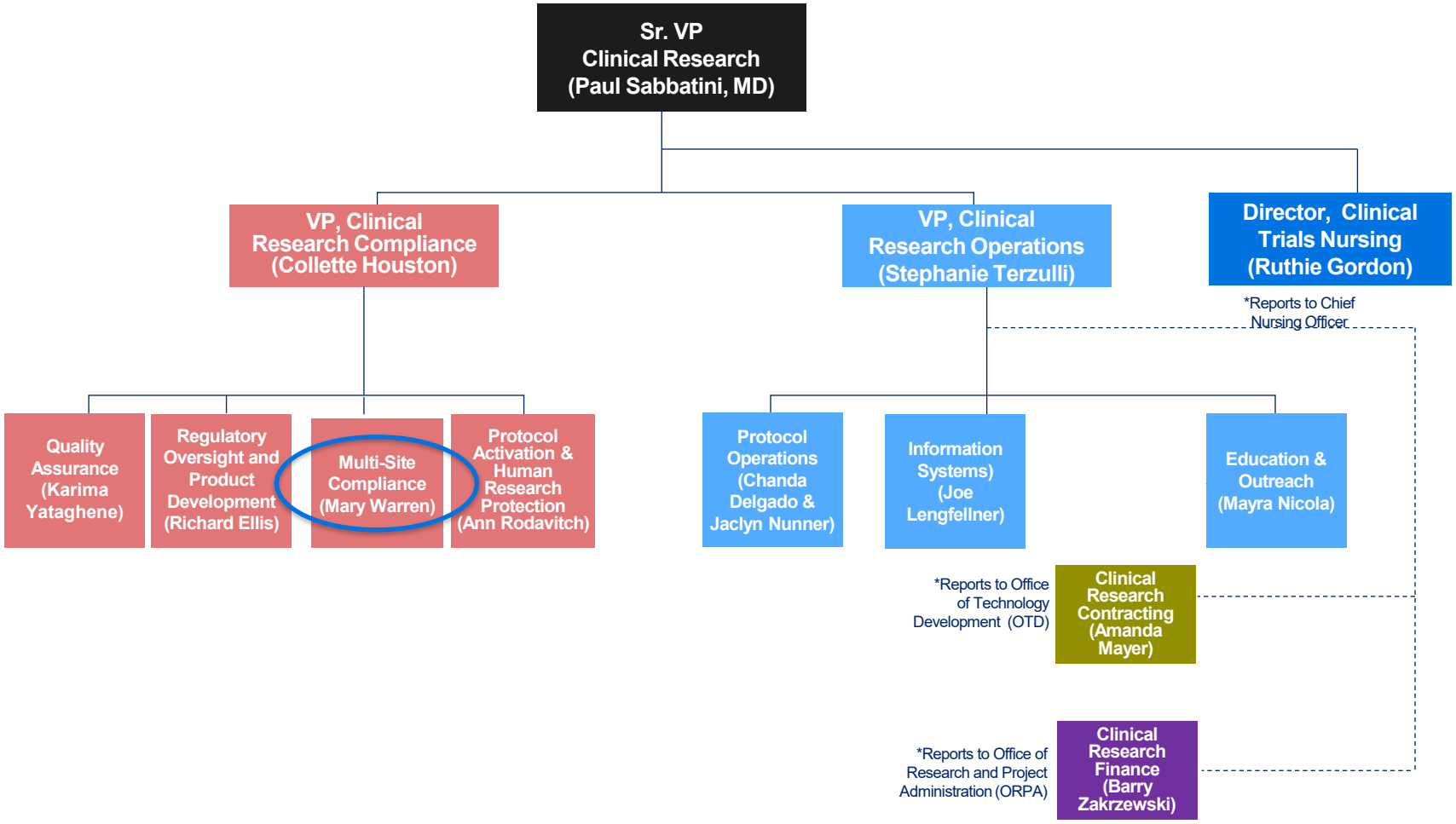
Multisite Compliance

Mary Warren
Sr. Director, Multisite Compliance
Clinical Research Administration

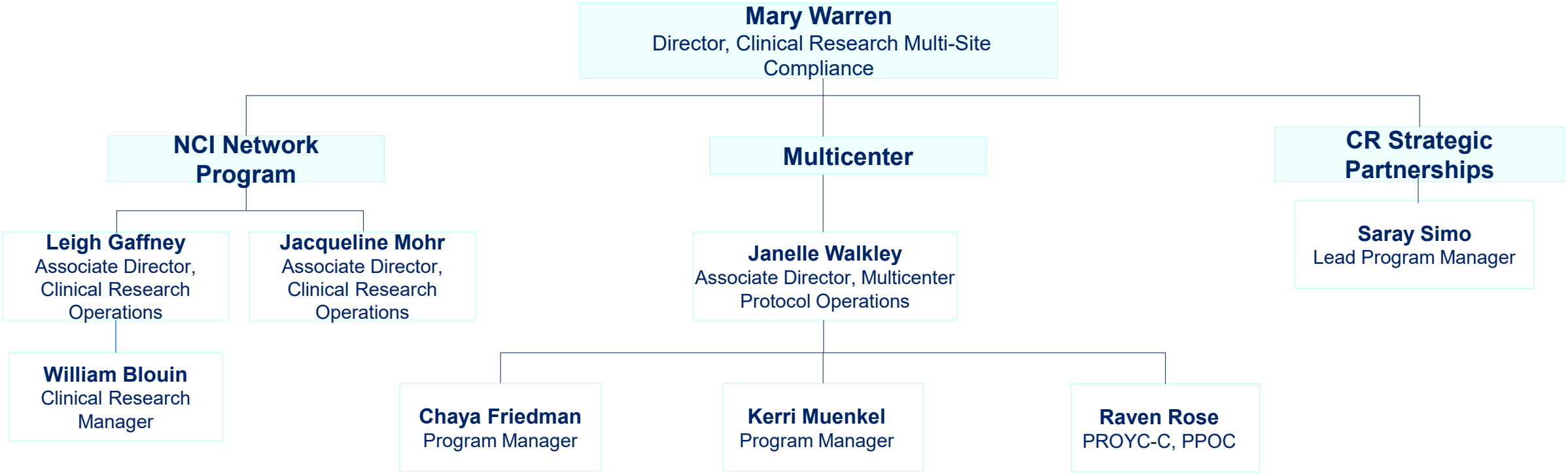
November 20, 2025

Memorial Sloan Kettering
Cancer Center

Clinical Research Administration



Multi-Site Compliance



RIF IMPACT: 1 Program Manager

Last updated October 1, 2025

Key Responsibilities Across all Units

- Activation
- Regulatory management
- Data entry
- Long Term Follow-Up
- Quality assurance
- Program operations

Importance of NCI Network Studies

As an NCI-designated Comprehensive Cancer Center, MSK receives funding via the Cancer Center Support Grant (CCSG). One of the expectations of the support from the CCSG is to collaborate and coordinate their research efforts with other NCI-funded programs and investigators. MSK meets this expectation largely though robust participation in NCI Network Programs which are supported through grant funding.

The current listing of NCI Network Programs at MSK includes:

- Adult Brain Tumor Consortium (ABTC)*
- AIDS Malignancy Consortium (AMC)
- Cancer Immunotherapy Trials Network (CITN)*
- Experimental Therapeutics Clinical Trials Network (ETCTN)
- National Cancer Institute/Cancer Therapy Evaluation Program (NCI/CTEP)
- National Clinical Trials Network (NCTN): includes Alliance Clinical Trials in Oncology; ECOG-ACRIN; NRG Oncology; Southwest Oncology Group (SWOG); Children's Oncology Group (COG)
- Pediatric Brain Tumor Consortium (PBTC)

**Dissolved since initiation*

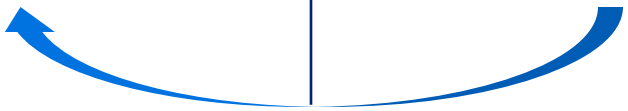
NCI Network Program

NCI Committee

- Protocol review/selection
- Monitor accruals
- Review data timeliness
- Grant and financial reporting
- Develop junior faculty

