The agency perspective- Patient authorship and plain language summaries

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December 10, 2019

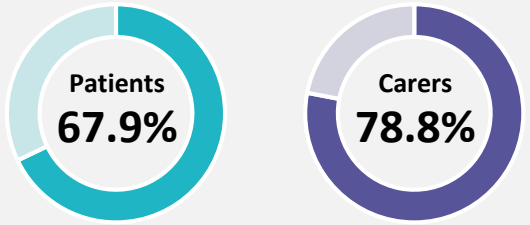
Objectives

- To gain an overview of where patients can be involved in the publications lifecycle
- To explore best practices and real-world examples of patient involvement in 2 key areas:
  - Patient authorship of publications
  - Plain language summaries (PLS)
    - Practical considerations

Many patients want to understand published research: but it isn't always that easy

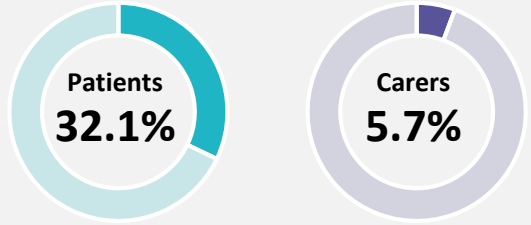
IN A SURVEY OF PEOPLE WITH FRIEDREICH'S ATAXIA AND THEIR CARERS:*

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



Few could understand scientific publications

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



*Amelot V, et al. *Pharm Med.* 2017;21:329-37 (study included 28 patients and 35 parents of patients).

How do we do it?

“Stakeholders agree that **more effective patient involvement is needed** to ensure that patient needs and priorities are identified and met.

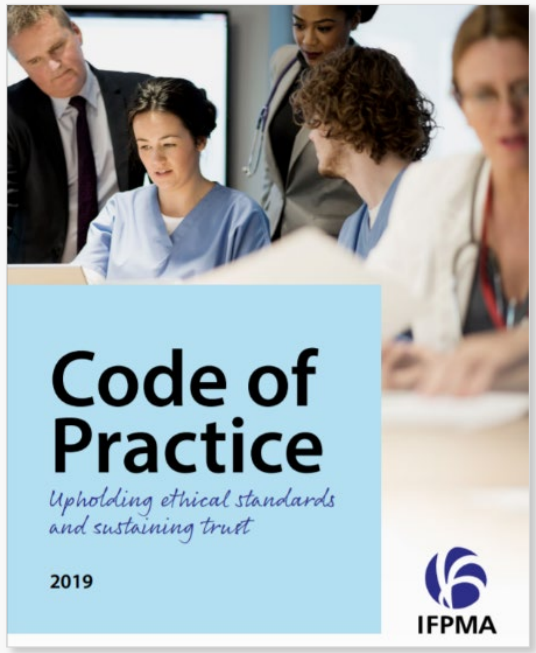
Despite the increasing number and scope of patient involvement initiatives, there is **no accepted master framework** for systematic patient involvement”

Hoos A et al. Partnering With Patients in the Development and Lifecycle of Medicines: A Call for Action. Therapeutic Innovation & Regulatory Science. 2015: 49: 929-939

First steps to involving patients in the publications lifecycle

Overcoming compliance concerns

Discuss the Code (early) – communication is not promotion



3. Pre-Approval Communications and Off-Label Use

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

> *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.

FDA perspective on involving patients in our publications

FDA speaker **encouraged** industry and publication professionals to continue to involve patients in drafting and publishing articles

Chinyelum (Chi-Chi) Olele, PharmD, CDR, USPHS
Patient Engagement Advisory Committee (PEAC) Manager
FDA's Center for Devices and Radiological Health (CDRH).

