

SITC Cancer Immunotherapy Winter School
A COMPREHENSIVE CANCER IMMUNOTHERAPY EDUCATION PROGRAM

sitc
Society for Immunotherapy of Cancer

Patient Considerations that Impact
Treatment & Clinical Trials

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PAIR: Patient Advocates In Research

#SITCWinterSchool 2022



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First: 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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"It is more important to know
what kind of a patient the disease has,
than to know what kind of a disease the patient has."

? Claudius Galen (130-210 CE)
In DDN, February 2021

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The U.S. healthcare disease crisis system

Patients are PEOPLE

Who just landed on a new
planet with:

- No roadmap
- No dictionary
- No survival training



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Clinic & trial issues start early

People need better results... Benefits MUST outweigh costs

Issues start with:

- (mis) Diagnosis
- Confusion at each step
- Technology for 'big data,' not patient results
- Costs (many kinds)
- Clinical trials?



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'Patient' can include...

People/patients

- Those who have a medical condition/disease/illness
- Can include comorbidities

Carers/caregivers/helpers

- Those who feel powerless, but want to help
 - Family, friends
- Those who are paid by someone to help patients function better

Sometimes even medical providers/sites

- Those in health systems who provide medical care
- Can include general care and clinical trials



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Congratulations!

You've just been diagnosed with unamit, a serious medical condition

Treatment options:

- xyzimab + ydonwunit - OR - wutzmortoxinib

New clinical trial:

- WOWzer therapy ± either treatment

Which would you like?

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WT...Heck?

Hey, where is my primer on being a patient?



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What is missing for patients?
CONTEXT

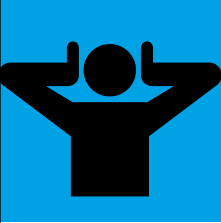
Stakeholders

I love it!

Me too!

Users

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Lots of Terms

Used by industry, regulatory, & research

Don't actually make sense to sites or the provider community, let alone patients & their carers!

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Words matter:
PAIR 101

Term	Scientific/Medical	Public Definition
Negative test	That's too bad	This is good, right?
Positive test	That's too bad	This is good, right?
Cure	5-year survival rate	Never again
Genomic profiling	Precision medicine	Targeting suspects?
Support services	Peripheral topics	Fit medical into life
Lay	Non-scientists	Down?
Environment	Patient controlled	External forces
Community	Non-academic center	Where I live
Medical advance	Incremental success	A cure
Clinical trial	Human research	Sterile, judgment
Biospecimens	Tissue for analysis	Mutant creature?

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What do patients want to know?

✓ I am not alone (others before me)

✓ Why are you doing it?


- What is known/unknown

✓ What to expect

- Exploratory v. validated

✓ How bad can it get... 'safe' word?

✓ What happens after?



MORE THAN INFORMED CONSENT

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Notes on immunotherapy...

The “latest greatest”?

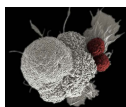
Few cancer patients are treated with IO

- Most still get surgery, radiation, and/or chemotherapy/biologicals

Immunotherapy promising, but...

- Many tumors don't respond
- Not a replacement therapy
- Side effects
- Trial results don't often transfer to commercial use

Please set **reasonable expectations!**



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What do patients want from immunotherapy?

Less hype, more realism

- C word is “cure,” not cancer
- Integrate w/other treatments
 - Surgery, radiation, chemo, etc.
- Better complete care

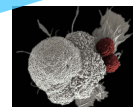
Report additional info

- Response rates
 - Compare to chemotherapy, etc.
- Duration of response
- Financial toxicities
- Patient & PROs

Fewer irAEs

- > grade 2 can be serious
- Autoimmune is
- Possible age factors?

CONTEXT +
Reasonable Expectations



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Words matter:
more
PAIR 101

Term	Scientific/Medical	Public Definition
Immunotherapy	Focused on immune system	Therapy to fix cancer
Informed consent	Legal paperwork	Understandable info
Efficacy	Drug evaluation	Effectiveness for me
Tumor Mutation Burden	Good!	Bad?
Vaccine	Vehicle for immunotherapy	Prevention
Cytokine Release Syndrome	Systemic inflammatory response	Death Star?
Direct/digital clinical trial	COVID-related study	Study that thinks about me
Artificial Intelligence (AI)	Machine learning, algorithms	A sci-fi movie, robots on steroids?
RWD	Real World Data	Is that mine? How to fix?

