ClinicalTrials.gov Basics

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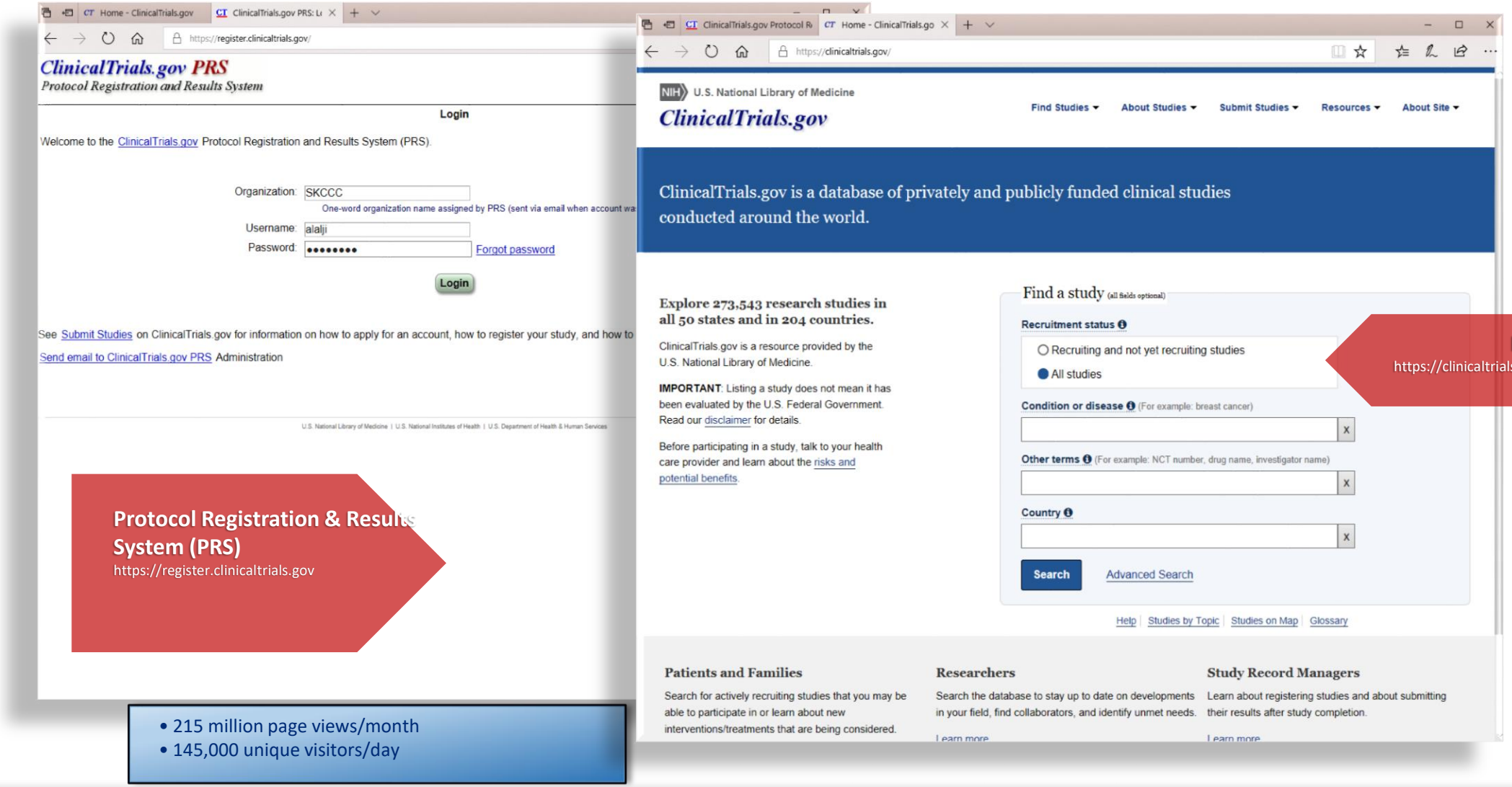
Introduction

Why this is important?

