

BREAST DISEASE SITE COMMITTEE MEETING

CHELSEA HOTEL, TORONTO, ON
ROOM: MOUNTBATTEN SALON
SATURDAY APRIL 26, 2025: 8:00 AM – 12:00 PM

CO-CHAIRS : S.CHIA / E. RAKOVITCH
SENIOR INVESTIGATORS: L. SHEPHERD / W. PARULEKAR

CME Credits:

Credits for Specialists: This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada and approved by Queen's University.

Learning Objectives:

- Identify and address, through clinical trial and translational research, the disease burden associated with breast cancer in Canada.
- Identify clinical trial research opportunities within the Canadian Cancer Trials Group.
- Integrate current knowledge regarding therapeutics and tumour biology in trial concept development and conduct.
- Apply best practices in clinical trials conduct and analysis to the Canadian Cancer Trials Group research agenda.
- To provide a learning and mentoring environment supportive to new investigators.

8:00am	Welcome & Review of Morning's Objectives (Feedback, Recognition of centres with high accrual)
	Introduction of Breast DSC Patient Representatives
	Introduction of Practicum Fellow(s) for Breast DSC
8:15am	Update: Publications/Abstracts 2024-2025
8:25am	Update from the IND Committee
8:45am	Approved Studies Pending Activation
8:55am	Studies Open to Accrual
9:45am	Coffee
10:00am	News from Closed/Analyzed Studies
10:45am	Potential New Studies
11:00am	Emerging Trends in treatment of CNS metastases – K. Jerzak
11:30am	Other Business and Final Comments
11:40am	Breast Disease Site Committee Meeting Adjourned
11:45am	Breast Disease Site Executive/Scientific Advisory Committee Closed Session
12:00pm	Breast Disease Site Executive/Scientific Advisory Committee Closed Session Adjourned

Appendix I – Agenda Details **Objectives**

CCTG Presentations for ASCO / 2024/2025 Publications

Update from the IND Committee (Arif Awan to introduce)



Canadian Cancer Society
Société canadienne du cancer

CCTG is a CCS national program.

Approved Studies Pending Activation:

- **NoLEEta** – No chemotherapy in intermediate-risk HR+ HER2- early breast cancer treated with Ribociclib (LEE-011) in the adjuvant setting, a non-inferiority Phase III trial – **S. Chia**

Studies Open to Accrual

- **IND.241** - A Liquid-biopsy Informed Platform Trial to Evaluate Treatment in CDK4/6-inhibitor Resistant ER+/HER2- Metastatic Breast Cancer – **A. Awan**
- **MA.39 - Tailor RT**: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer - **T. Whelan**
- **MAC.27 / A011801** - COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib - **P. Blanchette**
- **MAC.28 / NRG BR007** - A Phase III Clinical Trial Evaluating De-escalation of Breast Radiation for Conservative Treatment of Stage 1, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score ≤ 18 Breast Cancer (DEBRA) - **V. Theberge**
- **MAC.29/A012103/OptimICE-pCR** - De-escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy - **S. Chia**
- **MAC.30 / NRG BR009** - A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤ 25 (OFSET) **J.P. Ayoub**

News from Closed/Analyzed Studies

- **MAC.19 (A011202)** - A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1 -3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy - **S. Latosinsky**
- **MAC.20 (A011401)** - Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer - **V. Bernstein**
- **MAC.22 / TMIST** - ECOG-ACRIN EA1151 Tomosynthesis Mammographic Imaging Screening Trial (TMIST) - **L. Shepherd**
- **MAC .23 (A221505)**: A Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction - **I. Kong**
- **MAC.24 (SWOG 1418)** - A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (pN1) After Neoadjuvant Chemotherapy - **J. Lemieux**
- **MAC.25 (NRG-BR1751)** - Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2 Positive Metastatic Cancer - **S. Chia**
- **MAC.26 / S1706** - A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer - **E. Rakovitch**
- **MA.32** - A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer – **K. Jerzak**
- **MA.40** - A Double-Blind Placebo Controlled Randomized Phase III Trial of Fulvestrant and Ipatasertib as Treatment for Advanced HER-2 Negative and Estrogen Receptor Positive (ER+) Breast Cancer Following Progression on First Line CDK 4/6 Inhibitor and Aromatase Inhibitor (FINER) - **S. Chia**

Potential New Studies

- **SCARLET/SWOG S2212** – Shorter Anthracycline-free Chemoimmunotherapy Adapted to pathological Response in Early TNBC – **S. Chia**
- **Recurrence study** – **D. Cescon**

Other Business

Note: The List of Breast Publications 1 January 2024 – 25 February 2025 is only available with the electronic version of the agenda.



