

# CAREER PATHS IN R&D IN PHARMA:

## DRUG SAFETY & MEDICAL AFFAIRS

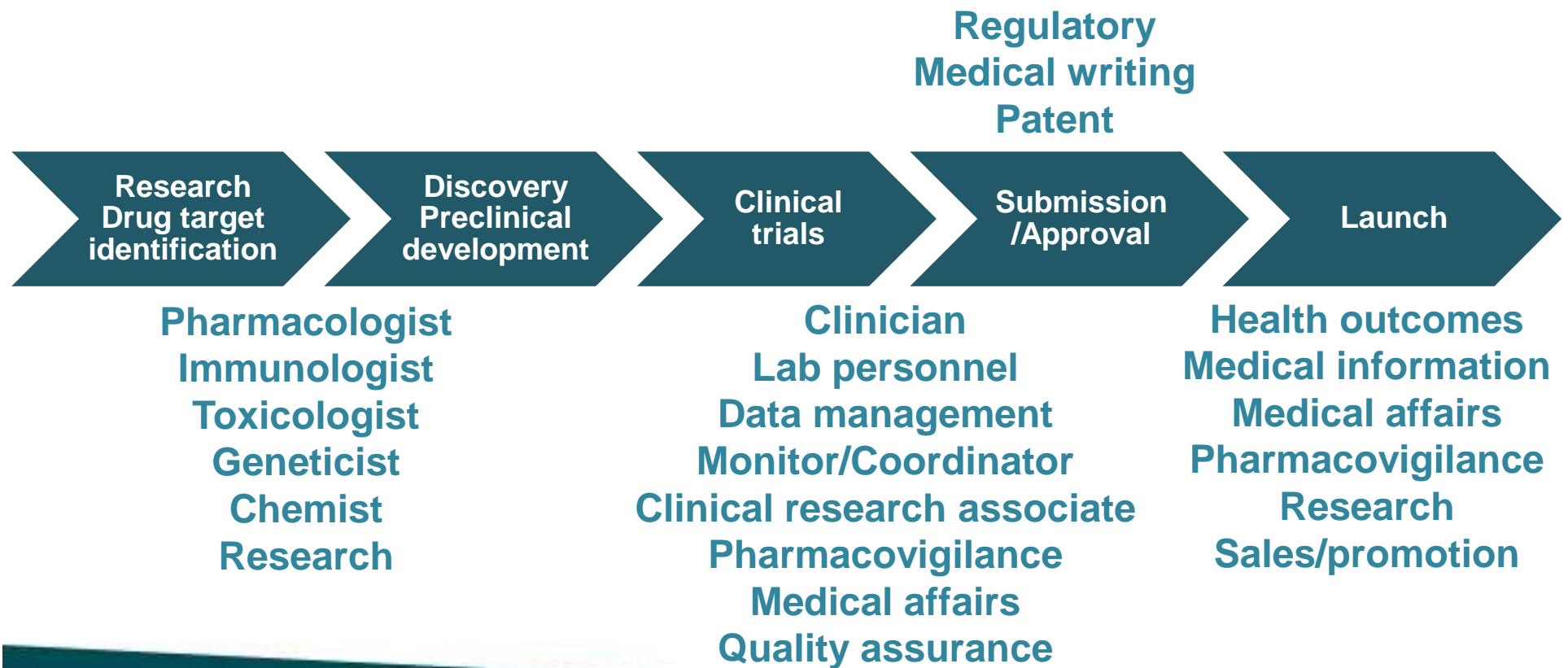


