






EFSPI 1-day meeting Decision-making in drug development




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Welcome! Servier at a glance

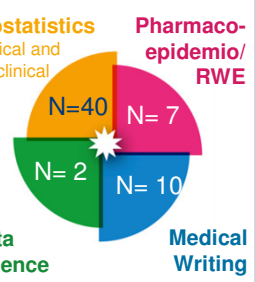
-  **2nd French pharmaceutical company**
30th worldwide
-  **Entirely independent**
Governed by a non-profit foundation
-  **A turnover of € 4.152 billion**
Servier's drugs € 2.94 billion
Generic drugs €1.21 billion

-  **A workforce of 21,700**
in 149 countries
4.500 in France
-  **A leader in cardiology**
2nd in Europe, 8th worldwide
-  **25% of turnover**
is invested in R&D, excluding
generic drugs

R&D specialized in 5 major therapeutic areas

CARDIOVASCULAR DISEASES	DIABETES	CANCER	IMMUNE-INFLAMMATORY DISEASES	NEURO-PSYCHIATRIC DISEASES
Heart failure	Type 2 diabetes	Solid tumors and hematological malignancies	Autoimmune disease	Neurodegenerative disease

**Center of Excellence
Methodology and
Valorisation of Data**

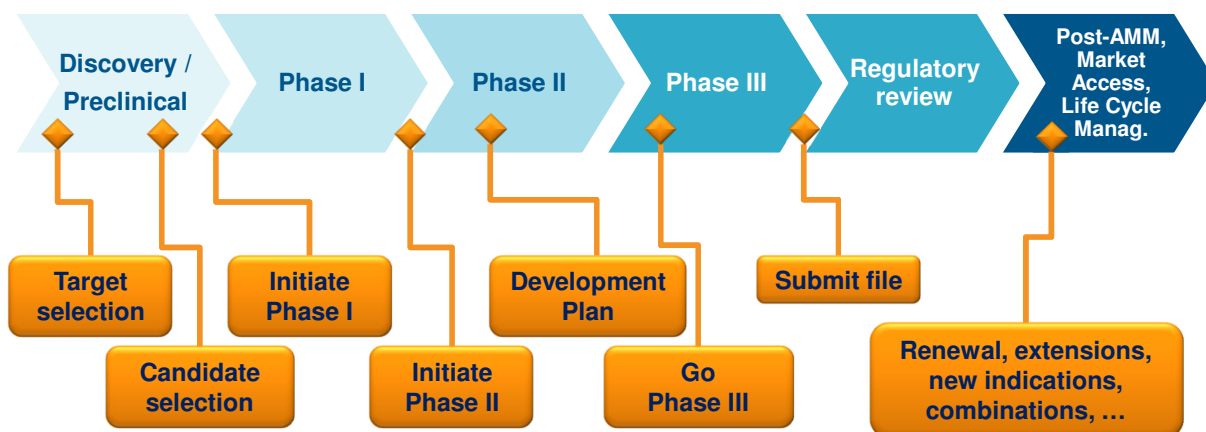


Biostatistics
Clinical and Preclinical (N=40)
 Pharmaco-epidemiology/RWE
(N=7)
 Data Science
(N=2)
 Medical Writing
(N=10)

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3

Decisions through the drug life-cycle

Research and Development
CentEX MVD

Source: ► PHARMALEX

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4

Decisions at different levels in drug development

Study level

- Dose range, treatment regimen,
- Population, CT design (sample size, control arms, duration)
- Stop/continue a trial at interim analyses
- Operational aspects (recruitment projections, target number of events,)

Development level

- Strategy: indication, population, number of studies, timing of the studies
- Go/No Go at key project milestones
- Due diligences
- Global project value assessment

Portfolio level

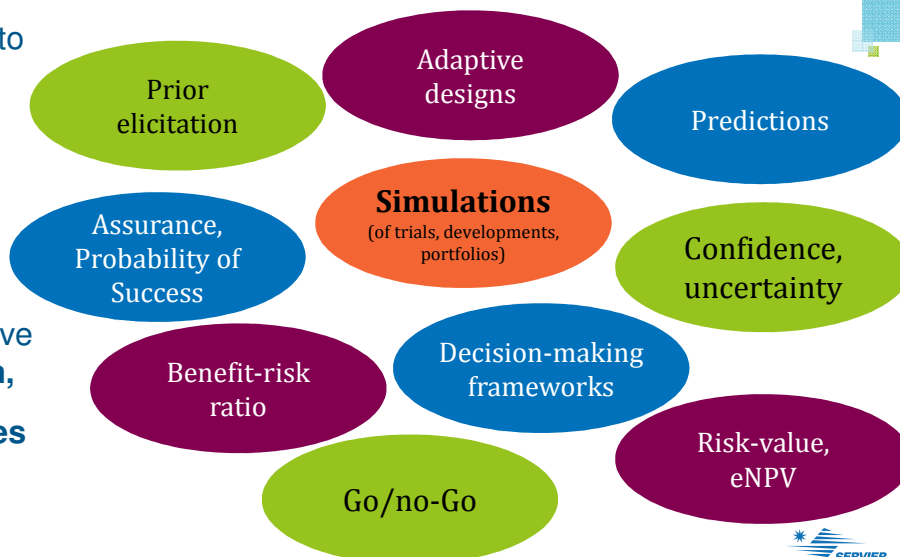
- Strategy: Go/No Go and selection of development projects
- Financial resource allocation
- Return-On-Investment evaluation

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Statistics and decision-making in drug development

Quantitative methods to support **optimal and informed choices**, at a given **time point**, between **several alternatives**, based on the cumulative **available information**, integrating **preferences of the decision-maker(s)**



Statisticians and decision-making in drug development

- **Quantitative decision-making is increasingly used in the Pharmaceutical Industry**
- Interactions between statisticians and multi-disciplinary teams
- Many different questions → many specific methods
- Statistical methods permit to incorporate **uncertainties**
- **Evidence-based methods** avoid to rely on questionable assumptions
- **Subjectivity** (preference elicitations, targets) can be incorporated but should also be challenged
- Quantitative tools are intended to **support** but **not to replace** the human decision-making process for strategic decisions

EFSPI SIG Quantitative Decision Making

- Group of statisticians from industry and academia, with experience and interests in **statistical methods for quantitative decision-making in drug development**
- Objectives
 - To **share cases studies**
 - To perform **literature reviews**, discuss and make **recommendations** on existing methodologies
 - To **develop new methodologies** or practices where needed
 - To **promote the role of the statistician** in supporting decision-making in pharmaceutical companies and/or other stakeholders
 - To **propose trainings, public meetings or publications** to share methods and experience
- Co-chairs: Pierre Colin (Sanofi, pierre.colin@sanofi.com)
Gaëlle Saint-Hilary (Servier, gaelle.saint-hilary@servier.com)



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