Citizen Petition

Date: March 9, 2022

The undersigned submits this petition pursuant to 21 CFR 10.30 of the __ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs) to request the Commissioner of Food and Drugs to amend the ***Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics -- Guidance for the Industry***.

A. Action Requested

To amend the *Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for the Industry* to require or strongly urge supplementary comparison of *Quality of Life-related patient reported outcome (QoL-PROs*)* for the following surrogate endpoints in randomized controlled clinical trials:

Endpoints Based on Tumor Assessments

Disease-Free Survival (and Event-Free Survival)
Objective Response Rate
Complete Response
Time to Progression and Progression-Free Survival (PFS)
Time to Treatment Failure

The guidance is currently worded as shown for progression free survival:

> *"A large improvement in progression-free survival (PFS) or high, substantiated durable ORR has been used to support traditional approval in select malignancies, but magnitude of effect, relief of tumor-related symptoms, and drug toxicity should also be considered when making the approval decision."*

Presently, important "tumor-related symptoms and drug toxicities" such as fatigue, brain fog, nausea, and pain, which can only be reported by the patient, is typically reported indirectly by the study team.

It is sometimes claimed that an improvement in PFS is in itself evidence of improved quality of life. However, this assumption (to our knowledge) is not supported by evidence or by the following investigation, which found:

> *PFS benefit was not strongly correlated with improvements in patients' quality of life, and, despite the palliative intent of treatments in the*

advanced/metastatic setting, the availability of quality of life data from clinical trials of cancer drugs was poor.[1]

Further, we note that for PFS (a composite endpoint) the word Survival is misleading to patients. It does not always follow that a study showing an improvement in this or other surrogate endpoints reliably predicts that patients will live longer. As reported here the correlation with improved survival is inconsistent and moderate overall:

Thirty-eight trials were included, and they comprised 19,031 patients across 8 tumor types. PFS-2 displayed a moderate correlation with OS (r = 0.67; 95% confidence interval [CI], 0.08-0.69). [2]

Addendum to this guidance urged and requested:

The assessment of *relief of tumor-related symptoms, and drug toxicity* should include a standardized set of **QoL-PROs**[3] on disease symptoms and treatment effects - reported directly by the patients.

Importantly, these outcomes will be secondary to the primary endpoints of tumor response serving to aid regulatory decisions when the magnitude of tumor assessments is questionable but also to inform clinical decisions by patients and physicians should the study protocol gain accelerated or full approval.

B. Statement of Grounds

Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics Guidance for Industry appropriately states that Progression Free Survival gains alone are not sufficient for granting marketing approval:

"A large improvement in progression-free survival (PFS) or high, substantiated durable Overall Response Rate has been used to support traditional approval in select malignancies, but magnitude of effect, relief of tumor-related symptoms, and drug toxicity should also be considered when making the approval decision.'

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[1] Association between progression-free survival and patients' quality of life in cancer clinical trials. Hwang TJ1,2, Gyawali B1,2. | Int J Cancer. 2019 Apr http://bit.ly/2ti7R17

[2] The validity of progression-free survival 2 as a surrogate trial end point for overall survival https://pubmed.ncbi.nlm.nih.gov/34985773/

[3] **QoL-PROs** effects of treatment or symptoms of the disease reported directly by the patients without interpretation from the study investigators or anyone else.

A primary goal of medicine is to provide relief from pain and suffering - and to restore our health by controlling or eliminating disease. Thus, comparing the effect of study drugs on *the patient's quality of life is integral to the assessment of clinical benefit in clinical research.*

Dr. Judith Karp in support of our petition writes:

> *"Quality of life (QoL) is critical to any response (or even without achieving so-called "objective response") -- and even if there is no quantitative improvement in survival, having a life that has quality is paramount to what we are supposed to be trying to accomplish! This has always been one of my major issues with bone marrow transplant -- chronic GVHD is no way to live. Or, in another vein, mere existence really is not fun (the "old man river syndrome:" tired of livin' and scared of dyin')."*

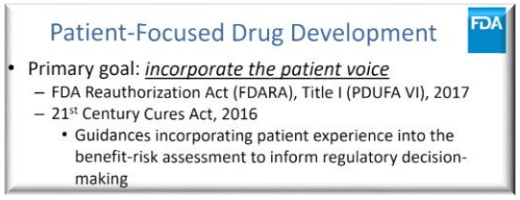
The unfiltered patient experiences compared in well-powered randomized controlled studies provides objective comparisons of the subjective experience of disease and treatment effects.

