OBJECTIVES
Meaningful patient engagement (PE) in medicines development and lifecycle requires that stakeholders have a common purpose and vision, and a clear understanding of respective expectations.

METHODS
The study was designed to explore four key themes from the perspective of each stakeholder group: (Appendix A)

1. Meaning of PE in the context of patient-focused medicines development
2. Views on, and value placed on PE
3. Perceptions of stakeholder groups on what each group believes their role to be, and what each stakeholder group expects from other groups, and degree of agreement in expectations within and between stakeholder groups, and
4. Next steps and priorities for PE (Figure 1).

RESULTS
There was generally good alignment across the stakeholder groups on meaning of PE; impact of promoting PE to a higher level than currently, and need for a more structured process and guidance.

(a) Constraints: Interim analysis of semi-structured interviews

- Although interviewees definitions varied, the underlying sentiment was consistent across each stakeholder group that focused medicines development meant involving patients in every step of the medicines lifecycle.

- There was a growing understanding towards the terminology and language used (patient involvement vs patient engagement), stakeholders were aligned on the need to be clear what is meant by each term, and to work together.

- Overall, stakeholders thought that PE should be more than it is now and that their stakeholder group is not doing enough to address the needs of patients. When asked what importance on a scale of 1-10, with 1 being least and 10 highest level of importance, the average importance of PE to all stakeholders was now 7.9 but should be 8.8 (Figure 1).

- A consistent theme was the need for a more systematic and structured process along with guidance for PE in medicines development.

(b) Priorities:

The way forward is for each stakeholder group to:

- Collaborate across stakeholder groups to agree on definitions and language. A common language across stakeholders and an overarching definition of PE needed.
- Determine the role each stakeholder group should play to support patient engagement. The key question here being how PE is going to work in practice.
- "PE role has to be an active role in terms of relationships with researchers and drug development and with the patients" (researcher).

CONCLUSIONS
Our findings confirm the priority of PE, but also shows where there is little alignment and unclear understanding of roles and expectations. They highlight three important elements:

1. There is agreement on the need for PE for medicines development and lifecycle. However, subgroups of patients have different values and views on what patient engagement should mean.
2. There is a disconnect and lack of synergy (both within and between stakeholder groups) in terms of expectations, understanding of roles and responsibilities, and who should be leading PE.
3. Our findings suggest leadership in PE must come from different sources and in different forms. Defining the leadership role and the level of that leadership across the organisation is required. For this to happen, divergent expectations will need to be aligned.

Table 1: Stakeholder expectations

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Patient/Consumer</th>
<th>Policymakers/Regulators</th>
<th>Industry</th>
<th>Research Funders</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evaluate and provide feedback to companies</strong></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Provide information on medicines development</strong></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Advise and represent</strong></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td><strong>Assess and provide evidence</strong></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Table 2: Stakeholders Expectations Matrix

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Policymakers/Regulators</th>
<th>Industry</th>
<th>Research Funders</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provide feedback about drug development</strong></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Advise and represent</strong></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assess and provide evidence</strong></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Stakeholder responsibility for PE

<table>
<thead>
<tr>
<th></th>
<th>Equal responsibility</th>
<th>Pharo/Pharma industry</th>
<th>Policy makers/regulators</th>
<th>Patients/Consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provide feedback to companies</strong></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Advise and provide evidence</strong></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assess and provide evidence</strong></td>
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