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Personalized Cancer Vaccines in the Clinical Trial Pipeline

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ABSTRACT

Aim: To present an overview of personalized cancer vaccines currently undergoing clinical development, aiming to enhance awareness and promote collaboration among academic, commercial researchers, and non-profit communities.

Methods: A dataset of 78 clinical trials for personalized cancer vaccines was generated using ClinicalTrials.gov database as of November 25, 2024. We conducted an analysis of the studies based on sponsors, conditions, phases, types of vaccines, and global geographic distribution.

Results: The majority of trials focused on peptide vaccines (40%) and dendritic cell vaccine (19%), targeting solid tumors, brain, pancreatic and breast cancers, among others. Phase 1 trials dominated the landscape, accounting for over 90% of studies, with significant activity in the United States (44%) and China (24%). Industry sponsors backed 22% of studies. Active trials represented 72% of the dataset, reflecting ongoing research efforts in this field. Enrollment sizes varied widely, ranging from small exploratory cohorts of fewer than 10 participants to larger-scale trials enrolling up to 700 patients. Completed clinical trials evaluating personalized neoantigen vaccines across various cancer types showed that vaccines were generally well-tolerated, elicited strong T-cell responses, and resulted in promising clinical outcomes such as tumor shrinkage or prolonged progression-free survival, particularly in melanoma, glioblastoma, and urothelial cancer, although no universal cure was demonstrated.

Conclusions: There is a broad early-stage pipeline of personalized cancer vaccines currently being tested in clinical trials for various cancer types.

1 | Introduction

The development of personalized cancer vaccines, tailored to a patient's tumor antigens, has emerged as a promising strategy in targeted cancer immunotherapy [1]. Unlike traditional therapies, personalized vaccines target tumor-specific mutations in individual patients, offering the potential for improved efficacy and reduced off-target effects [2].

In recent years, the development of personalized cancer vaccines has gained significant momentum, with numerous clinical trials exploring diverse vaccine platforms, including peptide-based, RNA-based, DNA-based, and dendritic cell-based approaches. This article provides an overview of the current clinical trial landscape for personalized cancer vaccines, highlighting trends, geographic distribution, sponsors, and vaccine platforms, as captured in the ClinicalTrials.gov database.

2 | Materials and Methods

Clinical trial data were downloaded from ClinicalTrials.gov on November 25, 2024, using the following search criteria:

- Condition: Cancer
- Intervention/treatment: Personalized vaccine
- Study type: Interventional
- Phase: Early Phase 1, Phase 1, Phase 2, Phase 3
- Status parameter: "Recruiting," "Not yet recruiting," "Active, not recruiting," "Enrolling by invitation," or "Completed."

In our analysis, trials designated as "Early Phase 1" were grouped with Phase 1 trials. "Phase 1/Phase 2" trials were also combined with Phase 1 trials, while "Phase 2/Phase 3" trials were merged with Phase 2 trials.

Clinical trial statuses of "Recruiting," "Not yet recruiting," "Active, not recruiting," and "Enrolling by invitation" were collectively categorized as "Active." For clinical trial NCT03929029, which has published results on ClinicalTrials.gov, the status was considered "Completed."

As of November 25, 2024, we identified 79 interventional clinical trials that met our search criteria. One trial evaluating a pneumococcal 13-valent conjugate vaccine was excluded as it was unrelated to the study focus.

Study details for each clinical trial were analyzed, including the type of vaccine and details on the conditions. Detailed clinical trial data are provided in Supporting Information File S1.

Cancer types were grouped according to the location of the cancer. The categories applied to the analysis are:

- "Brain Cancer"—Glioblastoma, Gliomas, Pediatric Brain Tumor, Childhood Glioblastoma
- "Breast Cancer"—Breast Cancer, Triple Negative Breast Cancer
- "Pancreatic Cancer"—Pancreatic Tumor, Pancreatic Adenocarcinoma
- "Hematologic Malignancies"—Lymphocytic Leukemia, Follicular Lymphoma, Smoldering Plasma Cell Myeloma
- "Lung Cancer"—Non-small Cell Lung Cancer, Small Cell Lung Cancer, Squamous Cell Lung Cancer, Squamous Non-small Cell Lung Cancer
- "Melanoma"—Melanoma, Cutaneous Melanoma
- "Prostate Cancer"—Prostate Cancer
- "Digestive System Cancers"—Colorectal Neoplasms, Esophageal Cancer, Hepatocellular Carcinoma, Digestive System Neoplasms
- "Bladder Cancer"—Bladder Cancer, Urothelial Cancer
- "Kidney Cancer"—Kidney Cancer