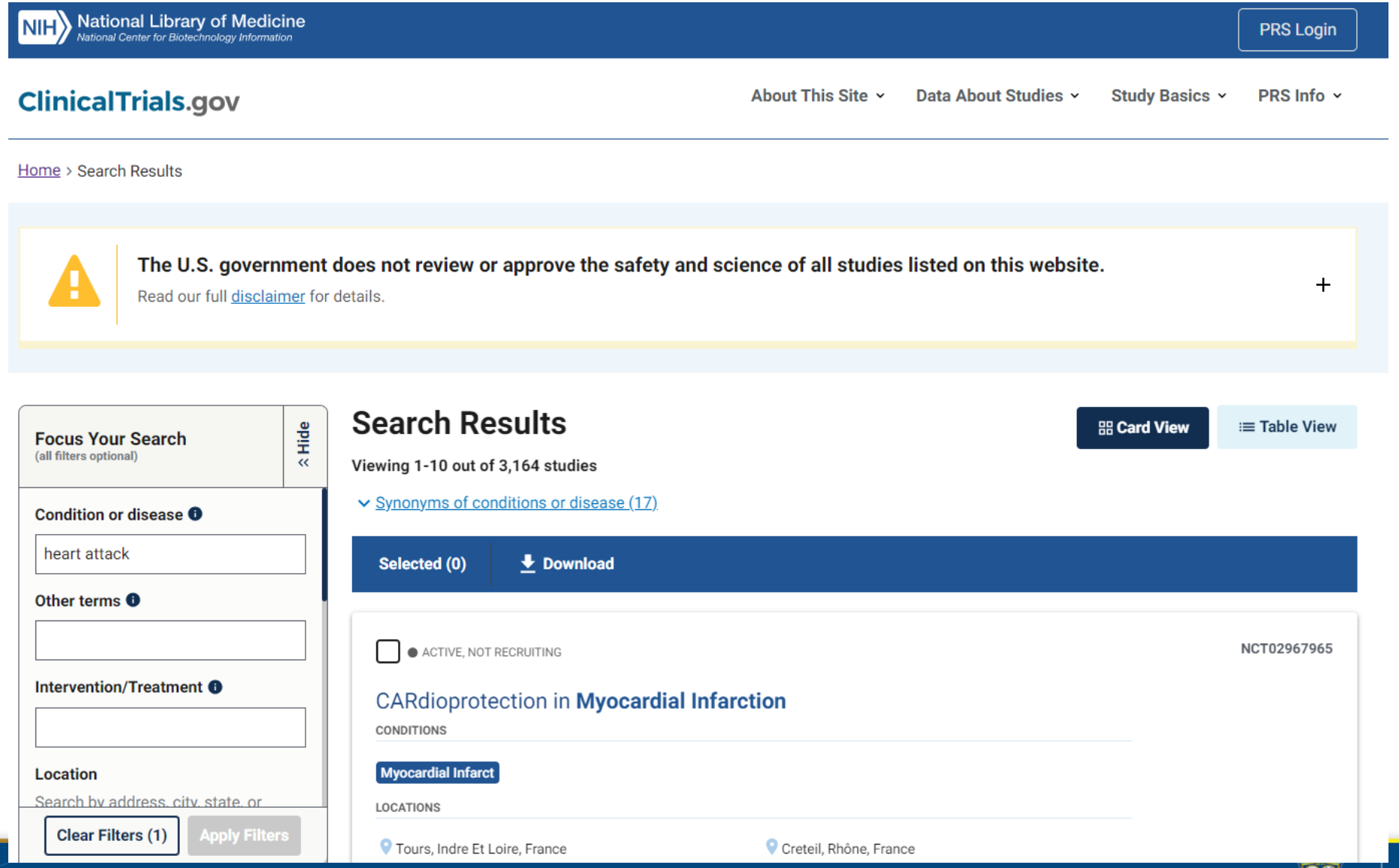
- Ethics
- Science
- Responsible stewardship of funds
- Compliance with federal statutes
- Avoid the penalties

Websites



- 215 million page views/month
- 145,000 unique visitors/day

Modernized Public Website



3 Reasons to Register

1. It’s the law.
2. NIH and other gov’t agency requirement
3. Journal requirement

Key Components of the HHS Final Rule under FDAAA

Final Rule (42 CFR Part 11)

Released: September 2016, Effective: January 2017, Compliance date: April 2017

- Applies to Applicable Clinical Trials (ACTs)
- Register within **21 days** of first participant enrollment
- Annual record verification (even if there are no changes)
- Update records within **30 days** (e.g., completion dates, recruitment status)
- Comment response within **15 calendar days** (registration) or **25 calendar days** (results)
- Submit results **365 days** from primary/study completion date
- Submit full protocol and statistical analysis plan with results

HHS: Health and Human Services; FDAAA: Food and Drug Administration Amendments Act

Applicable Clinical Trials (ACTs)

Trials of drugs/biologics

Trials of devices

And at least one of the following:

- One or more sites in the U.S.
- Conducted under an FDA IND/IDE application
- Manufactured in the U.S. or its territories and exported for research

ACT Wizard: http://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf
Identifying an ACT under FDAAA http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm

NIH Policy

National Institutes of Health

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

(NOT-OD-16-149) Released: September 21, 2016, Effective January 18, 2017

- Complementary to the Final Rule (released the same day)
- All NIH-funded clinical trials regardless of study phase, type of intervention (even if not an ACT), including behavioral interventions will be expected to register and submit results information
- Does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.
- Requires reporting of baseline race and ethnicity data (if collected)

Publication Requirements

ICMJE
INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Similar definition of a clinical trial as NIH

ICMJE journals will consider [for publication] clinical trials beginning on or after July 1, 2005
only if registration occurred **before** the first patient was enrolled
("prospective registration")

There have been many cases where a manuscript was rejected for publication because the study was not registered on ClinicalTrials.gov before enrolling participants

http://www.icmje.org/about-icmje/faqsclinical-trials-registration/

UR Policy

- NCT number required for IRB submissions
- Responsible Party is the PI
- Must be registered before anyone is enrolled, even for ACTs

Potential Penalties

Final Rule (42 CFR Part 11.66)

a) *Civil or criminal judicial actions*

b) *Civil monetary penalties* up to
$11,569 per study, per day

c) Responsible Party, PI is liable.

