



MRCT CENTER

THE MULTI-REGIONAL
CLINICAL TRIALS CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
AND HARVARD

**HEALTH LITERACY
MONTH WEBINAR**

Returning Summary Results to Participants:

Lessons from the Research Community

WELCOME!!

DATE:

Tuesday, October 27, 2026

TIME:

11am-12pm EST

Disclaimer



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Webinar Reminders and Instructions

- **This webinar is being recorded.**
 - The recording, slides and other resources will be made available on the MRCT Center website within the next week.
- **Please use the Q&A to ask questions.**
 - We will do our best to respond live – but will provide written responses to the questions we were unable to answer.
- **Please introduce yourself in the chat.**
 - We'd love to hear where you're joining from and why you decided to join this webinar today.
- **Please complete the brief experience survey at the end of the webinar.**

The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard



About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.



www.mrctcenter.org

Our Vision

Improve the integrity, safety, and rigor of clinical trials around the world.

Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



Long-standing Commitment to Health Literacy

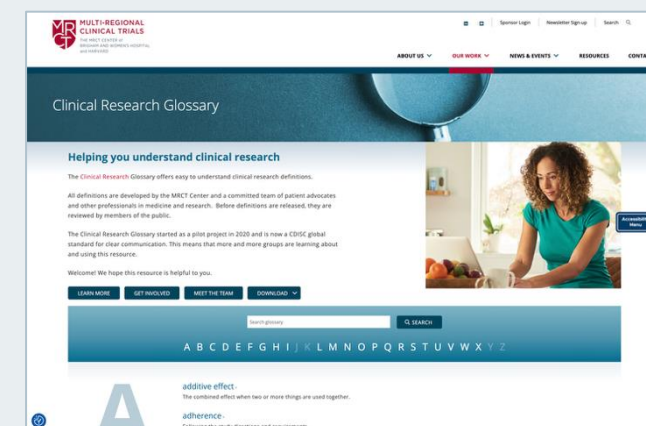


<https://mrctcenter.org/resource/return-of-aggregate-results-to-participants-guidance-document-version-3-1/>

<https://mrctcenter.org/resource/return-of-aggregate-results-to-participants-toolkit-version-3-1/>



<https://mrctcenter.org/health-literacy/>



www.mrctcenter.org/glossary

Returning Results: Definitions



In the context of clinical research, “**summary level study results**” refers to an overall, understandable report of what the study found and how individual participation contributed to the creation of generalizable knowledge.

Today, discussing only the return of **Summary Results**

and *not* Individual Results and Data

(e.g., personal data that was collected in the study)



Why Return Summary Level Study Results?



- Fulfills participant expectations and supports transparency
- Concordant with the ethical principles of
 - *Justice*: people have a right to their own data and information
 - *Beneficence*: research should maximize the possible benefits to participants
 - *Respect for Persons*: honor and acknowledge participant contributions to science
- Consistent with international standards (e.g., ICH E6(R3), CIOMS, Declaration of Helsinki) and exemplary international regulations (e.g., EU, UK; Others)



Return of Results Global Regulatory and Policy Environment



- **EU Parliament Regulation (EU) No 536/2014 (2014):**

The sponsor of a clinical trial must submit “a summary of the results of the clinical trial together with a summary that is understandable to a layperson, and the clinical study report, where applicable, within the defined timelines.”

- **UK Statutory Instrument No. 538/2025 (2025):**

The sponsor of a clinical trial must submit “a summary of the results of the clinical trial in the same public registry or registries (if more than one) as the trial was registered.”

- **US federal laws** require listing aggregate results of many studies on ClinicalTrials.gov (but not in plain language)

- **Revised Common Rule addition 45 CFR 46.116(c)(8)**

“A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.”

New NIH draft policy and RFI

(NOT-OD-26-113; Issued: August 27, 2026)

- Applies to all NIH-supported clinical research,* including but not limited to clinical trials
- Establishes the “requirement to responsibly share summary-level study results with clinical research participants in plain language, unless justifiably not appropriate, for all NIH-supported clinical research.”
- Clarifies that enforcement actions apply to the recipient institution and may affect future funding decisions
- Policy is intentionally high-level and flexible
- Supplementary guidelines will be issued acknowledging implementation challenges
- Broad application challenges coordination and consistency (e.g., multi-site research, FDA-regulated research, etc.)