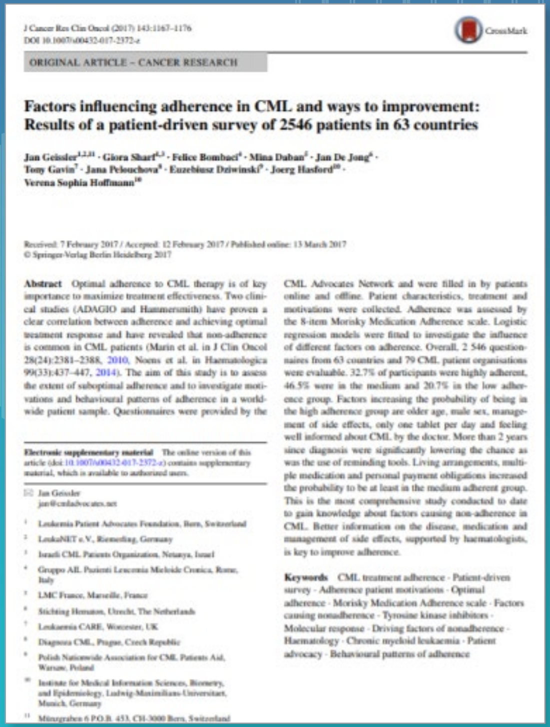
First steps to involving patients in the publications lifecycle

Patients are already authoring peer-reviewed publications. They are meeting authorship criteria set by:

General Medical Journals	Specialist Journals	Industry-focused Journals	Patient-focused Journals


RESEARCH

Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial


J Cancer Res Clin Oncol (2017) 143:1167–1176

ORIGINAL ARTICLE – CANCER RESEARCH

Factors influencing adherence in CML and ways to improvement: Results of a patient-driven survey of 2546 patients in 63 countries


Special Populations: Review

Partnering With Patients in the Development and Lifecycle of Medicines: A Call for Action

Anton Hoos, MD[1], James Anderson, MA, MBA[2], Marc Boutin, JD[3], Lode Dewulf, MD, Dip Pharm Med, FFPM[4], Jan Geissler, Dipl-Kfm[5], Graeme Johnston, LLB, IPFA[6], Angelika Joos, MPharm[7], Marilyn Metcalf, PhD[8], Jeanne Regnante, MS[9], Ifeanyi Sargeant, DPhil[10], Roslyn F. Schneider, MD, MSc[11], Veronica Todaro, MPH[12], and Gervais Tougas, MD, CM[13]


Research Involvement and Engagement

EDITORIAL — Open Access

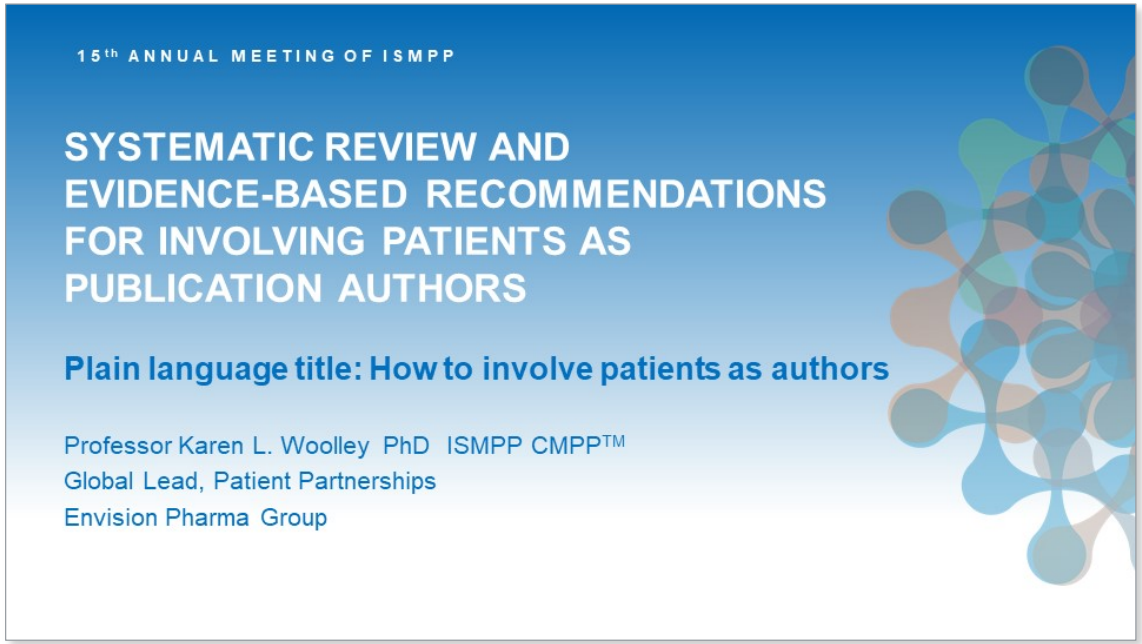
Research Involvement and Engagement: reflections so far and future directions

