



CLINICAL  
TRIALS  
**TRANSFORMATION**  
INITIATIVE

*October 17, 2019*

# Conduct of Clinical Trials: Drugs and Medical Devices

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# Disclaimer

- The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.
- The presenter is an Employee of Duke University. Salary support comes from pooled membership fees of the Clinical Trials Transformation Initiative and from FDA Cooperative agreement. Is an independent director on the board of TRxAde, Inc and on the Board of the Society of Clinical Trials and sits on the DiMe scientific leadership board.

# Agenda:

- ▶ Medical Product Development
- ▶ Ethical Conduct of Research
  - Good Clinical Practice(GCP - ICH E6)
  - Human Subjects Research Protection (HSRP)
  - Data Monitoring Committees
  - Bioresearch Monitoring (BIMO)
- ▶ Clinical Trials Registration & Results Reporting  
([clinicaltrials.gov](http://clinicaltrials.gov))
- ▶ Patients Organization's role medical product development



Public-Private Partnership  
Co-founded by Duke University &  
FDA

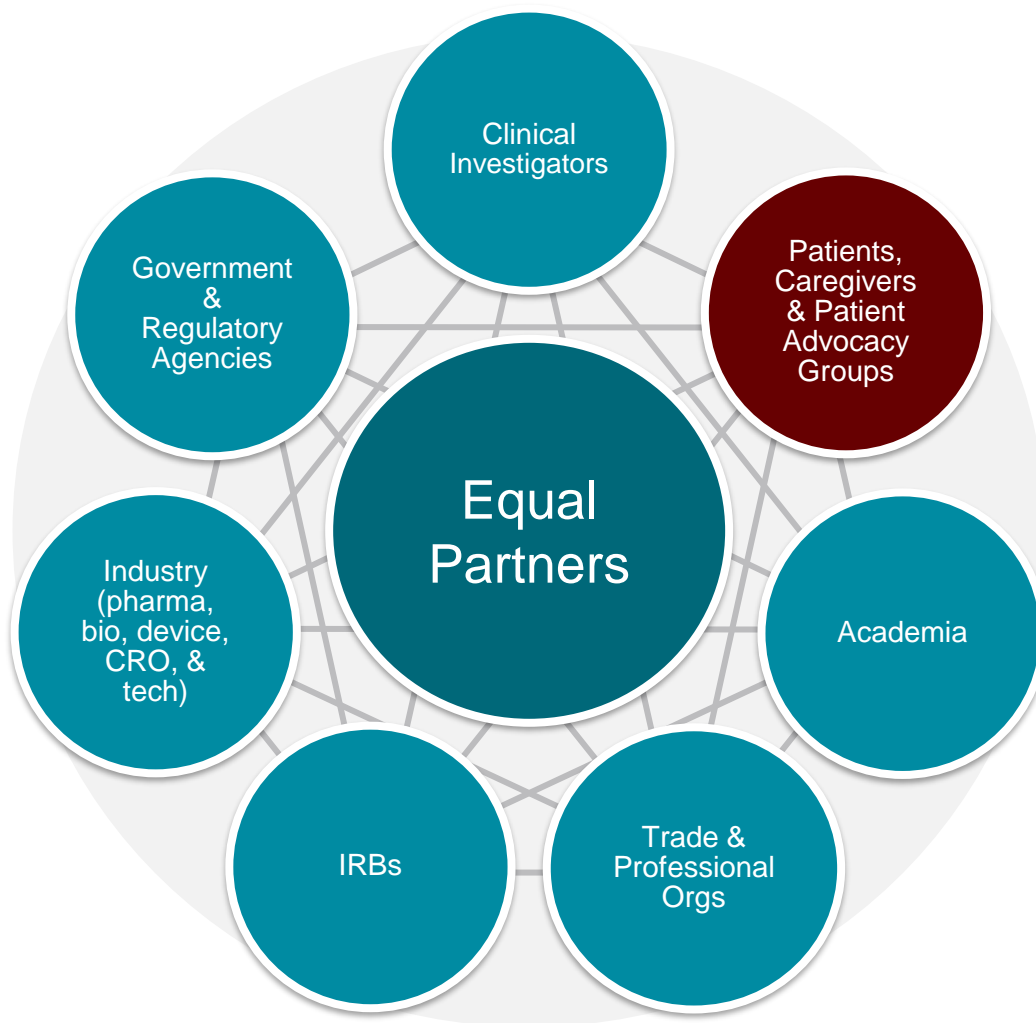
Involves all stakeholders

- Approx. 80+ members
- Participation of 400+ more orgs

**MISSION:** To develop and drive  
adoption of practices that will  
increase the quality and  
efficiency of clinical trials



