

# Elevating the Patient Voice

## Opportunities and Challenges for Medical Writers

Thursday, November 1, 2:00-3:30 PM


American Medical Writers Association's 2018 Medical Writing & Communication Conference

Renaissance Washington DC Downtown Hotel

Renaissance West B Room

999 9th Street NW, Washington, DC 20001

# Learning Objectives

1. Identify barriers that patients face when receiving care, including making care decisions
  2. Compare strategies for fostering patient engagement in care decisions and in clinical trials
  3. Outline various points of the drug development process where patient experiences can be included
  4. Develop content using patient-centered strategies that empower patients to be active partners in their care
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# Panel Discussion Sections



# Introductions

**Moderator:** Monique Pond, PhD, AAAS Science & Technology Policy Fellow

**Panelists:**

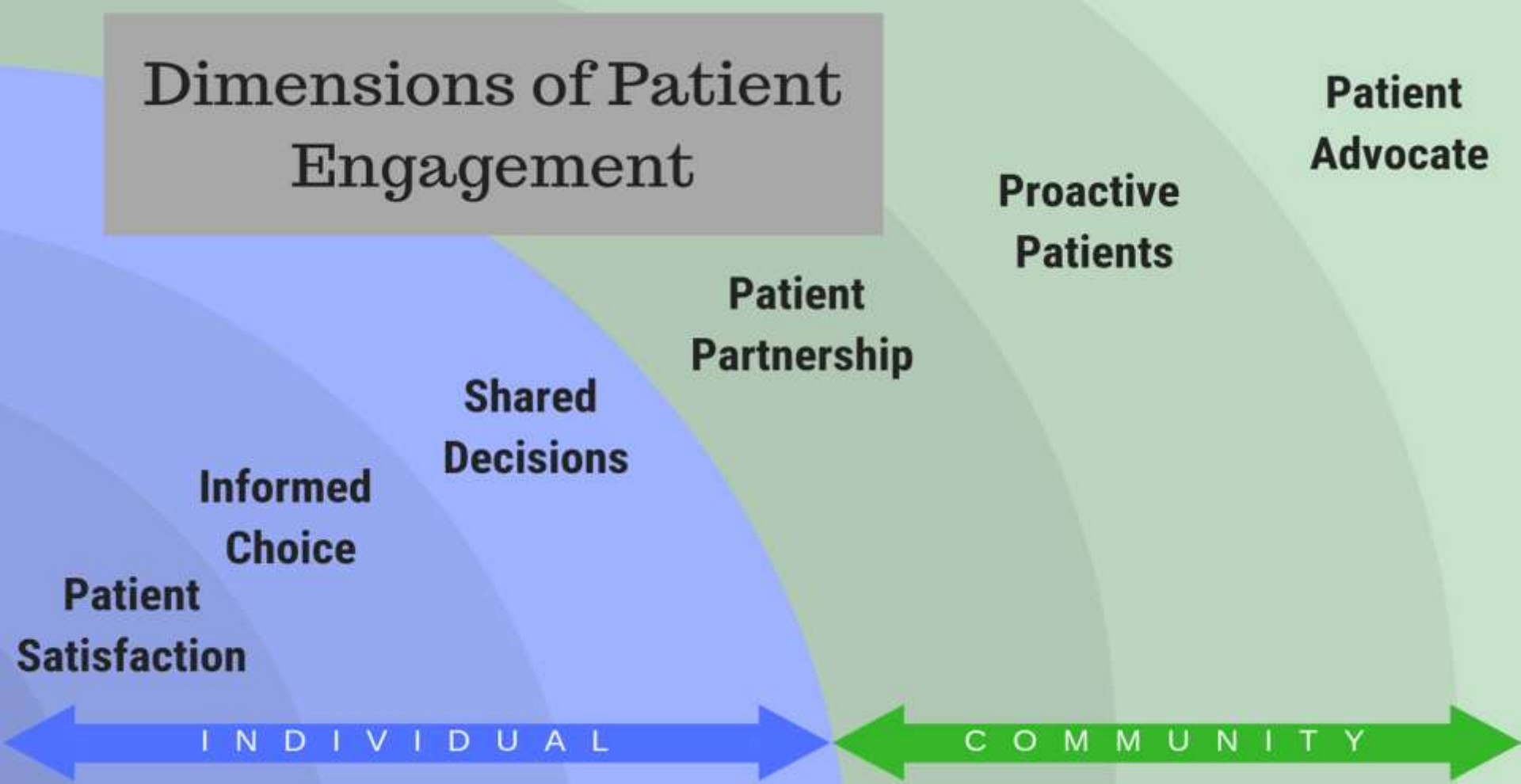
- Catina O’Leary, PhD, President & CEO at Health Literacy Media
- LaTasha Lee, PhD, MPH, Senior Manager, Partnership Engagement at American Society of Hematology
- Samir Shaikh, MBA, Deputy Director Office of Patient Affairs at FDA





