WORKSHOP 2

How to engage patients in clinical trial phases

Patient Engagement Open Forum
19.9.2019

PATIENT FOCUSED
MEDICINES DEVELOPMENT

Patient Engagement open forum
Beyond Aspiration

Introduction - Speakers and facilitators

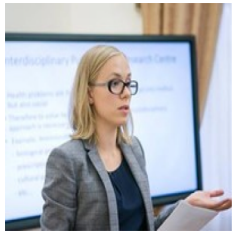
Laure Delbecque
Lilly

Ashley Duenas
Evidera

Paola Kruger
Patient expert

Séverine Wollenschneider
Roche

Thierry Escudier
Pierre Fabre



Olga Zvonareva
University of Maastricht

Anne Marie Hamoir
PFMD

Workshop agenda

Time	Session		
15:10	**Welcome and introductions to the WG team and 2 topics - set up expectations**		**Laure Delbecque** **Severine Wollenschneider**
15:30	**Description of workshop objectives/ what will happen next**		Anne Marie
15:35	**WORKSHOP** **Sub group 1 - Patient Engagement in Clinical Outcomes Assessment instruments**	**Round table discussions - 40 minutes** **Sub group 2 - Patient Engagement in protocol development**	Sub group 1 facilitators - Laure, Ashley & Paola Sub group 2 facilitators Severine, Thierry & Olga
16:15	**Feedback from the 2 groups**		
16:45	**Next steps** **Closing workshop**		**PFMD**
17:00	**End of workshop** - *Farewell drinks in the Plenary room*		

Welcome and Introduction to WG2 and 2 topics

By Laure Delbecque and Severine Wollenschneider

INTRODUCTION:

Patient engagement in the development of Clinical Outcomes Assessments

Patient engagement in the selection, development and interpretation of PRO, ObsRO, ClinRO and PerfO

Description of the Initiative

Aim: Provide guidance on how to engage patients and caregivers in any COA-related activities (e.g., selection of an existing PRO to include in a study; development of a new PRO or ObsRO; interpretation of PRO data)

Therapeutic area: all therapeutic areas

Phase: all phases (I-III)

Stakeholders: all

Current Team

- Paola Kruger (EUPATI)
- Ashley Duenas (Evidera)
- Laure Delbecque (Eli Lilly)

The structure and content of the “How to module”

How does PFMD Quality Criteria apply to the selection, development and interpretation of COA?

Definitions and resources

COA selection

COA development

COA interpretation

- How is a COA selected / developed / interpreted?
- How to engage with patients in this process?
- What are the risks of not engaging the patients?
- Practical examples

Expectations for the workshop - COA topic

20 min: **Your expectations for the “How to module” and your past experience with COA**

15 min: **Current structure and content of the “How to” module**

- Your feedback: are we taking the right approach ? What is missing / not needed ?
- Agreement on the structure and content of the “how to module” and next steps

5 min: **Identify additional resources**

INTRODUCTION:

Patient engagement in protocol development

Description of the Initiative

Aim: Provide guidance on how to engage patients and caregivers protocol setup

Therapeutic area: all therapeutic areas

Phase: all phases (I-III & IV)

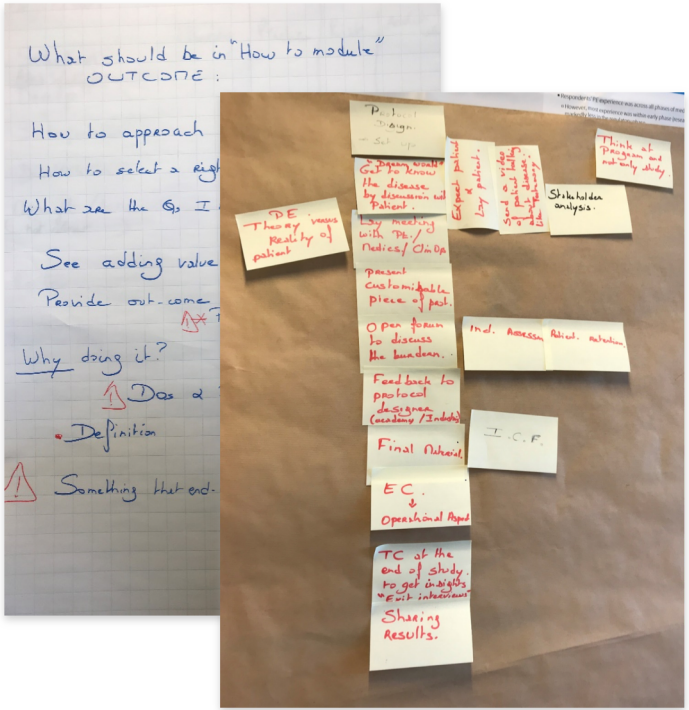
Stakeholders: all

Current team

- Séverine Wollenschneider (Roche)
- Thierry Escudier (Pierre Fabre)
- Olga Zvonareva (University of Maastricht)
- Jennifer Preston (University of Liverpool, eYPAGnet)
- Thomas Smith (Patient expert)

Outcomes of team workshop in June 2019

made with patients



Considerations on what should be included in a "how-to" module for Patient engagement in the protocol design.

