

Website Functionality Panel

Rebecca J. Williams

ClinicalTrials.gov

Alissa Gentile

The Leukemia and Lymphoma Society

Seth A. Morgan

National Multiple Sclerosis Society

Steven Woloshin

The Dartmouth Institute

Stephen J. Rosenfeld

Secretary's Advisory Committee on Human
Research Protections (SACHRP)

Website Functionality Session Goals

- Share the responses and top themes from the RFI
- Provide perspectives from panelists on user needs related to website functionality
- Obtain further input from meeting participants on topics related to RFI themes

RFI Topic 2: Website Functionality

NLM sought broad input on the [ClinicalTrials.gov](https://clinicaltrials.gov) website, including its [application programming interface](#) (API).

- a. Examples of unsupported, **new uses** of the ClinicalTrials.gov website
- b. Resources for possible **linking** from ClinicalTrials.gov (e.g., publications, systematic reviews, de-identified individual participant data, general health information)
- c. Examples of **current uses** of the ClinicalTrials.gov website
- d. Description of whether primary use of ClinicalTrials.gov relies on a **scope** of (1) wide range of studies, or (2) more limited range of studies.

Website Functionality

Facilitate use of information to help public and researchers find studies of interest

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 331,715 research studies in all 50 states and in 209 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)

Status ⓘ
 Recruiting and not yet recruiting studies
 All studies

Condition or disease ⓘ (For example: breast cancer)

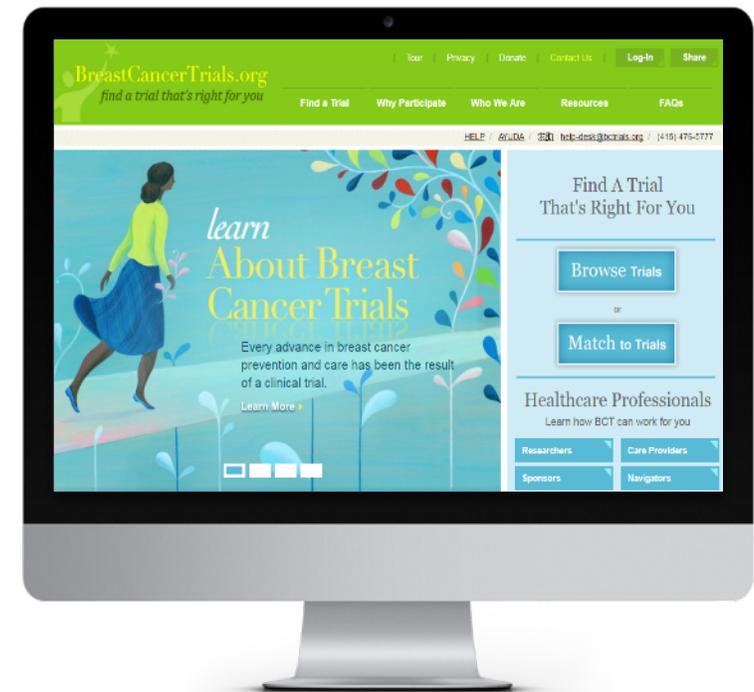
Other terms ⓘ (For example: NCT number, drug name, investigator name)

Country ⓘ

[Search](#) [Advanced Search](#)

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

ClinicalTrials.gov API



API Beta Key Features

- Supports 3rd party use of site content
- Over 300 search fields available (current API only has 24 key fields)
- Formats:
 - XML, JSON, SVI, tree
- Query and Info URLs
- Documentation available
- Interactive training demos
- <https://clinicaltrials.gov/api/gui>

NIH U.S. National Library of Medicine
ClinicalTrials.gov API API Home (BETA)

The ClinicalTrials.gov BETA application programming interface (API) is being made available for beta testing and feedback. After further development, it is intended to replace the current API.
If you are looking for information about clinical studies, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

ClinicalTrials.gov main site

The ClinicalTrials.gov application programming interface (API) provides a toolbox for programmers and other technical users to use to access all posted information on ClinicalTrials.gov study records data. The API is designed for encoding simple and complex search expressions and parameters in URLs. Clicking on query URLs retrieves study records from ClinicalTrials.gov. Use of ClinicalTrials.gov data is subject to these [Terms and Conditions](#).

If you are looking for information about clinical studies, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

Documentation

Use the following links to learn about the ClinicalTrials.gov API.

Link	Description
API URLs	List of info URLs for accessing information about the API and query URLs with parameters.
Query URL Responses	Description of information returned by query URLs.

Interactive Demonstrations

Use the following demonstrations to explore and develop the three types of [query URLs](#) available for accessing different levels of API data from ClinicalTrials.gov.

Query URL Type	Description	Example
Full Studies	Retrieves all content from the first study record returned for a submitted query by default. Returns up to 100 study records per query when the minimum rank and maximum rank parameters are set in a query URL and up to 100,000 records using the Full Studies interactive demonstration.	https://ClinicalTrials.gov/api/query/full_studies?expr=heart+attack
Study Fields	Retrieves the values of one or more fields from up to 100,000 study records returned for a submitted query by default. Returns up to 1,000 study records per query when the minimum rank and maximum rank parameters are set in a query URL and up to 100,000 records using the Study Fields interactive demonstration.	https://ClinicalTrials.gov/api/query/study_fields?expr=heart+attack&fields=NCTId,Condition,BriefTitle
Field Values	Retrieves a unique list of values for one study field from all study records returned for a submitted query.	https://ClinicalTrials.gov/api/query/field_values?expr=heart+attack&field=Condition

CURRENT API VERSION 1.01.01 [REPORT PROBLEM](#)