*Anastasia Sideri, PhD*  
*Medical Advisor, Zeincro Hellas SA*

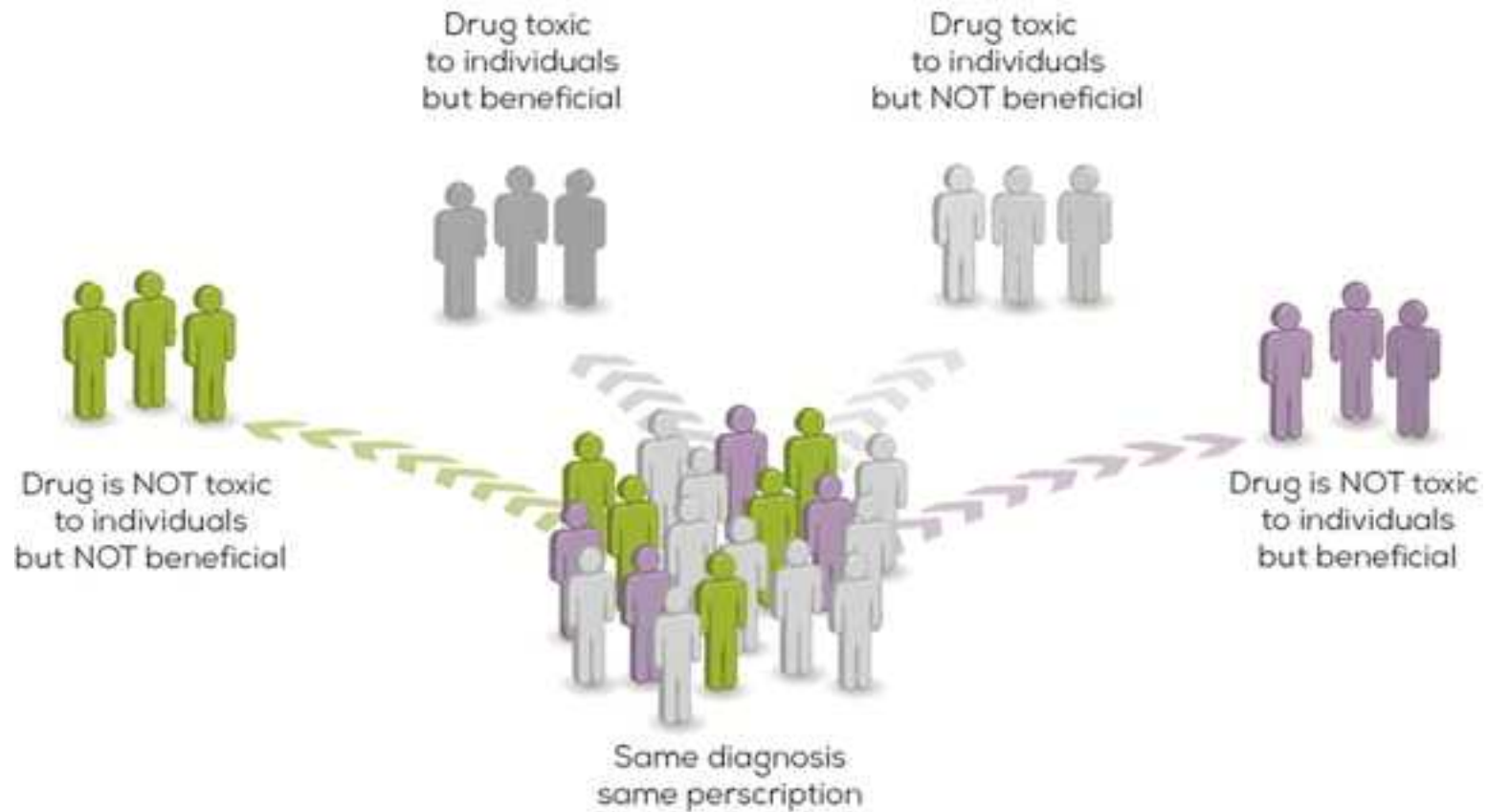
June 2017  
EL.E.F.I.



