UNIVERSITY OF HAWAI'I

CANCER CENTER

The Expanding Role of the APP in Cancer Clinical Research: It's About Time!!

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A Cancer Center Designated by the National Cancer Institute

Objectives

1) Review new NCI guidelines expanding APP involvement in research
2) Examine different roles APPs can contribute in clinical research
3) Discuss opportunities for oncology APPs to grow professionally in research
4) Identify barriers and facilitators to participating in clinical research within your practice/institution

Background

- Oncology Advanced Practice Providers (APPs) are highly trained health care providers that contribute significantly to quality cancer care.
- The number of Oncology APPs in clinical practice has grown significantly over last 10 years
- >80% of practice report employing APPs in 2017 ASCO survey
- Given low clinical trial enrollment, increased and focused utilization of APPs could enhance accrual and improve conduct of clinical trials
- Benchmarking data is lacking

Methods

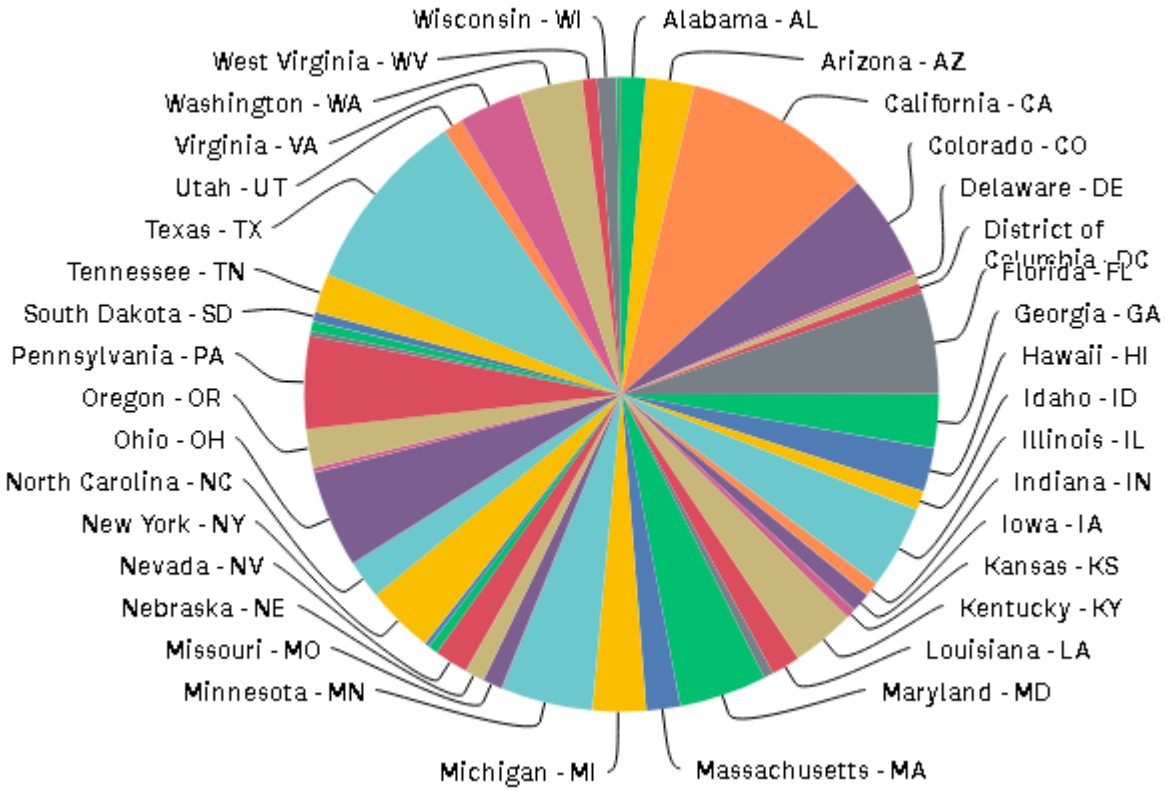
- University of Hawaii Cancer Center, Association of Community Cancer Centers (ACCC) and Harborside developed and disseminated 65-item survey of attitudes, beliefs and roles of oncology APPs in clinical research
  - Survey validated in 2 prior pilots
- Distributed in early 2020
- The survey was administered and data were analyzed using Survey Monkey

Braun-Inglis,, et al. (2022). Role of oncology advanced practitioners to enhance clinical research. *Journal of the Advanced Practitioner in Oncology, 13*(2), 107-119.

