Patient Interview - Questionnaire

JSCXX – Product Indication
Day/month/year

The questionnaire should be filled in during the interview. Notes taken during the TC will be shared for validation with the patient afterwards.

---

1. Background information

Name of group:

Role in the group:

Type of group (tick all that apply):

- Registered charity ☐
- Fellowship ☐
- Informal self-help group ☐
- Unincorporated organisation ☐
- Other ☐
- Please state_____

Purposes of group (tick all that apply):

- Advocacy ☐
- Education ☐
- Campaigning ☐
- Service ☐
- Research ☐
- Other ☐
- Please specify_____

Describe your membership (number and type of members, region that your group represents, demographics, etc)?

Information about patient (if applicable):

a. Disease stage

b. Disease history

a. Diagnostic date:
b. What kind of impairments and aspects are associated with the disease in daily life? What affects your quality of life?

c. Treatment history/experiences with current resp. previous therapies:

Patient Interview - Questionnaire

2. Impact of condition

a. How does the condition or disease for which the medicine is being developed, affect patients' quality of life?

Issues to consider in your response

- *Aspects of the condition that are most challenging (e.g. symptoms, loss of ability to work, loss of confidence to go out, inability to drive, social exclusion).*
- *Activities that patients find difficult or are unable to do.*
- *Aspects of the condition that are the most important to control (e.g. symptoms that limit social interaction or ability to work such as difficulty breathing, pain, fatigue, incontinence, anxiety).*
- *Support required for daily living (physical or emotional).*
- *Types of patients that are most affected by the condition (e.g. men/women, children, ethnic groups).*
- *Challenges in managing this condition when patients also have other medical conditions.*
- *What patients would most like to see from a new treatment (e.g. halting of disease progression, improvement in a particular symptom).*

b. How does the condition or disease affect carers/unpaid care-givers?

Issues to consider in your response

- *Challenges faced by family and friends who support a patient to manage the condition.*
- *Pressures on carers/care-givers daily life (e.g. emotional/psychological effects, fatigue, stress, depression, physical challenges).*

3. Experience with current therapies

How well are patients managing their condition with currently available therapies?

(Currently available therapies may include any form of medical intervention such as medicines, rehabilitation, counselling, hospital interventions etc. If no specific therapy is available that should be stated.)

Issues to consider in your response

- *Main therapies currently used by patients for this condition and how they are given (tablet, injection, physiotherapy, hospital check-ups, etc, at home, in hospital; dose and frequency, ease of access)*

- *Extent to which current therapies control or reduce the most challenging aspects of the condition.*
- *The most important benefits of current therapies.*
- *The burden of therapy on daily life (e.g. impact at different stages of disease, interruption to work, stigma, clinic visits to receive infused medicines, need for weekly blood tests or describe a typical episode of therapy over a week or period of treatment).*
- *Side effects from the therapies that are difficult to tolerate.*
- *Concerns about long-term use of current therapy.*
- *If the current therapy is a medicine:*
- *Challenges in taking it as prescribed (e.g. swallowing the pill, self-injecting, use of a device to deliver the medicine, taking after food, not being able to lie down for 30 minutes after taking medicine).*
- *Ways in which the dosing is modified compared to what is prescribed (e.g. dividing the dose to avoid unwanted side effects, missing doses to fit into daily life).*

4. Actual medicine and clinical development plan

Based on shared information on the new medicine, what are the expectations/ limitations of it?

Issues to consider in your response

- *Perceived advantages and disadvantages of the new medicine.*
- *Level of improvement patients would like to see.*
- *Impact the new medicine might have on use of healthcare services (e.g. fewer visits to hospital).*
- *Financial implications (e.g. cost of medicine, travelling costs, medicine administration supplies, days off work).*
- *The level of side effects that patients would tolerate for a given benefit.*
- *Groups of patients who might particularly benefit or who might benefit less from the new medicine than others.*
- *Aspects of patients' needs or expectations that it is hoped the new medicine will address (explaining specific issues for particular stages of disease).*

Based on shared information on the new medicine clinical development plan, what are the expectations/limitations of the current clinical trials proposed?

Issues to consider in your response

- *What is the current standard of care for patients who are included in relevant trials?*
- *Whether the comparator corresponds to current standard of care. The impact of disease stage/activity and treatment history on treatment choice.*
- *Specific Groups of patients to be considered in the analyses of drug efficacy*

- *Whether the clinical studies include outcomes that are important to patients. PROs considered (see questionnaires EQ-5D, SF-36 etc.) are easy to be filled in. Any recommendation on specific side effects data to be collected.*
- *Feedback on the time schedule of patients reported outcomes (questionnaires to be filled in by the patient himself e.g. EQ-5D, SF-36 etc.).*
- *Does the proposed length of study cover all the question you might have on safety and efficacy of the product?*
- *What will be from patient's perspective the criteria for re-treatment?*

Based on shared information on the new medicine clinical development plan, would you participate in the current clinical trials proposed?

5. Additional information

Please include any additional information you believe would be helpful to the HTA reviewers and committee (e.g. ethical or social issues).