Optimizing the Efficiency of NCI-Supported Clinical Trials

James H. Doroshow, M.D.
Director, Division of Cancer Treatment and Diagnosis
National Cancer Institute, NIH

NIH NATIONAL CANCER INSTITUTE

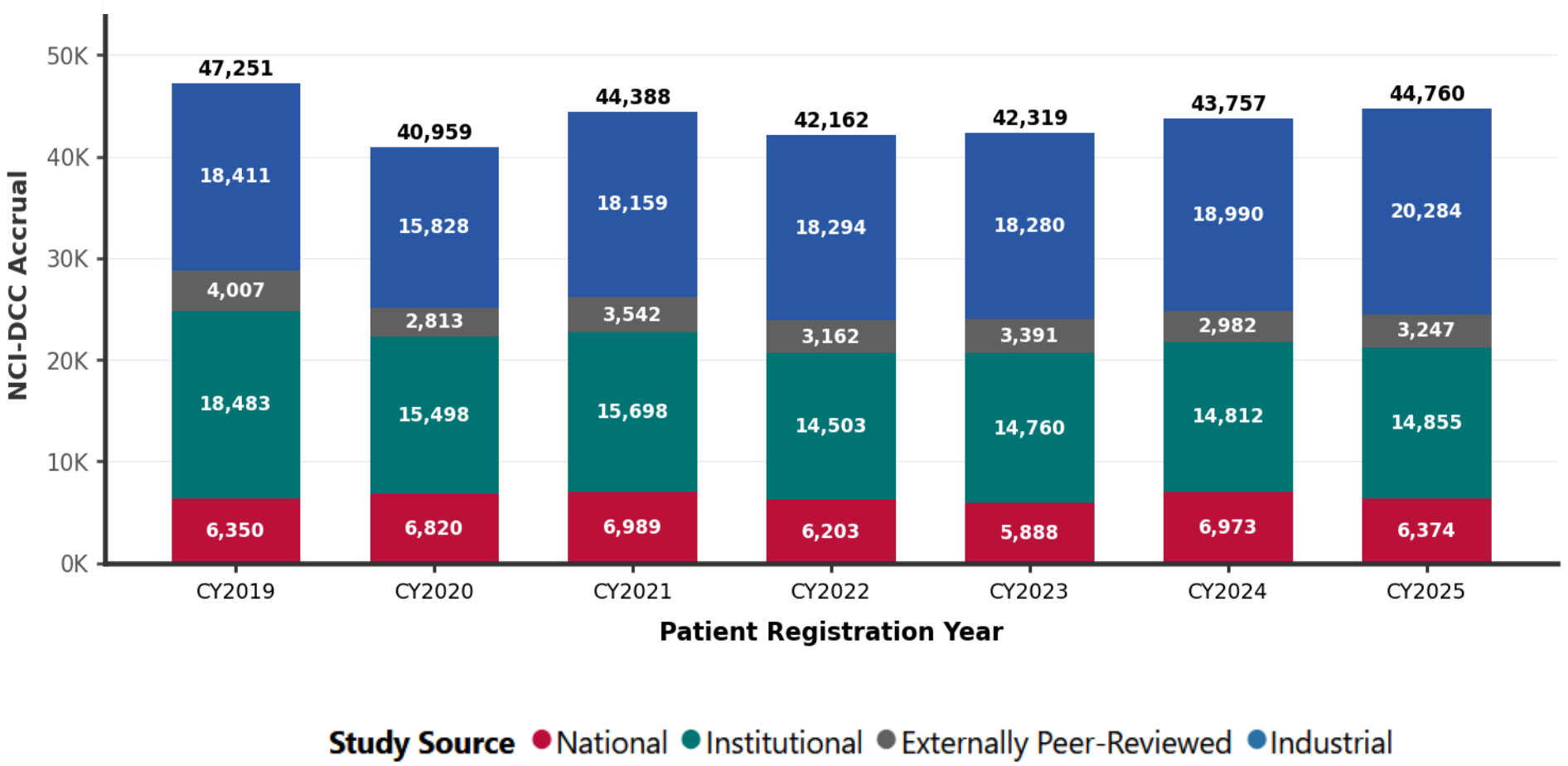
National Cancer Advisory Board