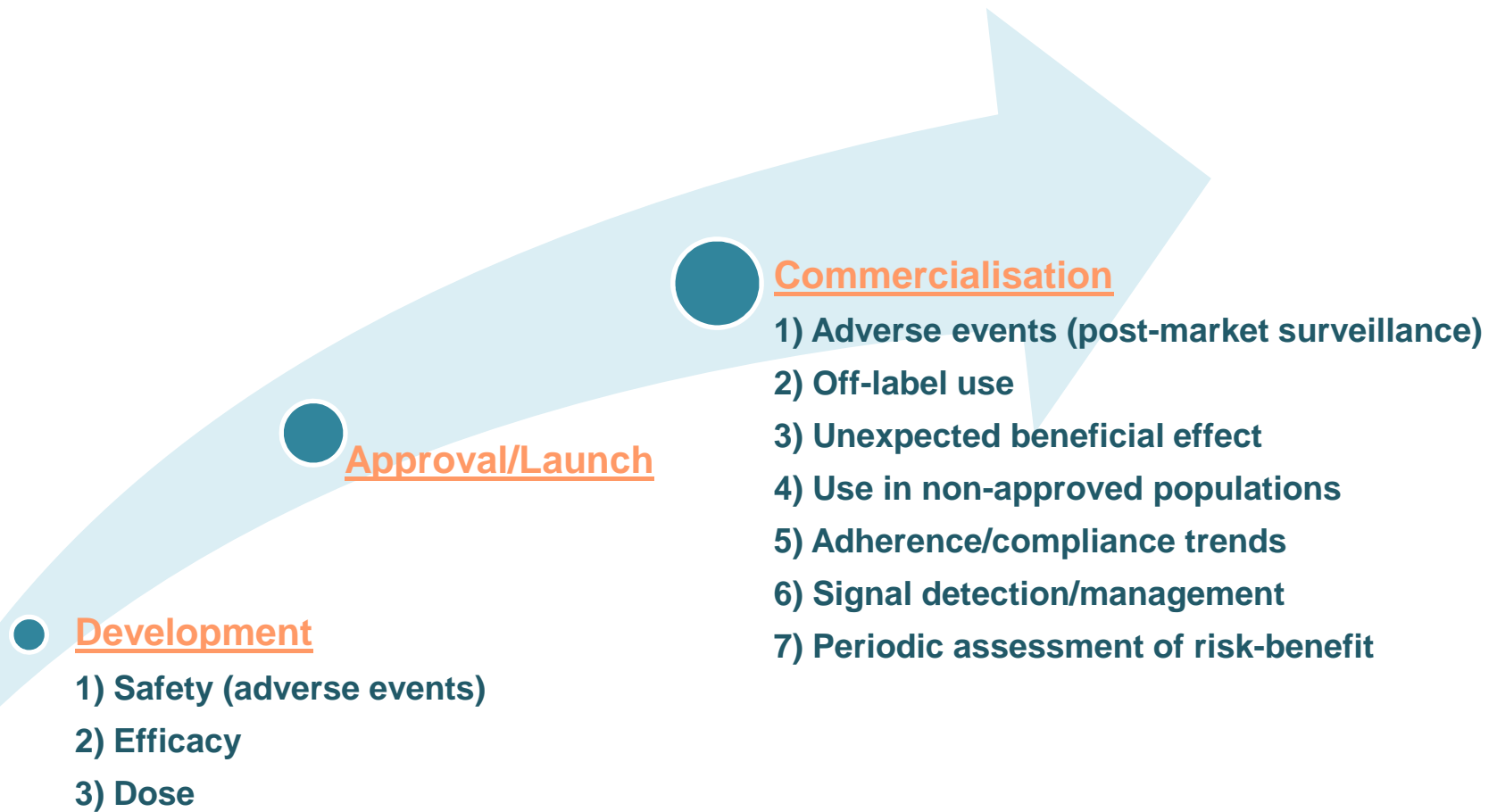
# R&D: Job roles in the birth of a medicine