Richard Stephens[1] and Sophie Staniszewska[2*]

Industry co-authors included Pfizer, Novartis, UCB Pharma, GSK, Merck (passed 'compliance concern' barrier)

Evidence

World-first systematic review… with patient authors



Selected by industry peers (via blinded peer review) for an oral presentation at the 15th Annual Meeting of ISMPP
21 Evidence-based recommendation, before during and after manuscript preparation

First steps to involving patients in the publications lifecycle

First steps to involving patients in the publications lifecycle

Plain language summaries can empower patients in their discussions with HCPs

- Access to PLS can give patients a sense of empowerment[1]
- In a survey of patients and caregivers, 81% felt that PLS would help them to discuss treatment options with HCPs[2]

VALUE TO PATIENTS[3]

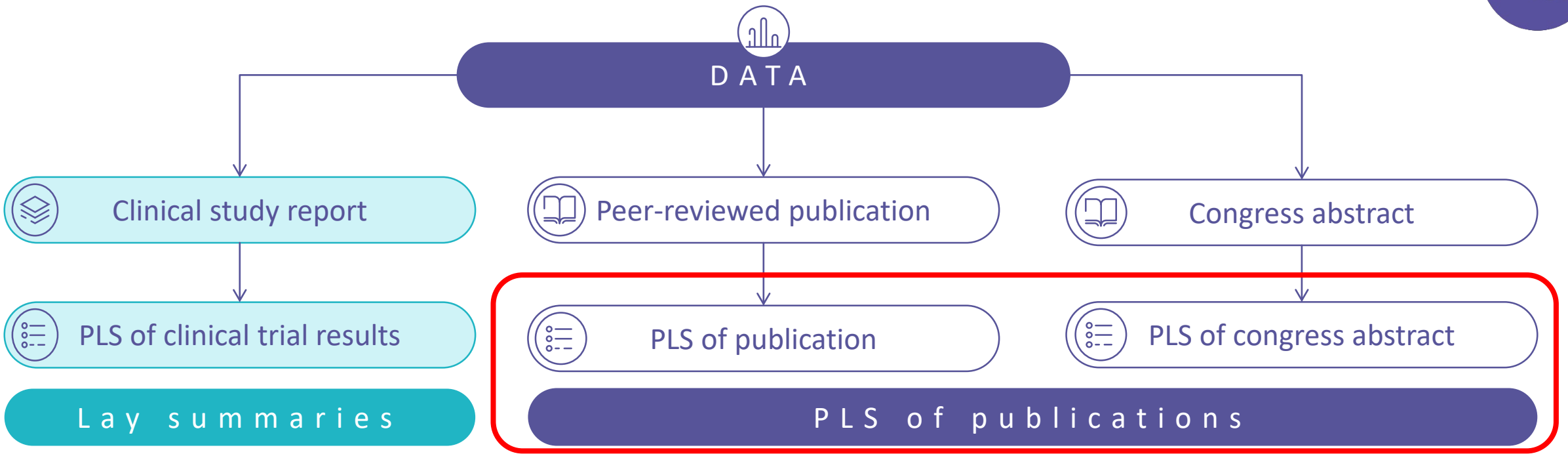
> *"The more informed a patient is, the better the conversation they can have with their doctors."*

VALUE TO DOCTORS[3]

> *"[Use of a plain-language summary] could help generate dialogue, increase efficiency and streamline communication between HCPs and patients."*

1. McKinnon VE. Poster presentation at EMBLive 2019.
2. Georgieva A et al. Poster presentation at ISMPP EU Meeting 2018.
3. Pushparajah DS et al. *Ther Innov Regul Sci.* 2017; https://doi.org/10.1177/2168479017738723.