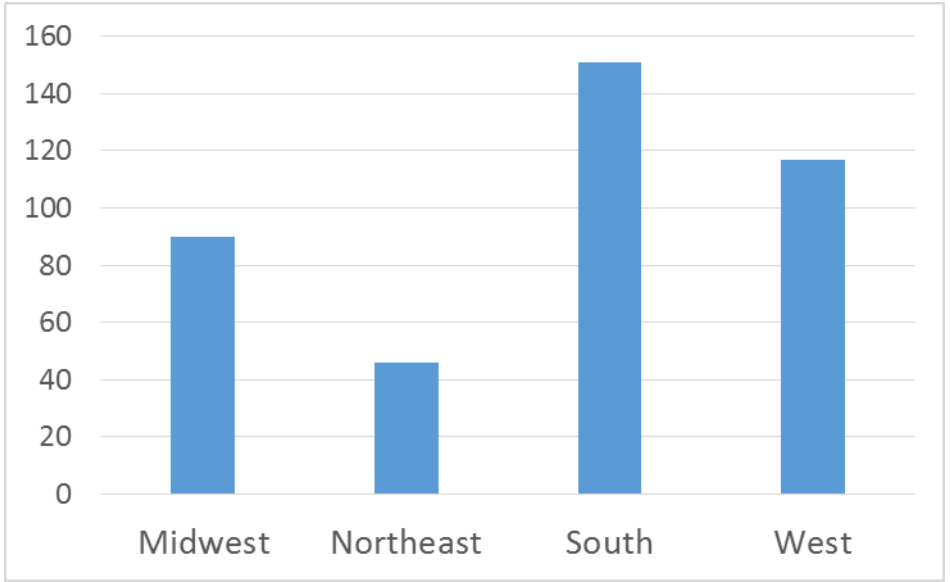
Results: Demographics

- 408 responses

State



Region



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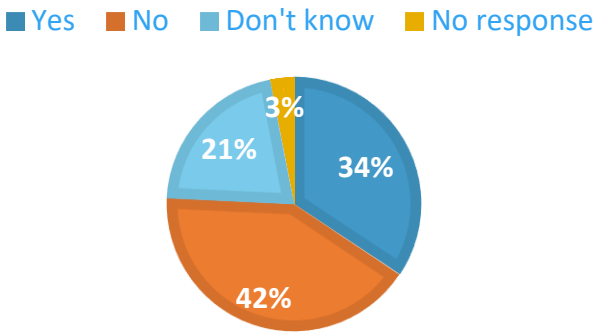
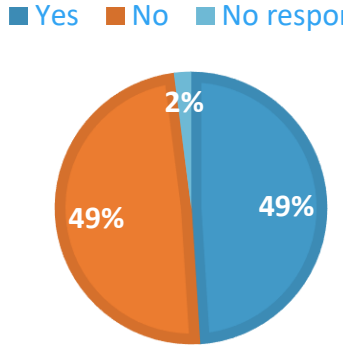
Results: APP Roles in Clinical Research-Investigator

