ISMPP University

Plain Language Summaries (PLS) of publications: Perspectives that will shape the future

February 3, 2021

ISMPP International Society for Medical Publication Professionals™

Webinar will begin promptly at:
11 AM ET / 4 PM GMT

ISMPP would like to thank...

. . . the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

AMGEN

Ashfield

AstraZeneca

Biogen

Bristol-Myers Squibb

CELLO HEALTH COMMUNICATIONS
MedErgy | SciFluent

Daiichi-Sankyo

ICON

McCANN HEALTH

MedThink SciCom

Roche

VERTEX

COMPLETE HEALTHVIZION

CAUDEX

CMC CONNECT

CMC AFFINITY

Pfizer

SANOFI

ISMPP International Society for Medical Publication Professionals

ISMPP announcements

- This webinar has been approved for 1.5 ISMPP CMPP™ Recertification Credits
  Please capture a screenshot to submit for credit
- Reminder to enter CMPP™ credits earned at the 2021 EU Meeting
- Registration for the 17th Annual Meeting now open!
  April 19-21, 2021

How to ask questions

Feel free to ask a question at any time, however all questions will be held until the end the of the presentation.

To ask a question, open the Q&A window, type your question into the Q&A box. Click Send

Note: Check Send Anonymously if you do not want your name attached to your question in the Q&A

We will make every effort to respond to all questions live (out loud)

Disclaimer

- Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers

Learning Objectives

At the end of this session, participants should be able to:

1. Understand the top 10 key questions to be addressed relating to PLS of publications

2. Identify the opportunities for accelerating the uptake of PLS of publications, as identified by 6 key stakeholder groups

3. Consider how future guidance about PLS may be relevant to you and your organization

ISMPP International Society for Medical Publication Professionals

Faculty

Jason Gardner
Head of Scientific Services,
CMC Connect, McCann Health
Medical Communications

Dawn Lobban
Global Lead, Patient Partnership,
Envision Pharma Group

Alexandra Freeman
Executive Director,
Winton Centre for Risk
& Evidence Communication

Richard Stephens
Patient advocate;
Co-Editor-in-Chief, Research
Involvement and Engagement

Laura Dormer
Editorial Director,
Future Science Group

ISMPP PLS Perspectives Working Group

ENVISION PHARMA GROUP

Dawn Lobban
Envision Pharma Scientific
Global Lead, Patient Partnership
Envision Pharma Group
dawn.lobban@envisionpharmagroup.com

MCCANN HEALTH MEDICAL COMMUNICATIONS

Jason Gardner
Head of Scientific Services
CMC Connect
jason.gardner@connect-cmc.com

ISMPP

Rob Matheis
President and Chief Executive Officer
ISMPP
rmatheis@ismpp.org

ENVISION PHARMA GROUP

Karen Woolley

Lauri Arnstein

Anne-Clare Wadsworth

Amanda Boughey

MCCANN HEALTH MEDICAL COMMUNICATIONS

Mary Gaskarth

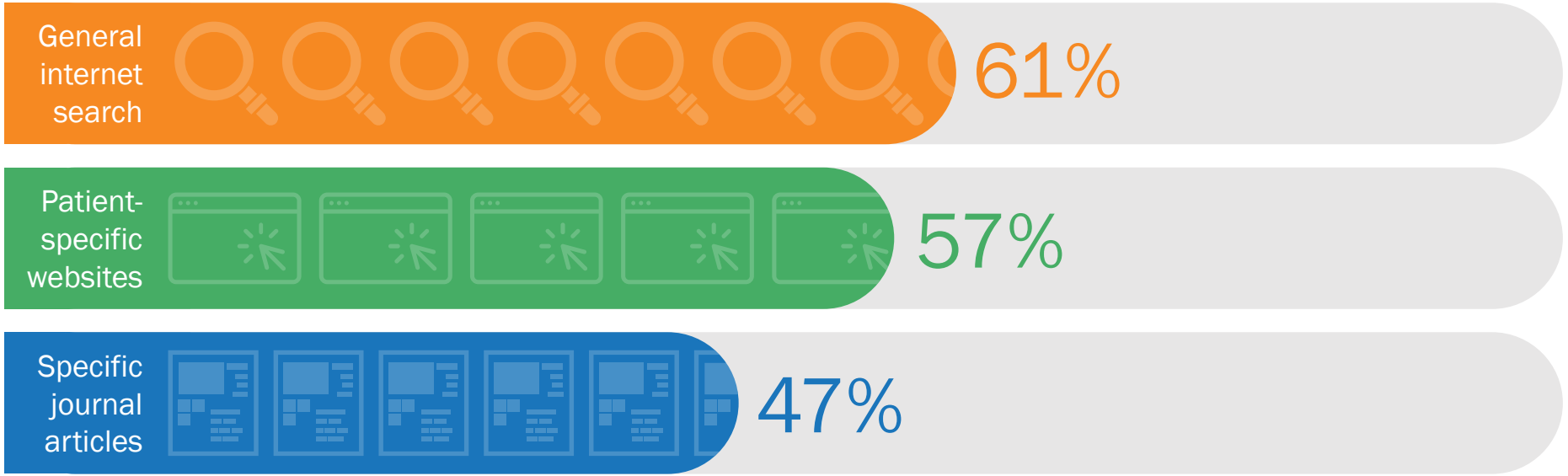
Jane Blyth

Andrea Plant

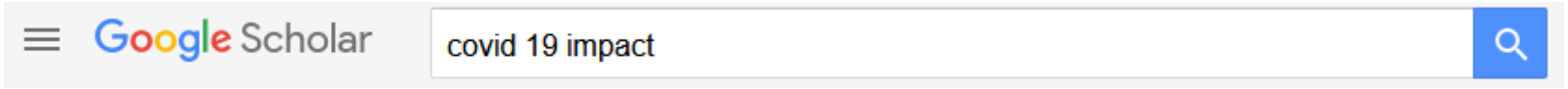
Karen King

People outside of the medical community are interested in the latest scientific research

Scientific journal articles ranked 3rd most important source of information



Pushparajah DS et al. Ther Innov Regul Sci 2018;52:474–481



Coronavirus disease 2019 (**COVID-19**): current status and ...

The **impact** of the **COVID-19** pandemic on cancer care

International Journal of Antimicrobial Agents 55 (2020) 105951

Contents lists available at ScienceDirect

International Journal of Antimicrobial Agents

journal homepage: www.elsevier.com/locate/ijantimicag

Coronavirus disease 2019 (COVID-19): current status and future perspectives

Heng Li[a,1], Shang-Ming Liu[a,1], Xiao-Hua Yu[b,1], Shi-Lin Tang[a,**], Chao-Ke Tang[a,*]

[a]Institute of Cardiovascular Disease, Key Laboratory for Arteriosclerology of Hunan Province, Department of Intensive Care Unit, the First Affiliated Hospital of University of South China, Medical Research Experiment Center, Hunan Province Cooperative Innovation Center for Molecular Target New Drug Study, Hengyang Medical College, University of South China, Hengyang, Hunan 421001, China
[b]Institute of Clinical Medicine, The Second Affiliated Hospital of Hainan Medical University, Haikou, Hainan 460106, China

ARTICLE INFO

Article history:
Received 6 March 2020
Accepted 19 March 2020

Editor: Jean-Marc Rolain

Keywords:
COVID-19
SARS-CoV-2
2019-nCoV
Coronavirus
Pneumonia

ABSTRACT

Coronavirus disease 2019 (COVID-19) originated in the city of Wuhan, Hubei Province, Central China, and has spread quickly to 72 countries to date. COVID-19 is caused by a novel coronavirus, named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [previously provisionally known as 2019 novel coronavirus (2019-nCoV)]. At present, the newly identified SARS-CoV-2 has caused a large number of deaths with tens of thousands of confirmed cases worldwide, posing a serious threat to public health. However, there are no clinically approved vaccines or specific therapeutic drugs available for COVID-19. Intensive research on the newly emerged SARS-CoV-2 is urgently needed to elucidate the pathogenic mechanisms and epidemiological characteristics and to identify potential drug targets, which will contribute to the development of effective prevention and treatment strategies. Hence, this review will focus on recent progress regarding the structure of SARS-CoV-2 and the characteristics of COVID-19, such as the aetiology, pathogenesis and epidemiological characteristics.

1. Introduction

Coronaviruses (CoVs) belong to the subfamily Orthocoronavirinae in the family Coronaviridae, Order Nidovirales. There are four genera within the subfamily Orthocoronavirinae, namely Alphacoronavirus (α-CoV), Betacoronavirus (β-CoV), Gammacoronavirus (γ-CoV) and Deltacoronavirus (δ-CoV) [1,2]. The CoV genome is an enveloped, positive-sense, single-stranded RNA with a size varying between 26 kb and 32 kb, the largest genome of known RNA viruses. Both α- and β-CoV genera are known to infect mammals, whilst δ- and γ-CoVs infect birds. Two recent outbreaks of viral pneumonia caused by β-CoVs are severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). In 2002, an outbreak of SARS was first reported in China and then spread quickly worldwide, resulting in hundreds of deaths with an 11% mortality rate [3,4]. In 2012, MERS first emerged in Saudi Arabia and subsequently spread to other countries, with a fatality rate of 37% [5–7]. In both of these epidemics, the viruses likely originated from bats and then infected humans through other intermediate animal hosts, e.g. the civet (*Paguma larvata*) for SARS-CoV and the camel for MERS-CoV [8–10].

Beginning in December 2019, a number of patients with pneumonia of unknown aetiology emerged in Wuhan City, Hubei Province, Central China. Genome sequencing has demonstrated that this pneumonia, named coronavirus disease 2019 (COVID-19), is caused by a novel CoV, namely severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known as 2019 novel coronavirus (2019-nCoV) [11–13]. Like SARS-CoV and MERS-CoV, this newly emerged SARS-CoV-2 virus belongs to the B lineage of the β-CoVs.

To date, COVID-19 has spread rapidly in 72 countries, causing >90 000 confirmed cases and over 2946 deaths as of 3 March 2020. Considering the global threat, the World Health Organization (WHO) has declared COVID-19 a public health emergency of international concern (PHEIC). However, there are no vaccines against SARS-CoV-2 or specific therapeutic drugs for this communicable disease. Thus, a better understanding of SARS-CoV-2 is essential for exploring effective vaccines and drugs. In this review, we sum-

* Corresponding authors. Present addresses: Institute of Cardiovascular Disease, University of South China, Hengyang, Hunan 421001, China.
** Department of Intensive Care Unit, the First Affiliated Hospital of University of South China, Hengyang, Hunan 421001, China.
E-mail addresses: 2867558123@qq.com (S.-L. Tang), tangchaoke@qq.com (C.-K. Tang).
[1] These three authors contributed equally to this work.

https://doi.org/10.1016/j.ijantimicag.2020.105951
0924-8579/

The impact of the COVID-19 pandemic on cancer care

The COVID-19 pandemic has disrupted the spectrum of cancer care, including delaying diagnoses and treatment and halting clinical trials. In response, healthcare systems are rapidly reorganizing cancer services to ensure that patients continue to receive essential care while minimizing exposure to SARS-CoV-2 infection.

Mike Richards, Michael Anderson, Paul Carter, Benjamin L. Ebert and Elias Mossialos

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative virus of coronavirus disease 2019 (COVID-19), continues to spread globally at an alarming rate. The unprecedented burden of COVID-19 on health systems worldwide has important implications for cancer care. First, although the data remain limited, patients with cancer appear to be more vulnerable to worse outcomes from the infection, including greater need for ventilator support[1] and elevated mortality rates[2,3]. Second, diagnosis may be delayed as screening programs and diagnostic services have been decreased or suspended in many countries, and patients, wary of exposing themselves to the risk of infection, have been more reluctant to present to healthcare services. Third, treatment pathways have been altered to minimize potential exposure of patients with cancer to SARS-CoV-2 and to reduce the risk during surgery or radiation therapy. Fourth, certain aspects of ongoing care have been deprioritized to enable health systems to respond to the COVID-19 pandemic, which has resulted in patients' receiving suboptimal or delayed care. Fifth, many clinical trials have been suspended, which has reduced current therapy options for patients who might have participated and has jeopardized longer-term therapy development. In response, healthcare professionals and managers in many countries have acted quickly to mitigate the repercussions of COVID-19 on the provision of cancer care by reorganizing cancer services and updating guidance for medical staff and patients. Here we consider these developments throughout the patient pathway, from diagnosis to treatment and ongoing care.

