PIANIFICAZIONE DI PERCORSO PROFESSIONALE NEL DRUG DEVELOPMENT: UN ESEMPIO DI PROGETTO AD ELABORAZIONE PROGRESSIVA.

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Opinions showed and/or described are personal and not the view of any of my past or present employer Company.

Is a career path in Drug Development a Project?



Vs.

- **Constructing Building**
- Software modification
- Business improvement
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Project:

- Career in Drug Research & Development

A project is a temporary endeavor undertaken to create

a unique product, service, or result.

• Projects are undertaken to fulfill objectives by producing deliverables

- Objective: an outcome towards which work is to be directed,
 - ✓ A strategic position to be attained,
 - ✓ A purpose to be achieved,
 - \checkmark A result to be obtained,
 - \checkmark A product to be produced,
 - \checkmark A service to be performed

Project Life Cycle



Scope – Schedule – Cost – Quality – **10 Knowledge Areas** Resource – Communication – Risk – Procurement – Stakeholders -Integration

How it all started...Research Career



• Chemistry degree (Bio-Organic, 5y)

- PhD (Chemical Science, 3y)
- CNR Fellowship (1y)
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tps://pubs.acs.org/page/vi/women-organic-chemistry-2020
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https://www.agi.it/cultura/la_sapienza

Scope: Academic career



Objective: Recognized Chemistry Expert – Researcher Position

Main interest: Organic Synthesis

- Functionalization of pentatomic heteroaromatics (pyrroles, indoles) with carbon radicals as potential synth. methods for pharmaceutical compds
- Publication of research results



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Agile/Adaptive: high degrees of uncertainty or scope not fully defined

Redefine: in practice



- Organic Synthesis School (against my Professor will!)
- Gathered info on Companies, collected suggestions

Medicinal Chemistry at IRBM – Merck Research Laboratories

- ✓ International environment
- ✓ High level Medicinal Chemistry synthesis
- ✓ Publication of results (papers & patents)
- Got Interview: Evaluated on research background, scientific production

TIPS

- Do no allow anyone to stop or slow you
- <u>Accept Risk as Opportunity</u>

 Starting
 Organizing & Preparing
 Carrying out (Conduction)
 Ending

Change in SCOPE: Research in Industry

IRBM – Merck Research Laboratories: Medicinal Chemistry

Antivirals: Drug design, Synthesis, Lead Identification, Lead Optimization, SAR



IRBM – Merck Research Laboratories: Automated Medicinal Chemistry

- Company pillars: continuous learning and improvement (Courses, Schools, Conferences, etc.)
- My interest: Parallel Synthesis, Microwave Synthesis
- Company decision to create a Parallel Synthesis Unit in Italy

In the labs of Craig Lindsley (MRL-West Point, PA - USA) to learn how to set up and run the facility.

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Automated Medicinal Chemistry Unit







Parallel Purification Lab



Scale-up Lab



IRBM – Merck Research Laboratories: Automated Medicinal Chemistry

Anticancer drugs: Drug design, Synthesis, Target Identification, Lead identification, Lead Optimization, SAR



Project Life Cycle





Project Life Cycle



Phase gate (= phase review = decision point)

A project can be composed of a number of Phases, each providing one/more deliverables/results



Duelen, R et al. (2019). Medicinal Biotechnology for Disease Modeling, Clinical Therapy, and Drug Discovery and Development. In: Matei F., Zirra D. (eds) Introduction to Biotech Entrepreneurship: From Idea to Business. Springer, Cham. https://doi.org/10.1007/978-3-030-22141-6_5

Masters: a 'preparation phase'



Project Management

- Project life-cycle and Project Mgt
- management: scope, quality, time, costs
- Critical Path Method, Earned Value Method: Evaluation and estimation
- Risk Management, Risk mitigation

Recognized by PMI as Project Management education requirements for PMP[®] certification eligibility:









https://www.vertex42.com/ExcelTemplates/excel-ganttchart.html

Istituto Italiano Project Mgt ISIPM-Base

Masters: a 'preparation phase'



Thesis title: Informed Consent in Clinical Trials in the case of Incapacitated Adults.



(source: Wikipedia)

Karl Brandt di fronte alla corte Albert Neisser, 1855–1916

(source: Wikipedia)

Nuremberg Code

- Helsinki Declaration
- D.Lgs. 211/2003
- Decisional capacity assessment in clinical trials (mental state tests)

TIPS

- Take opportunity to invest in preparation
- Try something completely different... •
- ...to eventually put aside (temporarily)

Clinical Trials: Start-up in CRO (PRA-HS)



To generate/collect documents and obtain approvals, required to start a Clinical Trial

Deliverables

- Clinical Trial start-up documentation
- AIFA (CA) Approvals
- CEC Approvals
- LEC Approvals

TIPS

- Regulatory can be a full career or a *gate*
- Gather info on various Regulatory roles for each Company
- Make yourself identifiable by Head Hunters:
 - ✓ LinkedIn

✓

- ✓ pharmiweb.jobs
- <u>https://it.indeed.com</u>
- ✓ www.Pharmapoint.it

Clinical Trials: CRA (Monitor)



Clinical Trials: Oncology (PhI – PhII – PhIII) (Gilead, AstraZeneca, Amgen, MSD, Roche)

CRO: PRA-HS, Covance, IQVIA

Drugs: Immunotherapy, Targeted Therapies

Therapeutic Areas: Oncology

- solid tumors (Lung Cancer, Bladder Cancer, Prostate Cancer, Renal Cancer, Head&Neck Cancer, Melanoma)
- oncohematology (Lymphomas)

Clinical Trials: CRA (Monitor)





As a CRA:

- You learn about: therapeutic area, disease diagnosis/ staging /disease assessment
- > You are the expert of the protocol

TIPS

- May be difficult to start, then very easy to change Company (be open)
- Regulatory experience makes the difference (look for access programs)



Medical Affairs: Medical Science Liaison - Oncology

From CRA (NSCLC targeted therapy)

To MSL (NSCLC targeted therapy) in Takeda



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Medical Affairs: Data Generation Manager – Oncology in Takeda

> Company strategic decision to provide to Medical Affairs a dedicated expert for research matters.



- R&D trials (Country Point of Contact)
- Investigator Initiated Research (Pharma is not the sponsor, D.M. 17/12/2004)
- Interactions with CROs







In summary...

- Career project can vary from «Predictive» to «Adaptive»: be open
- Gather info to make informed choices on positions...
 - ...but then get out there and try! (changing is easier than starting)
- Take advantage of network to:
 - find opportunities
 - ask for advice
- If 'something goes wrong', it might be the preparation phase for next step

In Drug Development there are a lot of opportunities, just waiting for new talents