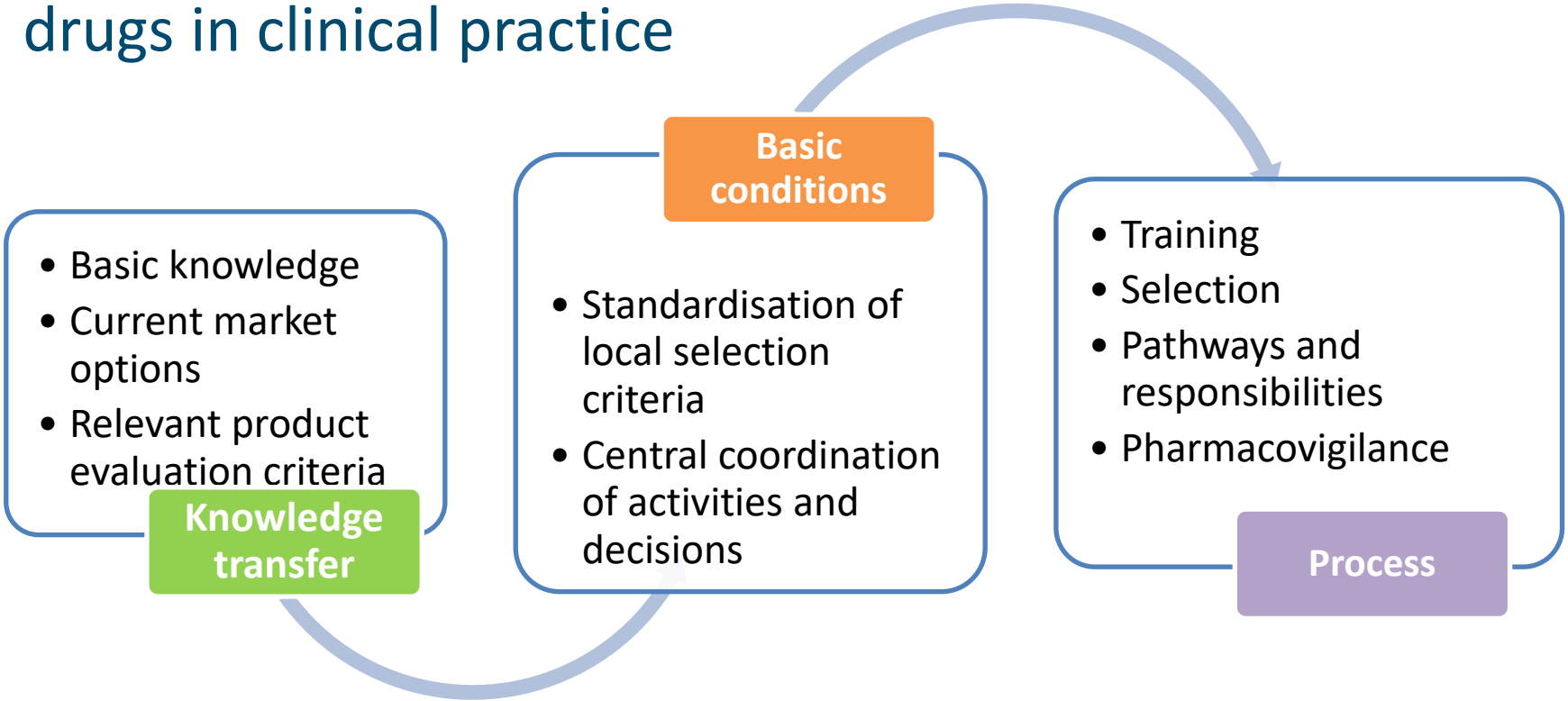
The role of pharmacists in oncology biosimilar treatment

