# Clinical Trials Operations

Robert H. Lurie
Comprehensive Cancer Center
of Northwestern University

Presented by: Tricia Kartcheske
Interim Sr Administrative Director, Clinical Trials Office
Date: October 8th, 2025

# Clinical research is…

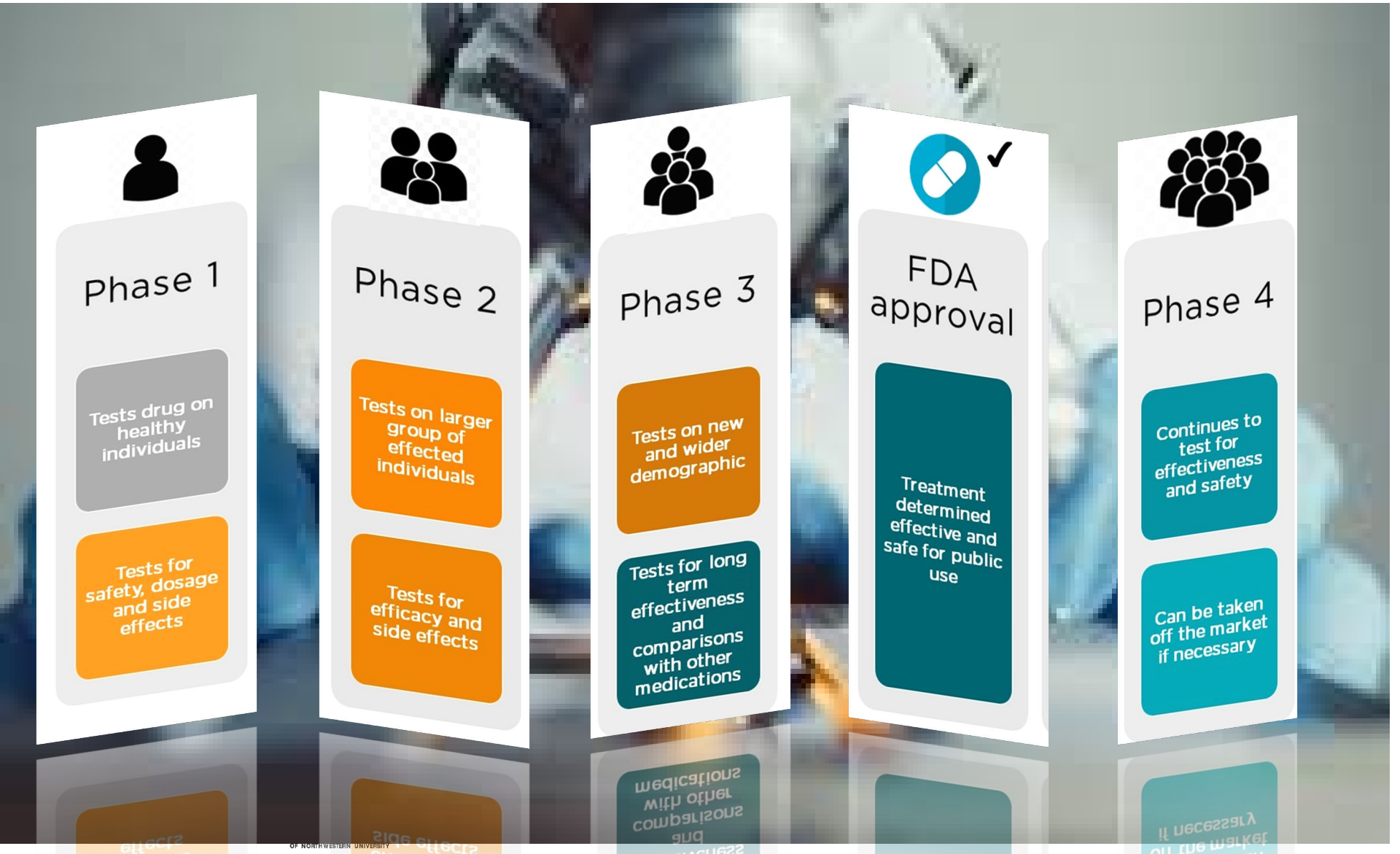
Key Point

Patient-Oriented Research

Epidemiologic &
Behavioral Research

Outcomes and
Health Services Research

# Phases of Clinical Trials – What is the goal?




4
Clinical Trial
Sponsor Types

1

# Investigator Initiated Trials

- Our faculty develop own trial protocols
- They can work with sponsor companies to supply drug and some financial support
- Often highest risk because they are considered the sponsors who hold the Investigational New Drug (IND) application
- Require FDA submissions

