

May 24, 2023

# The Value of Plain Language Summaries in Health Economics and Outcomes Research

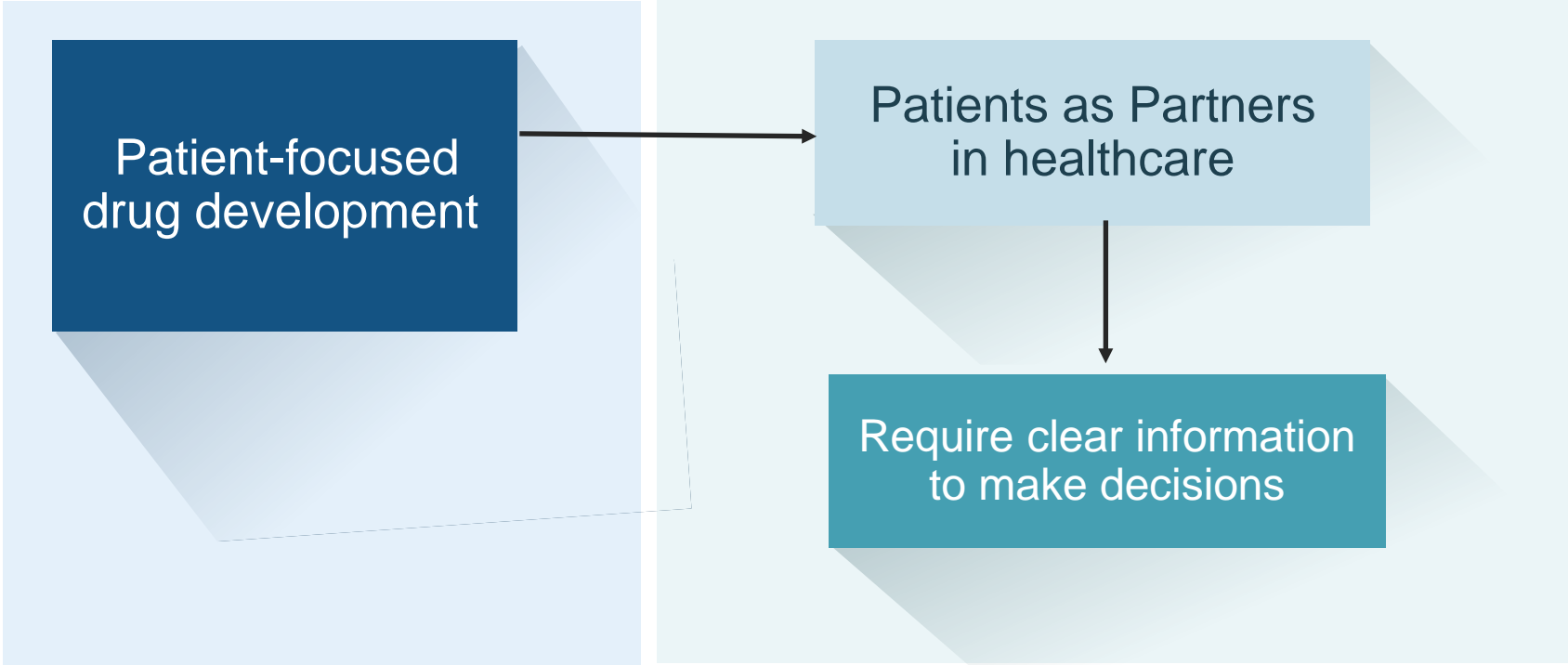
Lynda Doward

Sarah Sauchelli Toran

Sara Musetti Jenkins

The power of **knowledge.**  
The value of **understanding.**

## Plain language summaries



## Trends in plain language summaries




**Draft FDA Guidance on Provision of Plain Language Summaries**

**Issued by:** Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health


**Intended Audience:** Sponsors, Investigators and Institutional Review Boards

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“Mandatory requirement laid out in Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014... and a transparency obligation to all trial participants and the interested public.”





Scope of webinar



Clinical Trial  
Summaries



Publication  
Summaries

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Clinical Trial  
Summaries

Publication  
Summaries



## Sarah Sauchelli Toran

*Senior Researcher,  
Patient-Centered  
Outcomes Assessment*

**Senior Researcher, PCOA** has over 9 years' experience in patient-led research in healthcare and academic settings. In partnership with community organizations and patient advocacy groups, Sarah has set up patient and public involvement groups that continue to contribute to the design, conduct, and dissemination of research, including co-authoring peer-reviewed publications. Her work with patient groups has been presented as patient engagement case studies to the National Institute of Health Research (United Kingdom).



