

## How to Work with Patient Representatives to Make Your Research More Successful

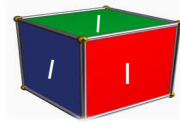

SITC Cancer Immunotherapy Winter School  
February 23, 2021

Deborah Collyar  
PAIR: Patient Advocates In Research

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## Why we need to work together...

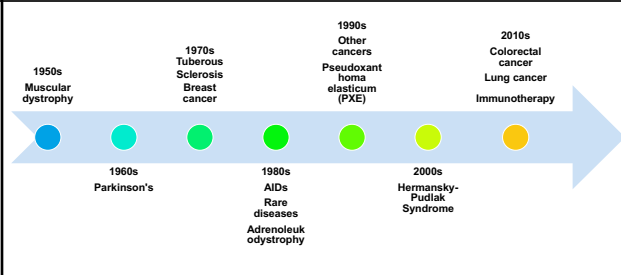
Scientists/researchers: experts on "I"

Patients: whole alphabets

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## Patients & Advocates have influenced research for decades, e.g.



1950s Muscular dystrophy

1960s Parkinson's

1970s Tuberculosis, Sclerosis, Breast cancer

1980s AIDs, Rare diseases, Adrenoleukodystrophy

1990s Other cancers, Pseudoxanthoma elasticum (PXE)

2000s Hermansky-Pudlak Syndrome

2010s Colorectal cancer, Lung cancer, Immunotherapy

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## What patients need from research

Talk to each other!

- Within company/institution
- With external fields

Work with us!

- Throughout product lifecycles
- Don't ASSUME

Standards, standards everywhere

- Biospecimens
- Reproducibility
- Data sharing & security
- Map ongoing findings

Health literacy approaches

- Clinical trials
- Information



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## What do patients want from immunotherapy?

Less hype, more realism

- Compared regimens > guidelines
- Integration w/other treatments
- Better care
- "C" word is "cure"

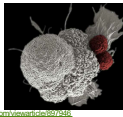
Report additional info

- Response rates
- Comparable to chemotherapy
- Duration of response
- Financial toxicities
- QOL & PROs

Fewer IrAEs

- ≥ grade 2 can be serious
- Autoimmune
- Possible age factors?

CONTEXT + Reasonable Expectations



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## We also want permanent COVID-19 changes +

Adaptive design in protocols (since 1969)

- Learn as we go, pre-determined
- Rules to analyze, stop, etc.

Platform & umbrella trials

- More chances for newer approaches


Patient-relevant endpoints

- Including PROs and patient experience


Broader eligibility

- FDA-endorsed: Age, comorbidities, HIV, brain mets + more

Crossover/treatment switching



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## Poll

Question #1

Which statement is correct?

1. A recruitment plan won't help
2. A recruitment plan will help
3. A recruitment plan is too hard to create

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## Recruitment plans help

**Journal of Clinical Oncology®**  
An American Society of Clinical Oncology Journal

Enter words / phrases / DOI / ISBN / authors / keywords / etc.

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COMMENTS AND CONTROVERSIES

**Managing Accrual in Cooperative Group Clinical Trials**

Tsai L, Denny J, Yoon M, Yasko J, Olszarski J, Calhoun M, et al. [Show More](#)

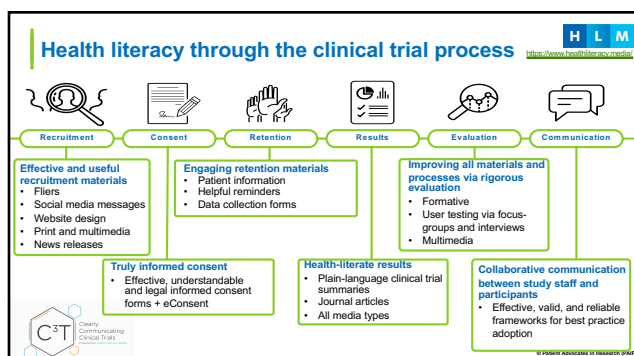
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Designing a multicenter clinical trial is a process affected by time, economic, and political constraints. Unfortunately, this can result in overlooking needs or concerns of the potential participants of the study. Given the magnitude of resources spent on developing and implementing clinical trials, we have examined the value of systematic accrual management at various stages of protocol development, activation, delivery, and enrollment.

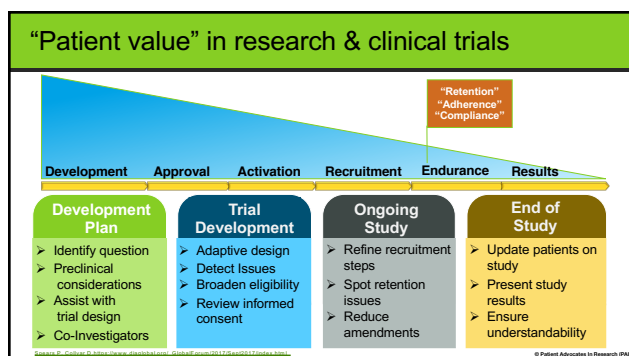
[MAGNITUDE OF THE PROBLEM](#)

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## Helping all patients = Health Equity

**Race ≠ ethnicity ≠ minority**

**Race**  
Differences/similarities in biological traits

**Ethnicity**  
A shared cultural heritage that is learned

**Minority**  
Smaller population than the controlling majority



**Ageism: pervasive**

**Socioeconomic status (SES) matters**

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## Patient advocates include diversity