NCI Network Team

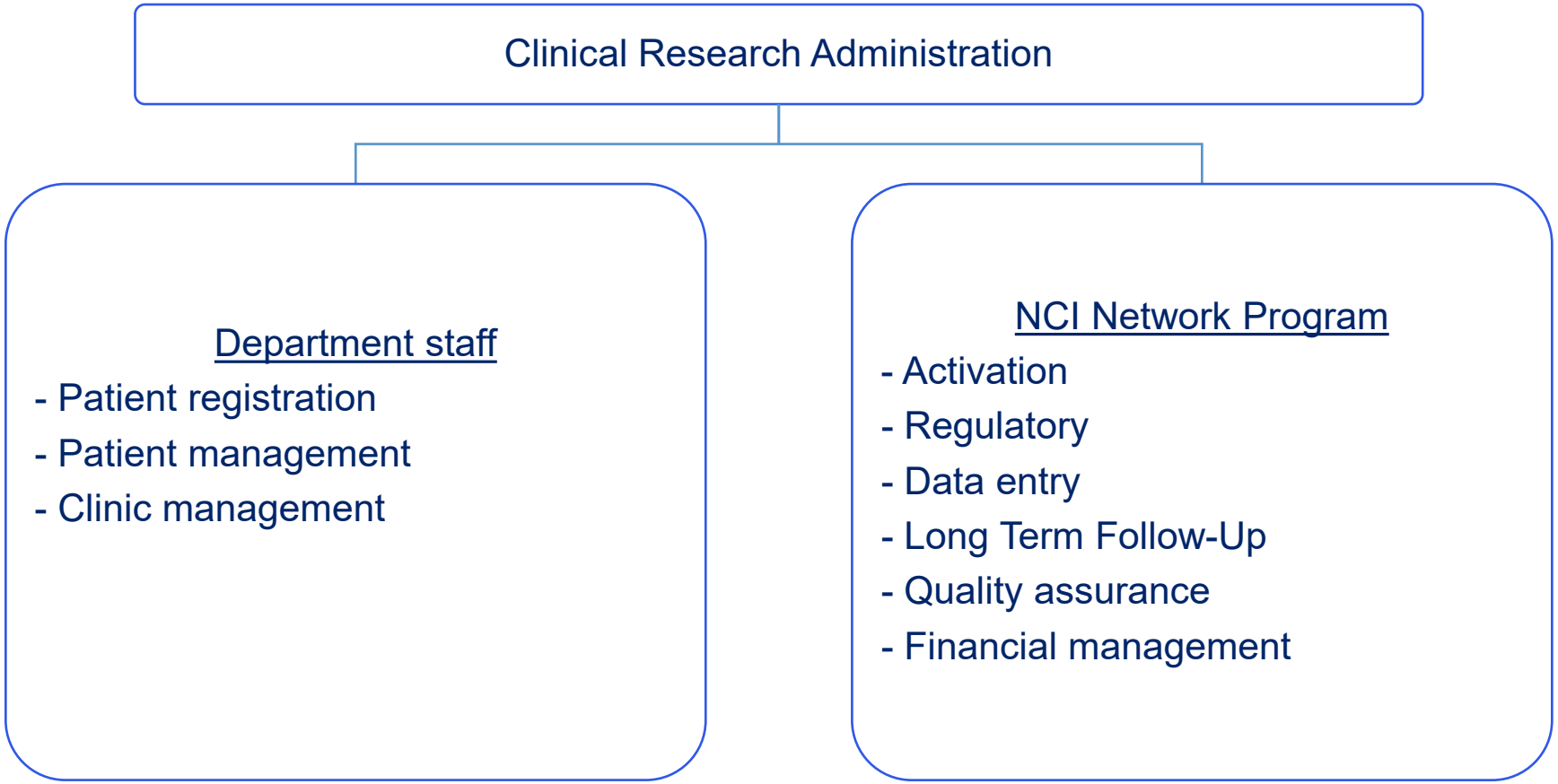
- NCI specific education
- Protocol activation
- Regulatory management
- Data entry
- Quality assurance