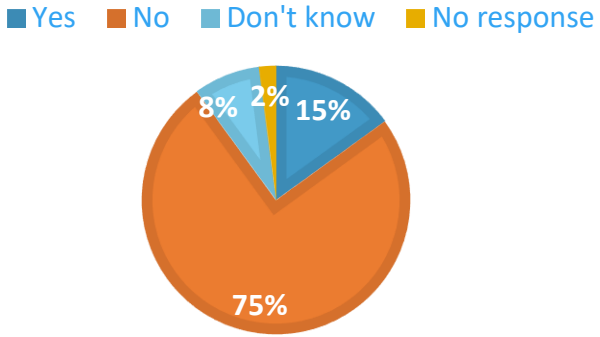
REGISTERED WITH NCI AS NPIVR



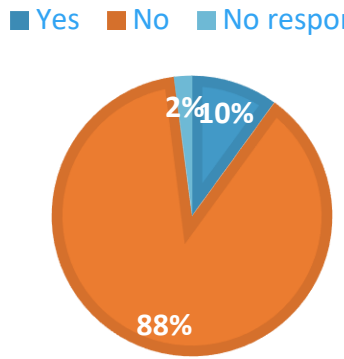
SUB-INVESTIGATOR AT PRACTICE SITE



ENROLLING INVESTIGATOR



PRIMARY INVESTIGATOR



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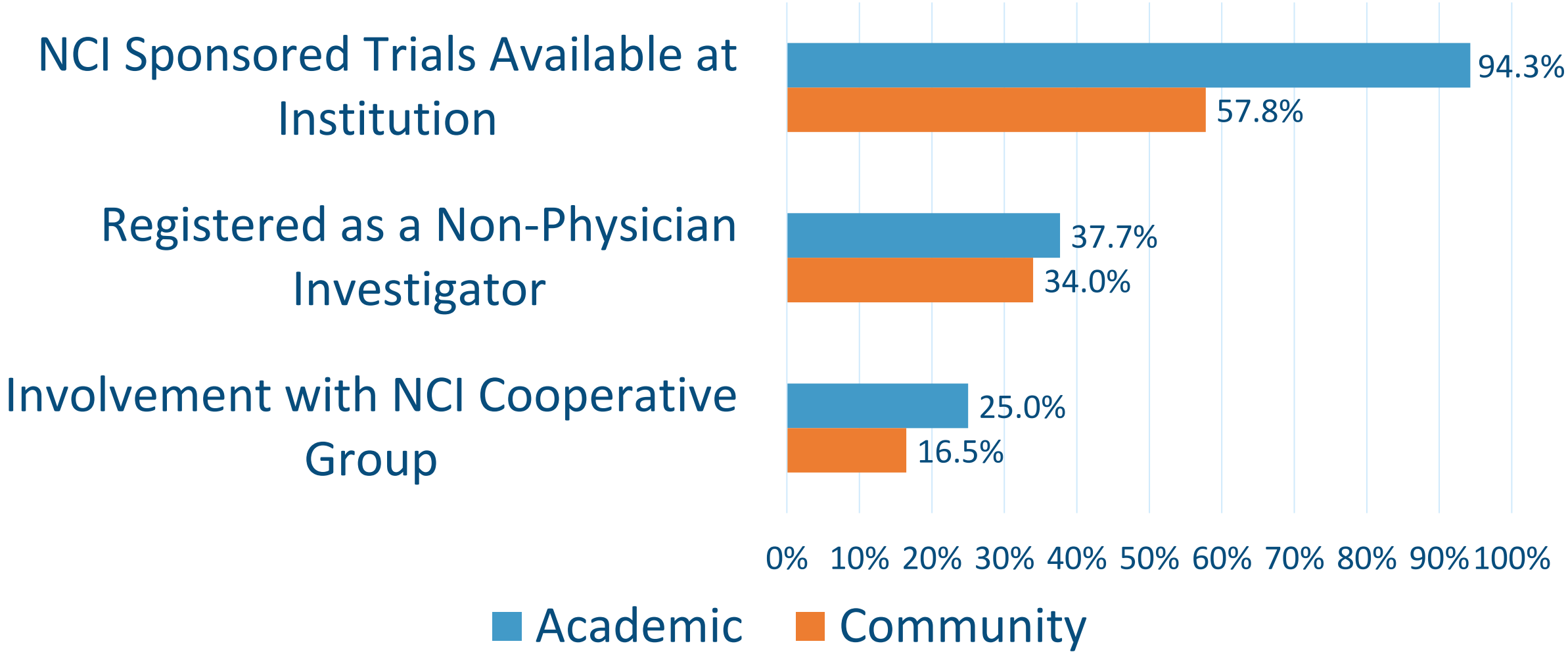
APP involvement in NCI Research Bases