# Clinical Trials Stakeholders



# CTTI Membership



\*Version: June 26, 2020



# CTTI Activities

## Quality

- ▶ Quality by Design
- ▶ Informing the Update of ICH E6
- ▶ Diversity
- ▶ Analysis of ClinicalTrials.gov
- ▶ Recruitment
- ▶ Planning for Pregnancy Testing
- ▶ State of Clinical Trials Report
- ▶ Monitoring

## Patient Engagement

- ▶ Patient Group Engagement
- ▶ Patient Engagement Collaborative

## Investigators & Sites

- ▶ Investigator Community
- ▶ Investigator Qualification
- ▶ Site Metrics

## Digital Health Trials

- ▶ Novel Endpoints
- ▶ Feasibility Studies Database
- ▶ Digital Health Technologies
- ▶ Decentralized Clinical Trials
- ▶ Engaging Patients and Sites

## Novel Clinical Trial Designs

- ▶ Trials in Health Care Settings
- ▶ Real-World Data
- ▶ Registry Trials
- ▶ Master Protocols
- ▶ Antibacterial Drug Development
- ▶ Large Simple Trials
- ▶ Using FDA Sentinel for Trials

## Ethics & Human Research Protection

- ▶ Single IRB
- ▶ Data Monitoring Committees
- ▶ Informed Consent
- ▶ Safety Reporting



# Medical Product Development



# Patient Group Engagement Across the Clinical Trial Continuum\*

Patient groups have potential to enhance the quality and efficiency of clinical trials by providing:

- Financial support for research
- Natural history data
- Input on relevance of research to patients
- Access to translational tools
- Help defining eligibility criteria
- Input on meaningful endpoints & PROs
- Advocacy for policy & funding issues†
- Education to patient community†

- Support to sponsors around key regulatory meetings
- Support preparing submissions for newborn screening for rare diseases
- Informing regulators on benefit-risk†
- Public testimony at regulatory meetings†

**Discovery & Preclinical†**

**Phase 1 - 3**

**Regulatory Review**

**Postapproval**

- Benefit-risk & patient-preference studies
- Protocol design & study feasibility input
- Study recruitment & retention strategy input
- Increased awareness about trials
- Participant feedback on trial experience
- Input on informed consent content & processes
- Peer advocates for participants†
- Clinical trial networks†
- Data and Safety Monitoring Board members†

Phase 1-3 activities and ...

- Support interpreting & disseminating study results
- Collaboration on post-marketing studies & surveillance initiatives
- Support developing access strategy & preparing for value or health technology review

\*Updated 2018; adapted from Parkinson's Foundation materials | †Patient group activities typically undertaken independently or with partners other than sponsors | ‡Includes early planning for trials

# Clinical Trials

- Clinical trials are an integral part of new product discovery and development
- Required by Regulatory Authorities (the Food and Drug Administration) before a new product can be brought to the market.

Research studies in which one or participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

# Duration of Development (drugs)

## Examples of the Duration and Size of Drugs Successfully Completing Clinical Trials

Drug Name	Treatment for	Years in Clinical Trials	Number of Study Volunteers
Allegra	Seasonal allergy relief	2	3,600
Celebrex	Rheumatoid arthritis	3	13,000
Lipitor	High cholesterol	2.5	20,000
Prilosec	Ulcers, GERO	4	4,000
Viagra	Erectile dysfunction	2.5	3,000
Vibativ	Skin infection	7.2	1,794
Vioxx	Osteoarthritis	4	10,000
Zocor	High cholesterol	2.5	20,000
Zytiga	Prostate cancer	5.3	1,195

Source: CISCRP

# Phases of Clinical Trials

- Phase I trials: Researchers test a drug or treatment in a small group of people (20–80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.
- Phase II trials: The new drug or treatment is given to a larger group of people (100–300) to determine its effectiveness and to further study its safety.
- Phase III trials: The new drug or treatment is given to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.
- Phase IV trials: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population, seeking more information about a drug or treatment's benefits, and optimal use.



