Patient Voices

What do patients think about their investigational medicinal products? A landmark survey by ISPE points to high levels of satisfaction with trial materials, but also the need for greater customisation. It’s time for the clinical supplies industry to get patient-centric.

Professionals and policymakers in the healthcare and pharmaceutical industries have known for some time that engaging patients in their own care makes sense. The World Health Organization noted in a 2008 policy brief: “Considerable evidence suggests that patient engagement can improve their experience and satisfaction, and also can be effective clinically and economically” (1).

Historically, the clinical supplies industry has focused on providing products and services without patient feedback. However, the industry is now at a ‘tipping point’ and is set to alter its focus toward patient engagement, with information flowing upstream from patients and sites to drive the downstream flow of user-focused products and services.

In an important first step, the International Society for Pharmaceutical Engineering (ISPE) – working with the professionals leading its Investigational Products Community of Practice – formed the ISPE Patient Survey Project Team in 2012, to create the first-ever survey investigating patient experiences with clinical trial materials (2,3).

The goals of the project were to:

- Increase understanding of patient experience with investigational medicinal products (IMP) to inform decisions related to future study materials
- Understand the impact of key patient differentiators on patient experiences
- Provide a dataset that impacts decisions, opens new areas of enquiry and generates practice implications for both current Good Manufacturing Practice (cGMP) and Good Manufacturing Practice (GMP)
- Increase collaboration between global regulatory bodies, companies engaged in the IMP sector, and facilitator organisations like ISPE

Project Background

In the clinical supply world, the challenge for IMP professionals is to get ‘the right product to the right patient at the right time, every time’, surmounting the growing hurdles of new product types, global trials and financial constraints which often require flexibility in pack design.

Currently, most technologies and decisions in the IMP business have focused on cGMP and current Good Distribution Practice. As a result, the decision-making process may not have included adequate focus on the downstream implications of GCP-related activities on the investigator site or the patient experience.

During the development of ISPE’s good practice guidance for interactive response technology and booklet labels (4,5), the document teams acknowledged the importance of reaching out to study sites to gain perspective in the design process.

The results of a small site survey suggested that a team should be charged with ascertaining information about the complete patient experience related to IMP materials during planning and design. With financial support from 11 underwriting companies and technical assistance from the non-profit Center for Information and Study on Clinical Research Participation (CISCRP), ISPE designed and implemented the project between November 2012 and October 2013.

Scope and Approach

Undertaken in two parts, the project comprised a survey followed by a focus group to explore specific findings in more depth. To be eligible to complete the survey, a patient must have taken part in a clinical trial and have taken the medication home. Participation in the survey was voluntary, and each patient could complete it just once.

The electronic survey was divided into four sections with 48 questions in total. Most were multiple choice, but there was at least one free text question in each group. The sections included: current/recent experiences, attitudes and perceptions, improvements for the future, and background/demographics.

A focus group in the metropolitan Boston area in the US made up the second phase of the project. Fourteen patients who had been involved in a clinical trial but who had not completed the survey met for a 90-minute discussion led by experienced facilitators from CISCRP. The goal of the focus group was to explore apparent themes in the survey’s quantitative data.
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THE TRIAL PACKAGING
WE THINK ABOUT THE TRIAL PATIENT.

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Clinical packaging is about patients. Blinding, packaging, automation, flexibility – at Almac, our patient-centric approach means maximising patient compliance while meeting the competing demands of regulation, cost, and time. From protocol to patient, our global supply chain managers offer the industry’s highest level of expertise, applying the experience gained from thousands of clinical trials to overcome the challenges of every trial still to come.
Patient Characteristics

The electronic survey launched the first week of May 2013 targeting patients globally. When the survey closed in early September, the resulting respondent cohort was very robust in most areas of inquiry, except global diversity. Despite the project team’s considerable efforts, 97 per cent of the 1,425 respondents were from the US.

Overall, the team was satisfied that the cohort of respondents was a reasonable representation of clinical trial participants, with the exception of their concentrated geographic location. Figures 1-3 depict the characteristics of the respondents.

Key Findings

The study found a generally high level of patient satisfaction with clinical trial medicine packaging and instructions. About 90 per cent of respondents found their kit to be either very easy or somewhat easy to use. The majority found their packaging to be just the right size, very easy to store, and very easy to use.

Patients also self-reported a good level of compliance/treatment adherence, with most (82 per cent) claiming they took their medicine when they should. Some 60 per cent reported that the design and layout of the medicine kit actually helped them take their clinical trial medicine on schedule.

Improving Medicine Kits

Despite the generally high satisfaction levels, the project revealed several areas for consideration in improving kits.

Patient preferences regarding the format of kits were divided. When patients were given the opportunity to provide feedback on improving their kits, there were no obvious themes to the parameters the patients would change in this initial high-level analysis.