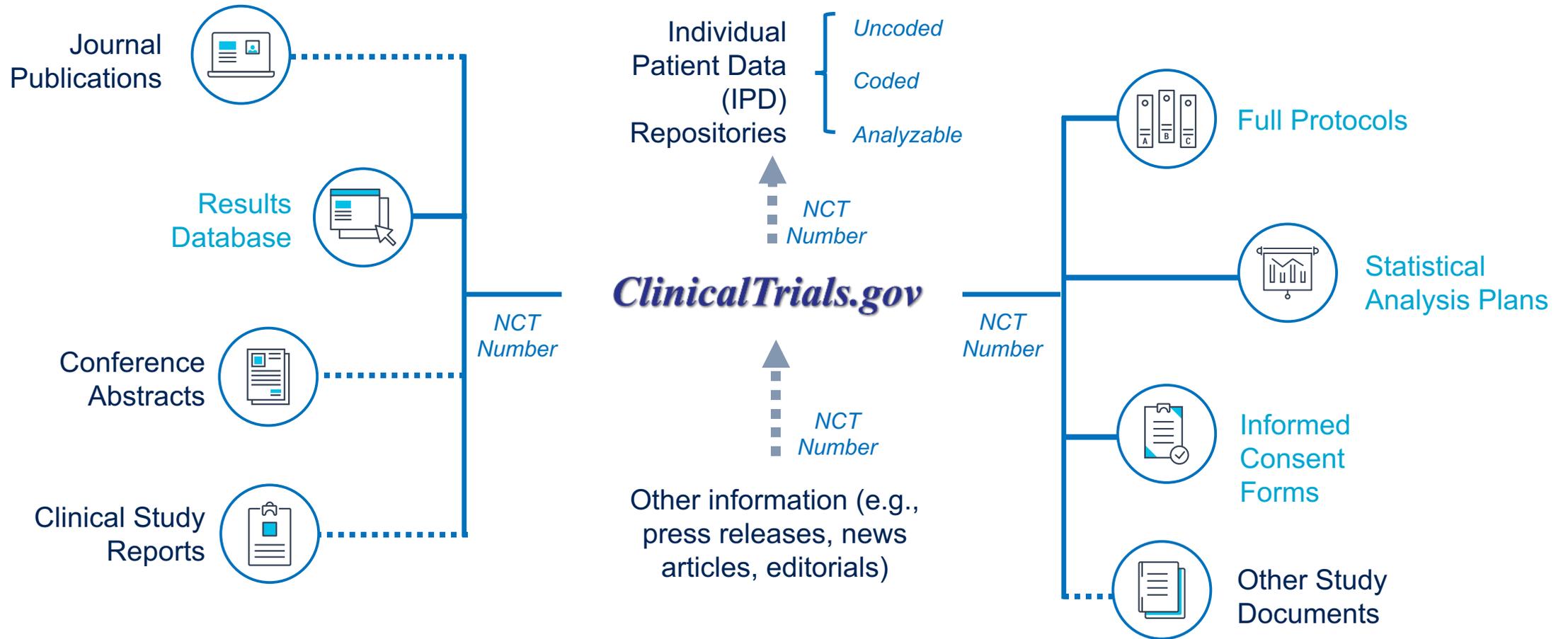
[Copyright](#) | [Privacy](#) | [Accessibility](#) | [Freedom of Information Act](#) | [USA.gov](#)
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health and Human Services

Website Functionality: RFI Responses

Number of Comments by Sub-question



ClinicalTrials.gov: Information Scaffold



Website Functionality

1a. New Uses

List specific examples of unsupported, new uses of the ClinicalTrials.gov website

Top Comments

Website Function	Percent	Comments
Study Record	19.7%	51
Alert	11.2%	29
Search Field	11.2%	29
Search	8.9%	23
Search Results	8.5%	22
Search – Manage	5.8%	15
Downloading Content for Analysis	5.0%	13
Results Narrative Summaries	4.2%	11
General	3.1%	8
Others	22.4%	58

Website Functionality 1c. Current Uses

Provide specific examples of how you currently use ClinicalTrials.gov, including potential improvements

Top Comments

Website Function	Percent	Comments
Study Record	16.9%	51
Search	11.3%	34
Search Field	9.3%	28
Usability	7.6%	23
General	5.0%	15
Data Quality	4.7%	14
Search Results	4.3%	13
Downloading Content for Analysis	4.3%	13
Search Filter	4.0%	12
Others	32.6%	98

| Top Response Themes

- Search options and managing search results
- Study record format and content
- Plain language information

Theme: Search Options and Managing Search Results (with selected examples)

Make search more user friendly

Step-by-step approach to building a search query

Customize approach for user type (e.g., patients and researchers)

Simplify

Add more options to search

Existing structured data elements (e.g., intervention type, study purpose)

Existing non-structured data elements (e.g., eligibility criteria)

Other: disease subtype; genetic mutation or biomarker

Improve tools for managing search results

Sorting and more filtering capabilities

Formats for downloading search results

Notifications about updates to saved searches

| Search Function

“

Most Federal sites have poor search engines. I have been very impressed with the quality of the ClinicalTrials.gov website search engine. It is worth continuing to enhance it ... because it enables you to find the study you are interested in reviewing”

“The search functions are not user-friendly with respect to finding outcomes for a particular topic. Bringing [search] functionality into the 21st century with search engines and functions like Google, Siri, Alexa is far more likely to serve the general public than the current interface.”

Theme: Study Record Format and Content (with selected examples)

Standardize more content

Examples: interventions, eligibility criteria

More prominently display certain content

Examples: eligibility criteria, funding sources, study status, contact information, updates

Make more content available

Videos to explain specific studies

Study locations displayed on a map

Out-of-pocket costs and payment to participants

Potential risks of study participation

Add features to make using content easier

Sharing study record content with others

Printer-friendly formats

| Standardize more content

“The biggest issue is the use of different nomenclature and names of indications”

“Using consensus common data elements (CDE) for outcomes would also be helpful, but we recognize that these are largely field specific.”

Theme: Plain Language Information (with selected examples)

**General health
information and
learning about
study
participation**

**Resources for
using site
features (for
patients and
researchers)**

**Study record
content, including
study
descriptions and
study results**

| Plain language information

**“The presentation on
ClinicalTrials.gov can be made more
user-friendly by use of graphics and/or
lay language”**

**“Healthy literacy and plain language
need to be applied to all content”**



Alissa Gentile, MSN, RN

Director of the CTSC,
The Leukemia and
Lymphoma Society

The Leukemia and Lymphoma Society Clinical Trial Support Center (CTSC)

Clinical Trial Nurse Navigators increase patients' opportunities for clinical trial participation by facilitating informed decision-making and minimizing logistical barriers for the patient and family.

Patients/providers access the Clinical Trial Support Center (CTSC)

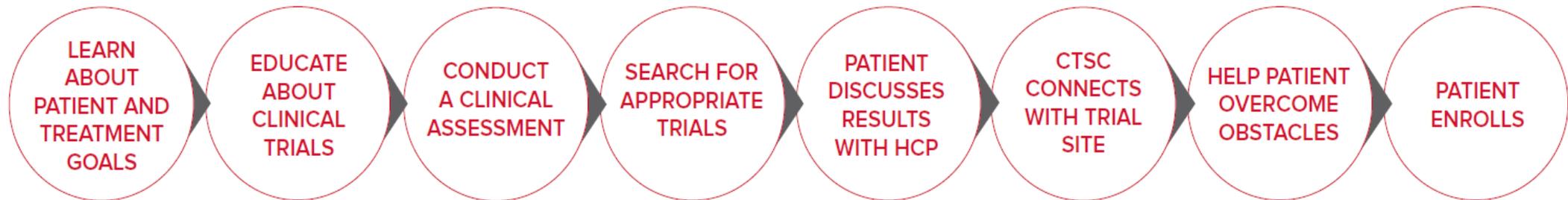
- Call the Information Resource Center (IRC) **1-800-955-4572**
- Patient or caregivers can also fill out the referral form online
<https://www.lls.org/navigation>
- American Society of Hematology (ASH) physicians can access the portal at
<https://www.hematology.org/clinicaltrialnavigation/>