d) Withholding of current or future funding to PIs or organizations that are out of compliance

https://www.govinfo.gov/content/pkg/FR-2019-11-05/pdf/2019-23955.pdf
Hudson KL, Lauer MS, Collins FS. Toward a New Era of Trust and Transparency in Clinical Trials. *JAMA*.2016;316(13):1353–1354. doi: https://doi.org/10.1001/jama.2016.14668

Revised Common Rule- Informed Consent Posting

- Trial supported by a Federal department or agency
- Redactions are permitted (with approval)
- The consent form must have been used
- Uploaded **no later than 60 days** after the last study visit
- Uploaded to either ClinicalTrials.gov or Regulations.gov

45 CFR Part 46.116

Summary of Requirements

Entity	Registration	Results Reporting	Penalties
U.S Dept. Health and Human Services (HHS)	Within 21 days of enrollment	Within 365 days of primary completion date for ACTs regardless of funding source	• Criminal proceedings • $12,103/study/day • Loss of grant funding
National Institutes of Health (NIH)	Within 21 days of enrollment	Within 365 days of primary completion date for clinical trials receiving NIH funding	Loss of grant funding (to include the institution)
National Cancer Institute (NCI)	Within 21 days of enrollment	Within 365 days of primary completion date of NCI-supported clinical trials (peer-reviewed journal and/or ClinicalTrials.gov)	Loss of grant funding
Veterans Health Administration (VHA)	Prior to enrollment; release of funding.	Within 365 days of primary completion date	Loss of grant funding

Summary of Requirements

Entity	Registration	Results Reporting	Penalties
Centers for Medicare & Medicaid Services (CMS)	All qualifying clinical trials	Study-specific	• Coverage denial • Costs and fraud investigations
Patient-Centered Outcomes Research Institute (PCORI)	All Clinical studies (including observational)	Expected of all PCORI Clinical studies – 500 word abstract on PCORI website	• Loss of grant funding
Department of Defense (DoD)	Prior to enrollment. Prior to release of funding.	Study-specific	• $12,103/study/day • Withholding or recovery of award funds
National Science Foundation (NSF)	N/A	N/A	N/A
Other Federal Agencies	Check grant expectations	Study-specific	• Loss of grant funding

Results to Report- Tabular format only

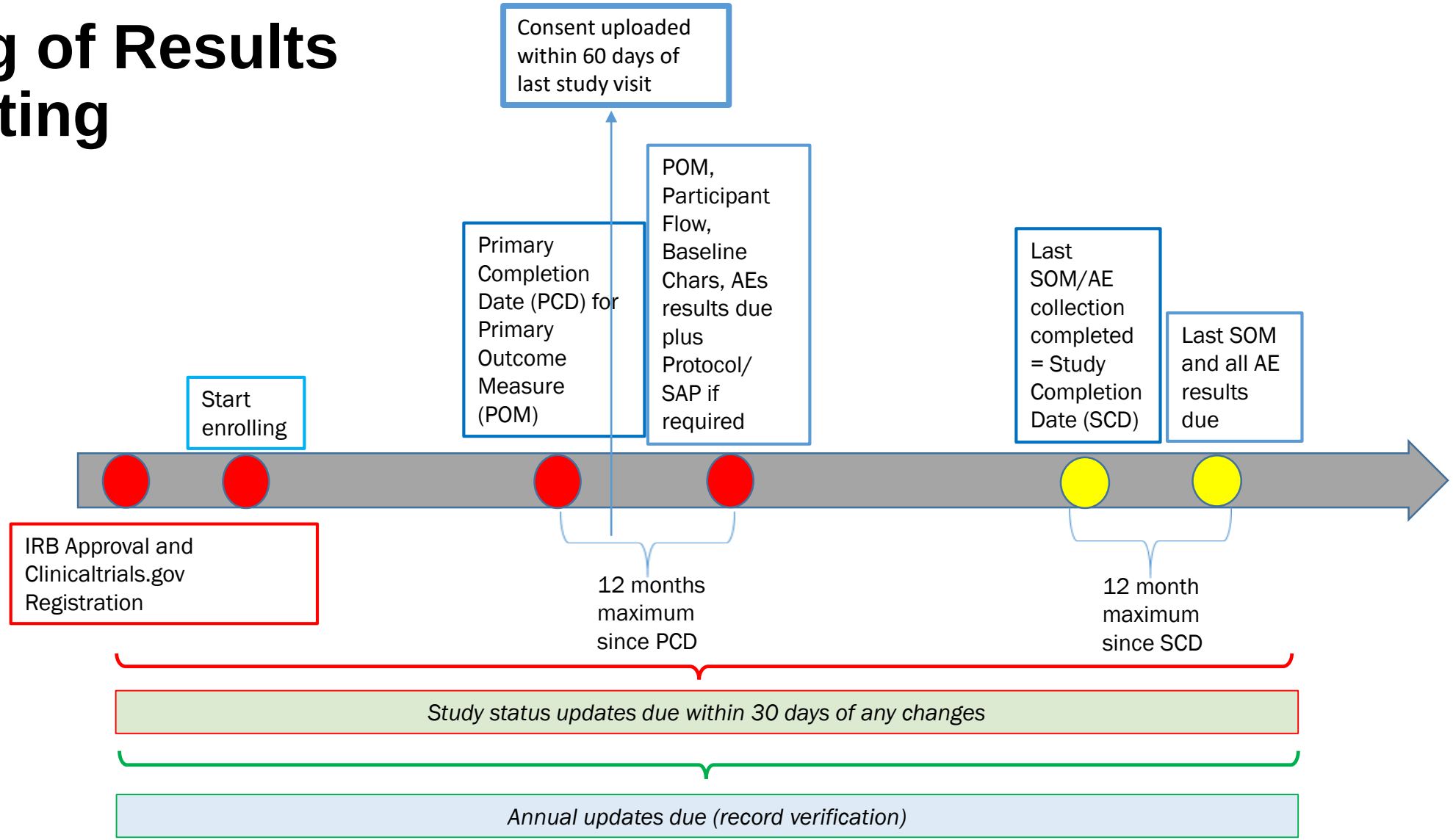
- Manual Entry
- Tabular format only
  - No figures or graphs
- 4 main sections
  - Participant Flow (consort diagram data)
  - Baseline characteristics
    - Age, race, gender, ethnicity, country of enrollment, study specific measures
  - Outcome measures
    - Primary and secondary, not exploratory
  - Adverse events
    - All cause mortality, serious and non-serious AEs that occur in ≥ 5% of participants