Implications for diagnosis

The necessity to divert healthcare staff and resources to address the pandemic has resulted in the suspension of cancer screening programs for asymptomatic patients in many countries. In March 2020, the Welsh government (https://phw.nhs.wales/news/novel-coronavirus-covid-19-temporarily-pauses-some-of-the-screening-programmes-in-wales/) and the Scottish government (https://www.gov.scot/news/health-screening-programmes-paused/) suspended screening programs for breast, cervical and bowel cancer. In April, the Northern Ireland government followed (https://www.health-ni.gov.uk/news/temporary-pause-routine-screening-programmes), with England yet to formally announce they are suspending screening. In the USA, the Centers for Medicare & Medicaid Services have classified screening as a low-priority service and suggested healthcare organizations consider postponing screenings[4]. In addition, many patients have been fearful of exposure to SARS-CoV-2 or of overburdening healthcare services and thus have been less likely to present to healthcare services for cancer screening and diagnosis. As an example, emergency-department visits in England dropped by nearly a third in March 2020 compared with the same month the previous year (https://www.england.nhs.uk/statistics/statistical-work-areas/ae-waiting-times-and-activity/). As approximately one in five cancers are diagnosed in emergency presentations (https://www.cancerdata.nhs.uk/routestodiagnosis/routes), this is likely to be responsible for considerably delayed diagnoses. In addition, the interim Chief Medical Officer for Scotland reported that urgent referrals of patients with cancer by primary-care physicians had been reduced by over 70% by mid-April compared with the weekly average over the past 3 years (https://www.bbc.co.uk/news/uk-scotland-52353657). Similar reductions have been reported in England[5]. By assuming urgent cancer referrals have a conversion rate of 7%, Cancer Research UK has estimated that this reduction in referrals could mean around 2,000 fewer cancers are being diagnosed per week[6].

Most forms of endoscopy, but particularly upper procedures, are classified as aerosol generating, which increases the risk of SARS-CoV-2 transmission, as also noted in the guidance of the British Society of Gastroenterology (https://www.bsg.org.uk/covid-19-advice/endoscopy-activity-and-covid-19-bsg-and-jag-guidance/). Colonoscopies are also risk prone, due to prolonged fecal shedding of the virus[6]. Thus, there has been consensus among the American College of Gastroenterology (https://gi.org/2020/03/15/joint-gi-society-message-on-covid-19/), the European Society of Gastrointestinal Endoscopy (https://www.esge.com/assets/downloads/pdfs/general/ESGE_ESGENA_Position_Statement_gastrointestinal_endoscopy_COVID_19_pandemic.pdf), and the Asian Pacific Society for Digestive Endoscopy that elective endoscopies should be suspended[7]. As a result, delivery of endoscopy services has been markedly decreased. For example, in the UK, the number of endoscopies undertaken were reduced by over 90% in April 2020 compared with the first 3 months of 2020, based on data from the UK National Endoscopy Database (https://ned.jets.nhs.uk/KPI/). It should be noted that as different countries pass their peak of COVID-19 cases, such recommendations are being reconsidered. In the meantime, demand for non-invasive imaging, such as computed tomography, has increased, as it carries a lower infection risk. To limit the need for prolonged deep cleaning of equipment after scanning of patients with COVID-19 and to decrease the risk of exposing other patients to infection, many hospitals are using separate COVID-19-exposed and non-exposed scanners. Moving forward, the continuation of diagnostic services, including endoscopy, may be facilitated by the setting up of diagnostic hubs that are kept as free as possible from SARS-CoV-2 exposure by being located in designated sites with extensive capacity for COVID-19

International Journal of Antimicrobial Agents 55 (2020) 105951

Contents lists available at ScienceDirect

International Journal of Antimicrobial Agents

journal homepage: www.elsevier.com/locate/ijantimicag

Coronavirus disease 2019 (COVID-19): current status and future perspectives

Heng Li[a,1], Shang-Ming Li

[a]Institute of Cardiovascular Disease, Key Lab
of University of South China, Medical Resea
Hengyang Medical College, University of So
[b]Institute of Clinical Medicine, The Second

ARTICLE INFO

Article history:
Received 6 March 2020
Accepted 19 March 2020

Editor: Jean-Marc Rolain

Keywords:
COVID-19
SARS-CoV-2
2019-nCoV
Coronavirus
Pneumonia

1. Introduction

Coronaviruses (CoVs) belong to the subfamily Orth
nae in the family Coronaviridae, Order Nidovirales. T
genera within the subfamily Orthocoronavirinae, na
coronavirus (α-CoV), Betacoronavirus (β-CoV), Gam
(γ-CoV) and Deltacoronavirus (δ-CoV) [1,2]. The CoV
enveloped, positive-sense, single-stranded RNA wit
ing between 26 kb and 32 kb, the largest genome
viruses. Both α- and β-CoV genera are known to i
whilst δ- and γ-CoVs infect birds. Two recent o
pneumonia caused by β-CoVs are severe acute
drome (SARS) and Middle East respiratory syndr
2002, an outbreak of SARS was first reported i
spread quickly worldwide, resulting in hundreds
11% mortality rate [3,4]. In 2012, MERS first eme

ly spread to other countries, with a fatality rate
th of these epidemics, the viruses likely orig-
nd then infected humans through other inter-
sts, e.g. the civet (*Paguma larvata*) for SARS-CoV
MERS-CoV [8–10].
ecember 2019, a number of patients with pneu-
wn aetiology emerged in Wuhan City, Hubei
China. Genome sequencing has demonstrated
onia, named coronavirus disease 2019 (COVID-
a novel CoV, namely severe acute respiratory
irus 2 (SARS-CoV-2), previously known as 2019
s (2019-nCoV) [11–13]. Like SARS-CoV and MERS-
emerged SARS-CoV-2 virus belongs to the B lin-
Vs.
ID-19 has spread rapidly in 72 countries, causing
med cases and over 2946 deaths as of 3 March
ng the global threat, the World Health Organization
lared COVID-19 a public health emergency of inter-
rn (PHEIC). However, there are no vaccines against
specific therapeutic drugs for this communicable
a better understanding of SARS-CoV-2 is essential
effective vaccines and drugs. In this review, we sum-

* Corresponding authors. Present addresses: Institute of
University of South China, Hengyang, Hunan 421001, China.
** Department of Intensive Care Unit, the First Affiliated
South China, Hengyang, Hunan 421001, China.
E-mail addresses: 286755823@qq.com (S.-L. Tang), ta
Tang).
[1] These three authors contributed equally to this work.

https://doi.org/10.1016/j.ijantimicag.2020.105951

The impact of the COVID-19 pandemic on cancer care

The COVID-19 pandemic has disrupted the spectrum of cancer care, including delaying diagnoses and treatment and halting clinical trials. In response, healthcare systems are rapidly reorganizing cancer services to ensure that patients continue to receive essential care while minimizing exposure to SARS-CoV-2 infection.

Mike Richards, Michael Anderson, Paul Carter, Benjamin L. Ebert and Elias Mossialos

rms of endoscopy, but
y upper procedures, are classified
generating, which increases
SARS-CoV-2 transmission, as
in the guidance of the British
Gastroenterology (https://
g.uk/covid-19-advice/
activity-and-covid-
-jag-guidance/). Colonoscopies
prone, due to prolonged fecal
of the virus[6]. Thus, there has been
among the American College of
erology (https://gi.org/2020/03/15/
ciety-message-on-covid-19/),
ean Society of Gastrointestinal
y (https://www.esge.com/assets/
s/pdfs/general/ESGE_ESGENA_
Statement_gastrointestinal_
_COVID_19_pandemic.pdf),
sian Pacific Society for Digestive
Endoscopy that elective endoscopies
should be suspended[7]. As a result, delivery
of endoscopy services has been markedly
decreased. For example, in the UK, the
number of endoscopies undertaken
were reduced by over 90% in April 2020
compared with the first 3 months of 2020,
based on data from the UK National
Endoscopy Database (https://ned.jets.nhs.
uk/KPI/). It should be noted that as different
countries pass their peak of COVID-19
cases, such recommendations are being
reconsidered. In the meantime, demand for
non-invasive imaging, such as computed
tomography, has increased, as it carries a
lower infection risk. To limit the need for
prolonged deep cleaning of equipment
after scanning of patients with COVID-19
and to decrease the risk of exposing other
patients to infection, many hospitals are
using separate COVID-19-exposed and
non-exposed scanners. Moving forward,
the continuation of diagnostic services,
including endoscopy, may be facilitated by
the setting up of diagnostic hubs that are
kept as free as possible from SARS-CoV-2
exposure by being located in designated
sites with extensive capacity for COVID-19

treatment pathways have been altered to
minimize potential exposure of patients with
cancer to SARS-CoV-2 and to reduce the risk
during surgery or radiation therapy. Fourth,
certain aspects of ongoing care have been
deprioritized to enable health systems to
respond to the COVID-19 pandemic, which
has resulted in patients' receiving suboptimal
or delayed care. Fifth, many clinical trials
have been suspended, which has reduced
current therapy options for patients who
might have participated and has jeopardized
longer-term therapy development. In
response, healthcare professionals and
managers in many countries have acted
quickly to mitigate the repercussions of
COVID-19 on the provision of cancer care
by reorganizing cancer services and updating
guidance for medical staff and patients. Here
we consider these developments throughout
the patient pathway, from diagnosis to
treatment and ongoing care.

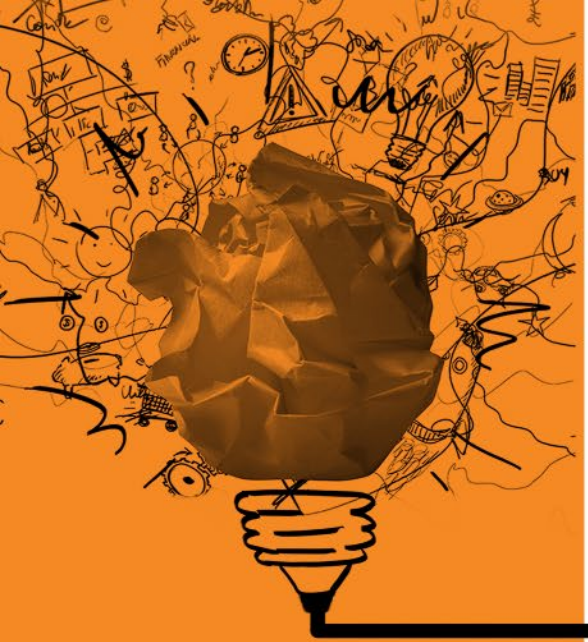
Implications for diagnosis

The necessity to divert healthcare staff
and resources to address the pandemic
has resulted in the suspension of cancer
screening programs for asymptomatic
patients in many countries. In March 2020,

Clarity

Democratisation of data

Diversity, equity and inclusion



PLS – change is coming!...

What do we mean by a plain language summary (PLS)?

The term ‘plain-language summary’ refers to a short summary of a piece of research presented in a way that is accessible to non-specialist lay audiences such as patients

The same term, PLS, may be used in different settings, “and the acronym may be expanded in different ways” which sometimes causes confusion

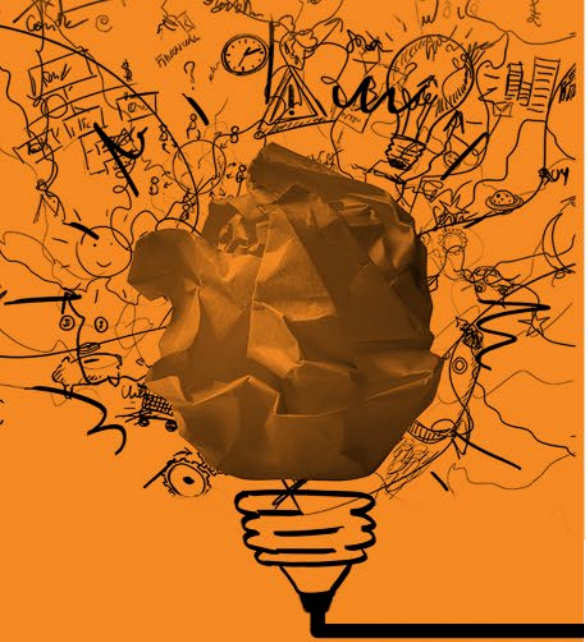
Publication PLS associated with a journal article, abstract, or congress presentation

This is the focus of our current project

Clinical trial PLS, also know as clinical trial summaries (CTS), to inform patients about trial results

This is NOT the focus of our project

**mandatory in the EU for all trials, as part of Clinical Trial Regulation EU No. 536/2014*



Publication PLS gallery

To provide you with some examples

Short text-only PLS published underneath the abstract within a manuscript

European Meeting | 2021 European Meeting Agenda | Structured benefit-risk evaluatio | Therapeutic Advanc

National Library of Medicine
National Center for Biotechnology Information

Log in

PubMed.gov

"Ther Adv Drug Saf"[Jour] AND "plain language summary"

Search

Advanced User Guide

Search results

Save Email Send to Display options

Review. > Ther Adv Drug Saf. 2020 Dec 8;11:2042098620976951. doi: 10.1177/2042098620976951. eCollection 2020.

