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NCORP RESEARCH BASE

Enhancing Community-based Participation and Engagement for Patients, Research Personnel, and Stakeholders on Large Network Trials

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NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

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Disclosures

Presenters have no relevant disclosures.

Introduction to WF NCORP RB

Emily V. Dressler, PhD

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What is the NCORP RB?

- NCI Community Oncology Research Program (NCORP) is a network of primarily community-based oncology practices involved in clinical research activities
- The NCORP Research Bases are hubs that design and spearhead the conduct of multi-center clinical trials
  - Focused on cancer control and cancer care delivery research
- Provide overall administration, data management, scientific and statistical leadership, operational processes and personnel, and regulatory compliance
- Became WF NCORP RB in 2014
  - Previously was a CCOP running these types of studies since 1999

5 RBs are within
NCI National Clinical
Trials Networks (NCTNs)

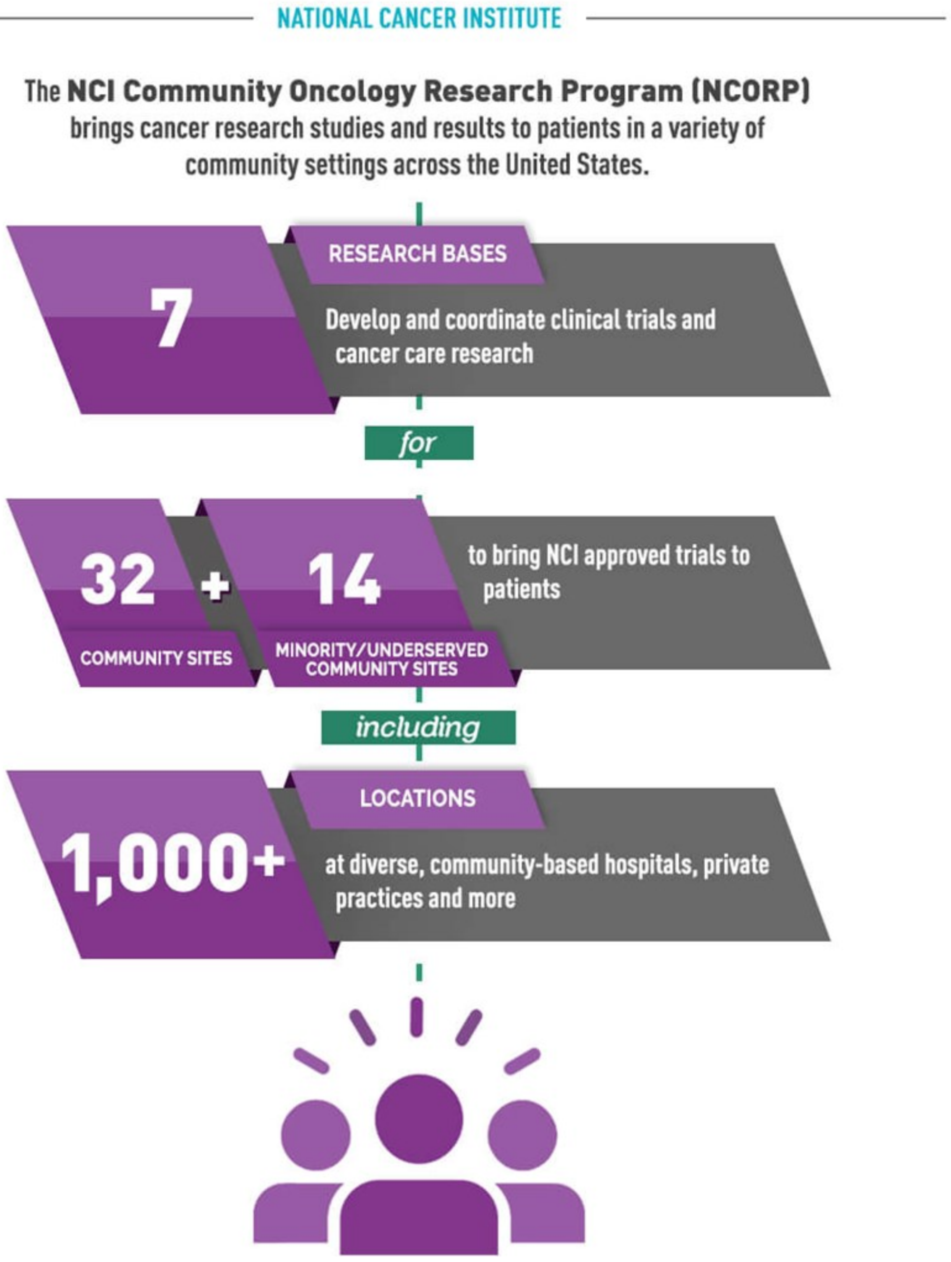
Alliance
for Clinical Trials
in Oncology

SWOG CANCER RESEARCH NETWORK

ECOG-ACRIN
cancer research group

CHILDREN'S ONCOLOGY GROUP

NRG ONCOLOGY
Advancing Research. Improving Lives.™



NATIONAL CANCER INSTITUTE

The **NCI Community Oncology Research Program (NCORP)** brings cancer research studies and results to patients in a variety of community settings across the United States.

7 RESEARCH BASES
Develop and coordinate clinical trials and cancer care research

for

32 COMMUNITY SITES + **14** MINORITY/UNDERSERVED COMMUNITY SITES
to bring NCI approved trials to patients

including

1,000+ LOCATIONS
at diverse, community-based hospitals, private practices and more

2 RBs are based at
academic institution
cancer centers

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URCC
NCORP Research Base

NCI Community Oncology Research Program
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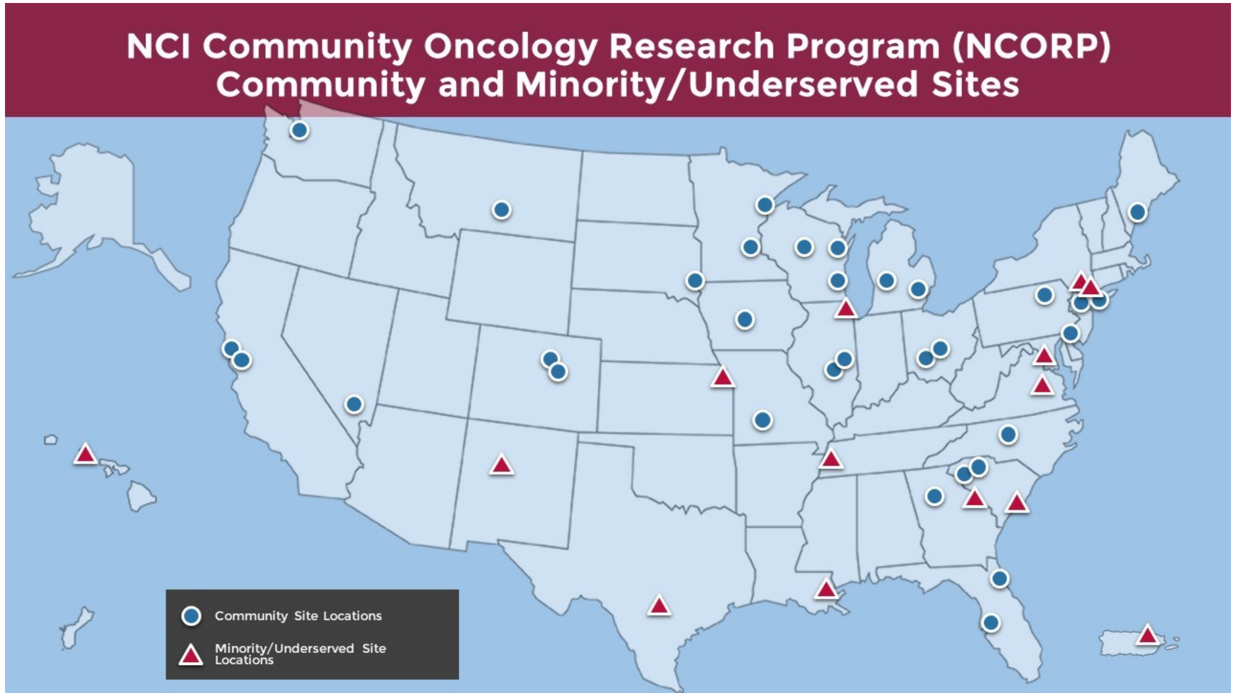
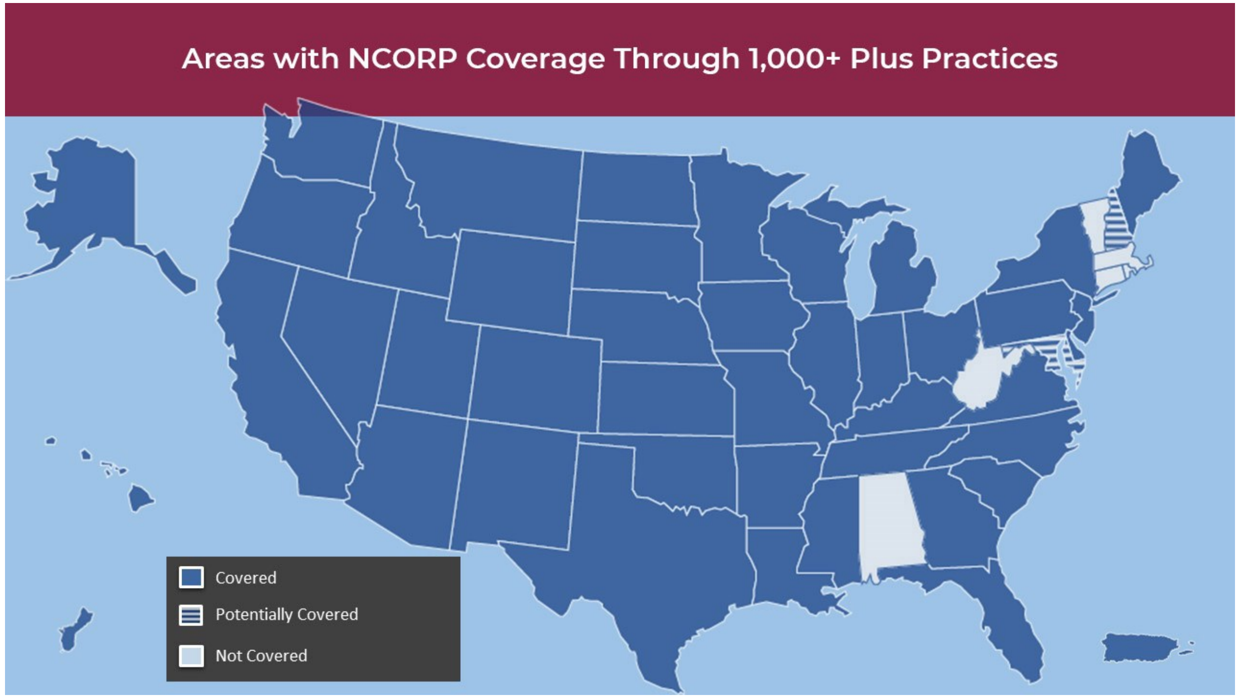
Sites Representation Nationally