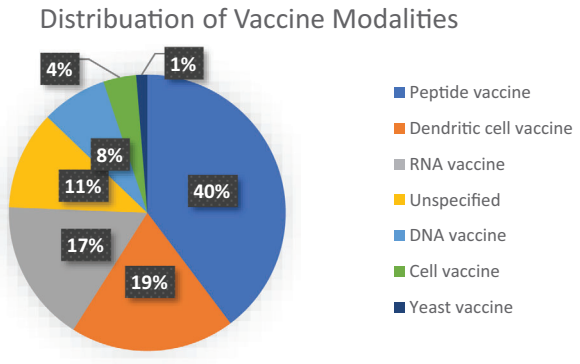

FIGURE 1 | Number of clinical trials by vaccine type.

- "Head and Neck Cancer"—Head and Neck Cancer, Squamous Cell Carcinoma of the Head and Neck
- "Ovarian Cancer"—Ovarian Carcinoma, Epithelial Ovarian Cancer
- "Sarcoma"—Ewing Sarcoma, Rhabdomyosarcoma, Synovial Sarcoma
- "Solid Tumors"—Three or more different types of solid tumors investigated in one clinical trial
- "Neoplasms (Unspecified)"—Neoplasms

Neoantigen vaccines were divided into 7 different categories: Cell vaccine, RNA vaccine, DNA vaccine, Yeast vaccine, Peptide vaccine, Dendritic cell vaccine, and Unspecified.

For trials classified as "Completed," publications associated with their respective NCT numbers were reviewed to extract details on safety, immunogenicity, and efficacy outcomes.

3 | Results

As of November 25, 2024, a total of 78 personalized cancer vaccine trials on ClinicalTrials.gov met our selection criteria. Of these, 70 were in Phase 1, with 50 active and 20 completed. In Phase 2, there were 8 trials, with 6 active and 2 completed. This dataset does not represent a complete list of trials during this period, as some clinical studies may not be registered on ClinicalTrials.gov.

The distribution of vaccine platforms is summarized in Figure 1. As of November 25, 2024, peptide vaccines were the most common, with 31 trials, followed by dendritic cell vaccines (15 trials) and RNA vaccines (13 trials). Nine trials were categorized as unspecified. DNA vaccines accounted for 6 trials, while cell-based vaccines were reported in 3 cases. Yeast vaccines were the least represented, with a single occurrence.

Further classification of trials based on conditions, sponsors, and geographical locations is shown in Figure 2 and summarized in Supporting Information File S1.

Solid tumors were the most commonly targeted condition, with 16 trials in Phase 1 and 1 in Phase 2 studies. Brain cancer followed with 12 Phase 1 trials. Pancreatic cancer accounted for