Structured benefit-risk evaluation for medicinal products: review of quantitative benefit-risk assessment findings in the literature

Marie-Laure Kürzinger [1], Ludivine Douarin [2], Ievgeniia Uzun [3], Chantal El-Haddad [2], William Hurst [3], Juhaeri Juhaeri [3], Stéphanie Tcherny-Lessenot [2]

Affiliations + expand

PMID: 33343857 PMCID: PMC7727082 DOI: 10.1177/2042098620976951

Free PMC article

FULL TEXT LINKS

SAGE JOURNALS Open access full text

PMC Full text

ACTIONS

Cite

Favorites

SHARE

PAGE NAVIGATION

- Title & authors
- Abstract
- Conflict of interest statement
- Figures
- Similar articles
- References
- Publication types
- Related information
- LinkOut - more resources

Abstract

A favorable benefit-risk profile remains an essential requirement for marketing authorization of medicinal drugs and devices. Furthermore, prior subjective, implicit and inconsistent ad hoc benefit-risk assessment methods have rightly evolved towards more systematic, explicit or 'structured' approaches. Contemporary structured benefit-risk evaluation aims at providing an objective assessment of the benefit-risk profile of medicinal products and a higher transparency for decision making purposes. The use of a descriptive framework should be the preferred starting point for a structured benefit-risk assessment. In support of more precise assessments, quantitative and semi-quantitative methodologies have been developed and utilized to complement descriptive or qualitative frameworks in order to facilitate the structured evaluation of the benefit-risk profile of medicinal products. In addition, quantitative structured benefit-risk analysis allows integration of patient preference data. Collecting patient perspectives throughout the medical product development process has become increasingly important and key to the regulatory decision-making process. Both industry and regulatory authorities increasingly rely on descriptive structured benefit-risk evaluation and frameworks in drug, vaccine and device evaluation and comparison. Although varied qualitative methods are more commonplace, quantitative approaches have recently been emphasized. However, it is unclear how frequently these quantitative frameworks have been used by pharmaceutical companies to support submission dossiers for drug approvals or to respond to the health authorities' requests. The objective of this study has been to identify and review, for the first time, currently available, published, structured, quantitative benefit-risk evaluations which may have informed health care professionals and/or payor as well as contributed to decision making purposes in the regulatory setting for drug, vaccine and/or device approval.

Plain language summary: Quantitative evaluation of the benefit-risk balance for medicinal products The review of the benefits and the risks associated with a medicinal product is called benefit-risk assessment. One of the conditions for a medicinal product to receive marketing authorization is to demonstrate a positive benefit-risk balance in which the benefits outweigh the risks. In order to enhance the transparency and consistency in the assessment of benefit-risk balance, frameworks and quantitative methods have been developed for decision making purposes and regulatory approvals of medicinal products. This article considers published quantitative benefit-risk evaluations which may have informed health care professionals and/or payor as well as contributed to decision making purposes in the regulatory setting for drug, vaccine and/or device approval.

Keywords: benefit-risk decision making; multi-criteria decision analysis; patient perspective;

Short text-only PLS published on a scientific poster

PLS

PLS FOR THIS POSTER

Simple summaries of medical research should be easier for patients to find

It seems hard to find the short, easy-to-read 'plain-language summaries' (PLS) of medical research. PLS are meant to be helpful to patients, but they will not help if patients can't find them.

We found that a range of names is used for PLS, which could make them hard to find with an internet search. Some names do not make it clear to patients that the PLS are for them to use. Also, PLS are not available for all research, and when they are available they are shared in different ways, like on journal websites or via social media.

Overall, we were pleased to find that PLS are free to read, but ways of naming and sharing should be standardized so that PLS are easier for patients to find.

Short text-only PLS published underneath the abstract within a manuscript

European Meeting | 2021 European Meeting Agenda | Structured benefit-risk evaluation | Therapeutic Advanc

National Library of Medicine
National Center for Biotechnology Information

Log in

PubMed.gov

"Ther Adv Drug Saf"[Jour] AND "plain language summary"

Search

Advanced

User Guide

Search results

Save | Email | Send to | Display options

Review > Ther Adv Drug Saf. 2020 Dec 8;11:2042098620976951.
doi: 10.1177/2042098620976951. eCollection 2020.

Structured benefit-risk evaluation for medicinal products: review of quantitative benefit-risk assessment findings in the literature

Marie-Laure Kürzinger [1], Ludivine Douarin [2], Ievgeniia Uzun [3], Chantal El-Haddad [2], William Hurst [3], Juhaeri Juhaeri [3], Stéphanie Tcherny-Lessenot [2]

Affiliations + expand

PMID: 33343857 PMCID: PMC7727082 DOI: 10.1177/2042098620976951

Free PMC article

FULL TEXT LINKS

SAGE JOURNALS Open access full text

PMC Full text

ACTIONS

Cite

Favorites

SHARE

PAGE NAVIGATION

Title & authors

Abstract

Conflict of interest statement

Figures

Similar articles

References

Publication types

Related information

LinkOut - more resources

Abstract

A favorable benefit-risk profile remains an essential requirement for marketing authorization of medicinal drugs and devices. Furthermore, prior subjective, implicit and inconsistent ad hoc benefit-risk assessment methods have rightly evolved towards more systematic, explicit or "structured" approaches. Contemporary structured benefit-risk evaluation aims at providing an objective assessment of the benefit-risk profile of medicinal products and a higher transparency for decision making purposes. The use of a descriptive framework should be the preferred starting point for a structured benefit-risk assessment. In support of more precise assessments, quantitative and semi-quantitative methodologies have been developed and utilized to complement descriptive or qualitative frameworks in order to facilitate the structured evaluation of the benefit-risk profile of medicinal products. In addition, quantitative structured benefit-risk analysis allows integration of patient preference data. Collecting patient perspectives throughout the medical product development process has become increasingly important and key to the regulatory decision-making process. Both industry and regulatory authorities increasingly rely on descriptive structured benefit-risk evaluation and frameworks in drug, vaccine and device evaluation and comparison. Although varied qualitative methods are more commonplace, quantitative approaches have recently been emphasized. However, it is unclear how frequently these quantitative frameworks have been used by pharmaceutical companies to support submission dossiers for drug approvals or to respond to the health authorities' requests. The objective of this study has been to identify and review, for the first time, currently available, published, structured, quantitative benefit-risk evaluations which may have informed health care professionals and/or payor as well as contributed to decision making purposes in the regulatory setting for drug, vaccine and/or device approval.

Plain language summary: Quantitative evaluation of the benefit-risk balance for medicinal products The review of the benefits and the risks associated with a medicinal product is called benefit–risk assessment. One of the conditions for a medicinal product to receive marketing authorization is to demonstrate a positive benefit–risk balance in which the benefits outweigh the risks. In order to enhance the transparency and consistency in the assessment of benefit–risk balance, frameworks and quantitative methods have been developed for decision making purposes and regulatory approvals of medicinal products. This article considers published quantitative benefit–risk evaluations which may have informed health care professionals and/or payor as well as contributed to decision making purposes in the regulatory setting for drug, vaccine and/or device approval.

Keywords: benefit–risk decision making; multi-criteria decision analysis; patient perspective;

Short text-only PLS published on a scientific poster

PLS

PLS FOR THIS POSTER

Simple summaries of medical research should be easier for patients to find

It seems hard to find the short, easy-to-read 'plain-language summaries' (PLS) of medical research. PLS are meant to be helpful to patients, but they will not help if patients can't find them.

We found that a range of names is used for PLS, which could make them hard to find with an internet search. Some names do not make it clear to patients that the PLS are for them to use. Also, PLS are not available for all research, and when they are available they are shared in different ways, like on journal websites or via social media.

Overall, we were pleased to find that PLS are free to read, but ways of naming and sharing should be standardized so that PLS are easier for patients to find.

Templated text PLS for a published manuscript, published on the KUDOS platform

KUDOS

Register | Sign In | Menu

Claim this publication

Prospective observational study in patients with obstructive lung disease: NOVELTY design

Helen K. Reddel, Maria Gerhardsson de Verdier, Alvar Agusti, Gary Anderson, Richard Beasley, Elisabeth H. Bel, Christer Janson, Barry Make, Richard J. Martin, Ian Pavord, David Price, Christina Keen, Asparuh Gardev, Stephen Rennard, Alecka Sveréus, Aruna T. Bansal, Lance Brannman, Niklas Karlsson, Javier Nuevo, Fredrik Nyberg, Simon S. Young, Jørgen Vestbo

ERJ Open Research, February 2019, European Respiratory Society (ERS)
DOI: 10.1183/23120541.00036-2018

NOVELTY: a large, global study of patients with asthma, COPD or both diagnoses

What is it about?

Asthma and chronic obstructive pulmonary disease (COPD; including emphysema and chronic bronchitis) are long-term conditions affecting the lungs. Asthma and COPD are often considered separate diseases, although they share some symptoms; some types of asthma have similar underlying causes to some types of COPD. Most research studies choose patients with either asthma or COPD, and exclude patients with both diagnoses (sometimes called asthma–COPD overlap). This means our current understanding of what causes these lung conditions, and how they relate to each other, is poor. NOVELTY is a study of around 12,000 patients with a diagnosis of asthma, COPD or both diagnoses, from 19 countries across North and South America, Europe and Asia. Most patients with any of these conditions are eligible for NOVELTY. The study aims to follow patients for 3 years, to better understand:

a) their symptoms
b) the different types of these lung conditions and the relationships between them
c) how these symptoms and types lead to better or worse outcomes for patients over time.

Why is it important?

Asthma and COPD are amongst the most studied chronic diseases but progress in finding new, more effective treatments has been slow and disappointing. NOVELTY is a very large, global and innovative study that goes beyond the scope of similar, previous studies to change the way people think about these diseases. It is enhanced by the wide range of patients from diverse settings, and by the fact that many different types of information are being collected over time. NOVELTY will provide a unique source of data that can be used to understand the similarities and differences between patients with asthma, patients with COPD and patients with both diagnoses. The study aims to identify new underlying causes of these diseases to enable treatments that are driven by biology, rather than by the broad diagnoses currently used. A greater understanding may result in more personalised healthcare, with treatments that are better tailored to each patient based on their specific type of disease.

Read Publication

In partnership with: ERS

Contributors

HR Helen Reddel
Woolcock Institute of Medical Research

You might also like...

Can your work affect your kidney's health?
Fabiana Baggio Nerbass et al., Kudos, 2019

Can your smartphone detect your emotion?
Daxiang Dai et al., Kudos, 2016

Safety analysis from a phase 3 trial of talazoparib in patients with germline BRCA-mutated advanced breast cancer
Hurvitz SA et al., Oncologist, 2020

Your Malpractice Advisor: Ten Things Never to Do at Your Trial
Ilene R. Brenner et al., Medscape

Powered by TREND MD

Text and visuals PLS published in the manuscript and as part of supplementary material (via Figshare)

A survey of people's understanding about type 2 diabetes and heart disease

WHY WAS THIS SURVEY DONE?

- This survey was done to find out what adults with type 2 diabetes (T2D) and people close to them know about the link between T2D and heart disease
  - People close to them included their relatives, friends, partners, or colleagues. They were called "SweetHearts"™ in this survey

WHO TOOK PART IN THE SURVEY?

1505 US adults took part (total) | 501 Adults with T2D + 1004 US adults including... 364 "SweetHearts"™

WHAT DID THE SURVEY FIND?

Approximately half of adults with T2D did not know that **patients with T2D are prone to heart disease and related medical problems, like a heart attack**

Around 7 in 10 of people with T2D and their "SweetHearts" did not know that **heart disease is the leading cause of death for people with T2D**

MOST PEOPLE WITH T2D WERE MOTIVATED TO ADDRESS THE RISK OF HEART DISEASE

Nearly 9 out of 10 people said **they would change their diet**

Around 7 out of 10 people said they would try to lower their risk in order to **live longer and spend more time with family**

Around 8 in 10 people said they **would talk to their doctor**

WHAT WAS THE MAIN CONCLUSION REPORTED BY THE RESEARCHERS?

- These results suggest that for people with T2D and the people close to them, the overall level of knowledge about T2D and heart disease is low.

WHERE DO I GO FOR MORE INFORMATION?

- You can find more information about type 2 diabetes and heart disease here: https://KnowDiabetesbyHeart.org/

Text and visuals PLS published as part of supplementary material

This summary has been prepared using the Plain Language Summaries Toolkit, co-created with patients http://www.envisionthepatient.com/plstoolkit

How to prepare and use Patient Experience Surveys in global clinical stu

The purpose of this plain language summary is to help you understand recent research about Patient Experience Surveys.