NCI CTEP Updated Policy on APPs Writing Orders

Before Sept. 7th 2021:

CTEP's Investigator Handbook (2014 version 1.2) states:

In Section: 14.2 Writing a Patient-specific Orders

Patient-specific orders for study agents should be written by NCI-registered investigators participating on the specific trial. If other licensed prescribers write orders, the registered physician investigator who is officially participating on the trial must cosign the order.

On Sept. 7th 2021 and going forward:

Patient orders for study agents, including IND agents and standard of care agents, may be written by qualified APPs without a physician cosignature.

Qualified APPs must be registered in NCI's Registration and Credentialing Roster (RCR) as Non-Physician Investigators (NPIVRs) and be added to site Delegation of Tasks Logs (DTLs) to the task of "**IND Prescribing**", where required. Site Clinical Investigators (CIs) must sign the DTL for the qualified NPIVR to conduct this new task.

- Must maintain active registration status in RCR as an NPIVR and renew registration and qualifications annually.

NCI CTEP Updated Policy on APPs Writing Orders

Qualified APPs may include:

- ✓Nurse Practitioners,
- ✓Physician Assistants,
- ✓Clinical Nurse Specialists,
- ✓Advanced Degree Nurses, and
- ✓Pharmacists

➢ who are licensed and qualified per institutional policy, local and state laws and regulations including requirements as mandated for international sites.

Definition from the Advanced Practitioner Society for Hematology and Oncology (APSHO) www.apsho.org

NCI trials covered under this policy include those in the DCP NCORP program and the ETCTN, NCTN, and other DCTD and CTEP-sponsored networks, consortia and studies.

APP Policy Implementation at Clinical Trial Sites

Sites must have an institution policy that qualifies APPs, including:

- Credentialing processes for APPs to write study agent orders that are consistent with their local and state laws and regulations including requirements as mandated for international sites.
- Statement that a qualified physician investigator is responsible for all trial-related medical decisions, including providing oversight of APPs in their capacity of writing study agent orders (GCP requirement).
- Institution policies can be stored in the site's regulatory files and be available for review.

Sites will need to ensure that APPs qualified to write study agent orders as NPIVRs are registered in NCI's RCR and renew and maintain their registration and qualifications annually. RCR verifies professional licenses, including APPs, during the annual registration process.

Site CIs will identify APPs qualified to write study agent orders on site DTLs, where required. Site DTL Administrators or CI will need to add the "IND Prescribing" task for the NPIVR and the CI must sign this task.

CTEP Policy Posted on the CTEP Investigator's Handbook Website

https://ctep.cancer.gov/investigatorResources/investigators_handbook.htm

NCI DCP/DCCPS APP Guideline

NCORP protocols funded by NCI DCP and DCCPS

- ✓ APPs with PhD, DNP, PharmD or Master's* will be qualified to:
  a. serve as chairs (PhD only),
  b. serve as co-chairs (PhD, DNP, PharmD, or Master's* level)
  c. serve as a local investigator to consent and enroll patients
  d. prescribe/write orders

- ✓ Must be actively rostered as NPIVR in RCR
- ✓ Added to DTL if applicable (i.e., consenting, writing orders, etc.)
- ✓ Writing orders – same policy as CTEP

* Masters level co-chair requirements: prior clinical trial research experience within NCTN/NCORP preferred; experience in the conduct of research as PI, Co-I, or Research Coordinator for investigator initiated, pharmaceutically sponsored, or quality assurance/improvement projects

Initially released 10/14/20; Revised 9/15/2021

Post Guideline Implementation Metrics

- More than 1000 APPs registered as non-physician investigators (NPIVRs)
- 800 patients were enrolled by APPs to NCI sponsored supportive care and cancer care delivery trials
- 418 sites implemented the policy to allow APPs to sign orders for investigational (IND) agents and 860 NPIVRs were approved for the IND prescribing task