Timeline

Example study:

Enroll 1000 people to determine the efficacy of vaccine X. Primary outcome is immunological response to vaccine at day 28. Secondary outcome is safety after 1 year. No exploratory outcomes.

Timing of Results Reporting



QC process

- CT.gov staff do this after it is released (submitted) and before it is published on ClinicalTrials.gov
- Focuses on
  - validity (when possible)
  - meaningful entries
  - Logic
  - internal consistency
  - formatting
- Comments may com back
- Have 15 business days to address them
- NCT Number will be available on ClinicalTrials.gov within 2–5 business days
- Same process for results except they have 30 days to come their review and you have 25 days to address comments

Results Posting

CT.gov must post results publicly within 30 calendar days of submission (42 CFR 11.52) regardless whether the QC process is complete

Results Submitted - Quality Control (QC) Review Has Not Concluded

Results information for an applicable clinical trial (ACT) is posted within 30 days of submission even if the submission has not completed the ClinicalTrials.gov Results Quality Control (QC) review process. Results information is submitted to ClinicalTrials.gov by the sponsor or investigator, and National Library of Medicine (NLM) staff assess for apparent errors, deficiencies, or inconsistencies. NLM staff do not verify the scientific validity or relevance of the submitted information.

All versions of ACT results information submissions that have not completed the QC review process are posted on ClinicalTrials.gov (since January 2020). After the QC review process is completed, the results information is posted without QC review comments and previous versions are archived.

Recruitment Status :	Completed
Actual Primary Completion Date :	May 30, 2022
Actual Study Completion Date :	August 30, 2022

Submission Cycle	Results Submitted to ClinicalTrials.gov	Results Returned after Quality Control Review
1	June 1, 2023	June 23, 2023 Submission with QC Comments
2	June 25, 2023	July 17, 2023 Submission with QC Comments
3	July 17, 2023	

Focus on Quality

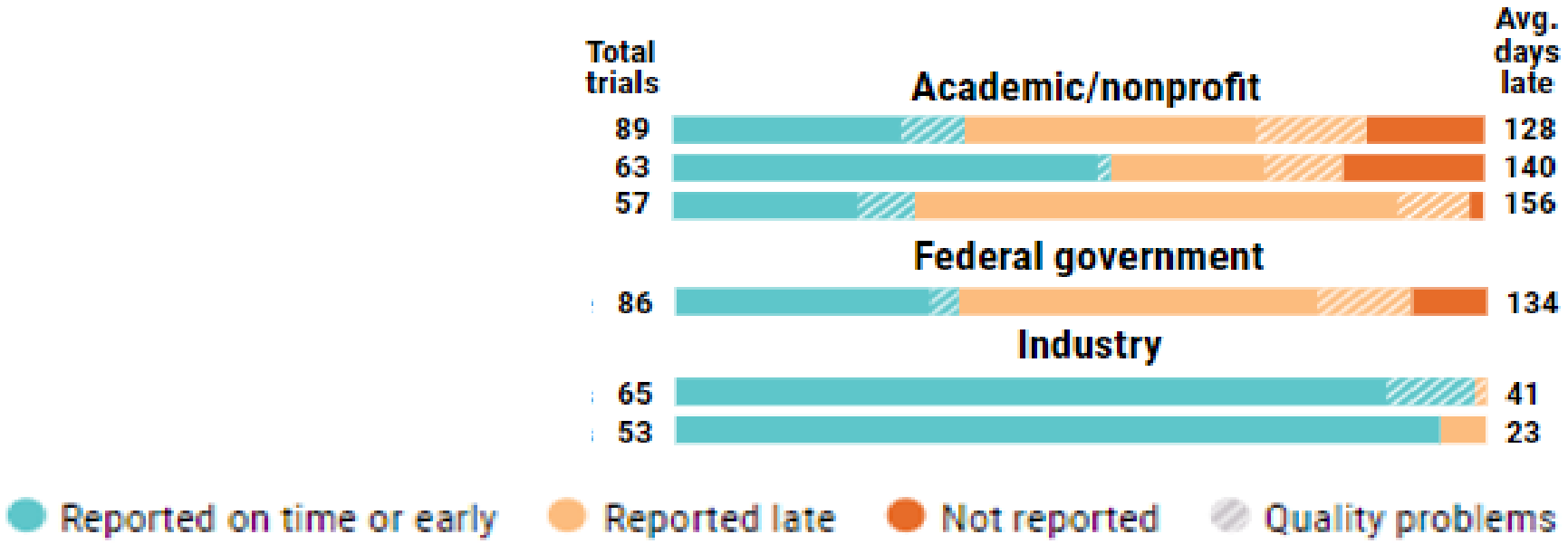
- Reputational risk with the public now seeing the number and type of comments
- Institutions are now more aligned to produce high-quality results