- *How to select and approach the "right" patients?*
- *What needs to be considered in the engagement activity?*
- *What's in it for the team and patients involved?*

Draft content expected to be finalised by end of year 2019

Preliminary topics to be included in the how-to module

Key points to consider while engaging patients in protocol set up

- Getting to know the protocol or the program
- Involvement of “expert and lay” patients
- Disease knowledge i.e. Patients’ & caregivers’ insights on the reality of patients’ life
- How to ensure that results are shared with patients

Preliminary topics to be included in the how-to module

Activities where patients can be engaged and contribute

- Study design & Target population (Inc./ excl criteria, medical history,...)
- Study objectives and endpoints definitions to support statistical analysis & innovative approach to support patients unmet needs.
- Patients burdens & study assessments

Expectations for the workshop - Protocol development

- **Team to provide** clarification on"where the working group" is standing so far and how we got there

- **Open discussion**
  - **Your feedback**
    - What do you think about our main topics
    - Are we taking the right approach?
    - What is missing / not needed?
  - **Next steps**
    - Agreement on the structure and content of the "how to module"

- **Identify additional resources**

Expectations for the workshop

- Co-creating a strong content together
- Identify additional resources

Join one of the subteam where you can most contribute (experience / expertise / interest)

- **Discuss and note down key points in each discussion topic**
- **Identify any gaps, validate approach**
- **Share your experience, needs, expectations, barriers**
  - How did you overcome barriers? Or what would have helped you in overcoming those barriers?
- **The moderator will then share 1-2 key points from your table group in the feedback session at 16:15**

WORKSHOPS

Front of the room:

Patient engagement in the development of Clinical Outcomes Assessments

Back of room:

Patient engagement in protocol development

WORKSHOP:

Patient engagement in the development of Clinical Outcomes Assessments

Patient engagement in the selection, development and interpretation of PRO, ObsRO, ClinRO and PerfO

Your expectations and past experience

5 min: Your expectations and past experience with COA (individual exercise) (on post-it). For example,

- Have you ever been involved in the development of COAs?
- What has been positive/negative about your experience?
- Would you be interested in contributing to this type of research? If yes, how?

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10 min: Identification of the common themes at your table

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5 min: Summary (reconciliation from the 3 tables)

Presentation of the structure and content

5 min: **Presentation of the “How to module” structure and content**

5 min:

- Feedback: are we taking the right approach? What is missing / not needed?
- Is it easy/difficult to understand ?
- Validation of the structure and content
- Identification of the common themes at your table

5 min: **Summary (reconciliation from the 3 tables)**

WORKSHOP:
Patient engagement in the protocol development

Preliminary topics to be included in the how-to module

1. Key points to consider while engaging patients in protocol set up
   - ➢ Getting to know the protocol or the program
   - ➢ Involvement of “expert and lay” patients
   - ➢ Disease knowledge i.e. Patients’ & caregivers’ insights on the reality of patients’ life
   - ➢ How to ensure that results are shared with patients

1. Activities where patients can be engaged and contribute
   - Study design & Target population (Inc./ excl criteria, medical history,)
   - Study objectives and endpoints definitions to support statistical analysis & innovative approach to support unmet needs.
   - Patients burdens & study assessments

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PE Open Forum workshop objectives

Co-creating a strong content together
Identify additional resources

Join one of the subteams that you are interested in contributing to

At your table group

- Assign a note-taker
- Discuss the proposal and note down key points in each discussion topic → 40 minutes
  - identify any gaps, validate approach
  - share your experience, needs, expectations, barriers
    - How did you overcome barriers? Or what would have helped you in overcoming those barriers?
- The moderator will then share 1-2 key points from your table group in the feedback session at 16:15

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Workshop

Round table discussion with moderator

1. Get to know the planned “how-to” module
2. Discuss
    a. Are there other topics in protocol design where patients should be involved and covered in this guide? In other words, what is missing?
    b. In which format would this type of tool be most easy to use?
    c. What is the patient burden when they are involved in protocol design? Do you have experience?
    d. What kind of support do you need as a 1) industry representative (sponsor), 2) patient representative, 3) other stakeholder involved in protocol design?
    e. What should be considered when disseminating the study results? (In addition to the forthcoming EU Clinical trial lay summary regulation)

Feedback on key points from each sub-group

THANK YOU FOR JOINING US TODAY!

FOR MORE INFORMATION
PLEASE CONTACT PFMD@THESYNERGIST.ORG

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