Updated APP Policy: Implementation Data By Protocol Sponsor

Category	October 4, 2021	March 9, 2022
Protocols with IND prescribing task on DTL	78	125
NCTN	**68**	**85**
Alliance	19	26
COG	6	6
ECOG-ACRIN	14	15
NRG	14	17
SWOG (includes LUNGMAP sub-protocols)	15	21
NCORP	**0**	**2**
Alliance	0	2
ETCTN	**9**	**25**
Other NCI Network/Program	**1**	**13**

Updated APP Policy: Implementation Data Site Approval

Category	October 4, 2021	March 9, 2022
Sites approved NPIVRs (APPs) for IND prescribing task on DTL	92	326
NCTN Protocols	**84**	**308**
NCTN LAPS Grantee Sites	15	55
NCORP Grantee Sites	52	162
NCTN Rostered Sites	17	91
NCORP Protocols	**0**	**43**
ETCTN Protocols	**11**	**32**
Other NCI Network/Program Protocols	**2**	**12**

NCORP & Non-NCORP Enrollments by NPIVRs (APPs) to NCORP Trials*

**NCI DCP/DCCPS Guideline permitting APPs to enroll participants to NCORP trials/studies released 10/14/20*

	8/1/19 – 7/31/20	8/1/20 – 7/31/21	8/1/21 – 2/28/22**
NCORP Clinical Trials			
NCORP Enrollments	0	458	342 *(annualized = 586)*
Non-NCORP Enrollments	0	12	18 *(annualized = 31)*
NCORP CCDR Studies	0	2	84 *(annualized = 144)*
Total	0	472	426 *(annualized = 761)*

** Reflects 7-months

NCORP data retrieved from NCORP-SYS 3/23/22
Non-NCORP data retrieved from CTSU RSS 3/29/22

Role of the APP in Clinical Trials

Methods/Approach/Workflow

APPs can add value to clinical research team in all aspects of trials

- Accrual
- Conduct
- Review
- Leadership

Collaborative vs Research

Collaborative

- Not always expected part of role
- OAP and MD work together to identify patients and provide care for them on clinical trial as part of routine practice
- OAP needs to be knowledgeable about specific trials available for patients

Research

- Expected part of role
- Primary provider for patient on research protocol
  - Experts in clinical trial conduct
- Pharmacist specific to research protocols
- Typically knowledgeable about different protocols available for patients

Accrual

Accrual: New patients

- APP reviews new consults with clinical research coordinator (CRC) weekly
- MD introduces potential trials at consult
- APP follow-ups potential participant at treatment counseling visit

Accrual: Existing patients

- MD & APP keep up to date on available trials, keep as a problem in the progress note, discuss upcoming trial opportunities with patients on regular basis

Accrual

- Consent/Enrollment
  - APPs primarily serve as sub-investigators on treatment trials and can assist with the consent and enrolling of the participant on to this trial
  - Educate patients about research medication and potential adverse events
  - APs can serve as a key asset to both the physician investigator and the research team checking:
    - Eligibility criteria
    - Ensuring all labs, scans and other baseline information is current and appropriate
    - Can assist to make sure initial orders are in and ready to be signed by physician and investigator or AP depending trial sponsor and institutional policy
  - Serve as a resource for the clinical research coordinator

Patterson & Barber, 2020, Clinical Journal of Oncology Nursing, 24(5), 479–481.
& Welch et al., 2017, *Journal of the Advanced Practitioner in Oncology*, *8*(6):631-636

Conduct

Collaborative

- Workflow same for patients on trial and not on trial
- MD/APP work collaboratively to care for patients
- Protocol patients easier for APP to follow as protocol serves as guideline for care
- APP also serves as resource for CRC, assisting with coordination and ordering protocol specific labs, imaging, appointments

Research

- APP primary provider (if APP) for patients on clinical
- APP also serves as resource for CRC, assisting with coordination and ordering protocol specific labs, imaging, appointments

Conduct

- APP's provide the majority of continuing care for cancer patients, especially treatment patients
- Grade and attribute AE's
- Manage side effects
- Tumor measurements: RECIST
- Manage dose reductions and/or dose changes
- APP involvement in protocol conduct enhances patient-focused, safe and reliable practice that ensures compliance with regulatory requirements.