Canadian Cancer Society
Société canadienne du cancer

CCTG is a CCS national program.

Breast Publications
1 January 2024 – 25 February 2025

1. Abdou Y, Barlow WE, Gralow JR, Meric-Bernstam F, Albain KS, Hayes DF, Lin NU, Perez EA, Goldstein LJ, Chia SKL, Dhesy-Thind S, Rastogi P, Alba E, Delaloge S, Schott AF, Shak S, Sharma P, Lew DL, Miao J, Unger JM, Tripathy D, Hortobagyi GN, Pusztai L, Kalinsky K. Race and clinical outcomes in hormone receptor-positive, HER2-negative, node-positive breast cancer in the randomized RxPONDER trial (ONLINE). JNCI: Journal of the National Cancer Institute 2024. Journal Article. MAC15 BRE Intergroup Other Lead Secondary analysis. Recd fr HStanton; entered COshea 2025JAN30.
2. Azim Jr HA, Niman SM, Partridge AH, Demeestere I, Ruggeri M, Colleoni M, Saura C, Shimizu C, Saetersdal AB, Kroep JR, Mailliez A, Warner E, Borges VF, Amant F, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Walshe JM, Ruiz-Borrego M, Moore HCF, Saunders C, Bjelic-Radisic V, Susnjak S, Cardoso F, Klar NJ, Spanic T, Ruddy K, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Peccatori FA. Fertility Preservation and Assisted Reproduction in Patients With Breast Cancer Interrupting Adjuvant Endocrine Therapy to Attempt Pregnancy. Journal of Clinical Oncology 42: 2822-2832. 2024. Journal Article. MAC18 BRE Intergroup Other Lead Secondary analysis. Recd fr HStanton; entered COshea 2024JUN06; updated 2024AUG26.
3. Chapman J-AW, Bayani J, SenGupta S, Bartlett JMS, Piper T, Quintayo MA, Virk S, Goss PE, Ingle JN, Ellis MJ, Sledge GW, Budd GT, Rabaglio M, Ansari RH, Tozer R, D'Souza DP, Chalchal h, Spadafora S, Stearns V, Perez EA, Gelmon KA, Whelan TJ, Elliott C, Shepherd LE, Chen BE, Taylor KJ. Adjunctive Statistical Standardization of Adjuvant Estrogen Receptor and Progesterone Receptor in Canadian Cancer Trials Group MA.27 Postmenopausal Breast Cancer Trial of Exemestane Versus Anastrozole. Journal of Clinical Oncology 42: 2887-2898. 2024. Journal Article. MA27 BRE CTG Lead Statistical. Recd fr LCallahan; keywords fr HStanton; entered COshea 2024JUN18; updated COshea 2024AUG20.
4. Chapman J-AW, Bayani J, SenGupta S, Bartlett JMS, Piper T, Quintayo MA, Virk S, Goss PE, Ingle JN, Ellis MJ, Sledge GW, Budd GT, Rabaglio M, Ansari RH, Tozer R, D'Souza DP, Chalchal H, Spadafora S, Stearns V, Perez EA, Gelmon KA, Whelan TJ, Elliott C, Shepherd LE, Chen BE, Taylor KJ. Adjunctive statistical standardization of quantitated adjuvant EV and PgR in CCTG MA.27. ASCO Annual Meeting. 42 [16 suppl], 567. 2024. Conference Proceedings. MA27 BRE ASCO. Recd fr HStanton; entered COshea 2024JUL17; poster presentation, 2024JUN02, ASCO, May 31-June 4, 2024, Chicago & Online.
5. de Azambuja E, Piccart-Gebhart M, Fielding S, Townend J, Hillman DW, Colleoni M, Roylance R, Kelly CM, Lombard J, El-Abed S, Choudhury A, Korde L, Vicente M, Chumsri S, Rodeheffer R, Ellard SL, Wolff AC, Holtschmidt J, Lang I, Untch M, Boyle F, Xu B, Werutsky G, Tujakowski J, Huang CS, Baruch NB, Bliss J, Ferro A, Gralow J, Kim SB, Kroep JR, Krop I, Kuemmel S, McConnell R, Moscetti L, Knop AS, van Duijnhoven F, Gomez H, Cameron D, Di Cosimo S, Gelber RD, Moreno-Aspitia A. Final analysis of the ALTTO trial: adjuvant trastuzumab in sequence or in combination with lapatinib in patients with HER2-positive early breast cancer [BIG 2-06/NCCTG N063D (Alliance)]. ESMO Open 9: 103938. 2024. Journal Article. MAC13 BRE Intergroup Other Lead Secondary analysis. Recd fr JDancey; keywords fr HStanton; entered COshea 2024NOV21; updated 2024DEC06.
6. Gandhi S, Ballman KV, Holmes MD, Visvanathan K, Symington B, Carvan M, Matyka C, Weiss A, Winer EP, Razaq W, Carey LA, Partridge AH, Chen WY. Association of higher baseline stress and pain with clinical outcomes: Secondary analysis from Alliance A011502. ASCO Annual Meeting. 42 [16_suppl], 11016. 2024. Conference Proceedings. MAC21 BRE ASCO. Recd fr HStanton; entered COshea 2024JUL17; rapid oral abstract session, ASCO, May 31-June 4, 2024, Chicago & Online.
7. Gandhi S, Ballman KV, Holmes MD, Visvanathan K, Symington B, Carvan M, Matyka C, Weiss A, Winer EP, Razaq W, Carey LA, Partridge AH, Chen WY. Correlation of stress, depression, sleep, and pain with race and body mass index (BMI): Secondary analysis from Alliance A011502. ASCO Annual Meeting. 42 [16_suppl], e23171. 2024. Conference Proceedings. MAC21 BRE ASCO. Recd fr HStanton; entered COshea 2024JUL17; publication only, ASCO, May 31-June 4, 2024, Chicago & Online.
8. Ganz PA, Bandos H, Španić T, Friedman S, Müller V, Kuemmel S, Delaloge S, Brain E, Toi M, Yamauchi H, de Dueñas E-M, Armstrong A, Im S-A, Song C-g, Zheng H, Sarosiek T, Sharma P, Geng C, Fu P, Rhiem K, Frauchiger-Heuer H, Wimberger P, t'Kint de Roodenbeke D, Liao N, Goodwin A, Chakiba-Brugère C, Friedlander M, Lee KS, Giacchetti S, Takano T, Henao-Carrasco F, Virani S, Valdes-Albini F, Domchek SM, Bane C, McCarron EC, Mita M, Rossi G, Rastogi P, Fielding A, Gelber RD, Scheepers ED, Cameron D, Garber J, Geyer CE, Tutt ANJ. Patient-Reported Outcomes in OlympiA: A Phase III, Randomized, Placebo-Controlled Trial of Adjuvant Olaparib in gBRCA1/2 Mutations and High-Risk Human Epidermal Growth Factor Receptor 2–Negative Early Breast Cancer. Journal of Clinical Oncology 42: 1288-1300. 2024. Journal Article. MA36 BRE Secondary Intergroup Other Lead. Recd fr HStanton; entered COshea 2024FEB09; updated COshea 2024APR08.



