AI virtual patient navigation to promote re-engagement of U.S. inner city patients nonadherent with colonoscopy appointments: A quality improvement initiative.

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Background: Colorectal cancer disparities loom large for underserved communities of color in the US where barriers to screening uptake can contribute to late-stage diagnosis and poor outcomes. Despite active outreach by skilled patient navigators (PN) at a NYC cancer center serving an ethnically minoritized and disadvantaged population, 59% (1,925/3,276) of patients either cancelled or did not show for their colonoscopy appointments in 2022. While PN re-engagement efforts led to 410 (21%) completing colonoscopy, 1,500 patients did not undergo potentially life-saving colon cancer screening that year. With the advent of conversational Artificial Intelligence (AI)-driven applications within health care offering a potential extension to a stretched workforce, our cancer center examined the use of an AI-based virtual patient navigator, MyEleanor, as part of a colorectal cancer screening quality improvement (QI) project. **Methods:** This QI project employed MyEleanor between Apr-Dec 2023 to target re-engagement of 2,400 patients nonadherent with colonoscopy appointments in 2022-2023. In place of human PNs, MyEleanor (a) called patients to discuss rescheduling, (b) assessed barriers to uptake, c) offered live transfers to clinical staff to reschedule, and d) provided procedure prep reminder calls. Evaluable outcomes included: (a) engagement with MyEleanor via identity confirmation, (b) live transfers accepted (actionable), (c) colonoscopy completion rate, and (d) patient volume, with (d) barriers to care, and (e) predictors of actionable engagement examined. **Results:** Over 8 months, 57% (1,368/2,400) of patients engaged with MyEleanor, with 58% (789) of this group, or 33% overall, accepting the live transfer. The completion rate for patients who did not show for initial appointment nearly doubled from 10% to 19% from 2022 to 2023 (pre to post-MyEleanor). Overall patient volume increased by 36%. Patients who engaged were a Mean age of 56.66 (41-79 yrs), female (66%), Hispanic (41%), Black (33%), English (73%) or Spanish (25%) speaking, and partnered (37%). Nearly one third reported at least two barriers to screening; top barriers included lack of perceived need (19%), time (18%), and MD encouragement (16%), medical mistrust (14%), and concerns about findings (13%) and cost (12%). Greater number of barriers predicted actionable engagement, ($F(1366) = 354$, $p < 0.001$), with Spanish-dominant patients and those declining to identify their race reporting nearly twice the number of barriers, $F(1366) = 138.98$ and $F(1366) = 5.17$, $p < 0.001$, respectively). **Conclusions:** This project demonstrates high potential of an AI patient navigator in helping to overcome patient attrition that can lead to colon cancer disparities while improving patient volume. Next phase of the project will examine impact on patient prep adherence, staff burden, and revenue. Research Sponsor: None.

Multimodal artificial intelligence models from baseline histopathology to predict prognosis in HR+ HER2- early breast cancer: Subgroup analysis.

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Background: Prognostic assessment in HR+ HER2- early breast cancer (EBC) remains challenging given relatively low rates of disease progression. Modern artificial intelligence (AI)-based techniques have already provided substantial medical progress, particularly in prostate cancer. We have leveraged ArteraAI's multimodal artificial intelligence (MMAI) platform to develop a research-level prognostic model in HR+ HER2- EBC, based on the WSG PlanB and ADAPT trials. Here, we quantify the value added by MMAI within clinically relevant subgroups. **Methods:** Histopathology image data was generated from pre-treatment breast biopsy and surgical hematoxylin and eosin (H&E) slides from the WSG PlanB and ADAPT trials. Patients with available images and complete data (n=5259) were allocated (stratified by trial, randomization arm and distant recurrence (DR)) to development (60%) and validation (40%) cohorts. An MMAI-based model using image data combined with clinical prognostic variables (age, T and N stage, tumor size) was developed to predict risk of DR. Univariable and multivariable Fine-Gray models were used to assess performance in the validation cohorts; subdistribution hazard ratios (sHR) refer to validation cohorts and are reported per standard deviation increase of the model scores (image-alone or combined). Pre-specified prognostic subgroups for analysis were defined by nodal status, menopausal status, and central tumor grade. All statistical tests were 2-sided at .05 significance. **Results:** The trained MMAI score was significantly associated with risk of DR in the validation cohort (sHR [95% CI] = 2.3 [2.0-2.8]) as a whole and in all considered subgroups. The score remained significant (sHR [95%CI] = 2.2 [1.7-2.8]) after adjusting for clinical prognostic factors. Moreover, the MMAI image component alone had significant prognostic value (sHR [95%CI] = 1.6 [1.3 - 1.9]) in the validation cohort. Remarkably, the MMAI image component alone had significant prognostic value separately within the G2 and G3 sub-groups, with sHR of about 1.5 per standard deviation increase, and also in most of the other predefined clinical subgroups. **Conclusions:** Preliminary results from the current MMAI breast model provide evidence that ArteraAI MMAI technology can be leveraged for outcome prediction in HR+ HER2- EBC using H&E-stained images to further personalize breast cancer management. The ability of image-only AI models to provide significant prognostic value *within* grade subgroups suggests that self-supervised AI has identified some novel image features with prognostic value beyond grade. To put the results into the clinical context, comprehensive validation analyses will be presented at the meeting.
Research Sponsor: None.