Review-Collaborative and Research

Treatment Trials

- Reviews trial for scientific merit & feasibility
- Assess appropriateness of trial for patient population
- Identify protocol specific barriers and facilitators

Cancer control, supportive care and health services research

- Reviews trial for scientific merit & feasibility
- Assess appropriateness of trial for patient population
- Works with clinic staff & CCDR coordinator for successful workflow integration for implementation trials
- Identify any protocol specific barriers and facilitators

Leadership-Collaborative and Research

Treatment trials

- Serves as PI
- Serves as sub-investigator

Symptom management and health services research

- Serves as PI
- Serves as enrolling investigator
- Site champion
- Pharmacist can potentially serve in all these roles

Integrating APPs across Hawaii M/U NCORP Network

Registered oncology APPs in Hawaii as NPIVR through the NCI Registration and Credential Repository.

- Sub-investigators
- Enrolling investigators
- Site PIs on cancer control, symptom management and CCDR trials
- Review cancer control, symptom management and CCDR trial for scientific integrity and feasibility
- Voting members of the Community Research Advisory Board
- Serve on UHCC regulatory and compliance committees

APP in Clinical Research Beyond the Investigator

- Clinical trial development
- Dissemination of clinical trial results
- Protocol implementation
- Other (e.g. institutional research committee-IRB)

Clinical Trial Development

- APPs can play key roles in the development of clinical trials
- APPs may play important roles in protocol development, beyond investigator, such as being on a study team for the protocol
- APPs have knowledge about patient populations, safety profiles of medications and clinic functions and can provide key input during protocol development
- APPs clinical knowledge uniquely positions them give valuable contributions when a trial is being developed

Braun-Inglis , et al. J Adv Pract Oncol. 2:107-119, 2022, Code of Federal Regulations (2022), 312.53 & 812.43

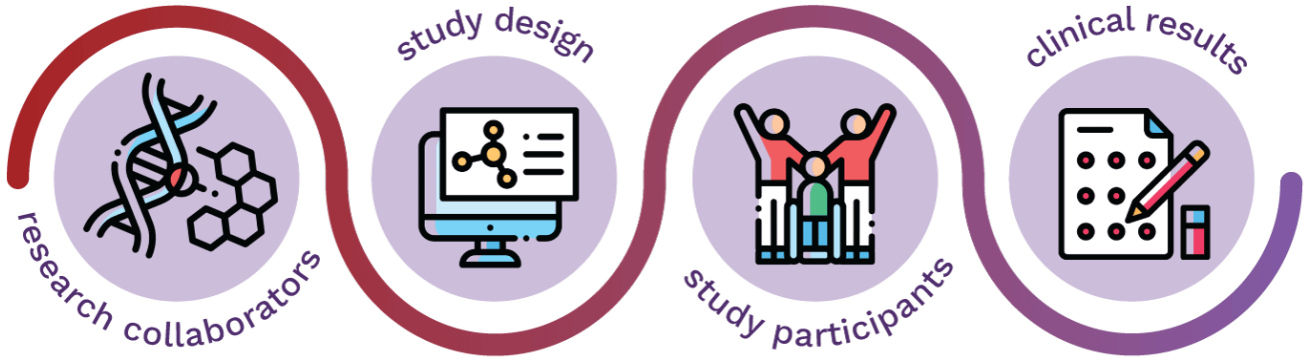
Dissemination of clinical trial results

- It is important for APPs be familiar with current data to provide quality patient care
  - APPs need to be familiar with current data and rationale behind current treatment decisions
  - APPs need to be knowledgeable about clinical trial results and be able to share them with their patients and discuss them with their colleagues

Braun-Inglis , et al. J Adv Pract Oncol. 2:107-119, 2022, Welch et al., J Adv Pract Oncol *8*(6):631-636, 2017

Protocol Implementation/Execution

- Education of staff
- Assuring adequate resources to conduct protocol
- Members of Data Safety Monitoring Boards
- Participate in Clinical Trial Audits



Other Valued Roles of APPs in Clinical Trials

- Research committees
  - institution or even at the national level
- Institutional review board (IRB).
  - APs have the clinical knowledge and are strong patient advocates therefore can add value to IRBs.