Three types of summaries broaden data dissemination: two relate to publications



- Mandated by the EU Clinical Trials Regulation No. 536/2014 – will be housed in the EU database (2020 onwards)[1,2]
- The FDA recognises their importance but does not mandate them[3]

- Not currently mandated
- Increasingly being explored by journals and industry
- Cover a much broader range of evidence types than clinical trial results lay summaries

1. European Commission. Clinical trials - Regulation EU No 536/2014. https://ec.europa.eu/health/human-use/clinical-trials/regulation_en. [Accessed February 7, 2019].
2. European Medicines Agency. Clinical trial regulation. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp. [Accessed February 7, 2019].
3. Food and Drug Administration. Draft FDA guidance on provision of plain language summaries. https://mrctcenter.org/wp-content/uploads/2017/06/2017-06-13-MRCT-Draft-FDA-Guidance-Return-of-Aggregate-Results.pdf [Accessed October 8, 2019]

Increasing numbers of journals are including PLS

FREQUENCY OF PLS PUBLISHING IS LOW, BUT INCREASING[1]

- In a review of ~7630 journals, **<1% published PLS** alongside the main abstract[1]
- Many journals currently publishing are **newly established** and have always included PLS in their formats[1]
- Submitting a PLS as **supplementary information** can provide more layout options that may improve readability

thebmj | BMC Research Involvement and Engagement | BJOG An International Journal of Obstetrics and Gynaecology | PLOS MEDICINE | Cochrane Library

1. Haughton M, Machin D. Poster presentation at ISMPP EU Meeting 2017.

Journal variation in *what*, *who*, *when*, where

Assessment of 10 journals from different publishers identified as having PLS using eLIFE

Terminology

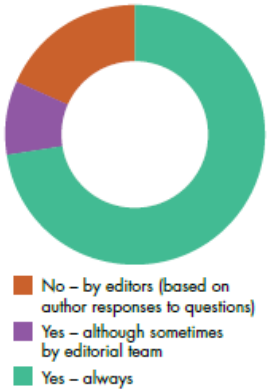
9 different terms for PLS were found

Annals of the Rheumatic Diseases refers to both 'patient summaries' and 'lay summaries'; *Autism Research* has changed from 'lay abstracts' to 'scientific summaries for families with ASD', and more recently to 'lay summaries'

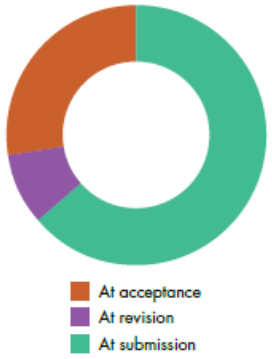
Some terms do not intuitively make the intended audience clear (eg 'significance statement', 'author summary'), meaning lay readers may overlook them

Requirements

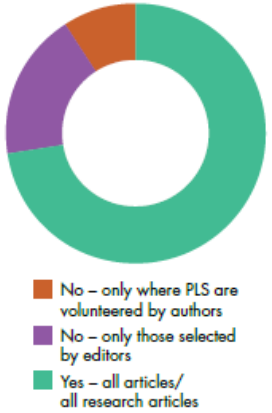
Are PLS developed by authors?



When are PLS required?

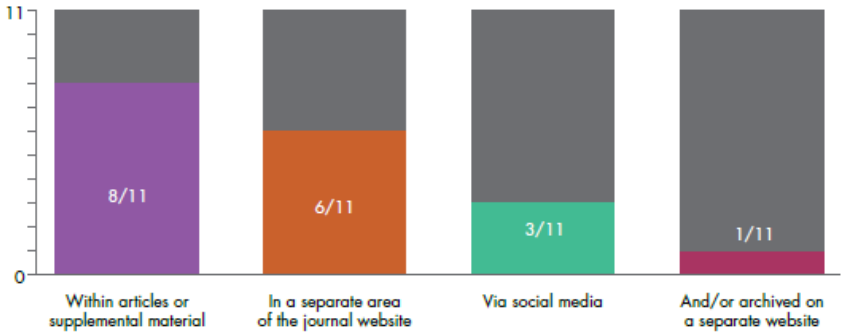


Are PLS required for all research articles?