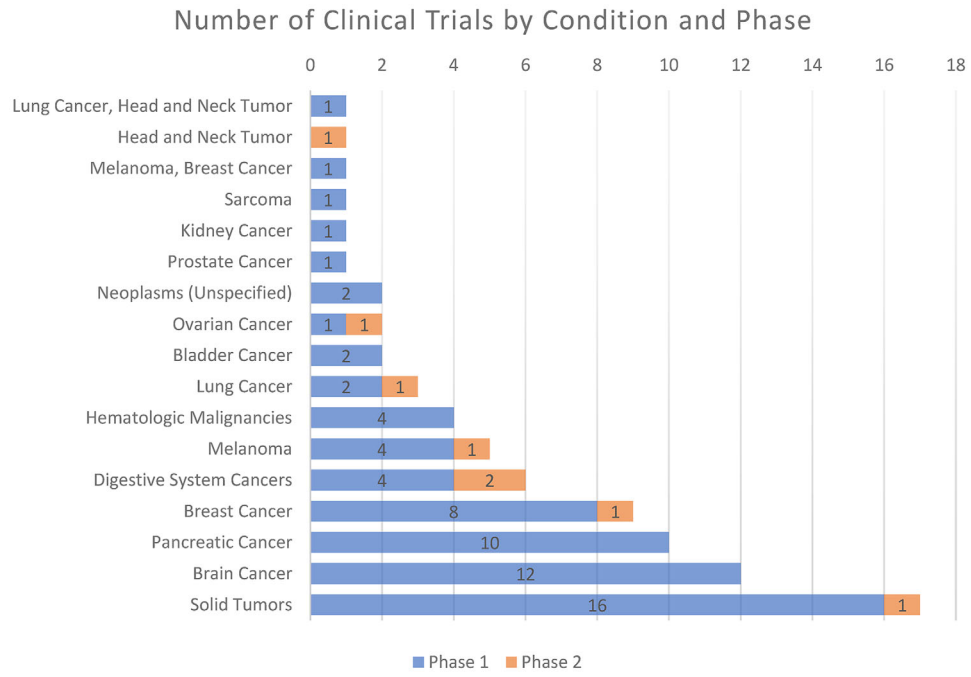

FIGURE 2 | Number of clinical trials by condition and phase.

10 Phase 1 trials, and breast cancer included 8 Phase 1 and 1 Phase 2 trials. Other cancers, such as digestive system cancers, melanoma, and hematologic malignancies, had 4 Phase 1 trials each, with varying representation in Phase 2. Less commonly targeted cancers included lung, bladder, and ovarian cancers.

Among 78 trials, industry sponsors conducted 17 studies. Gritstone Bio performed 3 trials, followed by Instituto de Medicina Regenerativa, BioNTech, and Mirror Biologics, each with 2 trials. Other sponsors, such as ModernaTX and Nykode Therapeutics ASA, contributed 1 trial each. Academic or non-profit funding supported 61 trials. Washington University School of Medicine was the leading sponsor with 6 trials, followed by Dana-Farber Cancer Institute with 5 trials. Several institutions, including Sir Run Run Shaw Hospital, Ruijin Hospital, and Universidad Nacional de Colombia, conducted 3 trials each.

The majority of trials were conducted in the United States (34 trials), followed by China with 19 trials. Further down the list are Colombia, Thailand, and Germany, with 3 trials each. Mexico and Switzerland each hosted 2 trials. Some trials were conducted across multiple countries, including the United States and Australia (2 trials).

Enrollment sizes varied widely, ranging from small exploratory cohorts of fewer than 10 participants to larger-scale trials enrolling up to 700 patients. The majority of trials (66) had fewer than 50 participants and only 4 trials aimed to enroll more than 100 patients.

The publications associated with NCT numbers for completed clinical trials were further investigated. The results of these trials are summarized in Table 1.

4 | Discussion

This report provides an overview of personalized cancer vaccines registered on ClinicalTrials.gov as of November 25, 2024. A total of 78 trials were identified, with 70 in Phase 1 and 8 in Phase 2, highlighting the early stages of the clinical development process. Among these, 56 trials are currently active, while 22 have been completed, reflecting the ongoing exploration of personalized vaccine approaches in oncology.

Our analysis showed that peptide vaccines were the most frequently tested modality, with 31 trials, followed by dendritic cell vaccines (15 trials) and RNA vaccines (13 trials). Other vaccine types, such as DNA, cell-based, and yeast vaccines, were less represented.

Most peptide vaccines focus on epitope peptides that activate CD8+ T cells or CD4+ T helper cells, targeting tumor-associated or tumor-specific antigens [16]. For example, personalized cancer vaccines based on synthetic long peptides (25–30 amino acids in length) are designed to elicit immune responses against cancer neoantigens (NCT05741242, NCT06529822). Peptide vaccines are sometimes evaluated in combination with immune adjuvants, such as poly-ICLC, to enhance immune readiness by activating TLR3 and associated pathways (NCT06614140). Granulocyte-macrophage colony-stimulating factor is another commonly used adjuvant (NCT05475106). Additionally, checkpoint inhibitors (e.g., anti-PD-1, anti-PD-L1, or anti-CTLA4) are included in some clinical trials to prevent immune exhaustion and sustain a robust immune response (NCT06614140). Patient-specific cancer vaccines are developed through next-generation whole-exome sequencing of tumor and normal tissue, as well as RNA sequencing of the tumor, to identify tumor-specific mutations. Based on these findings, a custom peptide

TABLE 1 | Results of completed trials (as of November 25, 2024, ClinicalTrials.gov).