Real-world and clinical trial validation of a deep learning radiomic biomarker for PD-(L)1 immune checkpoint inhibitor response in stage IV NSCLC.

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Background: Immune checkpoint inhibitor (ICI) therapy is standard-of-care for treatment of mutation-negative advanced non-small cell lung cancer (NSCLC). However, given known inaccuracy of PD-(L)1 markers, there is an unmet need to better identify patients most likely to derive clinical benefit from ICI. We developed and externally validated a generalizable CT imaging-based biomarker to predict response to ICI. **Methods:** We developed and validated a deep learning radiomic biomarker using an internally curated real-world dataset (RWD) of 2,010 stage IV NSCLC patients treated with PD-(L)1 ICIs in academic and community settings from US and Europe. Patients with missing baseline imaging, missing follow-up data, or EGFR/ALK oncogenic driver mutations were excluded, resulting in a total of 1,188 subjects. This RWD consisted of a discovery cohort (Dataset A, N=844) and a temporally distinct holdout cohort (Dataset B, N=344), which were used to generate performance metrics of the biomarker. To test generalizability, we validated our biomarker in a prospective clinical trial dataset evaluating Sasanlimab in PD-(L)1 therapy-naïve, advanced NSCLC patients (NCT02573259, Dataset C, N=54). We utilized a two-stage learning approach to model 6-month PFS. First, we used an independent multi-task deep-learning feature extractor trained on 19,184 whole chest CT scans. Second, we input the extracted features into a Cox proportional hazard (CoxPH) model along with age, sex, and baseline lesion measurements (sum of longest diameter and distant metastases counts), and the model generated a time-dependent PFS function and a response score. We performed 6-fold cross-validation on Dataset A to train and evaluate the models, which were subsequently ensembled and applied to independent Datasets B and C. To assess independence from PD-L1 status and key demographic covariates, we herein report multivariate adjusted hazard ratios (HR) for the group identified as low-risk based on the biomarker. **Results:** In Dataset A, the biomarker showed a cross-validation PFS adjusted HR of 0.49 (95% CI 0.38-0.63) in the all-comers cohort and 0.28 (0.17-0.46) in the first-line ICI monotherapy cohort (1LMono). In Dataset B, the PFS adjusted HRs were 0.54 (0.35-0.83) in all-comers and 0.18 (0.05-0.61) in 1LMono. In Dataset C, the adjusted HRs were 0.30 (0.14-0.68) for PFS, 0.29 (0.10-0.83) for OS, 0.31 (0.14-0.72) for TTP. **Conclusions:** In our validations in RWD and clinical trial cohorts, a deep-learning radiomic biomarker based on routine pre-treatment CT scans predicted response to ICI and stratified patients independently from PD-L1 status. This tool may inform clinical decision-making, such as to help guide whether concomitant chemotherapy may not be needed. In future work, we plan to further validate our approach in larger prospective datasets and expand its use to new indications. Research Sponsor: None.

Telisotuzumab vedotin monotherapy in patients with previously treated c-Met–overexpressing non-squamous *EGFR* wildtype advanced NSCLC: Primary analysis of the LUMINOSITY trial.