# Characteristics of Clinical Trial Phases

	Phase 0 "Exploratory"	Phase I	Phase II	Phase III	Phase IV
Description	First-in-man early trial to determine if drug engages its expected target	Initial safety evaluations, determine safe dosage range, identify common side effects, study toxicity profile of the drug	Begin to explore efficacy while maintaining safety	Final confirmation of safety and efficacy	Any trials conducted after FDA approval of the drug
Number of subjects	10-15 healthy volunteers	20-80 healthy volunteers	100-300 volunteers with the targeted medical condition	1,000-3,000 subjects with the targeted medical condition	Number of subjects depends on trial endpoints
Dose	Single, low dose (<1% of dose calculated to produce a clinical effect)	<ul style="list-style-type: none"> <li>• Single dose</li> <li>• Single ascending dose</li> <li>• Multiple ascending dose</li> </ul>	Multiple dose trials, often conducted against placebo	Multiple dose trials, ascending doses	Variable
Endpoints	Not expected to show clinical effect or significant adverse effects. Helps to choose between competing chemical analogs for further study.	Escalation of dose ends when unacceptable side effects occur; the previous dose is considered the maximum tolerated dose.	Explores clinical effects against the targeted condition, and reveals the less-common side effects	Confirms clinical efficacy of the drug against the targeted condition and evaluates safety and side effects	Confirms clinical efficacy and safety and explores other possible drug uses; may be required as a condition of drug approval
Timing	Can be conducted with prior approval while final IND review is pending	Together with Phase 0 trials, first clinical trials conducted in an IND process	Conducted after report to FDA of results of Phase I trials	Conducted after report to FDA of results of Phase II trials	Conducted after release of the drug by the FDA for marketing

Abbreviations as in Table 3.



**Ethical conduct of Research  
Good Clinical Practice & Human Subjects Research  
Protection**

- Adherence to the principles of good clinical practice (GCP), including human subject research protection (HSRP), is universally recognized as a critical requirement to the ethical conduct of research involving human subjects.
- Participants (vs subjects) in clinical trials
  - An individual who participates in a **clinical trial** either as a recipient of the investigational product(s) or as a control. The term “**subject**” is part of the federal regulation and may be used interchangeably with **participant**

# Good Clinical Practice (ICH E6)

- Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects
- The objective of ICH GCP guidance is to provide a unified standard for the European Union, Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.
- This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.



# ICH

- ▶ The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- ▶ Since 1990, a unique harmonisation effort to:
  - Improve efficiency of **new drug** development and registration process
  - Prevent duplication of clinical trials in humans and minimize use of animal testing ---without compromising safety and effectiveness

# ICH E6: A Global Standard for Clinical Trial Conduct

- **E6: Good Clinical Practice (GCP) – finalized in 1996**
  - Describes the responsibilities and expectations of stakeholders in the conduct of clinical trials.
  - GCP covers aspects of monitoring, reporting, and archiving of clinical trials
  - Addenda for essential documents and investigator brochures
- **E6(R2) – finalized in 2016**
  - Addendum to encourage implementation of improved and more efficient approaches to GCP, while continuing to ensure human subject protections
  - Updated standards for electronic records

## ICH E family of guidelines – need to be read together

### E8 General Considerations for Clinical Trials

#### Design and analysis:

E4 Dose-Response Studies  
E9 Statistical Principles for Clinical Trials  
E10 Choice of Control Group in Clinical Trials  
E17 Multi-Regional Clinical Trials

#### Conduct and reporting:

E3 Clinical Study Reports  
E6 Good Clinical Practice

#### Safety reporting:

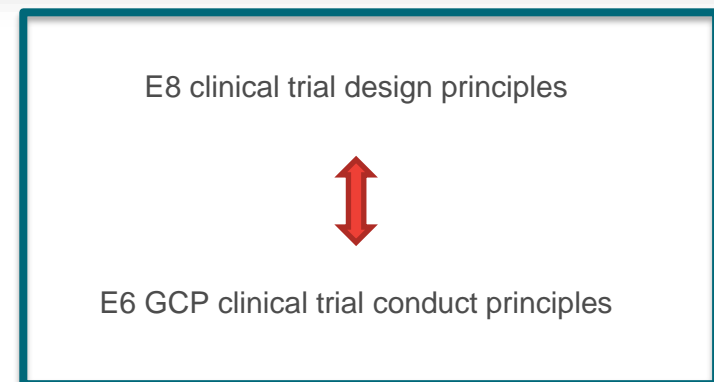
E1 Clinical Safety for Drugs used in Long-Term Treatment  
E2A - E2F Pharmacovigilance  
E14 Clinical Evaluation of QT  
E19 Safety Data Collection

#### Populations:

E5 Ethnic Factors  
E7 Clinical Trials in Geriatric Population  
E11 - E11A Clinical Trials in Pediatric Population  
E12 Clinical Evaluation by Therapeutic Category