Dr. Tilman Schoening

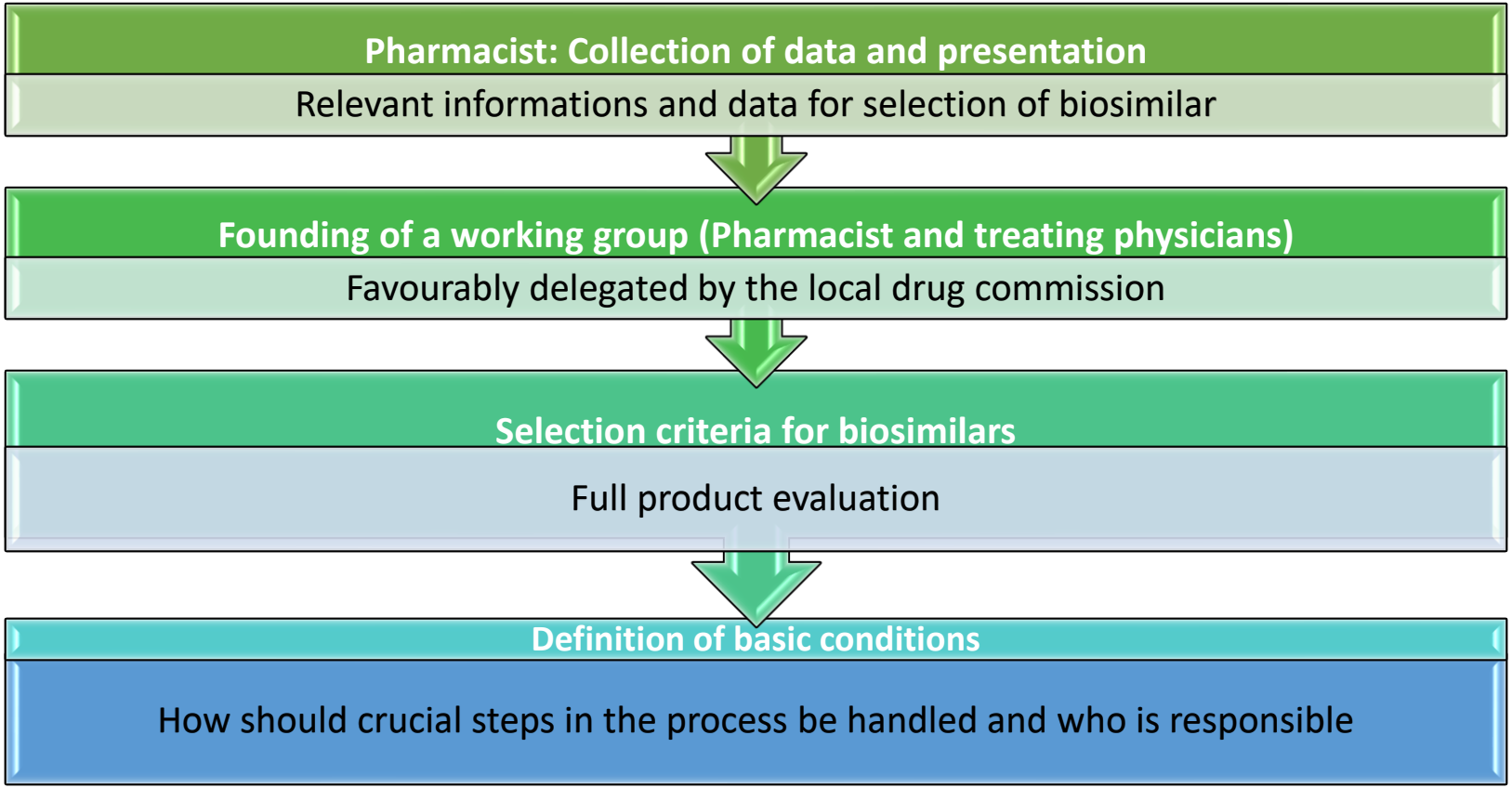
STAKEHOLDER EVENT ON BIOSIMILAR MEDICINAL PRODUCTS
BRUSSELS, 13 DECEMBER 2022

UK HD

Implementation steps for new oncology biosimilar drugs in clinical practice



Decision pathway



The role of the hospital pharmacist

"As stewards of appropriate selection, procurement, logistics and use of medicines and key players in pharmacovigilance, hospital pharmacists are capable of and uniquely positioned to promote the appropriate utilisation of biosimilar medicines."