# Drug Safety



# Drug Safety - R&D



# Drug Safety - R&D

## Post-marketing surveillance



Internal AERS



Individual Case Safety Reports



Medical Literature



Regulatory AERS



Clinical EHRs



Medical Claims



Clinical Trial Data



Social Media



Future Data Types

# Medical Affairs

Faculty of Pharmaceutical Medicine

www.jpm.org.uk

twitter.com/ucjpharmMed

facebook.com/ucjpharmaceuticalMedicine

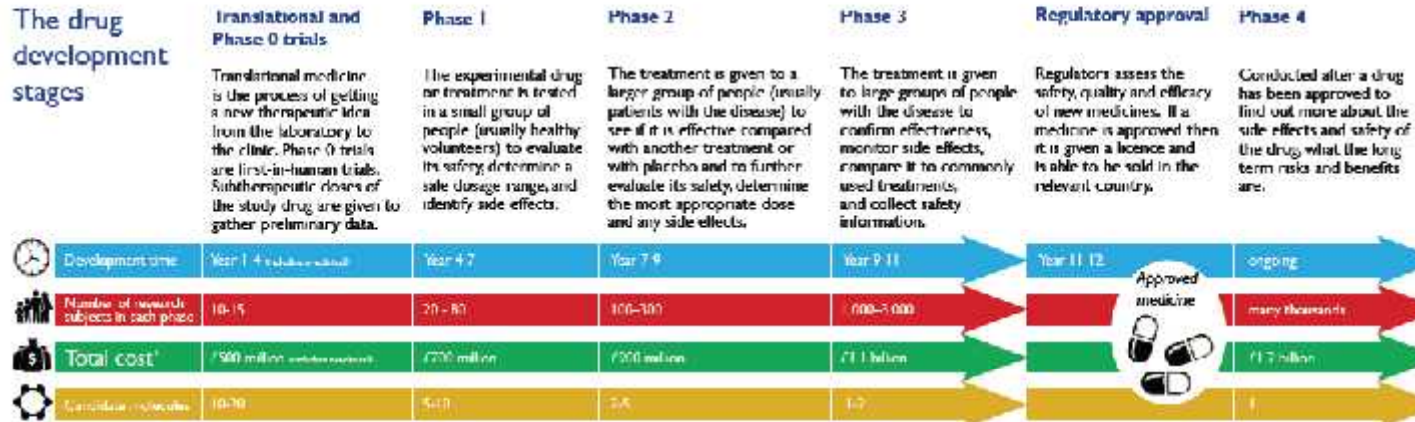


## The drug development process: what do pharmaceutical physicians do?

Pharmaceutical medicine is the medical specialty concerned with the discovery, development, evaluation, registration and monitoring of new medicines. Pharmaceutical physicians are involved in every step in the drug development process.



### The drug development stages



### The role of pharmaceutical physicians



#### Clinical Pharmacologist



Responsible for the design, performance and interpretation of studies focused particularly on the collection of pharmacokinetic data.

Working as an investigator is probably the role that is closest to clinical medicine. Physicians in this role take medical histories and perform physical examinations, predominantly in healthy volunteers.



#### Clinical research physician

Responsible for clinical plans, design of phase 2 and 3 clinical trials, safety monitoring and medical governance of new medicines.



#### Regulatory Affairs

Ensure the appropriate licensing, marketing and legal compliance of pharmaceutical and medical products in order to control the safety and efficacy of products.

#### Medical Assessor

Works in a regulatory body to approve new trials and to evaluate clinical efficacy and safety of medicines submitted for approval.

#### Medical Affairs

Work with commercial colleagues to ensure the sales and marketing strategies are based on accurate clinical data and executed in a medically sound and ethical way.



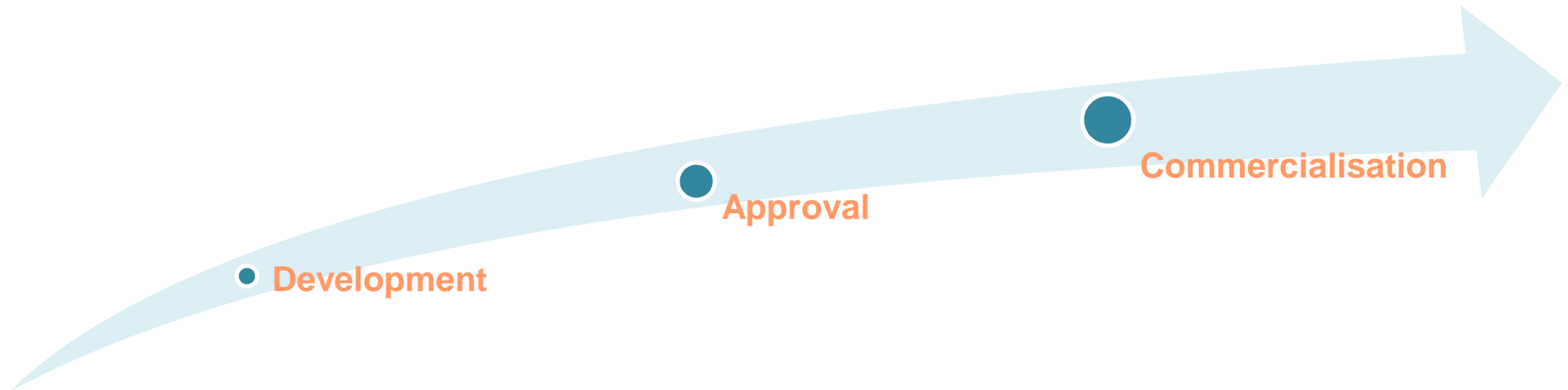
#### Pharmacovigilance

Analyses data to identify the safety profile of a medicine, including drug reactions, adverse reactions (or side effects), contraindications, warnings, interactions and special populations.