June 30, 2026

Overview

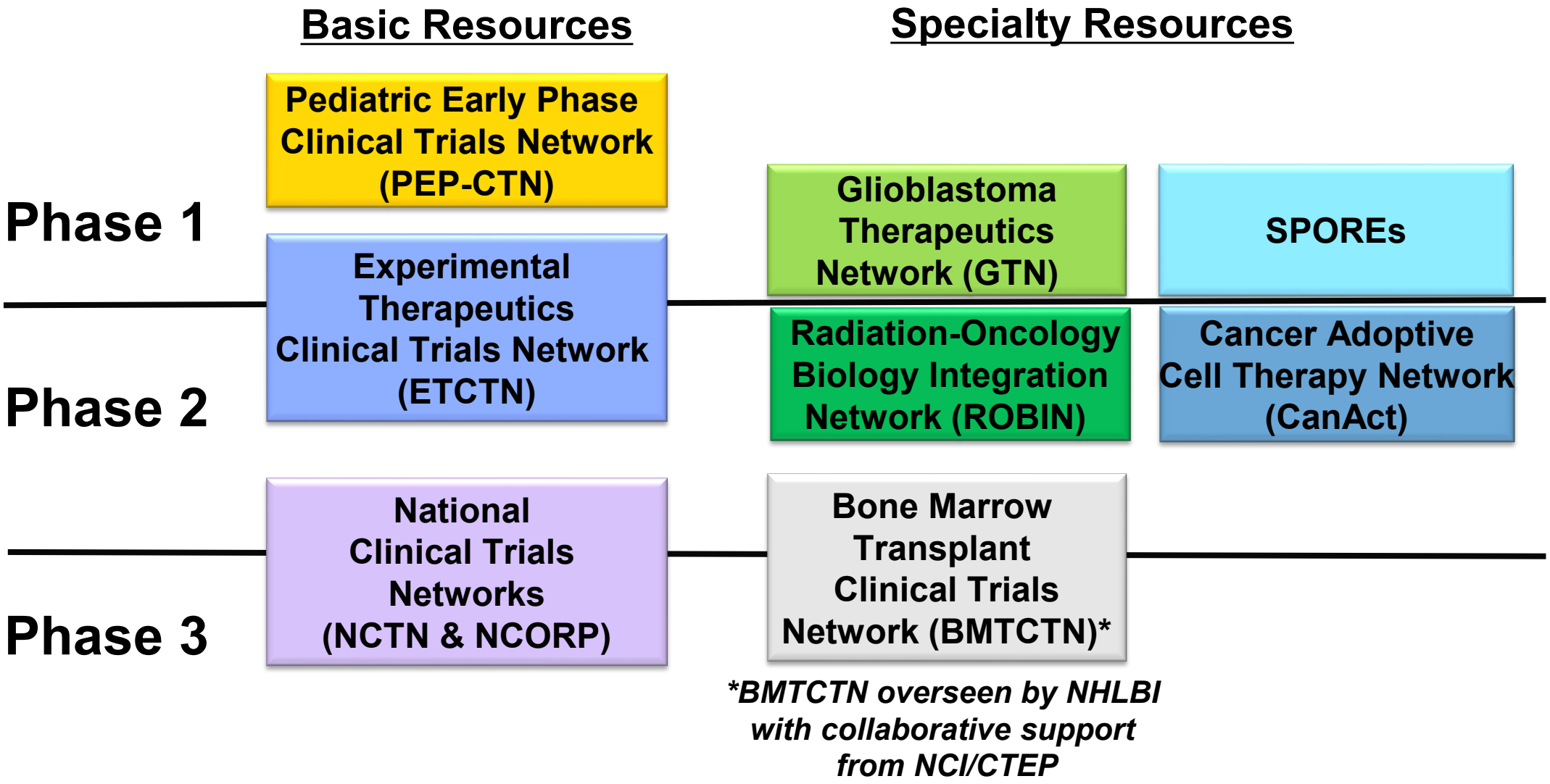
- Scope of NCI-Supported Cancer Treatment Trials
- Strategic Initiatives to Streamline NCI's Clinical Trials Networks
- Infrastructure to Enhance Trial Efficiency
- Future Plans