2

# National Clinical Trials Network (NCTN)

- Run by different cooperative groups
- NCI is considered the sponsor
- We are a Lead Academic Participating Site (LAPS), which means we enroll high numbers into these trials and show scientific leadership in the design and conduct of the trials

3

# Sponsored Trials

- Run by pharmaceutical companies
- Pharma holds IND for these trials and they are responsible for oversight and FDA reporting
- Will conduct monitoring visits and audits to ensure sites are compliant with protocol

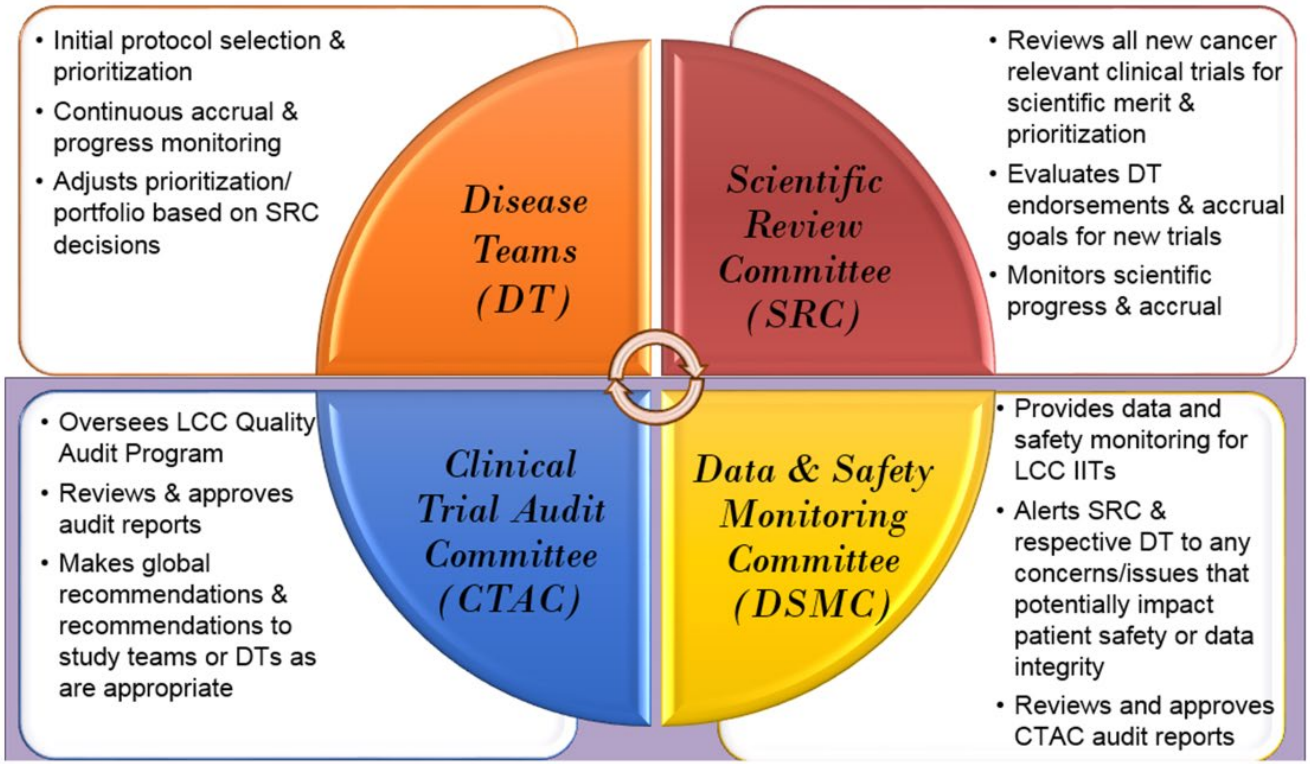
4

# External Investigator Initiated Trials

- Run by other Centers
- Other center PIs hold IND and are responsible for oversight and FDA reporting