Process for Supporting Patients



CLINICAL TRIAL SUPPORT CENTER (CTSC)

Process for Supporting Patients



Use of ClinicalTrials.gov Information in the Process

- Search all the fields within CTG
- Brief summary
- Eligibility requirements
- Sites and Site contacts
- NCT number links to CTG
- Study results (links to articles)

- CTSC Personalized Search for the Patient/Provider

The results of the clinical trial search are below. I have provided contact information for each trial, a brief description and when appropriate, **specific eligibility requirements that are important to consider**. If you are interested in any of these trials, I am happy to reach out on your behalf to learn more about your potential eligibility. You will see in **green** where I have reached out to the trial coordinator to discuss whether or not the trial accepts patients with CNS involvement and I have not received a response yet. Once I do receive a response, I will update you accordingly. **CAR-T trials are highlighted with an orange bar on the left hand side**. Over time trials may change, there may be additional trials open, or some may have closed. We can update this search at any time. Please let me know if you would like an updated or expanded search for you any time, I will be happy to do so for you. If you need a different search, i.e. treatment naive CLL after your doctor's appointments, I am also happy to do this for you. Below I have also included information on CLL, CAR-T therapy, and clinical trials.

To access more information about a particular trial, click on the **blue NCT number**. This will bring you to the individual trial page. Here you will find a list of centers where the trial is taking place and some general information about the protocol. If you have any questions about the search information, please let me know. As I mentioned, I can help facilitate communication with the sites/MD regarding enrollment or any trial questions you may have.

Selinexor and Ibrutinib in Treating Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia or Aggressive Non-Hodgkin Lymphoma
NCT02303392 Phase I **Open**

This phase I trial studies the side effects and best dose of selinexor when given together with ibrutinib in treating patients with chronic lymphocytic leukemia or aggressive non-Hodgkin lymphoma that has returned after a period of improvement or does not respond to treatment.

Significant Eligibility Requirements:

- CLL with at least one prior therapy that is relapsed or refractory.
- ECOG 0-2.
- **Patients with known CNS involvement of CLL or lymphoma are excluded but patients with history of CNS CLL or lymphoma now in remission are eligible for the trial**

Huntsman Cancer Institute Salt Lake City, UT 84112 Open	Trial contact: The Ohio State Comprehensive Cancer Center Tel: 1-800-293-5066 Email: OSUCCColinias@osu.edu	Arthur G. James Cancer Hospital and Solove Research Institute at Ohio State University Medical Center Columbus, OH 43210 Open	Trial contact: The Ohio State Comprehensive Cancer Center Tel: 1-800-293-5066 Email: OSUCCColinias@osu.edu
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Study of Immunotherapy in Combination With Ublituximab and Umbralisib in Patients With Relapsed-refractory CLL or Richter's Transformation
NCT02535286 Phase I/II **Open**

The purpose of this study is to evaluate the safety and effectiveness of targeted immunotherapy in combination with ublituximab and umbralisib, in patients with advanced CLL or Richter's Transformation.

Significant Eligibility Requirements:

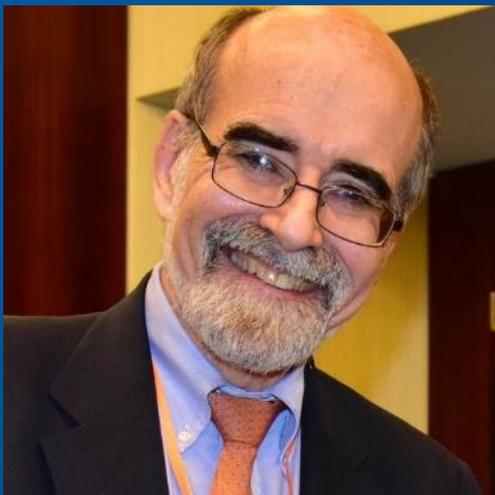
- Confirmed diagnosis of B-cell CLL that is refractory or relapsed after at least 1 prior treatment regimen
- ECOG 0-2.

Emailed TG Therapeutics regarding whether CNS involvement is allowed on this trial

University of Pennsylvania Philadelphia, PA 19104 Open	Teresa Waite, RN Email: Teresa.Waite@uphs.upenn.edu
	Tanya Letorre, RN Email: tanya.letorre@uphs.upenn.edu

| Clinical Trial Support Center (CTSC)

- The goal of the CTSC is NOT to enroll every patient into a trial, rather to increase the opportunities for participation by facilitating informed decision-making and minimizing logistical barriers for the patient.
- CTSC nurses work in collaboration with the patient's healthcare team to decide if a clinical trial is right for them.
- Ultimately, CTSC nurses educate, support, and empower patients to be active participants in, and have control over, their treatment decisions.



Seth A. Morgan, MD

National Multiple
Sclerosis Society

The Patient Perspective

| The Patient Perspective

“Fear of the future will likely rear its ugly head more often than you’d like...It can be difficult to keep your mind from wandering to a very dark place.” —Debi Wilson

“People are afraid of the dark because they don’t know what’s in it. People are afraid of the unknown.” —Matt Allen G

“More time on the internet caused my fear to spiral out of control.” —Judy Lynn

| The Patient Perspective

**“How can I save myself from despair?
How can I take back control of my
body, mind, and spirit?”**

—Cathy Chester

| The Patient Perspective

| Quotes NOT about COVID-19;

| Chronic, irreversible, and unpredictable future
with Multiple Sclerosis

| The Frantic Fear of chronic disease

| The Patient Perspective

Denial

Depression

Withdrawal

Grieving

Education about disease

Consideration of research participation

Grasping for anything regardless of scientific validity or risk potential

| The Patient Perspective

Access to research options

Gives hope

May present risks of modern day “snake oil salesmen”



Steven Woloshin, MD

Director of the Center for
Medicine and the Media,
The Dartmouth Institute &
Lisa Schwartz Foundation for
Truth in Medicine

Making Sense of Results

ClinicalTrials.gov Modernization Public Meeting

Disclosures

No industry funding.

Senior Scientific Consultant, NCI, Division of Cancer Control and Population Sciences, and Office of Communications and Public Liaison

Opinions expressed in this presentation are my own and do not reflect the view of the National Institutes of Health, the Department of Health and Human Services, or the United States government.

Cooking ~~Research~~

GOAL

Apple pie

Recipe



Follow recipe



Dessert!



Question

Does this sleeping pill work?

Protocol

Design, subjects,
Intervention(s)
Analysis plan

Implement protocol



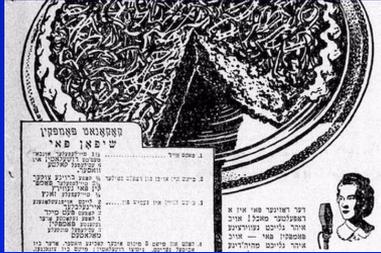
Results

Research

GOAL

Apple pie

Recipe



Follow recipe



Dessert!