Accrual to Treatment Trials at NCI-Designated Cancer Centers 2019-2025



Data from NCI's Clinical Trials Reporting Program (CTRP) as of 6/3/2026 (n=10,428 unique trials); Includes 64 Centers

NCI-Supported Therapeutic Clinical Trials & Translational Research Networks



**BMTCTN overseen by NHLBI with collaborative support from NCI/CTEP*

Scope of Treatment Trials Supported by NCI Networks

- Full Spectrum of Clinical Trials (Phase 0, Phase 1, Phase 2, & Phase 3)
- Currently **>100** agents sponsored by **>150** Investigational New Drug Applications (INDs) for which CTEP/DCTD is the legal sponsor
- Approx. **20,000** registered investigators (clinical & pre-clinical) at over **2,000** institutions in US & internationally
- Currently over **>250** actively accruing clinical treatment trials
- About **60-70** new treatment trials open/year, with **70%** under CTEP IND
- About **15,000 to 17,000** patients enrolled/year on treatment trials
- Over **100** collaborative agreements (CRADAs, CTAs) with pharmaceutical companies

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

Strategic Plan Recommendations

Theme	Recommendations
Trial Complexity and Cost	● Limit data collection to only essential elements; facilitate pragmatic trials
Decentralized Trials	● Make permanent COVID-19 pandemic local/remote study flexibilities ● Increase telehealth use for clinical trials
Promoting Accrual and Access	● Improve access for under-represented populations to NCI trials ● Modernize the informed consent process
New Data Collection Approaches	● Extract clinical trial data from EHRs ● Collect clinical trial data with mobile/remote devices
PRO Data for Clinical Trials	● Increase efficiency of PRO data collection via standard software
Operational Burden	● Integrate study documents into local EHRs ● Refine the NCI audit process
Statistical Issues	● Involve statisticians earlier in design of phase 1 and correlative studies ● Investigate the use of external controls
Workforce Outreach and Training	● Increase interest in NCI clinical trial participation among community oncologists ● Develop clinical trials training programs

