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Monica M. Bertagnolli, MD  
Alliance Group Chair

## MEMORANDUM

Date: 1 August 2018

To: Alliance Principal Investigators and Lead CRAs

From: Monica M. Bertagnolli, MD, Alliance Group Chair

Re: Alliance Data and Safety Monitoring Board (DSMB) Report

The Alliance Data and Safety Monitoring Board (DSMB) met on May 11, 2018. Attached please find a listing of each study reviewed, the DSMB recommendation, and the action taken in response to the recommendation.

These statements may be submitted to your IRB per local IRB guidelines.

Questions may be directed to Michael Kelly, MA, Director of Protocol Operations ([mkelly1@uchicago.edu](mailto:mkelly1@uchicago.edu))

## **Breast Committee**

**A011104** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011104, Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A011106** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011106, Alternate Approaches for Clinical Stage II or III Estrogen Receptor, Positive Breast Cancer NeoAdjuvant Treatment (ALTERNATE) in Postmenopausal Women: A Phase III Study, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A011202** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011202, A Randomized Phase III Trial Evaluating the Role of Axillary Lymph Node Dissection in Breast Cancer Patients (cT1-3 N1) who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy, during a meeting on May 11, 2018. The DSMB reviewed the adverse event and efficacy data and no issues requiring intervention were identified. The DSMB wanted clarification on the slow event rate observed in the trial, specifically knowing more about the trial assumptions, as well as how many events should have been observed versus what has actually been observed, and the study team's plan to address slower than expected event rates, if that is the case. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

**A011203** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011203, A Randomized Phase II Trial of Tamoxifen versus Z-endoxifen HCL in Postmenopausal Women with Metastatic Estrogen Receptor Positive, HER2 Negative Breast Cancer, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A011401** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011401, Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A011502** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A011502, A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial, during a meeting on May 11, 2018. The DSMB noted that the study team is currently working on the protocol amendment to change the eligibility criteria, which will be submitted to CTEP soon. The DSMB reviewed the current adverse event and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

**Z11102** The Alliance Data and Safety Monitoring Board (DSMB) reviewed Z11102, Impact of Breast Conservation Surgery on Surgical Outcomes and Cosmesis in Patients with Multiple Ipsilateral Breast Cancers, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB reviewed the data release request by the study team and voted to approve the request with the following note of caution: any results from these analyses should be

carefully weighed against the primary oncologic outcome and to ensure that release of such results would not negatively impact the primary trial outcome. The DSMB also requested that any publication or presentation of results from these analyses should be sent to the DSMB for review and approval prior to submission. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

## **Cancer Care Delivery Research**

**A191402CD** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A191402CD, Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men, on July 2, 2018. The DSMB reviewed the current study data, and no issues requiring intervention were identified. The DSMB requested the study team to include information on how many sites have entered patients on this trial with the next report, since with a cluster randomized design, it is important to have many units participating in order to ensure reasonable balance on important factors. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

## **Experimental Therapeutics**

**A091302** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A091302, Randomized Phase II Study of Sorafenib with or without Everolimus in Patients with Radioactive Iodine Refractory Hurthle Cell Thyroid Cancer, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A091304** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A091304, A Phase I/Randomized Phase II Study of MLN0128 (TAK-228) vs. Pazopanib in Patients with Locally Advanced/Unresectable and/or Metastatic Sarcoma, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A091401** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A091401, Randomized Phase II Study of Nivolumab with or without Ipilimumab in Patients with Metastatic or Unresectable Sarcoma, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

## **GI Committee**

**A021202** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A021202, Prospective Randomized Phase II Trial of Pazopanib versus Placebo in Patients with Progressive Carcinoid Tumors, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A021501** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A021501, Preoperative Extended Chemotherapy vs. Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A021502** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A021502, Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair, during a meeting on May 11, 2018. The DSMB agreed with the revision to the stopping rule proposed in the protocol amendment submitted to CTEP, and noted that the study was not temporarily suspended to accrual. The DSMB strongly urged the study team to do a more active monitoring on the study, specifically on the rate of grade 4 events and a plan of action as the current observed rate was higher on the experimental arm. The DSMB would like a monthly report from the study team summarizing the grade 4 and higher adverse events reported on the trial sent to Drs. Kirshner and Mandrekar, and a more detailed report summarizing the adverse event profile to be shared with the DSMB in 3 months. The DSMB also urged the study team to keep abreast of other data coming out. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**C80702** The Alliance Data and Safety Monitoring Board (DSMB) reviewed C80702, A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB noted that the data delinquency rates are continuing to improve and requested the study team to continue to keep abreast of the data clean up efforts. The DSMB noted that the rate of withdraw of consent for follow-up was reported in error in the last report. While the current rate is lower, the DSMB is still unclear on the reasons for the withdraw of consent for follow-up, and requested more information at the next meeting. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**N1048** The Alliance Data and Safety Monitoring Board (DSMB) reviewed N1048, A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