- Primarily community oncology locations, only a few academic institutions with M/U focus
- “Hub and spoke network” – sites (46), affiliates, sub-affiliates


NCI Community Oncology Research Program (NCORP)
Community and Minority/Underserved Sites


Areas with NCORP Coverage Through 1,000+ Plus Practices

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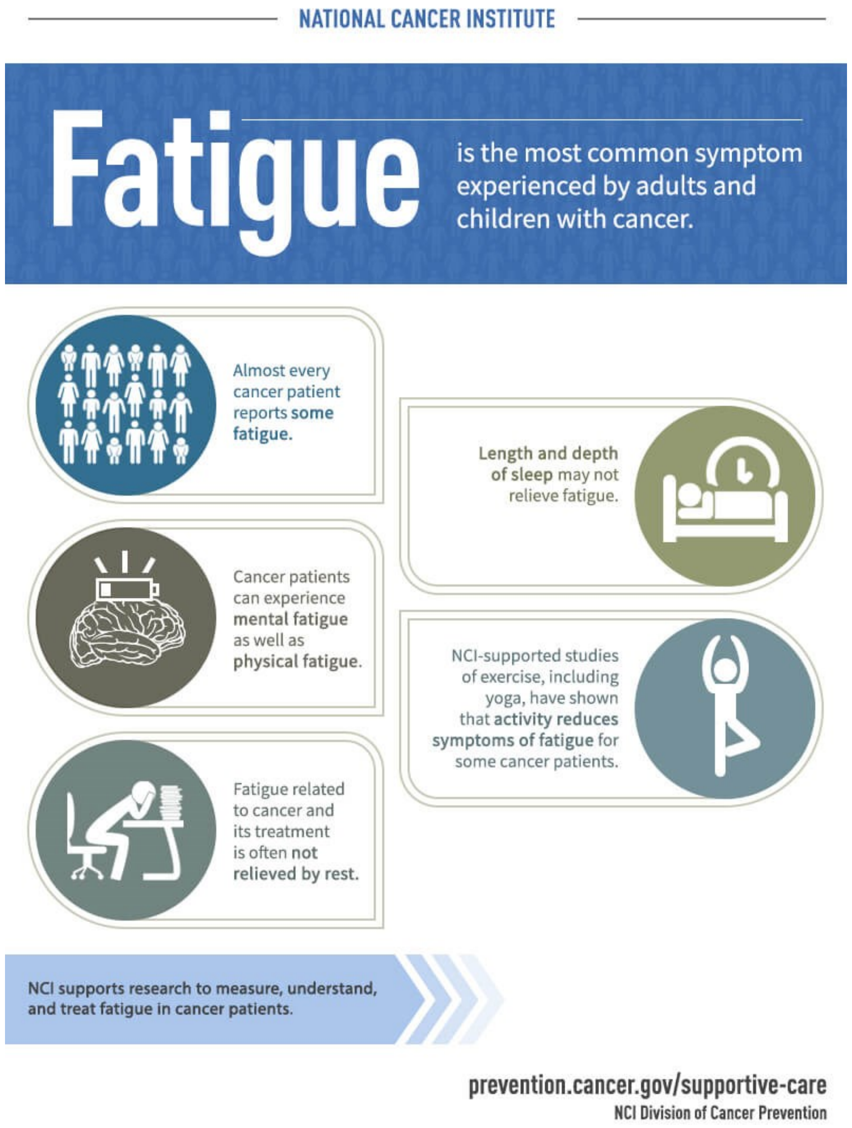


NATIONAL CANCER INSTITUTE

Fatigue

is the most common symptom experienced by adults and children with cancer.

Almost every cancer patient reports **some fatigue.**

Length and depth **of sleep** may not relieve fatigue.

Cancer patients can experience **mental fatigue** as well as **physical fatigue**.

NCI-supported studies of exercise, including yoga, have shown that **activity reduces symptoms of fatigue** for some cancer patients.

Fatigue related to cancer and its treatment is often **not relieved by rest.**

NCI supports research to measure, understand, and treat fatigue in cancer patients.

prevention.cancer.gov/supportive-care
NCI Division of Cancer Prevention

NATIONAL CANCER INSTITUTE

COGNITIVE PROBLEMS FROM CANCER AND CHEMOTHERAPY

Most often studied in women with breast cancer but seen in many types of cancer, cognitive deficits may be caused by the cancer or its treatment, including surgery and chemotherapy. Common problems affect:

- learning and retaining information
- trouble concentrating and difficulties in working memory (short-term memory)
- Impairment in executive functioning (organizational skills, problem solving)

Ongoing research includes exercise and cognitive training (brain games) to reduce cognitive deficits.

NCI supports research to measure, understand, and treat cognitive problems due to cancer.

prevention.cancer.gov/supportive-care
NCI Division of Cancer Prevention

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

ORIGINAL REPORTS | May 06, 2024

Phase III Randomized, Placebo-Controlled Clinical Trial of Donepezil for Treatment of Cognitive Impairment in Breast Cancer Survivors After Adjuvant Chemotherapy (WF-97116)

Authors: Stephen R. Rapp, PhD, Emily V. Dressler, PhD, W. Mark Brown, MA, James L. Wade III, MD, FACP, FASCO, FACCC, Nguyet Le-Lindqwister, MD, David King, MD, Kendrith M. Rowland, MD, Kathryn E. Weaver, PhD, MPH, Heidi D. Klepin, MD, Edward G. Shaw, MD, MA, and Glenn J. Lesser, MD | AUTHORS INFO & AFFILIATIONS

Publication: Journal of Clinical Oncology • Newest Articles • https://doi.org/10.1200/JCO.23.01100

Donepezil Failed To Improve Chemotherapy-Related Cognitive Impairment In Survivors Of Breast Cancer, Research Shows

MedPage Today reported, "The acetylcholinesterase inhibitor donepezil (Aricept) failed to improve chemotherapy-related cognitive impairment (CRCI) in breast cancer survivors," according to a study. Investigators found that "after 24 weeks of treatment, performance on a standardized battery of neurocognitive tests showed no significant improvement in immediate recall, the primary endpoint, compared with the placebo group." Meanwhile, "assessments performed at 12, 24, and 36 weeks showed no significant differences on any measurements of cognitive function." The findings were published in the Journal of Clinical Oncology.

Cancer.Net, ASCO's patient information website, features a guide to Breast Cancer.

NATIONAL CANCER INSTITUTE

Pain occurs frequently in patients with cancer and has many causes.

PAIN can be from **the tumor** and/OR **the treatment**.

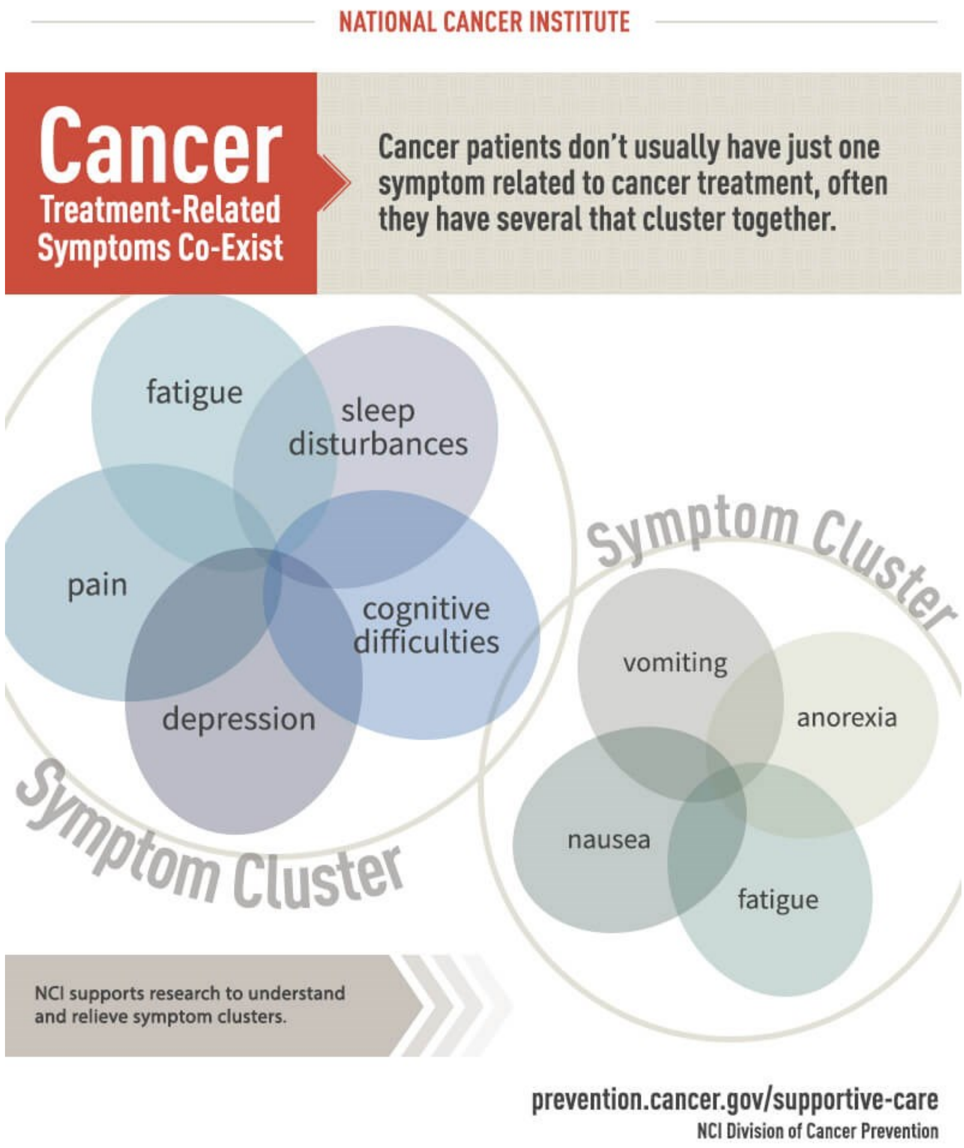
PAIN can be **acute** (short-term) or **chronic** (long-lasting).

