Plain Language Summary (PLS) Development and Implementation for the Targeted Agent and Profiling Utilization Registry (TAPUR) Study

ASCO TAPUR
Targeted Agent and Profiling Utilization Registry Study

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Presenting Author (A Gregory) Disclosures: Employment of Immediate Family Member through Pfizer

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Background

- The TAPUR Study is an actively enrolling precision oncology phase II basket trial started in March 2016, sponsored by the American Society of Clinical Oncology (ASCO).
- The study evaluates the antitumor activity of 17 commercially available targeted agents outside of their approved indication(s) in over 2,800 patients with advanced cancers with specific genomic alterations.
- In 2022, the TAPUR team developed processes for implementing PLS that are understandable at a 6th-8th grade reading level, while sharing necessary background and results of over 200 study cohorts.

TAPUR's Approach

Process and Content Development

Developing the PLS mid-study required the TAPUR team to first conduct a needs assessment and then develop and execute two processes simultaneously: 1) the consent and dissemination plan and 2) the PLS template content.

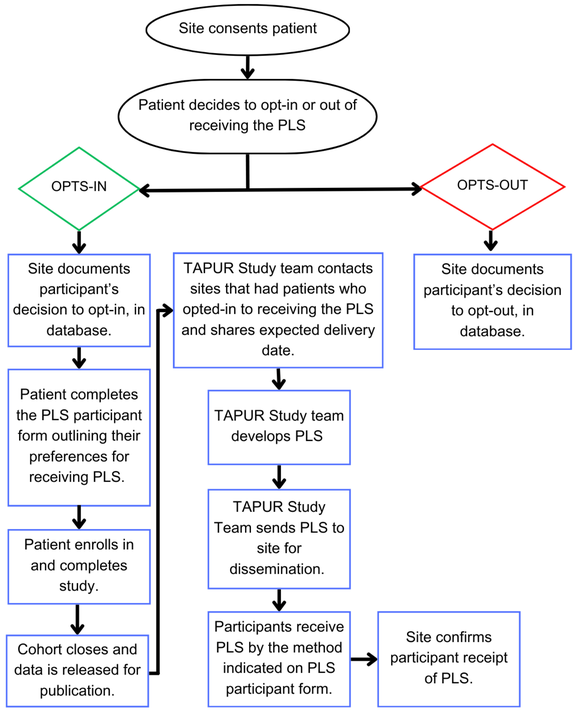
1. Consent and Dissemination Processes:

- Surveyed patients to determine how they would prefer to receive the PLS.
- Gathered feedback from clinical sites on dissemination.
- Coordinated internally to add PLS dissemination into the consent form and protocol.
- Identified how PLS would be disseminated to new participants (**Figure 1**) vs. participants who were enrolled prior to the consent form updates (**Figure 2**).
- Submitted the consent form and protocol updates to the IRB for approval.

2. PLS Content:

- Surveyed patients to determine what information they would like to see in the PLS.
- Identified topics best explained through a graphic vs. text (**Ex. 1 and 2**).
- Developed a study-specific dictionary of plain language adverse events (AEs) (**Ex. 3**).
- Engaged a multi-stakeholder group of reviewers comprised of Multi-Regional Clinical Trials (MRCT) representatives, patient advocates, TAPUR Steering Group members, clinical sites, participating pharmaceutical companies, and internal ASCO staff.
- Utilized the Hemingway App to ensure readability.
- Generated updates on public website to ensure ease of access.
- Started to develop collaborations for PLS translations.