# 1. Engaging Patients in Care

# Dimensions of Patient Engagement



Adapted from Regional Primary Care Coalition.

“[Some days] have gone very smoothly and everything is going well. And [some days] I’ve had to fight for every single thing. It seems like I’m fighting more than I’m being helped...[I want] the medical community as a whole to listen to what patients need.”



Marqus Valentine, patient with sickle cell disease and co-founder of Sick Cells

The 1A (2018, February 5). *Why You Don't Hear Much About Sickle Cell Anymore* [Radio broadcast]. NPR. <https://the1a.org/shows/2018-02-05/why-you-dont-hear-much-about-sickle-cell-anymore>

All the treatments and the lack of sleep contributed to an extremely high level of fatigue I had never before experienced.

When I'm extremely tired, the pain is greater... the two are intertwined.

## Patients with breast cancer

Center for Drug Evaluation and Research. (2016). *The Voice of the Patient Report: Breast Cancer*. U.S. Food and Drug Administration. <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM464932.pdf>



“I took myself off [hydroxyurea] when I was an adult because at the time the doctors couldn’t tell me the long-term effects of taking the drug. I don't want to substitute sickle cell for another disease that I know nothing about.”



## Patient with sickle cell disease

Center for Drug Evaluation and Research. (2016). *The Voice of the Patient Report: Sickle Cell Disease*. U.S. Food and Drug Administration.

<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM418430.pdf>



## 2. Engaging Participants in Trials



# 83%

patients considered potential benefits/risks of participating in a clinical trial as “very important”

The Center for Information and Study on Clinical Research Participation. (2017). *Perceptions & Insights Study: The Participation Decision-Making Process.*



# 49%

participants are motivated by helping to advance  
science and develop treatments

The Center for Information and Study on Clinical Research Participation. (2017). Perceptions & Insights Study: The Participation Experience.



# 53%

participants report receiving no update or report  
after completing a trial

The Center for Information and Study on Clinical Research Participation. (2017). Perceptions & Insights Study: The Participation Experience.

# Shared Decision Making





# 3. Collaborating with Patients

An ideal treatment would address the all-over pain, insomnia, and fatigue while also allowing clear-headed thinking and memory without fatigue or weight gain.