NCI Committee

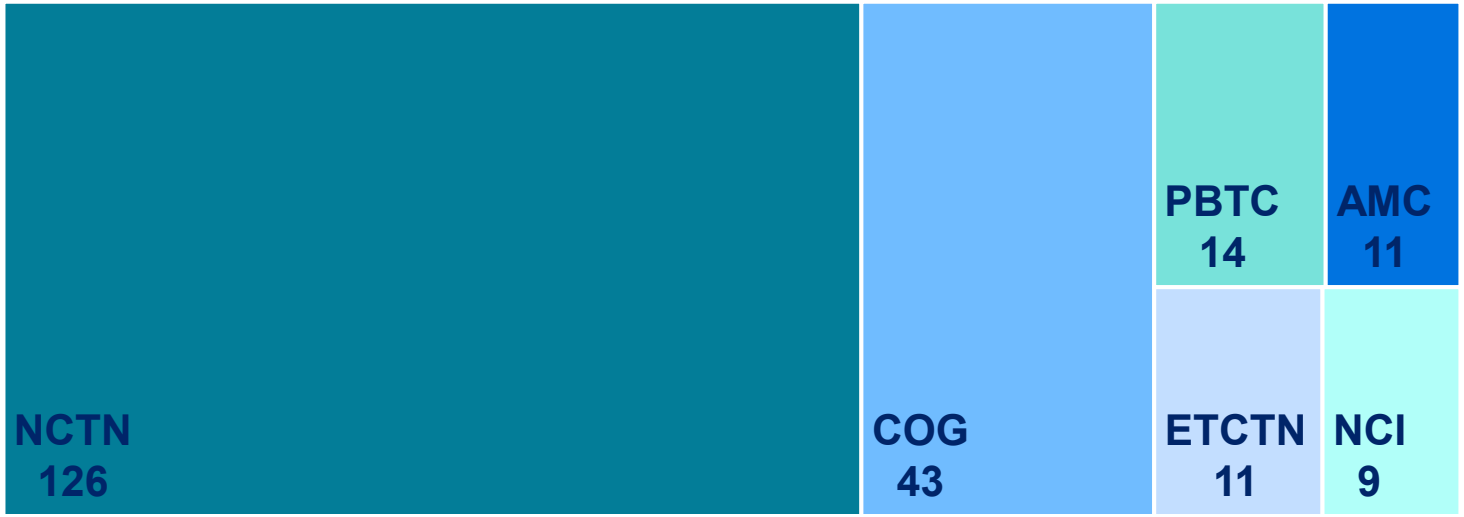
Carol Aghajanian	Director, NCI Network Program
Thomas Kaley	Adult Brain Tumor Consortium
Ariela Noy	AIDS Malignancy Consortium
Darren Feldman	Alliance for Clinical Trials in Oncology
Saad Usmani	Alliance for Clinical Trials in Oncology
Tara O'Donohue	Children's Oncology Group
Mike Morris	Special Advisor to the Director, NCI
Alison Moskowitz	Cancer Immunotherapy Trials Network
Christopher Comstock	ECOG-ACRIN
William Tap	Experimental Therapeutics Clinical Trials
Nancy Lee	NRG Oncology
Oliver Zivanovic	NRG Oncology
Ira Dunkel	Pediatric Brain Tumor Consortium
Julia Glade Bender	Pediatric Early Phase Clinical Trials Network
Daphna Gelblum	Radiation Oncology
Christopher Barker	Radiation Oncology
Valerie Rusch	Surgical Oncology

High Level: Program Implementation



NCI Network Program

MSK NCI Network Portfolio (n=214 studies)



Progress reported at the AACI June 2025 Meeting

- *85% Reduction in Median OOTA*
- *100% Increase in Risk-Based Monitoring*
- *78% Increase in forms submitted on time*
- *50% Reduction in Staff needed to manage the LTFU Program*

Clinical Research Strategic Partnerships (CR SP)

- The MSK Alliance is a transformative initiative to improve the quality of cancer care and the lives of cancer patients by bringing evidence based, world class standards to community health care providers.