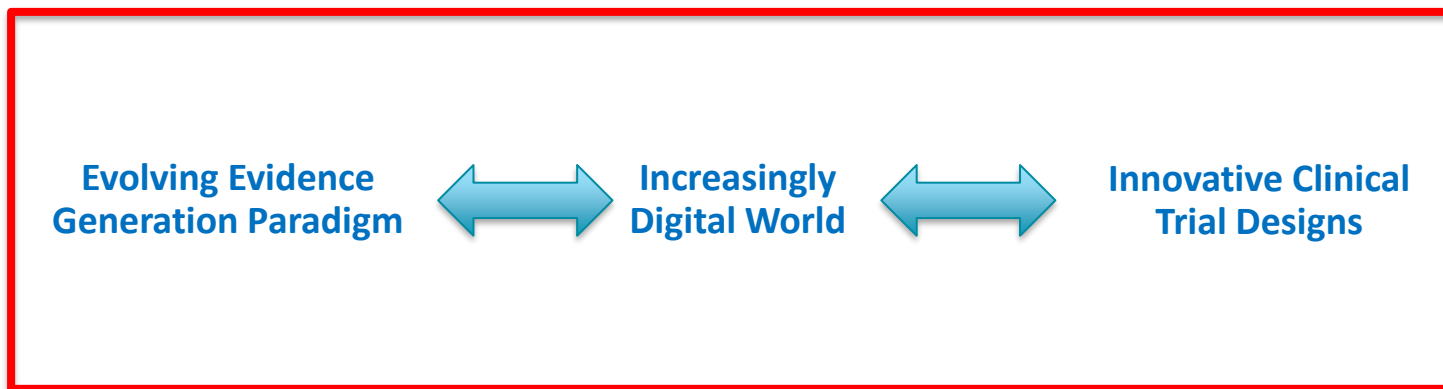
#### Genetics/genomics:

E15 Definitions in Pharmacogenetics / Pharmacogenomics  
E16 Qualification of Genomic Biomarkers  
E18 Genomic Sampling



# ICH E6: An Important Global Standard

## Global Clinical Trials



# Overview of ICH E6(R3) Revisions

## Annex 1 – Interventional Clinical Trials

- Considers principles as they relate to the use of unapproved or approved drugs in a controlled setting with prospective allocation of treatment to participants and collection of trial data

## Annex 2 – Non-traditional Interventional Clinical Trials

- Considers principles as they relate to the use of non-traditional clinical trial designs such as pragmatic clinical trials and decentralized clinical trials, as well as those trials that incorporate real-world data sources



# Human Subject Protection

Data Monitoring Committees

# DMC definitions

- **Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB)** – A group of individuals who review accumulating trial data by treatment group in order to monitor patient safety and efficacy, ensure the validity and integrity of the trial, and make a benefit-risk assessment.
- **External DMC** – An independent group of individuals that conducts these activities outside of the sponsor organization.
- **Internal DMC** – A group of individuals that conducts these activities within the sponsor organization.
- **Data Coordinating Center (DCC)** – A group whose role is to facilitate the collection and quality control of trial data as specified in the protocol
- **Statistical Data Analysis Center (SDAC)** – A group whose role is to prepare statistical analyses of accumulating data, and prepare and present reports of data to the DMC; this group may be within or separate from the organizational structure of the DCC

# Data Monitoring committee (DMC)

- DMCs traditionally have been used to monitor masked, randomized, controlled, multicenter trials that evaluate interventions intended to reduce major morbidity or mortality, whether sponsored by industry, government, or other entities.
- Use of DMCs is not dependent entirely on study size or study phase, but rather on the nature and extent of risk to trial participants.
- DMCs add transparency, and their use may enhance the credibility of trials among both patients and clinicians.
- DMCs typically oversee the conduct of a single trial but they are occasionally asked to review multiple related trials.
- The criteria for when a DMC is necessary are not well defined, and may vary substantially depending on the type of sponsor and their perceived need for independent trial monitoring and oversight.

# Role of the DMC

- ▶ DMCs should be used when there is a need to periodically review the accumulating unmasked safety and efficacy data by treatment group, and advise the trial sponsor on whether to continue, modify, or terminate a trial based on benefit-risk assessment.
- ▶ DMC members should be independent of the trial sponsor and should be provided with adequate resources and flexibility to perform their role of assessing benefit-risk (e.g., performing ad hoc analyses as needed, having full access to accumulating unmasked study data).
- ▶ The rationale for use of a DMC, and the roles, responsibilities, and operational structure of the DMC, should be addressed in a Charter agreed to by the sponsor and the DMC members prior to patient enrollment.
- ▶ The DMC and the SDAC preparing reports for the DMC should have access to all accumulating study data by treatment group beginning at trial initiation. The SDAC should have the flexibility and resources to perform additional analyses that may be requested by the DMC.



