CAREER PATHS IN R&D IN PHARMA: DRUG SAFETY & MEDICAL AFFAIRS



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

Regulatory
Medical writing
Patent

Research Drug target identification Discovery Preclinical development

Clinical trials

Submission /Approval

Launch

Pharmacologist
Immunologist
Toxicologist
Geneticist
Chemist
Research

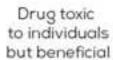
Clinician
Lab personnel
Data management
Monitor/Coordinator
Clinical research associate
Pharmacovigilance
Medical affairs
Quality assurance

Health outcomes
Medical information
Medical affairs
Pharmacovigilance
Research
Sales/promotion





Drug Safety



Drug toxic to individuals but NOT beneficial



Drug is NOT toxic to individuals but NOT beneficial



Same diagnosis same perscription



Drug is NOT toxic to individuals but beneficial





Drug Safety - R&D



- <u>Development</u>
 - 1) Safety (adverse events)
 - 2) Efficacy
 - 3) Dose

Commercialisation

- 1) Adverse events (post-market surveillance)
- 2) Off-label use
- 3) Unexpected beneficial effect
- 4) Use in non-approved populations
- 5) Adherence/compliance trends
- 6) Signal detection/management
- 7) Periodic assessment of risk-benefit





Drug Safety - R&D

Post-marketing surveillance







Medical Affairs

Faculty of Pharmaceutical Medicine







The drug development process; what do pharmaceutical physicians do?

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



The drug development stages

translational and Phase 0 trials

Translational medicine is the process of getting a new therapeutic idea from the laboratory to the clinic. Phase () tetals are lirst-in-human trials. Subtherapeutic doses of the study drug are given to gather preliminary data.

Phase I

The experimental drug or treatment is tested in a small group of people (usually healthy volunteers) to evaluate Its safety determine a sale dosage range, and identify side effects.

Phase Z

The treatment is given to a larger group of people (usually patients with the disease) to see if it is effective compared with another treatment or with placebo and to further. evaluate its salety, determine the most appropriate dose and any side effects.

Phase 3

The treatment is given to large groups of people with the disease to confirm effectiveness, monitor side effects, compare it to commonly used treatments. and collect safety information.

Regulatory approval

Regulators assess the safety, quality and efficacy of new medicines. If a medicine is approved then rt is given a licence and is able to be said in the relevant country.

Phase 4

Conducted after a drug has been approved to find out more about the side effects and safety of the drug what the long term risks and benefits





The role of pharmaceutical physicians



Clinical Pharmacologist

Responsible for the design, performance and interpretation of studies focussed 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, safely monitoring and medical governance of new medicines.

Medical Assessor

Works in a regulatory body to approve new trials and to evaluate dinical 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.



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.



Pharmacovigilance

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

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DEVOTION RELIABILITY EXPERTISE

Medical Affairs - R&D

Commercialisation

- Development
- 1) Interact with various stakeholders to <u>identify medical needs</u> (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.)



Commercialisation

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

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





Future R&D

R&D should **©Create value and reduce costs**

But

- **©** Personalised healthcare cost?
- **©** Pricing/reimbursement delays?

Source: 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