## Sara Musetti Jenkins

*Medical Writer,  
Medical Writing, Editing,  
and Design Services*

**Sara Musetti Jenkins** has been passionate about plain language in science communication since graduate school. In 2018, she co-founded a cancer research outreach blog, OncoBites, which has now published nearly 300 articles summarizing cutting-edge language in accessible language. Since joining RTI Health Solutions in 2021, Sara has been at the forefront of developing guidance for creating and including plain language summaries to accompany peer-reviewed publications, particularly for real-world evidence and patient-centered research studies. Additionally, Sara has spoken about best practices for plain language summaries at multiple national and regional conferences.

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What are plain language summaries?

2

Why do plain language summaries matter?

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How do you translate your research into plain language?


*Reading research articles can be like mountain climbing*








*Plain language is a tool to share  
research with a wide audience*


# Where is plain language being used?


 Plain language summaries

 Graphical abstracts

 Blogs

 Patient advocacy groups and newsletters

 Press releases

 Podcasts and video summaries

## PLSs should complement your article

A PLS *may* be the only thing your audience reads, but it does not *have* to be

## Widening your audience

- Patients and their family members
- Patient advocates
- Healthcare providers
- Healthcare payers/decision-makers
- Media
- Experts in other fields

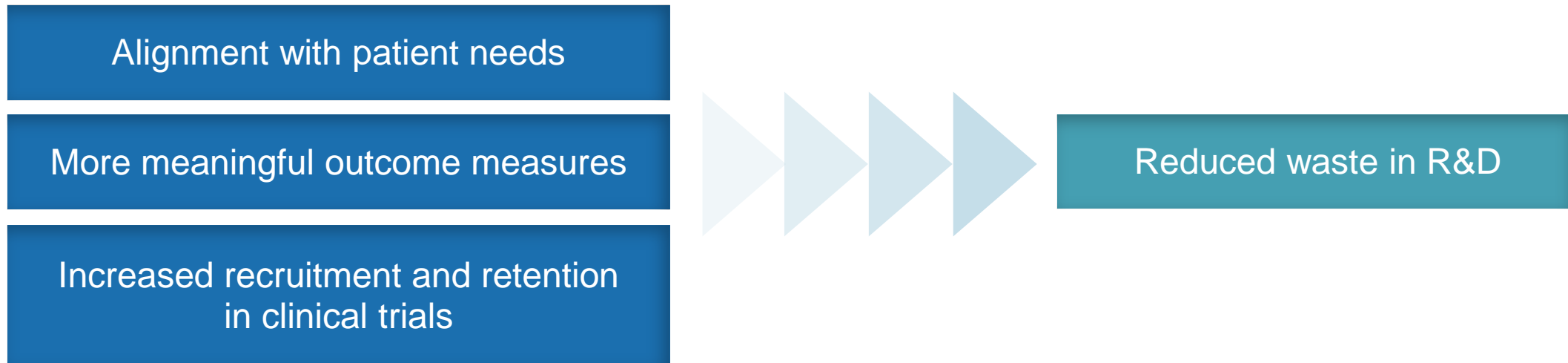


*PLSs improve patient engagement with research and clinical practice*

# Value of PLSs: From drug discovery to the clinic

# Facilitating meaningful patient engagement in R&D

Benefits of patient involvement in medicine R&D include



*Geissler et al., 2017*

# Facilitating meaningful patient engagement in R&D

Benefits of patient involvement in medicine R&D include

Alignment with patient needs

More meaningful outcome measures

Increased recruitment and retention  
in clinical trials



Reduced waste in R&D

*Geissler et al., 2017*

The Patient Focused Medicine Development initiative aims to build the conditions to scale up patient engagement in drug development



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MAKING SYSTEMATIC PATIENT ENGAGEMENT A REALITY ACROSS

Medicine and device lifecycles, digital health, data and health systems for better outcomes.