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-113.html/>



Welcome to our Panelists



Lawrence Appel, MD, MPH

C. David Molina Professor of Medicine, Epidemiology, and International Health
Johns Hopkins University

Abby Gregory, MPH

Program Manager
TAPUR Study, American Society of Clinical Oncology (ASCO)

Deborah Mascalzoni, PhD

Research Group Leader, Institute for Biomedicine, Eurac Research
Associate Professor of Biomedical Ethics, Uppsala University

30+ Years of Returning Trial Results to Participants: Why I did it and how it is done

Lawrence J. Appel, MD, MPH

Professor (Part time) of Epidemiology, Medicine, International Health, and Nursing
Johns Hopkins University

Oct 27, 2026

Brief bio

- Physician, clinical investigator, conducted 50+ studies
- Faculty member at Johns Hopkins (1989 - 2026)
- Research focus: prevention and control of hypertension
- Types of studies
 - Clinical trials
 - » Feeding studies, e.g. DASH
 - » Biobehavioral intervention studies
 - » Few drug studies
 - Observational studies
- Research program with many, long-term, committed staff
- A culture of participant-oriented approach to conducting research

Why I return results

- Trials of Hypertension Prevention, Phase 1 (TOHP)
 - I was a post-doctoral fellow, mentored by Paul Whelton, PI of TOHP
 - Close-out event (~1992): in-person with presentation and written materials
 - I programmed the individual-level report for 200+ persons
- Developed a focus on participants and ways to enhance their experience and engagement
 - Respect for their time and commitment to our research, evolving into an **obligation**
 - Many patient-oriented features, not just closeout. Examples:
 - » Easy-to-understand written materials
 - » Staged consent
 - » Orientation sessions, run-in
 - » Newsletters

Standard Practice: Closeout events and return of results

Who?	Participants (and also their guest at events)
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Who?	Participants (and also their guest at events)
<i>What types of results?</i>	<i>1) Main results (study-level) 2) Individual-level results (clinically meaningful results) [we often provide study- and individual level results together and with lay explanation]</i>
What materials to share?	For main results, the scientific paper AND a lay summary For individual-level results, their own data (just clinically relevant results) Randomized group

Standard Practice: Closeout events and return of results

Who?	Participants (and also their guest at events)
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What materials to share?	For main results, the scientific paper AND a lay summary For individual-level results, their own data (clinically relevant results) AND interpretation Randomized group
When?	<i>Typically close to publication or public announcement of main results</i> <i>[participants should be the first to know]</i>
How and where?	Mailed packet without an event, OR <i>Two step process (preferred)</i> <i>Mailed packet with invitation to attend presentation AND results</i> <i>In-person event with presentation (zoom during pandemic)</i>
Why?	Tangible expression of appreciation <i>[My opinion – sharing results is part of our obligation as researchers]</i>

Typical Items in a 'Closeout' Packet*



- Cover letter
- Copy of our published main paper
 - With lay summary of study results
- 2 copies of a report with individual level, clinically relevant data (one copy for participant, the other for health care provider)
 - With guide to interpret results

*same set of materials, whether or not there is an in-person event

One Lesson Learned, One Challenge and One Practical Recommendation

- Lesson learned: plan ahead
 - budget costs in grant
 - include closeout plans in consent form
 - discuss with participants from the start
- Challenge: logistics (costs, staffing, prep time), especially for small and underfunded studies
- Practical Recommendation: involve staff and investigators in preparing, reviewing and reviewing materials

Plain Language Summary Implementation During an Active Multi-Basket Trial

Targeted Agent and Profiling Utilization Registry (TAPUR) Study



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American Society of Clinical Oncology