PAIN can **continue after** successful cancer treatment ends.

Controlling **PAIN** is an **important part** of your cancer treatment plan.

NCI supports research to understand and treat all types of pain.

prevention.cancer.gov/supportive-care
NCI Division of Cancer Prevention



NATIONAL CANCER INSTITUTE

Cancer Treatment-Related Symptoms Co-Exist

Cancer patients don't usually have just one symptom related to cancer treatment, often they have several that cluster together.

NCI supports research to understand and relieve symptom clusters.

prevention.cancer.gov/supportive-care
NCI Division of Cancer Prevention

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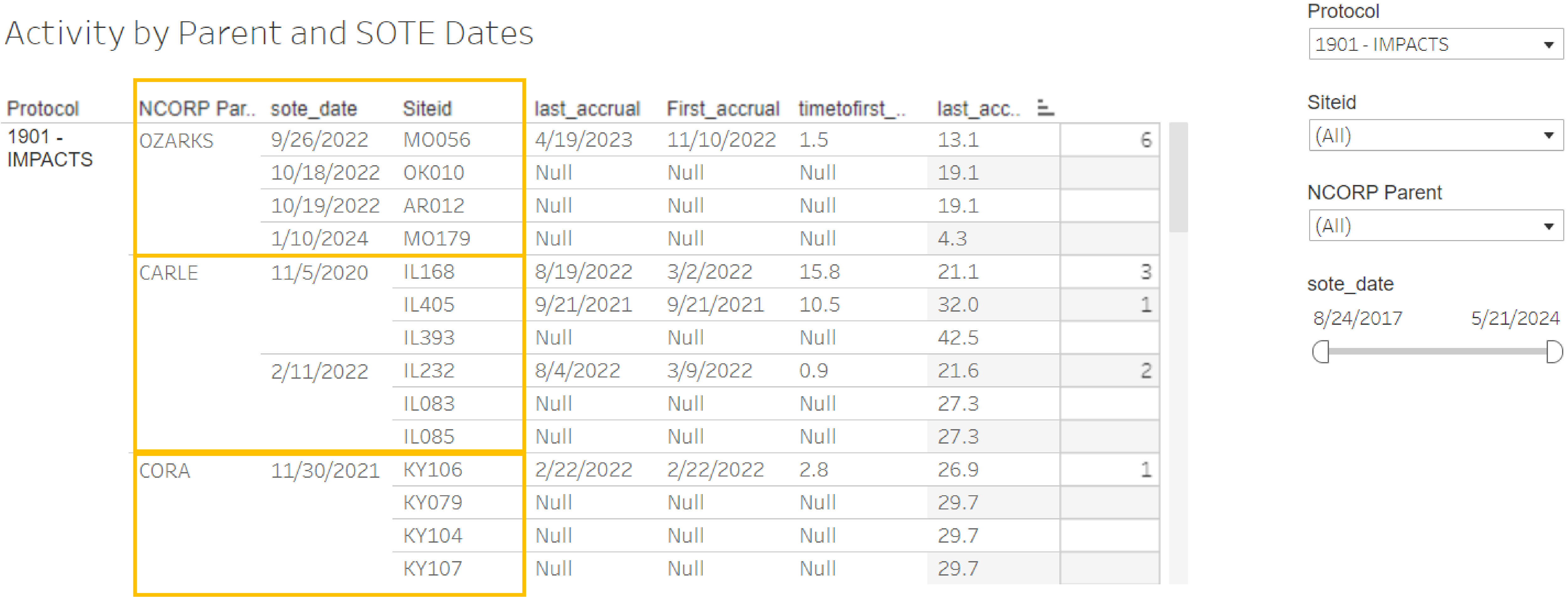
Some unique nuances about NCORP

- Sites can opt-in or out of studies
  - No guarantee of participation
- Site staff and resources screen and enroll participants
  - Resources differ between sites
- Unlike academic medical centers or NCI cancer centers, some community sites choose to open studies simply for availability to offer comprehensive options for patients

An example of site metrics

- Use Tableau (soon PowerBI) to compile accrual, demographics, and site activity across our portfolio of studies
- Allows for dynamic filtering across studies, dates, sites, etc.
- Gives a quick snapshot of activity without the need for multiple, customized reports

- Constructed a site onboarding and time to accrual table
  - Initially filtered by each individual site, and then realized they were clustered by SOTE date ("site open to enrollment")



Activity by Parent and SOTE Dates

Protocol	NCORP Par..	sote_date	Siteid	last_accrual	First_accrual	timetofirst_..	last_acc..	
1901 - IMPACTS	OZARKS	9/26/2022	MO056	4/19/2023	11/10/2022	1.5	13.1	6
		10/18/2022	OK010	Null	Null	Null	19.1	
		10/19/2022	AR012	Null	Null	Null	19.1	
		1/10/2024	MO179	Null	Null	Null	4.3	
	CARLE	11/5/2020	IL168	8/19/2022	3/2/2022	15.8	21.1	3
			IL405	9/21/2021	9/21/2021	10.5	32.0	1
			IL393	Null	Null	Null	42.5	
		2/11/2022	IL232	8/4/2022	3/9/2022	0.9	21.6	2
			IL083	Null	Null	Null	27.3	
			IL085	Null	Null	Null	27.3	
	CORA	11/30/2021	KY106	2/22/2022	2/22/2022	2.8	26.9	1
			KY079	Null	Null	Null	29.7	
			KY104	Null	Null	Null	29.7	
			KY107	Null	Null	Null	29.7	

Protocol: 1901 - IMPACTS

Siteid: (All)

NCORP Parent: (All)

sote_date: 8/24/2017 – 5/21/2024

Protocol and Design Considerations to Minimize Both Participant and Site Burden in NCI Community Oncology Research Program (NCORP) Trials

Anna C. Snavely, PhD

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Reducing Participant Burden

Engage Patient Advocates

Advocates ensure research:

- Maintains **patient-centered care**
- Addresses the most relevant clinical questions
- Will accrue expeditiously
- Will deliver appropriate value and risk/reward to the cancer community

Use patient advocates early and often during the design process!

Carefully Consider Patient Reported Outcomes

Patient reported outcomes (PROs) are critical for understanding the patient experience in clinical trials, but can be time consuming.

- Which PROs are necessary to answer the scientific question?
- How long does it take patients to answer the full battery of questionnaires proposed?
- Is a shorter version of a PRO possible?

INTERNET-DELIVERED MANAGEMENT OF PAIN
AMONG CANCER TREATMENT SURVIVORS

impacts

IMPACTS evaluates an internet-delivered pain coping skills training program.

Key outcomes are related to pain, but other outcomes are scientifically interesting as well.

- Health-related quality of life
- Fatigue
- Sleep disturbance
- Depression

- Anxiety
- ~~Positive affect~~
- Perceived cognitive problems
- ~~Cognitive performance~~

Used short forms for the remaining questionnaires

Carefully Consider Biological Samples

Biological samples (e.g., blood, tissue, saliva) may be necessary to answer important scientific questions, but the benefit must outweigh the risk and burden to the participant.

- Is the sample necessary?
- Can the sample be collected at the same time as a clinically required collection?
- Will the sample collection require an additional visit for the participant?
- Is there a specified analysis plan for the sample?

TASTE

TASTE evaluates a supplement to see if it can improve chemotherapy-induced taste and smell disturbances.

- Saliva samples are required at Baseline and 30-days as the saliva microbiome is important to understand taste.
- Blood sample required at Baseline to look at biomarkers known to be related to taste.
- Blood samples for future studies are optional at Baseline and 30-days.
- No samples are collected at 60-days to eliminate the need for an in-person visit.

Carefully Consider Participant Visits

- Does the visit need to be in-person or could everything be accomplished remotely?
  - Very important in rural settings
- If the participants are in active treatment, can trial visits overlap with clinical visits?
  - Ensure windows allow this when possible
  - Be aware of SOC for the patient population

INTERNET-DELIVERED MANAGEMENT OF PAIN
AMONG CANCER TREATMENT SURVIVORS
impacts

- Participants may or may not be on active treatment
- Remote-delivered intervention
- **All visits can be remote!**

TASTE

- Participants are on active treatment, but not on the same treatment schedule
- Baseline and 30-days in-person
- 60-day is optional and can be remote

Reducing Site Burden

Consider Centralizing Tasks

Are there aspects of the trial that can be managed or conducted centrally at the coordinating center instead of at each individual site?

- Particularly important to consider for time consuming tasks or tasks that require specialized personnel
- Helpful to engage sites early in design of centralized processes to get input

INTERNET-DELIVERED MANAGEMENT OF PAIN
AMONG CANCER TREATMENT SURVIVORS
impacts

For participants randomized to the internet-delivered pain coping skills training program:

- Usage is monitored
- Adherence calls made if needed
- Technical assistance is available

All done centrally!

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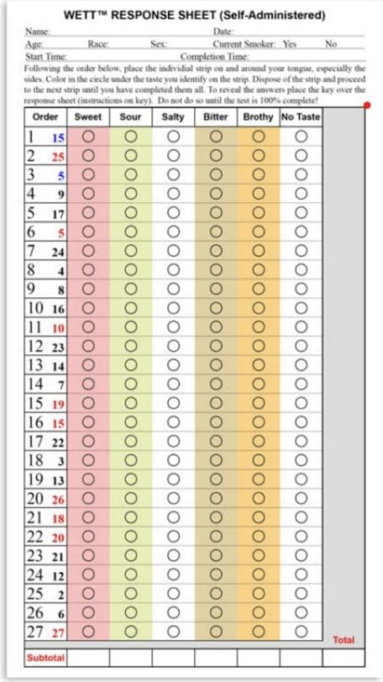
TASTE

- Objective taste and smell testing are done at Baseline and 30-days and specialized scoring is required.
- Pill count is required after 30-days to evaluate adherence.

All done centrally!