Question

Does this sleeping pill work?

Protocol

Design, subjects, Intervention(s) Analysis plan

Implement protocol



Results

ClinicalTrials.gov

[Home](#) > [Advanced Search](#)

Saved Studies (3)

Advanced Search

Fill in any or all of the fields below. Click on the label to the left of each search field for more information or read the [Help](#)

Search [Help](#)

Condition or disease: insomnia

Other terms:

Study type: Interventional Studies (Clinical Trials)

Study Results: Studies With Results

Status:

Recruitment:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status

Expanded Access:

- Available
- No longer available
- Temporarily not available
- Approved for marketing

[Home](#) > [Search Results](#) > Study Record Detail Save this study

Saved Studies (3)

Trial record **8 of 166** for: [Studies With Results](#) | [Interventional Studies](#) | [insomnia](#)[◀ Previous Study](#) | [Return to List](#) | [Next Study ▶](#)**A Phase III Study of Eszopiclone in Patients With Insomnia (Study SEP 190-150)**

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT00770692

[Recruitment Status](#) ⓘ : Completed[First Posted](#) ⓘ : October 10, 2008[Results First Posted](#) ⓘ : November 22, 2012[Last Update Posted](#) ⓘ : November 22, 2012**Sponsor:**

Eisai Co., Ltd.

Information provided by (Responsible Party):

Eisai Inc. (Eisai Co., Ltd.)

Study Details

Tabular View

Study Results

Disclaimer

? How to Read a Study Record

Study Description

Go to

Brief Summary:

The purpose of this study is to evaluate the long-term safety of eszopiclone (2, 3 mg) in non-elderly patients with insomnia and eszopiclone (1, 2 mg) in elderly patients with insomnia.

Condition or disease i	Intervention/treatment i	Phase i
Insomnia	Drug: Eszopiclone 1 mg- Elderly Drug: Eszopiclone 2 mg- Elderly Drug: Eszopiclone 3 mg- Non-elderly Drug: Eszopiclone 2 mg- Non-elderly	Phase 3

Detailed Description:

This is a multicenter, randomized, double-blinded study to evaluate the long-term safety of SEP-190 (2, 3 mg) in non-elderly patients with insomnia and SEP-190 (1, 2 mg) in elderly patients with insomnia.

Study Design

Go to

Study Type [i](#) : **Interventional**

Actual Enrollment [i](#) : 369 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Double (Participant, Investigator)

Primary Purpose: Treatment

Official Title: A Phase III Study of SEP-190 (Eszopiclone) in Patients With **Insomnia**

Study Start Date [i](#) : October 2008

Actual Primary Completion Date [i](#) : May 2010

Actual Study Completion Date [i](#) : May 2010

Links to glossary would be nice!

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double (Participant, Investigator); Primary Purpose: Treatment
Condition	Insomnia
Interventions	Drug: Eszopiclone 1 mg- Elderly Drug: Eszopiclone 2 mg- Elderly Drug: Eszopiclone 3 mg- Non-elderly Drug: Eszopiclone 2 mg- Non-elderly
Enrollment	369

Participant Flow

Go to

Recruitment Details	
Pre-assignment Details	181 non-elderly & 188 elderly participants were enrolled in the screening period 1 week prior to the first dose. Among these, 20 non-elderly & 24 elderly participants discontinued during the screening period. 161 non-elderly and 164 elderly participants enrolled. 1 elderly participant enrolled for treatment did not receive treatment.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
▼ Arm/Group Description	Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.	Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.

Period Title: Overall Study				
	Started ^[1]			
Completed	69	74	70	66
Not Completed	12	9	14	11
Reason Not Completed				
Withdrawal by Subject	7	9	9	6
Adverse Event	3	0	4	4
Investigator Judgment	2	0	1	1

^[1] 1 participant whose compliance was unknown, was regarded as a "treatment compliance unknown"

Baseline Characteristics

Go to

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly	Total
▼ Arm/Group Description	Elderly participants: Eszopiclone 1 mg	Elderly participants: Eszopiclone 2 mg	Non-elderly participants:	Non-elderly participants:	Total of all reporting groups

Outcome Measures

1. Primary Outcome

Title	Incidence of Adverse Events
▶ Description	Incidence of adverse eve...
Time Frame	Up to 25 weeks (24 weeks treatment period & 1 week follow-up)

▶ Outcome Measure Data

2. Secondary Outcome

Title	Mean Change From Baseline In Sleep Latency
▶ Description	Based on subjective symptoms, the participants recorded their sleep la...
Time Frame	Baseline (screening period) and 4 weeks of treatment

▶ Outcome Measure Data

3. Secondary Outcome

Title	Mean Change From Baseline in Wake Time After Sleep Onset (WASO)
▶ Description	Based on subjective symptoms, the participants recorded their WASO def...
Time Frame	Baseline (screening period) and 4 weeks of treatment

▶ Outcome Measure Data

4. Secondary Outcome

Title	Mean Change From Baseline in Total Sleep Time
▶ Description	Based on subjective symptoms, the participants recorded their total sl...
Time Frame	Baseline (screening period) and 4 weeks of treatment

▶ Outcome Measure Data

5. Secondary Outcome

Title	Mean Change From Baseline in Total Number of Awakenings
▶ Description	Based on subjective symptoms, the participants recorded their number o...
Time Frame	Baseline (screening period) and 4 weeks of treatment

▼ Arm/Group Description	Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.	Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.	Total of all reporting groups
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Overall Number of Baseline Participants	80	83	84	77	324
▼ Baseline Analysis Population Description	[Not Specified]				

Age Continuous Mean (Standard Deviation) Unit of measure: Years					
Number Analyzed	80 participants	83 participants	84 participants	77 participants	324 participants
	70.4 (4.5)	70.7 (4.7)	40.1 (10.8)	41.9 (11.5)	55.6 (17.1)

Sex: Female, Male					
Measure Type: Count of Participants Unit of measure: Participants					
Number Analyzed	80 participants	83 participants	84 participants	77 participants	324 participants
Female	45 56.3%	49 59.0%	55 65.5%	36 46.8%	185 57.1%
Male	35 43.8%	34 41.0%	29 34.5%	41 53.2%	139 42.9%

Outcome Measures

Go to

1. Primary Outcome

Title	Incidence of Adverse Events
▼ Description	Incidence of adverse events was defined as: (number of participants with adverse events/ number of participants analyzed in the safety analysis set)*100. An adverse event was defined as any unwanted or untoward disease or its symptom, sign, or abnormality in laboratory parameters in a subject who receives a study drug. An adverse event does not necessarily have a causal relationship with the study drug. The investigator or subinvestigator evaluated adverse events and recorded the results in the case report form.