Implementation Status: ● **Advanced** ● **Ongoing** ● **Deferred for now**

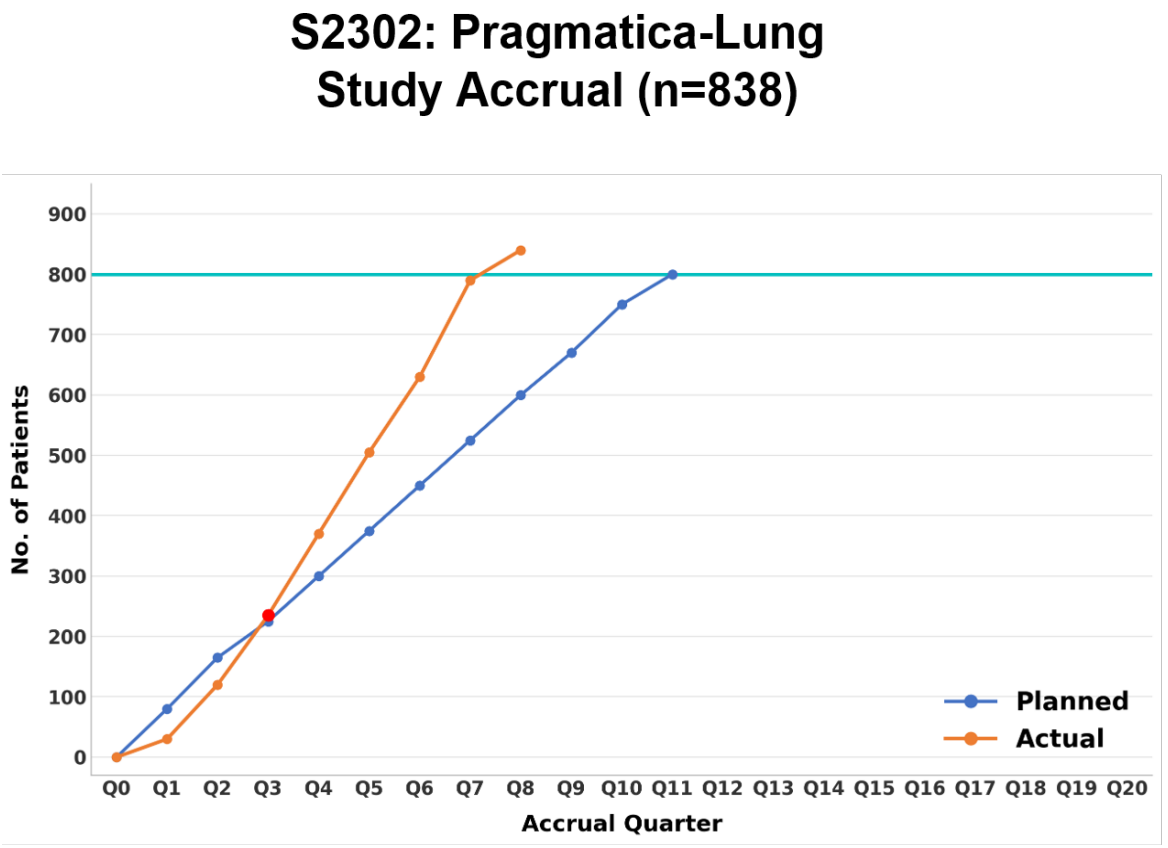
Trial Complexity and Cost (1)

- Limit data collection to essential elements
  - ✓ New standard practices for data collection developed by CTAC
  - ✓ IND-exempt Phase 2/3 and Phase 3 NCTN treatment trials (35% NCTN trials)
  - ✓ Effective **Jan 1, 2025** all trials activated must adhere to new standards

- Examples
  - ✓ ADVERSE EVENTS: Only submit Grade 3/4 unless a stated study objective; no AE attribution or start-stop dates
  - ✓ STANDARD PRACTICES: Only submit data pre-specified in statistical plan or for eligibility: Medical History and Exam, Concomitant Meds, Lab Testing, Imaging

Trial Complexity and Cost (2)

- Developing Pragmatic Trials
  - ✓ Broaden eligibility requirement
  - ✓ Minimize protocol mandated activities
  - ✓ Drug dosing per standard practice
  - ✓ Limit collection of Adverse Events
  - ✓ Only essential data submission
  - ✓ To enhance feasibility of community site participation; speed accrual



https://www.clinicaltrials.gov/study/NCT05633602

Reducing complexity decreases trial costs

Decentralized Trial Activities

- Local/remote procedures made permanent post-pandemic: shipping oral agents, remote consent, remote auditing option for sites, care by local providers, telehealth visits, local performance of lab tests and imaging, local radiation therapy if test/assessment not investigational
- Checklist for NCI-supported trials to assist study teams considering decentralized clinical trial elements for inclusion
- Sample protocol language for decentralized trial activities aligned with FDA and OHRP policies
- However, Investigational (IND) agent delivery via IV or intraperitoneal delivery not included as DCT elements in NCTN trials and would need FDA review and approval

Promoting Accrual and Access

- CTEP implementation of ASCO/Friends recommendations on broadened eligibility criteria to include: stable brain mets, controlled HIV or HBV, young adults, justification for all exclusions
- Advanced practice providers can write orders for study agents
- Connecting Underrepresented Populations to Clinical Trials (CUSP2CT): Outreach and education interventions to increase referral and accrual of underrepresented populations to NCI clinical trials