# DMC Composition

- Clinician(s) with expertise in the medical area under study, and statistician(s) knowledgeable about clinical trials and statistical monitoring plans are essential members of a DMC.
- Bioethicists and patient advocates may make important contributions to some DMCs. Other types of expertise may be needed in some trials (e.g., pharmacology, toxicology, behavioral science).
- DMC members should have experience in clinical research, and preferably clinical trials.

# Bioresearch Monitoring (BIMO)

FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities. The CPGM's described below form the basis of FDA's Bioresearch Monitoring Program. The purpose of each program is to ensure the protection of research subjects and the integrity of data submitted to the agency in support of a marketing application.

 [CPGM for Clinical Investigators](#)

 [CPGM for Sponsors, Contract Research Organizations, and Monitors](#)

 [CPGM for Institutional Review Boards](#) [1.02 MB]

# Observations: Common Clinical Investigator (US: 600 OUS: 179)

- Failure to follow the investigational plan; protocol deviations
- Failure to comply with Form FDA 1572 requirements
- Inadequate and/or inaccurate case history records; inadequate study records
- Inadequate accountability for the investigational product
- Inadequate subject protection; informed consent issues
- Safety reporting; failure to report and/or record adverse events
- Failure to comply with 21 CFR part 56 (IRB) requirements.

# Observations: IRB (US:140)

- Failure to have minutes of IRB meetings in sufficient detail to show attendance at the meeting; vote actions, quorum issues
- Failure to conform to membership criteria listed in 21 CFR 56.107; membership list
- Failure to conduct initial and/or continuing review of research
- Inadequate written procedures for prompt reporting of non-compliance, suspension or termination
- Failure to prepare and maintain documentation of IRB activities; inadequate copies of research proposals and related documents

# Observations: Sponsor/Monitor/CRO (US: 108 OUS: 5)

- Failure to select qualified investigators and/or monitors, ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan. (General responsibilities of sponsors)
- Failure to maintain and/or retain adequate records in accordance with 21 CFR 312.57; accountability for the investigational product.
- Failure to bring non-compliant investigators into compliance



# Clinical Trials.gov

# Key Clinical Trial Reporting Requirements

Reporting Requirement	ICMJE Policy (Effective in 2005)	FDAAA & Regulations (Effective 2007 & 2017)	Final NIH Policy (Effective 2017)
<b>What</b>	Registration*	Registration & results reporting	Registration & results reporting
<b>Scope</b>	Clinical trials (any)	Applicable clinical trials	Clinical trials (NIH-funded)
<b>Phase</b>	All	<u>Not</u> Phase 1 and device feasibility	All
<b>Intervention Type</b>	All	Drug, biological, & device products regulated by the FDA	All (including behavioral interventions)
<b>Enforcement</b>	Refusal to publish	Criminal proceedings and civil penalties (up to \$10,000/day); loss of HHS funding	Withholding/loss of NIH funding

\*ICMJE policy also: (1) **expects** compliance with results reporting requirements and (2) **encourages** results reporting for all other trials

# Other Clinical Trial Reporting Policies

- ▶ **World Health Organization (WHO)** considers registration to be a “scientific, ethical and moral responsibility” and states that there is an ethical imperative to report results
- ▶ **European Union (EU)** requires registration and results reporting of certain European Medicines Agency (EMA)-regulated drug and biologic clinical trials
- ▶ **Center for Medicare and Medicaid Services (CMS)** requires NCT Number for coverage of routine costs of qualifying clinical trials
- ▶ **U.S. Department of Veterans Affairs (VA)** requires registration and results reporting of clinical trials funded by the VA Office of Research & Development
- ▶ **Patient-Centered Outcomes Research Institute (PCORI)** requires registration and results reporting for interventional studies that it funds



# ClinicalTrials.gov Reporting Volume

(as of 5 February 2018)

## Registration

- 265,000 study records (including observational)
- 600 submissions/week
- 17,500 data providers (sponsors and investigators)

## Summary Results Reporting

- 30,000 records with results posted
- 140 submissions/week
- 3,000 data providers