9. Hoppe R, Winter S, Lo W-Y, Michailidou K, Bolla MK, Keeman R, Wang Q, Dennis J, Lush M, Kalari KR, Goetz MP, Wang L, Cairns J, Weinshilboum R, Shepherd L, Chen BE, Häberle L, Ruebner M, Beckmann MW, He W, Larson NL, Armasu SM, Schroth W, Chowbay B, Khor CC, Abubakar M, Antoniou AC, Brüning T, Castela JE, Chang-Claude J, Collaborators N, Dörk T, Eccles DM, Figueroa JD, Gago-Dominguez M, García-Sáenz JA, Gündert M, Hack CC, Hamann U, Han S, Hooning MJ, Huebner H, Investigators A, John EM, Ko Y-D, Kristensen VN, Linn S, Margolin S, Mavroudis D, Nevanlinna H, Neven P, Obi N, Park-Simon T-W, Pylkäs K, Rashid MU, Romero A, Saloustros E, Sawyer EJ, Tapper WJ, Tomlinson I, Wendt C, Winqvist R, Dunning AM, Simard J, Hall P, Pharoah PDP, Schwab M, Couch FJ, Czene K, Fasching PA, Easton DF, Schmidt MK, Ingle JN, Brauch H. Lessons learned from a candidate gene study investigating aromatase inhibitor treatment outcome in breast cancer. *npj Breast Cancer* 11: 18. 2025. Journal Article. MA27 BRE CTG Lead secondary analysis. Recd fr LShepherd; entered COShea 2025FEB25.