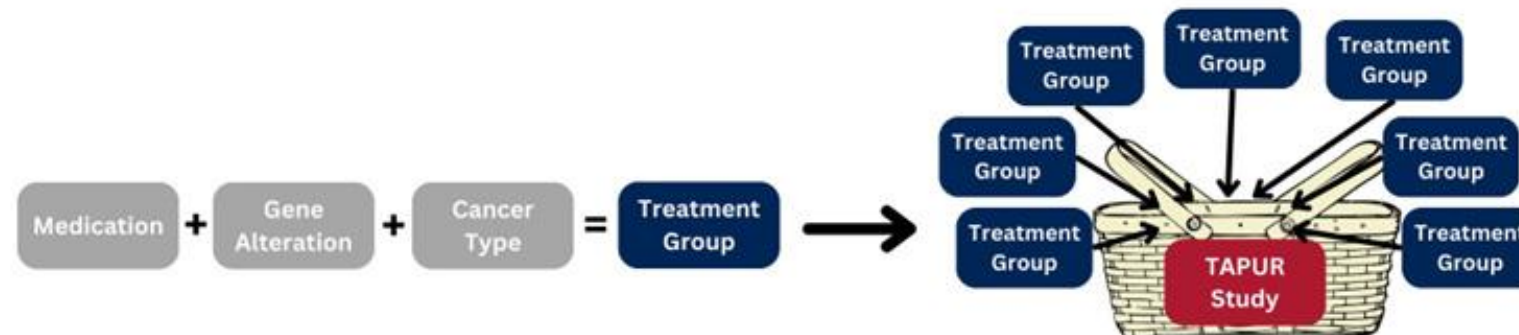
October 2026

Learn more at www.mrctcenter.org

Introduction to the TAPUR Study



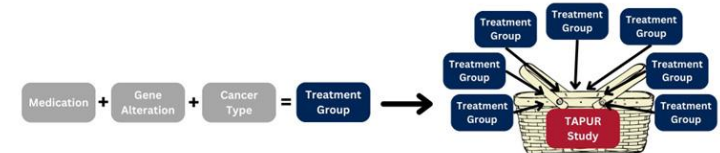
- The TAPUR Study is a large multi-basket study that helps us learn if approved targeted cancer treatments can successfully treat other cancers that share the same gene alteration.
- TAPUR has enrolled over 3,000 participants from over 260 sites across the United States since 2016.
- This is a pragmatic study that collects the minimum amount of data possible but shows real life impact of targeted therapies.



A few things going on simultaneously...



Continuous enrollment for over 500 treatment groups



2016

2026

Scientific Publication of Treatment Group Results

2019

2026

Plain Language Summary Development and Dissemination

2022

2024

2026

First PLS Published

Timeline for PLS Development and Dissemination



Continuous communication with:

- Patient advocates
- IRB
- Pharmaceutical companies
- Internal stakeholders



Date	Milestone	Significance
August 2022	Project Inception	The TAPUR publications team initiated the effort, marking the official start of the PLS development journey.
January 2023	Protocol & Consent Update	The TAPUR protocol and consent forms were updated to include PLS. This was a critical step that formally integrated PLS into the trial's operational and ethical framework.
August 2023 - June 2024	Template & Language Standardization	The PLS template and standardized definitions for complex terms were finalized. This created a scalable and consistent model for producing high-quality summaries.
June 2024 - November 2024	Final IRB Approvals	Securing final IRB approval was the last major regulatory hurdle, greenlighting the publication and dissemination process.
December 2024	First PLS Published	This marked the successful culmination of over two years of development and the transition from planning to active dissemination.
Present	Scaling and Future Development	With nearly 21 summaries published and new templates and translations in development, this demonstrates the project's ongoing success, impact, and evolution.



Implementation Details



Who reviewed the PLS template?

- Internal TAPUR and ASCO staff, patient advocates, clinical site staff, participating pharmaceutical companies, and third party PLS professionals.
- Gathered patients' general preferences through an IRB approved survey.

What approvals were needed?

TAPUR Study IRB review and approval of the PLS template.

Who drafts the final PLS?

TAPUR Study publications team implements the template that was developed with input from key stakeholders.

Looking Back at TAPUR Study PLS Development



- **Lesson Learned:**

- Implement PLS processes from the beginning of your study if possible.

- **Challenges:**

- Updating consent process to give participants the opportunity to consent to receiving PLS moving forward.
- Identifying ways to get PLS to patients who were unable to consent to receive PLS.