## Usage Stats

- 244M hits per month
- 171M page views per month
- 93K unique visitors per day

# Homepage - ClinicalTrials.gov Updates

A. Search for all studies or only those that are or will be recruiting participants

B. Search for studies within a certain distance of a city



NIH U.S. National Library of Medicine  
**ClinicalTrials.gov** Find Studies About Studies Submit Studies Resources About Site

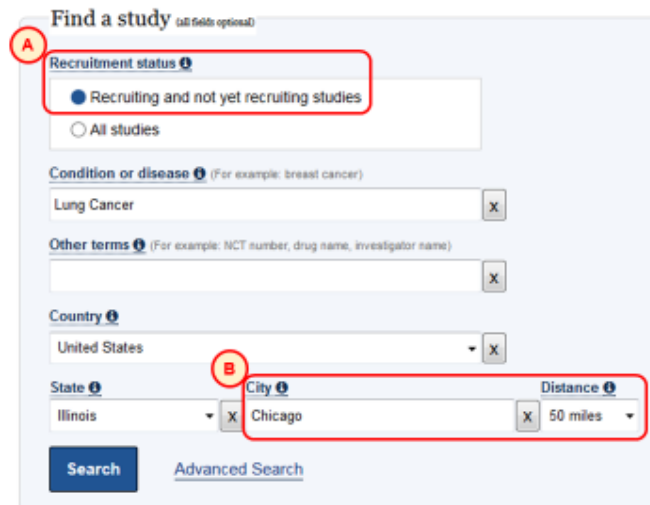
ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 254,799 research studies in all 50 states and in 200 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

**IMPORTANT:** Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).



Find a study (all fields optional)

**A** Recruitment status ⓘ  
 Recruiting and not yet recruiting studies  
 All studies

Condition or disease ⓘ (For example: breast cancer)  
Lung Cancer X

Other terms ⓘ (For example: NCT number, drug name, investigator name)  
X

Country ⓘ  
United States X

State ⓘ Illinois X

**B** City ⓘ Chicago X Distance ⓘ 50 miles X

Search Advanced Search

[Help](#) [Studies by Topic](#) [Studies on Map](#) [Glossary](#)

# Search Results - ClinicalTrials.gov

## Updates

### A. Search summary

- Number of study records found meeting criteria
- Synonyms used
- Filters applied

### B. Modify search

### C. List of study records

### D. Start over option

The screenshot shows the ClinicalTrials.gov search results page. The page header includes the NIH logo and the text "U.S. National Library of Medicine ClinicalTrials.gov". Navigation links for "Find Studies", "About Studies", "Submit Studies", "Resources", and "About Site" are visible. The search results section shows "38 Studies found for: Recruiting, Not yet recruiting Studies | Lung Cancer | within 50 miles of Chicago, Illinois, U.S.". Below this, there are buttons for "Modify Search" (labeled B) and "Start Over" (labeled D). A summary box (labeled A) displays the search criteria and applied filters: "Applied Filters:  Recruiting  Not yet recruiting". A table (labeled C) lists the search results with columns for Row, Saved, Status, Study Title, Conditions, Interventions, and Locations. The table shows three rows of study records. The first row is for a study on Stereotactic Body Radiation Therapy for Un-biopsied Early-Stage Non-Small Cell Lung Cancer. The second row is for a study evaluating Concurrent or Sequential Ipilimumab, Nivolumab, and Stereotactic Body Radiotherapy in Patients With Stage IV Non-Small Cell Lung Cancer. The third row is for a study on Nivolumab and Urokinase Hydrochloride in Treating Patients With Stage II-IV Non-small Cell Lung Cancer That Cannot Be Removed by Surgery. The table also includes a "Filters" sidebar on the left with options for Recruitment Status and Clinical Study type.

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	<a href="#">Stereotactic Body Radiation Therapy for Un-biopsied Early-Stage Non-Small Cell Lung Cancer</a>	• Non-Small Cell Lung Cancer	• Radiation: Group 1: Peripherally Located Tumors • Radiation: Group 2: Peripherally Located Chest Wall Adjacent Tumors • Radiation: Group 3: Centrally Located Tumors	• Loyola University Medical Center Maywood, Illinois, United States
2	<input type="checkbox"/>	Recruiting	<a href="#">Evaluate Concurrent Or Sequential Ipilimumab, Nivolumab, and Stereotactic Body Radiotherapy in Patients With Stage IV Non-Small Cell Lung Cancer</a>	• Stage IV Non-Small Cell Lung Cancer	• Drug: Nivolumab • Drug: Ipilimumab • Radiation: Stereotactic body radiation therapy	• University of Chicago Chicago, Illinois, United States
3	<input type="checkbox"/>	Not yet recruiting	<a href="#">Nivolumab and Urokinase Hydrochloride in Treating Patients With Stage II-IV Non-small Cell Lung Cancer That Cannot Be Removed by Surgery</a>	• Recurrent Non-Small Cell Lung Carcinoma • Stage II Non-Small Cell Lung Cancer • Stage III Non-Small Cell Lung Cancer	• Other: Laboratory Biomarker Analysis • Drug: Metformin Hydrochloride • Biological: Nivolumab	• Northwestern University Chicago, Illinois, United States

