Addressing the urgent need for PLS for clinical trials and medical publications

Dawn Lobban, Envision Pharma Group

Nicholas Brooke, Patient Focused Medicines Development
### Lay summaries of clinical trials: Regulatory requirement and key considerations

- The EU Clinical Trials Regulation No. 536/2014 requires trial sponsors to provide PLS of clinical trial results
- These will be housed in the EU clinical trial portal and database, under development by the EMA

Follow specific EU/FDA/academic/industry guidelines (EUAnnex V of Regulation 536/2014; MRCT toolkit)

<table>
<thead>
<tr>
<th>Step</th>
<th>Key Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical trial identifiers (include trial title, protocol number, EU trial number and any other identifiers)</td>
</tr>
<tr>
<td>2</td>
<td>Name and contact details of the sponsor</td>
</tr>
<tr>
<td>3</td>
<td>General information about the clinical trial (include where and when the trial was conducted, the main objectives of the trial, and the reasons for conducting it)</td>
</tr>
<tr>
<td>4</td>
<td>Population of participants (include the number of participants in the EU Member State concerned, EU nations and nations with third-country relationships with the EU; age group and gender breakdown; and inclusion and exclusion criteria)</td>
</tr>
<tr>
<td>5</td>
<td>Investigational medicinal products used</td>
</tr>
<tr>
<td>6</td>
<td>Type and frequency of adverse events</td>
</tr>
<tr>
<td>7</td>
<td>Overall results of the clinical trial</td>
</tr>
<tr>
<td>8</td>
<td>Comment on the outcomes of the clinical trial</td>
</tr>
<tr>
<td>9</td>
<td>Indicate if follow-up clinical trials are planned</td>
</tr>
<tr>
<td>10</td>
<td>Indicate where to find additional information</td>
</tr>
</tbody>
</table>

Do we need anything else?

**WHAT DATA WOULD WE MISS?**

- Systematic reviews
- Real-world evidence
- Global studies without an EU site
- Case studies
- Reviews on disease burden

**WHAT CONTEXT WOULD WE MISS?**

- CSR
  - Lay summary
- PLS

---

*Images credit: ENVISION PHARMA GROUP*
(Some) patients want to understand published research: but it isn’t that easy

In a survey of people with Friedrich’s Ataxia and their carers:

Most patients and carers were interested in scientific publications related to their condition:

- **Patients**: 67.9%
- **Carers**: 78.8%

Few could understand scientific publications:

- **Patients**: 12%
- **Carers**: 6.3%

Few considered the Internet (Facebook, discussion forums, etc) to be a useful source for better understanding:

- **Patients**: 32.1%
- **Carers**: 5.7%

(Some) patients aren’t waiting for the published data: they are attending conferences and writing their own summaries.

One of my biggest takeaways from the APSS 2018 SLEEP meeting last month was the great amount of drug development underway for narcolepsy! Below is a list of some of the emerging treatments “abuzz” at #SLEEP2018.

Please remember, I failed high school biology (sorry mom!).

However, I hope this post helps provide access to information. When navigating a serious condition like narcolepsy, information is power.

Addressing the need for PLS

**WHY?**

- Information that is easy to access and understand can prevent misinformation
- People have a right to information that is about them: transparency builds trust
- PLS can increase the reach of data to different audiences and are often shared on SoMe
- By empowering patients, PLS can facilitate shared decision making

**HOW?**

?
Overcoming compliance concerns

Discuss the Code (early) - communication is not promotion

FDA: “It has long been FDA policy not to consider a firm’s presentation of truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and not accompanied by promotional materials…”

FDA Memorandum – Public Health Interests and First Amendment Considerations...January 2017 p 21
Our approach to PLS is evidence based and constantly evolving
Expertise is required

Team approach is needed to co-create PLS of publications

If you can't explain it simply, you don't understand it well enough.

Albert Einstein
Co-creation workshop: London, Nov 2018

**Brought key stakeholders together to discuss**

- Patients
- Industry
- Publishers
- Publication professionals

**Evidence relevant to PLS**

**Real-world case studies**

**Co-creation of practical tools for PLS**

**How to ensure access, quality and integrity of PLS**

The Workshop was a ‘tools fest’ not a ‘talk fest’

Agreement and recognition of the need to prioritise patient preferences and take an evidence-based approach

A collaborative event where the voice of the patient was powerful throughout the day
Key learnings:
Ensuring ethical and effective preparation

- Avoid ‘cherry picking’ which publications have PLS. Transparency builds trust.
- Industry and publishing codes reinforce that communication does not equal promotion.
- Identify the ‘right’ patient reviewer – ‘lived’ experience, lay perspective, or both?
- Drive awareness – make PLS available and accessible to all who need them.
- Use an experienced and specialist PLS team to deliver at scale, on time, and to industry standards.
Output: The future of PLS

A world-first co-created PLS of publications toolkit will be released in early 2019

PLS TEMPLATE
QC CHECKLIST
PATIENT REVIEWER GUIDE
SPONSOR REVIEWER GUIDE

GLOSSARY
EVIDENCE BIBLIOGRAPHY
1 PG PLS VS LAY SUMMARY
1 PG DATAVISION UPDATE

Leverage publication software for the optimal management of PLS
Addressing the need for PLS

**WHY?**

- Information that is easy to access and understand can prevent misinformation
- People have a right to information that is about them: transparency builds trust
- PLS can increase the reach of data to different audiences and are often shared on SoMe
- By empowering patients, PLS can facilitate shared decision making

**HOW?**

- Work with legal teams from the outset to ensure a compliant plan that avoids ‘cherry picking’ of data for PLS
- Consider the optimal format and communication channels for PLS including open access journals and congresses
- Combine scientific understanding, plain language expertise, graphical communications skills and patient partner insights
For Further information please contact:

Dawn Lobban
Scientific Divisional Lead
Envision Pharma Group
+44 (0) 7557238550
Dawn.Lobban@envisionpharmagroup.com