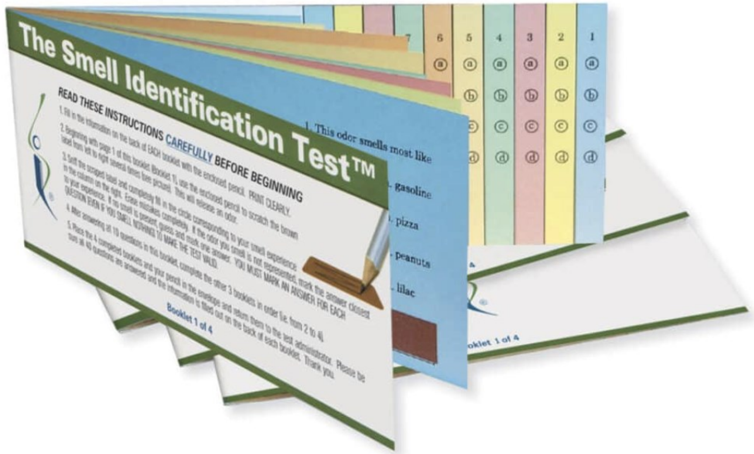


WETT™ RESPONSE SHEET (Self-Administered)

Name: Date:
Age: Race: Sex: Current Smoker: Yes No
Start Time: Completion Time:

Following the order below, place the individial strip on and around your tongue, especially the sides. Color in the circle under the taste you identify on the strip. Dispose of the strip and proceed to the next strip until you have completed them all. To reveal the answers place the key over the response sheet (instructions on key). Do not do so until the test is 100% complete!

Order	Sweet	Sour	Salty	Bitter	Brothy	No Taste	
1 15	○	○	○	○	○	○	
2 25	○	○	○	○	○	○	
3 5	○	○	○	○	○	○	
4 9	○	○	○	○	○	○	
5 17	○	○	○	○	○	○	
6 5	○	○	○	○	○	○	
7 24	○	○	○	○	○	○	
8 4	○	○	○	○	○	○	
9 8	○	○	○	○	○	○	
10 16	○	○	○	○	○	○	
11 10	○	○	○	○	○	○	
12 23	○	○	○	○	○	○	
13 14	○	○	○	○	○	○	
14 7	○	○	○	○	○	○	
15 19	○	○	○	○	○	○	
16 15	○	○	○	○	○	○	
17 22	○	○	○	○	○	○	
18 3	○	○	○	○	○	○	
19 13	○	○	○	○	○	○	
20 26	○	○	○	○	○	○	
21 18	○	○	○	○	○	○	
22 20	○	○	○	○	○	○	
23 21	○	○	○	○	○	○	
24 12	○	○	○	○	○	○	
25 2	○	○	○	○	○	○	
26 6	○	○	○	○	○	○	
27 27	○	○	○	○	○	○	Total
Subtotal							



Consider Flexibility for Site

All sites are different and it is unlikely that the trial will be operationalized the same way at each site. Allowing flexibility enables more sites to participate and enroll effectively.

- Allow questionnaire delivery via email before visit, in clinic on tablet or own device, or by paper if needed.
- Build in reasonable windows for assessments

Flexibility, Standardization and Engagement

Julie C. Turner, MS

Protocol Development Program Manager

Flexibility within Studies

WHY? *"If you have seen one NCORP Community Site; you have seen one NCORP Community Site."*

Community Clinic

Academic Medical Center

Two Key Areas:

- *Eligibility Criteria*
- *Consent Process*

Flexibility During Protocol Development

Eligibility Criteria

Why?: Different catchment populations and local treatment protocols

Example: Rare or difficult to treat cancers may not be abundant in community settings. (Leukemia)

Example: Imaging can take longer in community settings. (14 vs 21 days MRI pre-treatment)

Flexibility During Protocol Development

Eligibility Criteria

How to ensure flexibility?

- Have your sites review for understandability and practicality.

Example: Clarify what therapies are allowed in your eligibility criteria.

> *"…..actively receiving platinum- or taxane-based anticancer drug therapy. Hormonal therapies, immunotherapies, and/or targeted therapies are allowable, in conjunction with the platinum- or taxane-base chemotherapeutic agents. There are no restrictions on the amount or types of prior therapies received."*

Eligibility not documented in the EHR can be problematic. (Example: pain)

Flexibility During Protocol Development

Consent Process

Why? *Research regulations are different at each site.*

“Be vague, but specific.”

Flexibility will….

- lessen site burden
- makes studies more appealing
- allow for different consenting abilities (*i.e.,* Docusign, phone etc.)

How? *Waivers (when possible, under IRB regulations)*

- Waiver of documentation (signature not required) - remote consenting
- Waiver of consent for screening questions – less burden for sites upfront

Dictating step by step the consent process in the protocol can “tie the site’s hands”.

Standardization Across Study Operations

Standardization Across Study Operations

Who?

Research Base membership for our sites

What?

Start-up, database, forms, document language, etc.

Where?

Research Base website, central network website, central email address, etc.

Standardization Across Study Operations

Why?

Reduce site burden & encourage site participate

How?

Engagement of sites for valuable feedback

Engagement of Potential Sites

Engagement of Potential Sites

"Engage your sites early"

Why? They are the "boots on the ground" and have valuable feedback.

How? Early introduction to concepts/ideas

Examples:

- Present concepts/ideas at annual meetings for feedback to the study team.
- Invite site to be members of Scientific and Health Equity Committees
    - Review concepts/ideas and provide scientific feedback
    - Discuss translation to broaden diversity early in the development process

Engagement of Potential Sites

How? Review of draft protocols

Example:

Have staff and providers review the draft protocol and provide extremely valuable feedback

How? “Market” the studies

Example:

- Webinars, newsletters, bi-weekly emails, quarterly calls, word of mouth, etc.
- Start-up materials to facilitate engagement at sites

Reducing Site Burden

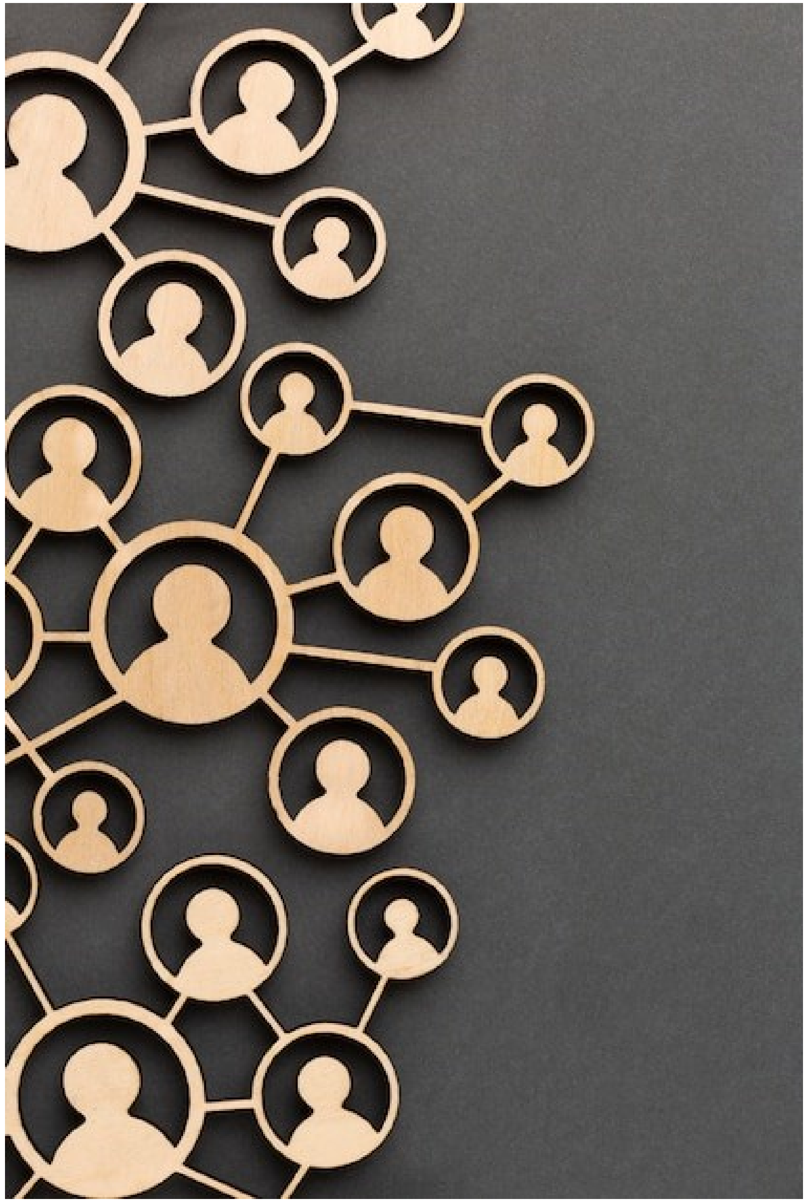
Tonya Henighan, MPH

Wake Forest NCORP RB Site Coordinator

Streamline Study Start-up

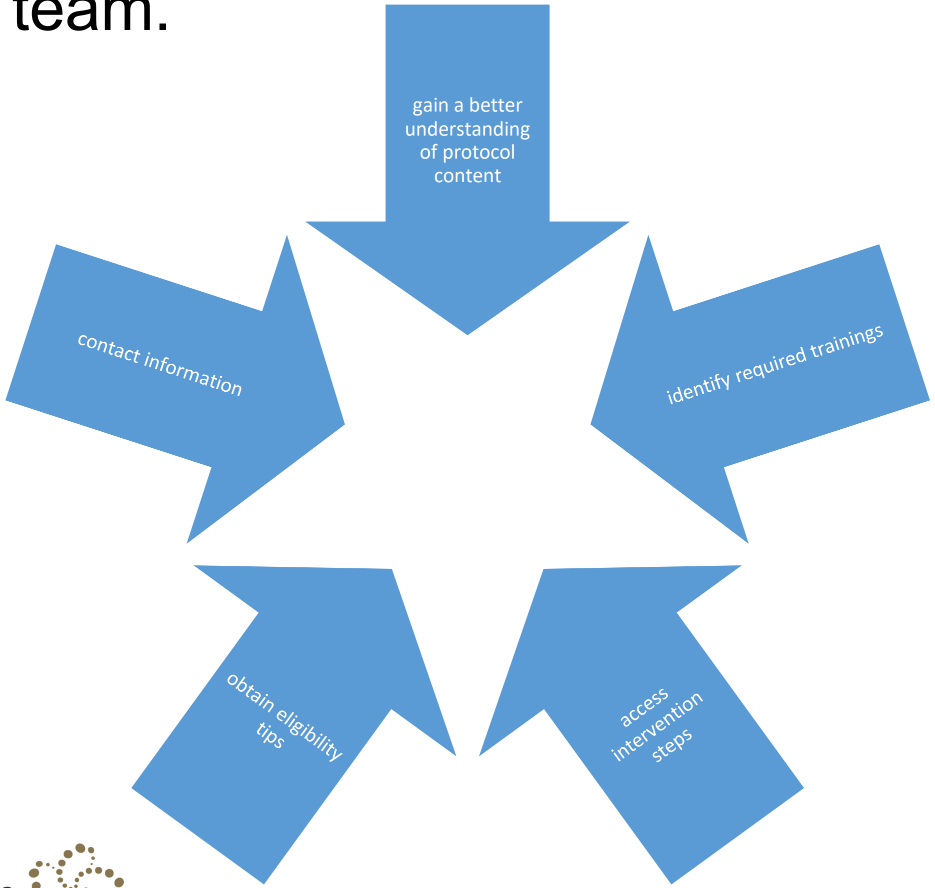
"Reduce Site Start-up Burden"