# Facilitating meaningful patient engagement in R&D

PLSs can help address hurdles in meaningful patient involvement

- Up-to-date scientific knowledge needs to be understandable
- Preparation is necessary to enable patient involvement in preclinical research
- Patients must be able to contribute as equal partners
- Patients need to have access to the scientific resources to participate in dissemination and postapproval communication



# Ensuring access to all relevant evidence during reimbursement and pricing negotiations



Reimbursement/national market access



Local market access

**Health Technology Assessment  
and Market Access**

# Ensuring access to all relevant evidence during reimbursement and pricing negotiations

Increased patient and public involvement in drug registration and reimbursement

## Example



Patient and public involvement contributed to reclassification of Gina 10 microgram vaginal tablets (estradiol)

MHRA, 2022

## Example



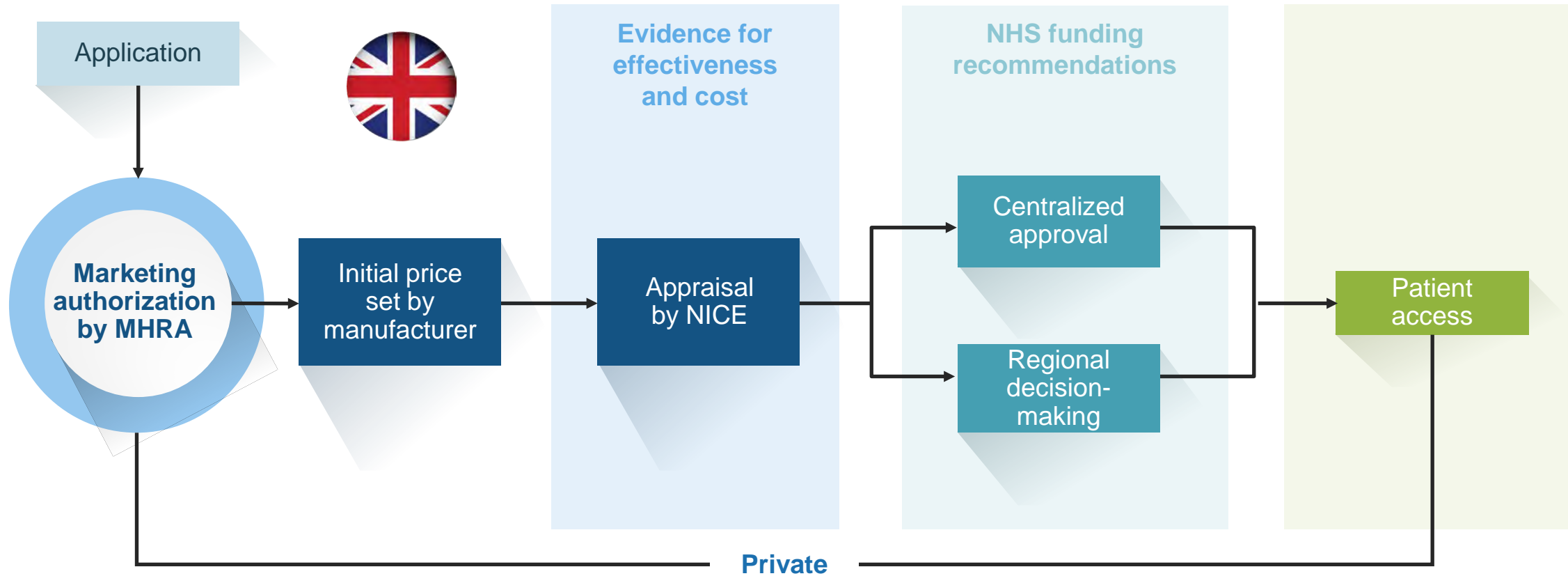
# Medicare

Drug Price Negotiation Program to include patient engagement

Medicare, 2022

# Ensuring access to all relevant evidence during reimbursement and pricing negotiations

Non-specialists play a key role on regional-level decisions on reimbursement



# Ensuring access to all relevant evidence during reimbursement and pricing negotiations

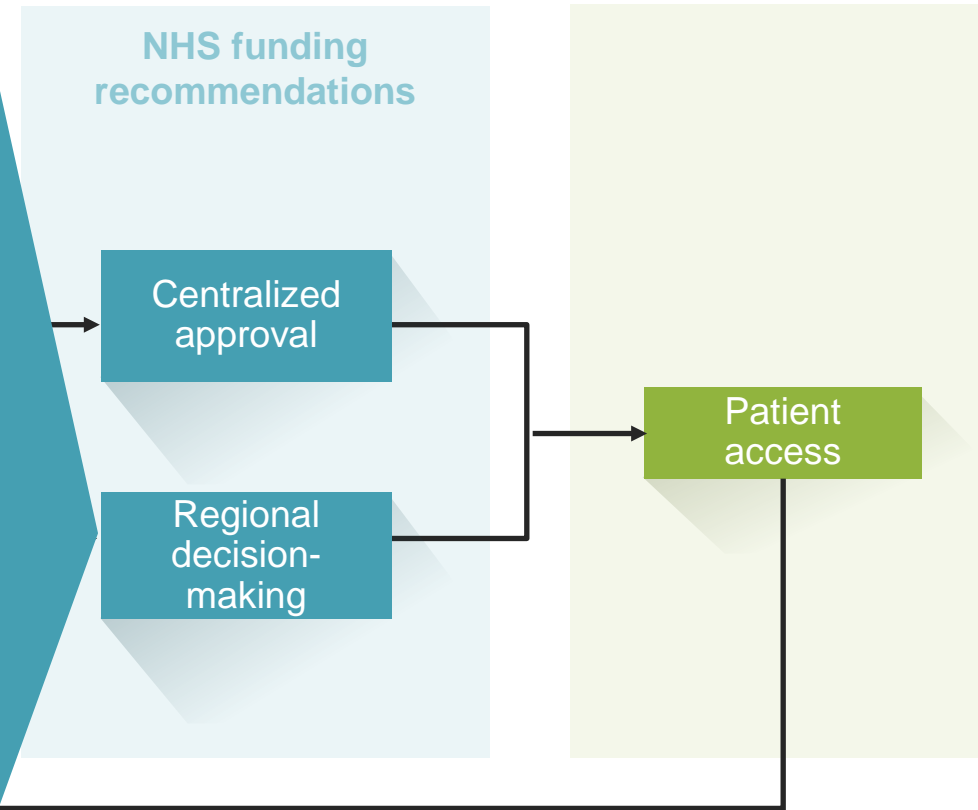
Non-specialists play a key role on regional-level decisions on reimbursement