- Strategic Partnerships are shared care partners providing our MSK patients with in-patient hospital access and ancillary services closer to home.

Shift from MSK Cancer Alliance to MSK Care Partners

- The Care Partners model is an evolution of the Alliance, offering more tailored knowledge-sharing, focused education, and collaborative opportunities.
- Potential Care Partners undergo a robust Concordance Assessment, encompassing Standards of Care™, Resources and Capabilities, clinical outcomes, and site visits.
- Upon a satisfactory conclusion and finding of concordance, MSK Care Partners receive access to branded marketing, facility co-branding, MSK guidelines and protocols, and educational and research support.

MSK Care Partner

Hartford HealthCare

- Hartford HealthCare at St. Vincent's Medical Center and the Blackrock outpatient center is the first MSK Care Partner
- Across the HHC System
  - 17% of the population report Hispanic/Latinx ethnicity
  - 9% report NELP
  - 1% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Peru
    - Dominican Republic
    - Puerto Rico
    - Mexico

Concluded Relationship

Lehigh Valley Cancer Institute

- From 2016 until July 2025, Lehigh Valley Cancer Institute was part of the MSK Cancer Alliance, a partnership that ended following Lehigh's merger with Jefferson Health.
- Ongoing clinical trials and research initiatives at the time of the separation will proceed to completion, and all patients currently enrolled will be able to finish their participation as originally intended.

Lehigh Valley Topper Cancer Institute

Future MSK Care Partner

Program Growth

- MSK is actively working to bring on a second MSK Care Partner – **Miami Cancer Institute**, which is currently undergoing a Concordance Assessment to review system-wide and location specific practice, process, and quality
- **MCI** has been an MSK Cancer Alliance member since 2017 and is engaged in numerous research studies with MSK
  - 77% of the MCI patient population report Hispanic/Latinx ethnicity
  - 35% report NELP
  - 1% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Cuba
    - Puerto Rico
    - South America
    - Mexico

- MSK plans to continue to grow the MSK Care Partners program with additional members over the next several years

Health Equity

Jamaica Hospital Medical Center (MediSys)

- MSK and Jamaica Hospital formalized a 5-year partnership in January 2023, renewed in June 2024, aimed at expanding cancer care access and improving health equity.
- MSK's goals for the relationship is to enhance access for underserved populations, diversify clinical trial participation, and extend specialty care. Jamaica's goals are to build a comprehensive cancer program, recruit oncology staff, and integrate MSK's expertise into their practice.
- Across the system:
  - 41% of the population report Hispanic/Latinx ethnicity
  - 29.5% report NELP
  - XX% clinical trial accrual for Hispanic/Latinx
  - Countries of origin:
    - Dominican Republic
    - Guyana
    - Jamaica
    - Bangledesh
    - Ecuador
    - Trinidad and Tobago
    - Haiti

MSK Strategic Partnerships

Inpatient Care at Strategic Partnerships

If an MSK patient has urgent symptoms that would normally bring them to MSK's Urgent Care Center or if they need to be admitted they can get care closer to home at HMH or NYCBS (hospitals).

MSK will call HMH/NYCBS before their arrival to let them know they are a MSK patient.

The patient's care team at HMH/NYCBS will share important health information including details of their condition.
The care they receive at the site will be coordinated with MSK team.

After the patient's hospital stay, they will once again be in the care of their MSK healthcare provider for their oncology care.

Multicenter Research Definitions

National Cancer Institute (NCI) Definition of Multicenter Study: *A clinical trial that is carried out at more than one medical institution.*

This can be an Industry Sponsored trial, an MSK IIT trial, Consortia trial or an NCI Network Trial

The NCI Dictionary of Cancer Terms does not include one for **Data Coordinating Center**, MSK defines this as - *A site that is responsible for the collection, verification, and storage of data collected from all sites involved in a multi-site trial.*

Other Terms

MSK-sponsored Multicenter Study - An MSK investigator-initiated trial (IIT) that is multicenter where there is at least one external participating site and MSK oversees the initiation, management, funding (if applicable) and contracting. This includes monitoring the conduct and progress of the trial.