Key Poi
- A Patie what it
- The re
  - Show Expe and a
  - Ident prepa
- Resear Other differe

1 What is a Patient Experier
- A Patient Experience Survey is lik satisfaction survey.
- It helps people tell researchers wh take part in a clinical study.

2 Why are Patient Experien

Researchers do clinical studi

But, over time, these studies

LONGER

Feedback from people who improve how they do these

"I would actually b Our outside persp project like this."

Feedback fr

3 What did this research project look at?
- So far, most research on Patient Experience Surveys has looked only at surveys done:
  - At the end of a study.
  - At a few clinical study sites.
- In this research project, researchers prepared and used a Patient Experience Survey:
  - At the start, during, and at the end of a study.
  - In clinical studies at many sites across the world.

4 Who took part in this research project?

Preparing the survey
- People who had taken part in clinical studies, clinical study experts, and survey experts helped prepare the survey.

Using the survey
- People taking part in 12 clinical studies (2017-present) used the surveys.
- These clinical studies were done in North America, Europe, and the Asia Pacific Region.
- Survey participation continues with several ongoing clinical studies.

5 What were the results of this research project?

Researchers found it was possible to prepare and use Patient Experience Surveys
- at the start, during, and at the end of a clinical study
- in global clinical studies

Researchers made the following suggestions to help other researchers do surveys:

To prepare a survey

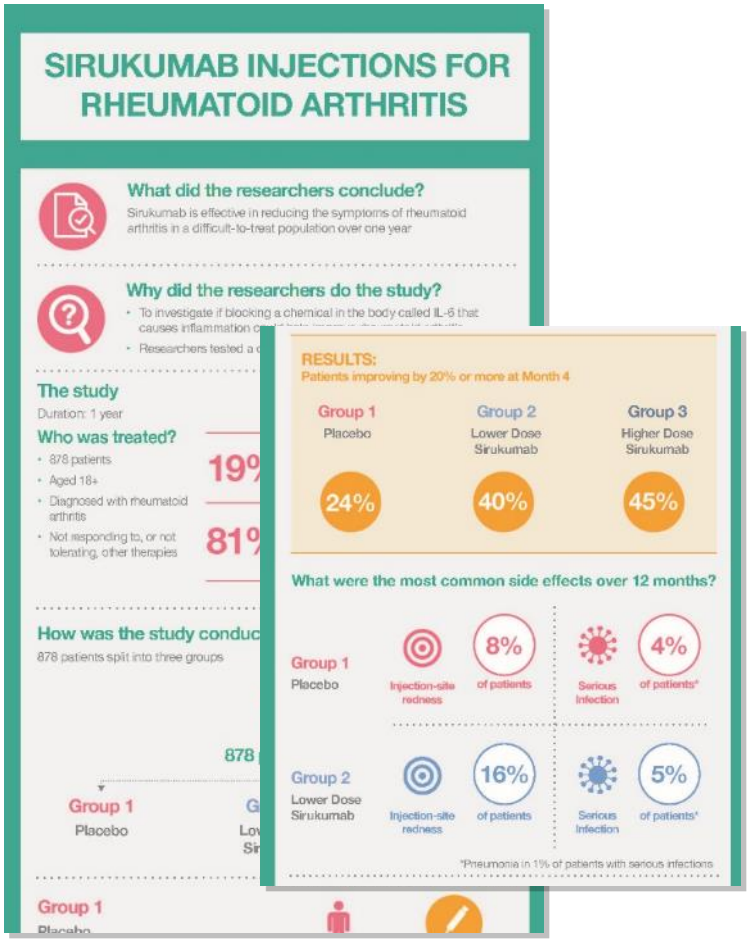
people
- Identify a survey champion who can motivate study teams* and explain the 'why' and 'how' of the survey.
- Involve patients and study teams who will use the survey.
- Involve patients and study teams from countries that will take part in the global studies.

time & money
- Fund experts to help you prepare and test the survey.
- Fund translation of the survey into other languages.
- Send the survey on time with other study documents to ethics committees.†
- Fund a tool to help you check the success of your survey.

other
- Include questions that will allow you to compare results with other surveys.
- Have a plan to manage risks (eg, forgetting to do the survey).
- Share what you learned from preparing the survey.

Page 2 of 3

Infographic PLS published with a scientific poster



SIRUKUMAB INJECTIONS FOR RHEUMATOID ARTHRITIS

What did the researchers conclude?
Sirukumab is effective in reducing the symptoms of rheumatoid arthritis in a difficult-to-treat population over one year

Why did the researchers do the study?
- To investigate if blocking a chemical in the body called IL-6 that causes inflammation
- Researchers tested a

The study
Duration: 1 year

Who was treated?
- 878 patients
- Aged 18+
- Diagnosed with rheumatoid arthritis
- Not responding to, or not tolerating, other therapies

19%

81%

How was the study conduc
878 patients split into three groups

878

Group 1
Placebo

Group 1
Placebo

Group 1

RESULTS:
Patients improving by 20% or more at Month 4

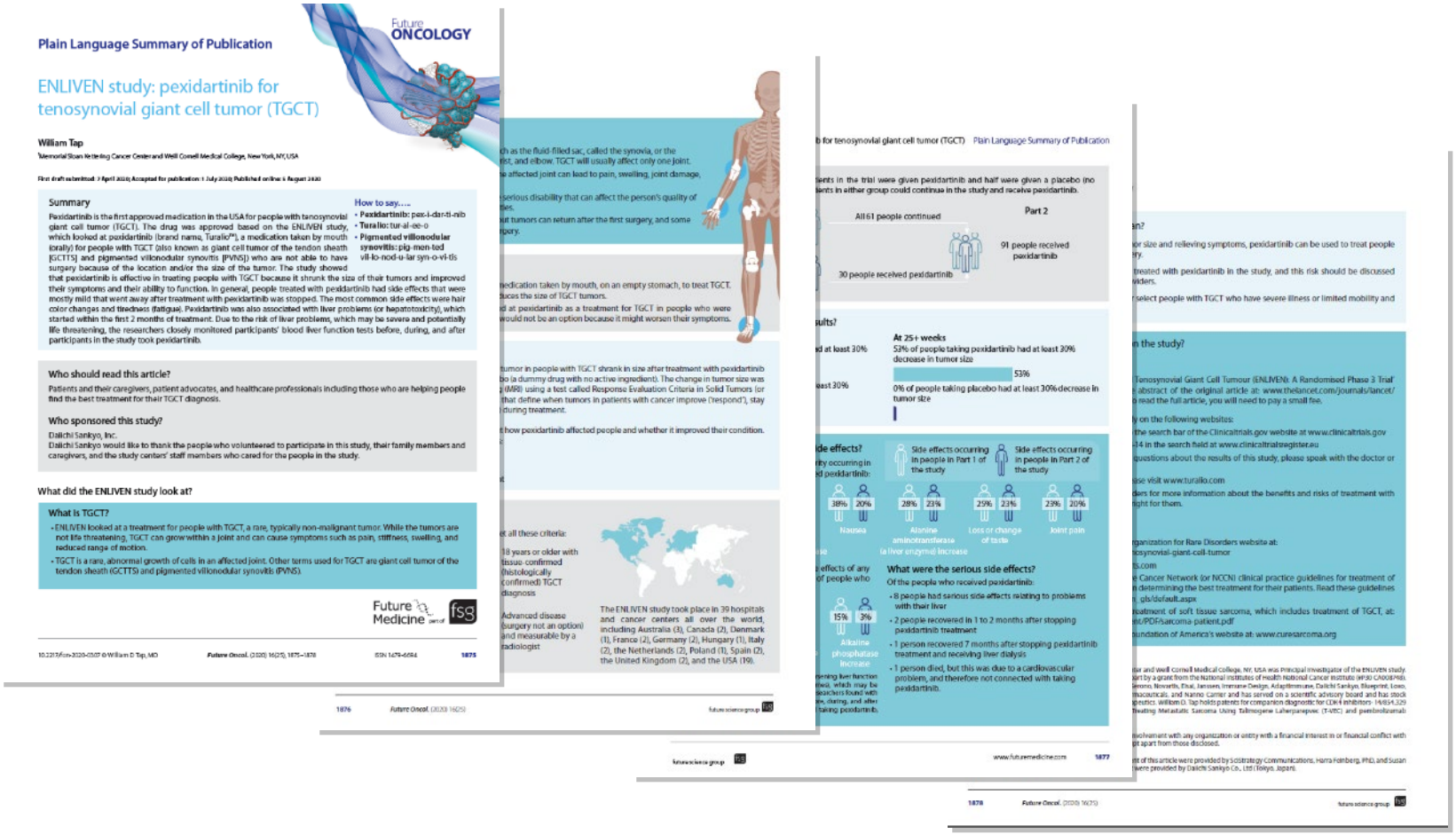
Group 1	Group 2	Group 3
Placebo	Lower Dose Sirukumab	Higher Dose Sirukumab
24%	40%	45%

What were the most common side effects over 12 months?

Group 1 Placebo	Injection-site redness	8% of patients	Serious infection	4% of patients*
Group 2 Lower Dose Sirukumab	Injection-site redness	16% of patients	Serious infection	5% of patients*

*Pneumonia in 1% of patients with serious infections

Standalone Plain Language Summary of Publication (PLSP) articles



Plain Language Summary of Publication

ENLIVEN study: pexidartinib for tenosynovial giant cell tumor (TGCT)

Future ONCOLOGY

William Tap

Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY, USA

Summary

Pexidartinib is the first approved medication in the USA for people with tenosynovial giant cell tumor (TGCT). The drug was approved based on the ENLIVEN study, which looked at pexidartinib (brand name, Turalio™), a medication taken by mouth (orally) for people with TGCT (also known as giant cell tumor of the tendon sheath [GCTTS] and pigmented villonodular synovitis [PVNS]) who are not able to have surgery because of the location and/or the size of the tumor. The study showed that pexidartinib is effective in treating people with TGCT because it shrunk the size of their tumors and improved their symptoms and their ability to function. In general, people treated with pexidartinib had side effects that were mostly mild that went away after treatment with pexidartinib was stopped. The most common side effects were hair color changes and tiredness (fatigue). Pexidartinib was also associated with liver problems (or hepatotoxicity), which started within the first 2 months of treatment. Due to the risk of liver problems, which may be severe and potentially life threatening, the researchers closely monitored participants' blood liver function tests before, during, and after participants in the study took pexidartinib.

How to say.....

- **Pexidartinib:** pex-i-dar-ti-nib
- **Turalio:** tur-al-ee-o
- **Pigmented villonodular synovitis:** pig-men-ted vil-lo-nod-u-lar syn-o-vi-tis

Who should read this article?

Patients and their caregivers, patient advocates, and healthcare professionals including those who are helping people find the best treatment for their TGCT diagnosis.

Who sponsored this study?

Daiichi Sankyo, Inc.

Daiichi Sankyo would like to thank the people who volunteered to participate in this study, their family members and caregivers, and the study centers' staff members who cared for the people in the study.

What did the ENLIVEN study look at?

What is TGCT?

- ENLIVEN looked at a treatment for people with TGCT, a rare, typically non-malignant tumor. While the tumors are not life threatening, TGCT can grow within a joint and can cause symptoms such as pain, stiffness, swelling, and reduced range of motion.
- TGCT is a rare, abnormal growth of cells in an affected joint. Other terms used for TGCT are giant cell tumor of the tendon sheath (GCTTS) and pigmented villonodular synovitis (PVNS).

Future Medicine part of fsg

10.2217/fon-2020-0507 © William D. Tap, MD — Future Oncol. (2020) 16(25), 1875–1878 — ISSN 1479-6694 — 1875

...ch as the fluid-filled sac, called the synovia, or the ...st, and elbow. TGCT will usually affect only one joint. ...e affected joint can lead to pain, swelling, joint damage, ...serious disability that can affect the person's quality of ...ies. ...ut tumors can return after the first surgery, and some ...pory.

...edication taken by mouth, on an empty stomach, to treat TGCT. ...uces the size of TGCT tumors. ...d at pexidartinib as a treatment for TGCT in people who were ...would not be an option because it might worsen their symptoms.

...tumor in people with TGCT shrank in size after treatment with pexidartinib ...bo (a dummy drug with no active ingredient). The change in tumor size was ...(MRI) using a test called Response Evaluation Criteria in Solid Tumors (or ...that define when tumors in patients with cancer improve ('respond'), stay ...during treatment.

...how pexidartinib affected people and whether it improved their condition.

...t all these criteria:

...18 years or older with ...tissue-confirmed (histologically confirmed) TGCT diagnosis

...Advanced disease (surgery not an option) ...and measurable by a ...radiologist

The ENLIVEN study took place in 39 hospitals and cancer centers all over the world, including Australia (3), Canada (2), Denmark (1), France (2), Germany (2), Hungary (1), Italy (2), the Netherlands (2), Poland (1), Spain (2), the United Kingdom (2), and the USA (19).

