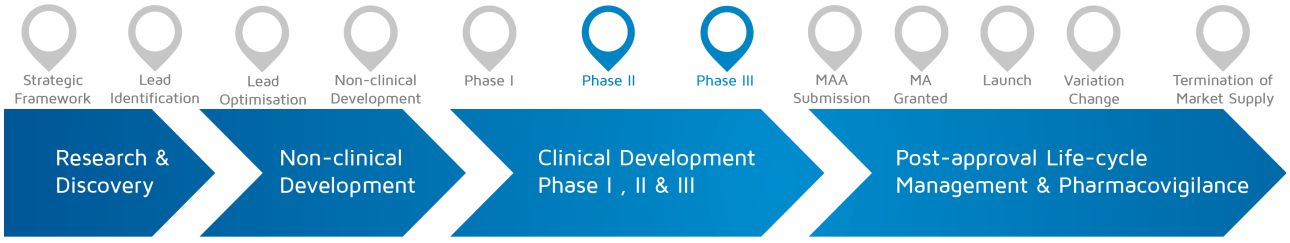
Patients Involved – Collaboration in an oncology trial

Introduction

A French patient association (La Ligue contre le cancer – http://www.ligue-cancer.net/), developed a collaboration with the Sanof-French Clinical Study Unit (CSU) to involve patients in the review of informed consent forms and a survey about patient participation in clinical studies.



When does it happen? – Phase II-III

Description of the case

Two years ago, the Sanofi-French Clinical Study Unit (CSU) began a fruitful collaboration with a French Patient Association called 'La Ligue contre le cancer'.

The success factors of this collaboration were:

- 'La Ligue contre le cancer' established a specific Patient Committee in collaboration with the National Institute of Research Against Cancer. The objective was to respond to the French 'Plan Against Cancer II'

launched by the National Authorities requesting patient involvement in clinical studies. This Patient Committee has been structured and trained to be able to review informed consent and protocol (review done under confidentiality agreement).
- Sanofi-French CSU already created a patient oriented informed consent template, recognised as a gold standard (used for 10 years with clear presentation, glossary, adapted wording).
- This collaboration was aiming primarily to involve patients in reviewing Sanofi informed consents prior to submission to Ethics Committee. A second objective was to contribute to a survey about patient participation in clinical studies in oncology to collect patient's insights and better understand their needs.

Type(s) of patient (advocates) involved

- Expert patient / patient advocate with good expertise on disease and good R&D experience.

Benefits of patient involvement

The feedback from the Patient Committee is concrete and pragmatic. The wording and vocabulary were adapted accordingly for better understanding of the information consent by the patients. The advices and recommendations received were:

- 'What are plasmocytes? White cells? A definition is needed
- The treatment details need to be more specific: it is an injection? What is the frequency?
- Is there a rest period between the 28 days cycles?
- What is the participation duration? Can you provide the information earlier in the document?

- Can you give more details about the different types of visits? Should we plan a half day or entire day for the intravenous infusion? An hospitalisation?

We also started to give this Patient Committee the opportunity to review our study protocol extended synopsis: the first experience with a Phase III trial protocol was positively perceived from the Patient Committee and led to three recommendations taken in to account by Sanofi: (1) a critical point on the study design, (2) an emotional approach about the study protocol (3) an advice on the informed consent presentation.

Challenges and barriers

No specific challenges and barriers for conducting this project outside necessary alignment between the different partners at the beginning of the project.

Learnings

Beyond the need to better informed the patients at the time of their consent, the results of the survey highlighted other difficulties encountered by the patients in participating to clinical trials in oncology and gave important directions to be taken into account in the future.

- At the beginning of the study: the complexity of the informed consent process; a step with potential misunderstandings because patients are often looking for better treatments.
- During the study: issues and constraints faced by the patients and not always addressed e.g. time to get reimbursement of transport fees, time spent at hospital, lack of knowledge about their where they are in the course of the protocol, need to speak with medical representatives, etc.

- At the end of the study: the need for patients to get the results and to be better prepared to what will happen after the study.The following statement on the document acknowledges the Patient Committee review step: ‘This informed consent has been reviewed by the Patient Committee from the Ligue contre le cancer’.
- Sanofi has been the first company in France to implement this process in 2014. We now plan to continue this collaboration, expand it to future protocols and other therapeutic areas and implement some concrete actions following the patient survey results.
- Today all the informed consents from Sanofi-French CSU for clinical trials in Oncology are reviewed by the Patient Committee prior to the submission to Ethics Committee.

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Attachments

- case-report-Oncology-trials-v1-EN

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  An infographic describing a collaboration between the Sanofi-French Clinical Study Unit (CSU) and the French Patient Association ‘La Ligue contre le cancer’.