



We need your help to improve Waldenström Macroglobulinaemia research!

What is crucial in management and treatment of this very rare disease? Participate in the HARMONY Delphi Survey to define a Core Outcome Set in Waldenström Macroglobulinaemia.

We want to define a set of outcomes that is crucial for patients with Waldenström's macroglobulinemia (WM) by consensus of different stakeholder groups. Included stakeholder groups are Patients, Clinicians, Regulators and Members of the European Federation of Pharmaceutical industries and associations (EFPIA). Definition of a so-called "Core Outcome Set" (COS) relies on your help in giving patients' perspectives. A "Core Outcome Set" (COS) is an agreed set of outcomes that are meaningful to patients (and others). It is a recommendation of what should be measured and reported in all trials in a specific area.

You are invited to take part in this survey to give your perspective on what is crucial in management and treatment of Waldenström Macroglobulinaemia disease.

Please take time to read the following information about the planned survey and if there are any questions, please contact us:
communications@harmony-alliance.eu.

Purpose of the study

Various clinical trials in the area of CML result in different measured outcomes. Definition of a COS will help to improve comparability of these various trials. Involvement of different stakeholder groups will ensure that future clinical trials will meet the needs of patients and every different stakeholder group. Patients' perspective is of particular interest to better understand the treatment outcomes from a patient's

view, by adding relevant outcome data that are relevant and sensitive to patients, their families and health care teams, not always captured by trials.

What will happen to me if I decide to take part in the study?

Participation is entirely voluntary. If you decide to take part in the study, you will be invited to answer an online series of surveys to rate importance of different outcomes. The study will use a method called "Delphi", which is a quantitative way of generating consensus. Two surveys will be used to find out what you think should be included in the Core Outcome Set.



- Answering the first round will take you approximate 30 minutes.
- After all participants have finished the rating in the first round, the answers will be summarised.
- You will be invited to take part in a second round.
- A new survey will then be generated, based on what you tell us, and you will be invited to take part in the second survey. In the second round you will be provided with your own answers from the previous round and with an anonymized, graphical summary of the other participants' answers across the different stakeholder groups. Therefore, you can revise your previous ranking.
- Rating the outcomes in each round will take you approximate 30 minutes.
- Rating the outcomes will take place in a virtual meeting, so you have always an opportunity to ask any questions or ask for support.

It will help the HARMONY group running the study if everyone completes each round of the Delphi survey to guarantee meaningful results. However, you are free to withdraw from the project at any time.

Will information I provide be confidential?

Any rating you will give are anonymized and confidential. This also applies to your personal data (name, mail address and home country). All these data will be stored only for the duration of the survey on a secure server provided by the DelphiManager. The DelphiManager is a web based system designed to facilitate the building and management of Delphi surveys, provided by the COMET initiative www.comet-initiative.org/delphimanager.

After completion of the survey all data will be deleted. The survey will follow ethical and legal practice.

What will happen after the survey?

After three rounds of the survey a final consensus meeting will take place to discuss the results and reaffirm the defined COS. Subsequently the defined COS will be made publicly available for everybody. The results will be spread by WM patient umbrella organisation as well.

Who is organizing and funding this study?

The survey will be conducted within the scope of HARMONY PLUS, a project of the HARMONY Alliance.

The project counts on the collaboration of WM patient umbrella organisation to ensure that patient preferences are properly incorporated and ethical procedures are guiding all stages of the project.

Contact

Waldenström Macroglobulinaemia patient umbrella organisation

p/a Patvocates: www.patvocates.net

Thank you very much for taking the time to read this information and we look forward to your contribution to this survey.