# Clinical Trial Committees

## Clinical Trial Committees




Northwestern Medicine | Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# Clinical Trials Office (CTO) Services Overview

Devalingam Mahalingam, MD, PhD
CTO Medical Director

Study Endorsed by Disease Team

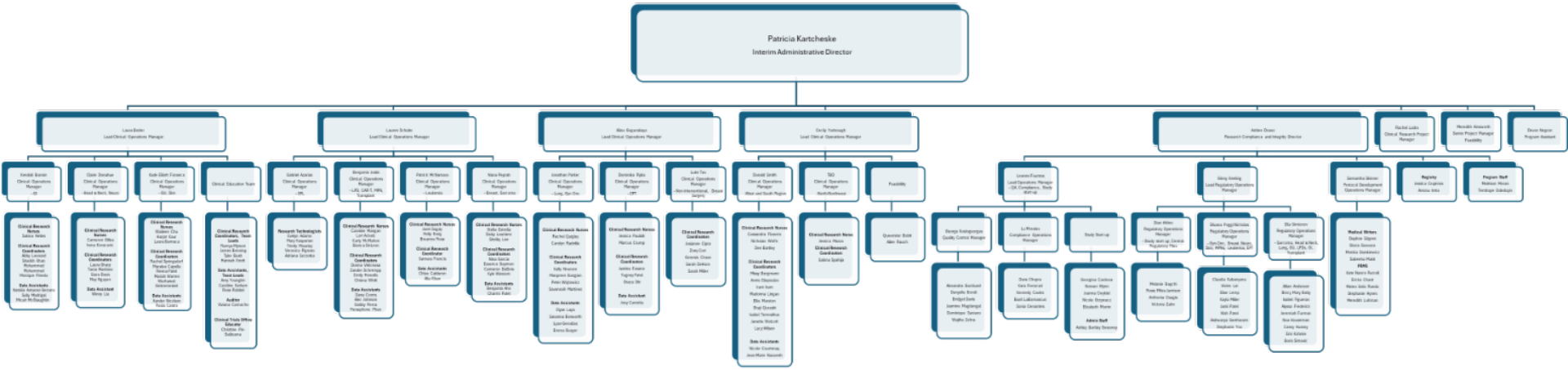
- Scientific Review Committee (SRC) → Meeting → Approval
- Budget → Start-Up Approval → Development & Negotiation → Finalized
- Contract → Contract Review & Negotiation → Executed upon Budget & IRB Approval
- Regulatory → Submission to IRB → IRB Approval

→ Site Initiation Visit → Study Conduct

Northwestern Medicine®
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# CTO TEAMS

## CTO Organization Chart




Northwestern Medicine®

Robert H. Lurie Comprehensive Cancer Center
of Northwestern University

# CTO TEAMS

STUDY ACTIVATION

MEDICAL WRITERS

CLINICAL OPERATIONS

REGULATORY

QUALITY ASSURANCE AND COMPLIANCE TEAM

# CTO TEAMS

- Study Activation

**Tracking and submission** of **new protocols** from Disease Team review through study open to enrollment

**Processing** of confidentiality agreements

**Liaison** for sponsor, CTO staff, and investigators throughout study activation process

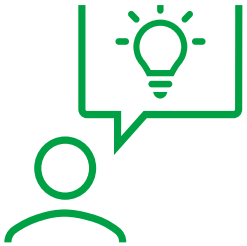
**Track** metrics for improvement of activation timelines

Northwestern Medicine®

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# CTO TEAMS

- Medical Writers



Assist investigators with **protocol design and concept submission**

Coordinate **protocol development** with collaborators

Provide guidance on **protocol interpretation and revisions** as needed

Coordinate **activation and on-going support** for participating sites

# CTO TEAMS

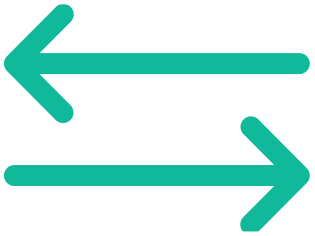
- Clinical Operations – Research Nurses, Study Coordinators, Data Managers

