Statement by Prof. Dr. Michael Frass on Oncologist's retraction of lung cancer study Study withdrawn due to overqualification

Below, I describe the reasons that ultimately led to the withdrawal of the article on improving quality of life and prolonging survival in patients with small cell lung cancer from the renowned journal *The Oncologist*.

Summary of the statement

After two years of meticulous review, the validity of our data was confirmed in September 2024. Then, on July 29, 2025, while I was on vacation, I received a surprise email from Prof. Susan Bates, Editor of *The Oncologist* journal. This email is included in the following long version of the statement

I was asked to respond within 3 (three!) days, otherwise the article would be withdrawn. I replied within 2 days. To this day, I still don't understand what is meant by "one-armed study," as I always compare 2 groups as a clinician. I was also surprised by the question about the use of homeopathic medicines (HMPs) in my private practice.

Even after sending another email, I received no response for about 2.5 months. Suddenly, I received an email dated October 24, 2025, informing me that the withdrawal had now been confirmed. The reason given was that the study might not be reproducible due to its individualized nature.

Of course it would be, since several hundred Austrian doctors in the respective societies until today AND students at the Medical University of Vienna had been trained in classical homeopathy until 2018.

Apart from the fact that none of the authors ever "marketed" homeopathic medicines at the respective clinics, the assumption that there is a conflict of interest at a price of around €15 per vial seems ridiculous. Neither I nor any of the co-authors ever received a commission from the pharmacy; on the contrary, the study medication had to be paid for.

The data, which was verified as correct in September 2024, was not questioned in any way.

The reason for the retraction is therefore the overqualification of the homeopaths, who have completed this additional medical training and have mastered the method.

Conclusion

The data in the study are correct, as they were thoroughly checked by the journal several years ago. The abstract of the study can therefore still be cited:

Frass M. Additive Homeopathy Improves Quality of Life and Prolongs Survival in Patients With NSCLC: A Prospective, Randomized, Placebo-Controlled, Double-Blind, Three-Arm, Multicenter Study. World Health Congress, Prague, Czech Republic, Oct 3–5, 2025. Available from: https://www.whc2025prague.com/program-en/michael-frass2

Long version of the statement

Email from the editor of the journal

"At the suggestion of the Committee on Publication Ethics (COPE), I had an informative meeting with representatives from the Medical University of Vienna and the Austrian Agency for Research Integrity (ÖAWI) regarding their ongoing concerns about your article, 'Homeopathic Treatment as an Add-On Therapy May Improve Quality of Life and Prolong Survival in Patients with Non-Small Cell Lung Cancer: A Prospective, Randomized, Placebo-Controlled, Double-Blind, Three-Arm, Multicenter Study.'

The meeting raised the following questions, which I would appreciate your responses to:

Did your randomized controlled trial include any participants who were enrolled originally in your single-arm study? If so, could you please indicate how many patients were enrolled in the single arm portion of the trial and how that was managed when the randomized portion of the study opened?

Can you please disclose the specific homeopathic compounds used in your study, including their potencies and dosing regimens? If these varied by patient or group, how were those variations determined and recorded?

At the time your study was submitted to and published in *The Oncologist*, were you also recommending or prescribing the same homeopathic compounds to patients in your private practice?

Please respond to these questions no later than August 1st. If you do not respond by then or cannot provide satisfactory explanations, I now feel I will need to retract the paper.

Sincerely, Susan E. Bates, MD Editor-in-Chief The Oncologist

Email reply from the author

Given the three-day ultimatum, I responded within two days. Below is a summary of my response:

"Ad 1) This question is concerning as it suggests serious misunderstanding by the private association OeAWI about the conduct of our trial. I have not been asked to respond to a question about a single-armed phase of our study before, and am alarmed that it has arisen now after our detailed rebuttal of the OeAWI case, and your consideration of our response.

From this question, it appears the OeAWI believes there was an 'original single-armed study' leading up to the DB-RCT, with the patients in that non-randomized single group being transferred into the later randomized trial. If this were the case, questions about blinding and randomization would indeed be pertinent and your concerns understandable.

However, I cannot stress more clearly that there was no such prospective singlearmed lead-in study related to the published DB-RCT. I am of course happy to respond further if there is additional information or a particular interpretation that I have not yet been made aware of. My concern here is that a misunderstanding has crept into the discussion with the OeAWI which I have not been afforded the opportunity to correct.

As we have noted previously, all recruited and randomized participants were logged in the computerized Randomizer[®] audit trail, which you have seen, and were noted in the CONSORT participant flow diagram, along with the non-randomized observation group. This audit trail guarantees an accurate log of included patients and prevents undetected post-hoc exclusion of already included patients.

Thus, in answer to your question, our randomized controlled trial did not include any participants who were originally enrolled in a single-arm trial (nor in a two-arm open trial), as such a phase did not exist. We have already clarified this question in detail in our previous communication.

(To this day, I still don't understand what is meant by a 'one-armed study', since as a clinician I always compare two groups, whether openly or blindly, as in this study.)

