EU-PFF
EUROPEAN PULMONARY FIBROSIS FEDERATION

Pulmonary Fibrosis Community Advisory Board (PF-CAB)

13th October 2022

Boehringer Ingelheim

WHAT IS A COMMUNITY ADVISORY BOARD? (CAB)

A Community Advisory Board (CAB) is a working group of patient advocates formed to monitor pharmaceutical or non-pharmaceutical developments for a given disease. CABs are interactive and cooperative with key stakeholders, over the long-term, including: pharmaceutical companies, regulators, and the scientific community.

THE PF - CAB

The European Pulmonary Fibrosis Federation (EU-PFF) has set up a **Pulmonary Fibrosis Community Advisory Board (PF-CAB**) as a working group of the EU-PFF. It comprises a panel of leading European patient advocates who can also call on other international experts. PF-CAB members work together to address issues of strategic importance to the PF community. They advocate for the best possible research and improved and equal access to innovative treatments and are for PF patients. PF-CAB monitors pharmaceutical developments, research and other developments in PF through, long-term cooperation and continued dialogue with pharmaceutical partners, regulators, medical experts, and the scientific PF-community.

This report covers the first PF-CAB meeting, which was organised with Boehringer-Ingelheim.

PARTICIPANTS

- PF -CAB Members
- Boehringer Ingelheim (BI) Representatives

Meeting moderated by:
Jan Geissler, Patvocates

Minutes prepared by:
Stefanie Bockwinkel, Medical Writer

SUMMARY

Community Advisory Boards provide an opportunity to build a meaningful relationship between pharmaceutical companies and the patient community to overcome the challenges and needs associated with pulmonary fibrosis (PF).

The **main objectives of the CAB meeting with Boehringer Ingelheim**:

1. To discuss various aspects around the drug development pipeline for PF
2. To discuss patient engagement activities at BI and to facilitate a dialogue on how to involve the PF patient community in BI's Research and Development
3. To take tangible actions forward for BI, PF-CAB and both in collaboration with regard to patient engagement in Research and Development

The meeting was held under confidentiality terms from all parties to allow for an open and frank discussion.

BOEHRINGER INGELHEIM'S DRUG DEVELOPMENT PIPELINE OF PF DRUGS

A highlevel overview of current developments was given and patient involvement at different stages was discussed between EU-PFF board and BI participants.

- PF-CAB/BI to explore opportunities for early patient involvement

THE ILD - COLLECTIVE

The ILD- collective is a non-interventional study to assess patients' experiences and outcomes.
BI is running a study in several countries, looking into patients' route to getting access to drugs and into patients' experiences

- BI to continue to keep PF-CAB informed about the ILD-Collective including confirmed countries
- PF-CAB/BI to further collaborate on the project aiming to make this initiative 'as patient centric as possible'
- PF-CAB/BI to work together on involving local patient advocacy groups and sharing information about the ILD-Collective
- BI to share early synopsis for ILD-Collective and PF-CAB to provide feedback

COUGH

To understand cough in PF, BI and PF-CAB discussed different patient experience questions around cough. How much cough is normal? How to monitor cough?

- PF-CAB to organise special session to further discuss cough in PPF/IPF
- PF-CAB/BI to further work on remaining questions surrounding cough in PPF/IPF from BI and CAB and to jointly generate patient evidence on cough

SPECIFIC CURRENT DEVELOPMENT PROGRAMS IN PF

Understanding how to develop a method of administration (MOA)for patient facing audience, choosing right Patient Reported Outcome's (PRO), trial design, number of visits in a trial.

- BI to create a patient-friendly version of the MOA video with simpler language and less technical terms
- PF-CAB to provide feedback on PRO questionnaires (Relevance for ILD? Too many questionnaires/questions?)
- BI will consider patient involvement and work with the PF-CAB and patient community as well as the regulatory systems to make sure that when PRO's are developed they are relevant and meaningful for patients.
- PF-CAB to advise on how to best communicate phase III trials to a wider patient community and to address unmet needs in ILD
- BI to continue to involve PF-CAB in clinical trials designs (e.g. comparator, PROs) as early as possible (ideally already for phase I and II)

BIOMARKERS

BI and PF-CAB discussed different current biomarkers for PPF & IPF and the current aims for using them.

- PF-CAB to continue to learn more from BI about the biomarker development for PPF/IPF
- BI to provide information on further publications and open sources (e.g. biobank registries) related to biomarkers
- PF-CAB suggested a cartoon based video for patients that explain biomarkers

OVERVIEW OF BI'S PATIENT ENGAGEMENT PLAN

Overview of BI's Patient engagement plan, the global structure and ways they engage patients and patient organisations.

- BI to consult PF-CAB on guidance development for early patient involvement in clinical trials to enhance early involvement in clinical development throughout the whole product life cycle
- BI to further work on engaging patients earlier and more systematically into drug development, including pre-clinical and post-authorization trials
- BI/PF-CAB to organise joint meeting to discuss/co-create feasible metrics for patient engagement in R&D
- PF-CAB/BI to further explore opportunities to involve patient organizations in gathering general feedback from trial participants

PF-CAB CAB'S EXPECTATIONS OF PATIENT ENGAGEMENT

Exploring shared opportunities for patient engagement in trials of BI based on the EUPATI model. Discussion about how to work with the PF-CAB for back to back patient feedback and how the PF-CAB provides training for members to be able to advocate for wider population.

- No specific action items identified

PATIENT ENGAGEMENT PLAN IN BI'S CLINICAL DEVELOPMENT AND OPERATIONS TEAM

Presentation of BI's strategy of involving patients in early research and how this is done now.
Discussion around the sometimes existing reluctancy of pharma for patient involvement due to programs being at a very early stage.

- BI to continue to interact with PF-CAB and EU-PFF through Advisory Boards, trial simulation, patient advisor panels and CAB meetings to design PF clinical trials
- BI/PF-CAB to run pilot on early patient involvement with early assets to map out and define 5-6 touch points and involvement of patient advisors throughout the drug development process
- BI to liaise internally to create framework for pilot project (e.g. contracting procedures for long-term collaboration) and to come back to PF-CAB with suggestions
- BI to report back to PF-CAB what has been done with feedback from previous CAB meetings and via the online platform etc.
- PF-CAB to share more information on the UK Innovation Passport

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