

Patients Involved – Phase III Hepatitis C

Introduction

This is a collaboration between Bristol-Myers Squibb (BMS) with FUNDHEPA (patient organisation) to give more patients the opportunity to receive an innovative treatment for Hepatitis C through the participation in a clinical trial.



When does it happen? – Phase III

Description of the case

In Mexico, the prevalence of Hepatitis C in general population is 1.4% and almost 60% of patients treated with standard interferon and ribavirino do not respond to treatment. Non treatment or treatment failure can lead to cirrhosis and hepatocarcinoma. Results of clinical trials Phase II of Bristol-Myers Squibb (BMS) hepatitis molecules were very encouraging. Mexico was invited to participate in Phase III hepatitis studies. FUNDHEPA was contacted and several meetings were held with the ultimate goal of giving the opportunity to Hepatitis C patients to receive an innovative treatment that had already proved efficacy. The characteristics that patients need to fulfil to participate in the clinical trial, were

reviewed in meetings and well understood by FUNDHEPA staff because they were going to be the first contact with patients. They were going to explain the patients the purpose of the clinical trial and the benefits. An invitation for participating in the Hepatitis C clinical trials was posted in FUNDHEPA's web page. Patients contacted FUNDHEPA, and staff from the organisation asked questions in order to refer them to the nearest investigational centre.

Fifteen patients were referred, and nine were included in the clinical studies and received the treatment.

Type(s) of patient (advocates) involved

- Patients / parents with personal disease experience.
- Expert patient / patient advocate with good expertise on disease, but little R&D experience.

Benefits of patient involvement

Bristol-Myers Squibb (BMS) mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. In R&D, we ensure that this happens through the conduction of clinical trials. With the help of FUNDHEPA, the patients received treatment, and, at the same time they received information regarding efficacy and safety. In BMS Mexico a new process was built to ensure the right approach to the right person(s) to this kind of organisations.

Challenges and barriers

This was our first collaboration with an organisation that takes action for the patients benefit. Basically there were two challenges: 1) it was necessary to have several meetings with FUNDHEPA staff to reinforce the importance of giving the

opportunity to patients to receive an innovative treatment for their disease through the participation in a clinical trial. This made the process longer, and 2) the time needed for an agreement between BMS and FUNDHEPA regarding the text that the invitation to be posted in the web page had to have. This text had to be approved by the FUNDHEPA medical committee and by BMS.

Learnings

It's very important to have an early contact with patient organisations when working together since there are several points where an agreement has to take place in order to take actions. Sometimes, because of the nature of the organisation, it is required a greater time investment for any of these actions to take place. BMS Mexico currently has a program to contact and work with patient organisations or patient advocated groups before the clinical trials arrive to the country, thus giving the opportunity to set action plans for the patients benefit. To add value to the program, the information regarding the clinical study and its benefits must be disseminated and communicated to patients in advance.

A3-HepC-V1.0

Attachments

- **Case-Report-HepatitisC_v1_EN**

Size: 472,847 bytes, Format: .pdf

An infographic describing a collaboration between Bristol-Myers Squibb (BMS) with FUNDHEPA (patient organisation) to give more patients the opportunity to receive an innovative treatment for Hepatitis C through the participation in a Phase III clinical trial.