Operational Burden

- Streamlining EHR study builds: EHR Pilot Consortium
  - ✓ NCI-funded Clinical Trials Rapid Activation Consortium developing and testing tools to automate integration of study documents into local EHRs: Research EHR builds customized at each site
  - ✓ Multiple treatment plans needed based on arms, cohorts, etc.
  - ✓ Health systems may have many separate instances of same EHR
  - ✓ 40-50% of all research EHR treatment plans never used
  - ✓ Defining procedures to extract content from study documents and build instances in a standardized fashion across institutions
- Clinical Trial Support Unit Site Study Setup Initiative: extraction of key study information into a standard template for study builds

Central Support Services Help Support NCI-Funded Clinical Trials Networks (NCTN, NCORP, ETCTN, PEP-CTN, AIDS Malignancy Consortium)

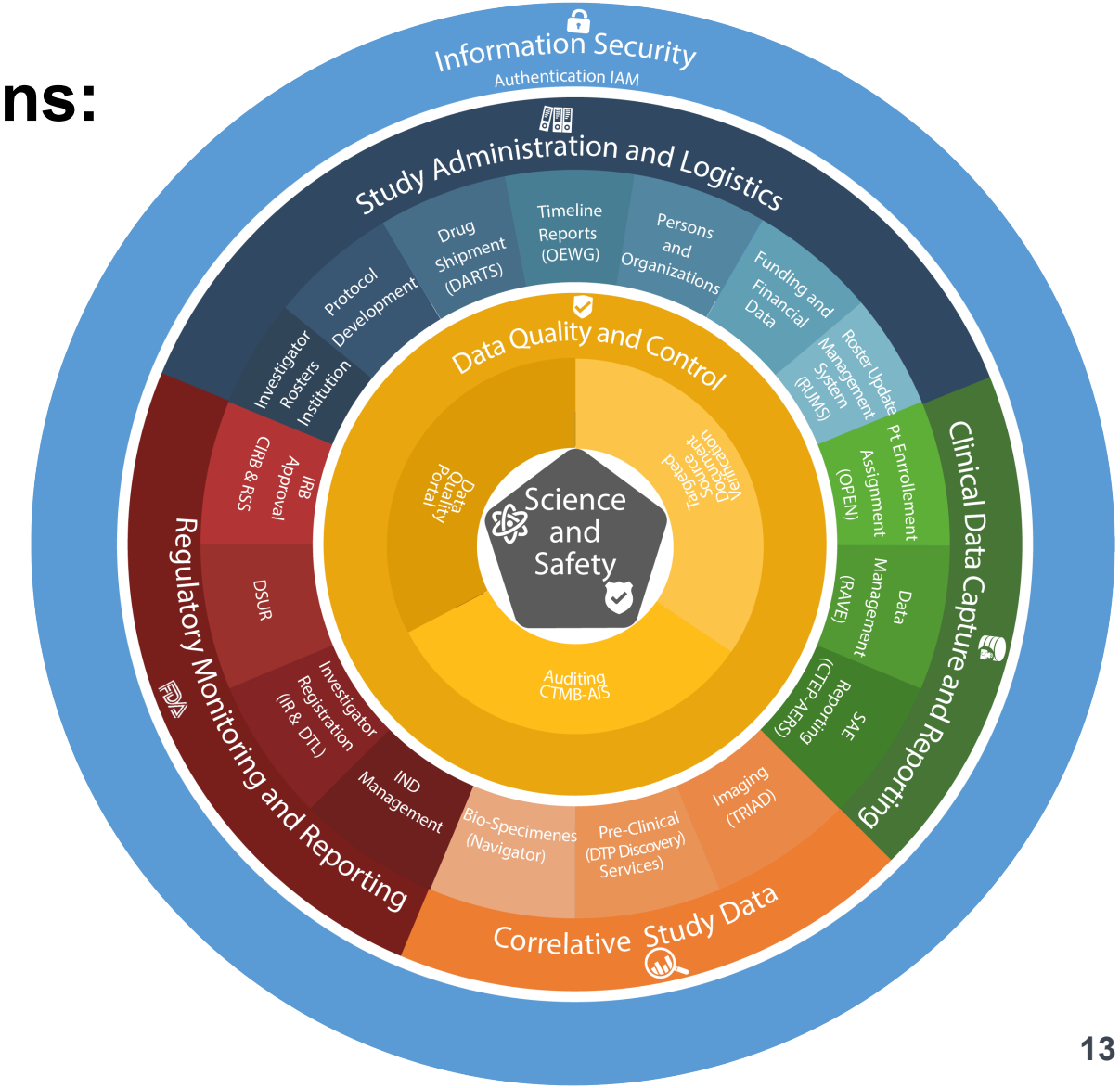
Contract support in following domains:

- **Information Security**
- **Study Administration & Logistics**

  Protocol versions & amendments
- **Clinical Data Capture & Reporting**

  Patient Enrollment, Medidata Mgt System
- **Regulatory Monitoring & Reporting**

  Investigator Credentialing
  NCI CIRB & Regulatory Support
  IND Sponsor Activities/FDA Reporting
- **Data Quality & Control**
- **Correlative Study Data**



Virtual Clinical Trials Office (VCTO) Components Supporting Accrual to NCI Trials

- Research nurses, CRAs, & regulatory affairs personnel organized through NCI-Frederick National Lab Clinical Research Directorate used in past primarily by NIAID
- Initial services by VCTO personnel (working remotely) to support local research site health professional staff at NCTN and NCORP sites:
  - ✓ Eligibility screening and study coordination/registration; promoting trial entry of underserved/rural patients
  - ✓ Assistance with informed consent, enrollment, protocol queries, ‘help desk’ functions
  - ✓ Data entry/abstraction from EHR to Medidata-RAVE for NCTN, ETCTN, NCORP trials (requiring approval by health provider to access protocol patient data in EHR by remote login)
  - ✓ Coordinating study visits, procedures, and participant reminders; all to improve retention
  - ✓ Regulatory support; audit assistance; query management
  - ✓ Adverse event reporting

VCTO: A Scalable, Surge-Ready National Clinical Trials Operations Model

Risks

Operational Risks Without Surge Capacity

- Inexperienced workforce
- Provider shortages
- Labor disruptions

Observed Operational Impact

- Accrual pauses
- Data quality gaps
- Delays in safety reporting

Outcomes

VCTO Surge Capabilities

- Experienced, centralized clinical research professionals
- Modular, rapid deployment aligned to trial needs
- Coordinated national support across sites

Preserved Trial Continuity & Integrity

- Continuous accrual
- Maintained data integrity
- Timely safety reporting
- Improved NCTN audit results

VCTO Metrics

	12/12/23-12/31/24	1/1/25-12/31/25	1/1/26-6/4/26	Total
Sites (start → finish)	1 → 11	11 → 35	35 → 37	37+
Protocols (start → finish)	7 → 14	14 → 24	24 → 29	29
Total Protocol Screenings	34,245	51,005	7,154	92,404
Total Potentially Eligible Identified	557	945	961	2,463
Total Facilitated Accruals	92 (33)	157 (34)	143	392

Future Plans to Enhance Efficiency of NCI Trials

- Decrease data collection for studies requiring INDs (greatest burden) and for non-treatment trials
- Standardize clinical trial audit procedures across NCTN and ETCTN
- Reduce timelines: Obtaining commitments and negotiations with industry to supply agents, FDA review, protocol development times at network sites and NCI
- Develop a validated AI infrastructure for a standardized protocol to EHR service:
  - ✓ Structured protocol and consent form authoring to generate outputs for EHRs and Clinical Trial Data Management Systems
  - ✓ Automated content extraction and validation including processing amendments and protocol tracking