Keyes, et. al, JAMA Intern Med. October 2019
Zarin, Invited Commentary. The Culture of Trial Results Reporting at Academic Medical Centers

Science Magazine

FDA and NIH let clinical trial sponsors keep results secret and break the law

Pillar C: January 13, 2020



https://www.sciencemag.org/news/2020/01/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law

Lancet

Compliance with legal requirement to report clinical trial results on ClinicalTrials.gov: a cohort study

Devito NJ, Bacon S, Goldacre B: January 17, 2020

- Only 2686/4209 (63.8%) reported results
- Only 1722/4209 (40.9%) reported results on time
  - Industry (50.3%)
  - Non-Industry (33.8%)
  - US Government (31.4%)

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)33220-9/fulltext

Office of the Inspector General

OIG did an audit of 72 NIH funded clinical trials from 2019 and 2020.

Table: Summary of Clinical Trials Requiring Results To Be Submitted in 2019 or 2020

	Intramural	Extramural	Total
Submitted on Time	20	15	35
Submitted Late	11	1	12
Results Not Submitted	5	20	25
Subtotal of Noncompliance	16	21	37
Total	**36**	**36**	**72**

https://www.jdsupra.com/legalnews/oig-audit-finds-lack-of-compliance-with-9190431/

US Government Accountability Office

- 16-18% of NIH-funded clinical trials were registered late in the public database ClinicalTrials.gov
- about half of NIH-funded clinical trials submitted results on time to the database in calendar years 2019 and 2020 due to insufficient monitoring and enforcement by NIH

U.S. Government Accountability Office

GAO

https://www.gao.gov/products/gao-23-105656

http://fdaaa.trialstracker.net/

FDAAA TrialsTracker

Single trials | Ranked sponsors | FAQ | Blog | Fund this work! | @FDAAATracker

+AllTrials campaign

Who's sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.

Trials reported
13174 out of 17257

Percent reported
76.3%

US Govt could have imposed fines of at least
$46,920,219,765

Fines claimed by US Govt
$0

Filter trials by status:

On Overdue | On Overdue (cancelled results) | Off Ongoing | Off Reported | On Reported (late)

University of Rochester

Status	Sponsor	Trial ID	Title	Completion date	Days overdue
reported-late	University of Rochester	NCT04606134	A Single Center, Prospective, Blinded Study to Evaluate the Efficacy and Safety of a Tripeptide/Hexapeptide Topical When Used With Er:YAG Hybrid Laser for the Treatment of Acne Scars	2021-06-18	31
reported-late	University of Rochester	NCT02559505	Understanding How the Initial Encounter With Influenza Virus Poises Children for Protective Immunity [pACT]	2020-07-03	33
reported-late	University of Rochester	NCT02466009	Regorafenib in Adults 70 Years or Older With Metastatic Colorectal Cancer: A Phase II Study [pACT]	2019-07-31	222
reported-late	University of Rochester	NCT04342130	Brain Effects of Opiate Agonist and Antagonist	2019-04-16	152
reported-late	University of Rochester	NCT02168842	Phase 3 Double-blind Placebo-controlled Parallel Group Study of Isradipine as a Disease Modifying Agent in Subjects With Early Parkinson Disease [pACT]	2018-11-30	6

Your role

- Use public site to look up studies
- Help PI determine if study needs to be registered
  - Contact PRS administrator
- Complete study registration
- Work with PI to ensure results reporting
  - PRS administrator can help or enter results for them to review

Institutional Support

- Located in the CTSI in the Office of Regulatory Support (ORS)
- ORS Director, Joan Adamo, PhD
- **Institutional PRS administrator**
  - **Carrie Dykes, PhD**
    - Help you determine is registration is required
    - Help you get study record information entered (outcome measure writing)
    - Help you keep the record up-to-date
    - Help you work with PI to get results entered on time
- Monthly emails

Communication Process

Email	PI/Record Owner	Division or Department Director	Institutional Official/Dean
Stage #1	✓		
Stage #2	✓	✓	
Stage #3	✓	✓	✓

Decision Tree

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

The study involves the recruitment of research participants who are randomized to receive one of two approved drugs. It is designed to compare the effects of the drugs on the blood level of a protein.

Does the study involve human participants? Yes, the study involves human participants.

Are the participants prospectively assigned to an intervention? Yes, the participants are prospectively assigned to receive an intervention, one of two drugs.

Is the study designed to evaluate the effect of the intervention on the participants? Yes, the study is designed to evaluate the effect of the drugs on the level of the protein in the participants' blood.