1. Primary Outcome

Title	Incidence of Adverse Events
▼ Description	<p>Incidence of adverse events was defined as: (number of participants with adverse events/ number of participants analyzed in the safety analysis set)*100.</p> <p>An adverse event was defined as any unwanted or untoward disease or its symptom, sign, or abnormality in laboratory parameters in a subject who receives a study drug. An adverse event does not necessarily have a causal relationship with the study drug. The investigator or subinvestigator evaluated adverse events and recorded the results in the case report form (CRF). The investigator or subinvestigator recorded all adverse events occurring after the start of study treatment in the CRF, irrespective of the causal relationship with the study drug or the study procedures. All data collected from the follow-up was recorded in CRF.</p>
Time Frame	Up to 25 weeks (24 weeks treatment period & 1 week follow-up)

▼ Outcome Measure Data

▼ Analysis Population Description

Safety analysis set: All 161 non-elderly participants who were enrolled in the treatment period were included. All 164 elderly patients who were enrolled in the treatment period were included. The participant who was excluded from the efficacy analysis set was included in the safety analysis set because the participant had evaluable safety data.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
▼ Arm/Group Description:	<p>Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks.</p> <p>Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.</p>	<p>Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks.</p> <p>Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.</p>	<p>Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks.</p> <p>Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.</p>	<p>Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks.</p> <p>Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.</p>
Overall Number of Participants Analyzed	81	83	84	77
Measure Type: Number				
Unit of Measure: Percentage of Participants	81.5	79.5	82.1	87.0

2. Secondary Outcome

Title	Mean Change From Baseline In Sleep Latency
▼ Description	<p>Based on subjective symptoms, the participants recorded their sleep latency (the amount of time measured in minutes it takes to fall asleep) in a sleep diary questionnaire for the week preceding the start of the study treatment (the day on which the patient was enrolled in the treatment period), as well as between the day on which the study treatment started and the Week 4 visit. For pre-treatment (screening period), the representative value was calculated from the data of the 7 days preceding enrollment in the treatment period. A portion of all the data between the day of enrollment in the treatment period and the day</p>

▼ Outcome Measure Data

▼ Analysis Population Description

Efficacy analysis set: all of the 161 non-elderly participants who were enrolled in the treatment period. Among the 164 elderly participants who were enrolled in the treatment period, 163 (80 in the 1 mg group and 83 in the 2 mg group) were included in the efficacy set, excluding 1 participant in the 1 mg group who had no evaluable efficacy data.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
▼ Arm/Group Description:	Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.	Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg tablet additionally until the end of study treatment.	Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred after 4 weeks of treatment. Participants received 1 mg placebo tablet additionally to maintain blind until the end of study treatment.
Overall Number of Participants Analyzed	80	83	84	77
Mean (Standard Deviation) Unit of Measure: minutes				
Baseline	65.5 (40.5)	70.7 (47.1)	71.8 (53.5)	64.0 (42.2)
Overall Period (Change From Baseline)	-32.1 (35.6)	-37.0 (42.7)	-36.7 (51.8)	-32.8 (35.4)

3. Secondary Outcome

Title	Mean Change From Baseline in Wake Time After Sleep Onset (WASO)
▼ Description	Based on subjective symptoms, the participants recorded their WASO defined as total awakening time from falling asleep to final awakening in a sleep diary questionnaire for the week preceding the start of the study treatment (the day on which the patient was enrolled in the treatment period), as well as between the day on which the study treatment started and the Week 4 visit. For pre-treatment (screening period), the representative value was calculated from the data of the 7 days preceding enrollment in the treatment period. A median of all the data between the day of enrollment in the treatment period and the day before dose escalation judgment was presented as the data of the overall period. The change was calculated as the WASO of the overall period assessment - WASO at baseline (screening period).
Time Frame	Baseline (screening period) and 4 weeks of treatment

▼ Outcome Measure Data

▼ Analysis Population Description

Efficacy analysis set: all of the 161 non-elderly participants who were enrolled in the treatment period. Among the 164 elderly participants who were enrolled in the treatment period, 163 (80 in the 1 mg group and 83 in the 2 mg group) were included in the efficacy set, excluding 1 participant in the 1 mg group who had no evaluable efficacy data.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
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Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
▼ Arm/Group Description:	Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks.	Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks.	Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks.	Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
Overall Number of Participants Analyzed	80	83	84	77
Mean (Standard Deviation) Unit of Measure: minutes				
Baseline	314.2 (73.2)	307.9 (60.0)	290.7 (44.0)	308.2 (57.7)
Overall Period (Change From Baseline)	63.6 (64.1)	74.2 (61.4)	70.2 (50.2)	61.8 (54.7)

▼ Analysis Population Description
 Efficacy analysis set: all of the 161 non-elderly participants who were enrolled in the treatment period. Among the 164 elderly participants who were enrolled in the treatment period, 163 (80 in the 1 mg group and 83 in the 2 mg group) were included in the efficacy set, excluding 1 participant in the 1 mg group who had no evaluable efficacy data.

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
▼ Arm/Group Description:	Elderly participants: Eszopiclone 1 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred	Elderly participants: Eszopiclone 2 mg tablet and 1 tablet placebo 1 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred	Non-elderly participants: Eszopiclone 2 mg tablet and 1 tablet of placebo 3 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred	Non-elderly participants: Eszopiclone 3 mg tablet and 1 tablet of placebo 2 mg daily by mouth at bedtime for 24 weeks. Dose escalation occurred

Outcome: Do you sleep longer if you take pill?

Arm/Group Title	Eszopiclone 1 mg- Elderly	Eszopiclone 2 mg- Elderly	Eszopiclone 2 mg- Non-elderly	Eszopiclone 3 mg- Non-elderly
Overall Number of Participants Analyzed	80	83	84	77
Mean (Standard Deviation) Unit of Measure: minutes				
Baseline	314.2 (73.2)	307.9 (60.0)	290.7 (44.0)	308.2 (57.7)
Overall Period (Change From Baseline)	63.6 (64.1)	74.2 (61.4)	70.2 (50.2)	61.8 (54.7)

What if you didn't take the drug at all?

What is this in hours?

Pain in neck to look at other outcomes

****including harms****

Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

What this drug is for:

To make it easier to fall or to stay asleep

Who might consider taking it:

Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:

No blood tests, watch out for abnormal behavior

Other things to consider:

Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold

What difference did LUNESTA make?

People given
a sugar pill

People given LUNESTA
(3 mg each night)

Did Lunesta help?

LUNESTA users slept longer
(37 minutes longer due to drug)

5 hours 45 minutes

6 hours 22 minutes

LUNESTA users slept longer (37 minutes longer due to drug)	5 hours 45 minutes	6 hours 22 minutes
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Did Lunesta have side effects?