Braun-Inglis , et al. , 2022, J Adv Pract Oncol. 2:107-119, 2022, Welch et al., J Adv Pract Oncol *8*(6):631-636, 2017

APP Involvement within NCI Research Bases

- Needs a PI champion
- Support from physicians and cancer center for involvement
- Consistent travel support is essential
- Active engagement in committees rather than passive participant
- Increased leadership role enhances engagement
- Cooperative group work increases credibility of role with patients
- Role of APP in cooperative groups is still being defined
- APPs, opportunities for project work: QI, EBP, implementation science, cancer care delivery

Increasing Involvement of APPs in NCI Research Bases

- Opportunity for clinical research training- formally and informally
- Education of physicians, APPs, and practice leadership about the importance and need for involvement in clinical research
- Cancer centers must provide academic support time
- Primary Investigators at centers must engage APPs in cooperative groups and champion for their support
- Research bases should create committees or task forces specific to APP role
- APPs are essential providers for symptom control trials and increasing accrual
- APP review of protocol at development is additive

Barriers/Facilitators to Research Participation

Barriers:

- Clinic time
- Lack of education
- Primary role expectation
- Lack of financial Support
- Lack of protected time

Barriers/Facilitators to Research Participation

Facilitators:

- Physician champion
- Understanding of APP value in clinical research
- Education
- Interest in professional growth
- We are in the era of DEI!
- Become a study champion

Where Do We Go From Here?

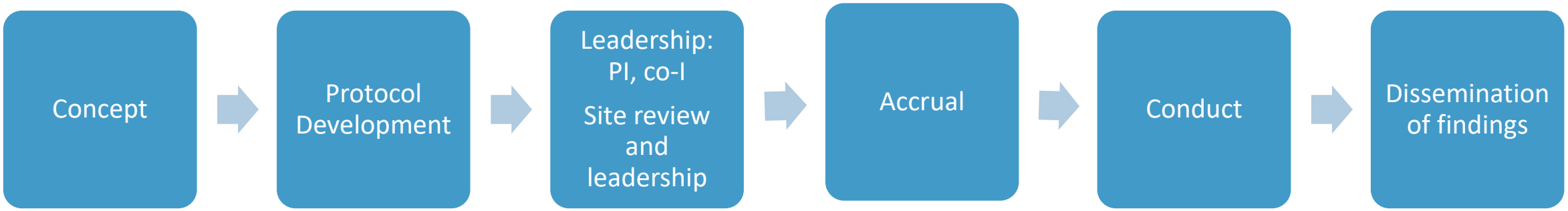
APP Education Initiative

- Targeted workshop in conjunction with the SWOG Fall meeting

APP Integration

- Task force formation: Will be accepting applications following the workshop this Fall

APPs can positively impact clinical trials on all levels



Upcoming APP Workshop!

SAVE THE DATE!

Advanced Practice Provider Clinical Research Workshop

A special session of the
SWOG Cancer Research Network fall group meeting

Sponsored by the SWOG nursing research subcommittee and the palliative and end of life care committee; funded by The Hope Foundation for Cancer Research

Wednesday, October 19, 2022, 9am-12pm CT
Hyatt Regency, Chicago, IL and virtually

This hybrid event will focus on the essentials for advanced practice providers to provide safe care to patients on clinical trials and enhance their involvement with NCI-based research.

3 hours of CME devoted to the nuts and bolts of participating in NCI-sponsored trials at your practice site and beyond!

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MAHALO!

Questions?

NCI Cancer Center

A Cancer Center Designated by the National Cancer Institute

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