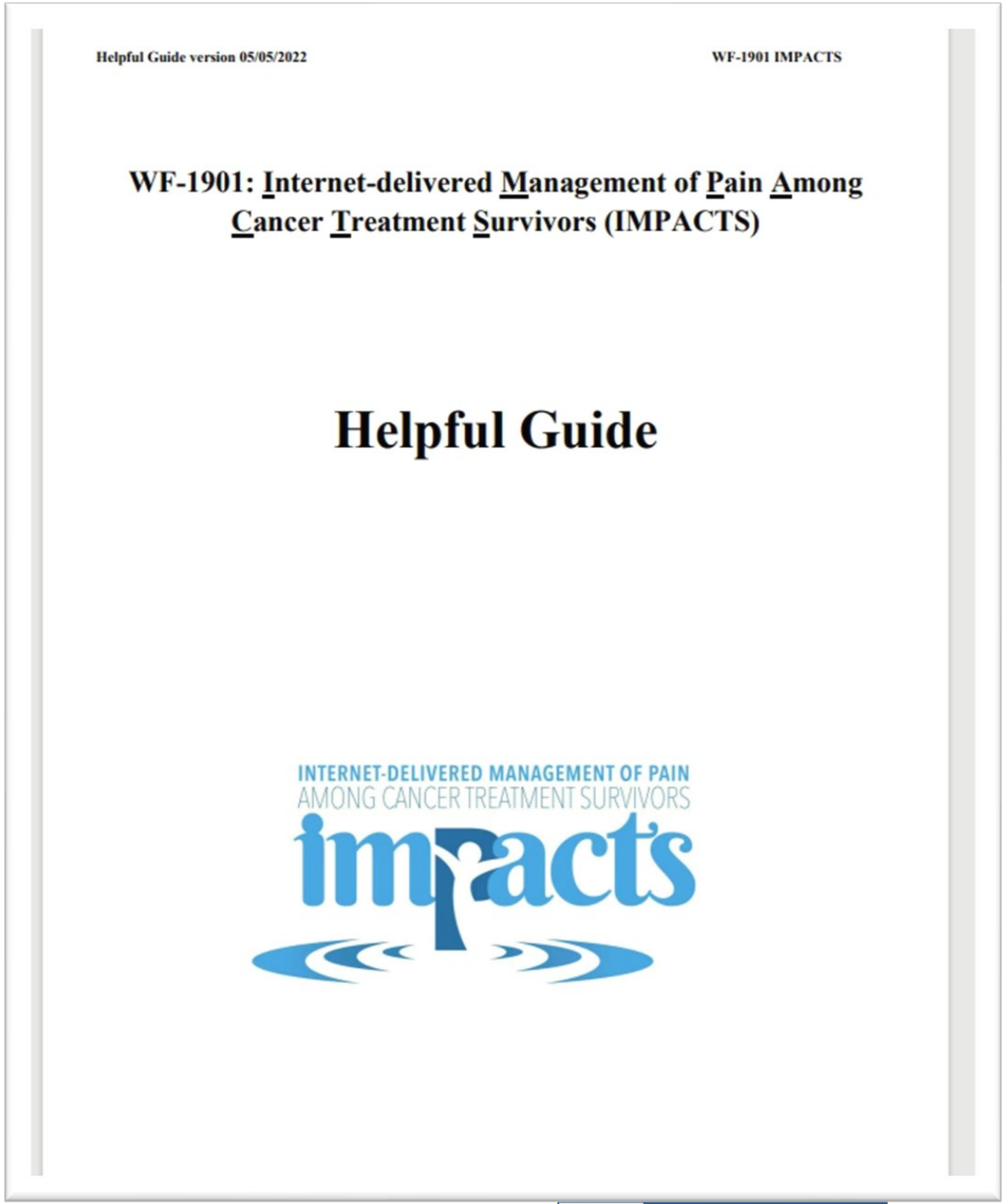
- Standard Start-up Materials
- Brief PowerPoint for sites to present to get study approvals
- Background, scheme, eligibility, schedule of events
- Invitation for a Site Initiation "Visit" (virtual planning session)
  - Walk through study and discuss specific clinic flow
  - Review patient recruitment, screening and enrollment
  - Review questions about data capture
  - Complete study specific trainings
  - Checklist listing all start-up requirements (training, supplies, etc)



Helpful Guides One Stop Shop!

Documents created specifically for each study, that provides detailed guidance to the study team.




Helpful Guide version 05/05/2022 WF-1901 IMPACTS

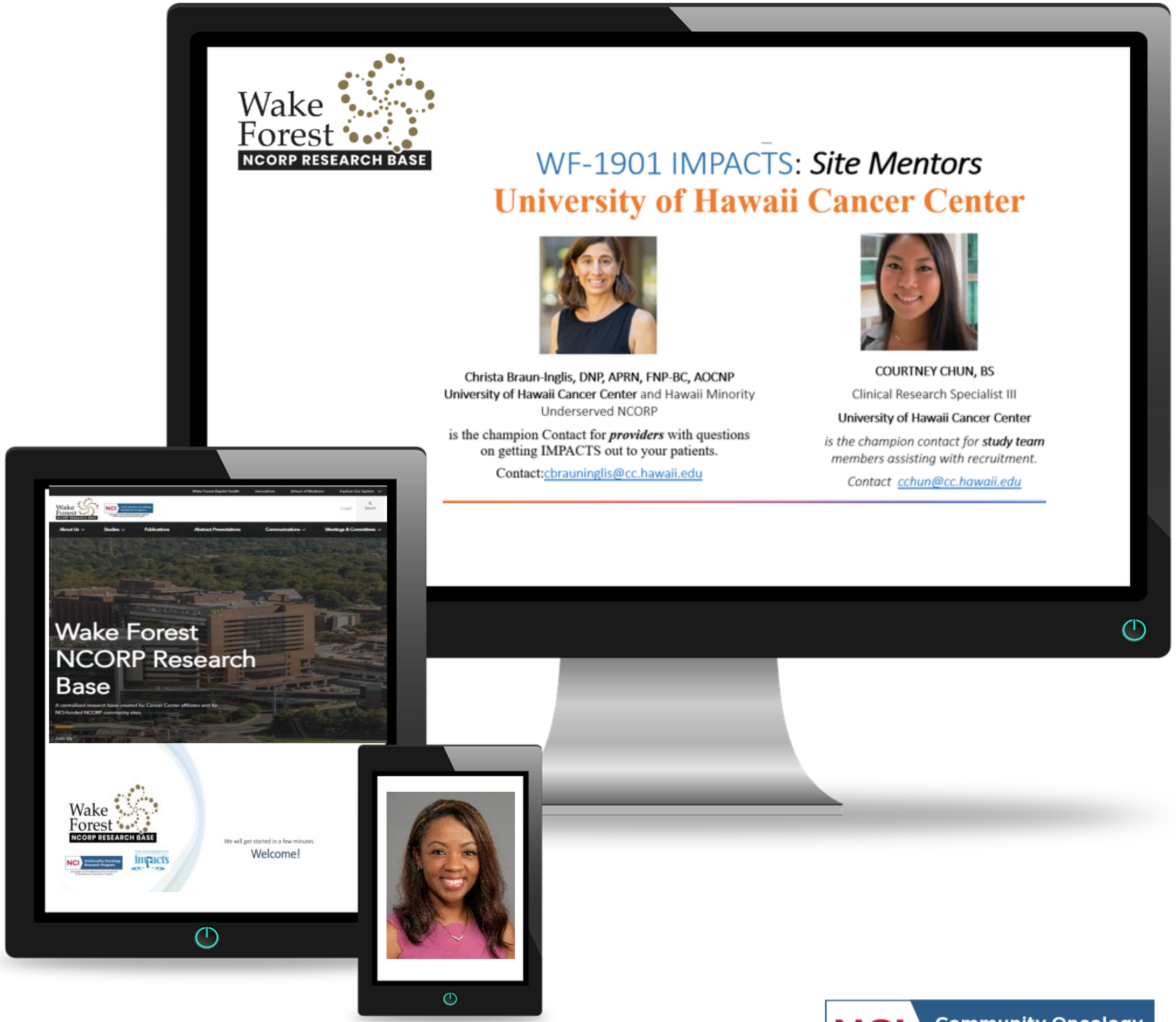
WF-1901: Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)

Helpful Guide

INTERNET-DELIVERED MANAGEMENT OF PAIN
AMONG CANCER TREATMENT SURVIVORS
impacts

Training: Examples

- Webinars
- Study specific trainings- *as needed*
- Site Calls- *bi-monthly*
- Mentorships between sites to help with recruitment-*ongoing*



WF-1901 IMPACTS: *Site Mentors*

University of Hawaii Cancer Center

Christa Braun-Inglis, DNP, APRN, FNP-BC, AOCNP
University of Hawaii Cancer Center and Hawaii Minority Underserved NCORP

is the champion Contact for ***providers*** with questions on getting IMPACTS out to your patients.

Contact:cbrauninglis@cc.hawaii.edu

COURTNEY CHUN, BS
Clinical Research Specialist III
University of Hawaii Cancer Center

*is the champion contact for **study team** members assisting with recruitment.*

Contact cchun@cc.hawaii.edu

Wake Forest NCORP Research Base

A centralized research base created for Cancer Center affiliates and for NCI-funded NCORP community sites.

We will get started in a few minutes.

Welcome!

Future Trainings

CTSU Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

- Will be moving newer trainings to CTSU-CLASS where attendees can do training on their own time and receive a certificate immediately for completion.

- All site staff with a CTEP id can access CLASS with the same user and password as the other CTSU services. Also we offer refresher video conferences by request to assist sites with new employee who will be helping with the study.

Site Resources

- Recruitment Tools:
  - Brochures, flyers, site specific QR codes, patient engagement videos

To learn more about an option for managing cancer-related pain, please contact us!

[Insert contact information]

Did you know?
Pain is one of the most common symptoms experienced by people with cancer, and it can be very challenging for patients to manage.

