Opportunities in Clinical Drug Development for Physicians

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Objectives

1) To get better understanding of the different roles & responsibilities for physicians in clinical drug development

2) To get informed on the why, when, what and how of making the switch to pharma industry ?

Facts and figures

Who ?

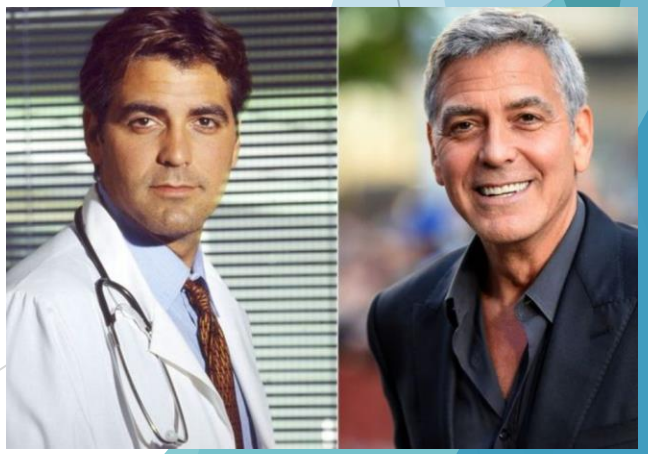
What ?

How ?

?

Why ?

When ?



How different is pharma industry from medicine practice ?

