Session 2: Framework and metrics for monitoring and evaluation of patient engagement
Thank you for joining this session today!

Meeting objectives:

- To show the Patient Engagement Monitoring & Evaluation Framework;
- To explain how the framework can be used to develop a tailored evaluation approach;
- To share experiences.

Share your views via www.menti.com code: 43 41 44 7
Patient Engagement Monitoring and Evaluation Framework

The framework includes:

- 6 evaluation components
  - 17 subcomponents
  - 87 metrics and 15 context factors
- Description of each metric with examples of related metrics
- 4 sample sets of metrics
- Sample questions, methods and measurement tools

Based on literature, expert knowledge and case studies, co-created
Co-developing a tailored M&E framework

Co-develop tailored framework:

**Step 1:** Determine the objectives of the initiative and the purpose of M&E

**Step 2:** Develop roadmap from input to impact and select metrics

**Step 3:** Identify suitable methods and create a M&E plan

**Step 4:** Establish a feedback loop and consider context factors
Working with the framework: 3 examples

**Persona 1**
**Name:** Richard
**Role:** Programme officer, Patient Organisation

**Persona 2**
**Name:** Amanda
**Role:** Patient relations associate, Pharmaceutical company

**Persona 3**
**Name:** Philip
**Role:** Public involvement manager, Regulatory agency
Persona 1: Richard, Patient Organisation

Initiative:
• Half-yearly community advisory committee meetings
• 15 patients (representatives) from various countries who invite pharmaceutical companies
• Discuss clinical trials and identify patient relevant endpoints

Expectations of M&E framework:
• Concrete guidance on how to evaluate engagement
• To develop a measurement strategy that shows value for their organization, the patients and companies whom with they engage
• To see examples of different evaluation methods used in practice
Persona 1: Richard, Patient Organisation

Richard organizes a workshop with all stakeholders: patients, industry and his team

Co-develop tailored framework:

Step 1: Determine the objectives of the initiative and the purpose of M&E

Step 2: Develop roadmap to impact and select metrics

Step 3: Identify suitable methods and create a M&E plan

Step 4: Establish a feedback loop and consider context factors
Persona 1: Richard, Patient Organisation

Step 1: Determine objectives of initiative and purpose of M&E

A) Objectives of the initiative
• To ensure that clinical trials collect information about outcomes relevant to patients
• To improve access to clinical trials for patients in all European countries
• To build trust between the company and the patient community

B) Purpose of M&E
• To acquire greater insight into the changes in medicines R&D which engagement stimulates
• To learn how they can improve their engagement practices
• To understand the value of the engagement to all stakeholders involved
Persona 1: Richard, Patient Organisation

Step 2: Develop roadmap to impact and select tailored set of metrics

**Input**
- Diverse group of patients from various European countries
- Company representatives from various departments

**Activities/process**
- Patients and company meet to discuss trial
- Understanding of outcomes that matter to patients, recommendations are documented and distributed in the company

**Learnings and changes**
- Company includes Patient-Relevant-Outcomes in the research protocol
- Company changes inclusion and exclusion criteria of trials
- Patients share outcomes of the collaboration with the patient community

**Impacts**
- Outcome measures in clinical trials reflect the needs and experiences of the patient population
- Increased number of trial sites is in underrepresented countries
- Participants in trials are more diverse
- Empowerment of patient community
- Improved company reputation

**Objectives**
- To ensure that clinical trials collect information about outcomes relevant to patients
- To improve access to clinical trials for patients in all European countries
- To build trust between the pharmaceutical company and the patient community
Persona 1: Richard, Patient Organisation

Step 2: Develop roadmap and select tailored set of metrics
## Persona 1: Richard, Patient Organisation

### Step 2: Develop roadmap and select tailored set of metrics

<table>
<thead>
<tr>
<th>Input</th>
<th>Activities/ process</th>
<th>Learnings &amp; changes</th>
<th>Impacts</th>
</tr>
</thead>
</table>
| • Diversity of patient representatives  
• Diversity of staff/department representatives | • Clarity of the goals of patient engagement  
• Usefulness of the patient engagement activity/activities  
• Feelings of trust, honesty, transparency, respect, shared learning and/or a give-and-take relationship | • Number of clinical trials changing inclusion and exclusion criteria  
• Number and type of actions/recommendations implemented | • Degree to which outcome measures and endpoints of a trial are patient centric  
• Number of (new) trial sites in underrepresented countries  
• Number of clinical trials including a previously excluded patient population (diversity) |
Persona 1: Richard, Patient Organisation

Step 3: Define suitable methods

Metric: Diversity of patient representatives

Component: Input
Subcomponent: Representativeness of stakeholders

Description
This metric provides information on the different characteristics of patients (e.g. demographics, education, literacy levels, socio-economic backgrounds, geography, language, as well as disease state/co-morbidities, variety of treatment experience, experience with patient engagement, degrees of exposure to/involvement in clinical studies, etc).

It indicates the variety of perspectives and experiences of patients involved, stimulating the diversity of learnings and recommendations given, indirectly impacting diverse aspects of the medicine life cycle. This metric could be used to assess the representativeness of patients involved in the project relative to the patient population.

Possible methods
A survey/questionnaire could be administered in which relevant characteristics are asked about. Details of patient representatives' demographics could be recorded from initiative documentation. Comparison of demographic data with affected populations' demographics.

