

# Definition of a core outcome set in MM

## Delphi survey patient information sheet

Version 3 dated 28/05/2020

### **HARMONY (Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Haematology)- WP2 Outcomes Definition**

#### **Introduction**

HARMONY Alliance needs the help of multiple myeloma (MM) patients to define a set of treatment outcomes that is crucial and meaningful for them.

This “Core Outcome Set” (COS) will be developed using a multi-round survey (known as a Delphi survey) to reach consensus amongst patients and other stakeholder groups.

The consensus reached through the survey will develop the COS, which will form a recommendation of what should be measured and reported in all clinical trials in MM. This is important to ensure that the measurement of outcomes is consistent, comparable and that outcomes that are important to patients are also captured across clinical trials.

Alongside patients, other stakeholder groups participating in the survey are doctors, regulators and representatives from the pharmaceutical industry.

#### **Your involvement**

The definition of the COS relies on your help in giving the MM patient perspective.

You are therefore invited to participate in this survey to give your opinion on what treatment outcomes are important for MM patients and what you think is important to measure in MM clinical trials.

To decide on your involvement, please take time to read the following information about the planned survey and please ask any questions ([katharina-maria.lang@charite.de](mailto:katharina-maria.lang@charite.de)).

## Purpose of the study

Within the context of a clinical trial, an outcome is something that is monitored during the trial to measure and understand the impact that a treatment has on a group of patients. For example, does the treatment improve or reduce survival and quality of life?

MM clinical trials are often conducted with different measured outcomes, which can limit the ability of researchers to compare the results of different trials. The definition of a COS will help to improve the consistency and comparability MM trials. Reaching stakeholder consensus on the COS will also ensure it meets the needs of all relevant groups, including patients, and ensure it is used by the myeloma research community.

Patient involvement in the COS definition is important to better understand their perspectives on meaningful treatment outcomes and to ensure that the COS includes these meaningful outcomes, as they may not routinely be captured in MM clinical trials.

## What happens if I decide to take part in the study?

Your 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 amongst stakeholders. Three surveys will be used to find out what you think should be included in the COS.

- Answering the first round will take you approximately 30 minutes for rating 60 outcomes.
- 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.
- The same summary process will be repeated after the second survey and you will be asked to fill in a final survey at the end of the study to foster consensus.
- Rating the outcomes in each round will take you approximate 30 minutes.

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 response to the survey or 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 (<http://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 and agreed COS will be made publicly available for everybody. The results will be disseminated by Myeloma Patients Europe too.

## Who is organising and funding this study?

The survey will be conducted within the scope of HARMONY. HARMONY is a private-public partnership that currently includes 53 partners and 32 associated members from 22 countries. For more information please visit: <https://www.harmony-alliance.eu>

The project is funded by HARMONY.

The project counts on the collaboration of Myeloma Patients Europe to ensure that patient preferences are properly incorporated and ethical procedures are guiding all stages of the project.

## Who has reviewed the study?

The study protocol has been peer reviewed by the HARMONY Alliance, including Myeloma Patients Europe.

## Contact details

For any information about the study, please contact:

[Julia Tolley \[tolley@mpeurope.org\]](mailto:tolley@mpeurope.org) or [Ana Vallejo \[vallejo@mpeurope.org\]](mailto:vallejo@mpeurope.org)

**Thank you for taking time to read the information and for your contribution to this survey** - <https://delphimanager.liv.ac.uk/MMdelphi/>