Is the effect being evaluated a health-related biomedical or behavioral outcome? Yes, the effect being evaluated, the level of a protein, is a health-related biomedical outcome.

•This study is a clinical trial by FDAAA, NIH and journals.

The study involves the recruitment of research participants with disease X to test an investigational in vitro diagnostic device (IVD). It is designed to evaluate the ability of the device to measure the level of an antibody in blood.

Does the study involve human participants? Yes, the study involves human participants.

Are the participants prospectively assigned to an intervention? Yes, device

Is the study designed to evaluate the effect of the intervention on the participants? Yes

Is the effect being evaluated a health-related biomedical or behavioral outcome? No, in this context the IVD would not be considered an intervention. The IVD is being used to test its ability to measure antibody levels, but not to test its effects on any health-related biomedical or behavioral outcomes.

This study is NOT a clinical trial, it is observational.

The study involves the recruitment of research participants with disease X to be evaluated with an investigational in vitro diagnostic device (IVD). The study is designed to evaluate how knowledge of certain antibody levels impacts clinical management of disease.

Does the study involve human participants? Yes

Are the participants prospectively assigned to an intervention? Yes, measurement of an antibody level, with the idea that knowledge of that antibody level might affect clinical management

Is the study designed to evaluate the effect of the intervention on the participants? Yes, the study is designed to evaluate how knowledge of the level of an antibody might inform treatment.

Is the effect being evaluated a health-related biomedical or behavioral outcome? Yes, the effect being measured, how blood antibody levels inform treatment, is a health-related outcome.

This study is a clinical trial, by FDAAA, NIH and journals.

The study involves the recruitment of research participants with a behavioral condition to receive either an investigational behavioral intervention or a behavioral intervention in clinical use. It is designed to evaluate the effectiveness of the investigational intervention compared to the intervention in clinical use in reducing the severity of the obsessive compulsive disorder.

Does the study involve human participants? Yes
Are the participants prospectively assigned to an intervention? Yes
Is the study designed to evaluate the effect of the intervention on the participants? Yes, behavioral intervention
Is the effect being evaluated a health-related biomedical or behavioral outcome? Yes, OCD.

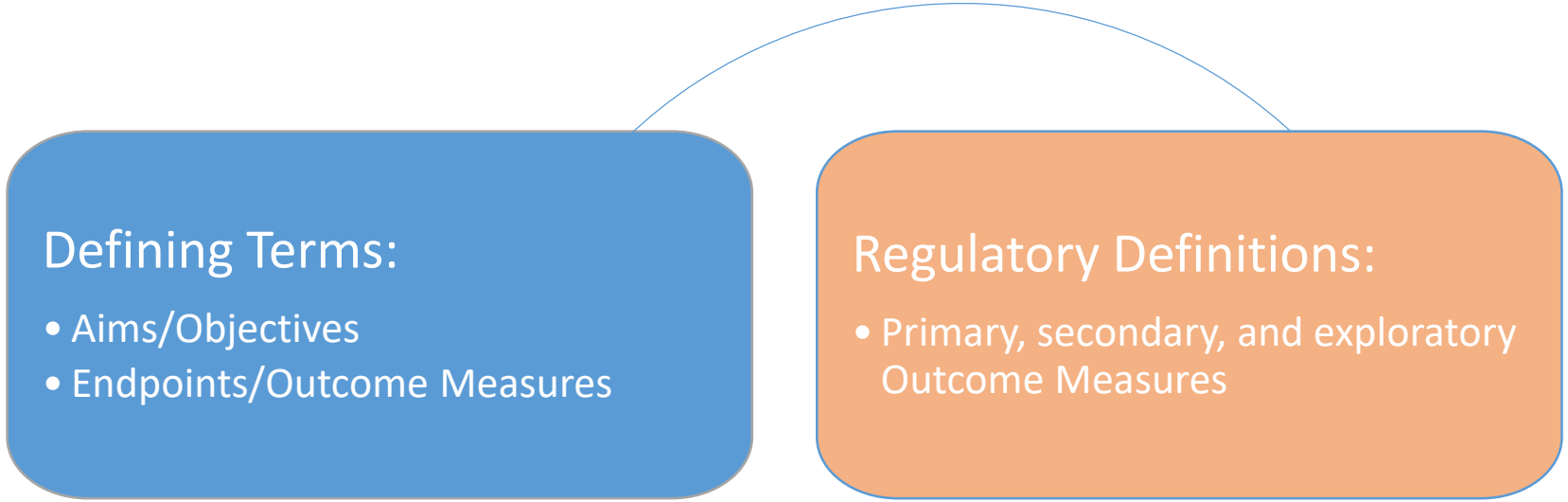
It is a clinical trials for NIH and journals but not FDAAA.

The study involves the recruitment of research participants with disease X vs. healthy controls and comparing these participants on a range of health processes and outcomes including genomics, biospecimens, self-report measures, etc. to explore differences that may be relevant to the development of disease X.

Does the study involve human participants? Yes
Are the participants prospectively assigned to an intervention? No
Is the study designed to evaluate the effect of the intervention on the participants?
Is the effect being evaluated a health-related biomedical or behavioral outcome?