1876 Future Oncol. (2020) 16(25) — future science group fsg

...b for tenosynovial giant cell tumor (TGCT) Plain Language Summary of Publication

...ients in the trial were given pexidartinib and half were given a placebo (no ...ients in either group could continue in the study and receive pexidartinib.

All 61 people continued

Part 2

91 people received pexidartinib

30 people received pexidartinib

...sults?

...d at least 30%

At 25+ weeks

53% of people taking pexidartinib had at least 30% decrease in tumor size

53%

...least 30%

0% of people taking placebo had at least 30% decrease in tumor size

...de effects?

...nty occurring in ...d pexidartinib:

Side effects occurring in people in Part 1 of the study

Side effects occurring in people in Part 2 of the study

38% 20% Nausea

28% 23% Alanine aminotransferase (a liver enzyme) increase

25% 23% Loss or change of taste

23% 20% Joint pain

...effects of any ...of people who

What were the serious side effects?

Of the people who received pexidartinib:

- 8 people had serious side effects relating to problems with their liver
- 2 people recovered in 1 to 2 months after stopping pexidartinib treatment
- 1 person recovered 7 months after stopping pexidartinib treatment and receiving liver dialysis
- 1 person died, but this was due to a cardiovascular problem, and therefore not connected with taking pexidartinib.

15% 3% Alkaline phosphatase increase

...ening liver function ...ked, which may be ...searchers found with ...es, during, and after ...taking pexidartinib.

www.futuremedicine.com 1877

...or size and relieving symptoms, pexidartinib can be used to treat people ...ery.

...treated with pexidartinib in the study, and this risk should be discussed ...viders.

...select people with TGCT who have severe illness or limited mobility and

...the study?

...Tenosynovial Giant Cell Tumour (ENLIVEN): A Randomised Phase 3 Trial ...abstract of the original article at: www.thelancet.com/journals/lancet/ ...read the full article, you will need to pay a small fee.

...y on the following websites: ...the search bar of the Clinicaltrials.gov website at www.clinicaltrials.gov ...14 in the search field at www.clinicaltrialsregister.eu

...questions about the results of this study, please speak with the doctor or

...ase visit www.turalio.com

...ders for more information about the benefits and risks of treatment with ...ight for them.

...rganization for Rare Disorders website at: ...osynovial-giant-cell-tumor ...s.com ...e Cancer Network (or NCCN) clinical practice guidelines for treatment of ...h determining the best treatment for their patients. Read these guidelines ...gls/default.aspx ...eatment of soft tissue sarcoma, which includes treatment of TGCT, at: ...et/PDF/sarcoma-patient.pdf ...undation of America's website at: www.curesarcoma.org

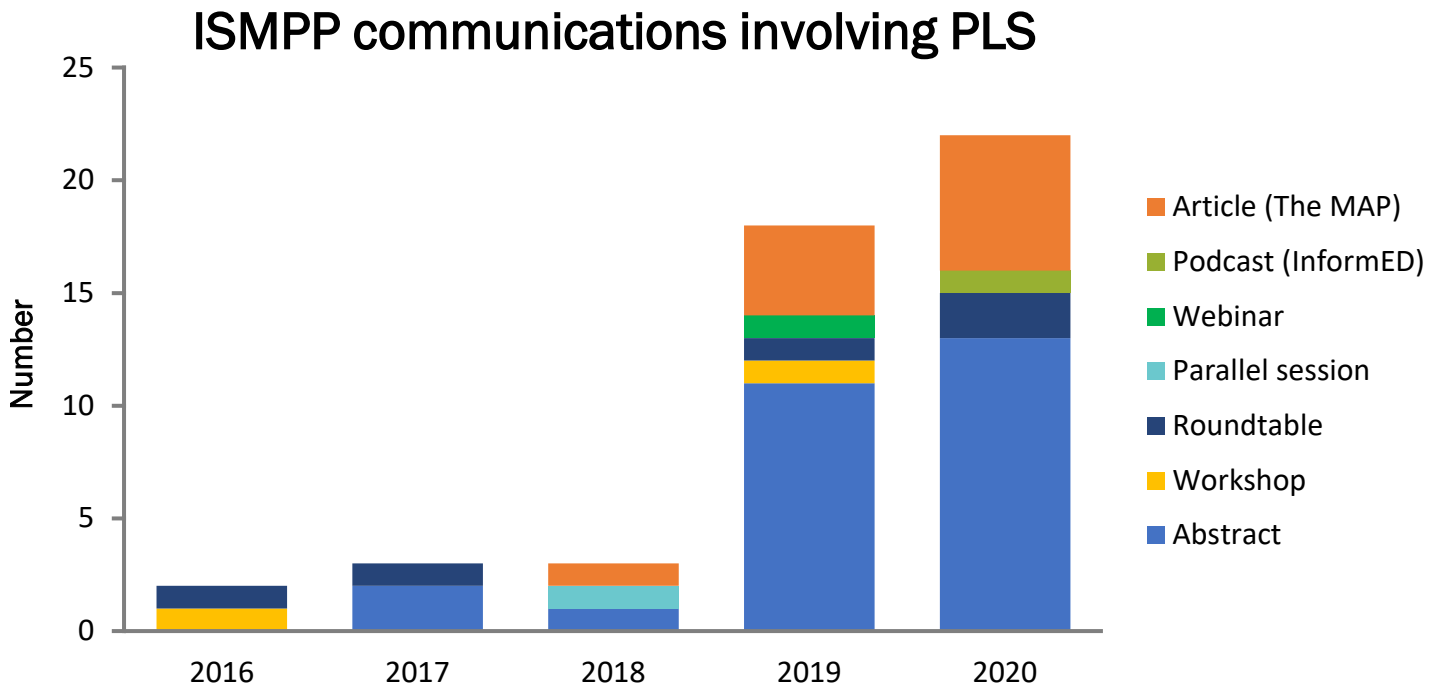
...ior and Weill Cornell Medical College, NY, USA was Principal Investigator of the ENLIVEN study. ...ort by a grant from the National Institutes of Health National Cancer Institute (#5R01CA208486). ...ceros, Novartis, Eisai, Janssen, Immune Design, Adaptimmune, Daiichi Sankyo, Blueprint, Loxo, ...Pharmaceuticals, and Nanno Carrier and has served on a scientific advisory board and has stock ...Genetics. William D. Tap holds patents for companion diagnostic for CDK4 inhibitors- 14/854,329 ...Treating Metastatic Sarcoma Using Talimogene Laherparepvec (T-VEC) and pembrolizumab.

...volvement with any organization or entity with a financial interest in or financial conflict with ...ct apart from those disclosed.

...nt of this article were provided by Scistrategy Communications. Harra Feinberg, PhD, and Susan ...were provided by Daiichi Sankyo Co., Ltd (Tokyo, Japan).

1878 Future Oncol. (2020) 16(25) — future science group fsg

ISMPP interest in PLS continues to grow!



European meeting of ISMPP – Jan 2021

Patient Advocacy

Patient Advocacy

How readable are plain language summaries?

34 2 63

Patient Advocacy

Plain language summaries of publications: what key questions do we need to address?

35 0 65

Patient Advocacy

Is the patient voice being heard in peer-reviewed medical publications?

36 2 56

Patient Advocacy

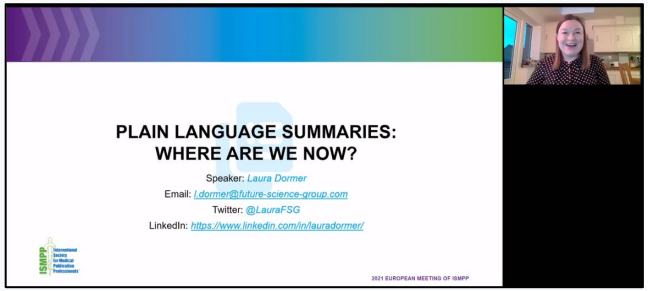
Publishing Plain Language Summaries of Publications as stand-alone journal articles: a publisher's case study

37 4 72

Patient Advocacy

Are plain language summaries of health economic publications needed for patients and non-expert audiences?

38 0 33



Tracey Brown

Speaker

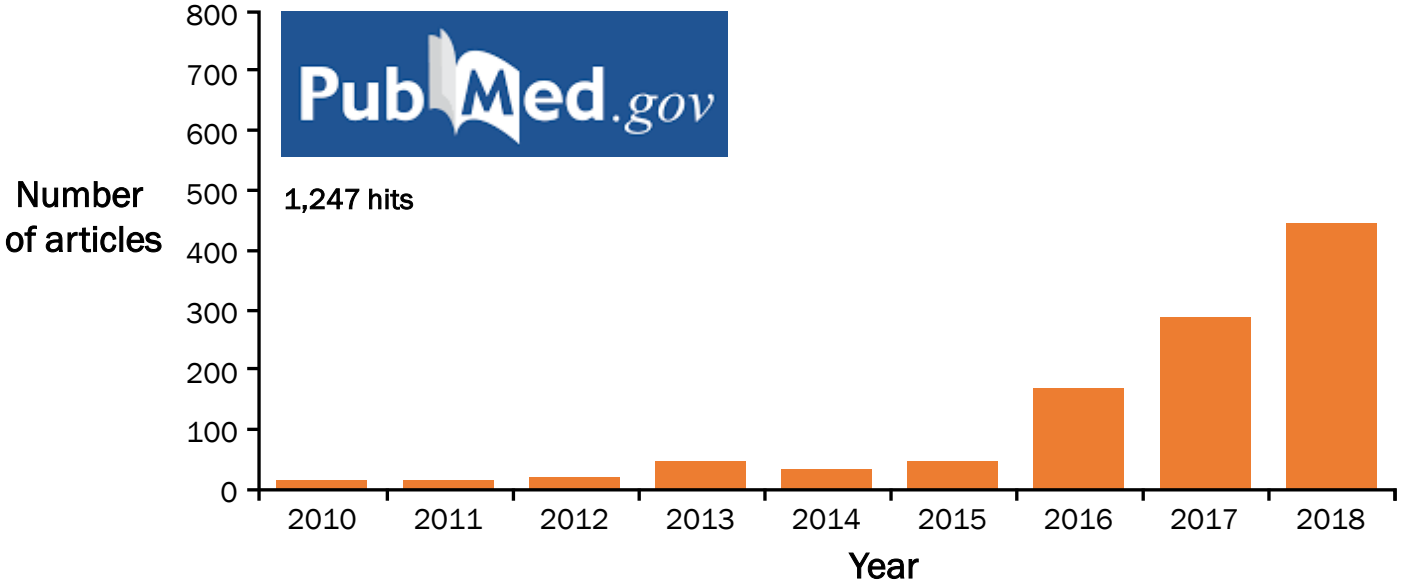
SENSE about SCIENCE

The public needs to understand the scientists; to do this, scientists need to understand the public

Think about what audiences want to know rather than what we want to tell them

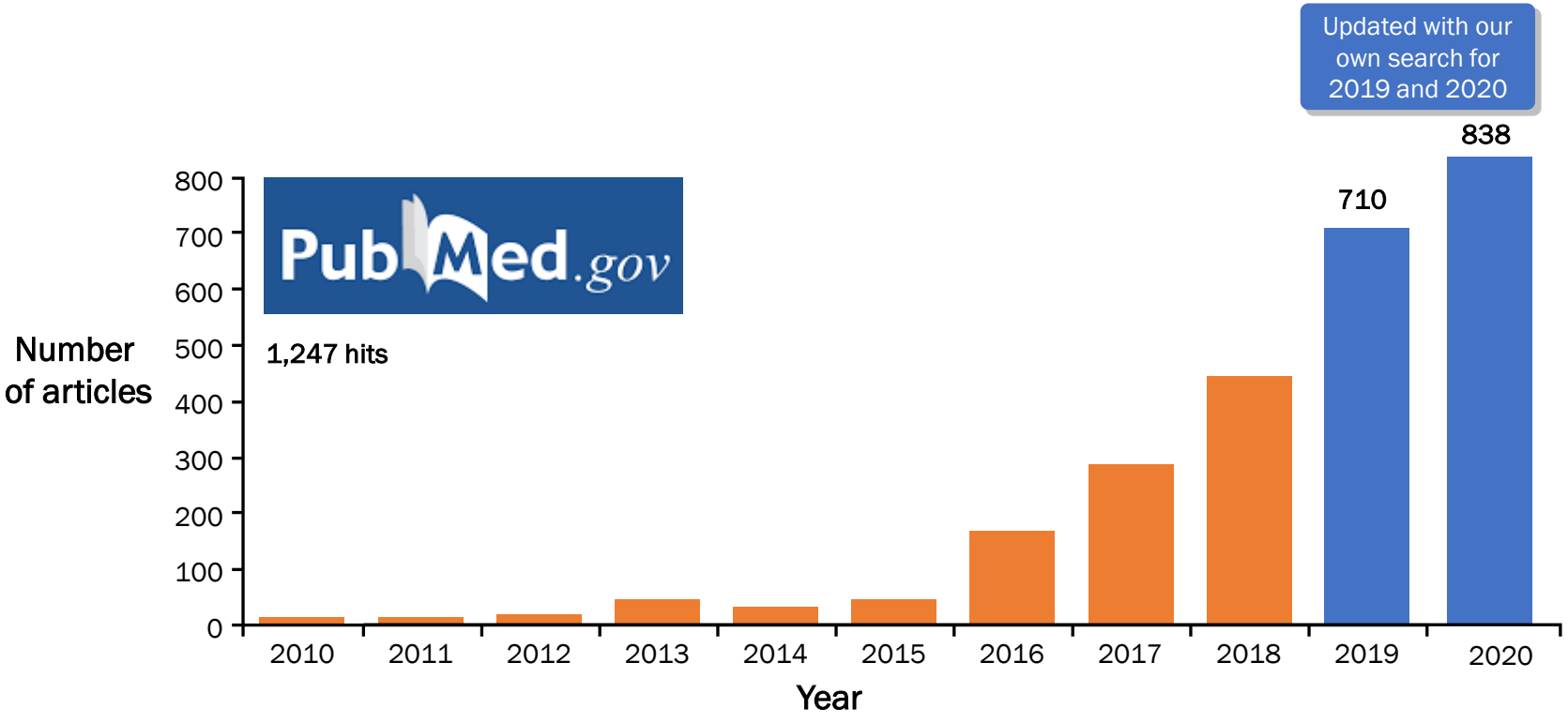
ISMPP International Society for Medical Publication Professionals