Is relying on the study team to report what only the patient can describe a scientific way to assess how well patients actually live while on treatment and how these effects change from baseline and in follow up?

Bishal Gyawali, and colleagues report (BMJ 2018;363:k4383) that *"studies of cancer drugs often use terms that downplay the seriousness of adverse events:"* [4]

The assessment and comparisons of QoL-PROs may be particularly relevant and to study drugs given continuously until disease progression or until unacceptable toxicity. Here we assert that the patient needs to know, and has a right to be informed about what to expect – if the possible improvements based on tumor assessments are offset, or further supported, by the side effects experienced.

We note that representatives to the F.D.A have called for "incorporating the patient voice," and rightly so. What better and more appropriate way to achieve this goal than to permit the patients participating in clinical research to report symptoms and drug effects directly?[5]



[4] Reporting harms more transparently in trials of cancer drugs | The BMJ 2018 | Bishal Gyawali, http://bit.ly/2BUnArQ

[5] Defining and Assessing Clinical Benefit:
A Regulatory Perspective - Sophia Bous Hufnagel, MD https://www.fda.gov/media/131585/download

Further clarification of the aims of petition:

Benefits

We maintain that the *secondary* assessment of QoL-PROs in registration trials comparing the study protocol with the standard of care would have the following benefits:

1. **Aid in regulatory decision-making.**

   When the primary efficacy outcome is modest in relation to the control and based on a surrogate that may not predict that the intervention is helping patients to live longer.

   An improvement in QoL-PROs in the study group, or no change, together with marginal improvement in PFS could support conditional or full approval; whereas a decline in quality of life would support the decision to require survival data to confirm clinical benefit. Having key secondary QoL-PROs would help the FDA to make and explain its regulatory decisions in close calls. We note that the call for inclusion of the patient experience is widely supported:

   "The American Society of Clinical Oncology, United Kingdom National Institute for Health and Care Excellence, and European Medicines Agency have all outlined the need to improve the quality of PRO trial results to better inform technology appraisals and licensing decisions"[6]

   Here we provide an EXAMPLE in the published literature:
   Quality of Life Effect of the Anti-CCR4 Monoclonal Antibody Mogamulizumab Versus Vorinostat in Patients With Cutaneous T-cell Lymphoma www.clinical-lymphoma-myeloma-leukemia.com/article/S2152-2650(20)30511-5/pdf

   "The symptoms, emotions, function, and overall QoL effects on patients treated with mogamulizumab were generally more improved compared with patients treated with vorinostat across most of the function and symptom areas. Overall, these results suggest that patients receiving mogamulizumab had improved QoL associated with their disease- and cancer-specific conditions and overall QoL, with a statistically significant decreased risk of experiencing a more rapid deterioration in their QoL compared with vorinostat."

- [6] Systematic evaluation of Patient-Reported Outcome protocol content and reporting in cancer trials | JNCI: Journal of the National Cancer Institute | Oxford Academic http://bit.ly/2UmKcYx

Possible scenarios:

Major improvement in time to relapse with modest impairment in QoL.
(Approval could still be justified)

Modest improvement in time to relapse with impairment of QoL
(Longer follow-up justified)

Modest improvement in tumor response with improvement in QoL
(Approval could still be justified)

2. **Foster public trust in clinical research and regulatory decisions** by making what is studied truly patient-centered, and improving its scientific validity. *(If the COVID-19 crisis has taught us anything it is the need to increase public trust in clinical science and in the standards and independence of regulatory review.)*

3. **Guide clinical decisions made by doctors and patients** for the study treatments approved using this methodology. On this Dr. Ethan Basch writes:

"Regulators and industry continue to prioritize survival-based end points rather than patient-experience end points in cancer-drug development. Yet as patients live longer with cancer, they must increasingly choose among agents with varying efficacy–toxicity balances." [7]

We remind that cancer is a disease that disproportionally afflicts the elderly and that comfort care is a common focus of medicine in this population.[8]

Related is the need to raise and create standards for *how QoL-PROs are captured and reported in clinicaltrials.gov*. The results should provide clarity to aid in public and physician understanding.