Clinical trial	Design	Results
NCT02035956	The clinical study evaluated the safety, tolerability, and immunogenicity of personalized vaccination using the IVAC MUTANOME vaccine with or without prior treatment using the RBL001/RBL002 vaccine in patients with advanced melanoma.	Thirteen patients were evaluated for safety and immune response. A strong poly-neo-epitopic immune response was detected in all patients, with 60% of the 125 selected neo-epitopes triggering T-cell responses. No severe adverse reactions occurred, and signs of clinical activity were observed [3].
NCT03929029	The clinical trial was a Phase 1 study evaluating the safety of a personalized neoantigen vaccine (NeoVax) combined with montanide, nivolumab, and ipilimumab in patients with cutaneous melanoma. The study also sought to define the appropriate dose (2.5 mg or 5.0 mg per injection site) of investigational Ipilimumab to use for further studies.	No participants (0%) in either dose group (2.5 mg or 5.0 mg of ipilimumab) experienced Dose-Limiting Toxicity within 7 weeks of the first dose of NeoVax. In 2.5 mg group, 3 out of 5 participants (60%) achieved an objective response, and 2 out of 5 participants (40%) experienced disease progression or recurrence within the 2-year follow-up period. In 5.0 mg group, 1 out of 5 participants (20%) achieved an objective response and 1 out of 5 participants (20%) experienced progression or recurrence [4].
NCT03633110	The clinical trial evaluated the safety, tolerability, immunogenicity, and antitumor activity of personalized neoantigen vaccine GEN-009 in combination with a PD-1 inhibitor therapy for advanced solid tumors.	GEN-009 was well-tolerated, with adverse events limited to injection site reactions, mild myalgias, or fatigue. Sequential vaccination enhanced T-cell responses, persisting in some patients for over 12 months [5].
NCT03953235	This study aimed to assess the dose, safety, immunogenicity, and preliminary clinical activity of GRT-C903 and GRT-R904, a neoantigen-based therapeutic cancer vaccine, in combination with immune checkpoint inhibitors, in patients with advanced or metastatic non-small cell lung cancer, microsatellite-stable colorectal cancer, pancreatic cancer, and tumors positive for shared neoantigens.	Overall, the vaccine regimen was well tolerated, with the most common treatment-related adverse events being pyrexia, fatigue, nausea, vomiting, and diarrhea, all of which were Grade 1/2 except for one Grade 3 fatigue. Of the 19 patients, 8 (42%) achieved the best overall response of stable disease, with 3 showing reductions in target lesions. Eleven patients (58%) experienced progressive disease, resulting in a clinical benefit rate of 42%. There were no confirmed objective responses, so the duration or deepening of responses could not be assessed. The median progression-free survival was 1.9 months (95% CI: 1.7–3.9), and the median overall survival was 7.9 months (95% CI: 4.7–10.9) [6].
NCT02808416	The Phase 1, open-label, single-arm, single-institution study was designed to evaluate the safety and efficacy of personalized cellular tumor vaccines in cancer patients with brain metastases.	All adverse events were Grade 1/2, including local skin reactions and mild flu-like symptoms such as low fevers, which did not require treatment. No Grade 3/4 adverse events were reported during the treatment period. All five Non-small Cell Lung Cancer with brain metastases patients treated with immunotherapy showed partial responses. Median survival of 17 months for lung cancer and 19 months for glioblastoma [7].
NCT02709616	The clinical trial was an open-label, single-arm, single-institution, Phase 1 study designed to investigate the safety and efficacy of personalized cellular tumor vaccine for patients with newly diagnosed glioblastoma.	
NCT02808364	The clinical trial was an open-label, single-arm, single-institution, Phase 1 study designed to investigate the safety and efficacy of personalized cellular vaccines for patients with recurrent glioblastoma.	
NCT02149225	The clinical trial was a multicenter, open-label, single arm, first-in-man Phase 1 trial. The primary objective of this study was to assess the safety and tolerability, feasibility and immunogenicity of the actively personalized vaccination (APVAC) concept in newly diagnosed glioblastoma patients.	Adverse events primarily consisted of reversible injection site reactions, two cases of anaphylaxis, and one instance of increased cerebral edema. Among patients who received at least one APVAC ($N = 15$), the median progression-free survival was 14.2 months, and the median overall survival was 29 months from diagnosis [8].