Life threatening side effects:

No difference between LUNESTA and a sugar pill	None observed	None observed
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Symptom side effects:

More had unpleasant taste in their mouth (additional 20% due to drug)	6%	26%
More had dizziness (additional 7% due to drug)	3%	10%
More had drowsiness (additional 6% due to drug)	3%	9%
More had dry mouth (additional 5% due to drug)	2%	7%
More had nausea (additional 5% due to drug)	6%	11%

WARNING!

Lots can go wrong

~~GOAL~~
Apple pie

~~Recipe~~

~~Follow recipe~~



~~Dessert!~~

Just because you see results doesn't mean you should believe them!



GOAL
Sleeping pill

Protocol
Design, subjects,
Intervention(s)
Analysis plan

Implement protocol



Results

Results

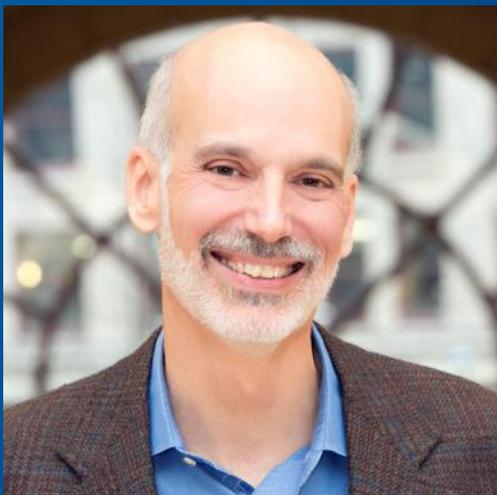
What is the question?

Good design?

Outcomes you care about?



Cochrane
Library



Stephen J. Rosenfeld, MD, MBA

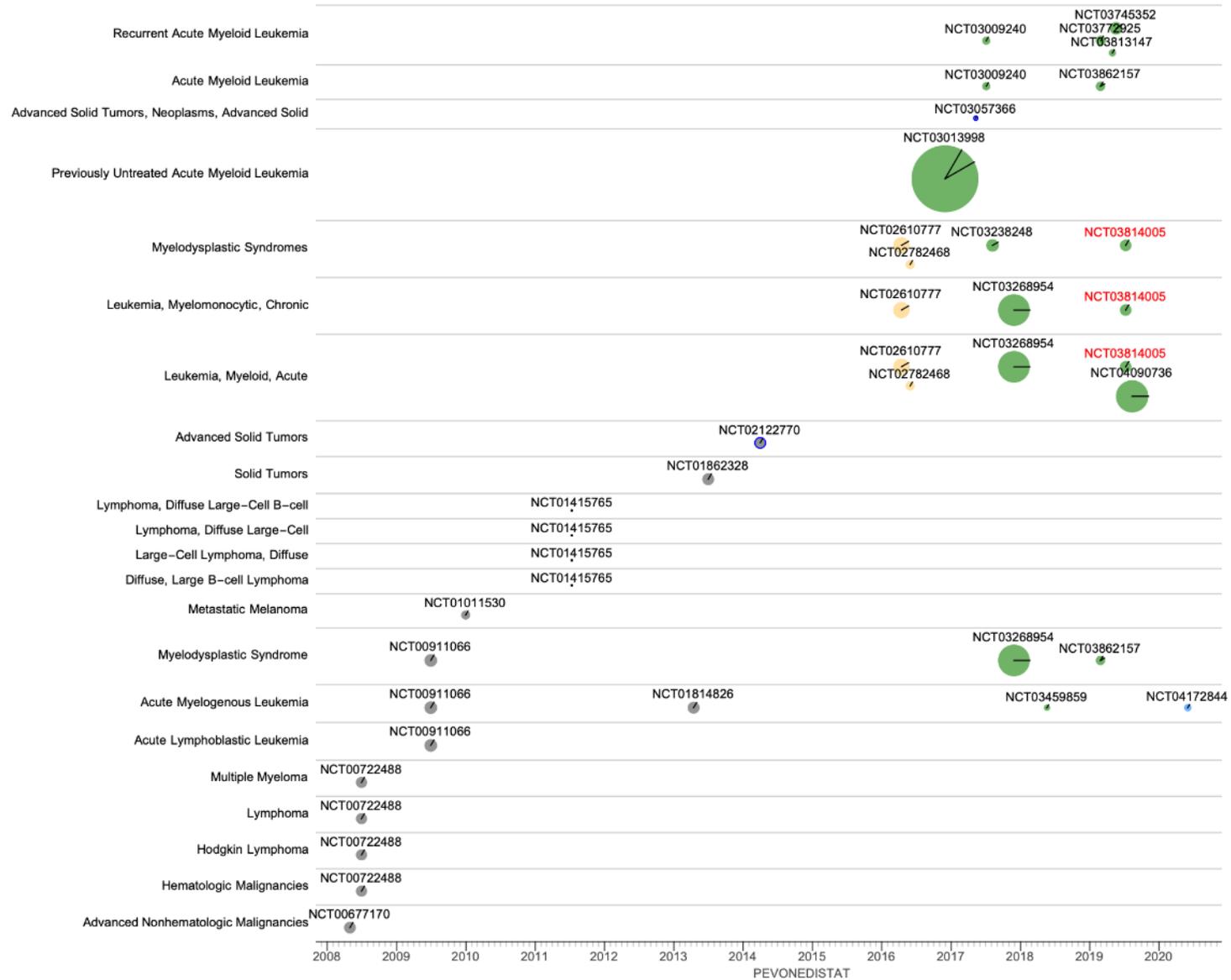
Chair, Secretary's Advisory
Committee on Human Research
Protections (SACHRP)