## **GU Committee**

**A031102** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A031102, A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors (TIGER), during a meeting on May 11, 2018. The DSMB noted the steady improvement in accrual and the addition of international sites, and noted the study team's efforts to increase accrual. The DSMB requested an updated report at the next meeting. The DSMB reviewed the current adverse events and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**A031201** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A031201, Phase III Trial of Enzalutamide (NSC#766085) versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer, during a meeting on May 11, 2018. The DSMB approved the data release request to support the PK analysis. The DSMB noted the clarification by the study team in the patient withdrawal numbers reported in the last report. The DSMB reviewed the current adverse events and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**A031501** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A031501, Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) vs. Observation, during a meeting on May 11, 2018. The DSMB reviewed the changes

outlined in the protocol amendment, and had no concerns. The DSMB reviewed the current adverse events data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**C90203** The Alliance Data and Safety Monitoring Board (DSMB) reviewed C90203, A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer, during a meeting on May 11, 2018. The DSMB noted that the data delinquency rates have continued to improve and that the primary endpoint data are being cleaned rigorously. The DSMB urged the study team to continue these efforts so the primary study results can be reported out in a timely manner, and requested an updated report at the next meeting. The DSMB reviewed the current adverse events and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**C90601** The Alliance Data and Safety Monitoring Board (DSMB) reviewed C90601, A Randomized Double-Blind Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma, during a meeting on May 11, 2018. The DSMB urged the study team to significantly step up the data clean up efforts so the primary study results can be reported out in a timely manner. The DSMB requested an updated report at the next meeting. The DSMB reviewed the current adverse events and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

## **Leukemia Committee**

**A041202** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A041202, A Randomized Phase III Study of Bendamustine plus Rituximab Versus Ibrutinib plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients ( $\geq 65$  years of age) with Chronic Lymphocytic Leukemia (CLL), during a meeting on May 11, 2018. Based on the planned interim analyses comparing I to BR, and IR to BR, both demonstrating a superior PFS for the I regimens, the DSMB voted unanimously to release these data to the study team. In a separate interim analysis, in comparing I to IR, the futility boundary was crossed, demonstrating that IR is NOT superior to I in terms of PFS. The DSMB voted unanimously to release these data to the study team, as well. There are no data, to date, demonstrating differences in overall survival, a secondary endpoint. The DSMB reviewed the current adverse events data and no issues requiring intervention were identified. The DSMB voted unanimously to release these data to the sponsor and to submit these results to a scientific journal and/or ASH. With evaluation of the primary endpoint completed for all three comparisons, the DSMB recommended termination of future DSMB monitoring and continuing follow-up of patients per protocol.

Action: Recommendation Accepted

**A041501** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A041501, A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab ozogamicin (a conjugated anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 16-39 years) with Newly Diagnosed Precursor B-Cell ALL), during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

## **Lymphoma Committee**

**A051301** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A051301, A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype, during a meeting on May 11, 2018. The DSMB noted the proposed changes and the ongoing discussions with CTEP to increase accrual. The DSMB requested an updated accrual report at the next meeting. The DSMB reviewed

the current adverse events, and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

## **Myeloma Committee**

**A061202** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A061202, A Phase I/II Study of Pomalidomide, Dexamethasone, and Ixazomib Vs. Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Refractory to Lenalidomide and Proteasome Inhibitor-Based Therapy, during a meeting on May 11, 2018. The DSMB reviewed the adverse event data and no issues requiring intervention were identified. The DSMB noted the revised study design. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**A061402** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A061402, Solitary Plasmacytoma of Bone: Randomized Phase III Trial to Evaluate Treatment with Adjuvant Systemic Treatment and Zoledronic Acid versus Zoledronic Acid after Definite Radiation Therapy, during a meeting on May 11, 2018. : The DSMB continued to be concerned with the slow accrual, and urged the study team to actively reach out to other groups, identify a champion from each group, and present at their group meetings. The DSMB especially recommended reaching out to NRG and work with Dr. Bogart. The DSMB requested an updated report at the next meeting showing the accrual enhancement efforts supporting improvement in accrual activity to the trial. The DSMB reviewed the current adverse events, and efficacy data and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

## **Neuro-Oncology Committee**

**A071102** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A071102, A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**N0577** The Alliance Data and Safety Monitoring Board (DSMB) reviewed N0577, Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma, during a meeting on May 11, 2018. The DSMB was encouraged by the steady increase in accrual rate and the anticipated participation of EORTC to the trial in the summer. The DSMB reviewed the current adverse events, and no issues requiring intervention were identified. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