10. Ligibel J, Ballman K, mccall L, Goodwin P, Weiss AC, Crane T, Irwin M, Thomson C, Hahn O, Spears P, Hershman DL, Paskett ED, Hopkins JO, Bernstein V, Stearns V, White J, Wadden TA, Winer EP, Carey LA, Partridge AH. 1817MO Effect of a weight loss intervention (WLI) on exercise behaviors in women with breast cancer: Results from the breast cancer weight loss (BWEL) trial. *ESMO Congress 2024*. 35 S1078. 2024. Conference Proceedings. MAC20 BRE Intergroup Other Lead ESMO. Recd fr HStanton; entered COShea 2024NOV25; oral presentation, ESMO, September 13-17, 2024, Barcelona.

11. Luen SJ, Brown LC, van Geelen CT, Savas P, Kammler R, Dell'Orto P, Biasi O, Coates AS, Gelber RD, Thürlimann B, Colleoni M, Fleming GF, Francis PA, Regan MM, Viale G, Loi S. Genomic Characterization and Prognostic Significance of Human Epidermal Growth Factor Receptor 2–Low, Hormone Receptor–Positive, Early Breast Cancers From the BIG 1-98 and SOFT Clinical Trials. *JCO Precis Oncol* e2400599. 2025. Journal Article. MAC4 BRE Intergroup Other Lead Secondary analysis. Recd fr HStanton; entered COShea 2025JAN30.

12. Metzger O, Ballman KV, Gnant M, Watson M, Chen E, Tran K, O'Brien P, Hlauschek D, Martin M, Balko JM, Nowecki Z, Hahn OM, Denkert C, Curtis C, Liu Y, Dueck AC, Fesl C, Mayer EL, DeMichele A, Symmans WFF. Analysis of the sensitivity to endocrine therapy (SET) assay in the PALLAS adjuvant trial of palbociclib in HR+/HER2- breast cancer (ABCSG-42/AFT-05/BIG-14-13). *ASCO Annual Meeting*. 42 [16_suppl], 538. 2024. Conference Proceedings. MA37 BRE ASCO. Recd fr HStanton; entered COShea 2024JUL17; poster presentation, ASCO, May 31-June 4, 2024, Chicago & online.

13. Poppe MM, Le-Rademacher J, Haffty BG, Jr., Hansen EK, Agarwal J, Wagner J, Kong I, Armer J, Arthur DW, Whelan TJ, Lee MK, Kour O, Lustberg M, Partridge A, Carey LA, Ruddy KJ, Gaffney DK, Stecklein SR, Bernstein MB, Khan AJ. A Randomized Trial of Hypofractionated Post-Mastectomy Radiation Therapy (PMRT) in Women with Breast Reconstruction (RT CHARM, Alliance A221505). *ASTRO*. 120 [2], S11. 2024. Conference Proceedings. MAC23 BRE ASTRO. Recd fr HStanton; entered COShea; oral, plenary presentation, ASTRO, Sept 29 - Oct 2, 2024, Washington DC.

14. Shenasa E, He Y, Wang Z, Tu D, Gao D, Kos Z, Thornton S, Nielsen TO. Digital Profiling of Immune Biomarkers in Breast Cancer: Relation to Anthracycline Benefit. *Modern Pathology* 38: 100718. 2025. Journal Article. MA5 BRE CTG Lead correlative science secondary analysis trainee. Recd fr DTu; keywords fr HStanton; entered COShea 2025FEB25.

15. White JR, Cecchini RS, Harris EE, Mamounas EP, Stover DG, Ganz PA, Jagsi R, Anderson SJ, Bergom C, Théberge V, El-Tamer M, Zellars RC, Shumway D, Chen G-P, Julian TB, Wolmark N. NRG-BR007: A phase III trial evaluating de-escalation of breast radiation (DEBRA) following breast-conserving surgery of stage 1, HR+, HER2-, RS ≤18 breast cancer. *ASCO Annual Meeting*. 42 [16_suppl], TPS622. 2024. Conference Proceedings. MAC28 BRE ASCO. Recd fr HStanton; entered COShea 2024JUL17; poster presentation, ASCO, May 31-June 4, 2024, Chicago & online.