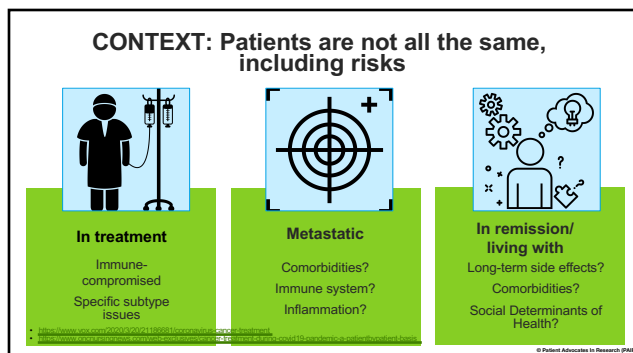
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1st words to eliminate

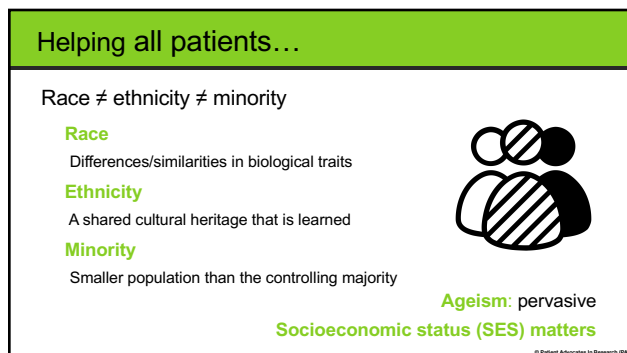
- Informed consent
- Schema
- Randomized
- & many more!

SUBJECT
SUBJECT

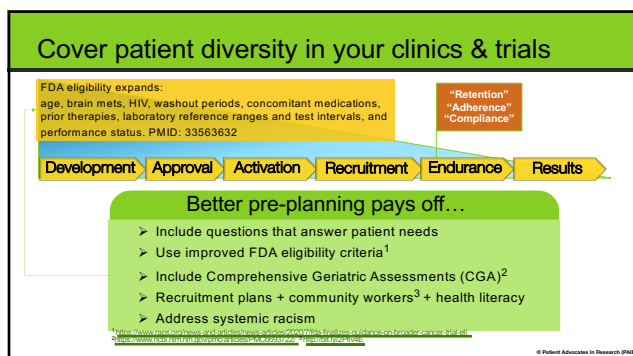
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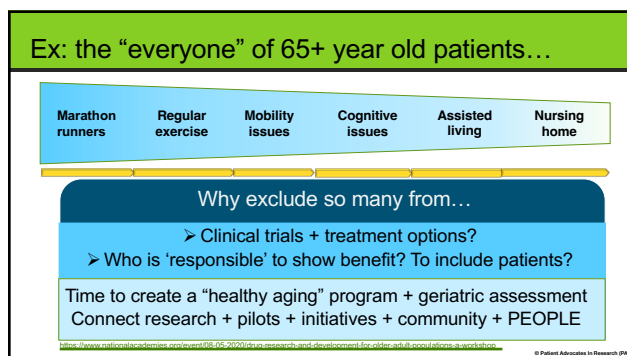
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Remember that roadmap idea?

- Details**
 - What is my condition/disease?
 - General information exists
 - Details usually don't
- Experts**
 - Who do I talk to?
 - How many specialists?
 - Where do I find them? Who coordinates my care?
- Options**
 - What can I do?
 - For my condition/disease? Clinical trials?
 - How will this impact my lifestyle?
- Trials**
 - Are there clinical trials for ME?
 - No matter the sponsor
 - What should I expect?
- Cost**
 - How much will this take?
 - For treatment, tests, checkups, other care?
 - Initially? Ongoing?

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We also want **permanent** COVID-19 changes +

- DCTs, **local options**, telemedicine, etc.
- Adaptive design** in protocols (since 1969)
 - Learn as we go, pre-determined
 - Rules to analyze, stop, etc.
- Master protocols**
 - Platforms, umbrellas, baskets, whatever
 - More chances for newer approaches
- Patient-relevant endpoints**
 - Include PROs and patient experience
- Crossover/treatment switching**
 - https://www.clinicaltrials.gov/ct2/resources/Treatment_Switching_Guidance_Document_OCT_2016.pdf

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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/>

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Recruitment plans help

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

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Treat them for financial toxicity. Every. Time.




Serious Adverse Events (SAE)

- Adds to physical, mental, emotional & financial stress
- Impacts Overall Survival (OS)
- It's never over for them



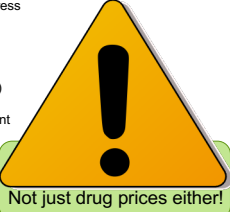
Don't assume. In US...

- At least 67 million people uninsured (post-COVID)
- Another 28% are underinsured (> 92m)
- Many choose between rent, food, kids, or treatment



Extend life + wellbeing

- Social determinants of health matter
- What about comorbidity treatments?




Not just drug prices either!

Ramsey SD, et al. Financial toxicity as a risk factor for early mortality among patients with cancer. JCO 2016; 34:980-986. © Patient Advocates In Research (PAIR)

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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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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.c3i.media/>

PROs & Patient Engagement
<https://www.fda.gov/media/104969/download>
<https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical>
<https://www.valuenetjournal.com/articles/1038-015/12/01451-9/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>


Training
<https://www.ctti-clinicaltrials.com/projects/patient-groups-clinical-trials>
<https://www.paintrials.org/>
<https://www.paintrials.org/enrollment>
<https://researchadvocacy.org/>

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Where research meets reality


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