Sample questions
- What are the characteristics of the patients and carers involved? (e.g. gender, year of birth, level of education, employment status, ethnic identity, geographical location)?
- Those most affected by the decision were appropriately represented in the engagement activity.
- Did you establish a profile of the type of person you wanted as a patient/caregiver partner prior to looking for candidates?
- Did the people included in the PE initiative reflect those that you wanted to engage with?

Tools/references
Persona 1: Richard, Patient Organisation

Step 4: Create a feedback loop and consider context factors

- Data collection
- Analysis
- Reflection
- Adjust patient engagement activities

Context factors:
- Community
- Policy
- Institutional
- Decision-making
Persona 2: Amanda, Pharma company

Step 1: Determine the objectives of patient engagement and the purpose of monitoring and evaluation

1) Objectives of PE
- To optimize the consent process in order to reduce drop-outs
- To improve participant experience
- To increase the efficiency of trials to reduce time to market for medicines

2) Purpose of M&E
- Demonstrating the effects (cost reduction, improved efficiency) on company performance
- To learn how they can use the available (human and financial) resources optimally
- Demonstrate to patients how their input is implemented

Activities
- Focus group discussions with caregivers of leukemia patients (<15 years old)
- Gain insight into lived experience
- Inform the design/protocol of trial
- Review of informed consent form

Expectations of M&E framework
- Concrete actions to take to make evaluating patient engagement a possibility
- To be educated about important and often-used metrics to M&E patient engagement
Amanda and her team decide to go for guided exploration using the Metrics sets.
## Persona 2: Amanda, Pharma company

### Step 2: Develop roadmap and select tailored set of metrics

<table>
<thead>
<tr>
<th>Input</th>
<th>Activities/process</th>
<th>Learnings &amp; changes</th>
<th>Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Expectations of patient engagement</td>
<td>• Clarity of the goals of patient engagement</td>
<td>• Number and type of actions/recommendations implemented</td>
<td>• Study participant experience in trial/perceived burden</td>
</tr>
<tr>
<td>• Money spent</td>
<td>• Timing of patient engagement activities with stages of R&amp;D cycle</td>
<td>• Learnings from patient engagement activity</td>
<td>• Drop out rate/retention rate</td>
</tr>
<tr>
<td>• Time spent</td>
<td>• Number, type and frequency of patient engagement activities</td>
<td></td>
<td>• Trial completion rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient understanding/accessibility of information materials and informed consent form</td>
</tr>
</tbody>
</table>
Persona 3: Philip, Regulatory agency

Activities
- Various activities, for example:
  - Review rounds of trial designs
  - Participate in early dialogues
- Large pool of patients with diverse backgrounds and disease experiences

Expectations of M&E framework
- To guide him in developing comprehensive overview of engagement in organisation
- To transparently report on the costs, effects and impacts of patient engagement

Step 1: Determine the objectives of patient engagement and the purpose of monitoring and evaluation

1) Objectives of PE
- To improve quality of scientific advice given to developers and to ensure it reflects the needs of patients

2) Purpose of M&E
- To improve the satisfaction of the stakeholders involved
- To understand the added value of engagement in different activities using different methods of engagement
### Persona 3: Philip, Regulatory Agency

#### Step 2: Develop roadmap and select tailored set of metrics

<table>
<thead>
<tr>
<th>Input</th>
<th>Activities/process</th>
<th>Learnings &amp; changes</th>
<th>Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Number of stakeholders involved</td>
<td>• Number, type and frequency of patient engagement</td>
<td>• Number and type of (actionable) insights and recommendations</td>
<td>• Number of trials where insights from patients were implemented</td>
</tr>
<tr>
<td>• Belief of stakeholders in the value of patient engagement</td>
<td>• Methods of gaining patients' insight</td>
<td>• Number and type of actions/recommendations implemented</td>
<td>• Percentages of studies with patient reported outcomes (PROs)</td>
</tr>
<tr>
<td>• Diversity of patients involved</td>
<td>• Satisfaction with the patient engagement activity/activities</td>
<td>• Changes in awareness and knowledge about patients' needs</td>
<td>• Quality of (scientific) advice provided by regulators/HTAs</td>
</tr>
<tr>
<td></td>
<td>• Satisfaction with support from activity organisers</td>
<td></td>
<td>• Willingness to continue the collaboration between stakeholders</td>
</tr>
</tbody>
</table>

**Paradigm**

Patients Active in Research and Dialogues for an Improved Generation of Medicines
Summary

• Monitoring and evaluation of patient engagement is **important** but also **complex**

• This tool supports:
  • Meaningful monitoring and evaluation by offering **structured guidance** for developing a roadmap and selecting metrics
  • Inclusion of relevant stakeholders to **co-create** sustainable impact
Audience questions
using the tool in your organisation
Panel discussion

Chair
Paul Robinson
MSD

Panel members
François Houyez
EURORDIS

Melissa Herman
Lundbeck

Maria Jose Vicente-Edo
Aragon Health Sciences Institute (IACS)

Michaela Dinboeck
Novartis
This tool was developed by PARADIGM Work Package 3
For more information contact:
Tjerk Jan Schuitmaker
Assistant Professor System Innovations in Health Care
Athena Institute, Amsterdam

t.j.schuitmaker@vu.nl