FDA eligibility expands to: age, comorbidities, brain mets, HIV, washout periods, concomitant medications, prior therapies, laboratory reference ranges and test intervals, and performance status. PMID: 33563632

**"Retention", "Adherence", "Compliance"**

Development
Approval
Activation
Recruitment
Endurance
Results

**Better pre-planning pays off...**

- Include questions that answer patient needs
- Use improved FDA eligibility criteria<sup>1</sup>
- Include Comprehensive Geriatric Assessments (CGA)<sup>2</sup>
- Recruitment plans + community workers<sup>3</sup> + health literacy
- Address systemic racism

<sup>1</sup> <https://www.fda.gov/oc/2019/07/19/fda-eligibility-criteria-only-broadening-access.html>  
<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6888882/>  
<sup>3</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6888882/>

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**Ex: the “everyone” of 65+ year old patients...**

Marathon runners   Regular exercise   Mobility issues   Cognitive issues   Assisted living   Nursing home

**Why exclude so many from...**

- Clinical trials + treatment options?
- Who is “responsible” to show benefit? To include patients?

Time to create a “healthy aging” program + geriatric assessment  
Connect research + pilots + initiatives + community + PEOPLE

<https://www.nationalacademies.org/event/108-05-2020/nap-research-and-development-for-older-adult-populations-a-workshop>

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**Traditional data...**

**All Other “Patient” Data**

- THIS is real world!

Clinical Trial Data

Family   Economic   Medical   Biological   Demographic   Social   Work/Career

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**Patient Reported Outcomes (PROs), etc.**

**Patient-Reported Outcomes for Cancer Patients Receiving Checkpoint Inhibitors: Opportunities for Palliative Care-A Systematic Review**

- ✓ <https://pubmed.ncbi.nlm.nih.gov/30905677/>

**Patient-Reported Outcomes During Immunotherapy for Metastatic Melanoma: Mixed Methods Study of Patients’ and Clinicians’ Experiences**

- ✓ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7180512/>

**Evaluating the psychometric properties of the Immunotherapy module of the MD Anderson Symptom Inventory**

<https://pubmed.ncbi.nlm.nih.gov/30905677/>

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**Regulators are interested too!**

**Regulatory Focus™**

Regulatory Focus™ > News Articles > 12 > Patient Experience Data: FDA Drafts Guidance

**Patient Experience Data: FDA Drafts Guidance**

Posted 20 December 2018 | By Zachary Brennan

Thanks to the 21st Century Cures Act, the US Food and Drug Administration (FDA) on Thursday published new draft guidance to help stakeholders submit a proposed draft guidance on patient experience data.

The 12-page draft guidance, which provides information in a Q&A format, addresses questions relating to both guidance development and other potential pathways for contributing patient experience data.

“Today’s guidance document is part of our commitment to advance patient focused drug development and is one of several guidances that we’re developing regarding the collection of patient experience data, and the use of such data and related information in drug development,” FDA Commissioner Scott Gottlieb said. “This guidance document proposes a roadmap for stakeholders who are interested in developing and submitting proposed draft guidance to the FDA relating to patient experience data.”

<https://www.fda.gov/oc/2018/12/20/patient-experience-data-guidance>

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**I have a dream... you can help!**

**Create future clinical trials + products that meet patient needs**

- ANALYZE EXISTING TRIALS**  
*What can we do better?*
- WHAT PATIENT QUESTIONS COULD BE ANSWERED?**  
*Learn from real world use*
- INCORPORATE LESSONS INTO NEW TRIALS**  
*e.g. endpoints, eligibility, PROs, biomarkers, site aids*

**Help us win for patients!**

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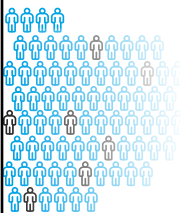
**Takeaway messages**

- ✓ Pre-plan with patients in mind + in design
- ✓ Build trust + relationships
- ✓ Include diversity in language, age, ethnicity, etc.
- ✓ Help create equity in health systems & clinical trials
- ✓ Help train sites + patient representatives
- ✓ Include patient experience/PRO data
- ✓ Health literacy builds understanding + action

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**A reminder: please don't blame patients**



**Patients don't 'fail' treatment.**

**TREATMENTS fail patients.**

**PATIENTS also respond**  
...their disease may not




Let's work together on **accurate** language

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Where research meets reality


**Thank you! Get in touch**  
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**Resources (a few examples)**

**Health Literacy (HL) & Plain Language (PL)**

- <https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html>
- Health Literacy Media (HLM), <https://www.healthliteracy.media/> and <https://www.cit.media/>

**PROs & Patient Engagement**

- <https://www.fda.gov/media/104989/download>
- <https://www.fda.gov/cdms/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>
- [https://www.valueinhealthjournal.com/article/S1098-3015\(12\)01451-9/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(12)01451-9/fulltext)

**SHARE services & materials (e.g. Novela in English & Spanish)**

- <https://www.sharecancersupport.org>
- [https://www.sharecancersupport.org/wp-content/uploads/sites/1731/2016/04/Be\\_Brave\\_They\\_re\\_Your\\_Breasts\\_en-us.pdf](https://www.sharecancersupport.org/wp-content/uploads/sites/1731/2016/04/Be_Brave_They_re_Your_Breasts_en-us.pdf)

**Training**

- <https://www.ctti-clinicaltrials.org/projects/patient-groups-clinical-trials>
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