(Continues)

TABLE 1 | (Continued)

Clinical trial	Design	Results
NCT03359239	This study aimed to evaluate the feasibility and safety of administration of atezolizumab combined with a personalized cancer vaccine in patients with urothelial cancer, either following surgery to remove the organ where the tumor originated (such as bladder removal) or in cases where the cancer has metastasized to other organs.	The most common treatment-related adverse events included Grade 1 injection site reactions, fatigue, and fever. One patient experienced Grade 3 immune-related hepatitis. All evaluated patients exhibited ex vivo T-cell responses, indicated by IFNγ production, including circulating multifunctional CD4+ and CD8+ neoantigen-specific T-cell responses upon expansion. With a median follow-up of 32 months, all four patients treated in the adjuvant setting remained recurrence-free, and two out of five patients with metastatic urothelial cancer achieved an objective response [9].
NCT01998542	The Phase 2 clinical study evaluated safety and tumor debulking mechanism of an individualized cancer vaccine (Allovax) in patients with metastatic or recurrent cancer of the head and neck.	Clinical responses, characterized by a visible reduction in tumor burden, were observed in 50% (5/10) of patients. The vaccine was well tolerated, and the reduction in tumor size was associated with increased CD3+ immune cell infiltration and decreased CTLA-4 expression [10].
NCT02721043	The purpose of the Phase 1 clinical study was to test the safety, tolerability, and immunogenicity of Personalized Genomic Vaccine 001 (PGV001) in subjects with advanced non-hematologic malignancies.	Participants experienced mild Grade 1 or 2 adverse reactions, as classified by CTEP v4.0. All vaccinated patients developed immune responses specific to the vaccine neoantigens [11].
NCT01970358	The Phase 1 study aimed to evaluate safety and immunogenicity of a personalized neoantigen cancer vaccine in melanoma patients.	The study demonstrated the feasibility, safety, and immunogenicity of the vaccine. Among six vaccinated patients, four remained recurrence-free 25 months post-vaccination, while two with progressive disease were subsequently treated with anti-PD-1 therapy, resulting in complete tumor regression [12].
NCT04552886	The Phase 1 clinical trial assessed the safety of a personalized dendritic-cell vaccine administered to patients diagnosed with glioblastoma after undergoing neurosurgical tumor resection, and in whom a neuropathological diagnosis has been established.	The most common treatment-related adverse events were Grade 1 injection site reactions and Grades 1–3 fatigue and urticaria, with no dose-limiting toxicities observed. In the cohort of 15 out of 16 patients with MGMTp-unmethylated tumors, the median survival has not been reached at the time of analysis and was statistically significantly greater ($p < 0.02$) compared to matched historical controls, following a median follow-up of 13.7 months [13].
NCT02348320	The Phase 1 clinical trial assessed the safety and immune response of a personalized polyepitope DNA vaccine in breast cancer patients who had persistent triple-negative disease after undergoing neoadjuvant chemotherapy.	The vaccinations were well tolerated, with minimal adverse events reported. Neoantigen-specific T-cell responses were detected in 14 out of 18 patients. After a median follow-up of 36 months, the recurrence-free survival rate in the vaccinated cohort was 87.5% (95% CI: 72.7%–100%) [14].
NCT03645148	The Phase 1 clinical trial assessed safety, tolerability and partial efficacy of a personalized neoantigen cancer vaccine in patients with advanced pancreatic cancer.	No serious vaccine-related adverse effects were observed among the patients enrolled in this study. The mean overall survival, vaccine-associated overall survival, and progression-free survival were reported as 24.1 months, 8.3 months, and 3.1 months, respectively [15].

vaccine is formulated to target neoantigens (NCT06094101, NCT06614140).