## Potential value of PLSs

- Identifying relevant evidence
- Sharing the evidence with stakeholders consulted

## Types of research sought

- Evidence synthesis
- Humanistic burden
- Cost-effectiveness



# Supporting patient engagement with treatment in clinical practice



Betty. Aged 84 years

PMH: MIs x2  
Heart failure  
Hypertension  
Type 2 diabetes  
Presumed osteoporosis (#hip, Colles #)  
Gout

**New presentation of AF**

Already on 13 meds:

- Simvastatin
- Digoxin
- Furosemide
- Allopurinol
- Alendronate
- Ca & Vitamin D
- Metformin
- Gliclazide
- Dapagloflozin
- Bisoprolol
- Ramipril
- Aspirin
- Lansoprazole

6 (now 7) separate conditions (some related)  
13 medicines

## Report from a physician on call

“We surveyed one acute medical take in our hospital. In a relatively quiet take, we saw 18 patients with a total of 44 diagnoses. The guidelines that the on-call physician should have read, remembered, and applied correctly for those conditions came to 3,679 pages. This number include only NICE, the Royal Colleges, and major societies from the last 3 years. If it takes 2 minutes to read each page, the physician on call will have to spend **122 hours** reading to keep abreast of the guidelines” [for one 24-hour on-call period]

*Similar for Betty’s 7 conditions and 13 medicines...*

# Supporting patient engagement with treatment in clinical practice

Both patients and healthcare professionals see value in PLSs to make informed decisions about treatment choices