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Background: Approximately 25% of patients (pts) with non-squamous (NSQ) *EGFR* wildtype (WT) NSCLC have c-Met protein overexpression (Ansell et al. 2022 CRUK), which is associated with a poor prognosis (Liang, Wang. *Onco Targets Ther*. 2020). Telisotuzumab vedotin (Teliso-V) is a c-Met–directed antibody-drug conjugate comprising the mAb telisotuzumab and the microtubule polymerization inhibitor monomethyl auristatin E. The phase 2 LUMINOSITY trial (NCT03539536) aimed to identify the c-Met–overexpressing (OE) NSCLC population best suited to Teliso-V and expand selected group(s) for further evaluation of efficacy. We report on the primary analysis for pts with c-Met OE NSQ *EGFR*WT NSCLC. **Methods:** This phase 2, non-randomized, multicenter study enrolled pts with locally advanced/metastatic c-Met OE NSCLC, ≤2 prior lines of therapy (chemotherapy [CTx] + immunotherapy [IO] or sequential CTx + IO), and ≤1 line of chemotherapy. c-Met OE (Ventana MET [SP44] clinical trial assay [CTA]) was defined as ≥25% tumor cells with 3+ staining (high: ≥50% 3+; intermediate [int]: 25 to <50% 3+). Teliso-V was dosed at 1.9 mg/kg IV Q2W. Primary endpoint was overall response rate (ORR) by independent central review per RECIST v1.1. **Results:** 172 pts with NSQ *EGFR* WT NSCLC received ≥1 dose of Teliso-V and comprised the safety population; 161 (c-Met high, 78; c-Met int, 83) were included in baseline and efficacy analyses. Median age was 64 yrs (range 33–83), 69% were male, and 70% had ECOG PS 1. 97.5% had prior platinum and 82.0% had prior immune checkpoint inhibitor. Efficacy data are presented in Table below. ORR was 34.6% (c-Met high), 22.9% (c-Met int), 28.6% (overall). Median DOR was 9.0 mo (c-Met high), 7.2 mo (c-Met int), 8.3 mo (overall). Most common any-grade treatment-related AEs (TRAEs) were peripheral sensory neuropathy (30%), peripheral edema (16%), and fatigue (14%). Grade 5 TRAEs occurred in 2 pts (interstitial lung disease, respiratory failure). **Conclusions:** Teliso-V has shown compelling and durable responses in pts with c-Met OE NSQ *EGFR* WT NSCLC, especially in pts with c-Met high. Teliso-V had an acceptable safety profile that was clinically manageable, which is consistent with previous data. Clinical trial information: NCT03539536. Research Sponsor: AbbVie.

Efficacy endpoints.

	c-Met High n=78	c-Met Int n=83	c-Met OE Total N=161
ORR,* n (%) [95% CI]	27 (34.6) [24.2, 46.2]	19 (22.9) [14.4, 33.4]	46 (28.6) [21.7, 36.2]
DCR,* n (%) [95% CI]	47 (60.3) [48.5, 71.2]	48 (57.8) [46.5, 68.6]	95 (59.0) [51.0, 66.7]
Median DOR,* mo [95% CI]	9.0 [4.2, 13.0]	7.2 [5.3, 11.5]	8.3 [5.6, 11.3]
DOR* ≥6 mo, n/no. of responders (%)	17/27 (63.0)	9/19 (47.4)	26/46 (56.5)
Median PFS,* mo [95% CI]	5.5 [4.1, 8.3]	6.0 [4.5, 8.1]	5.7 [4.6, 6.9]
Median OS, mo [95% CI]	14.6 [9.2, 25.6]	14.2 [9.6, 16.6]	14.5 [9.9, 16.6]
Median follow-up, mo	20.2	18.9	19.3

*Per independent central review.

Sacituzumab tirumotecan (SKB264/MK-2870) in patients (pts) with previously treated locally recurrent or metastatic triple-negative breast cancer (TNBC): Results from the phase III OptiTROP-Breast01 study.