Ad 2) According to the 'classical homeopathy' approach, homeopathic medicinal products are prescribed after careful history taking, tailored to the individual patient. The appropriate potency and dosing strategy is also individualized, according to the needs of each patient at each appointment: there is no general regimen, but all decisions are underpinned by in-depth homeopathic knowledge.

This level of detailed individualization requires several years of medical study, and 'individualized homeopathic treatmen' is a methodological approach recognized throughout the homeopathic sector, worldwide. To support transparent reporting and replicability of our published RCT, in Tables 6 and 7 of our work (see attached), the homeopathic medicinal products used in our study were listed in full, with the numbers of patients that were prescribed each medicine and which randomized group they belonged to. The prescriptions were based on the physician's assessment at each visit and were documented in the case files.

Ad 3) Although I do not see the relevance of this question to the study or any case of misconduct, I will answer it for the sake of transparency. Yes, at the time of submission and publication of the study, I also prescribed the same homeopathic medicines in my private practice.

It is not clear for me how this is relevant to the RCT, as it appears well beyond the scope of any points previously made in the misconduct and retraction case to date. To answer your question, at the time the study was submitted to and published in *The Oncologist*, I was also recommending and prescribing the same homeopathic medicinal products (not compounds!) to patients in my private practice. I have also been doing this simultaneously for 15 years with numerous patients (not included in the study) in the outpatient unit 'Homeopathy for cancer patients' of the Department for Internal Medicine I (Head: Prof. DDr. Christoph Zielinski) of the Medical University of Vienna. This outpatient clinic for additive homeopathy was founded and endorsed by Prof. Christoph Zielinski, Austria's leading oncologist, together with the then Rector of the Medical University of Vienna, Prof. Dr. Wolfgang Schütz (Pharmacologist), and the then Director of Vienna General Hospital (AKH Vienna), Prof. Dr. Reinhard Krepler. I emphasize that the medicines used in the RCT are commonly used across homeopathic practice and

were not used as a replacement for conventional treatment, but were adjunctive. Homeopathy is also used and taught in many universities around the world, including e.g. Shaare Zedek Hospital in Jerusalem (Israel).

I received no response for about 2.5 months, even after sending another email. Suddenly, I received an email dated October 24, 2025, informing me that the withdrawal had now been confirmed. The following two reasons were given:

- "1) The published paper omitted an important methodological detail: each patient received an individualized homeopathic treatment tailored to their condition, personality, and constitution, meaning both dosing strategies and potencies were also individualized and could vary over the course of treatment. Although the published paper discloses all prescribed medicinal products in Tables 6 and 7, along with the number of patients per product and group allocation, it does not report changes in dosing or potency, making the study's findings difficult to reproduce.
- 2) At the time of article publication, the authors did not disclose to the journal that the same homeopathic medicinal products were being marketed and prescribed by the first author's clinic while the clinical trial was ongoing. This should have been disclosed as a conflict of interest in the published paper."

My (abridged) response

"Ad 1) When considering whether sufficient detail has been provided for a trial to be replicated, there are two related issues to consider – whether the technique itself is inherently replicable and the level of reporting detail.

Firstly, it is essential to clarify that individualizing both the homeopathic medicinal substance and potency to suit each patient is a fundamental requirement for individualized homeopathic treatment (IHT) to be efficacious. The homeopathic regimen was therefore delivered correctly for a trial which aimed to assess the efficacy of IHT.

Thus, as IHT is a truly personalised medicine, during a standard DB-RCT design, what is being assessed is the technique itself, not efficacy of the individual medicines: this has already been demonstrated by multiple independent research teams.

Ad 2) I must confess that this argument was unexpected and is deeply confusing. I can only surmise that it represents a genuine, yet fundamental misunderstanding of the nature of homeopathic medical practice, and risks misrepresenting both myself, as the lead author, and the homeopathic profession at large.

The proposed retraction notice claims that "homeopathic medicinal products were being marketed and prescribed" while the clinical trial was ongoing and suggests that this prescription of medicines (as part of normal homeopathic medical practice) is a conflict of interest: I fail to see how. The intervention assessed in this study (IHT) is the same technique, involving the same range of unpatentable medicines, as that used by homoeopathically-trained physicians worldwide. If the concern is that I was using this modality in my private practice during the study, this same situation frequently applies to doctors who work in both conventional clinical practice and research. As for categorization of the medicines themselves, there is no pathway available for me to benefit personally or financially by prescribing them, in such a way as to create bias in

the trial outcome. In fact, I never "marketed" homeopathic medicines; I merely prescribed them.

Point 1 explains that homeopaths are obviously overqualified. Of course, trained homeopaths can replicate such a study, as can the hundreds of students who had the opportunity to learn homeopathy as part of an elective course at the Medical University of Vienna."

Conclusion

The data in the study are correct, as they were thoroughly checked by the journal several years ago. The abstract of the study can therefore still be cited:

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