Standards and Website Functionality

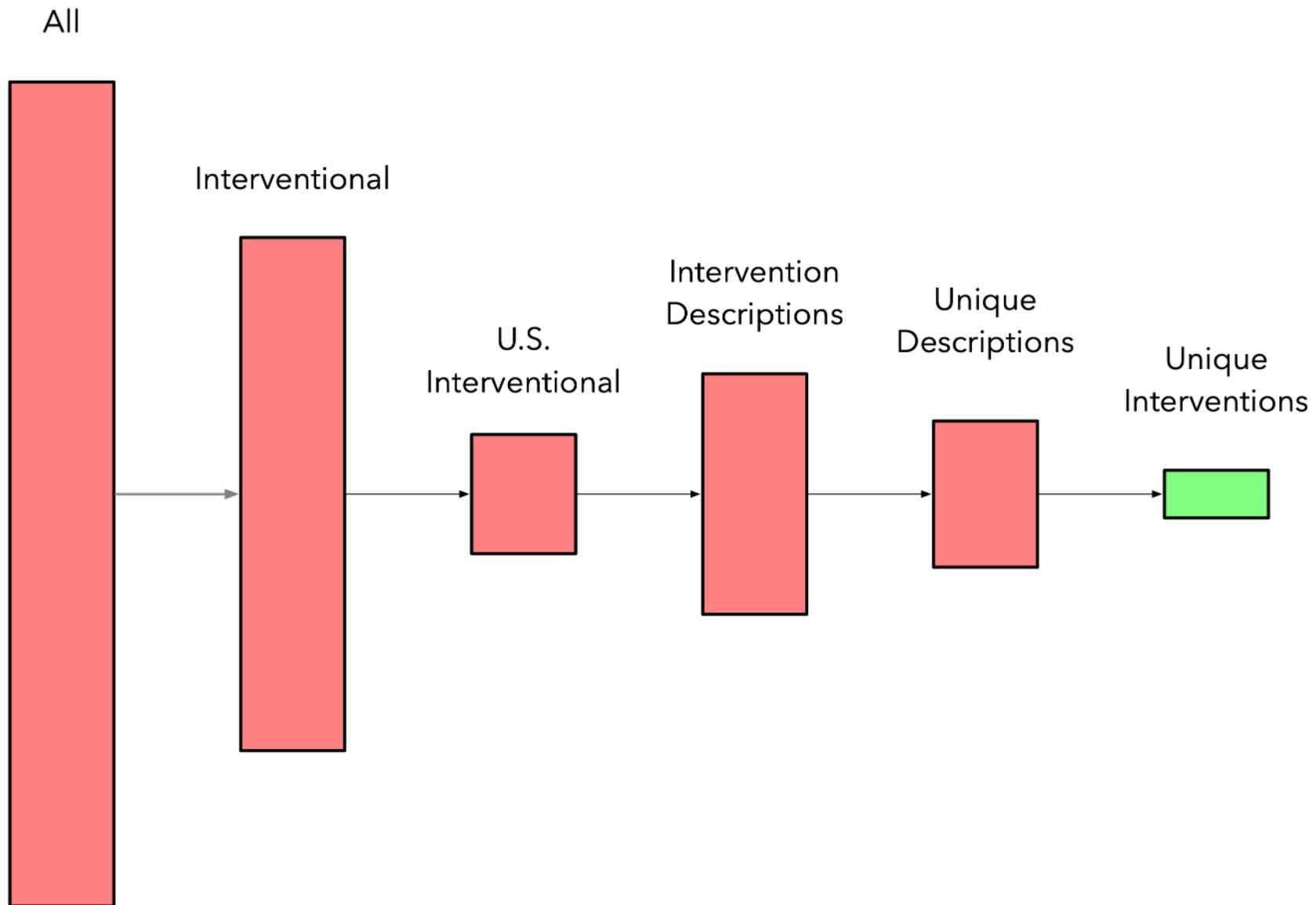
my (personal) perspective

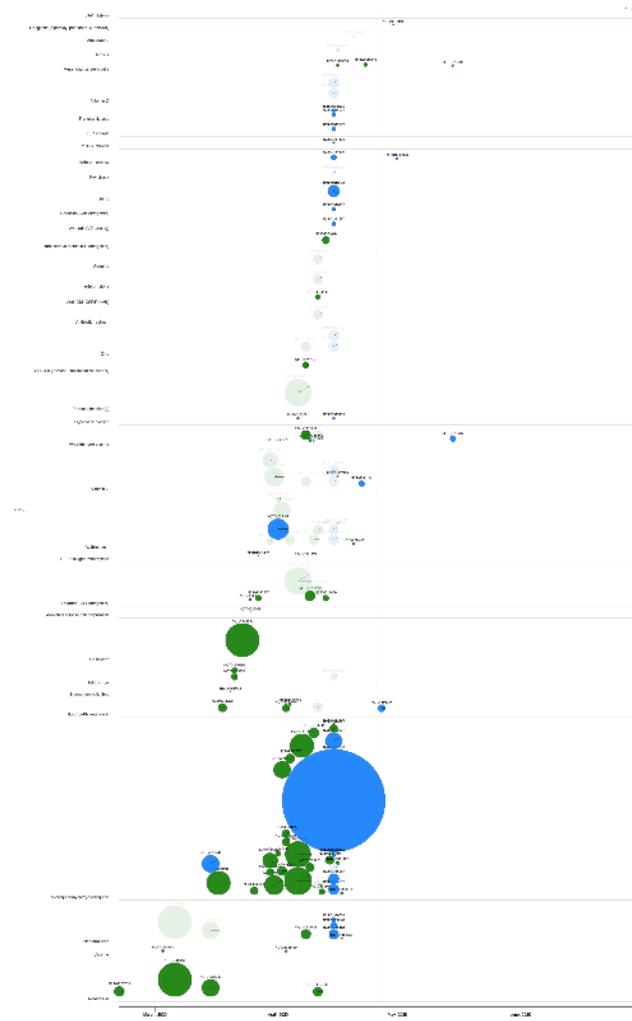
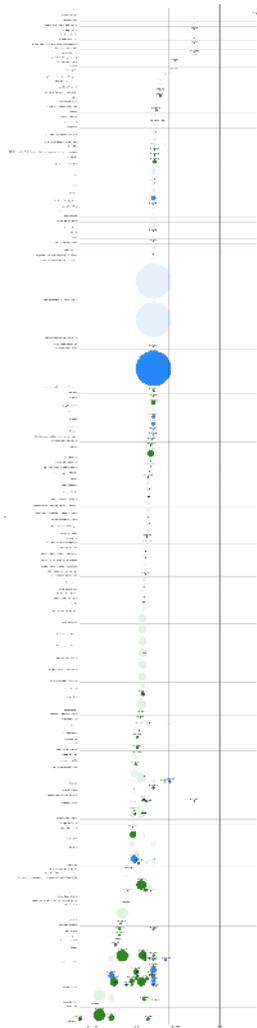
uninformative trials and the role of the IRB

**scientific validity
v.
scientific value**



some (exploratory) data







| Standards and Website Functionality

“If I have seen further it is by standing on the shoulders of Giants.”

—Isaac Newton

“‘Normal science’ means research firmly based upon one or more past scientific achievements, achievements that some particular scientific community acknowledges for a time as supplying the foundation for its further practice.”