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Background: TROP2 (trophoblast cell surface antigen 2) is highly expressed in TNBC and is associated with worse survival. Sacituzumab tirumotecan (SKB264/MK-2870) is a TROP2 ADC developed with a novel linker to conjugate the payload, a belotecan-derivative topoisomerase I inhibitor with a drug-to-antibody-ratio (DAR) of 7.4. The hydrolytically linker permits both extracellular pH-sensitive cleavage and intracellular enzymatic cleavage to release the membrane permeable payload enabling the "bystander effect". Here, we report the results from a phase III study of sacituzumab tirumotecan in pts with advanced TNBC (OptiTROP-Breast01, NCT05347134). **Methods:** In this randomized phase III trial, SKB264 was compared with physician's choice of chemotherapy (eribulin, vinorelbine, capecitabine, or gemcitabine) in pts with locally recurrent or metastatic TNBC who had received two or more prior therapies including at least one for metastatic setting. The primary endpoint was progression-free survival (PFS) by blinded independent central review (BICR). The TROP2 expression was determined by immunohistochemistry (IHC) using the semi-quantitative H-score method. **Results:** Pts were randomly assigned to receive SKB264 (n = 130) or chemotherapy (n = 133). The median age was 51 years; 87% had visceral metastases; 26% received prior PD-1/PD-L1 inhibitors; 48% received three or more prior lines of chemotherapy for advanced disease. The primary endpoint of PFS was met based on interim analysis (data cutoff: Jun 21, 2023) with a 69% reduction in risk of progression or death (HR 0.31; 95% CI, 0.22 to 0.45; P $<$0.00001). The median PFS assessed by BICR was 5.7 months (95% CI, 4.3 to 7.2) with SKB264 and 2.3 months (95% CI, 1.6 to 2.7) with chemotherapy; PFS at 6 months was 43.4% vs 11.1%. In the subset of pts with TROP2 H-score $>$ 200, the median PFS was 5.8 months with SKB264 and 1.9 months with chemotherapy (HR 0.28; 95% CI, 0.17 to 0.48). At the first planned interim analysis for overall survival (OS) (data cutoff: Nov 30, 2023) with median follow-up of 10.4 months, OS was statistically significant in favor of SKB264 (HR 0.53; 95% CI, 0.36 to 0.78; P =0.0005); the median OS was not reached (95% CI, 11.2 to NE) with SKB264 and 9.4 months (95% CI, 8.5 to 11.7) with chemotherapy. The objective response rate assessed by BICR was 43.8% with SKB264 and 12.8% with chemotherapy. Most common grade $\geq$ 3 treatment-related adverse events (SKB264 vs chemotherapy) were neutrophil count decreased (32.3% vs 47.0%), anemia (27.7% vs 6.1%) and white blood cell count decreased (25.4% vs 36.4%). **Conclusions:** Sacituzumab tirumotecan monotherapy demonstrated statistically significant and clinically meaningful PFS and OS benefit over chemotherapy, with a manageable safety profile in pts with heavily pretreated advanced TNBC and limited treatment options. Clinical trial information: NCT05347134. Research Sponsor: Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.

LBA105 **Clinical Science Symposium**

Results from the randomized phase 3 DREAMM-8 study of belantamab mafodotin plus pomalidomide and dexamethasone (BPd) vs pomalidomide plus bortezomib and dexamethasone (PVd) in relapsed/refractory multiple myeloma (RRMM).

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The full, final text of this abstract will be available at meetings.asco.org on the day of presentation and in the online supplement to the June 10, 2024, issue of the *Journal of Clinical Oncology*.

Discontinuation of maintenance therapy in multiple myeloma guided by multimodal measurable residual disease negativity (MRD2STOP).

