



## Internship Position in Sanofi

**Internship project title:**

Exploration and application of Statistical methodologies for the use of Real World Data to support projects in clinical trial development

**Contact names in Sanofi**

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Team: Clinical Modeling & Evidence Integration, Digital & Data Sciences, Sanofi R&D, Chilly-Mazarin

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**PROJECT DESCRIPTION**

In medicine, Real-World Data (RWD) are observational data obtained outside the context of randomized controlled clinical trials, coming from different sources such as Electronic health records, insurance claims, disease registries. Although randomized clinical trials stay the gold standard for demonstrating the evidence of efficacy and safety of a medical product, RWD are playing an increasing role in health care decisions and medical product development, by providing large datasets from diverse patient populations. However, RWD are often heterogeneous, complex, unstructured, messy, and due to the absence of randomization, are associated with many sources of biases or confounding factors.

During this internship, the intern will explore statistical methodologies for the use of RWD in Oncology. The aims are to enhance our understanding of the connection between clinical trial data and RWD, and to explore the impact of unmeasured confounding factors on treatment effect estimation. Differences between RW and clinical trial analyses will be assessed, in particular differences between populations and between measured endpoints. Methods for comparing the degree of similarity between different populations will be explored ("comparative effectiveness research"). Then the concordance between the drug efficacy observed in a conventional Phase 3 clinical trial and in a Real World cohort based on a similar population will be analyzed, using methods such as Cox regression analyses, propensity score matching, subclassification, weighting techniques.

The intern will perform first a literature review on statistical methodologies for the use of Real World Data, and get familiar with the disease specificities. Then, he will manipulate a Real World database and apply the methodologies to a particular Oncology case. Finally, the intern will provide a full report and recommendations. The intern will work closely with the members of the Sanofi team with statisticians across different sites (France, US), will attend related meetings in English and if required, report his/her work through presentations. This internship position will



allow you to discover the RWD and how they can benefit drug development, learn new statistical and machine learning methodologies, expand your career network and communication skills.

#### **ADDITIONAL INFORMATION**

##### **Skills Required**

1. Expertise in (bio)statistics in general, knowledge of machine learning (is a plus)
2. Computing skills: R, SAS (is a plus), Python (is a plus)
3. Good communication and writing skills
4. Scientific rigour and interest in Life science, biology, clinical development
5. Ability to work in English

##### **Expected Qualification / Experience**

Master 2 in Statistics, knowledge in theoretical and applied statistics