Encourage HCPs confidence

- hospital executives and pharmacy and therapeutics committees should look at safety and efficacy, label indications, and comparative clinical data to reinforce to their physicians that a biosimilar is as safe and effective as its reference product.
- Absent a centralized database of this information, pharmacists should educate physicians and nurses about a product's rigorous approval process to ensure that they feel comfortable prescribing a biosimilar in lieu of an innovator biologic

Source: ECOP training programm

Checklist for product evaluation of biosimilar drugs

- Basic knowledge
- Current market options
- Relevant product evaluation criteria

Knowledge transfer

	Originator (reference drug)	Biosimilar 1	Biosimilar 2	Biosimilar 3
Approved indications				
Bioidenticals				
Administration route				
Infusion time				
Phase III trial data				
Extrapolated indications				
Safety data				
Pharmacovigilance				
Storage conditions				
Stability data				
Estimation on supply availability				
Cost reduction				
Important informations concerning implementation of biosimilar				

Schöning T, Krämer I; KPH; 11, 2018

Relevant selection criteria for biosimilar mAb from the medical institutions perspective

- Phase III trial evidence
  - Sensitive disease entity , trial design, patient numbers, endpoints
- Safety data
- Off-Label Use
- Administration route, Handling in clinical setting
- Pharmakovigilance requirements
- Stability data, Complete removal of labeled content
- Reliable supply chain
- Handling of Switching
- Cost analysis

Basic conditions

→ To be set by the working group (Pharmacist and the senior physicians of the clinical departments)

- Which patients should be treated with the biosimilar(s) of a certain originator?
- How should the order process be handled?
- Consented process for switching
- Tracking process (lot no. etc.)
- AE reporting plan (e.g. → at first to the pharmacy, which informs regulatory bodies)
- Data collection
- Training

UNIVERSITÄTS KLINIKUM HEIDELBERG	**Standard Operation Procedure (SOP)**	**Klassifikation Stufe 2 TLP green**
WG Biosimilars	**Use of biosimilar antibodies at Heidelberg University Hospital**	

Basic conditions

- Standardisation of local selection criteria
- Central coordination of activities and decisions

6.1 Selection and use of biosimilar antibodies

6.1.1 Detailed process for implementation in clinical practice

6.1.2 Prescription and ordering process

6.1.3 Process of switching from originator to biosimilar and vice versa

6.1.4 Documentation

6.1.5 Pharmacovigilance action plan

After approval and market access of a new biosimilar the pharmacy should coordinate efforts to fix the conditions under which it should be used toegther with the responsible clinicians. This is supported by a dossier about all available biosimilars to a certain originator. A decision has to be made, which of these biosimilars are considered to be part of a tendering process performed by the pharmacy. The decisions will be subject to confirmation of the drug commission

Switching and substituion

- Implement a definition for an individual switching process in the local institution
  - This can be different according to entity and special drug
  - take all practical issues into account (prescription etc)
- Define pharmacovigilance action plan
- Define re-evaluation timelines for the process
- Document decisions as an internal guidance
- Define a start date

Prescribing

- Master data in prescribing systems should always be unmistakable
- Standardized prescribing and ordering process is crucial to prevent errors
- Therapy regimes should contain clear information, if originator or biosimilar is used
- Double check by pharmacist
- Action in compounding areas to prevent mix-ups between originator and biosimilar

- Training
- Selection
- Pathways and responsibilities
- Pharmacovigilance

Process

Universitätsklinikum Heidelberg
Apotheke
Pharm.-Onkol. Service
Im Neuenheimer Feld 670
69120 Heidelberg
Tel. 6782 Fax. 4094

Stationsdaten

Medizinische Klinik-Innere V Tagesk
Hämatologie / Onkologie
Im Neuenheimer Feld 410
D-69120 HEIDELBERG