Data Coordinating Center (DCC) - the site that is responsible for the collection, verification, and storage of data collected from all sites

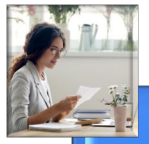
Sponsor - An individual, pharmaceutical company, academic institution, government agency or private organization who takes responsibility for and initiates a clinical investigation. (21 CFR 312.3)

Participating site - The location(s) where trial-related activities are conducted.

Source Documents - Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or
transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

Essential Documents - Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

MSK Sponsored Multicenter IITs



Letter of Intent

- For a new clinical trial, the PI will submit a concept and budget to the pharmaceutical company to request study drug and funding. This can also be done via grant or foundation submission.

Protocol

- Protocol inclusive of Primary, Secondary and Exploratory Endpoints, Study Schema, study drug risks, SAE language, biostatistics, data safety monitoring and quality assurance.
- Lab Manual, pharmacy manual, SAE external site form, MCT addendum and patient facing documents

Budget

- Each unit works collaboratively with CR Finance and Study Team on Budget. Initially submitted during the LOI phase. Award letter informs MSK of amount funded. Internal budget modified if necessary.
- Multicenter Office fees and external participating site fee's are inclusive in this budget.

Contract

- Each unit works with CR Legal to ensure contract reflects the study is multicenter and to answer legal questions to operationalizing the trial to ensure contract, protocol and MSK Sops align.
- MCT obtains sub-contract for external sites and is point of contact with legal reviewing all red-lines and having meetings with Funder/participating sites as needed.

Vendors

- Drug distribution, central lab, central radiology review, device, etc. may be required for the protocol and need to be included in all budget, contracts and workflows.
- MSK has a Master Agreement with McKesson for Drug Distribution.

Multicenter Office (MCT)

The Multicenter Office is responsible for the Institutional oversight of regulatory compliance for MSK-Sponsored multicenter clinical trials.

- The Multicenter Office is responsible for the management and day to day operations of MSK-Sponsored multicenter trials when the protocol is a moderate or high risk therapeutic study with or without an IND/IDE.

High level responsibilities of the DCC to support principal investigator:

- Protocol/ICF writing: Including the Multicenter Addendum as an appendix to the MSK IRB approved protocol
- Oversee participating site(s) activation: Including budget and contract negotiations and regulatory approval
- Train & provide day to day operational support to external sites
- Data Management: Monitoring/Auditing
- Compliance: protocol and regulatory

Institutional SOPs & Protocol Development Resources

MSK has multiple SOPs & protocol development resources for MSK Sponsored multicenter studies listed below and can be found on the MCT SharePoint page

Multicenter Office SOPs:

Include the required multicenter language as an appendix or within the MSK protocol, as applicable per the site role

- CR SOP 419: Requirements for MSK Sponsored Multicenter IND/IDE Protocols
- IRB/PB SOP RI-802: Requirements for the Coordination of Multicenter Research Projects
- Multicenter Therapeutic Addendum
- Multicenter Non-therapeutic Addendum
- Multicenter External Site SAE Report Form Template
- Consultant/Data/Specimen Analysis Language
- Deviation Form for relying sites

Documents not submitted to the IRB

- Multicenter Protocol Eligibility Checklist
- Relying Site SWP- is distributed to the relying sites

MCT Standard Protocol Language

1. Multicenter Addendum-Multicenter Office standard requirements for data collection participating sites that do not rely on MSK's IRB are outlined in the Multicenter Addendum
   - Multicenter Therapeutic Addendum
   - Multicenter Non-Therapeutic Addendum
     - The addendum is study specific, IRB approved, and must be distributed with the protocol documents to any non-relying, data collection sites.
     - Last update: January 2025