\* Net list of prices (not including pharmaceutical industry cost charge) from British Drug Directory (June 2006)



# Medical Affairs - R&D



- 1) **Interact with various stakeholders to identify medical needs** (decision makers, influencers, patients, patient advocates etc.) **and/or medical gap**
- 2) **Enhance medical value for patients in a cost-effective manner** (e.g. reduce out-of-pocket costs, quality of life), **government** (cost on healthcare system, health policy implementation) etc.
- 3) **Be proactive** (embrace and experiment with new technologies in social media, mobile health devices etc.)
- 4) **Interact with other departments and translate insights in opportunities**

# Medical Affairs - R&D (cont.)

## Development

- 1) Clinical trial design
- 2) Credible and unbiased analysis of clinical trial data
- 3) Risk/benefit assessment

## Approval

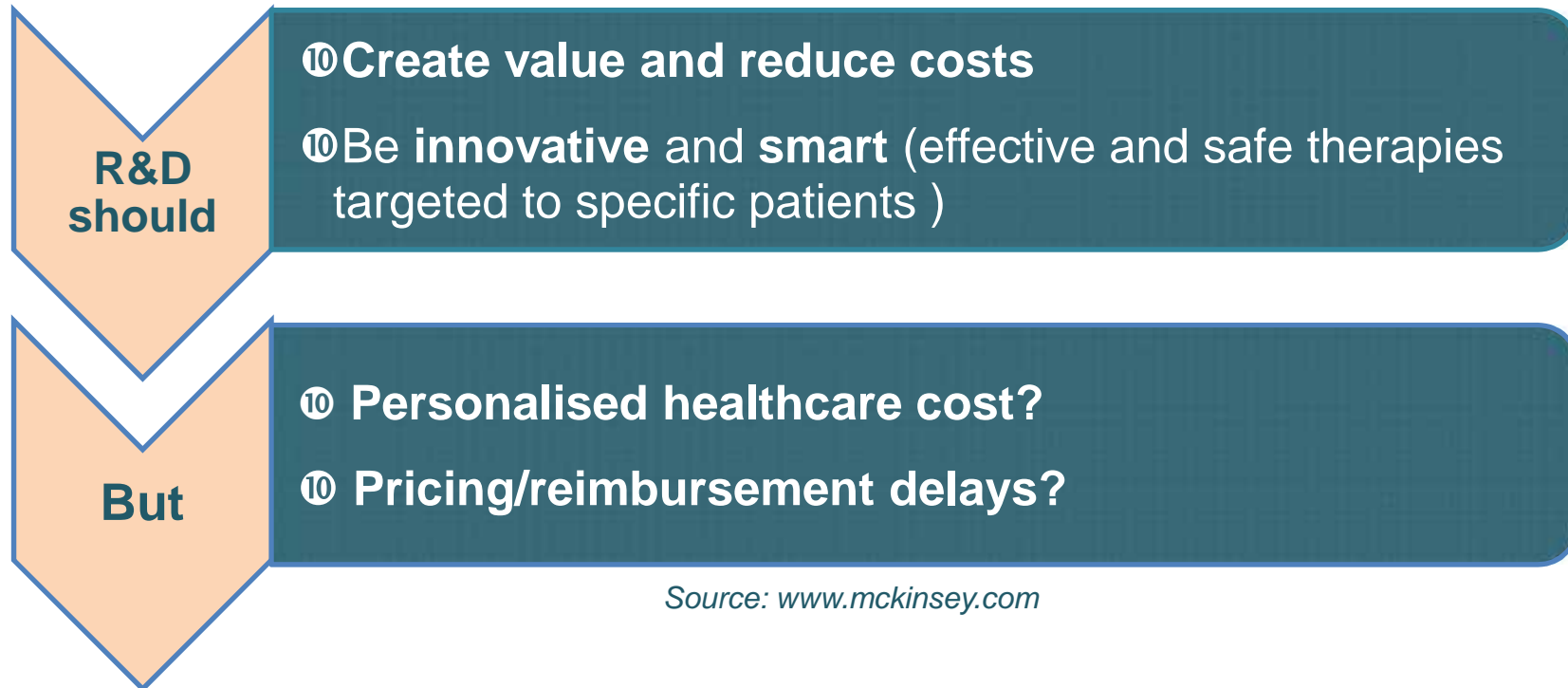
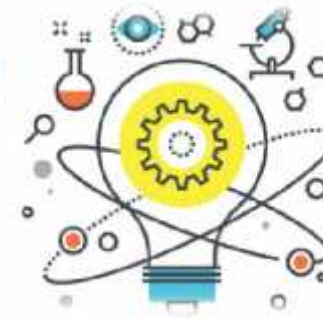
Medical writing