Participant Testimonials

"When I told [my family] I was going through this program, they said that's amazing because we see a change. It's like they were just standing at the door waiting for me to walk through it. But if I was feeling so badly, that feeling was so bad as I was acting out, they didn't want to bother me. So that's why they were happy..."
(Man with Multiple Myeloma and neuropathy)

"I felt that being able to make my life livable right now was really a gift from you guys... I just felt that the whole thing was excellent. I really liked it."
(Woman with metastatic breast cancer)

"I feel like now I've got a host of tools besides the bottle of pills to deal with the pain... that aren't dependent on a location or a supply of pills. So, it's nothing but extra [tools]... You know, for that reason alone [it] was worth my time."
(Woman with breast cancer)

Impacts

Are you experiencing persistent pain related to cancer or cancer treatment?

Is your pain interfering with your quality of life?

What is the IMPACTS Study?

IMPACTS stands for "Internet-delivered Management of Pain Among Cancer Treatment Survivors"

This study is a clinical trial to test whether an internet-based pain coping skills training program can reduce the burden of pain among people with stable cancer or people who have completed treatment for cancer.

What are the benefits of being in the IMPACTS Study?

- All participants will receive information about coping skills to help manage pain.
- Participants may experience a decrease in the severity of their pain.
- Participants may experience improvements in their quality of life.

Do I Qualify?

You may be able to participate in this study if:

- You have pain or discomfort that is affecting your quality of life
- Your pain is related to cancer and/or cancer treatment (the pain began with, or got worse, after your cancer diagnosis and/or treatment)
- You currently are receiving treatment for cancer that is considered stable/controlled OR it has been less than 5 years since you completed cancer treatment
- You are at least 18 years old
- You are able to speak and read English
- You have access to a working email address

*Anyone with any type of cancer may be eligible for this study and you do not have to change any of your medications.

What is it like to be in the IMPACTS study?

If you are eligible and agree to participate, you will randomly be put into one of two groups:

- Group One will receive educational materials for cancer pain and control while continuing their usual care with their typical care provider(s).
- Group Two will receive the same educational materials mentioned above and will be given access to an online program that teaches pain coping skills once a week for 8-10 weeks.

At the end of the study, participants who were randomly put in Group One will be given access to the same online pain coping skills program as Group Two.

Choosing to be in this study includes 4 visits and lasts 34 weeks.

- All visits can be done remotely by telephone or video visit.
- You will be asked to complete and return a medication diary at each visit.
- At the end of the study, you may be asked to complete an optional telephone interview about your experience and feedback about the study.
- If you are placed in the internet-based coping skills study group, a study team member will show you how to use the program. If you do not have reliable access to the internet, you may be provided with a study tablet at no cost to you. You will be asked to return this tablet when you have completed the program.
- You will receive compensation for each of the completed visits, medication diaries and optional interviews.

Do you have pain related to your cancer or cancer treatment?

We are conducting this study to see if an internet-based pain coping skills training program helps adult cancer survivors to better manage the consequences of persistent cancer-related pain and to improve the quality of their lives. The **Internet-delivered Management of Pain Among Cancer Treatment Survivors (IMPACTS)** study allows us to learn about two different pain management programs for cancer survivors who have pain. If you qualify to participate and decide to take part in this study, you will be assigned to either an internet-based pain management program or will receive pain management education materials to use while following your usual care plan for pain. Both groups will complete in-person and remote visits and complete surveys at the beginning of the study and at 10 weeks, and will complete surveys again (either in-person or online) after 22 and 34 weeks.

You may be eligible for this study if you:

- Are a cancer survivor over age 18 that experiences pain from cancer or cancer treatment on most days of the week
- Are willing to participate in pain management and answer questions about your experience
- The pain you have experienced has interfered with your quality of life or your ability to engage in and/or enjoy activities

For more information on this study, please contact:
Site Name or Coordinator Name
Telephone No.
Website or Email Address, if applicable

impacts
Site or Clinic Logo (optional)

Do you experience physical or emotional pain related to your cancer or cancer treatment?

- ✓ Pain* is one of the most common symptoms in cancer patients and one of the symptoms least likely to be adequately treated.
  *Unpleasant sensory and emotional experience that may include either physical pain and/or non-painful discomfort such as aching, throbbing, numbness, tingling, burning, etc.
- ✓ **The IMPACTS Study** - *Internet-delivered Management of Pain Among Cancer Treatment Survivors*, is designed to help you manage your pain so you can enjoy your quality of life.
- ✓ Cancer patients 18 or older who experience pain from cancer or cancer treatment are invited to discuss possible participation in the **IMPACTS** study.
- ✓ Compensation for your time will be provided. In-person and remote visits are available!

Based on your response below, you may be eligible to take part in the IMPACTS Study.

Scan QR code with your phone's camera to access a short survey.	Insert Site Specific QR Code here

impacts

Site Resources-
Provided by Wake Forest NCORP Research Base

- Supplies *Tablets, lab kits*
- Tablet Lending Program-As a part of some research study, some participants will need regular and reliable access to the internet.
- Gift Card Distribution-*sent to participants electronically*
- Link to Database and any instructions

Site Resources- *Refresher Trainings*

- Refresher trainings can be provided upon request to support sites with new employees who will be assisting with the study. Additionally, if sites are experiencing slow accrual, guidance can be offered to help improve the process.

- Conference calls can provide a platform for open discussion, allowing sites to address challenges and barriers and help us find ways to improve assistance to sites.

Communication

- Standardized communication process for all studies
- Central email address
- Dedicated research base study site coordinator
    - Back up coordinator

Strategies for Recruiting Spanish Speaking Populations and Community Informed Research

Mariana Rodriguez-Pardy, MPH, CHI™

Wake Forest NCORP Research Base Project Manager

Wake Forest NCORP RESEARCH BASE

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

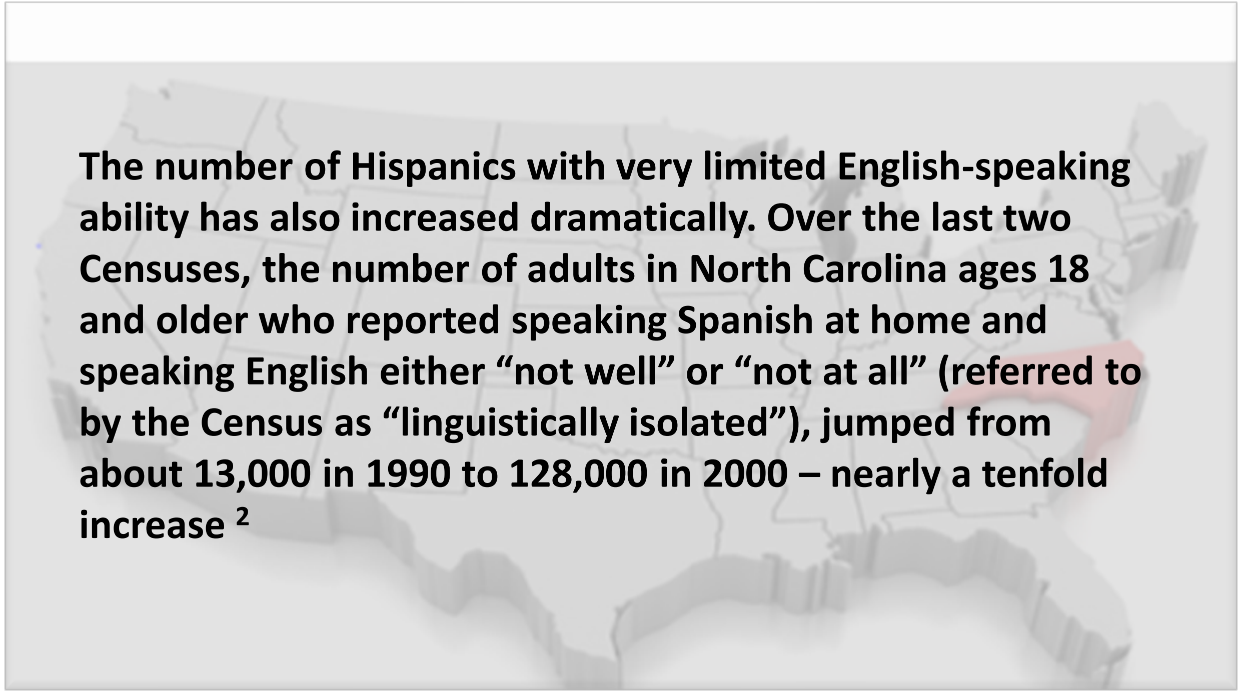
Demographic Background

63.7 million

The Hispanic/Latino/a/e/x population of the United States as of July 1, 2022, making it the nation's **largest racial or ethnic minority** — 19.1% of the total population.

2022 US Census Bureau

North Carolina's Hispanic population is now greater than **one million people**[1]



The number of Hispanics with very limited English-speaking ability has also increased dramatically. Over the last two Censuses, the number of adults in North Carolina ages 18 and older who reported speaking Spanish at home and speaking English either "not well" or "not at all" (referred to by the Census as "linguistically isolated"), jumped from about 13,000 in 1990 to 128,000 in 2000 – nearly a tenfold increase [2]

Barriers to Minority Participation in Research

- **Socially determined** disparities: Transportation, childcare, lower SES, limited educational attainment
- **Mistrust**
- Lack of information about research and clinical trial awareness
- Time and resource constrains
- **Language barriers**

For researchers:

- **Lack of knowledge about the cultural differences among ethnic minorities &**
- **Ineffective communication strategies and inadequate linguistically and culturally appropriate material**

Language and Cultural Considerations

Language Considerations

- Spanish uses more words vs English
- Gender specific terminology
- Formal vs informal forms (Tu vs Usted)
- More than one way to say the same word, depending on country or region

Cultural Considerations

- Hispanics/Latino/a/e/x -> Heterogenous group -> united by language
- Lack of culturally tailored material:
- Images representing Hispanics (no such thing as Hispanic looking)
- Role of family and spirituality

Language Adaptations

Interpreting (oral form) uses clarification and substitutions

Translation (written form)

Recontextualization

- Localization (changing specific elements so they match target audience: dates, currencies, addresses, weight)
- Transcreation (creative translation-adapting a message while maintaining intent, style, tone, context)

Cultural Brokering (delivered by someone from that culture or accepted by that culture)

- Language concordant research staff
- Community engagement approach
- Targeting specific populations/people with lived experience

Why is cultural brokering important?