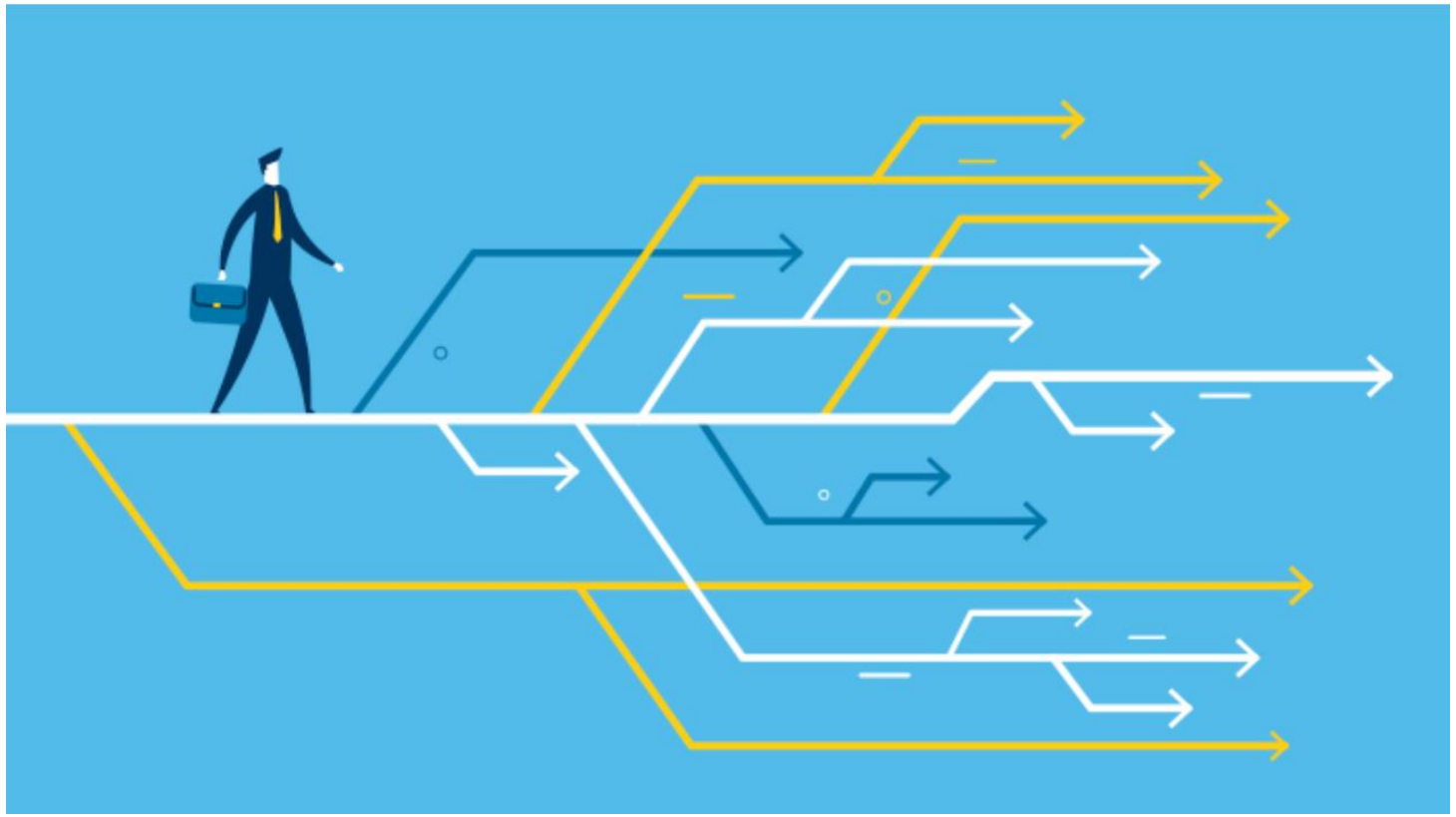
Similarities

- Improve lives of patients
- Scientific rigor
- Extensive medical knowledge and continuous education
- Collaboration with experts