Increasing numbers of articles are being published with a PLS



Havran LM et al. Poster presentation at ISMPP Annual Meeting. March 2019

Increasing numbers of articles are being published with a PLS



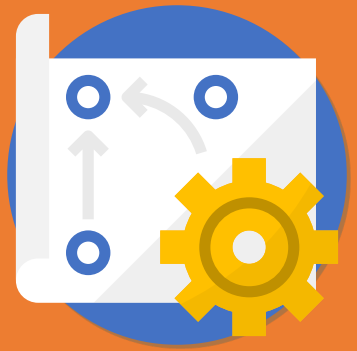
Havran LM et al. Poster presentation at ISMPP Annual Meeting. March 2019

But with little consistency in approach

Evidence to support the value of visual PLS for non-specialist healthcare professionals and patients is growing

1. Bredbenner K, Simon SM. PLoS ONE 2019;14:e0224697;
2. Chapman SJ et al. Br J Surg 2019;1611–1616 [online ahead of print];
3. Gardner J et al. Poster presented at ISMPP Annual Meeting 2019

Effective communication can help to avoid misunderstanding and misinterpretation



Increasingly, pharmaceutical industry sponsors are considering PLS in their publication plans

1. https://www.globaldata.com/globaldatas-top-20-global-pharmaceutical-companies-by-market-cap-year-ended-december-31-2018/;
2. Internal survey of Envision publication account leads (N=27; October 2019)

2020

EUROPEAN MEETING of ISMPP

PRECISION COMMUNICATION: ACHIEVING CLARITY, REACH AND VALUE

ISMPP International Society for Medical Publication Professionals
www.ismpp.org

21-22 January, 2020 | London, UK

Questions remain regarding how to develop PLS effectively and in line with company policies

There is strong support for further PLS guidance to be provided by ISMPP to encourage PLS and ensure best practice

ISMPP EU London Jan 2020. Vote for further guidance on PLS from ISMPP

The PLS Perspectives project was born!

Lobban D, Gardner J, on behalf of the ISMPP PLS Perspectives Working Group. Plain language summaries of publications: What key questions do we need to address? ISMPP EU Poster 35

What are the key objectives?

To provide multi-stakeholder perspectives on the key issues relating to publication PLS of company-sponsored medical research

PART 1:

Identify the **key questions** to be addressed

PART 2:

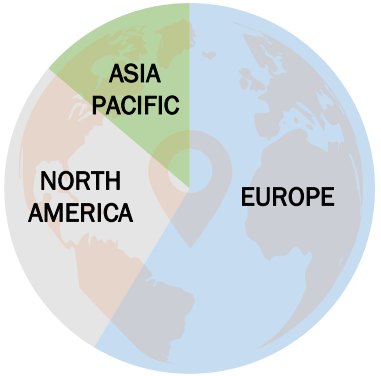
Identify **key considerations**, **highlight opportunities**, and **acknowledge potential barriers**

Diverse stakeholder groups are involved

Who is involved?

29 stakeholders identified based on expertise in their field, familiarity with PLS, and location

- Pharmaceutical industry
- Publishers, journal editors, and NIH/NLM
- Publication/medical education agencies
- Patient partners
- Health care professionals/clinical researchers
- Media/ISMPP/MRCT



Diverse stakeholder groups are involved

Who is involved?

29 stakeholders identified based on expertise in their field, familiarity with PLS, and location

- Pharmaceutical industry
- Publishers, journal editors, and NIH/NLM
- Publication/medical education agencies
- Patient partners
- Health care professionals/clinical researchers
- Media/ISMPP/MRCT

Laura Dormer
Editorial Director,
Future Science Group

Dawn Lobban
Global Lead, Patient Partnership,
Envision Pharma Group

Richard Stephens
Patient advocate;
Co-Editor-in-Chief, Research
Involvement and Engagement

Alexandra Freeman
Executive Director,
Winton Centre for Risk
& Evidence Communication

What approach are we taking?

PART 1	
Project introduction and PLS landscape	Provide pre-read information to explain the project and provide an overview of PLS
Gain initial feedback from stakeholders on priority questions to be considered	Modified Delphi approach: Survey 1
Interactive discussion of Survey 1 results and PLS landscape	Webinar results discussion
Final feedback from stakeholders on priority questions to be considered	Modified Delphi approach: Survey 2

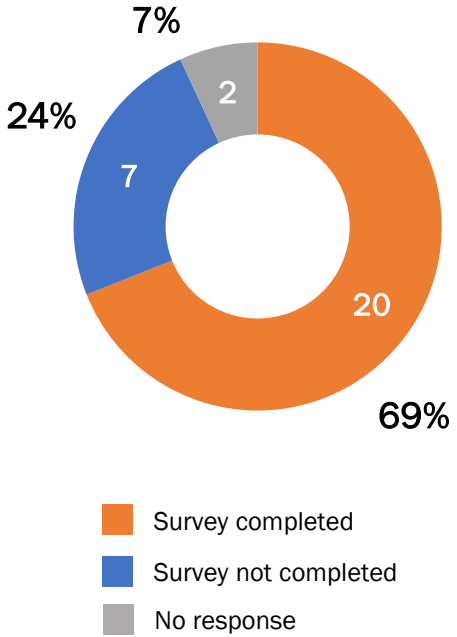
PART 2	
Stakeholder perspectives	Moderated virtual sessions to discuss priority topics by stakeholder groups
Perspective collation and presentation	Ensure stakeholder agreement on content for publication

Initial questions proposed by the Working Group

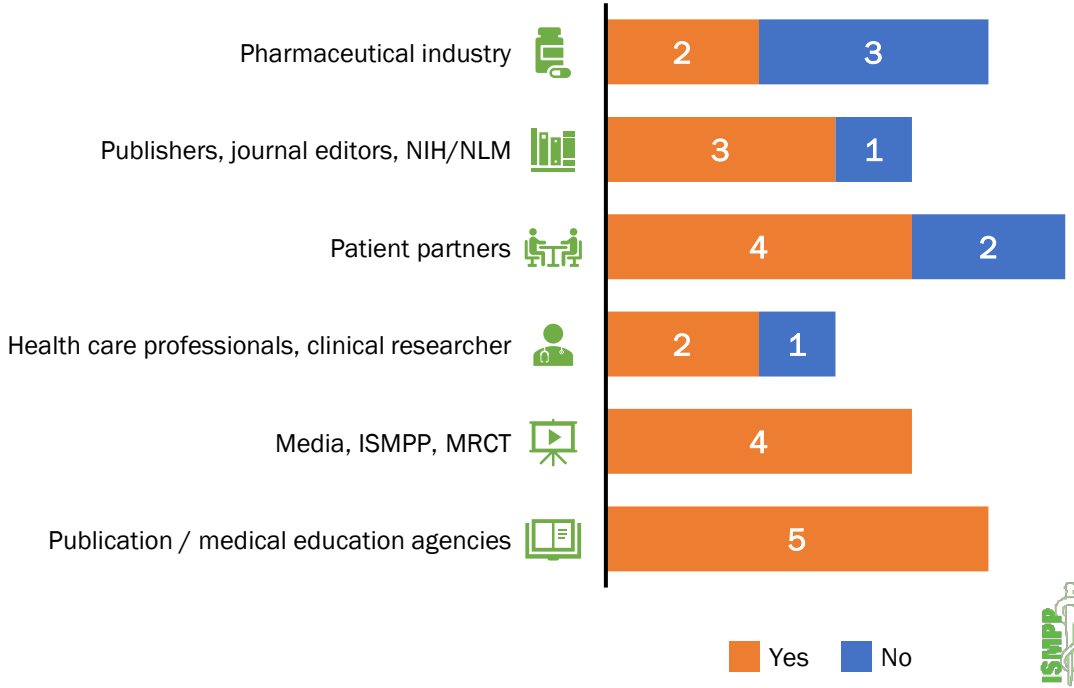
1. Who are the **target audiences** for PLS, and why?
2. What is needed to ensure PLS are **considered to be appropriate vehicles**, not med ed or promo materials?
3. What **nomenclature** should be used for a PLS, whether that be a congress presentation or a journal manuscript?
4. What criteria should be met for developing a PLS for an article **already published**?
5. What process should be followed to **select publications for** a PLS **to avoid** the perception of **selection bias**?
6. What conditions must be met for a PLS to be acceptable as a **standalone publication**?
7. What is/are the **optimal format(s)** for a PLS?
8. What information **must, and must not, be included** in a PLS?
9. How can PLS meet the needs of **non-English-speaking audiences** and account for different cultures?
10. What is the **optimal PLS development / review / approval process**?
11. Where and how should PLS be published to ensure optimal **reach and discoverability**?
12. What would the ideal PLS **repository** look like?
13. How can the **reach, quality, and value** of a PLS be measured?
14. How can a facility for feedback and **scientific exchange** be incorporated into the model for PLS?