- Reflects a humble approach and cultural sensitivity
- Helps build trust
- Helps avoid cultural shock
- Humor-> is different depending on culture
- It is inclusive
- Relevant to community needs

A Culturally Appropriate, Non-opioid, Pain Coping Skills Training Intervention for Spanish-speaking Hispanic/Latino/a/e/x Patients with Cancer Pain

Administrative Supplement to the WF NCORP RB IMPACTS trial

NIH HEAL INITIATIVE

NCI Community Oncology Research Program
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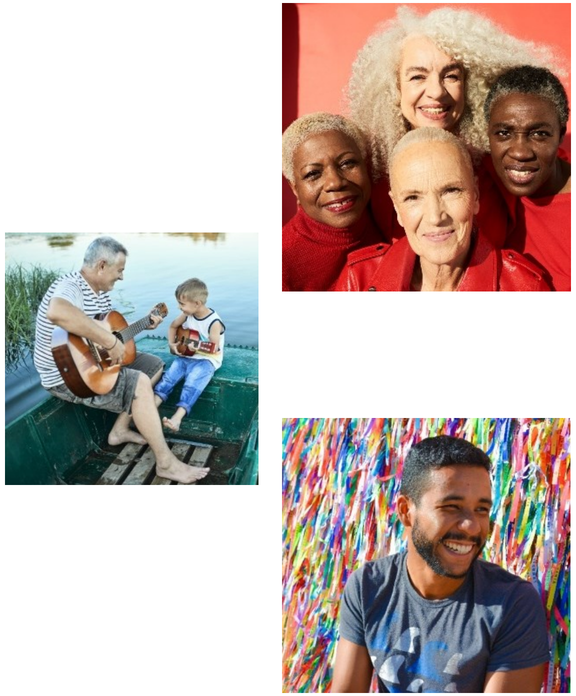
Study co-PI Team: Dr. Donald B. Penzien (WFSOM) Dr. Megan Irby (Wake Forest University) **Co-Investigators:** Dr. Glenn Lesser (WFSOM) Dr. Chris Rini (Northwestern University) Dr. Francis Keefe (Duke University) Dr. Kathy Ramos (Duke University)

Address an unmet but growing need for cancer-related pain management services among historically and traditionally marginalized populations: Spanish-speaking Hispanic/Latino/a/e/x patients.

Enhance inclusion, recruitment, and retention of primarily Spanish-speaking Hispanic and Latinx patients via community-engaged methodologies and a health-equity relevant design.



- Community Engaged Approach
- Linguistic Translation & Cultural Adaptation
- Trust Building
- Equitable Collaborations & Sustainable Partnerships

Wake Forest NCORP RESEARCH BASE

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Background

- Cancer-related pain is a significant adverse effect of cancer and cancer treatment, which poses significant management challenges for patients.

- Compared to non-Hispanic whites, Spanish-speaking Hispanic patients routinely experience disparities in cancer-related care that negatively impact quality of life, including more significant barriers in accessing quality care, less adequate pain management, and later-stage cancer diagnosis and treatment initiation.

- Limited English proficiency is a particularly difficult barrier among primarily Spanish-speaking Hispanic patients, as communication challenges with providers contributes to poorer pain outcomes and suboptimal pain management.

painTRAINER®

painTRAINER en Español

What is painTRAINER?

PainTRAINER is an online program based on scientific research, developed by Drs. F. Keefe and C. Rini. PainTRAINER is a cognitive behavioral therapy-based program led by a virtual coach. Patients can freely access and engage in a highly personalized, interactive PCST without the need for a therapist.

Duke University School of Medicine

Northwestern University Feinberg School of Medicine

The program includes 8 weekly 45-minute modules led by a virtual coach who guides patients as they develop, practice and master coping skills and strategies to help people manage their pain.

Internet-Delivered Management of Pain Among Cancer Treatment Survivors

impacts

Support Spanish-speaking populations and strive towards more equitable care, our group is leveraging our prior work in Pain Coping Skills Training (PCST) through the cultural and linguistic adaptation of an online PCST program, painTRAINER.

This evidence-based program, delivered online over eight weeks, facilitates development of pain coping skills to improve pain outcomes while also reducing reliance on opioids for pain management.

Relevant, Engaging, Accessible, and Sustainable:

- Addresses numerous barriers to clinical care
- Enhances opportunities for therapeutic participation
- Engage in treatment when/where they want
- Accessible technology regardless of computer literacy

Wake Forest NCORP Research Base

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Scientific Study Team & Community Advisors

Translation Development Leadership Team (TDLT) -> Academic study team (Study PIs, bilingual project manager, research associates trained in community engagement and bilingual consultants from partnering institutions)

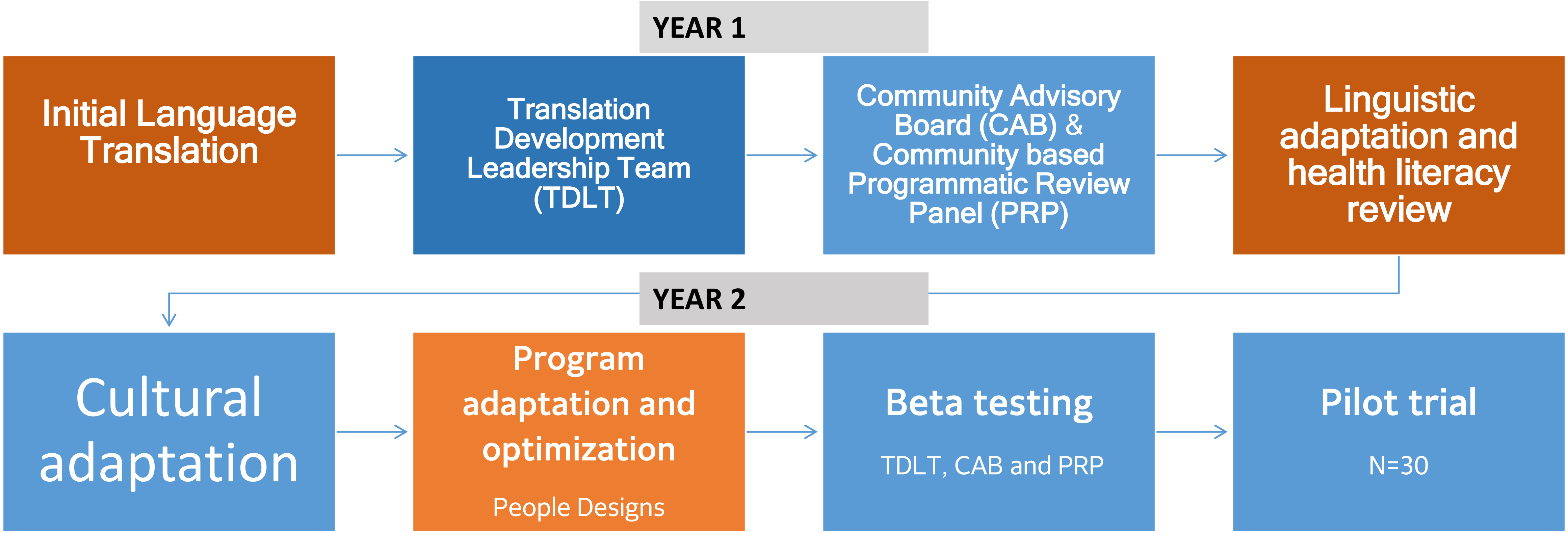
Community Advisory Board (CAB) -> Diverse group of H/L community members and leaders of local community organizations.

- Ensure that research activities address community needs
- Perspectives of the patients and community members are being reflected
- Facilitates transparent and bidirectional communication between the community and the academic study team

Programmatic Review Board (PRP) -> H/L community representatives, people with lived experience, bilingual patient advocates, certified health care interpreters and translators.

- Reviewed translated materials for potentially difficult terms and health literacy
- Made recommendations for culturally relevant substitutions including leisure activities, colors, images and accents
- Active participation (casting for character images and voice overs)
- Helped with recruitment efforts

Study Overview



YEAR 1

Initial Language Translation

Translation Development Leadership Team (TDLT)

Community Advisory Board (CAB) & Community based Programmatic Review Panel (PRP)

Linguistic adaptation and health literacy review

YEAR 2

Cultural adaptation

Program adaptation and optimization

People Designs

Beta testing

TDLT, CAB and PRP

Pilot trial

N=30

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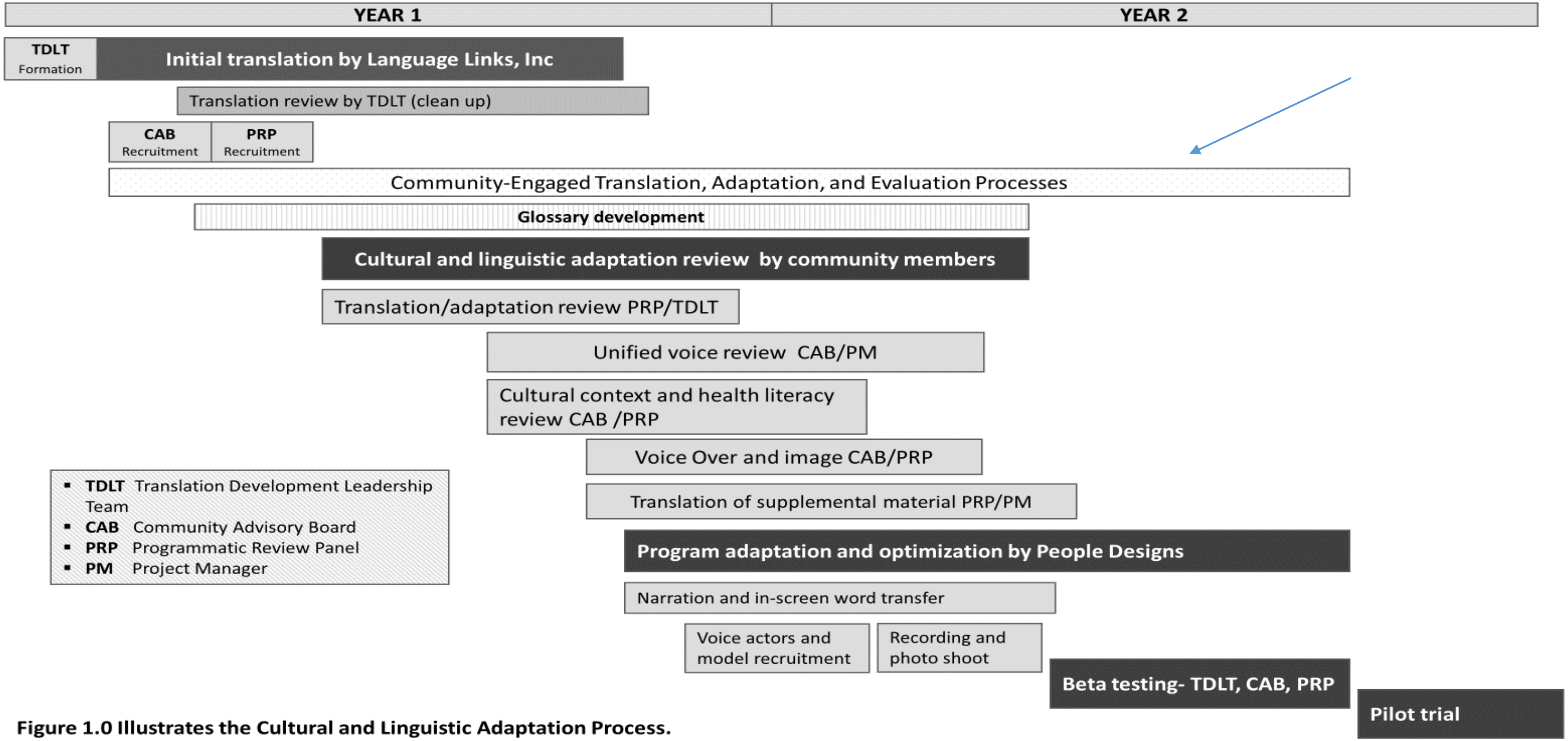
Cultural and Linguistic Adaptation Process