This is not a clinical trial for FDAAA, NIH or journals. Observational

Definitions



Objectives

Primary Objectives of a Clinical Trial:

- Drive statistical planning (e.g., sample size calculation / statistical power).
  - Are goals expressed as a statement of purpose (e.g., to assess; to determine; to compare; to evaluate).
- Describe:
  - General purpose (e.g., efficacy, effectiveness, safety).

or

  - Specific purpose (e.g., dose-response, superiority to placebo, effect of an intervention on disease incidence, disease severity, or health behavior).

Secondary Objectives of a Clinical Trial:

- Are goal that will provide further information on use of the intervention.

Source: NIH Protocol Templates for Clinical Trials https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

Source: NIH Protocol Templates for Clinical Trials https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

Primary Outcome Measures

Primary Outcome Measures:

A specific measurement or observation to assess the effect of the study intervention.

- Corresponds to the study objective and hypotheses
- Basis for concluding whether the study met its objective

Precisely define the endpoints used to address the study's primary objective:

- lab tests
- clinical or psychological assessments
- patient reported outcomes, behaviors or health outcomes

Include time points at which data will be assessed

Examples:

- Change in Pain Severity Scores as Measured by the Brief Pain Inventory (BPI)
- Post-op Normative Isokinetic Knee Extension Strength

Note: "Endpoint" and "outcome measure" are synonymous.

Secondary Outcome Measures: NIH Definition

Secondary Objectives *and* ***Secondary Outcome Measures/Endpoints*** *are written in the same manner as primary objectives and primary outcome measures/endpoints.*

Secondary Outcome Measures / Endpoints:

Address goals of secondary objectives.

May be related to efficacy and/or safety.

May provide supportive information about the intervention's effect on the primary endpoint or demonstrate additional effects on the disease or condition.

Examples:

- Number of participants that refuse treatment
- Hip Disability and Osteoarthritis Outcome Score
- Patient-Reported Satisfaction with Coordination of Care

Source: NIH Protocol Templates for Clinical Trials https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

Exploratory / Other Outcome Measures

ClinicalTrials.gov Definition: "Any other measurements used to evaluate the intervention."

- Must be pre-specified in the protocol.
- Have fewer obligations than Primary and Secondary outcome measures.
  - Results reporting not required.
- Have no impact on:
  - Primary Completion Date;
  - Study Completion Date;
  - Results due dates;
  - Informed Consent upload due date *(45CFR46 "Common Rule" requirement)*

Ensure exploratory or other outcome measures are **clearly delineated in the protocol document**.
If not clearly specified, the regulations will consider it a secondary outcome measure for which results reporting is required. (42 CFR 11.48(a)(5))

Aims/Objectives May Differ from Outcome Measures

Aims/Objectives:	Outcome Measures
Serve as deliverables. They involve **intent to do something** with data derived from outcome measures.	**Primary outcome measures** are the most important data **measurements** gathered by the study, the ones that determine its design and the study size.
Are typically expressed with **verbs.**	Outcome measures are measurements expressed in quantifiable units (with **nouns**).
E.g., ***To assess*** *the efficacy of the STOMP intervention to improve opioid risk understanding and decision-making*	E.g., ***Number*** *of opioid-related adverse events*

Outcome Measures: QC Criteria

Outcome measures frequently attract QC comments. Often, this is due to:

- Misunderstanding the differences between outcome measures and protocol aims
- Inappropriately combining outcomes
- Failing to sufficiently describe the measurement to meet QC criteria

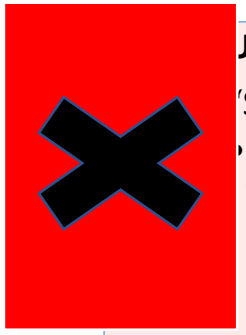
How would you report meaningful data for this in a data table?

Example of a protocol aim:	Example of inappropriately combined measures	Example of an acceptable Outcome Measure:
"Safety of Drug A"	Safety assessed via number of SAEs and maximum tolerated dose.	"Safety, as measured by the number of participants with at least one SAE"

Number of SAEs and *maximum tolerated dose* are separate measures

This Outcome Measure is a measurable, reportable outcome!

Descriptions Should be Thorough, Precise, and Understandable to the Public



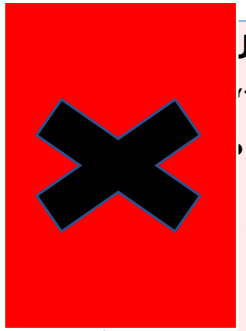
Unacceptable Outcome Measure

- "Satisfaction with exercise program"
- "The satisfaction of participants with their assigned exercise program"

Acceptable Outcome Measure

"Satisfaction with Exercise Program"

- "Participant's satisfaction with their assigned exercise program as assessed using a 5-point Likert scale. Scores range from "very unsatisfied" (1) to "very satisfied" (5)."



Unacceptable Outcome Measure

- "To Determine Physical Function"
- "The primary outcome is to determine if the surgery improves physical function in patients."

Acceptable Outcome Measure

"Change in Physical Function as assed via WOMAC Scores"

- "The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) assesses pain, stiffness, and physical function in patients with hip and / or knee osteoarthritis. Possible scores range from 0-96. Total score is computed by summing three subscales: pain (range 0-20), stiffness (range 0-8), and functional limitations (range 0-68), then dividing by total points possible. Higher scores indicate worse pain, stiffness, and functional limitations."