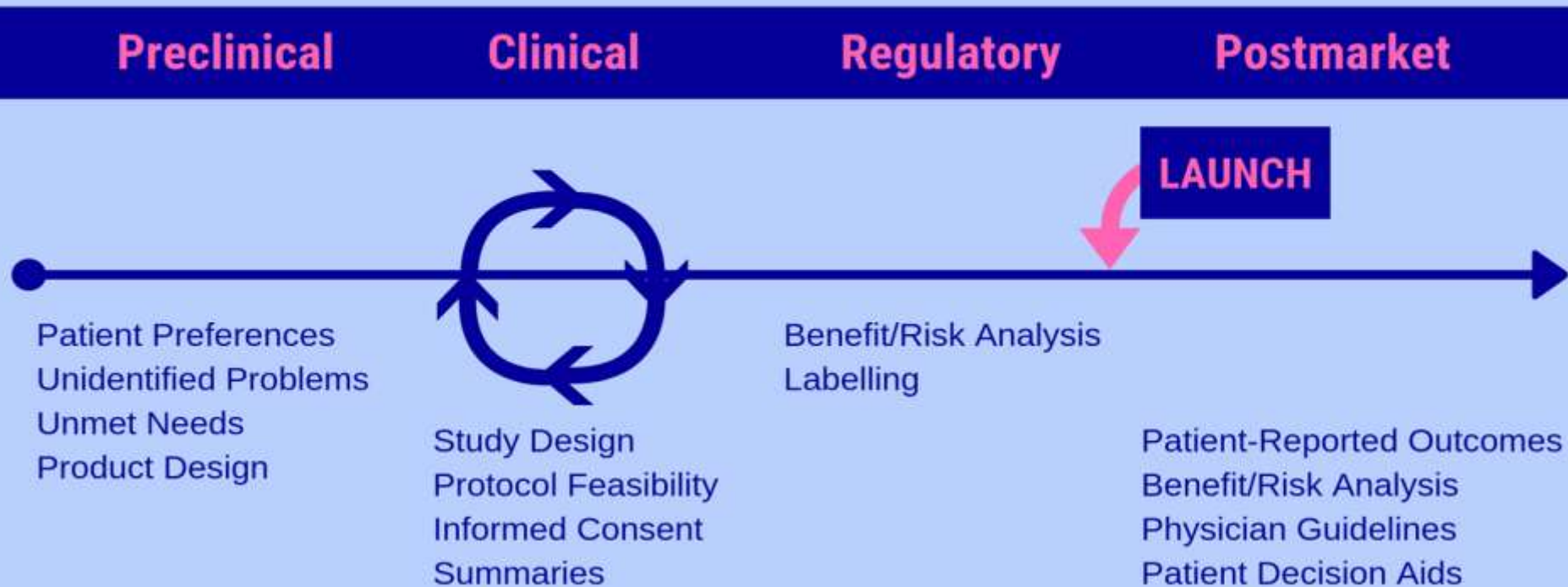
Patient with fibromyalgia

Center for Drug Evaluation and Research (2017). *The Voice of the Patient Report: Fibromyalgia*. U.S. Food and Drug Administration.

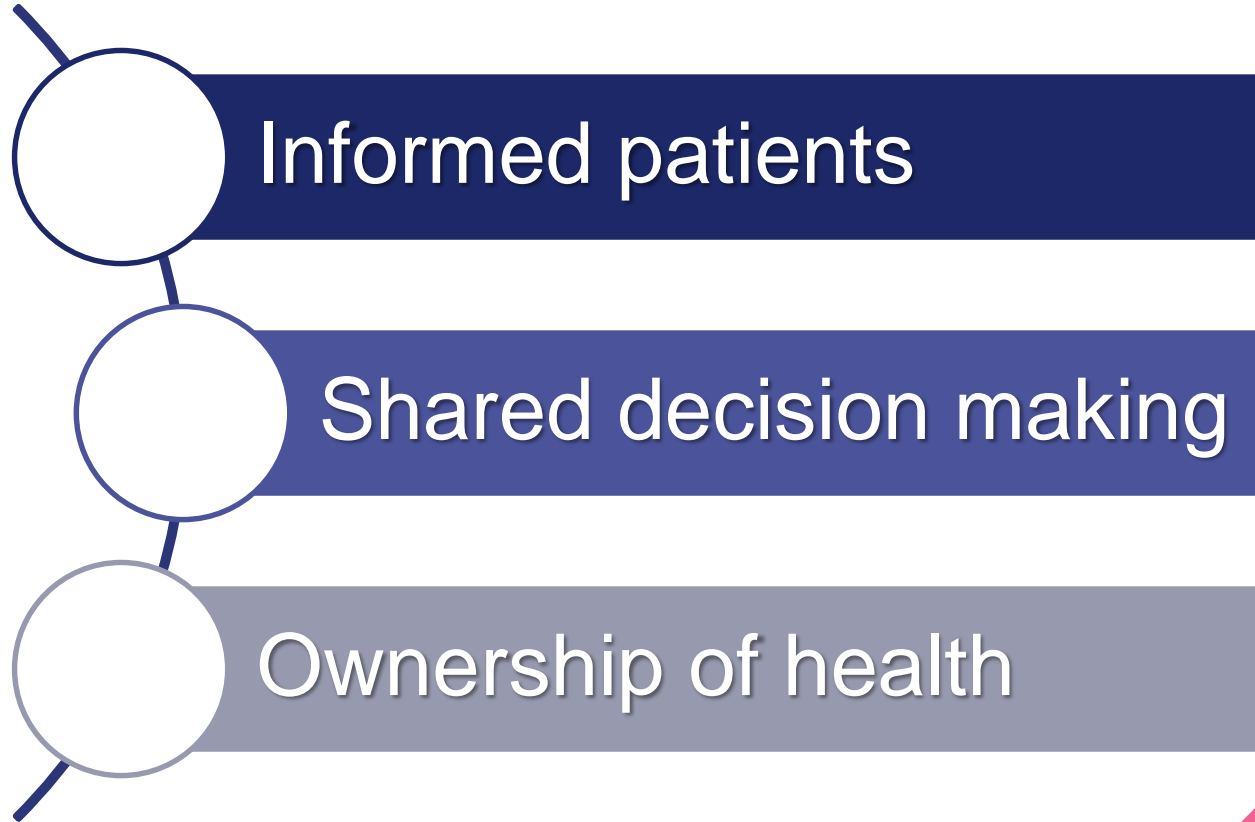
<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM422351.pdf>