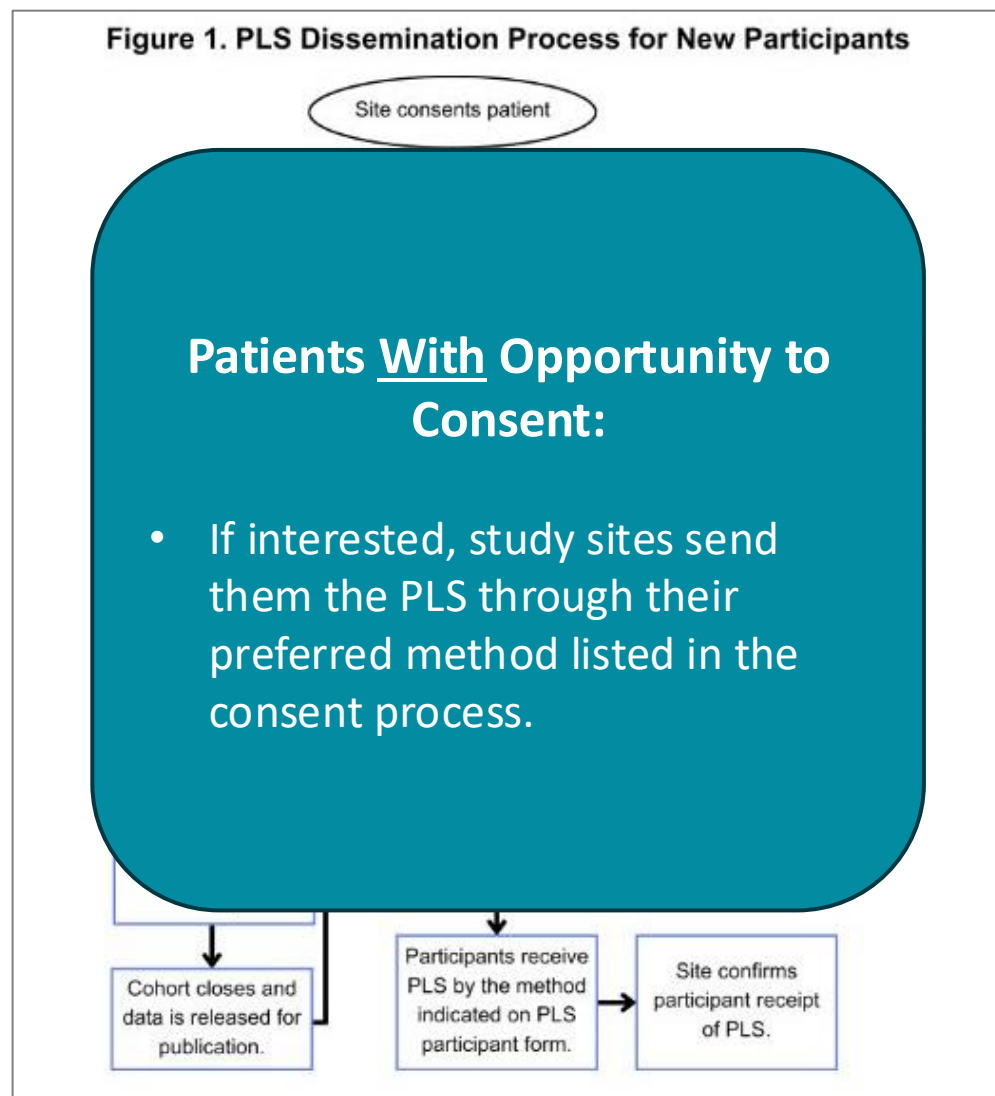
- **Recommendation:**

- Engage patients, patient advocates, study sponsors, sites, and IRB in developing PLS that meet the needs of the patients.

Two-Tiered Dissemination Process



Figure 1. PLS Dissemination Process for New Participants



Patients Without Opportunity to Consent:

- **If patient was alive at last follow-up:** Site reaches out to ask if they would like to consent to receiving a PLS. They then share it with them via their preferred method.
- **If the site is unable to make contact, or the patient has passed and is unable to consent:** The site keeps PLS on file and the PLS is shared publicly for anyone to find.

TAPUR PLS Template Vs. Published Examples



The results below show the best response seen for all people that were evaluable in the study.			
Response Category	Definition	Results	Visual
Progressive Disease	The cancer did not stabilize or shrink. The cancer grew, spread, or got worse despite treatment with drug name(s) .	# out of # (%) people had progressive disease.	
Stable Disease	The cancer did not shrink, but it did have a period of time (at least 16 weeks) when it did not grow. People continued receiving drug name(s) for as long as their cancer was stable.	# out of # (%) people had stable disease for at least 16 weeks.	
Partial Response	The cancer got smaller for a period of time while a person was on treatment. This means that the tumor responded to drug name(s) but didn't completely disappear. The cancer may have grown or progressed after the partial response.	# out of # (%) people had partial response.	
Complete Response	The cancer disappeared in response to treatment with drug name(s) . There were no signs of cancer in the person's body. Although there were no signs of cancer, the cancer may have returned after the complete response.	# out of # (%) people had complete response.	