Survey 1
Sample size and survey response

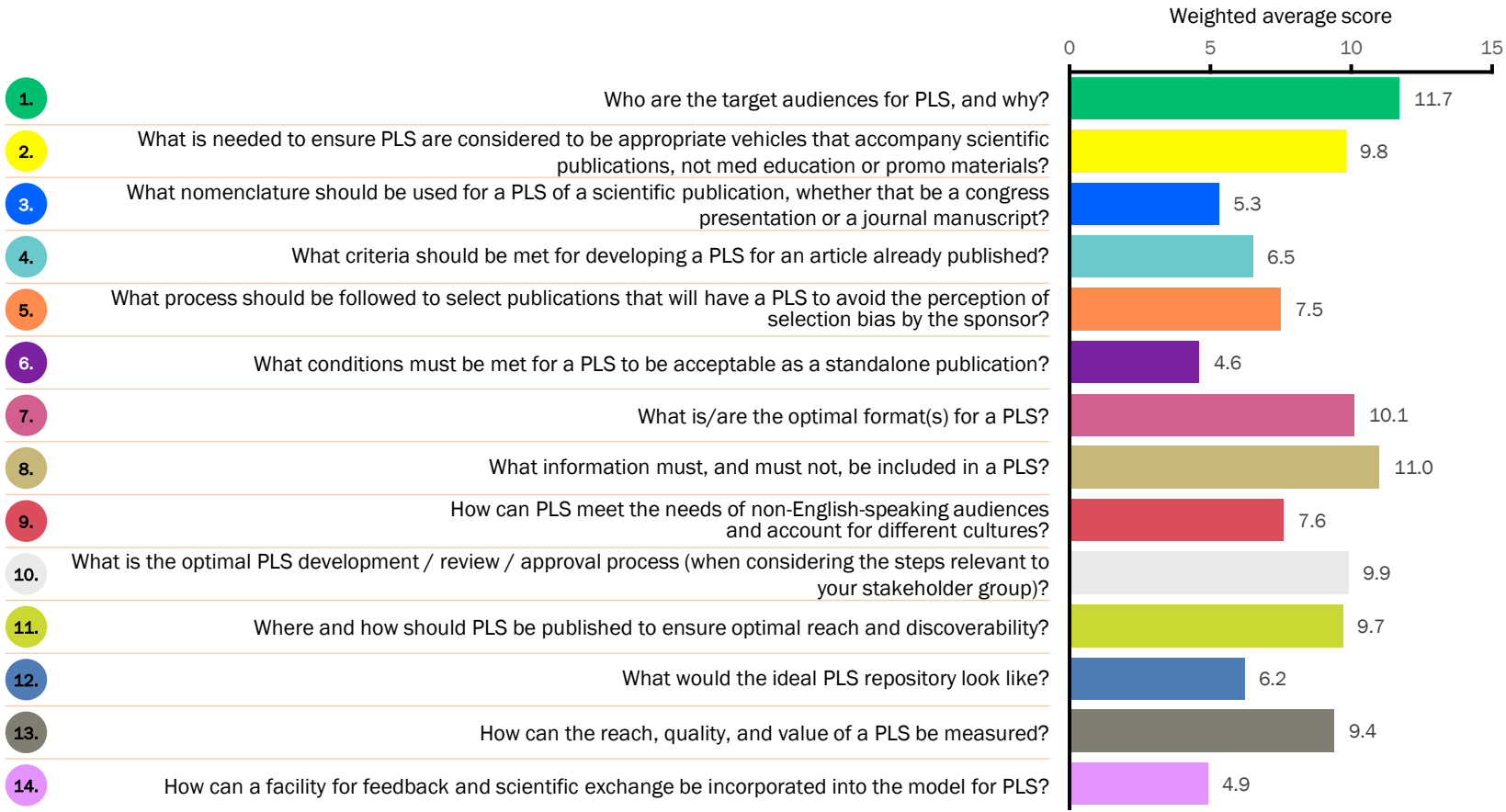
29 Participants



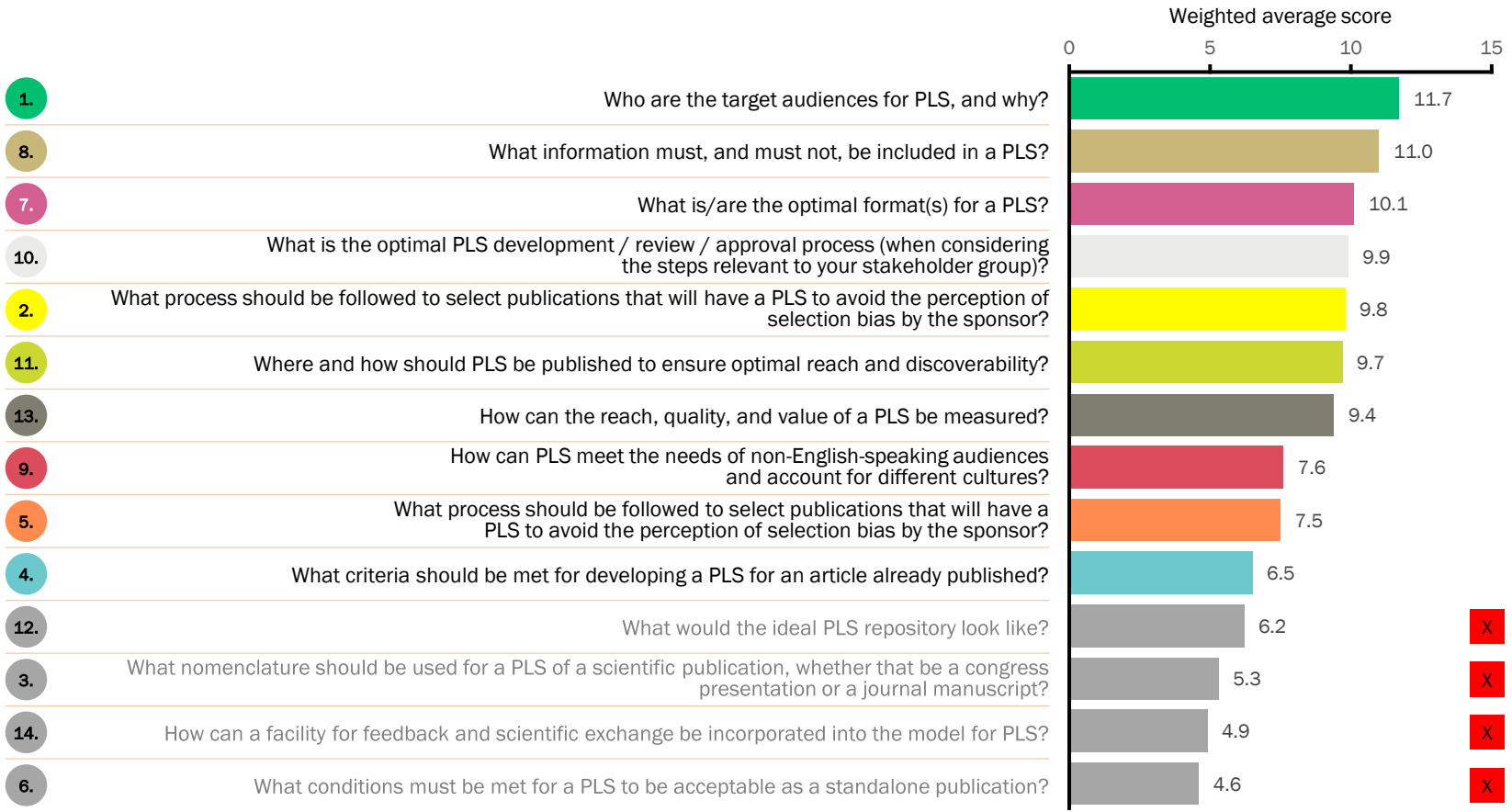
Response to the survey by group



This is what the stakeholders thought



This is what the stakeholders thought – reordered



Which of the top 5 questions do you want answered most?

Process to avoid the perception of selection bias?

Optimal format(s) for a PLS?

What information must, and must not, be included?

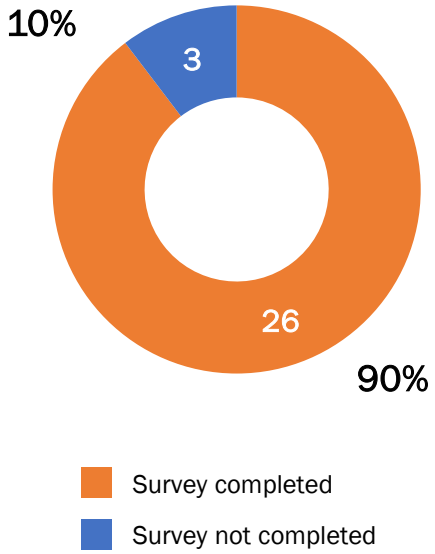
Target audiences for PLS?

Optimal PLS development / review / approval process?