# Patient Input in Drug Development



# Wrap-up



# Resources

- [PCORI: The Value of Engagement](#)
- [Dartmouth: Center for Shared Decision Making \(toolkits\)](#)
- [Mayo Clinic: Shared Decision Making Resource Center](#)
- [HLM's Health Literacy in Action: Caregiver Guide](#)
- [CISCRP: 2017 Public and Patient Perceptions & Insights Study](#)
- [Amer Society Hematology: Sickle Cell Disease Coalition](#)
- [FDA: Patient Affairs Initiatives](#)
- [FDA: The Voice of the Patient Reports](#)
- [CTTI: Patient Groups & Clinical Trials](#)
- [Nature: Co-Production from Proposal to Paper](#)

# Resources (Expanded)

- Patient-Centered Outcomes Research Institute. (2018). *The Value of Engagement*. <https://www.pcori.org/about-us/our-programs/engagement/value-engagement>
- The Dartmouth Institute Center for Shared Decision Making. (2018). *Decision Support Toolkits*. [https://med.dartmouth-hitchcock.org/csdm\\_toolkits.html](https://med.dartmouth-hitchcock.org/csdm_toolkits.html)
- Mayo Clinic. (2018). *Shared Decision Making Resource Center*. <https://shareddecisions.mayoclinic.org/>
- Health Literacy Media. (2018). *Health Literacy in Action: Caregiver Guide*. <https://www.healthliteracy.media/blog/health-literacy-in-action-traumatic-brain-injury-caregiver-guide>
- Center for Information & Study on Clinical Research Participation. (2017). *Public and Patient Perceptions & Insights Study*. <https://www.ciscrp.org/services/research-services/public-and-patient-perceptions-insights-study/>
- American Society of Hematology. (2018). *Sickle Cell Disease Coalition*. <http://www.scdcoalition.org/>
- U.S. Food & Drug Administration. (2018). *Patient Affairs Staff Initiatives*. <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/ucm589472.htm>
- Center for Drug Evaluation and Research. (2016). *The Voice of the Patient Reports*. U.S. Food & Drug Administration. <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm368342.htm>
- Clinical Trials Transformation Initiative. (2018). *Patient Groups & Clinical Trials Project*. <https://www.ctti-clinicaltrials.org/projects/patient-groups-clinical-trials>
- Hickey, G., Richards, T., & Sheehy, J. Co-production from proposal to paper. (2018). *Nature*, 562(7725), 29–31. <https://doi.org/10.1038/d41586-018-06861-9>

Questions?  
Comments?  
Suggestions?

Let's continue this conversation!

Moderator: Monique Pond [[LinkedIn](#)]

Coordinator: Kristin Roynesdal [[LinkedIn](#)]