## Commercialisation

- 1) Combination of medical knowledge and patient experience (real-world evidence)
- 2) Medical information
- 3) Medical writing
- 4) Clinical trial/study design



# Future R&D



Source: [www.mckinsey.com](http://www.mckinsey.com)

# Future R&D (cont.)

- **Real-life data** across a product's lifecycle to guide clinical trials & decision making
- **Selection** (*specific therapeutic area vs broad portfolio or segmentation?*)
- **Make the most of differentiated assets**
- **Embrace collaboration/partnerships**
  - A) Pharma mergers
  - B) Drug co-development
  - C) CROs take the lion's share of operational work under R&D team coordination**



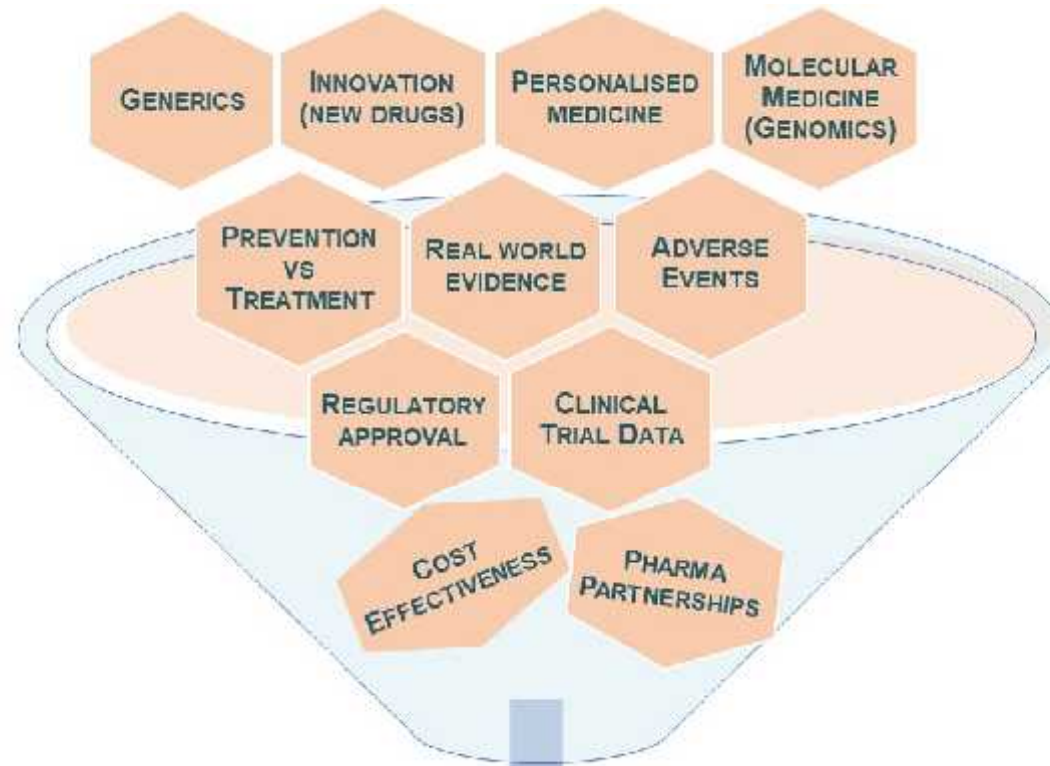
# Why choose a career in R&D?

- **Combine various skills** (mobile health applications, patents, social media, health economics, sales)
- **Diverse career and personal development opportunities in pharma and outside-** inc. independent consultant(s), assessor in competent authorities
- **Operating at the fore-front of medicine/Innovation**
  
- **Limited/indirect contact with patients/benchwork (depending on function)**
- **Working in a corporate environment**

# Thank you!



# R&D Components



**DYNAMIC** Pharma R&D