Anforderung: **1176428** vom: **08.01.2018**
von: **SCHOENING**
Chemotherapieplan (Scan)
002006

Patientendaten (1091253)

Mustermann, Muster

***01.01.2000**

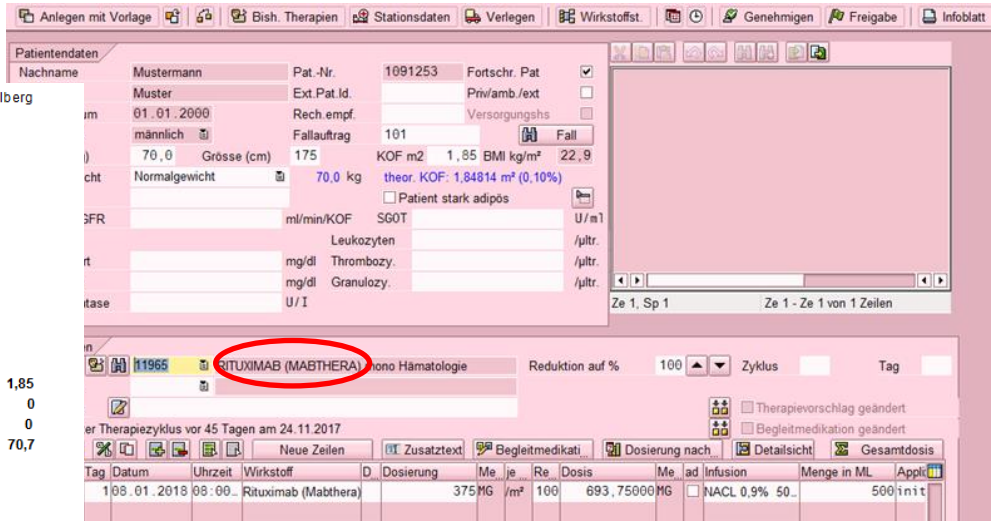
Körpergewicht (kg)	**70,0**	Körperoberfläche (m²)	**1,85**
Körpergrösse (cm)	**175**	Zyklus **1**	Tag **0**
Estimated GFR ml/min/KOF			**0**
angepasstes Idealgewicht (AIBW)			**70,7**

KOF: 1,84814 m² KOF mit Normalgewicht berechnet

Anordnungsbogen RITUXIMAB (MABTHERA) mono Hämatologie

Bemerkung

Tag	Uhrzeit/ Hz	Hz. Arzt	Zeitpunkt	Substanz (Generic)	Dosierung	Red. auf %	Dosis	Trägerlösung	Volumen(ml)	Appl.art
Tag 1 / Datum 08.01.2018										
1			vor	Rituxi Clemastin (Tavegil®)	1 MG		1 MG			oral
1			vor	Rituxi Paracetamol (Ben-u-ron®)	500 MG		500 MG			oral
1				Rituximab (Mabthera) (MABTHERA) N703,30.06.2019	375 MG/m²	100	690 MG	NACL 0,9% (500)	569	initial 50 mg/h



Apotheke der Universitätsklinik
Pharm. Onkol. Service, INF670, 69120 HD

08.01.2018 08:00 Uhr 1176428/001
Mustermann, Muster geb. 01.01.2000
Rituximab (Mabthera) 690,00 MG
NACL 0,9% ad 569,00 ML initial 50 mg/h
Lagerung: 2-8°C

Conclusion- Role of pharmacists

Pharmacists play a crucial role in providing information, enhancing confidence in biosimilars and ensuring a safe handling of biosimilar medicines:

- Providing scientific and pharmacoeconomic information
- Implementation of safe processes for the clinical use of biosimilars
- Supporting the pharmacovigilance-management including AE reporting
- Defining a safe and comprehensible switching-process in cooperation with the responsible physicians
- Creating a safe and practicable prescription process of biosimilars especially in electronic software systems
- Evaluating biosimilar impact on cost and return calculation