4. **Improve safety for study participants** – particularly if QOL-PROs are captured in real time with ePROs – this by alerting the study team to the need for study drug dosing adjustments or discontinuation.[9] Including real-time QOL-PROs could also help to improve accrual in future trials.

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[7] Toward Patient-Centered Drug Development in Oncology
Ethan Basch, M.D. https://www.nejm.org/doi/10.1056/NEJMp1114649

[8] Quality of Life in elderly patients with cancer | Health and Quality of Life Outcomes | Full Text
http://bit.ly/2KEm2sB

[9] Electronic Patient-Reported Symptom Monitoring Associated With Increased Survival Among Patients with Metastatic Cancer - For The Media - JAMA Network | Ethan Basch, M.D http://bit.ly/2XlWB1o

We anticipate that the benefits of including QoL-PROs (particularly making use of electronic instruments for capture and reporting) would add little to the workload of investigators or costs to drug sponsors. In one report on the cost of surveillance using we web-based PROs the study team concluded:

"Surveillance of lung cancer patients using web-based PRO reduced the follow-up costs. Compared to conventional monitoring, this surveillance modality represents a cost-effective strategy and should be considered in cancer care delivery.[10]

For the reasons explained in detail above, we (the undersigned) respectfully request that the F.D.A. take the following actions:

Provide guidance to clinical trialists, drug sponsors, and Institutional Review Boards regarding the need to capture and compare QoL-PROs as secondary (supplemental) endpoints – particularly when the primary endpoint is a surrogate for clinical benefit based on tumor imaging.

Help to set standards for secondary QoL-PRO reporting, beginning with ClinicalTrials.gov. This so that what is reported can be readily utilized to interpret the study results in order to guide clinical practice and better-informed patient choice. Indeed, the failure to include QoL-PROs seems related to how inconsistent and poorly-designed the efforts have been to report QoL-PRO results to date:

"The current standard of reporting of HRQL needs to be improved. Major deficiencies that should be addressed are failure to provide a rationale for HRQL assessment and inadequate description of methodology." [11]

C. Environmental Impact

(A) We claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic Impact

The economic impact will be submitted upon the request of the commissioner.

E. Certification

[10] Cost-Effectiveness of Web-Based Patient-Reported Outcome Surveillance in Patients With Lung Cancer https://www.jto.org/action/showPdf?pii=S1556-0864%2819%2930113-3

[11] The standard of reporting of health-related quality of life in clinical cancer trials. - PubMed - NCBI http://bit.ly/2WNqojs J Clin Epidemiol. 2000 May;53(5):451-8. Lee CW1, Chi KN

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Karl Schwartz
Patient advocate, caregiver
Formerly: President of Patients Against Lymphoma, FDA patient representative, CIRB member – adult early phase, NCI Steering committee for lymphoma and co-chair Patient Advocate committee.

(b) (6)
[redacted]
[redacted]

See also below: Endorsing the enclosed Citizen Petition

Related Publications

- **How often and well are QoL-PROs reported in Lymphoma and CLL studies?**

  Presently few phase 3 trials have included quality of life assessment (20%) and fewer have reported results (10%).

  Further the QoL *reporting of results appears lacking in standards* and is difficult to compare or interpret.

  ClinicalTrials.gov
  Search for completed phase 3 Lymphoma OR CLL studies
  including QoL assessments as of 2/4/19:

  Completed Studies | Phase 3
  336 studies http://bit.ly/2GajYG2

  Completed Studies | Phase 3 | QoL OR Quality of Life
  68 studies (20%) http://bit.ly/2UzaSpk

  Completed Studies | Phase 3 | Quality of Life OR QoL | With Results
  34 studies (10%) http://bit.ly/2UEL3E9