# Glossary - ClinicalTrials.gov Updates

- A. Icons to help identify when a glossary entry is available
- B. Description of term
- C. Search box

**Sponsor:**  
Northwestern University

**Collaborators:**  
Bristol-Myers Squibb  
National Cancer Institute (NCI)

**Information provided by (Responsible Party):**  
Northwestern University

**Study Details** | **Tabular View** | **No Results Posted** | Disclaimer | How to Read a Study Record

**Study Description**

**Brief Summary:**  
The purpose of this study is to find the benefits of combining nivolumab with metformin in advanced non-small cell lung cancer with also be looking at the safety of the combination. Nivolumab is currently approved in certain cancers such as melanoma, lung cancer, and colorectal cancer. Metformin is currently approved by the U.S. Food and Drug Administration (FDA) to treat diabetes. In this study, Metformin is being used to treat cancer. This use is not approved by the U.S. Food and Drug Administration (FDA). Experimental means the U.S. FDA has not approved the drug for use in your type of cancer. Nivolumab is an antibody (protein) that blocks a protein (PD-1) on immune cells (T-cells) designed to allow the body's immune system to work against tumor cells. It is believed that metformin has immune system. As a result, it may help certain cancer treatments, known as immunotherapy, to work better.

Condition or disease	Intervention/treatment
Recurrent Non-Small Cell Lung Carcinoma	Other: Laboratory Biomarker Analysis
Stage II Non-Small Cell Lung Cancer	Drug: Metformin Hydrochloride
Stage IIIA Non-Small Cell Lung Cancer	Biological: Nivolumab
Stage IIIB Non-Small Cell Lung Cancer	
Stage IV Non-Small Cell Lung Cancer	

**Glossary**

Study record managers: refer to the [Data Element Definitions](#) if submitting registration or results information.

Search for terms

intervention/treatment

**Intervention/treatment**

A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.



# Patients in product development

# Patient Group Engagement Across the Clinical Trial Continuum\*

Patient groups have potential to enhance the quality and efficiency of clinical trials by providing:

- Financial support for research
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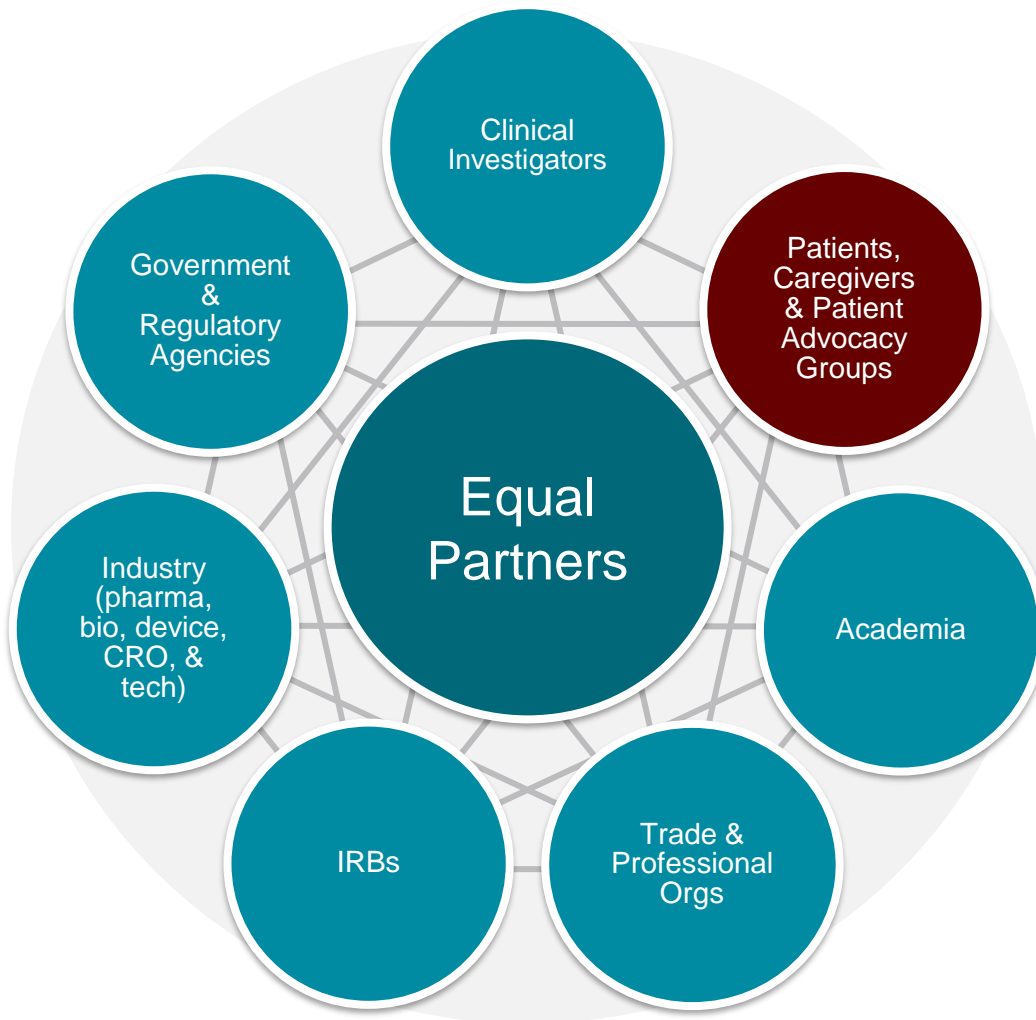
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# Clinical Trials Stakeholders