The results below show the best response seen for all people that were evaluable in the study.			
Response Category	Definition	Results	Visual
Progressive Disease	The cancer did not stabilize or shrink. The cancer grew, spread, or got worse despite treatment with pertuzumab and trastuzumab.	17 out of 28 (61%) people had progressive disease.	
Stable Disease	The cancer did not shrink, but it did have a period of time (at least 16 weeks) when it did not grow. People continued receiving pertuzumab and trastuzumab for as long as their cancer was stable.	2 out of 28 (7%) people had stable disease for at least 16 weeks.	
Partial Response	The cancer got smaller for a period of time while a person was on treatment. This means that the tumor responded to pertuzumab and trastuzumab but didn't completely disappear. The cancer may have grown or progressed after the Partial Response.	8 out of 28 (29%) people had partial response.	
Complete Response	The cancer disappeared in response to treatment with pertuzumab and trastuzumab. There were no signs of cancer in the person's body. Although there were no signs of cancer, the cancer may have returned after the Complete Response.	1 out of 28 (4%) people had complete response.	

TAPUR PLS Template Vs. Published Examples



What Were the Side Effects?

Common and serious side effects that occurred during the study are shared in this section.

What is the Difference Between a Side Effect and a Serious Side Effect?

Side effects are any negative or unintended symptoms or diseases that happened during a person's time in the TAPUR Study. These effects may be related or unrelated to [a treatment](#).

Serious side effects include any side effects that result in:

- death or life-threatening medical issues
- need for medical attention
- disability impacting a person's life on a regular basis
- birth defects

The TAPUR Study collects information on any side effects that needed treatment by professionals. You or your loved one may have had side effects that are not listed below. Not all participants in this study had the side effects listed below.

Side effects are also commonly known as "adverse events."

What Side Effects Did We See in Cancer Type-Gene Alteration-Drug(s) Treatment Group?

Side effects and serious side effects that were reported as likely related to [drug name\(s\)](#) included:

- List of plain language [AE's](#) combined with [SAE's](#) with the number of people who experienced them (Ex: 2 out of 29 participants had a decline in red blood cell count that could have required a transfusion (anemia). Definitions of [AE's](#) for this section will be pulled from the AE dictionary.

OR

Patients in this treatment group did not have **reportable** side effects or serious side effects. However, this does not mean that you or your loved one did not have any side effects. Reportable side effects must [either](#):

- Be related to treatment with [DRUG NAME\(S\)](#)
- Require treatment by professionals
- Be severe enough to stop your daily activities, be life threatening, or cause death

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What Side Effects Did We See in Biliary Tract Cancer-ERBB2/3-Pertuzumab & Trastuzumab Treatment Group?

Side effects and serious side effects that were reported as likely related to pertuzumab and trastuzumab included:

- 1 out of 29 participants had low red blood cell count that could have required a transfusion (anemia).
- 1 out of 29 participants had diarrhea.
- 1 out of 29 participants had fatigue.
- 1 out of 29 participants had a reaction during or shortly after getting the medicine. This reaction can include fever, chills, rash, or low blood pressure.

Main Take Away

You can implement PLS in the middle of an active study.



Resources



- **TAPUR Study Resources**
 - o [Published TAPUR Plain Language Summaries](#)
 - o [Poster Presentation on TAPUR PLS - 2024 Society for Clinical Trials](#)
- **Recommended Tools:**
 - o [Hemingway Editor](#)
 - o Progress for Patients - [Glossary of Terms](#)
 - o [NCI Dictionary of Cancer Terms](#)
 - o [CTCAE v5](#) - The adverse event dictionary is a great starting point for generating plain language definitions.
- **Contact:**
 - o Abby.Gregory@asco.org
 - o TAPURPublications@asco.org

Thank you to the patients, loves ones, patient advocates, clinical sites, pharmaceutical companies, and TAPUR Study staff that make this research possible!



Returning information to CHRIS Participants: a matter of mutual respect

Deborah Mascalzoni PhD

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Centre for Research Ethics and Bioethics, Uppsala University, Sweden

Institute for Biomedicine, ELSI, Eurac Research, Italy

WHO TAG-G

SPEAKER SLIDES NOT AVAILABLE
CONTENT CAN BE VIEWED ON WEBINAR RECORDING

Moderated Discussion and Q&A



Closing Reflections



THANK YOU!!

Please reach out with any follow-up questions:

sbaedorfkassis@bwh.harvard.edu

(And please complete the brief experience survey that will pop up after you leave the webinar!)

