RAPID Working Group
Phase II-III
Implementation and Application "101"

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Piloting NEST Principles

CRN structure for clinical trials:
- Leveraging RWE
- Site-based research: from double the work to dual purpose

Core minimum data set

Use/re-use

Today’s focus:
- Peripheral artery revascularization devices (RAPID)
- First CRN-based clinical trial (SPEED)
De-Constructing The 21st Century (NEST) Clinical Trial Model: From doubling to dual-purposing site-based work

Site based work flow:
- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

Structured RWE
Clinical Trial Database:
- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

RAPID Phase I
Structured Core Data:
- BUILD (Sentinel)
- UDI/GUDID/SUDI
- RAPID core min data set

Implementation:
- VQI
- NCDR
- EPIC
- VAMC
- SIR

Phase II
Phase III
Clinical report work flow:
- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

Electronic record systems:
- VQI
- NCDR
- EPIC
- VAMC
- SIR

Part 11 compliant
Clinical Trial Database:
- Clinical descriptors
- Device identification
- Procedural information
- Outcomes of interest

Study Site Coordinator

Autos Study CRFs

Structured Core PAD Data Elements

Novel Ancillary Study Data
(Core Laboratory, QOL)
Today’s RAPID Objectives

- Phase II: Implementing Structured Core Data Elements
- Phase III: RAPID Clinical Trials
- Today’s Goals:
  - Identify expert-based working groups:
    - Implementation from registry/EHRs to clinical trial database
    - First pilot clinical trial: SPEED
  - Map next step deliverables & timelines
  - Identify resource needs
    - In kind resources
    - Fiscal resources (Phase I: $9,800)
The NEST CRN Vision:
*With a continuous river of structured data you can float a lot of RCT boats*
*If you don’t have to re-build the river every single time*

"Traditional" Perspective

21st Century Perspective
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