

Patients perspective

Patient's role in clinical trial design from perspective of PED/PROs

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What is relevant to know about me?



FH and HF (CRT-P device)



Retired Psychologist and Manager HR

Since 2016 Patient Representative



- In different roles
- At different levels
- For different stakeholders

Can patients contribute in trials?

From the early start until HTA?

Yes we can!

Our added value:

 **pay attention to PROM's / PED**

two examples:

- 2-DECIDE study
- I-HARP study

2-DECIDE study / a co-creation process

Idea for a trial

- Add input regarding benefits for patients

Trial proposal

- Finetuning regarding patient perspective.
- Add input regarding different patient characteristics

Co-creation proces

- Full equivalent member of the co creation group
- Together worked out mainly the trial design, PICO, the primary and secondary endpoints
- Goal: no hurdles for implementation after positive outcome trial

Trial 2-DECIDE

- Full member of the project team

I-HARP study

Creation of the tool itself

- Deliver input about needs / topics of patients
- Paid attention to family members and their specific needs
- Paid attention to the wording
- Asked attention for the knowledge / competence gaps of caregivers

Implementation of (I-HARP) tool

- Active role in workshops for HF Nurses + General Practitioners.
- Gave interview regarding the benefits of I-HARP for HF patients

How to make it a success?



Invest in the relationship:

- be open about expectations
- understand the needs of the other
- What is needed for a longtime commitment



Be approachable as a person



Discuss and listen at equal level

What more is needed?



Patient representatives *need to have an understanding about the whole process*

Trialists *need to have an understanding how to work together with patient representatives*

- ★ Training to fill the gaps on both sides (knowledge and competences)
- ★ A network where one can find each other
- ★ Some kind of (financial) rewarding

Don't take a patient representative for granted!