



TIPS FOR COMPLETING A PATIENT ORGANISATION SUBMISSION OF EVIDENCE TEMPLATE

FOR EACH ASPECT OF THE SUBMISSION:

Describe the number of patients from whom input was obtained

Include patient demographics (age, sex, ethnicity, disease severity)

Exclude information on statistics and scientific published references

Describe experiences of patients/caregivers that REFLECTS THE POPULATION WHO WILL USE THE PROPOSED DRUG

Including specific and detailed experiences can be very helpful in providing context

SECTION 1

INFORMATION GATHERING – Q1 and Q5

- Describe the methods used to collect data
- How many patients are there from each method of data collection?
- Please include data/insights beyond what is already published in the literature.

Q1 - If possible, include input from patients who received the drug in question and patients who received no treatments/other therapies in a similar clinical context. Input from carers is also valuable.

IMPACT OF CONDITION ON PATIENTS/CARERS/FAMILIES – Q2

- How are daily functions and quality of life affected?
- Describe the range of experiences – what is going well and what isn't?
- Is there a financial impact?
- Have relationships been affected?
- How do current treatments impact on carers/families?

Q2 - Information should be obtained directly from patients/carers/families.

Direct quotes can be very helpful.

If possible report on the experiences of many individuals rather than exceptional cases.

PATIENTS EXPERIENCE WITH *CURRENT* STANDARD TREATMENT – Q3

- How do patients/carers describe some of their experiences with current therapy?
- How effective is it in reducing/controlling side effects?
- What are the most important benefits?
- What are the side effects which are difficult to tolerate?
- Concerns about long-term use of current therapy.
- Be specific about what is going well and what is not, and if experiences might vary by different subgroups of patients.
- Are there challenges in taking it as prescribed?
- Is the dosing modified compared to what is prescribed?

Q3 - If no comparative treatment exists discuss best supportive care.

WHAT ASPECTS OF LIVING WITH THEIR CONDITION DO PATIENTS NEED MOST HELP? – Q4

- What concerns are unaddressed by current treatment?
- Identify major areas of change you would like addressed



SECTION 2

EXPECTATIONS FOR NEW TREATMENT – Q6

- What is the **anticipated** impact and the desired outcomes of using this medicine compared to current therapy
- Include any expected disadvantages or negatives with the new treatment compared to current treatment
- How will the new treatment address unmet needs described in Q4
- Include information on quality of life, daily functioning, side effects, etc.

Q6 - Information should be obtained from patients who have NO experience with the drug

EXPERIENCES WITH NEW TREATMENT TO DATE – Q7

- How many patients have direct experience with the drug being assessed?
- How has it affected QoL and ability to perform daily activities?
- What specific symptoms have improved?
- What are the key side effects? Include side effects that are most debilitating to quality of life, AND side effects that are tolerable.
- What concerns are unaddressed by new treatment?
- Are there any accessibility and financial implications?
- Include information about how patients with experience are accessing the drug under review.

Q7 - This section is only to be completed by patients who have used the drug being assessed (in the past or are currently on the medicine)

HOW WILL THE NEW TREATMENT ADDRESS UNMET NEEDS? – Q8

- Will the new medicine fill any of these gaps?
- How does it fill those gaps?
- Will it make a real difference to patients' lives?
- How strongly do you support this medicine?

Q8 - Relates to unmet needs or gaps in current treatment choices that are available to patients or people affected by the condition, identified in Q4

SECTION 3

SUMMARY – Q9

- This section requires special consideration to ensure that you are getting across your key messages
- Provide a 5 point summary of the KEY points
- Include QoL data, limitations of current treatments, benefits of new treatment

ADDITIONAL INFORMATION – Q10

- Are there any additional data which you believe may be helpful to the decision maker
- Include ethical or social issues
- Data on societal costs of the condition, costs of not treating the condition etc.

SECTION 4

FUNDING FROM PHARMACEUTICAL COMPANIES – Q11

- Full details of all funding received for EACH project within the last TWO years should be highlighted.

DECLARATIONS FROM INDIVIDUALS INVOLVED IN THIS SUBMISSION – Q12

- Relates to individuals that are a shareholder, director or employee of the applicant company, or are in receipt of payments direct or indirect from the applicant company.
- Mention cash/kind received by person or organisation from the applicant company, including expenses.
- Whether the interest relates to the specific medicine under consideration
- Whether it relates to clinical trial work for the medicine under consideration

Don't forget to send your submission as a Word document