



A Deep-Sea Dive into Building a CTC at your NPC- Part 1

Presenters

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Background

- Tertiary care VA with strong academic affiliation (1a complexity VHA facility with 70,000+ unique patients)
- Strong clinician educator workforce
- VA NPC on site to support extramural grants
- Four VA Centers of Excellence-no ct exp
- Small number of investigators with coordinators AND clinical trials(Most using VA funded coordinators for additional work)
- No dedicated regulatory coordinators
- No central coordinator support
- Struggles to process reg approvals
- Diverse experience level and compliance among clinical coordinators
- Diverse experience level and compliance among clinical coordinators
- High turnover



New Investigator Scenario

- ✓ New, highly engaged and highly motivated clinician recruited
- ✓ Approached by industry to participate in a clinical trial
- ✓ No clinical coordinator available
- ✓ No regulatory expertise
- ✓ No residual funds available

Options:

- X Unable to initiate the study
- X Attempts to work as coordinator and investigator
- X High risk of non-compliance



What VA Needed



- ✓ Compliance with internal and global research regulations
- ✓ High level of compliance with data security and patient privacy
- ✓ Making more clinical trials available to Veterans to reduce disparities in clinical trial access
- ✓ Alternative staffing models independent of the CSP studies

The Vision

- ✓ Establish a central infrastructure for CT's
- ✓ Recruit highly experienced clinical/reg coordinators
- ✓ Establish a dedicated investigational drug pharmacy

Desired Outcomes

- ✓ Improve access to clinical trials for Veterans
- ✓ Increase clinical trial volume and spectrum
- ✓ Improve clinical coordinator efficiency
- ✓ Reduce regulatory approval timelines
- ✓ Reduce clinical trials related non-compliance
- ✓ Reduce clinical coordinator turnover
- ✓ Improve compliance
- ✓ Improve clinician educator satisfaction and recruitment by offering clinical trial participation





A Deep-Sea Dive into Building a CTC at your NPC- Part 2

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The Ask

- ✓ The VA NPC should invest in a Clinical Trials Center
- ✓ Investigator recruitment/Incentivize Clinicians



Mistakes Made

- ✓ One clinical coordinator assigned to a major clinical service
- ✓ Support existing and new clinical trials for all sections under the service
- ✓ Primary supervision by service line VP
- ✓ Overstaffed



Phase 2

- ✓ No single CRC assigned to any investigator or service
- ✓ When possible clustered studies from similar specialties
- ✓ No overlap between clinical trial coordination and regulatory work
- ✓ Experienced clinical /reg/ancillary staff.
- ✓ investigational drug service
- ✓ Leverage assets for additional resources from the affiliate- fill a gap



Measurable Outcomes





Thank you

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