Outcome Measure QC Comments-Scales

QC Comment:	How to address:
"**Major Issue:** The Measure includes a scale. Please provide the following scale information…"	Make sure the Outcome Measure description includes the following information about the scale/score: • The **full name** of the scale (not just the abbreviation) • **What it measures** • **Minimum/maximum** possible scores • **What do higher or lower scores represent**? Are higher scores better or worse, and is there a "normal" range? **TEMPLATE**: The **[FULL NAME OF THE SCORE/SCALE]** measures **[WHAT IT MEASURES]**. Possible scores range from **[MINIMUM POSSIBLE SCORE]** to **[MAXIMUM POSSIBLE SCORE]**, with higher scores indicating a **[BETTER/WORSE]** outcome.

Unacceptable Outcome Measure	• **Title:** "Depression" • **Description:** "Ham-D scores."
Acceptable Outcome Measure	• **Title:** "Severity of Depression as Measured by the Hamilton Depression Rating Scale" • **Description:** "The Hamilton Depression Rating Scale (Ham-D) is used for rating the severity of depressive symptoms. Possible scores range from 0 to 50, with higher scores indicating greater severity of depression."

Outcome Measure QC Comments- More than one

QC Comment:	How to address:

"**Major Issue:** More than one outcome measure appears to be described."	• Make sure that you are reporting distinct measurements/variables as a separate Outcome Measures.
	• Measurements must use the **same unit of measure** to be grouped in an Outcome Measure.
	  • Example: If you are reporting "Food Intake", but your measurement specifies "Carbohydrates (grams)" and "Sodium (milligrams)", you must enter those as separate outcome measures because grams and milligrams are different units of measurement.
	• Combining measures as a single score (e.g. "Count of participants with either X or Y)
	  • Art versus Science. Refer to the protocol and the P.I.'s intention.

Unacceptable Outcome Measure	• **Outcome 1**: "Body composition" **Description**: "Body Mass Index (BMI) and Visceral Fat Index."
Acceptable Outcome Measures	• **Outcome 1**: "Body Mass Index (BMI)" **Description**: "Body Mass Index (BMI) is a person's weight in kilograms divided by the square of height in meters. Scores between 18.5 and 24.9 indicate healthy weight." • **Outcome 2**: "Visceral Fat Index (VFI)" **Description**: "Visceral Fat Index (VFI) will be assessed using a CT scan. Scores range between 1 and 59. Scores between 1 and 12 indicate healthy levels of visceral fat. Scores of 13 and above indicate excessive, unhealthy levels of visceral fat." **OR** • **Outcome 1**: "Count of participants with either a BMI of 25 or higher or a VFI of 13 or higher."

Outcome Measure QC Comments- Time Frame

QC Comment:

"**Major Issue:** The Time Frame does not appear to be specific and/or in the correct format."

How to address:

- Specify the (unabbreviated) **time points** when you collect data (Month 3, Day 5, up to 5 Minutes), **not the visit names** (Visit 2, Follow-up).
- If the measure is assessed in relation an event (e.g. "post surgery"), specify the time in relation to that event. Time frames such as "Post-intervention" will not be accepted.
  - Examples: "Baseline up to 1 hour post-surgery"; "Day 1, immediately prior to administration of the intervention".
- "Duration of study" is never acceptable.
  - If the time frame is intrinsically dependent on duration of participation, specify the maximum time frame over which the measure will be assessed,
  - **Example**: "Baseline up to 24 months or disease progression, whichever is first".
- If reporting **multiple time points**, add "Change in…" to the title (if reporting change between 2 time points) or specify "Up to [time point], or divide into separate outcomes

Unacceptable Outcome Measure Time Frames:		Acceptable Outcome Measure Time Frames:	
• "Duration of study" • "D1, D14, D30" • "Duration of participation"	• "Hospitalization" • "Hospital admission until discharge"	• "Week 2" • "Baseline, 6 Weeks*" (Title = "Change in…")* • "Day 1, Day 14, Day 30"	• "Up to 100 Weeks" • "Day 1 up to 20 minutes post surgery"

Time to Event Outcome Measure Descriptions

COMMONLY USED OUTCOME MEASURE DESCRIPTIONS	
Overall Survival (OS)	Number of days/weeks/months until death from any cause
	Time Frame: Baseline until death, assessed up to [#] days/weeks/months
Progression-Free Survival (PFS)	Number of days/weeks/months until disease progression or death
	Time Frame: Baseline until date of first observed disease progression or death, assessed up to [#] days/weeks/months
Event-Free Survival (EFS)	Number of days/weeks/months until disease progression, death or discontinuation of treatment for any reason (ie: toxicity, patient preference or physician decision)
	Time Frame: Baseline until death/discontinuation/progression, up to [#] days/weeks/months
Objective Response Rate (ORR)	Percentage of participants with x% reduction in tumor burden.
	Time Frame: Up to Day/Week/Month [#]
Duration of Response (DoR)	Number of days/weeks/months from documented tumor response to disease progression
	Time Frame: Date of response until progression, assessed up to [#] days/weeks/months

Research Help Desk

researchhelp@urmc.Rochester.edu

585-275-2107