2. Consultant, Data and or Specimen Analysis Language- is included within the protocol and Informed Consent form as applicable
   - Multicenter Consultant and Analysis Site Language

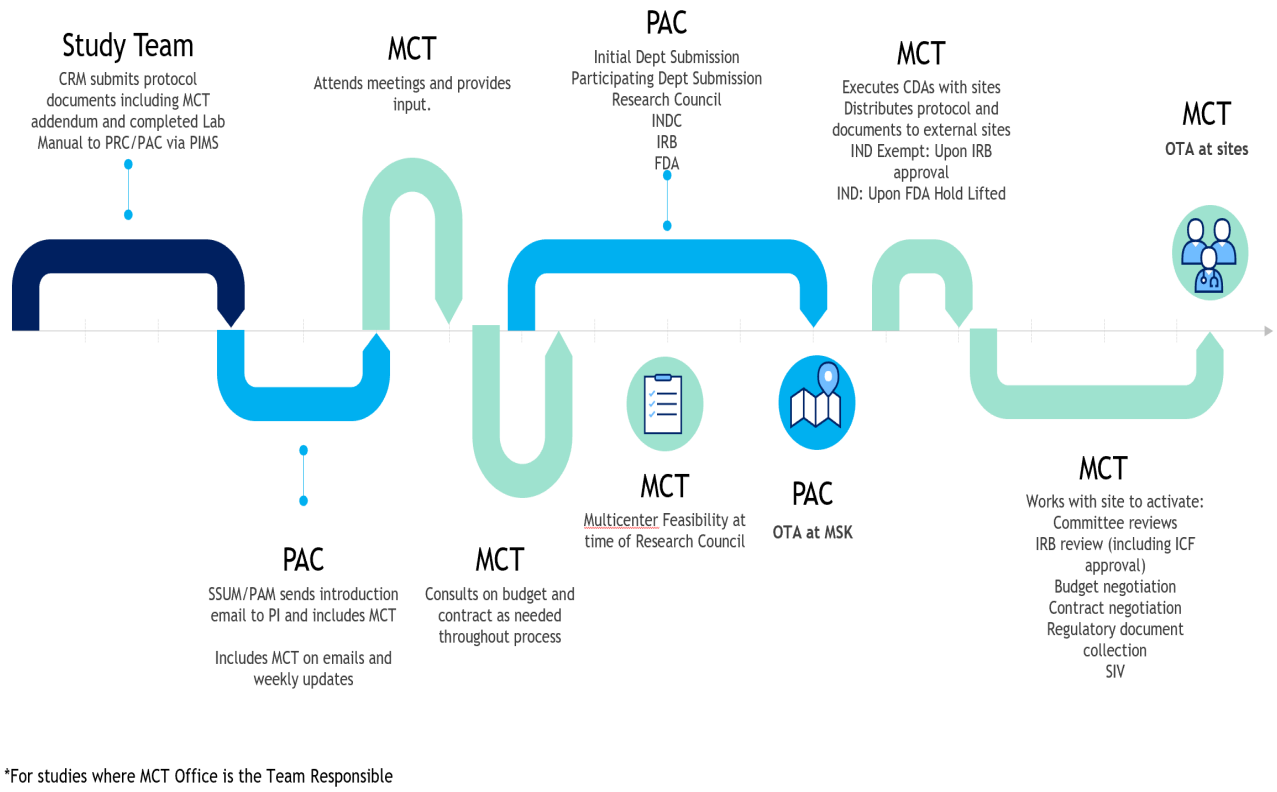
Overview of the Multicenter Activation Team's Role

The protocol should be submitted to PAC with the standard multicenter language that is applicable for the site roles and per the usual process for initial IRB approval. Non-relying sites should be listed in the RPSF. If the protocol includes data collection sites, the SAE report form must be included as an appendix. If the protocol includes non-relying, data collection sites, the Multicenter Addendum must be included as an appendix.

PAC will submit multicenter trials for Multicenter Feasibility. PAC and study team will work together with PI to address comments and questions.

Participating sites may not begin to work on the trial until Multicenter Feasibility is approved.