However, a deeper examination of the free text responses, as well as responses from the focus group, revealed that to enhance their satisfaction and overall clinical trial experience, patients prefer having options to customise their packaging at the individual level. Examples included the ability to select

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**Figure 1:** General respondent characteristics

- **Currently participating in clinical trials:** 23%
- **Participated less than six months ago:** 46%
- **Participated over six months ago:** 31%
- **Female:** 40%
- **Male:** 60%
- **US-based:** 97%

**Figure 2:** Respondent characteristics by format of clinical trial medicine received

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>Bottles</th>
<th>Blister packs</th>
<th>Syringe</th>
<th>Topical</th>
<th>Inhaler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone/muscle disorder</td>
<td>39%</td>
<td>51%</td>
<td>12%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Bowel/ovary problem</td>
<td>64%</td>
<td>27%</td>
<td>4%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Cancer</td>
<td>46%</td>
<td>23%</td>
<td>10%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>46%</td>
<td>16%</td>
<td>40%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Heart disease</td>
<td>52%</td>
<td>40%</td>
<td>21%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Lungs/breathing disorder</td>
<td>22%</td>
<td>20%</td>
<td>8%</td>
<td>8%</td>
<td>12%</td>
</tr>
<tr>
<td>Pain/stress disorders</td>
<td>42%</td>
<td>43%</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Psychiatric/central nervous system disease</td>
<td>48%</td>
<td>63%</td>
<td>2%</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>Skin/eyes/ears/nose/throat disorder</td>
<td>19%</td>
<td>10%</td>
<td>16%</td>
<td>52%</td>
<td></td>
</tr>
</tbody>
</table>

Base: All respondents n = 1,425

No significant differences among gender and age groups.
whether their clinical trial medicine bottles have child-resistant caps, and whether instructions are sent electronically. Some requested email or text reminders to assist in compliance.

**Patients and Products**

Most patients (60 per cent) felt the kit design and layout were helpful in adhering to the schedule for taking their medicines. Blister packs (75 per cent) and topical medication (71 per cent) rated significantly higher than other types of packaging.

Although the qualitative information showed that patients believed blister packs can be difficult to open, participants commented that they could track their scheduled doses better than with bottles. Some 14 per cent of patients admitted to removing their trial medicines from the original packaging.

The survey also suggested that IMP professionals and their colleagues should consider strategies that will discourage patients from keeping study medications for future use. One of the most surprising findings was that only 66 per cent of patients always return their clinical trial medicine, and 22 per cent kept unused products for future use. There was a wide variety of participant experience, with clinical supply returns suggesting a lack of consistency with instructions, including when and how return requirements are communicated to patients.

**Investigative Site Support**

The data gathered in this project supports the belief that investigative site support is instrumental in ensuring that study volunteers have positive experiences and are provided with all the necessary information to comply with study protocols (see Figure 4).

It appears that patients perceive the study is of high quality and they are a valuable part of the process – improving their experience and increasing their confidence - when study staff and/or the pharmacist take the time to review the instructions, explain the protocol, and show them how to use, take and store the clinical trial medicine. It is also beneficial when patients are given the opportunity to ask staff questions.

**Design and Labelling Aid Compliance**

Patients reported that clarity of instructions and ease of use are the two most important medicine kit factors from their perspective. The data further showed that medicine kit design and labelling could play an even stronger role in assisting compliance. Patients find it very useful to have dosing instructions on the label, colours as adherence reminders, and individually organised daily or weekly dosing units within the medicine kits.

Patients also appear to be receptive to the use of pictures (pictograms) to help communicate and simplify instructions. However, patients cautioned that the pictures must be easy to interpret, communicating correct and consistent messages about the medicines which do not contribute to confusion or other problems in compliance.

**Role of Technologies**

A number of questions in the survey were aimed at assessing how new technology solutions assist patients with compliance.

One issue was label information. Figure 5 (see page 16) depicts the percentage of patients, by category, who responded that receiving label information by electronic means would be “very useful”. While there were no significant differences by respondent gender or therapeutic area, there were differences by age group, which complements the previously reported comments around customisation options.

Interest in reminder technologies was also highlighted. Younger patients indicated that they would be either
Giving patients information how and when they want it may play a crucial role in supporting patient compliance. Study professionals need to find ways to accommodate choice and embrace modern communication technologies.

Finally, the project explored patients’ attitudes toward home delivery options for repeat prescriptions/refills (see Figure 6). About 78 per cent of patients indicated that it would be either “very helpful” or “somewhat helpful” to have their repeat prescriptions delivered to their homes, versus travelling to investigator sites. This was more pronounced in younger patients.

**Industry Support**

In summary, this landmark study has shown that patients want to comply with study requirements and that, for studies to succeed, customisation and accommodation of individual preferences is essential. There is also a clear need for improvement in clinical trial medicine return processes.

The ISPE Patient Survey Project Team will continue to analyse the data throughout 2014, and engage both industry leaders and regulators in planning follow-up projects, thus supporting the industry to move forward with a more patient-centric approach to clinical trial materials.

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**References**

1. Where are the patients in decision-making about their own care? World Health Organization Policy Brief, 2008

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