

# Impact of Relaxing Brain Metastases Exclusion Criteria on Colon Cancer Trials Population

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## Objectives

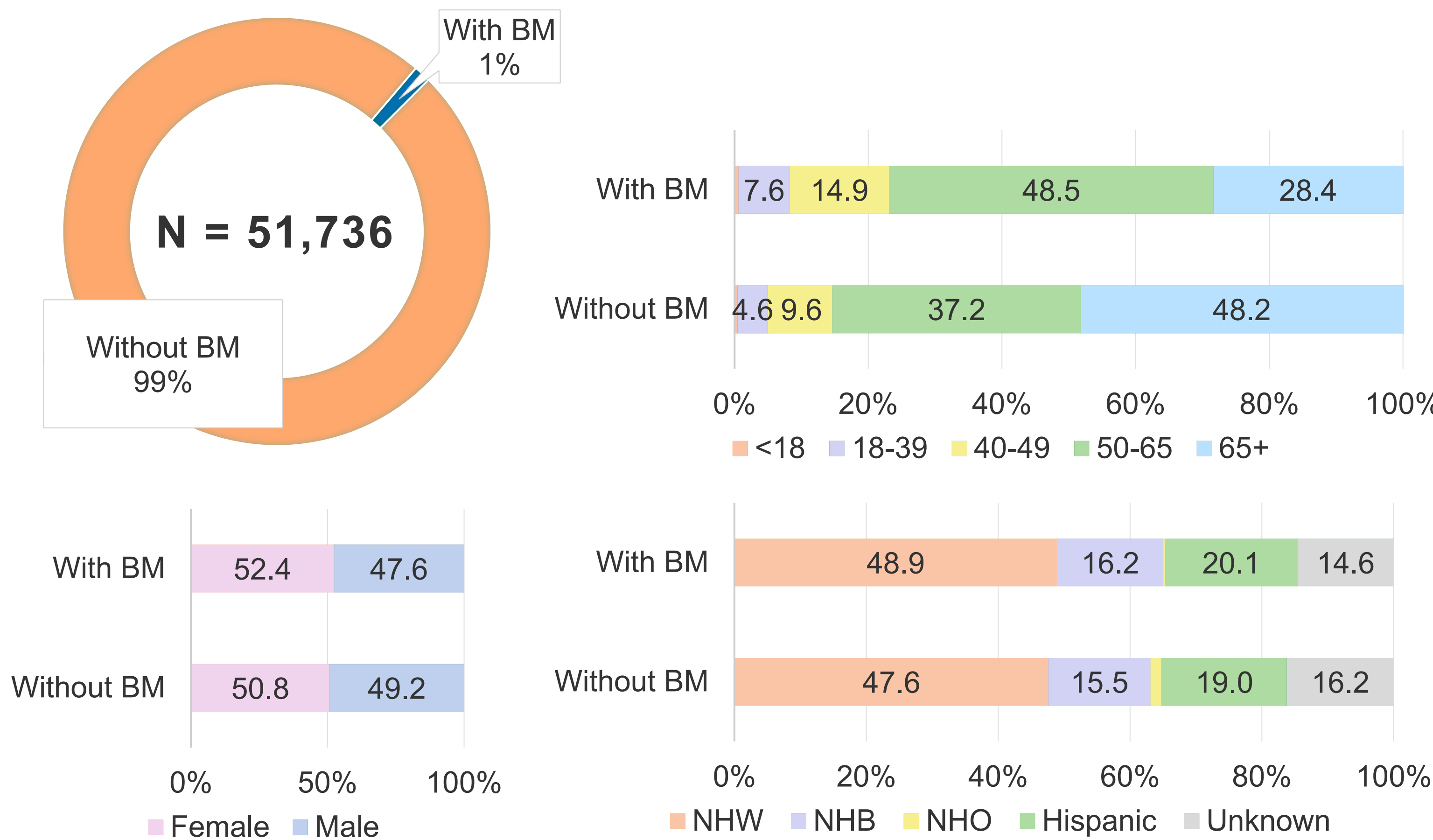
- Many oncology clinical trials have excluded patients with brain metastases (BM), despite the FDA recommending their inclusion.
- The inclusion of BM patients would lead to a more accurate efficacy and safety profile.
- The study aimed to assess the impact of relaxing BM exclusion criteria on colon cancer trials population by:
  - Identifying the proportion of colon cancer patients with BM.
  - Examining whether BM patients have poorer survival.

