## Bayesian Statistics in Early Phase Clinical Trials

### Funded By
Dipartimento DISMA

### Supervisor
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### Context of the research activity
Bayesian statistical approaches using external data to optimize early phase clinical trials.

### Objectives
The early phase development is an integral part of the drug development with the overall aim to reduce the risks and to maximize its probability of success by determining the right patient populations, the right indications, the right dosing schedules and the right therapeutic combinations. The consideration of external data from multiple sources such as clinical data, real-word data, pre-clinical data from animal studies, biomarker data and pharmacokinetics is critical to support decision-making. For example, such external data could be used to elicit informative priors on the statistical model parameters, to be incorporated in the analysis of clinical trials within a full Bayesian framework. It could also permit to optimize the sample size calculation of such studies.

Moreover, the extrapolation from adult data and other data is particularly important in pediatric drug developments, where a full independent program to demonstrate efficacy may not be ethical and/or feasible.

Finally, exploring the accumulated data could generate new hypotheses regarding the future drug development such as new indications, patient subgroups with greater benefits from the drug, or possible synergies between treatments supporting the development of combination-therapies.

The objective of this PhD is to:

a) Conduct a comprehensive review of the available Bayesian statistical methods making use of external data to optimize early phase clinical trials, evaluating when they can provide benefits.

b) In early phase clinical trials, develop new methods for:
   - Elicitation of informative priors to be used in the analysis,
   - Optimal sample size calculation,
   - Data extrapolation.

The Ph.d. candidate will work in close collaboration with the pharmaceutical industry, through the tutorship of Dr. Gaelle Saint-Hilary.

### Skills and competencies for the development of the activity
MSc, Laurea or equivalent degree in applied mathematics, statistics, physics, computer engineering, data science or related fields. Around 30 credits in Statistics, Probability and related fields. Good programming skills in R or Python. Interest for biomedical research and for collaboration with industry.