Location

The sharing mechanism/location of PLS varies:



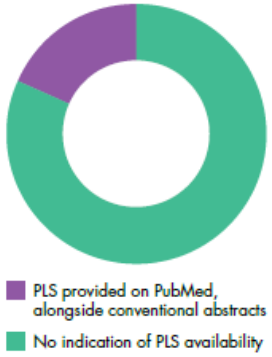
Accessibility

All PLS are **freely accessible**, with the exception of *ACS Infectious Diseases* – e-mail follow-up determined that these PLS are only for the press, and are not publicly available

PLS published within articles are freely accessible, even when the main article sits behind a paywall

PubMed visibility

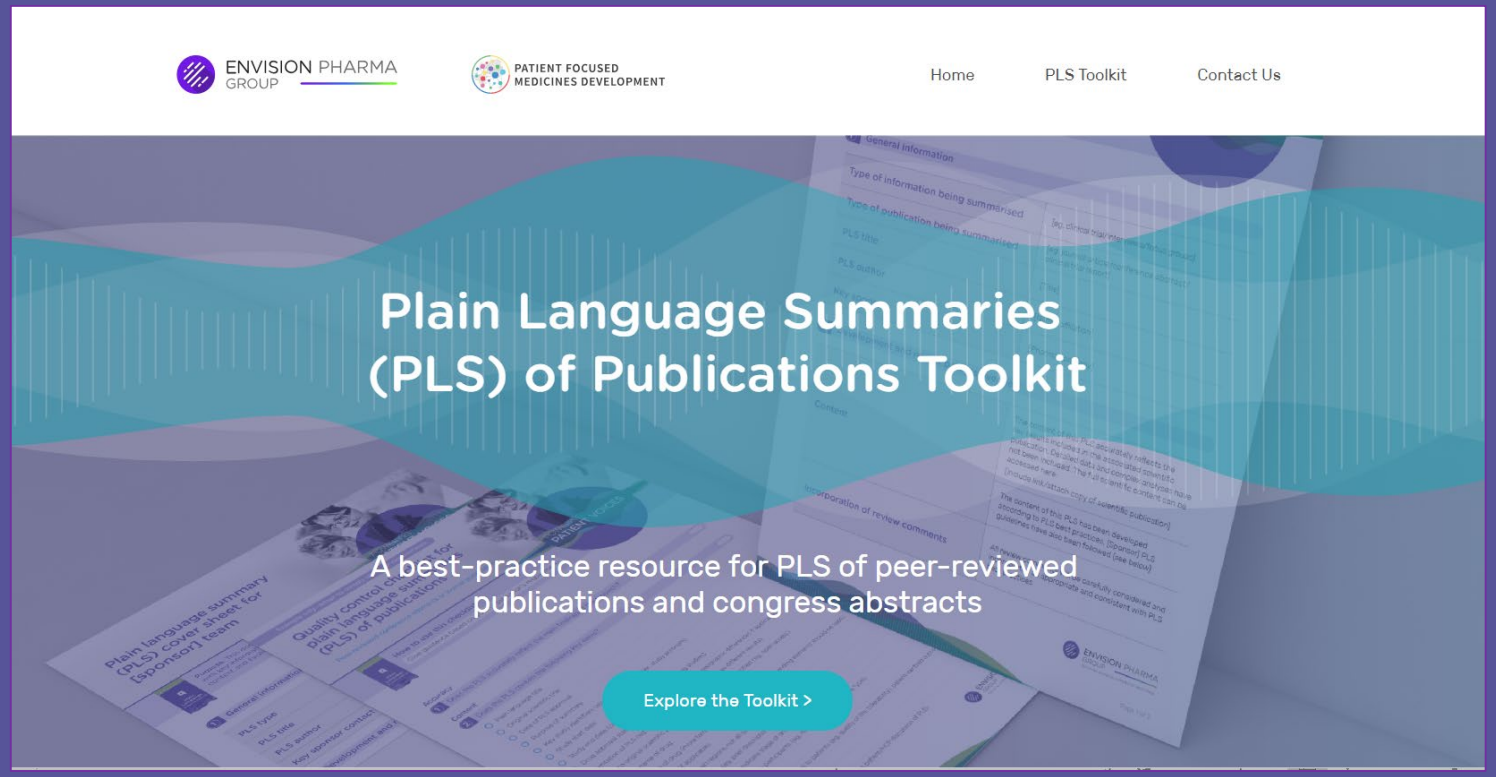
Are PLS noted on PubMed?