## **Prevention Committee**

**A211102** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A211102, Testing for Atypia in Random Periareolar Fine Needle Aspiration (RPFNA) Cytology after 12 Months Metformin (1,1-dimethylbiguanide hydrochloride) Chemoprevention versus Placebo Control in Premenopausal Women, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**A211401** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A211401, Reducing Surgical Complications in Newly Diagnosed Lung Cancer Patients who Smoke Cigarettes, during a meeting on May 11, 2018. he

DSMB noted that sites require significant coordination of a multidisciplinary team before the trial is ready to enroll patients. Although ~200 sites have IRB approval, none of the sites are ready to enroll patients. The DSMB noted the study team's efforts to provide recruitment handouts and training sessions to the sites, and requested an updated report at the next meeting. Since no patients are enrolled to the trial at this time, there were no adverse events data to review. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

## **Respiratory Committee**

**A081105** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A081105, Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)), during a meeting on May 11, 2018. The DSMB reviewed the current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB approved the data release request related to dosing and duration of treatment from the first 150 patients with the study team. The DSMB noted that these data will be utilized only to assess whether the protocol needs to be amended in terms of initial dosing in order to improve the high discontinuation rate and withdrawal from study. Dr. Mandrekar was excused during the voting and discussion due to conflict with the study. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

**C30610** The Alliance Data and Safety Monitoring Board (DSMB) reviewed C30610, Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted

**C140503** The Alliance Data and Safety Monitoring Board (DSMB) reviewed C140503, A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (<2 CM) Peripheral Non-Small Cell Lung Cancer, during a meeting on May 11, 2018. The DSMB reviewed the current adverse events and efficacy data, and no issues requiring intervention were identified. While the DSMB noted the improvement in data delinquency, it remained concerned with the high rate of overdue follow-up. The DSMB strongly urged the study team to step up the data clean up efforts significantly in an effort to be more current with data by the next meeting. The DSMB voted unanimously to continue the study per protocol.

Action: Recommendation Accepted

## **Symptom Intervention Committee**

**A221101** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221101, A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil) To Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiforme, during a meeting on May 11, 2018. The DSMB noted the various efforts made by the study team to reduce the rate of non-evaluable patients. The DSMB encourages the study team to continue its educational activities, and provide an updated report at the November meeting. The DSMB reviewed the current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

**A221208** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221208, Randomized Phase II Study: Corticosteroids + Bevacizumab vs. Corticosteroids + Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases, during a meeting on May 11, 2018. The DSMB was appreciative of the efforts made the study team to enhance accrual and requested an updated report at the next meeting. The DSMB reviewed the current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB voted unanimously (Dr. Goulet was excused during the voting) to continue study per protocol.

Action: Recommendation Accepted

**A221303** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221303, Randomized Study of Early Palliative Care Integrated with Standard Oncology Care versus Standard Oncology Care Alone in Patients with Incurable Lung and Non-Colorectal Gastrointestinal Malignancies, during a meeting on May 11, 2018. Release study results and terminate DSMB monitoring per December meeting.

Action: Recommendation Accepted

**A221502** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221502, Pulmonary Rehabilitation Before Lung Cancer Resection, during a meeting on May 11, 2018. The DSMB reviewed current adverse events and efficacy data, and no issues requiring intervention were identified. The DSMB noted that 7 sites have IRB approval, with 6 sites ready to enroll patients. While the DSMB recognizes the logistical issues with accrual due to the trial complexity, the DSMB requested the investigators to identify a surgeon champion at each site, and make an effort to reach out to other NCTN groups. The DSMB requested an interim report in 3 months outlining the accrual status and reach out efforts, and an updated report demonstrating improvement in accrual at the November meeting. The DSMB reviewed the current study data, and no issues requiring intervention were identified. The DSMB voted unanimously to continue study per protocol.

Action: Recommendation Accepted

**A221504** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221504, A Randomized, Double-Blind, Placebo-Controlled Pilot Study of an Oral, Selective Peripheral Opioid Receptor Antagonist in Advanced Non-Small Cell Lung Cancer (Adenocarcinoma), during a meeting on May 11, 2018. The DSMB noted the study team's efforts to reach out to sites to increase accrual, and consideration to potentially expand eligibility to non-squamous patients. The DSMB recommended the study team to identify champions from other groups and requested an updated report at the next meeting. The DSMB reviewed the current adverse events data, and no issues requiring intervention were identified. voted unanimously to continue study per protocol.

Action: Recommendation Accepted

**A221505** The Alliance Data and Safety Monitoring Board (DSMB) reviewed A221505, Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction, during a meeting on May 11, 2018. The DSMB reviewed current study data, and no issues requiring intervention were identified. The DSMB recommended unanimously to continue per protocol.

Action: Recommendation Accepted