YEAR 1

YEAR 2

TDLT Formation

Initial translation by Language Links, Inc

Translation review by TDLT (clean up)

CAB Recruitment

PRP Recruitment

Community-Engaged Translation, Adaptation, and Evaluation Processes

Glossary development

Cultural and linguistic adaptation review by community members

Translation/adaptation review PRP/TDLT

Unified voice review CAB/PM

Cultural context and health literacy review CAB /PRP

Voice Over and image CAB/PRP

Translation of supplemental material PRP/PM

Program adaptation and optimization by People Designs

Narration and in-screen word transfer

Voice actors and model recruitment

Recording and photo shoot

Beta testing- TDLT, CAB, PRP

Pilot trial

- **TDLT** Translation Development Leadership Team
- **CAB** Community Advisory Board
- **PRP** Programmatic Review Panel
- **PM** Project Manager

Figure 1.0 Illustrates the Cultural and Linguistic Adaptation Process.

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Program Adaptation and Optimization

People Designs incorporated all translated text and CAB/PRP recommendations into painTRAINER-SP.

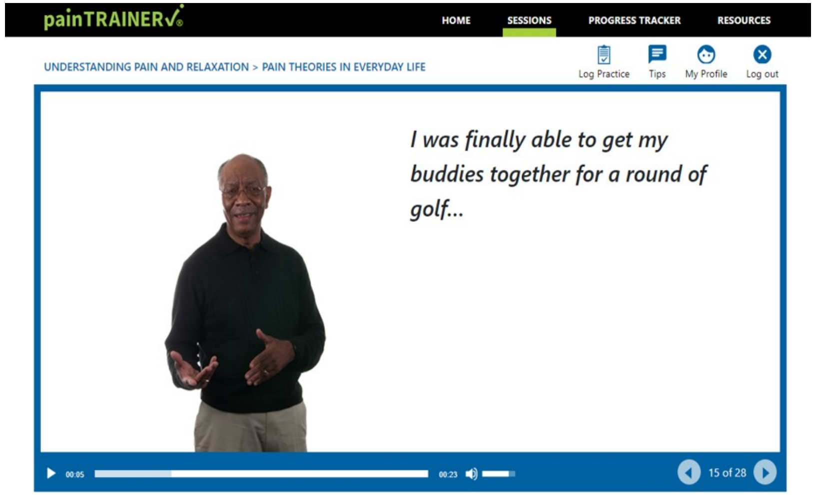
- Bilingual computer programming experts and software engineers.
- Spanish-speaking voice actors were vetted by community advisors and academic teams to ensure voices and accents are suitable.

Integration of new characters and modified visual content that reflects diverse H/L cultures

Beta testing was conducted under various conditions (devices, Internet platforms, users) drawn from the CAB, PRP, academic study team, and affiliated volunteers.

Substitutions

painTRAINER en Español



UNDERSTANDING PAIN AND RELAXATION > PAIN THEORIES IN EVERYDAY LIFE

I was finally able to get my buddies together for a round of golf...

BENEFICIOS DE LAS ACTIVIDADES PLACENTERAS

Si pudiera volver a salir a caminar hasta el parque sentiría que he logrado algo importante.

LA TEORÍA DE LA COMPUERTA EN TU VIDA

Imagina los PENSAMIENTOS que podrías tener.

ENTENDIENDO EL DOLOR Y LA RELAJACIÓN > TEORÍAS DEL DOLOR EN LA VIDA COTIDIANA

Finalmente pude reunir a mis amigos para un partido de fútbol

Rini, C., Keefe, F. (2020) [PainTrainer][Photograph]. painTRAINER. https://www.mypaintrainer.org

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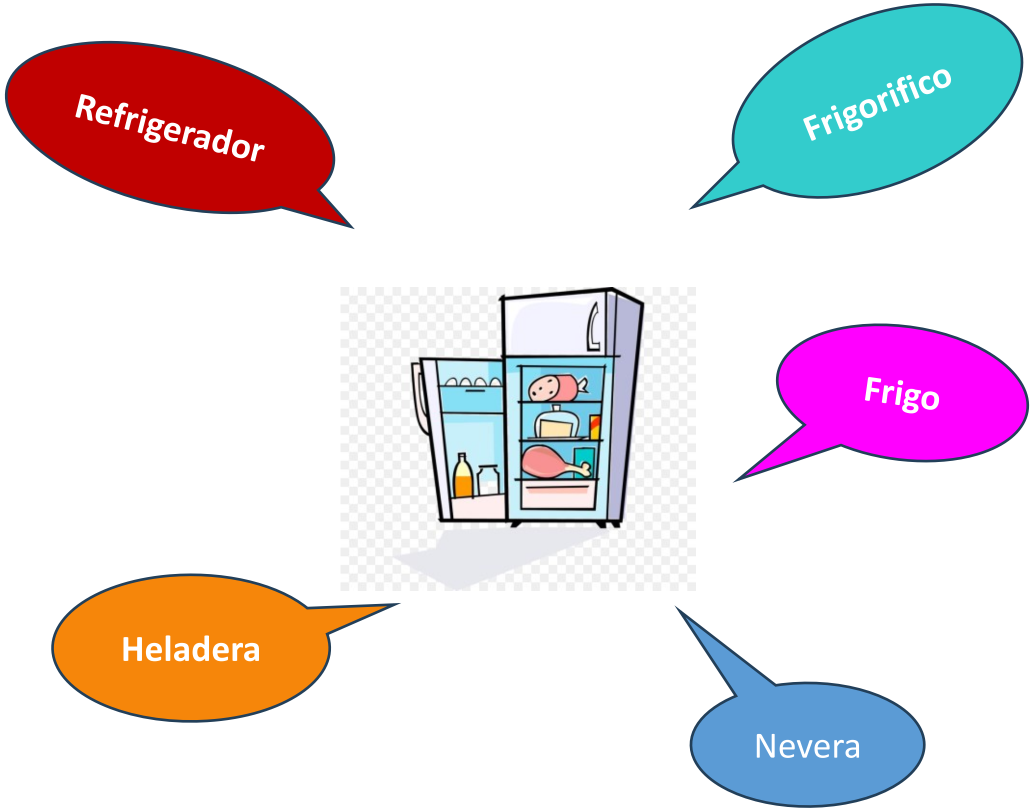
Navigating Challenges

How to maintain a neutral and unified voice?

- Non gender specific words
- Diverse community advisory board
- Use of glossary from beginning to end
- Use of translation software/tools to keep consistency (Trados)
- Translation reviews (extra step as if it had been written in Spanish)



Recruitment Strategies

Pilot Study
N=30 in 3 months

- Culturally and linguistically **concordant research staff and/or Cultural Brokers**
- Literal translation is not enough -> **linguistic and cultural adaptation**
- Provide **culturally tailored** recruitment and educational **material** and **culturally relevant** examples
- Use Hispanic Media outlets
- Look for preferred ways to **communicate**
- Meet patients where they are, go to events, **get involved**
- Option to consent **remotely or in person**

Authentic Partnerships

”I feel very honored to be part of a team that elected to come together and use their knowledge, energy and resources in a project that provides Spanish speakers not just in our community, but anywhere in the world, the opportunity to relieve their pain in a natural, safe and cost-free way.”

MR (Colombia, CAB)

“It was a great experience. We worked very hard to find out the best way of using the multiple expressions from all of our diverse Latin American Countries in order to achieve a pleasant understandable and useful translation. Thank you. “

Dr. L Melendez (Venezuela, PRP)

“My experience as a collaborator in the development of the program to learn how to manage pain was very motivating. As a person living with chronic pain, I know the need that exists among the Latino community to have a program in Spanish with an easy, everyday language, understandable for all the different Latin American groups.

I think it will be very useful for anyone who is willing to learn strategies for managing pain without the use of opioid medications.”

L M (Mexico, PRP)

“I loved that (the program) tackles the language barrier. It also has a cultural component that I think is very important plus, you can fit it in your schedule as it is very flexible. In general, I think it is very (culturally) appropriate and diverse.”

Pilot study participant (Puerto Rico)

Conclusion: What can we do as Researchers?

Study design ->if you are planning to include minority participation and non-English speakers, include it in your protocol and grant application.

Do not let it be an afterthought…

Budget ahead of time:

- Translating/interpreting services
- Bilingual staff
- Trainings
- Development culturally relevant material (including SWAG)

Calculate **timelines and deadlines** (transcreations can be more time consuming)

- Consider hiring **language concordant staff** member and/or work with **healthcare interpreters** and **bilingual** patient navigators, partner with community liaisons (In some cases consider **cultural brokers** when working with a specific target community)

Building Trust

- **Partner with community** (Faith and community-based organizations, Hispanic media, survivorship and interest groups, etc)
- Community advisors and study participants = **partners in research**
- Start **building bridges** before recruitment & create long lasting relationships for **sustainability.**
- Maintain a **culturally humble approach ->** Respect
- Maintain **transparency** and **bidirectional** communication
- **Disseminate results** with the community, research partners and study participants (in a culturally and health literacy appropriate manner) AND **request feedback** to guide future projects

Panel Discussion and Q&A