**Screening & enrollment** of research patients

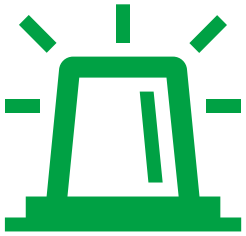
**Schedule and Coordinate** Site Initiation, Interim Monitoring, and Close Out Visits

**Coordinating** study visits

**Collecting data and documentation** of required elements



**Reviewing and implementing** protocol revisions



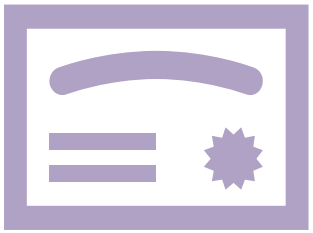
**Collecting and reporting** adverse events.

Northwestern Medicine®

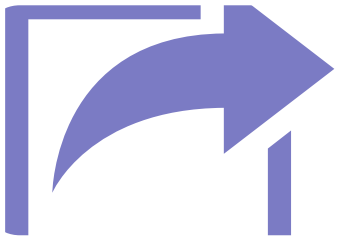
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# CTO TEAMS

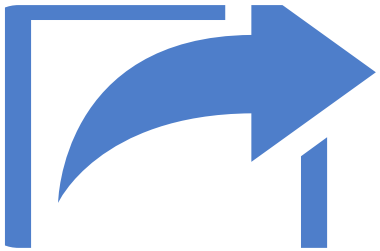
- Regulatory



Provide centralized intake and maintenance of site and personnel **research credentials**



**Institutional Review Board (IRB) submissions** (initial, on-going, termination) working with various local and central IRBs



Institutional Biosafety Committee (IBC) submissions

**FDA submissions** (IND/IDE applications, safety reporting)

**Maintenance** of study-specific regulatory binders

**Disease team support** for common questions (consenting issues, deviation reporting, conflict of interest reporting, guidance on interpreting regulations

Northwestern Medicine®

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# CTO TEAMS

- Quality Assurance and Compliance Team

IIT Monitoring & Auditing

- Conduct routine monitoring of IITs according to Data Safety Monitoring Plan
- Perform first-patient and rolling audits of IITs
- Assist with activation of new IITs (scientific review, eCRF development & SIV, multi-site training)
- Data analysis (summarization, manuscript assistance, reporting)
- FDA reporting

Internal Spot-Checking

- Random, non-IIT chart reviews
- NOTIS data entry compliance review
- For-cause, targeted chart reviews
- External audit prep

Three Milestones –
Cancer Clinical Trials Integration

ONE TEAM
Merging of legacy
West Region Cancer CTO staff with
Central/North

ONE TEAM
Merging of legacy West Region Cancer CTO staff with Central/North

ONE PROCESS
Trial activation process to include NM Network cancer sites

**ONE UMBRELLA**
**All NM sites under Lurie's prestigious Lead Academics Participating Site (LAPS) designation**

# North Region-LAKE FOREST

- LAPS integrated component since 2020
- 1 Full Time Research Nurses
- 1 Float Study Coordinator
- Over 60 Studies Open

## West Region-Warrenville, CDH, Delnor, Kishwuakee

- LAPS integrated component since 2021
- Have 12 Full-Time Research Staff
- 1 Research RN
- Over 150 Studies Open


## South Region- Orland

- LAPS integrated component since 2022
- 1 Full Time Research Nurse
- 1 Full time study coordinator
- Over 20 Studies Open

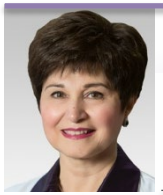
## 2023: North Expansion-Glenview & Grayslake

- LAPS integrated component since 2022
- 1 Float Study Coordinator at each location
- 5 Studies open at each


## 2023: Northwest Expansion- McHenry & Huntley

- LAPS integrated component since 2022
- Process of hiring 1 Full-Time Study Coordinator

