# CTAC Streamlining Clinical Trials Working Group Report

**Sumithra Mandrekar, Ph.D.**
**Neal Meropol, M.D.**

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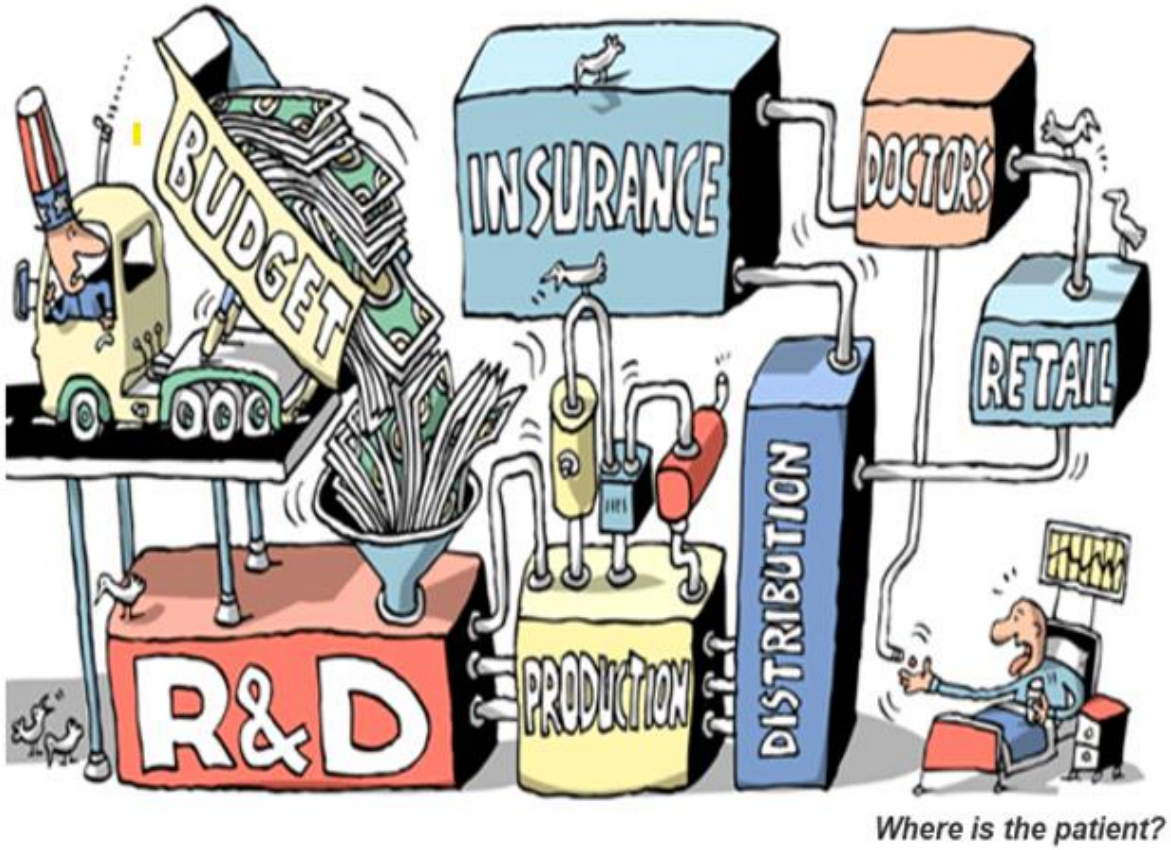
# Today's Topics

- Introduction
  - Strategic Planning Working Group (SPWG) report
- Standard Practices for Limiting Clinical Trial Data Collection
- Utilizing EHRs to Support Clinical Trials
- Discussion

# Introduction

# Current State of Clinical Trials

- Expensive
- Complex designs
- Data collection often in excess of what is used
- Long activation process
- Inequitable access