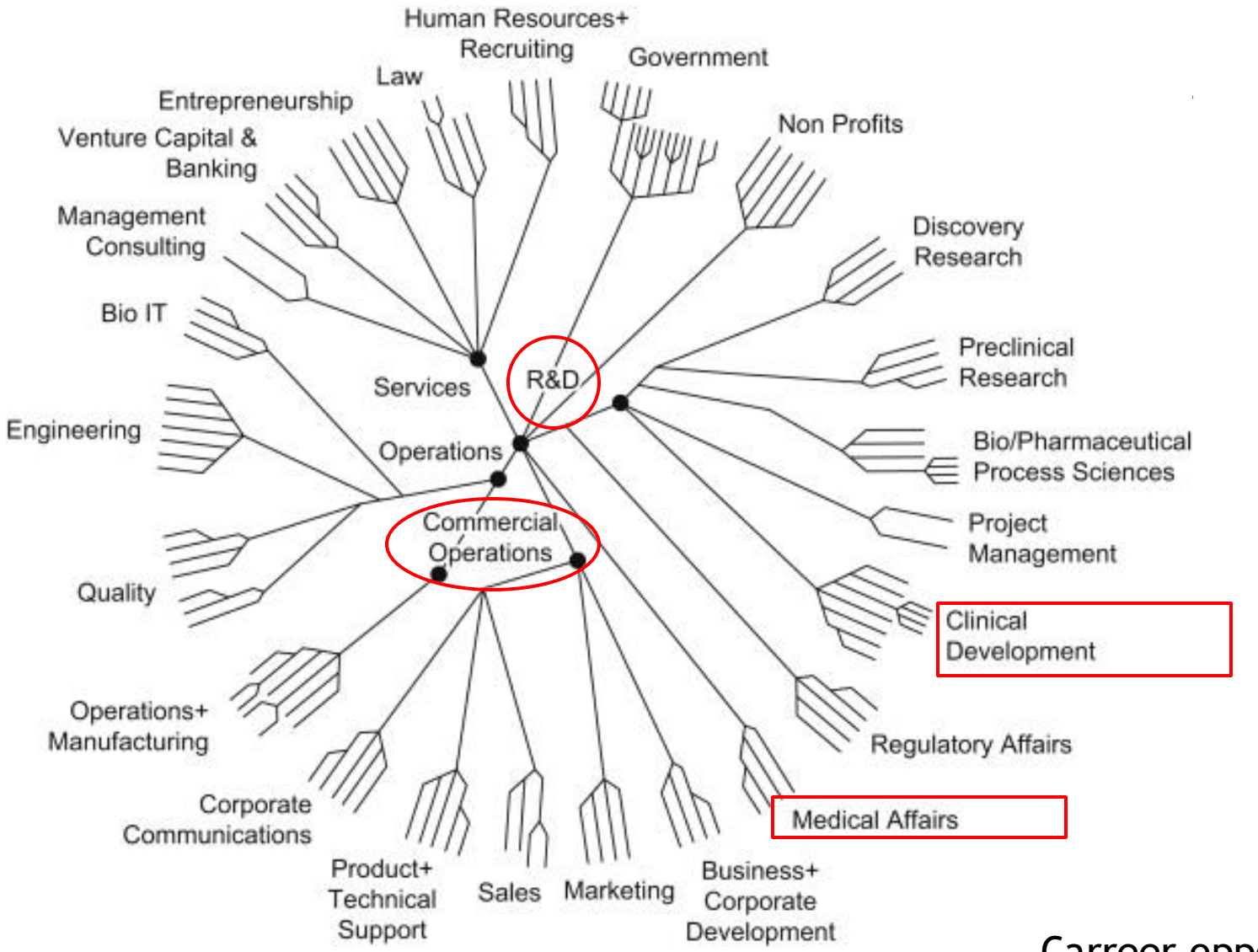
Differences

- No direct patient contact
- Individual level >< larger scale
- Longer term
- No individual recognition/ team effort
- Exposed to different functions
- Career plan

Physicians have many career opportunities in biopharmaceutical industry



Careers in biopharmaceutical industry

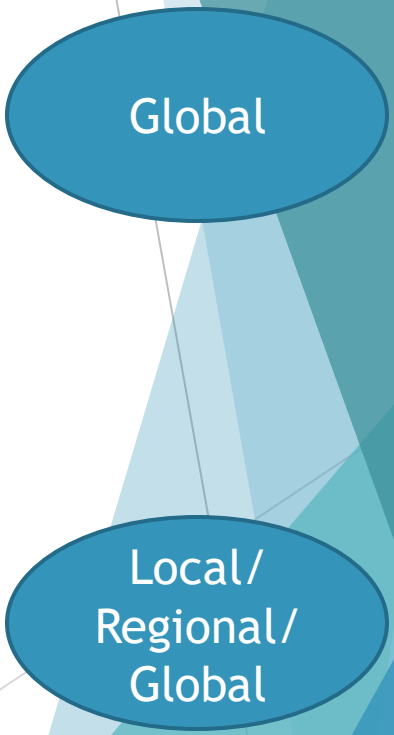


Carreer opportunities in Life science, Toby Freedman

What is difference between R&D and Medical Affairs

- R&D: To support the clinical development of an asset from discovery until post-approval monitoring
  - Pre-clinical and translational research
  - Early-Late stage development
  - Drug safety and pharmacovigilance

- Medical Affairs: Manage the commercialisation of the molecule troughout life cycle (external focus)
  - To develop and implement medical strategy and develop plan to address data gaps and meaningful evidence by deep understanding clinical landscape
  - Develop scientific communication strategy
  - Interactions with experts/societies/ patient associations