# Practice Defining Clinical Trials



Maha Hussain

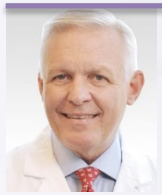
## Prostate Cancer

| | |
|---|---|
| PROSPER trial<br>*NEJM* 358:2465, 2018 | Enzalutamide in refractory PCa<br>**FDA approval** |
| PROfound trial<br>*NEJM* 383:2345, 2020 | Olaparib in refractory PCa<br>**FDA approval** |
| ARASENS trial<br>*NEJM* 386:1132, 2022 | Darolutamide + ADT/rocetaxel in refractory PCa<br>**FDA approval** |

Leo Gordon

## Lymphoma

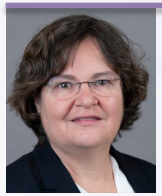
| | |
|---|---|
| ZUMA 7 trial<br>*NEJM* 386:640, 2022 | Axicabtagene Ciloleucel in refractory DLCBL<br>**FDA approval** |
| PILOT trial<br>*Lancet Oncol* 23:1066, 2022 | Lisocabtagene Maraleucel in refractory DLCBL<br>**FDA approval** |



William Gradishar

## Breast Cancer

| | |
|---|---|
| Sophia Study Group trial<br>*JAMA Oncol* 7:573, 2021 | Margetuximab in ErbB2+ breast cancer PCa<br>**FDA approval** |



Daniela Matei

## Endometrial Cancer

| | |
|---|---|
| GOG-258<br>*NEJM* 380:24, 2019 | *Addition of radiation therapy to chemotherapy does not improve outcomes* |

Jessica Altman

## Acute Myeloid Leukemia

| | |
|---|---|
| Venetoclax plus Gilteritinib for Flt3 + AML<br>*J Clin Oncol* 40:4048, 2022 | Gilteritinib in AML<br>**FDA approval** |
| Gilteritinib as maintenance in Flt3 + AML<br>*J Clin Oncol* 41:4236, 2023 | Gilteritinib in AML<br>**FDA approval** |

# PUBLICATION IMPACT


| Member | Drug | Disease | Publication | FDA Approval |
|---|---|---|---|---|
| Hussain<br>Hussain<br>Hussain | Enzalutamide<br>Olaparib<br>Darolutamide | Prostate ca<br>Prostate ca<br>Prostate ca | NEJM 2018/ NEJM 2020<br>NEJM2020, NEJM2020<br>NEJM2022 | 2018<br>2020<br>2022 |
| Matei | Chemoradiation | Endometrial | NEJM 2019 | -- |
| Gradishar | Margetixumab | Breast ca | JAMA Oncology 2022 | 2020 |
| Sosman | Pembrolizumab | Renal ca | NEJM 2019 | 2018 |
| Matei | Niraparib | Ovarian ca | Lancet Oncology 2019 | 2018 |

# FACUTLY IMPACT-FDA APPROVALS

| Faculty | Drug | Disease | Approved |
|---|---|---|---|
| Altman | Ivosidenib | AML | 2018 |
| Altman | Gilteritinib | AML | 2018 |
| Benson | Lu 177 dotatate | NET | 2018 |
| Dinner | Moxetumomab | HCL | 2018 |
| Frankfurt | Venetoclax | AML | 2018 |
| Hussain | Enzalutamide | Prostate Ca | 2018 |
| Patel | Larotrectinib | NTRK/Lung | 2018 |
| Pro | Mogamulizumab | CTCL | 2018 |
| Pro | Brentuximab | PTCL | 2018 |
| Ma | Venetoclax | CLL/SLL | 2019 |

| Faculty | Drug | Disease | Approved |
|---|---|---|---|
| Matei | Niraparib | Ovarian | 2019 |
| Gradishar | Margetuximab | Breast | 2020 |
| Hussain | Olaparib | Prostate | 2020 |
| Matei | Olaparib | Ovarian | 2020 |
| Patel | Selpercatinib | NSCLC | 2020 |
| Weinstein | Rylaze | ALL | 2021 |
| Gordon | Lisocabtagene Maraleucel | LBCL | 2022 |
| Gordon | Axicabtagene Ciloleucel | LBCL | 2022 |
| Hussain | Darolutamide | Prostate | 2022 |

Northwestern Medicine®

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

# Thank You