*Resulting in a model that is unsustainable*

# CTAC Strategic Planning Working Group (SPWG)

# November 2020 Report

Re-assess strategic vision for clinical trials system for 2030 and beyond

Review and address necessary clinical trials infrastructure

Developed 15 recommendations and 3 operational initiatives

| Themes: |
| --- |
| Trial Complexity and Cost |
| Decentralized Trial Activities |
| Promoting Accrual and Access |
| New Data Collection Approaches |
| PRO Data for Clinical Trials |
| Operational Burden |
| Statistical Issues |
| Workforce Outreach and Training |

https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

# NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible**, **faster**, **simpler**, **less expensive**, **high-impact** clinical trials that seamlessly integrate with clinical practice

- Streamline processes for trial design and execution
- Focus on essential endpoints
- Decrease regulatory hurdles and broaden trial access
- Increase efficiency of data collection

Clinical and Translational Research Advisory Committee (CTAC) Strategic Planning Working Group Report 2020
https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

# Activities Towards Achieving the SPWG Strategic Vision

## Streamlining Clinical Trials

- Limiting Clinical Trial Data Collection
- Utilize EHRs to Support Clinical Trials

## Decentralized Trials

- Adopt Local/Remote Study Procedures
- Telehealth Research Centers of Excellence (TRACE)

## Patient Access to Trials

- Broaden Eligibility Criteria
- Connecting Underrepresented Populations to Clinical Trials (CUSP2CT)

# Streamlining Clinical Trials Working Group Focus

| | |
|---|---|
| **Limiting Data Elements Collected** | **Limit clinical trial data collection in late phase trials to data elements essential for primary and secondary objectives** |
| **Utilizing EHRs to Support Clinical Trials** | **1) Engage vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products**<br><br>**2) Resolve the logistical and data quality challenges of extracting clinical trial data from electronic health records** |

# Streamlining Clinical Trials Working Group (SCTWG)

***Charles D. Blanke, M.D.***
Oregon Health and Sciences University

***Gary C. Doolittle, M.D.***
University of Kansas Medical Center

***Michael V. Knopp, M.D.***
University of Cincinnati

***Seth P. Lerner, M.D., F.A.C.S.***
Baylor College of Medicine

***Sumithra J. Mandrekar, Ph.D. (Co-Chair)***
Mayo Clinic

***Robert S. Mannel, M.D.***
University of Oklahoma Health Sciences Center

***Neal J. Meropol, M.D. (Co-Chair)***
Flatiron Health

***Suresh S. Ramalingam, M.D., F.A.S.C.O.***
Emory University School of Medicine

***Victor M. Santana, M.D.***
St. Jude Children's Research Hospital

***Julie M. Vose, M.D.***
University of Nebraska Medical Center

***George Wilding, M.D.***
University of Wisconsin, Madison

# Standard Practices for Limiting Clinical Trial Data Collection

# SCTWG Timeline for Developing Standard Practices

- **July 2022 – October 2022**: Initial draft of Standard Practices
- **November 2022:** CTAC Interim Report on Standard Practices*
- **May – September 2023:** NCTN Streamlining Clinical Trials Implementation Committee feedback on operational implementation of the Standard Practices
- **November 2023:** Recommended Standard Practices finalized based on Implementation Committee input

* https://deainfo.nci.nih.gov/advisory/ctac/1122/Meropol-Mandrekar2.pdf

# Trials Covered by Standard Practices

- NCI CTEP/CIB-managed
- Phase III and Phase II/III
- Interventional
- Focused on treatment
- Adult & Pediatric
- IND-exempt (~ 40% of NCTN trials)

# Standard Practice Data Categories

- Adverse Events
- Medical History
- Concomitant Medications
- Physical Exam
- Laboratory Tests
- Imaging and Other Assessment Procedures
- Patient-Reported Data

# Application of Standard Practices

- Standard Practices address submission of data to the clinical trial database
  - Not data collected in local medical records
- Departures from the Standard Practices
  - Must be justified by investigators on a trial-specific basis based on clinical/regulatory requirements and/or scientific objectives
  - Requires approval by CTEP and Group

# Standard Practices Applicable Across Data Categories

## Data Categories

- Medical History
- Concomitant Medications
- Physical Exam
- Laboratory Testing
- Imaging
- Other Assessment Procedures

## Submit only data needed for:

- **Analyses pre-specified in the statistical plan** (endpoint data, stratification factors, etc.)
- **Documentation of patient characteristics** for publication or other reporting purposes
- Determination of eligibility or treatment assignment/dosing (at Group discretion)

# Standard Practice for Adverse Event (AE) Data

- Submit only:
  - **Grade 3 AEs or higher** unless there is a stated objective for use of lower grade AEs in analyses pre-specified in the statistical plan
  - **CTCAE term and CTCAE grade** for each AE
  - Solicited AEs if needed for analyses pre-specified in the statistical plan
- No submission of AE attribution or start/stop time data

# Standard Practice for Patient-Reported Data

- Submit only data needed for analyses pre-specified in the statistical plan (endpoint data, stratification factors, etc.)