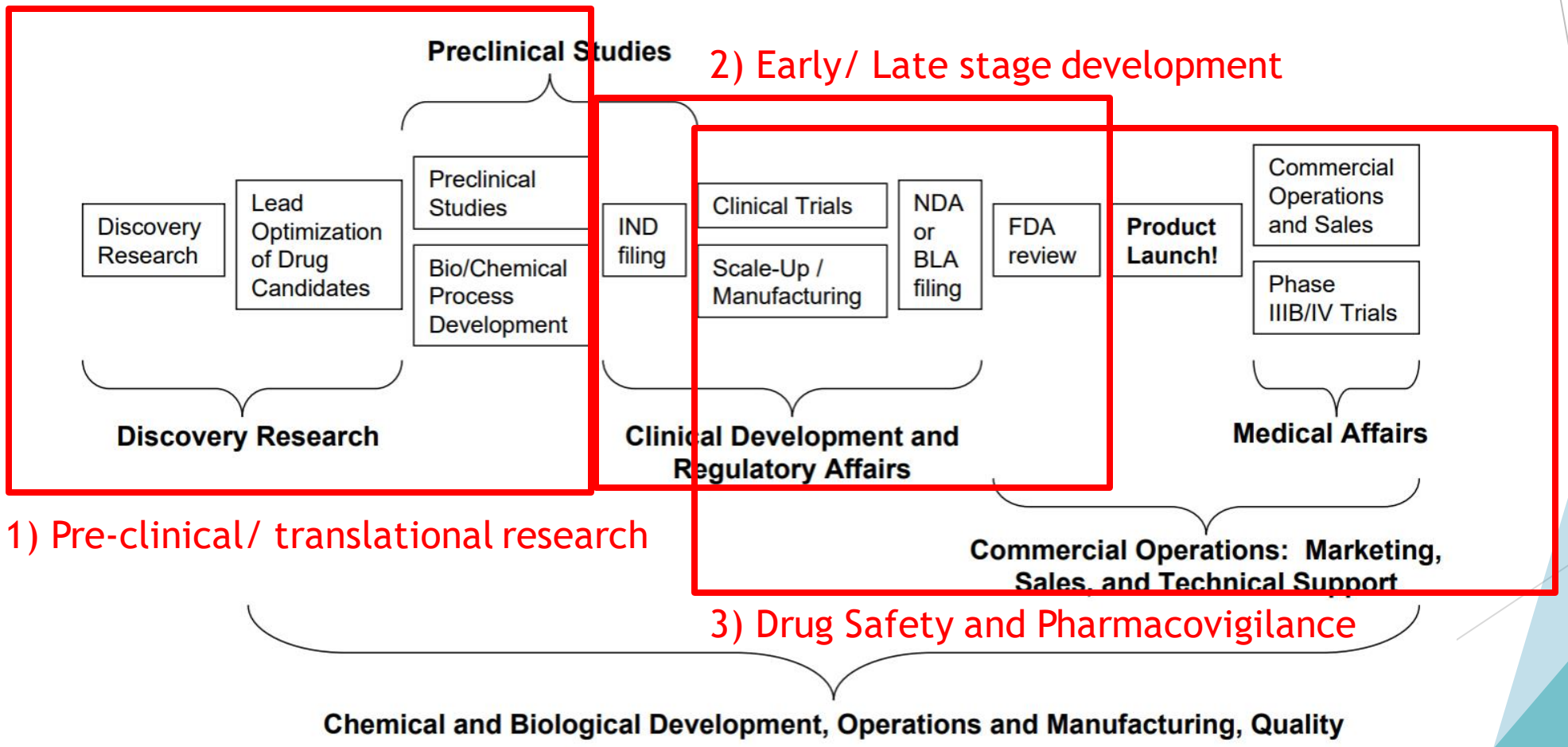


Responsibilities of MD in clinical drug research

- Successful clinical research strategy
- Correct and Safe execution of clinical studies
- Publication of study data
- Liaison between company and clinical investigators
- Evaluating the efficacy of new potential treatments in patients.

Pharmaceutical industry is highly regulated environment
Ethical behavior is crucial

Physicians are needed throughout the drug development phases



1) Pre-clinical/ translational research

- Identify and investigate new molecules, molecular entities, biomarkers, or drug targets
- Develop and implement experimental strategies as well as author or review regulatory documents.
  - Experience in medicinal chemistry, in vivo testing, or pharmacology

2) Early/ Late stage development

- Strong involvement and leadership in **clinical trial activities**: protocol writing, CRF development, study start-up process, operational execution, support trial-related advisory boards/ investigators meetings, medical monitoring, safety follow-up, review of final data, clinical study report writing. Ensures that all activities are in compliance.
- Review **study data manuscripts and abstracts** (including publications, congress-related activities)
- Review and **evaluate the company clinical research results** to determine marketability of products.
- Review and determine results of phase I-IV investigations in preparation for **new drug application** to the regulatory agencies.
- Develop credible **relationships** with investigators, opinion leaders, medical directors, and key regulatory officials.

2) Early/ Late stage development

- Clinical leads or study responsible physicians: answer questions from sites and other physicians who are actually treating subjects in a clinical trial
- Clinical Development MD: Direct and oversee the **clinical development plan and strategy (from product to therapeutic area)**.
  - Experience as principal investigators (PIs) or sub-PIs on clinical trials. (FIH)
  - Therapeutic Area expertise
  - Strong relationships with key stakeholders and partners in external collaborative efforts (universities, government agencies, not-for-profit organizations, pharma/biotech companies).

3) Drug Safety and Pharmacovigilance

- To improve the safe and adequate use of medications and to ensure patient safety.
- Collect and monitor the adverse events from clinical trials and routine clinical practice.
- *Safety Scientists* or *Pharmacovigilance Specialists:* collect and monitor the adverse events. Collaborate with clinical development MD to see of actions, such as dose adjustments and treatment discontinuations are needed.
  - Experience as principal investigators (PIs) or sub-PIs on clinical trials.

What you need to be succesful in clinical development ?

- Detail-oriented
- Pro-active
- Good leadership skills
- Can-do attitude
- Team-player

Dare to take risks
Deliberate but flexible career plan
Know you strengths and interests and aim to become a better you

Questions ?

- Drug Discovery Today. 2019;24 (9):1865-1870
- Pharmaceutical Medicine. 2020;34:175–184
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