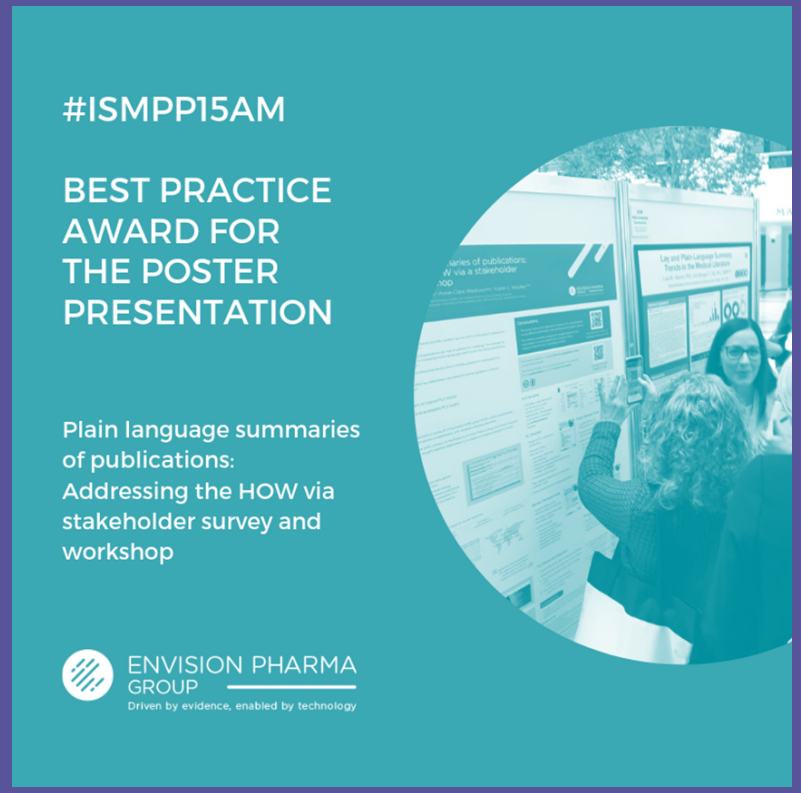
Fitzgibbon et al, ISMPP EU 2019.

The PLS of Publications Toolkit

Launch of the world's first PLS of Publications Toolkit
Supported by Envision's partner, Patient Focused Medicines Development,
and co-created with patients, publishers, editors, industry



Winner, 'Best Practice' Award,
at ISMPP Annual Meeting 2019 and
selected for Guided Poster Tour



https://www.envisionthepatient.com/plstoolkit/

ENVISION PHARMA GROUP
Driven by evidence, enabled by technology

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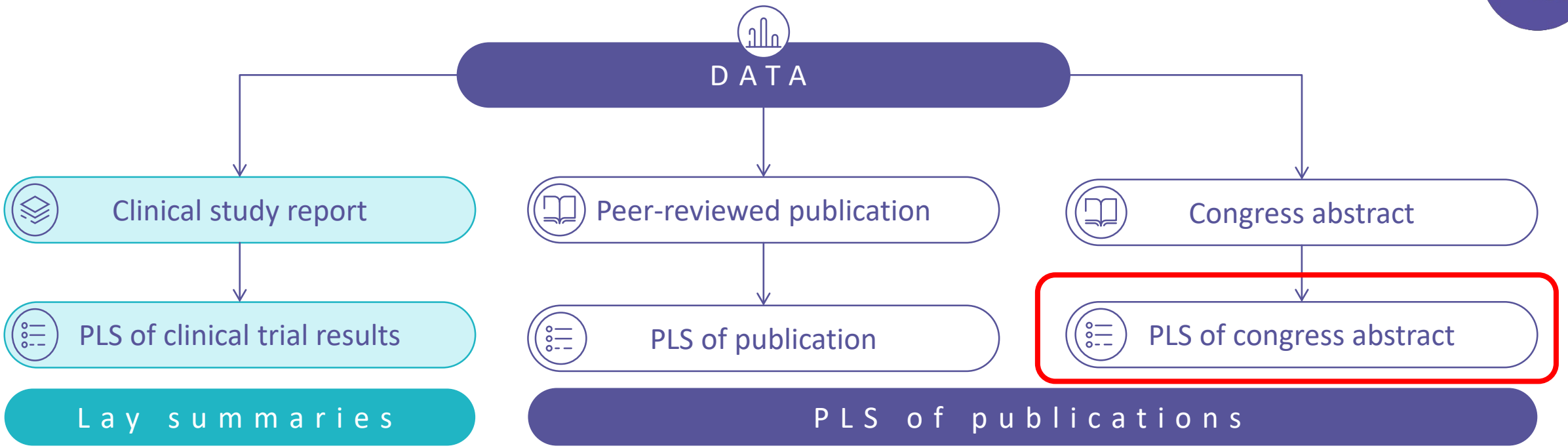

