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

1

Why we need to work together…

Scientists/researchers: experts on “I”

Patients: whole alphabets

2

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

3

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

4

What do patients want from immunotherapy?

Less hype, more realism
•Compared regimens > guidelines
•Integration w/other treatments
•Better care
•“C” word is “cure”

Fewer irAEs
•> grade 2 can be serious
•Autoimmune
•Possible age factors?

5

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

6
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

Health literacy through the clinical trial process

- Effective and useful recruitment materials
  - Flyers
  - Social media messages
  - Print and multimedia
- Engaging retention materials
  - Incentives
  - Study newsletters
  - Data collection forms

Recruitment plans help

- Patients
  - Situation, influencers, needs & preferences
- Sites
  - Logistics, barriers, communication tips
- Referrals
  - Awareness, inclusion, positioning

“Patient value” in research & clinical trials

Development Plan
- Identify question
- Preclinical considerations
- Assist with trial design
- Co-Investigators

Trial Development
- Adaptive design
- Detect issues
- Broaden eligibility
- Review informed consent

Ongoing Study
- Refine recruitment
- Spot retention issues
- Reduce amendments

End of Study
- Update patients on study
- Present study results
- Ensure understandability

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

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

Better pre-planning pays off…
- Include questions that answer patient needs
- Use improved FDA eligibility criteria
- Include Comprehensive Geriatric Assessments (CGA)
- Recruitment plans + community workers + health literacy
- Address systemic racism

© Patient Advocates In Research (PAIR)
How to Work with Patient Representatives to Make Your Research More Successful

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

Traditional data…

All Other ‘Patient” Data
• THIS is real world!

Clinical Trial Data

Economic
Family
Medical
Biological
Social
Demographic
Work/Career

Patient Reported Outcomes (PROs), etc.

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

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

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

Regulators are interested too!

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

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

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

Resources (a few examples)

Health Literacy (HL) & Plain Language (PL)
- [https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html](https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html)
- Health Literacy Media (HLM), [https://www.healthliteracy.media/](https://www.healthliteracy.media/) and [https://www.c3t.media/](https://www.c3t.media/)

PROs & Patient Engagement
- [https://www.fda.gov/media/104969/download](https://www.fda.gov/media/104969/download)

SHARE services & materials (e.g. Novela in English & Spanish)
- [https://www.sharecancersupport.org](https://www.sharecancersupport.org)

Training
- [https://eupati.eu/training/](https://eupati.eu/training/)
- [https://www.pcori.org/engagement](https://www.pcori.org/engagement)
- [https://researchadvocacy.org/](https://researchadvocacy.org/)

ICONS from [https://thenounproject.com/](https://thenounproject.com/)

© Patient Advocates In Research (PAIR)