Dendritic cell vaccines stimulate specific immune reactions capable of precisely targeting and eliminating selected cells [17]. Different types of dendric cell vaccines are in development, including peptides loaded autologous (NCT04105582, NCT05714306, NCT04627246, NCT06253234), tumor-lysate loaded (NCT03879512, NCT05714306), and mRNA tumor antigen pulsed dendritic cell vaccines (NCT02808364). In some clinical trials, regulatory T cells are depleted through a short course of metronomic cyclophosphamide prior to vaccine administration

to enhance immune response induction (NCT03879512). Dendritic cell vaccines are typically investigated in combination with anti-PD-L1, anti-CTLA4, or anti-VEGF during the post-vaccine phase and maintenance period to enhance the efficacy of primed T-cell responses (NCT03879512, NCT05767684, NCT04627246).

RNA vaccines have emerged as a cost-effective approach for developing neoantigen-based cancer vaccines [18]. Different formulations are under development, including naked RNA vaccines (NCT02035956, NCT06685653) and RNA lipid particle vaccines (NCT06389591). RNA vaccines are frequently investigated in combination with checkpoint inhibitors to enhance their therapeutic efficacy (NCT06156267, NCT03897881, NCT04161755, NCT05916261).

Of the registered trials covered in this analysis, 16 Phase 1 trials targeted solid tumors. These trials investigated unspecified solid tumors or included three or more different tumor types. Brain cancer was analyzed in 12 trials, with the majority enrolling patients with glioblastoma, the most aggressive type of brain cancer. These trials included studies on newly diagnosed glioblastoma (NCT03223103, NCT02709616, NCT02149225, NCT04015700, NCT05743595), recurrent glioblastoma (NCT02808364, NCT06389591), and childhood glioblastoma (NCT03879512). Given the limited treatment options for glioblastoma, new effective therapies are needed for these patients [19]. Ten trials focused on pancreatic cancer. Standard-of-care treatments for pancreatic patients often face challenges due to resistance, underscoring the need for personalized and precise therapeutic approaches [20]. Breast cancer was investigated in 8 Phase 1 and 1 Phase 2 trials. Seven of these studies enrolled patients with triple-negative breast cancer, the most aggressive form of breast cancer, which is typically associated with a poorer survival rate compared to other subtypes [21].

Sponsorship data indicate that the majority of trials (61 out of 78) were funded by academic institutions or nonprofit organizations, highlighting the critical role of academic research in advancing cancer vaccine development. Industry sponsors backed 22% of studies, with companies such as Gritstone Bio, Instituto de Medicina Regenerativa, BioNTech, and Mirror Biologics sponsoring multiple trials.

Geographically, the United States leads in the number of trials (34 studies). China follows with 19 trials, while several other countries, including Colombia, Thailand, and Germany, have made notable contributions. The multinational nature of these trials underscores the global interest in personalized cancer vaccines.

Completed clinical trials evaluated various personalized neoantigen vaccines across different cancer types, focusing on safety, immunogenicity, and clinical responses. Across these studies, vaccines were generally well-tolerated, with mild adverse events such as injection site reactions, fatigue, and fever. Strong immune responses were observed, with many patients developing T-cell responses against neoantigens. Some trials reported objective responses, such as tumor shrinkage or prolonged progression-free survival, particularly in melanoma, glioblastoma, and urothelial cancer. While no trial demonstrated a universal cure, several showed promising signs of activity, and immune responses persisted in some cases for extended periods.

While this analysis provides insights into the ongoing efforts to develop personalized cancer vaccines, it is important to note that this dataset is not exhaustive. Many trials, particularly those not registered on ClinicalTrials.gov, may not be captured here. Additionally, the data presented only reflect trials registered up until November 25, 2024, and ongoing studies or trials that have recently commenced may not be included.

In conclusion, the landscape of cancer personalized vaccine trials is expanding, with a diverse array of vaccine types under investigation, a strong emphasis on solid tumors, and substantial involvement from both academic and industry sponsors. As these trials progress, further data on the safety, efficacy, and long-term outcomes of personalized vaccines will be crucial in determining their potential to revolutionize cancer treatment.

Author Contributions

Both authors had contributed to all the stages in the preparation of this manuscript for publication.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available in the Supporting Information of this article.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Supplementary File 1: ajco70006-sup-0001-SuppMat-File1.xlsx