**PLSs save time:** HCPs can review evidence quicker



**PLSs are more credible:** published in peer-reviewed sources



**PLSs as focal point of clinical discussion**



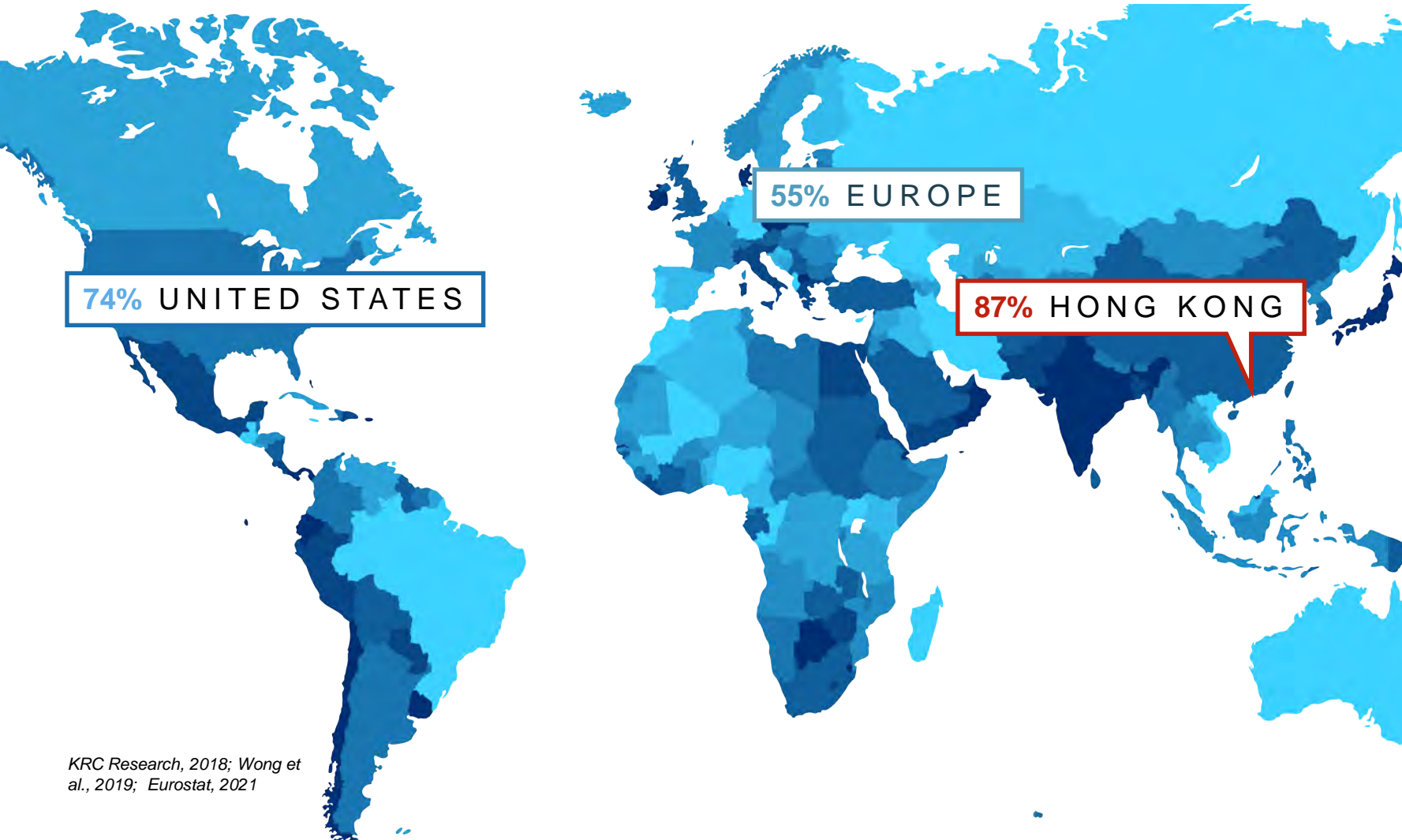
# Empowering consumers





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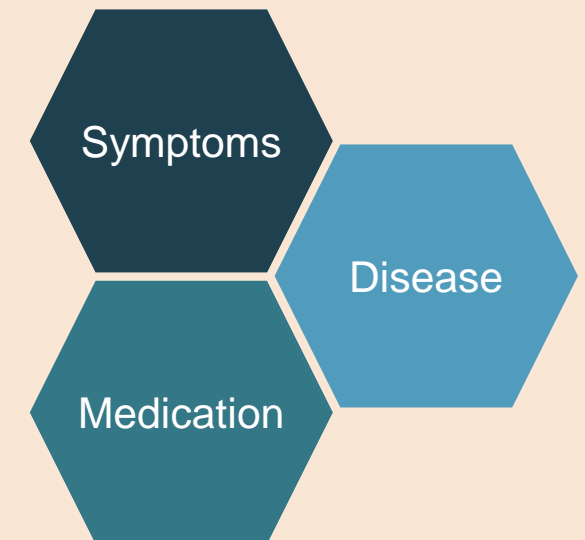
## Online health information seeking