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PLS of congress abstracts (APLS)

THE CHALLENGE

- Patients are demanding access to the latest scientific information
  - Becoming more involved at congresses (eg, ASCO, ESMO)
- Pharma client wanted to address this unmet need
  - demonstrate a compliant, tangible commitment to patient involvement

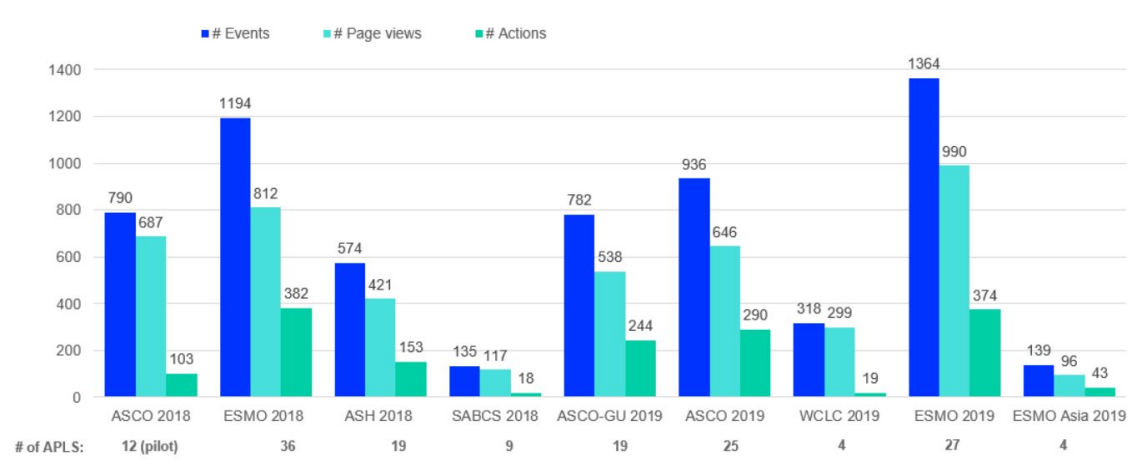
THE SOLUTION

- Accessible, understandable, usable APLS
- Scan QR code to access PLS
- View PLS on a device
  - Menu options to:
    - Download PLS
    - Print PLS, or
    - Access original scientific abstract (redirected to the congress website)
- An information sheet listing the titles and hyperlinks to the full APLS are made available to patient advocates if permitted by congress
- Press release and news article on company website