# Opportunities to Further Streamline Data Collection

- Full utilization of IROC infrastructure and capabilities for managing submission of imaging and radiation therapy data
- Reduction in the number of data elements submitted to document administration of pharmacologic therapies (“treatment data”)
- Extension, in certain clinical and regulatory contexts, of the Standard Practice principles to studies conducted under an IND

# Recommendations (1)

**RECOMMENDATION 1:** The Working Group recommends implementation of the Standard Practices for Data Submission to the Clinical Trial Database for the following categories of data:

- Adverse Events
- Medical History
- Concomitant Medications
- Physical Exam
- Laboratory Tests
- Imaging and Other Assessment Procedures
- Patient-Reported Data

# Recommendations (2)

**RECOMMENDATION 2:** The Working Group recommends that NCI, IROC and the NCTN Groups work together to address the institutional privacy/confidentiality and data flow issues hampering submission of imaging and RT data

**RECOMMENDATION 3:** The Working Group recommends that NCI and the NCTN work together in a timely manner to develop guidance for submission of **treatment data** that aligns with the Standard Practice principles

# Recommendations (3)

**RECOMMENDATION 4:** The Working Group recommends that NCI work with FDA to identify the clinical and regulatory contexts in which the Standard Practices for Data Submission could be extended to studies conducted under an IND/IDE

# Utilizing EHRs to Support Clinical Trials

# SPWG Recommendations: Utilizing EHRs to Support Clinical Trials

1. Resolve the logistical and data quality challenges of extracting clinical trial data from electronic health records (EHRs)

2. Engage EHR and Clinical Trial Management System (CTMS) vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products

# EHR Clinical Trial Data Extraction

- SCTWG discussed **current landscape** of academic and commercial initiatives targeting automated or semi-automated extraction of oncology clinical trial data from EHRs
- Potential pilot testing of such tools in NCI clinical trial networks will be informed by the recent Childhood Cancer Data Initiative (RFI NOT-CA-24-021) collecting information on:
  - Current capabilities in automated data entry and extraction from EHRs, including tools to automatically populate clinical trial case report forms with data from EHRs

# Recommendation

**RECOMMENDATION 5:** The Working Group recommends that NCI support the timely further testing and implementation within NCI clinical trial networks of tools for extracting clinical trial data from electronic health records and report periodically to CTAC on progress

# Integration of Study Documents: EHR Study Builds (1)

- SCTWG briefed on two current NCI initiatives aimed at efficient implementation of clinical trial order sets and investigational drug medication data in trial site EHRs
- Clinical Trials Support Unit (CTSU) Site Study Setup Initiative (SSSI)
  - Extracts key protocol information needed for EHR study builds into structured Excel template, sparing duplicative efforts at clinical trial sites
  - Completed templates currently provided for all CTEP-sponsored NCTN studies as well as for Experimental Therapeutics Clinical Trials Network (ETCTN) studies for which protocols have been centrally drafted

# EHR Study Builds (2)

- NCI-funded Clinical Trials Rapid Activation (CTRAC) consortium
  - Developing tools to automate tasks associated with site EHR study builds
  - Initial goals
    - Standard, structured representations of protocol-specified investigational drug data, treatment plans, and assessment procedures
    - Software tools to facilitate import of these structured electronic documents to EHRs

# Recommendation

**RECOMMENDATION 6:** The Working Group recommends that NCI maintain the CTSU Site Study Setup Initiative (SSSI), continue to support the Clinical Trials Rapid Activation consortium (CTRAC), and report periodically to CTAC on CTRAC progress

*Questions?*



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