- Toward Patient-Centered Drug Development in Oncology
  Ethan Basch, M.D. https://www.nejm.org/doi/10.1056/NEJMp1114649
- The validity of progression-free survival 2 as a surrogate trial end point for overall survival https://pubmed.ncbi.nlm.nih.gov/34985773/
- Patient-reported outcomes in randomized clinical trials: development of ISOQoL reporting standards | Qual Life Res. 2013; 22(6): 1161–1175. Published online 2012 Sep 18. doi: 10.1007/s11136-012-0252-1 http://bit.ly/2Uo3QqU
- Electronic Patient-Reported Symptom Monitoring Associated With Increased Survival Among Patients with Metastatic Cancer - For The Media - JAMA Network | Ethan Basch, M.D http://bit.ly/2XlWB1o
- Cost-Effectiveness of Web-Based Patient-Reported Outcome Surveillance in Patients With Lung Cancer https://www.jto.org/action/showPdf?pii=S1556-0864%2819%2930113-3
- Baseline quality of life as a prognostic indicator of survival: a meta-analysis of individual patient data from EORTC clinical trials - ScienceDirect | Chantal Quinten, MSc Corneel Coens, MSc Murielle Mauer, PhD Sylvie Comte, MD Prof Mirjam AG Sprangers, PhD Prof Charles Cleeland, PhD et al. http://bit.ly/2CN6kFn
- Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial - Ethan Basch , Allison M. Deal , Mark G. Kris , Howard I. Scher , Clifford A. Hudis , Paul Sabbatini... http://bit.ly/2WB3LhU
- Cancer Therapy and Prevention Association between progression-free survival and patients' quality of life in cancer clinical trials Thomas J. Hwang Bishal Gyawali http://bit.ly/2G9pjxd
- The Emerging Patient Role in Toxicity Reporting... http://bit.ly/2RB0CuX
- The standard of reporting of health-related quality of life in clinical cancer trials. - PubMed - NCBI http://bit.ly/2WNqojs J Clin Epidemiol. 2000 May;53(5):451-8. Lee CW1, Chi KN
- Analysis of the quality of reporting of randomized controlled trials in acute and chronic myeloid leukemia, and myelodysplastic syndromes as govern... - PubMed - NCBI http://bit.ly/2HWPDMR Ann Epidemiol. 2009 Jul;19(7):494-500. doi: 10.1016 Ziogas DC1, Zintzaras E.
- Association between progression-free survival and patients' quality of life in cancer clinical trials. - PubMed - NCBI http://bit.ly/2ti7R17 Int J Cancer. 2019 Apr 1;144(7):1746-1751. Hwang TJ1,2, Gyawali B1,2.
- Reliability of an e-PRO Tool of EORTC QLQ-C30 for Measurement of Health-Related Quality of Life in Patients With Breast Cancer: Prospective Randomized Trial http://bit.ly/2E7RBG6 J Med Internet Res. 2017 Sep; 19(9): e322. | Gunther Eysenbach
- Capturing Patient-Reported Outcome (PRO) Data Electronically: The Past, Present, and Promise of ePRO Measurement in Clinical Trials http://bit.ly/2NwnR8N Patient |

Stephen Joel Coons,corresponding author Sonya Eremenco, J. Jason Lundy, Paul O'Donohoe, Hannah O'Gorman, and William Malizia

- Implementing ePRO Systems in Clinical Trials | Jovana Vojnovic, M.Sc.; Jerry Legierski, B.Comm. July 2015 HealthDiary Inc http://bit.ly/2T1CxCX
- Reporting harms more transparently in trials of cancer drugs | The BMJ 2018 | Bishal Gyawali, http://bit.ly/2BUnArQ
- Development of an integrated electronic platform for patient self-report and management of adverse events during cancer treatment http://bit.ly/2BZpffM
- Measurement of Quality of Life in Patients with Mycosis Fungoides/Sézary Syndrome Cutaneous T-Cell Lymphoma: Development of an Electronic Instrument http://bit.ly/2EWGAqr J Med Internet Res. 2019 Jan; 21(1): e11302. Instrument Download: https://www.openresearchexchange.com/
- Graft Versus Host Disease Clinical Trials: Is it Time for Patients Centered Outcomes to Be the Primary Objective? - PubMed - NCBI http://bit.ly/2TuzRJg
- Reporting on quality of life in randomised controlled trials: bibliographic study | The BMJ http://bit.ly/2FL7AJE
- Systematic Review of Radiation Therapy Toxicity Reporting in Randomized Controlled Trials of Rectal Cancer: A Comparison of Patient-Reported Outcomes... Int J Radiat Oncol Biol Phys. 2015 Jul 1;92(3):555-67. doi: 10.1016/j.ijrobp.2015.02.021. http://bit.ly/2TL6ItN
- Systematic evaluation of Patient-Reported Outcome protocol content and reporting in cancer trials | JNCI: Journal of the National Cancer Institute | Oxford Academic http://bit.ly/2UmKcYx Derek Kyte Ameeta Retzer Khaled Ahmed Thomas Keeley Jo Armes Julia M Brown Lynn Calman Anna Gavin Adam W Glaser Diana M Greenfield
- Quality of Life in elderly patients with cancer | Health and Quality of Life Outcomes | Full Text http://bit.ly/2KEm2sB
- Focusing on Core Patient-Reported Outcomes in Cancer Clinical Trials: Symptomatic Adverse Events, Physical Function, and Disease-Related Symptoms | Clinical Cancer Research | Paul G. Kluetz, Richard Pazdur et al. http://bit.ly/2UidzuY
- Association between progression-free survival and patients' quality of life in cancer clinical trials. Hwang TJ1,2, Gyawali B1,2. | Int J Cancer. 2019 Apr http://bit.ly/2ti7R17