➤ CDRH/CBER 2019 draft guidance: “FDA believes medical device clinical investigations prospectively designed with input from patient advisors may help to address common challenges.”

➤ ICH E8(R1) 2019 draft: “Clinical study design is best informed by input from a broad range of stakeholders, including patients and treating physicians.”



# Patient Engagement at CTTI



Normed (no question) inclusion of patients as equal partners into every aspect of clinical trial (reform)

Full integration into the Steering Committee in 2015  
Individual patients reimbursed for time on CTTI activities including projects



Patient/caregivers on project teams have played critical role in shaping projects



Co-founded Patient Engagement Collaborative with FDA



Almost all CTTI recommendations to date include a recommendation to involve all stakeholders, particularly patients, in the process



# CTTI Resources Developed for Engaging Patient Groups in Clinical Trials

## Identifying Best Practices

- ▶ Recommendations: Effective Engagement with Patient Groups Around Clinical Trials
- ▶ Implementation resources
  - Patient Group Organizational Expertise and Assets Evaluation
  - Assessment of Patient Group Internal Aspects
  - Assessment of Patient Group External Relationships

## Describing Value & Impact

- ▶ Economic model to quantify the financial value of patient engagement
- ▶ Online prioritization tool for identifying high-value engagement opportunities

# CTTI Patient Engagement Resources



## Economic Model:

[https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/new\\_ctti\\_resource\\_26feb2020\\_final.pdf](https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/new_ctti_resource_26feb2020_final.pdf)



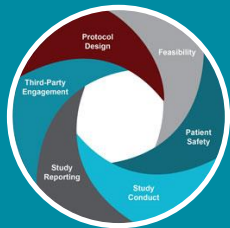
## Prioritization Web Tool:

<https://prioritizationtool.ctti-clinicaltrials.org/>

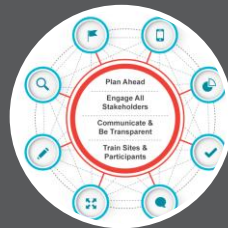


## Recommendations: Realizing the Value of Effective Patient Group Engagement

<https://www.ctti-clinicaltrials.org/projects/patient-groups-clinical-trials>



Quality by Design  
(QbD)



Mobile Clinical  
Trials



Patient  
Engagement  
Collaborative

Additional Resources for Engaging Patients in Clinical Trials



## Patient Engagement Collaborative



Patient Engagement Collaborative (PEC) brings together diverse representatives from the patient community to meet with the FDA several times a year and discuss how to achieve more meaningful patient engagement in medical product development and other regulatory discussions. The PEC, launched in December 2017, is a joint effort of CTTI and the FDA.



# THANK YOU.



Webinar recording & slides available at:

<https://www.ctti-clinicaltrials.org/briefing-room/webinars>



[www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org)

Sign up to receive CTTI's monthly e-newsletter for updates.