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Background: Measurable residual disease (MRD) negativity is a potential marker for the absence of disease in multiple myeloma (MM), which could be used to guide treatment cessation. MRD2STOP (NCT04108624) is a prospective study investigating outcomes among patients with sustained multimodal MRD negativity who discontinue maintenance therapy. **Methods:** Discontinuation of maintenance was permitted if MRD negative by PET/CT, flow cytometry (limit of detection [LoD] 10^{-5}), and NGS by clonoSEQ (threshold 10^{-6}). Patients underwent serial blood testing along with clonoSEQ, flow, and PET/CT annually for 3 years. Concurrent BM aspirate samples also underwent $CD138^{+}$ immunomagnetic enrichment analyzed using clonoSEQ to achieve MRD 10^{-7} sensitivity. Primary endpoints were MRD resurgence rate at the 10^{-6}threshold, along with progression-free survival (PFS) and overall survival among those MRD negative by the standard non-enriched clonoSEQ. **Results:** 83 patients were screened, and 47 patients met eligibility to discontinue maintenance as of 1/21/24. Median age was 66 years (range 39-84). 17 (36%) had high-risk disease at diagnosis (8 with 1q copy abnormalities, 5 with ISS stage 3, 2 with t(4;14), 1 with t(14;16), and 3 with del17p). Most (45/47, 96%) had one line of therapy; 26 (55%) received a triplet and 19 (40%) a quadruplet. Prior autologous transplant was received by 30 (64%) and multi-drug consolidation in 36 (77%) prior to single-agent maintenance. 96% received lenalidomide as maintenance. Median duration of consolidation/maintenance therapy prior to discontinuation was 36 months (range 12-95), including 14 (30%) with $<$27 months. Median follow-up was 30 months. Of 47 enrolled patients, 5 (11%) experienced disease progression and an additional 6 (13%) had MRD resurgence at 10^{-6}. Of 11 MRD resurgent events, 4 (36%) were MRD 10^{-7} positive at baseline, and 3 (27%) were MRD 10^{-7} positive 1 year prior to MRD 10^{-6} resurgence. 2 second hematologic cancers occurred during follow-up: 1 Hodgkin lymphoma and 1 B-ALL, the latter which resulted in the only patient death on study. The estimated 3-year PFS was 85%, including 93% for patients MRD 10^{-7} negative (n=40) at baseline and 31% for those MRD 10^{-7} positive (n=7) at baseline (logrank $p<0.001$). Among the MRD evaluable patients (n=45), the 3-year MRD-free survival (MRD-FS) was 68%; 78% for patients MRD 10^{-7} negative (n=38) and 33% for patients MRD 10^{-7} positive (n=7) (logrank $p<0.001$). There were no differences in MRD-FS or PFS when stratified by high-risk disease, receipt of transplant, consolidation, or duration of maintenance. **Conclusions:** Discontinuation of maintenance therapy among patients with MM and multimodal MRD-negativity results in a high rate of sustained MRD-negativity and lack of disease progression. $CD138^{+}$-enriched MRD samples using the clonoSEQ assay may help to even better identify patients who can discontinue therapy. Clinical trial information: NCT04108624. Research Sponsor: None.

The potential role of serial circulating tumor DNA (ctDNA) testing after upfront surgery to guide adjuvant chemotherapy for early stage pancreatic cancer: The AGITG DYNAMIC-Pancreas trial.

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Background: Recurrence rates following upfront resection of pancreatic adenocarcinoma are high, with some benefit from adjuvant chemotherapy (AC). A biomarker that improves risk stratification and/or provides real time indication of AC benefit could improve routine clinical management and accelerate trial progress. Previous studies in pancreas cancer suggest that patients with detectable ctDNA post surgery are at an elevated risk of recurrence. Detectable ctDNA at the completion of AC may also be associated with an elevated recurrence risk. **Methods:** Patients with early stage pancreatic adenocarcinoma were enrolled following upfront resection at 26 Australian centres. Patients were ECOG 0-1 and fit for AC. A tumour-informed ctDNA assay was used to identify somatic mutations for tracking in circulating cell-free DNA. ctDNA+ patients received 6 months of AC (FOLFIRINOX or gemcitabine/capecitabine selected at the clinician's discretion), while ctDNA- patients could de-escalate to 3 months at the clinician's discretion. ctDNA was assessed again at the end of AC. The primary study endpoint was the feasibility of ctDNA-guided therapy. Secondary endpoints included the association of ctDNA with clinicopathologic risk factors and survival outcomes. **Results:** A total of 102 patients were enrolled from March 2019 to Nov 2023. Median age was 68 years (range 41 – 86), with 50% male and 95% ECOG 0-1. Tumours were located in the head of pancreas in 72%. Histology revealed T1 (18%), T2 (50%), and T3 (32%) tumors, with nodal involvement in 71%, and an R0 resection in 77%. Post-operative Ca19-9 was elevated in 29%. Forty patients (40%) were ctDNA+ve post resection, 54 (53%) were ctDNA-ve, and no result was obtained in 4 (4%) due to the absence of tumor mutation, and as a result, they were considered ineligible. The presence or absence of ctDNA was not associated with known clinicopathologic risk factors. Median time to ctDNA collection was 5 weeks (range 3 – 9) and to commencing AC was 6 weeks (range 4-12). Of 54 ctDNA-ve patients, 24 (44%) were de-escalated to receive a planned 3 months of AC. With a median follow-up of 36 months (range 2-56) the median recurrence free survival (RFS) in ctDNA+ve patients was 13 months compared to 22 months for ctDNA-ve patients (HR 0.52, p = 0.003). **Conclusions:** A tumor informed ctDNA approach to AC selection is feasible for patients undergoing upfront resection of pancreatic adenocarcinoma, with the first blood draw to be scheduled at week 5, allowing time for ctDNA analysis to determine AC selection. A high proportion of patients had detectable ctDNA, which appears independent of known prognostic markers. ctDNA detection was associated with earlier recurrence. Analyses of the impact of changes in ctDNA over time on survival are ongoing. Clinical trial information: ACTN12618000335291. Research Sponsor: Marcus Foundation.