Endorsing the enclosed Citizen Petition

Your name (with optional credentials/affiliation)	**Zip code**	**Optional Comment**
T. Trischetta	18064	
Bruce Whitesell	18081	Too many friends and family members have suffered from Lymphomas, with information on outcome scanty. Not enough information about survivors.

Jama Beasley, Patient & Advocate	23336	Quality of life IS the endpoint to living post-diagnosis for the patient. Patients are people who want to live well even WITH cancer.
Robert McEachern	6517	
Mary Pat Berry	53562	Including Patient Reported Outcomes as part of trials can at minimum inform future patients of how their quality of life may be affected by a treatment.
Margot Freund	33131	
Peg Ford	33770	
Neil T, Jesiolowski	18972	
Ann Fonfa, Founder/President Annie Appleseed Project	33446	As Patient Advocates, we are always concerned about quality of life. Without quality, there is no real life.
Linda Gerstley, Ph.D.	34241	
Joanne Schwartz	18064	This would also help the public to trust clinical research
Susan Baer	11570	You are asking important survivor questions.
Virginia R Hetrick, Patient Advocate,	9E+08	Inflammatory Breast Cancer patient and survivor with no recurrences since initial diagnosis on 14 March 1991; Endometrial cancer patient and survivor with no recurrences since initial diagnosis in May, 1993; President of You Are Not Alone since Summer,1995; presenter of research at SABCS, AACR-Annual Meeting, AACR-Disparities Conference and other meetings; member of UCLA Patient-focused Technology Council; Research Patient Advocate on research teams at City of Hope and University of Southern California Norris Cancer Center; Peer Counselor for patients at City of Hope.
Patricia Spears	27615	
Kay Kays	85351	
Marilyn Beaudin	80020	
Carolyn A Beery/fNHL patient	27712	
William May	22025	For follicular lymphoma patients, the disease a chronic condition so progression free survival (PFS) and quality of life are very important ,meaningful measures when selecting a treatment.
Gretchen May	22025	For follicular lymphoma patients, the disease a chronic condition so progression free survival (PFS) and quality of life (QoL) are very important, meaningful measures when selecting a treatment.
Helen Esposto	10804	
Diane Daum	60487	
Wenora Johnson	60435	
Michelle McDermott	2649	As a patient with Follicular Lymphoma, I want to know that during treatment my quality of life will be preserved and that the treatment is giving me the best opportunity for progression free survival.
Michael Abrams, Patient Advocate, Alliance	2889	