—Thomas Kuhn

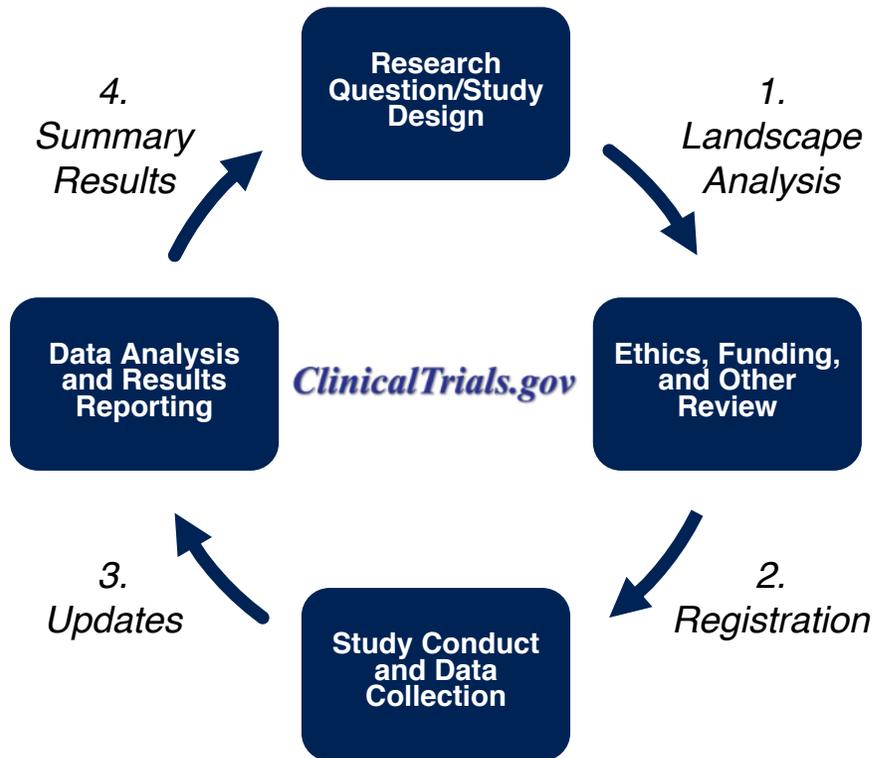


**Rebecca J.
Williams,
PharmD, MPH**

Acting Director of
ClinicalTrials.gov

Summary and Next Steps

ClinicalTrials.gov Modernization Overview



Current year: Engagement

- Engage with stakeholders to determine and validate approach and specifications
 - Request for Information (RFI) and Public Meeting
- Develop modernization roadmap
- Enhance internal business processes

Future (years 2 – 5): Implementation

- Implement modernization roadmap
 - User testing/evaluation and continue engagement
 - Improvements to support compatibility across clinical trial lifecycle (seamless end-to-end process)
 - Upgrade system infrastructure components

ClinicalTrials.gov Modernization Goals



Establish a modern infrastructure to support long-term sustainability



Make information easy to find and use to maximize its value



Simplify submission process to improve user experience and enhance data quality

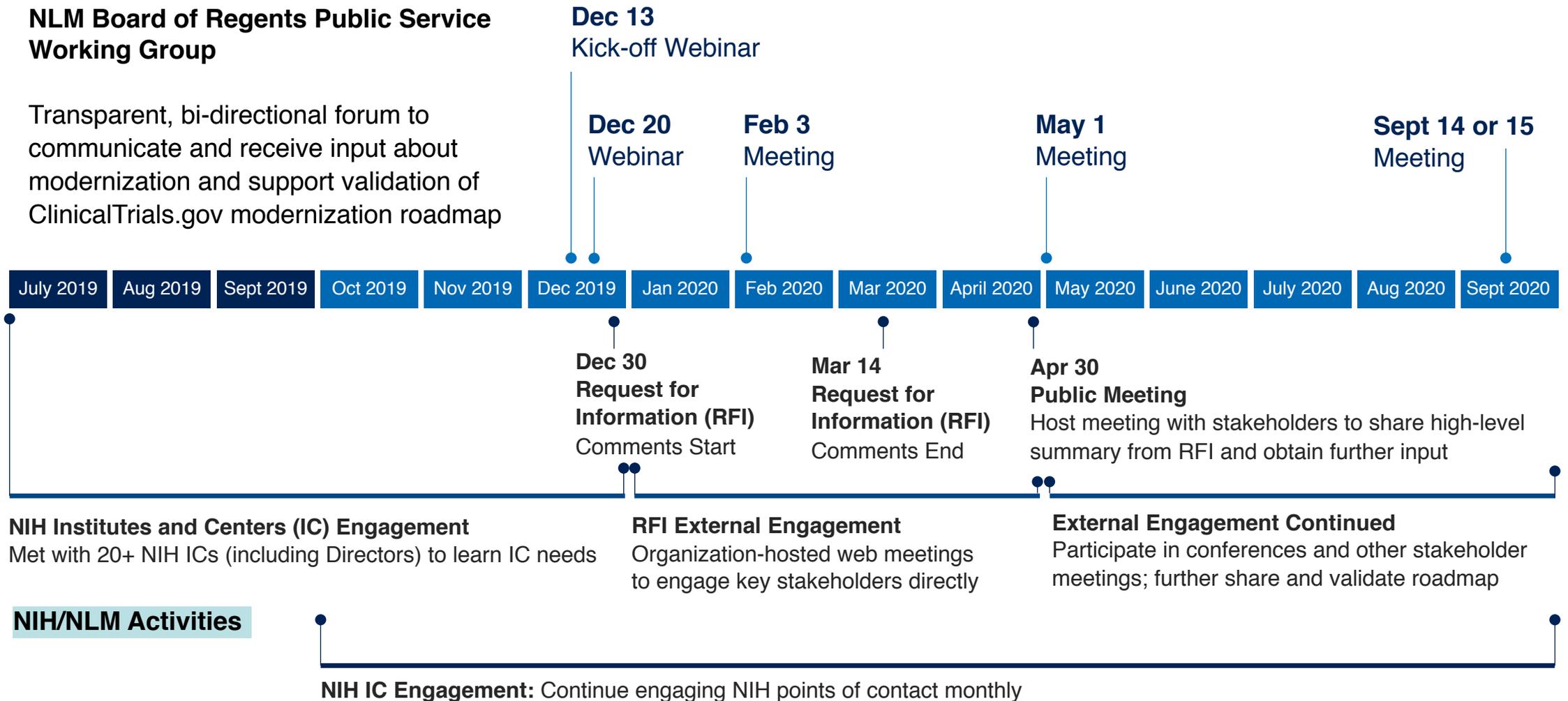


Enhance quality control review process efficiency to accommodate growth

Modernization External Activities FY2020

NLM Board of Regents Public Service Working Group

Transparent, bi-directional forum to communicate and receive input about modernization and support validation of ClinicalTrials.gov modernization roadmap



Thank you again for joining us today!

Please visit the [ClinicalTrials.gov](https://clinicaltrials.gov) Modernization [webpage](#) for the latest updates on the modernization effort.

- [Public Comments Received in Response to Request for Information \(RFI\): ClinicalTrials.gov Modernization and ClinicalTrials.gov Summary of Responses to the RFI](#) and are currently available.
- The meeting recording and presentation slides will be available within 30 days.
- You can also [subscribe](#) to receive Hot Off the PRS! email updates.
- Additional questions/comments? Email register@clinicaltrials.gov.