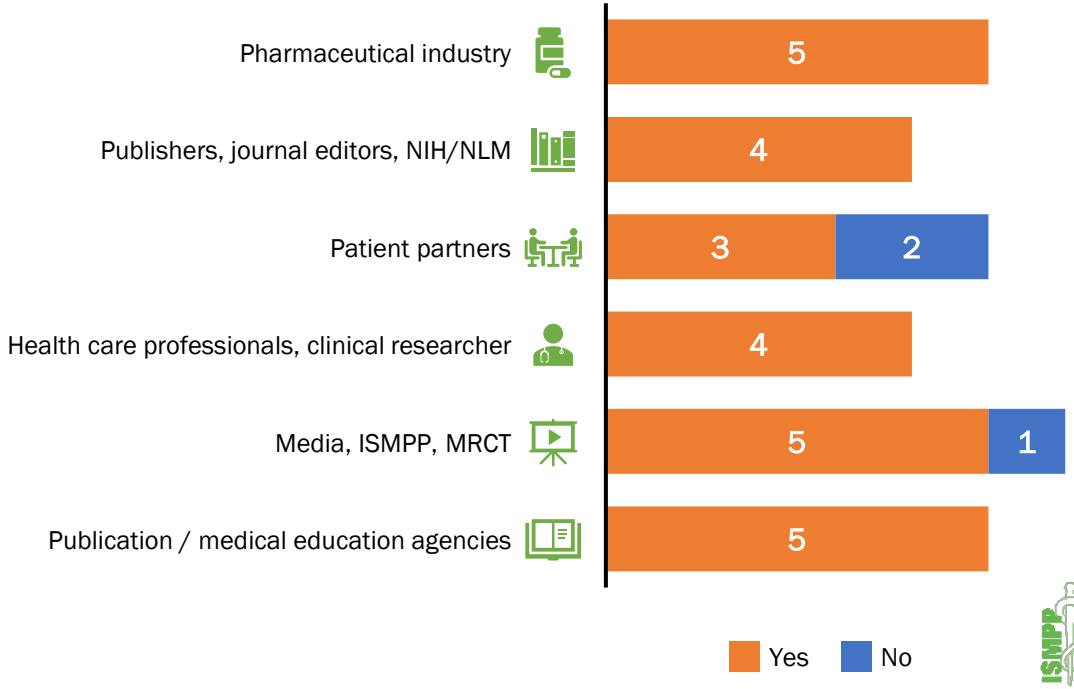
Reordered – random

Survey 2
Sample size and survey response

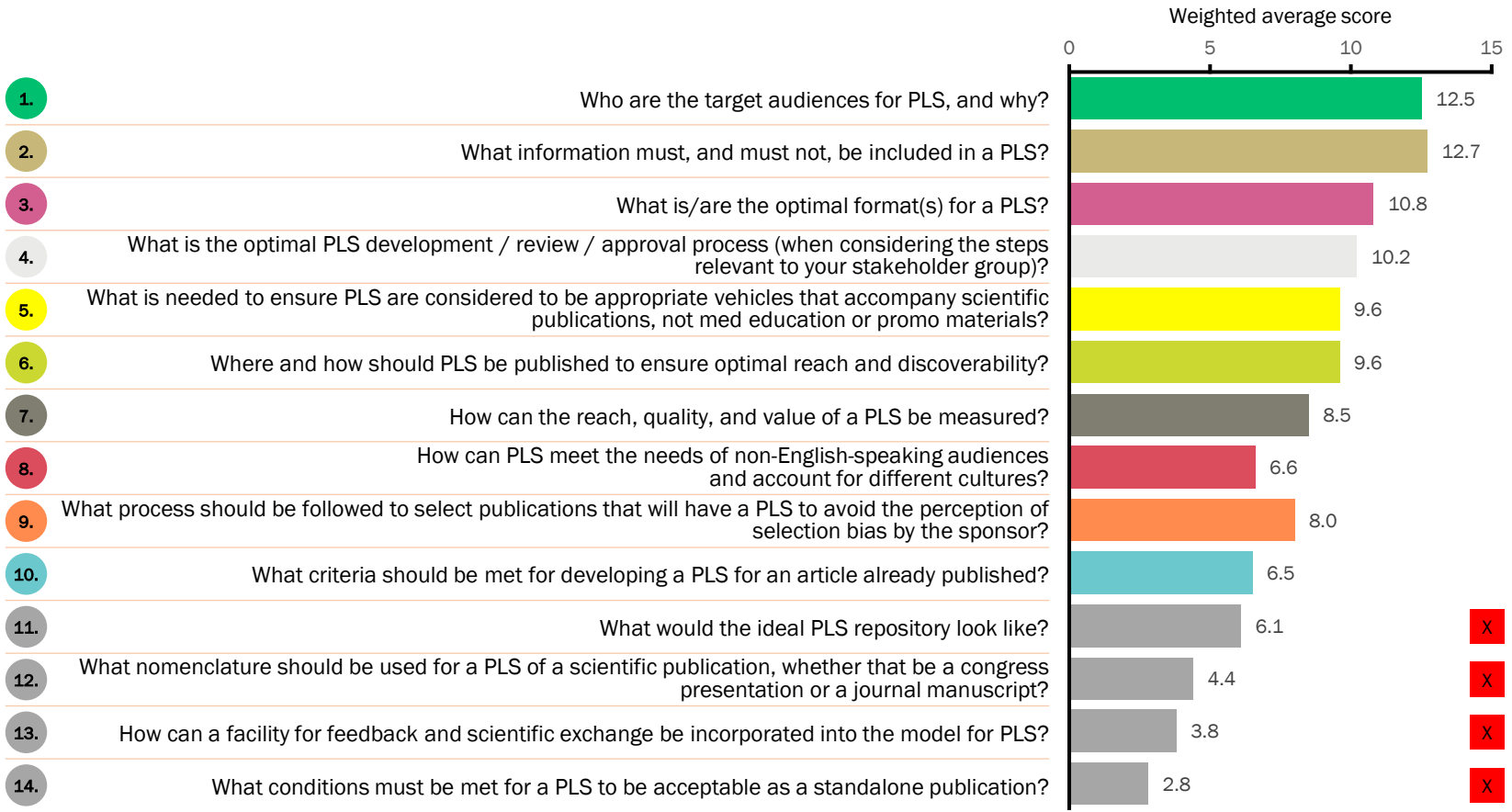
29 Participants



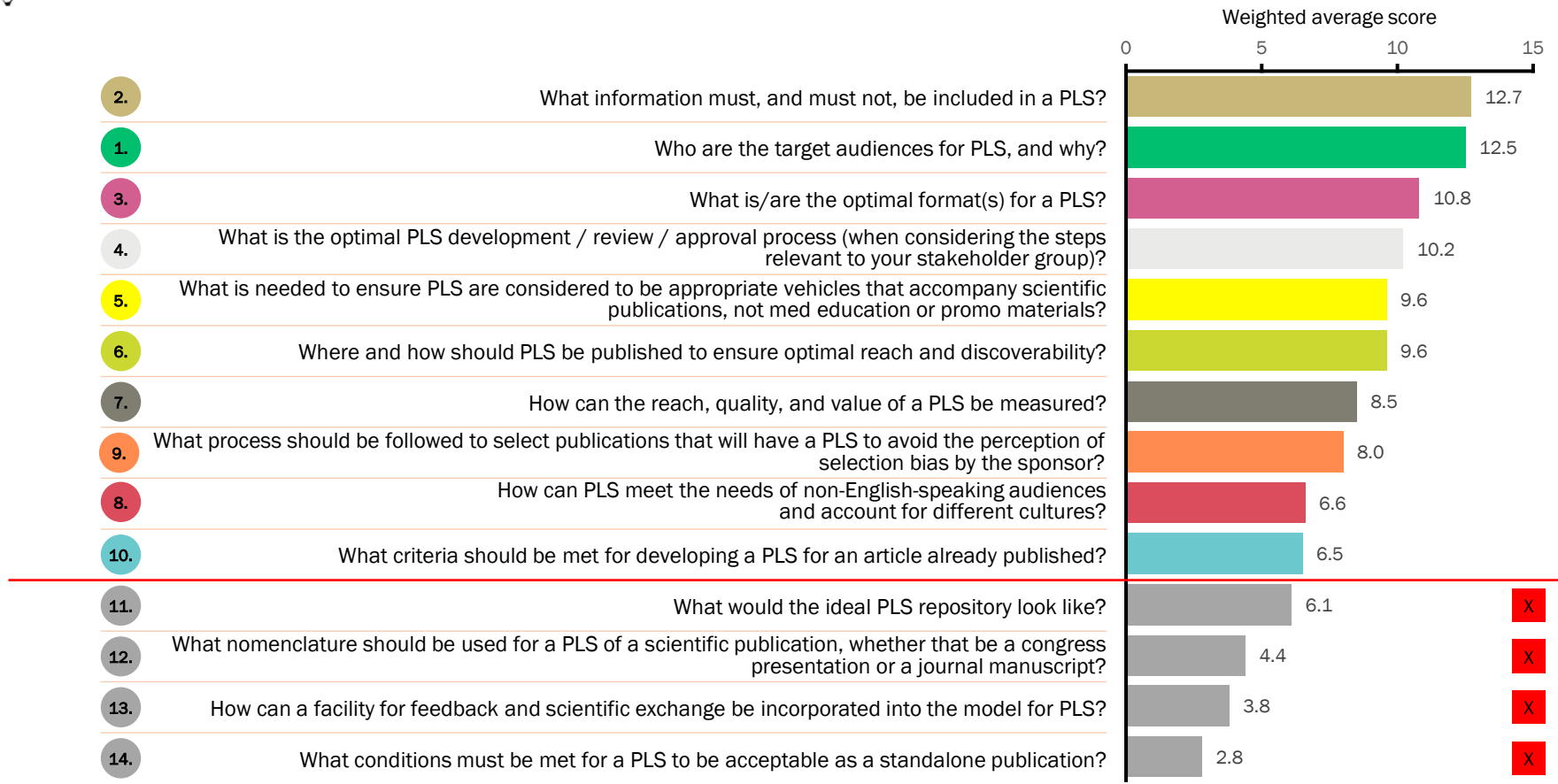
Response to the survey by group



Overall data in survey order



Overall data in priority order



What are the key objectives?

To provide multi-stakeholder perspectives on the key issues relating to publication PLS of company-sponsored medical research

PART 1:

Identify the key questions to be addressed

PART 2:

Identify key considerations, highlight opportunities, and acknowledge potential barriers

Please submit your own queries / comments to the panel while we go through the following questions for PLS…

1 What information must, and must not, be included in a PLS?

No more than contained in the article?
Or OK to provide further context and implications for a broader audience?

1 What information must, and must not, be included in a PLS?

No more than contained in the article? Or OK to provide further context and implications for a broader audience?

Any disclaimers? eg medRxiv

CAUTION

Preprints are preliminary reports of work that have not been certified by peer review. They *should not be relied upon to guide clinical practice* or *health-related behaviour*, and *should not be reported in news media as established information*

- Drug approval status
- What's known about this therapy to date
- Study objective
- Drug mode of action
- Trial design
- Trial patient population
- Primary/secondary/all endpoints
- What the study adds and if/how it is likely to impact on care
- Context of other studies/competitor studies
- Study limitations
- What's being looked at next
- Pronunciation guide
- Glossary of terms
- Thank you to study participants
- Who sponsored the research
- Who wrote the PLS
- Has the PLS been reviewed and approved by manuscript authors?
- Has the PLS has been reviewed by patients and/or the general public?
- Where readers should go for further information

2 Who are the target audiences for PLS, and why?

The general public?

Patients and carers?

The media?

Nonspecialist HCPs?

Time-poor specialist HCPs?

2 Who are the target audiences for PLS, and why?

The general public?

Patients and carers?

The media?

Nonspecialist HCPs?

Time-poor specialist HCPs?

Should patients be the default audience for PLS?

2 Who are the target audiences for PLS, and why?

The general public?

Patients and carers?

The media?

Nonspecialist HCPs?

Time-poor specialist HCPs?

Should patients be the default audience for PLS?

Should patients be considered at all as an audience for PLS?

...given that PLS are contained within, or associated with, publications, traditionally the vehicle of scientific exchange between HCPs?

Are registry CTS the acceptable means of patient communication rather than publication PLS?

2 Who are the target audiences for PLS, and why?

The general public?

Patients and carers?

The media?

Nonspecialist HCPs?

Time-poor specialist HCPs?

Should patients be the default audience for PLS?

Should patients be considered at all as an audience for PLS?

…given that PLS are contained within, or associated with, publications, traditionally the vehicle of scientific exchange between HCPs?

Are registry CTS the acceptable means of patient communication rather than publication PLS?

Paucity of data on benefits of PLS to HCPs and with no HCP-driven demand—is there an argument for optimising and improving the readability of scientific abstracts / articles rather than creating yet more elements for HCPs to read?

3 What is/are the optimal format(s) for a PLS?

DOES IT DEPEND ON

The audience?

(eg, age, language, culture, any special requirements, such as sensory impairment, information-seeking behaviours)

The type of data?

Therapy area?

Where the PLS is to be hosted/discovered?

4 What is the optimal PLS development/review/approval process? (when considering the steps relevant to your stakeholder group)

When should development of a PLS start?

How do you choose the format of a PLS to be developed?

Written by authors of the original publication?

Do all authors need to write/review/approve, or just the lead?

Do those involved in PLS development need training on communicating in plain language?

Should patients/nonauthors be involved in PLS co-creation?

- Planning the content of the PLS?
- Writing the PLS? Added as an author?
- At what point(s) in PLS development should patient reviewer/ user testing occur?

All pharmaceutical industry sponsors have their own publication SOPs, but...

- Should there be a requirement for certain publications to carry PLS?

Patient Focused Medicines Development (PFMD) guidance on PLS

1. Scope and prioritisation
2. Identify your target audience
3. PLS co-creation and tool selection
4. PLS dissemination
5. Evaluation

GPP, Good Publication Practice; ICMJE, International Committee of Medical Journal Editors; SOPs, standard operating procedures.
Khawaja S et al. Poster presented at ISMPP US Meeting 2020.

5 What is needed to ensure PLS are considered to be appropriate vehicles that accompany scientific publications, and are not medical education or promotional materials?

How important is PLS peer review?

What are the risks and barriers that may prevent industry sponsors from actively supporting PLS?

How could these risks and barriers be addressed?

6 Where and how should PLS be published to ensure optimal reach and discoverability?

What are the differences between journal vs congress PLS access?

What if journals don't provide a facility for PLS?

How would you like to discover PLS?

- Use of Google Scholar, FigShare, PubMed.gov; other platforms
- Sponsoring company site, Patient organisation site
- New repository aimed specifically at PLS audiences?

What's the role of social media?

Opportunities to overcome real or perceived barriers to the uptake of PLS

CATEGORY	EMERGING THEMES
Why?	Target end-users highlight **unmet need and advocate** for PLS
When?	Clear directive for **when** manuscripts should have a PLS Call on **key journals** to lead the way by **publishing** PLS
Who?	PLS stakeholders would benefit from **guidance on optimal co-creation**
What?	**Tools**, such as templates, to guide **content development** Industry-recognized **guidelines** to define and maintain quality
How?	Use **specialist PLS writers** and/or undertake **PLS training** for medical writers and researchers (including patients) Clarity on **optimal format and development process** from start to finish
Where?	Optimal dissemination and **easy access** (including searchable repository) Explore **use of social media** to facilitate dissemination Work with patient advocacy groups and charities to **expand the reach** of PLS

Which category do you think is the most important to accelerate the uptake of PLS?

CATEGORY	EMERGING THEMES
Why?	Target end-users highlight **unmet need and advocate** for PLS
When?	Clear directive for **when** manuscripts should have a PLS Call on **key journals** to lead the way by **publishing** PLS
Who?	PLS stakeholders would benefit from **guidance on optimal co-creation**
What?	**Tools**, such as templates, to guide **content development** Industry-recognized **guidelines** to define and maintain quality
How?	Use **specialist PLS writers** and/or undertake **PLS training** for medical writers and researchers (including patients) Clarity on **optimal format and development process** from start to finish
Where?	Optimal dissemination and **easy access** (including searchable repository) Explore **use of social media** to facilitate dissemination Work with patient advocacy groups and charities to **expand the reach** of PLS

Questions

To ask a question, open the Q&A window, type your question into the Q&A box. Click Send

Conclusions

The key opportunities highlighted provide broad insight into the real and perceived barriers to PLS identified by diverse stakeholders

Each emerging theme presents a possible action behind which stakeholders can mobilize towards the common goal of accelerating PLS uptake

What's next?

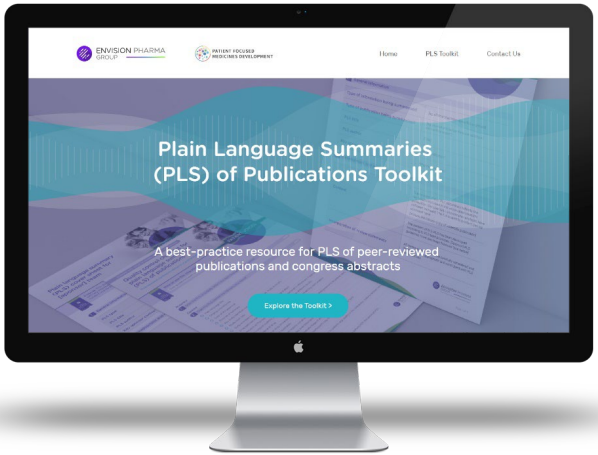
Detailed discussion of each topic to be presented at a future congress + manuscript + further communications and lobbying of stakeholders to accelerate uptake of PLS

GPP4

Then… GPP4 to provide us with the guidelines that we all need to progress PLS for publications with clarity and confidence

GPP, Good Publication Practice

The PLS of Publications Toolkit



www.envisionthepatient.com/plstoolkit

Supported by Patient Focused Medicines Development, and co-created with patients, publishers, editors, pharmaceutical industry

Upcoming ISMPP U webinars

February 24th: Member Research Spotlight: 2021 EU Meeting

This spring…

- Managed Care
- Real world evidence/ISPOR
- Medical Devices

How Membership Benefits YOU:

Knowledge
Community
Professionalism

ISMPP International Society for Medical Publication Professionals™

www.ismpp.org

Thank you for attending!

We hope you enjoyed today's presentation.

After closing out of Zoom, please click the CONTINUE button on your screen to take our short survey. Thank you!

ISMPP University

Plain Language Summaries (PLS) of publications: Perspectives that will shape the future

February 3, 2021

ISMPP International Society for Medical Publication Professionals™

Webinar will begin promptly at:
11 AM ET / 4 PM GMT