- When MCT is the "Team Responsible" for the participating sites, the Activation team is also responsible for:
  - Input on study budget, contract terms, protocol language that may impact sites and MCT workflows
  - Oversight of external site activations, once MSK is activated:
  - Assessing feasibility of participating sites
  - Communication with external sites
  - Regulatory
  - Contract
  - Budget
  - SIV



*For studies where MCT Office is the Team Responsible

Activation of Participating Sites

A CDA must be executed prior to sharing the protocol and protocol document(s) with the site(s).

Once a CDA is in place, the IRB approved documents may be shared with the site to complete their local review process. For non-relying sites, they will transfer the content from the model ICF (MSK ICF) to their own template. The Team Responsible reviews against the ICF Review Checklist to ensure it is complete and accurate.

A contract and budget (if applicable) must be executed with the site.

All required regulatory documents must be collected from the site and filed in PIMS in the site regulatory binder.

An SIV is conducted, and documentation of training must be filed in PIMS in the site regulatory binder.

Once the study is IRB approved, contract is executed, SIV is conducted, submit Participating Site Document Submission Form (PSSF) and applicable documentation to the MCT Office

How To Submit Multicenter Documents to the Multicenter Office

- MCT will provide an official memo noting site is open to accrual, and the MSK Team Responsible will distribute to site

Multicenter Feasibility

The MCT Activation team reviews all multicenter clinical trials. This review occurs concurrently with RC review, and it is a complete review of protocol for multicenter protocol language and feasibility as a multicenter study

What types of questions are reviewed during Multicenter Feasibility?

- Has the PI received written approval from the study funder to conduct a multicenter trial?
- If a study is federally funded, is the grant written as multicenter and are the sites named?
- If therapeutic and involving drug, does the drug supplier agree to ship drug directly to the external sites? If not, is a vendor being utilized?
- Does the protocol have required multicenter language?
  - SAE language, data analysis and consulting language descriptions
  - Multicenter Addendum and External Site SAE Form
  - If there are correlatives, is there a lab manual? Does it adequately describe processing and shipping for the external sites
- Are there relying sites?
- Are there international sites?
  - Is MSK IRDP team engaged, if necessary?
- Is the study budgeted as a multicenter trial?

sIRB of Record

Revised Common Rule effective July 2018, institutions were not permitted to implement until January 2019; Compliance date for this part of the regulation was January 2020

- For institutions located in the United States that are engaged in cooperative research to rely upon approval by a single IRB for that portion of the research that is conducted in the U.S.
  - Institutions are engaged if they receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research.
  - Additional OHRP engagement criteria
- The reviewing IRB will be specified by the federal department or agency supporting or conducting the research; the "lead institution" may propose the reviewing IRB, but final federal approval will be required.
- Specifies circumstances when requirement for single IRB does not apply (reasons of law or as determined by the federal department or agency conducting or supporting the research)

Below is required when a site will be relying on MSK IRB.

- Reliance Agreement
- MSK Local Context Form
- Add relying site to the protocol
- Manage the relying site post IRB approval

International Research Data Privacy

General Data Protection Regulation (GDPR) went into effect May 25, 2018

- Lawful basis for the use of data: The Data Controller/Processor needs to have a lawful basis for the use of data and this needs to be stipulated in the contract

Under GDPR, entities are:

- Data Controller- the entity, the organization or the person that determines the purpose and means of processing personal data. This would typically be the sponsor.
- Data Processor- the entity, the organization or the person processing data on behalf of a controller, on their instructions.
- When GDPR applies, entities must ensure that (1) there is a legal basis to process personal data and (2) there is a legal basis to transfer data outside the EU, EEA, UK.

Country Specific International Law:

- At the same time or shortly there after, individual countries established their own research data privacy laws. These studies will also be reviewed by the IRDP group to ensure appropriate protocol, ICF, contractual language and privacy notification is included for these studies.

Email IRDP@mskcc.orgfor review and guidance on how to process all protocols/ projects that involve a site in the EU/EEA/UK.

MSK Protocol Text for General Data Protection Regulation