IMPACT: Every APLS was accessed

185 APLS have been co-developed with patients and authors

- Over 4600 page views
- Over 1600 additional actions



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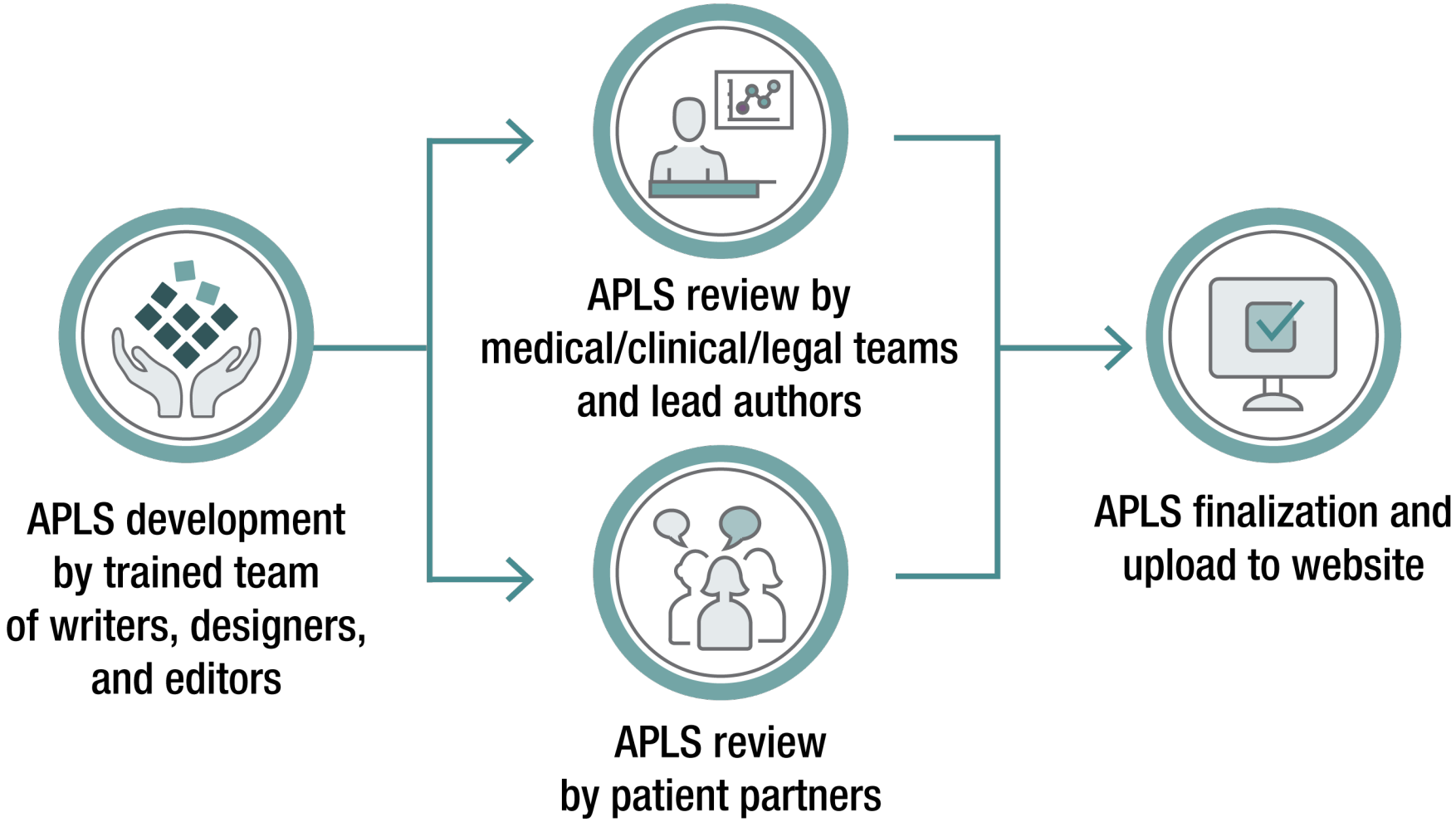

APLS practical considerations

Source

- Abstract vs poster
- Which abstracts?

Appropriate language, discordant comments

- Plain language vs scientific
- Widely understandable vs accuracy
- Consistency: across abstracts, across meetings
- Glossary

Training

- Agency, different type of writing for MWs
- Pharma company
- Authors
- Patients

Final adjudication

Timeline

- Draft text
- Graphics
- Data QC
- Reviews
- Layout

Conclusions

Patients are authoring peer-reviewed publications.

- Evidence-based recommendations can help us to minimise risks and maximise benefits

Key considerations include

- Keeping to plain language
- Consistency across outputs
- Timelines

Interest from publishers, pharma and patients is increasing

Practical tools and guidance are available to support you

Plain language summaries are an ‘easy’ first step to involving patients in publications