Francis Kelly	13027	I very firmly support this effort. PROs very important but ignored.
Jacqueline Cardoza	93274	13 year fNHL survivor.
Carol Lee	92124	
Betty Post	93953	
Mark Sutter	43206	
Gregg Kapp	93065	
Gabe Torok	33418	
Margot Freund	33131	So important to hear directly from patients.
S. Krivacic	78731	
Bishal Gyawali	2149	
Jan Waters	43229	
Marilyn Beaudin	80020	
Melissa Olive, PhD, BCBA-D, LBA	6525	
Rosemary James	95928	
Judith E. Karp, MD	21208	Much needed effort in the overall assessment of clinical benefit!
Debbra Kulhanek	33914	As a cancer patient, the importance of QoL is critical to making treatment decisions with my medical team.
Hedy Weiner	2067	
S. Kruvacic	78731	
Alexis Soule	1945	This is a very important idea.
Joseph Franlin	18942	
Marilyn Beaudin	80020	
Iva Lesky	14850	
Stacy Joslin	55331	
Farhana Ali	16648	
Jan Waters	43229	
Susan Baer	11570	
Patti A. Miller	49089	I have had follicular lymphoma for 16 years. I have been treated three times over the course of my disease, and am participating in a clinical trial (currently in my 5th year of the trial).
Diana T Chingos, MS, MFA Cancer Patient Advocate, Los Angeles	91604	
Edward Blank	94520	
Carol Lee	92124	
Lynda Olender PhD, RN	7020	
Ilse Ortabasi	81133	CLL patient
Edmund Epstein	60089	I agree that Qol should be a consideration in clinical trials. I participated in a NCI trial in 2000.
Diane Heditsian, Advocate UCSF Breast Oncology Program	94062	ENDORSE!
Edward Blank (patient)	94520	

Kay Kays- Patient Research Advocate for NIH, NCI, PCORI, DoD, CSC, TGEN, G4CR, PanCAN, ACS, SU2C, Methods for Clinical Research, Alliance for Clinical Trials in Oncology	85351	This would be an enhancing addition for patient accrual into clinical trials which would both benefit research and cancer patients and their families peace of mind
Massimo Di Maio	10028	
Todd Olson	14850	
Larry and Patti Schoenenberger	18036	
Michael Abrams	2889	
Karni Perez - blood cancer patient	36830	This is an important way to gather information on effects of medications.
Ellen Stegman	10075	
Todd Stone	18930	
Sally Schott	97504	Quality of life is at least as important as length of life. Abjectly miserable weeks or months are not a win I'd want. I've seen them.
Rudnei de Lorenzi Cancellier	8.1E+07	Qualitativo of Life and sidde effects are Very important in follicular lymphoma due It Will returno, so between remission s patients should have a normal life
Carolyn A Beery	28617	
Helen Esposto	10804	
Michelle McDermott	2649	This is so very necessary to be added to the FDA's requirements. What good does it do to put a person in a remission if they are left with constant pain, fatigue, nausea, etc that never lets up.
Judith E. Karp, MD, Professor Emerita, Oncology and Medicine, Johns Hopkins SChool of Medicine	21208	Karl Schwartz's effort toward rigorous evaluation of quality of life issues is of paramount importance to determining the optimal application of any oncology drug. Bravo!!!!!
Elihu Estey	98109	
Linda Gerstley	34241	
Ann Fonfa, founder/president Annie Appleseed Project	33446	I serve on the Cochrane Collaboration's Adverse Effects Methods Group and remain very concerned about the too-casual way harms are accepted, ignored and downplayed in clinical trials. When adverse effects are KNOWN to occur, steps should be taken to PROTECT the humans involved.
Debbie Kulhanek	33914	
Jon Waggoner	95811	I have fNHL and this information on treatments is important to me
Barbara Coyle	14850	let's listen more to what patients have to say.....
James Shaw	14850	
Elisabeth Stahl	14850	I am 92....I want my voice to be heard
Theresa Trischetta	18930	
Todd Stone	18930	
Theresa Rutigliano	10309	
Karen Marie Bedics	18036	Important to consider effects on patient!

Rose Strong	18930	As a caregiver to someone with cancer, I think this is an integral part of their quality of life. Patients need to be involved, especially during clinical trials.
Deborah A Yerger	18036	
James J Yerger	18036	
Amie Benner	18055	
Pat Krueger	18036	
Arianne Elinich	18036	
Lauren Bullsnake	18014	
Sally Schott	97504	20 years ago when I first worked in this space as my brother's caregiver, this information could be obtained almost only through patient/caregiver support forums, online or in communities. It was very happenstance. The movement to interweave patient-reported quality-of-life outcomes into drug assessments is important.
William May	22025	
Toni Montserrat	8172	As a CML Patient, and Patient Advocate, absolutely agree!!!
Marcia Brace	22102	
Stacy Joslin	55331	
David C. Norris, MD	98102	
Nancy Santanello	18938	
Carol Lee	92124	
Joan Venticinque	94061	