Figure 1. PLS Dissemination Process for New Participants



Tools and Resources

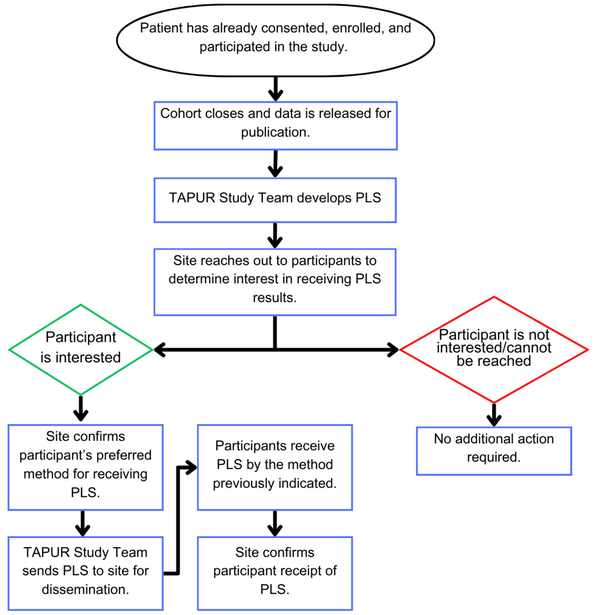
- *MRCT Toolkit:* TAPUR based the development of the PLS on the MRCT Center of Brigham and Women's Hospital and Harvard 2017 toolkit.
- *Hemingway App:* Accessible through hemingwayapp.com, this free tool shares real time feedback on reading level of your writing.
- *CTCAE v4.0 Terms with Lay Terms:* Outlines Common Terminology Criteria for Adverse Events' (CTCAE) approved lay definitions of AEs.

Challenges

Unique issues that the TAPUR team identified include:

- Developing a PLS template that addresses nuances found within a basket trial, mid-study.
- Developing and acquiring IRB approval for multiple templates to meet the unique needs of various cohorts.
- Tailoring the language of the PLS to suit audiences that include prospective, current and previously enrolled patients, while acknowledging that the primary audience may be those who have lost a loved one.
- Variation of clinical sites and levels of engagement.

Figure 2. PLS Dissemination Process for Participants Enrolled Prior to Consent Form Update



Note: All PLS will also be publicly available on the TAPUR Study webpages on asco.org.

Conclusions & Recommendations

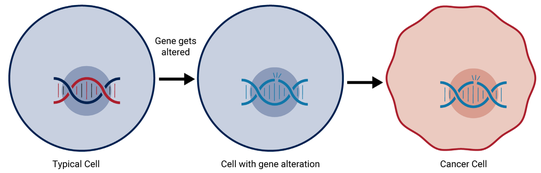
- PLS are important to patients and their loved ones and should be considered for implementation in all cancer trials.
- Incorporate PLS from the beginning of the study, but know it is possible to implement processes mid-way.
- Involving stakeholders at various stages is crucial to ensure content is comprehensive and accessible to all audiences.
- Translating PLS materials into other languages can improve accessibility and diversity of enrollment.
- Use graphics where appropriate to help explain complex topics.

Examples from the PLS Template

Example 1. Graphic outlining response categories in a cohort.

Response Category	Definition	Results	Visual
Progressive Disease	The cancer grew, spread, or got worse despite treatment with drug name. People who experienced this may have stopped treatment early.	# out of # (%) people had progressive disease.	
Stable Disease	The cancer didn't grow or shrink during a person's time on treatment. People continued receiving drug name 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 during a person's time on treatment. This means that the tumor responded to drug name but didn't completely disappear.	# out of # (%) people had partial response.	
Complete Response	The cancer disappeared in response to treatment with drug name. There were no signs of cancer in the person's body.	# out of # (%) people had complete response.	

Example 2. Graphic used to explain a gene alteration.



Example 3. Section of PLS outlining AEs for a specific cohort.

What Side Effects Did We See in Lung Cancer-CDKN2A-Palbociclib Treatment Group?

All side effects and serious side effects that are likely related to palbociclib included:

- 2 out of 29 participants had a decline in red blood cell count that could have required a transfusion (anemia).
- 2 out of 29 patients developed an infection.
- 1 out of 29 participants developed a loss of appetite.
- 1 out of 29 participants had fatigue.
- 1 out of 29 participants had vomiting.
- 19 out of 29 participants had abnormal bloodwork. This could be a sign of organ damage or infection. However, some people with abnormal bloodwork may recover on their own without any symptoms.

Acknowledgements

- The authors thank the TAPUR Study participants, coordinating center staff, clinical centers and staff for their ongoing support.
- Funding for the TAPUR Study is provided by AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Genentech, Merck, Pfizer, Seagen, now a wholly owned subsidiary of Pfizer Inc, and Taiho Oncology.