Circulating tumor DNA analysis guiding adjuvant therapy in stage II colon cancer: Overall survival and updated 5-year results from the randomized DYNAMIC trial.

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Background: Previous results of the DYNAMIC study demonstrated that a ctDNA-guided approach versus standard management in stage II colon cancer (CC) reduced adjuvant chemotherapy (ACT) use without compromising 2-year recurrence-free survival (RFS). MMR status defines two distinct subsets of stage II CC. Here, we report the impact of ctDNA burden, end of ACT (EOT) ctDNA, and updated survival data including overall survival (OS). **Methods:** DYNAMIC is a multi-center randomized phase II trial. Eligible patients (pts) had resected stage II CC and were suitable for ACT. Pts were randomly assigned 2:1 to ctDNA-guided management or standard management (clinician-guided based on conventional criteria). For ctDNA-guided management, a ctDNA-positive result at 4 or 7 weeks after surgery with a tumor-informed assay prompted oxaliplatin-based or fluoropyrimidine ACT; ctDNA-negative pts were not treated. Between Aug 2015 and Aug 2019, 302 received ctDNA-guided and 153 standard management. The primary endpoint was RFS, with a non-inferiority margin of 8.5%. Pre-specified key secondary endpoints were ACT use and OS, with an additional secondary endpoint of ctDNA clearance rate. **Results:** With a median follow-up of 59.6 months (IQR 55.0–61.5), 5-year RFS were 88% and 87% with ctDNA-guided and standard management, respectively (difference 1.1%, 95% confidence interval, -5.8% to 8.0%). 5-year OS for ctDNA-guided treatment was 93.8% and standard management 93.3% (HR 1.05; 95% CI, 0.47 to 2.37; P = 0.887). 5-year OS was significantly worse in treated ctDNA-positive versus untreated ctDNA-negative pts (85.6% vs 95.3%, HR 3.30; 95% CI, 1.02 to 9.05; P = 0.014). The 5-year OS for ctDNA-negative T3 and T4 disease were 96.0% and 90.6%, respectively (HR 2.45; 95% CI, 0.65 to 9.25; P = 0.171). For treated ctDNA-positive pts, ctDNA clearance was observed at EOT in 35/40 (87.5%). The 5-year RFS for EOT ctDNA clearance vs ctDNA persistence were 85.2% and 20.0%, respectively (HR 15.4; 95% CI, 3.91 to 61.0; P $<$ 0.001). Pts with $\geq$ 0.38 (the median) mutant tumor molecules (MTM/mL) had a lower ctDNA clearance rate and worse RFS than pts with $<$ 0.38 MTM/mL (ctDNA clearance 75% vs 100%, P = 0.047; 5-year RFS 58.9% vs 95.2%, HR 10.62, P = 0.005). Post-op ctDNA was detected in 5/59 (8.5%) of dMMR and 40/235 (17%) of pMMR cases. In an exploratory analysis, ctDNA clearance was observed in 3/4 (75%) and 32/36 (89%) of dMMR and pMMR cases, respectively. **Conclusions:** Mature outcome data confirms the previous finding of non-inferiority of RFS with a ctDNA-guided approach to ACT for stage II CC. For ctDNA-positive pts, the post-surgery mutation burden provides additional prognostic information, as does the EOT ctDNA result. Additional data is needed to define any differential impact of ACT by MMR status. This data supports a role for ctDNA analysis, including serial sampling, in the management of stage II CC. Clinical trial information: ACTRN12615000381583. Research Sponsor: NHMRC; U.S. National Institutes of Health.