KRC Research, 2018; Wong et al., 2019; Eurostat, 2021

## Drivers

- Reassurance
- Accessing specialist knowledge
- Second opinion on treatment
- Supplement information received
- Becoming an informed consumer
- Anonymity



Wong et al., 2019

# Empowering consumers

Absence of robust information increases vulnerability to sensationalism and misinformation

## Example (COVID-19 pandemic)

- AstraZeneca vaccine was first to receive approval in EU and UK
- February 2021: blood clots identified in some recipients of the vaccine

# Empowering consumers

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## Empowering consumers

Absence of robust information increases vulnerability to sensationalism and misinformation

*Could PLSs be used to counteract misinformation?*

# Empowering consumers



# Reaching the wider, more diverse audience



# How do you translate your research into plain language?



## Define your audience

- For much clinical and outcomes research, clinicians and patients are the primary audience
- Development of new patient-reported outcomes measures will be most valuable to clinicians and industry



The most effective way to engage your audience is to include an author or review from that audience in the development of your PLS



## What resonates with readers?

- Inclusive language
- Medium complexity
- Graphics
- Emphasis on survival



# Example

## Technical abstract

Historically, high hepatocellular carcinoma (HCC)–related mortality has been, in part, due to lack of effective therapies; however, several systemic therapies have been recently approved for HCC treatment, including regorafenib and ramucirumab. These two treatments utilize different routes of administration (four daily tablets and biweekly intravenous infusions, respectively) and have different risks of adverse events (AEs).

# Example

## Technical abstract

Historically, high hepatocellular carcinoma (HCC)–related mortality has been, in part, due to lack of effective therapies; however, several systemic therapies have been recently approved for HCC treatment, including regorafenib and ramucirumab. These two treatments utilize different routes of administration (four daily tablets and biweekly intravenous infusions, respectively) and have different risks of adverse events (AEs).

# Example

## Plain language translation

In recent years, the number of treatment options for patients with liver cancer have grown substantially. Many of the newly available treatments have similar survival rates but different risks of side effects and may be given in different ways. In this article, researchers compared two of these drugs, regorafenib and ramucirumab. Patients on regorafenib take four tablets each day, whereas patients on ramucirumab spend 15-30 minutes every other week getting an infusion at a doctor's office.

# Publication options

*Many journals recommend publishing PLSs alongside articles*



Cochrane

*When journals do not publish PLSs, there may be additional avenues to publish your PLS*

- Standalone PLS
- Patient advocacy sites

# Summary of Key points

1

PLSs allow us to **share scientific information** with patients, public and other stakeholders in a clear, accessible form

2

PLSs are **viewed as a valuable source of comprehensive, trustworthy and understandable information** about disease and treatment

3

PLSs can **facilitate meaningful patient involvement in drug R&D**, by providing patients with resources to actively engage as equal partners

4

PLSs can **support healthcare teams and patients work together** to reach a decision about care

# Q&A

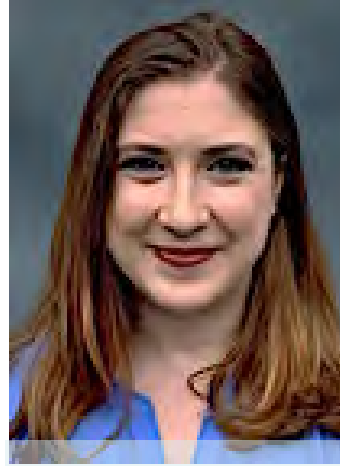
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# Resources

# Guides for Drafting PLS

- [Plain Language Webinar Package \(mycrowdwisdom.com\)](http://mycrowdwisdom.com)  
(AMWA)
- Patient-Focused Medicines Development Guide:  
[WG5.pdf \(pemsuite.org\)](http://pemsuite.org)
- [Guidance for writing a Cochrane Plain language summary | Cochrane Training](#)

# Inclusive Language

- [Webinar: Best Practices for Inclusive Language in Life Science Research and Communications | RTI Health Solutions \(rtihs.org\)](#)

# Peer-Reviewed Literature

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- Medicare, 2023 Fact Sheet: Medicare Drug Price Negotiations Program Initial Guidance chrome-extension://efaidnbnmnibpcjpcglclefindmkaj/https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-initial-guidance.pdf. Accessed April 22 2023
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