## Methods

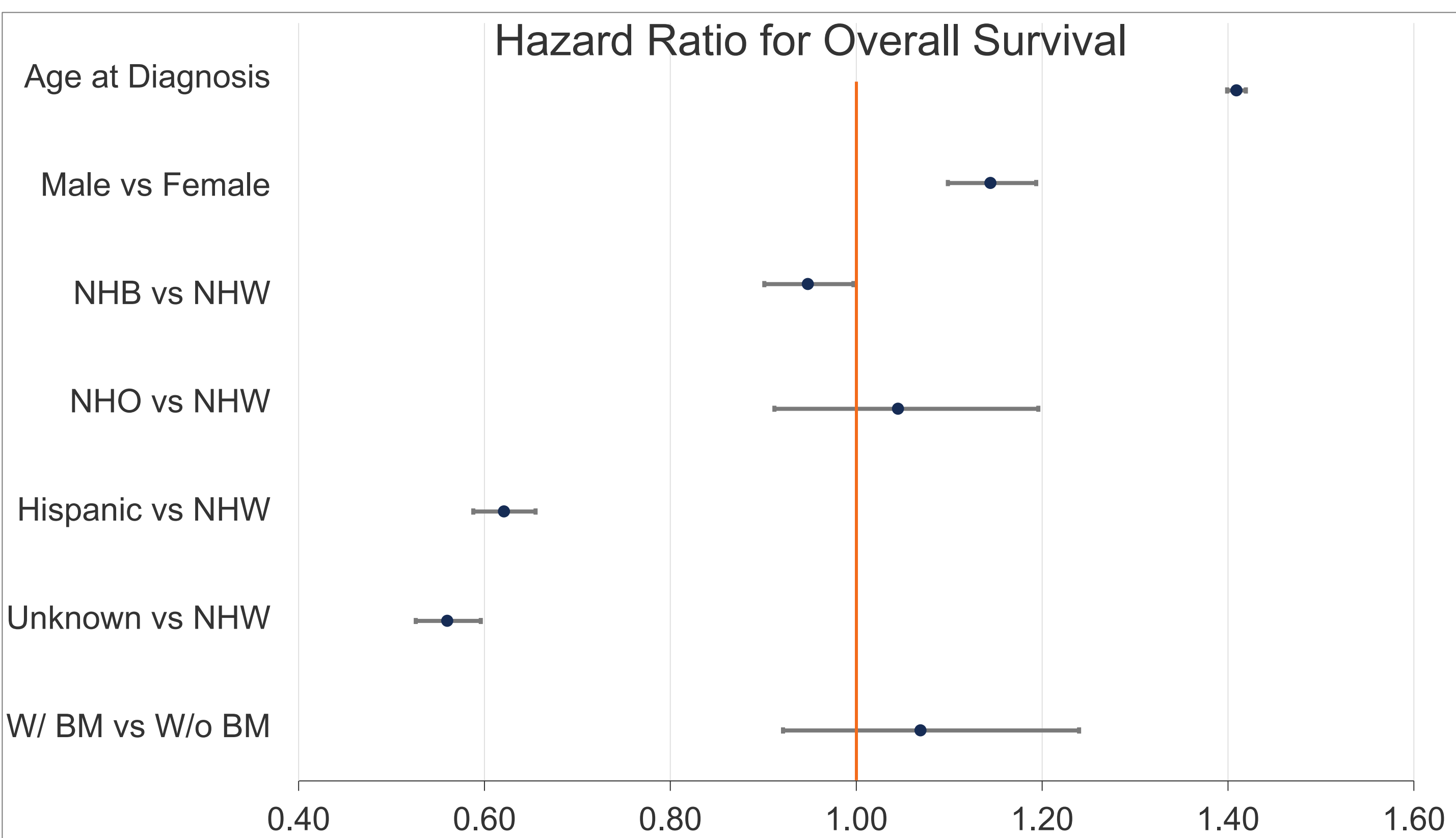
- Study design:** A retrospective study
- Data source:** OneFlorida clinical research network database, electronic health records (EHRs) data
- Cohort:** Colon cancer patients, group by BM diagnosis status
- Analysis:** Multivariate cox proportional hazard model on overall survival

## References

- Tan AC, Boggs DH, Lee EQ, Kim MM, Mehta MP, Khasraw M. *Clinical Trial Eligibility Criteria and Recently Approved Cancer Therapies for Patients With Brain Metastases*. Front Oncol. 2022 Jan 3;11:780379.
- Patel RR, Verma V, Miller AB, Lin TA, Jethanandani A, Espinoza AF, Mainwaring W, Augustyn A, Fuller CD, Sulman EP, Yeboa DN, Chung CC, McAleer MF, Li J, Yoshor D, de Groot JF, Mandel JJ, Ludmir EB. *Exclusion of patients with brain metastases from cancer clinical trials*. Neuro Oncol. 2020 Apr 15;22(4):577-579.
- FDA/CDER/Fox S. *Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs*.



BM: Brain metastases, NHW: Non-Hispanic White, NHB: Non-Hispanic Black, NHO: Non-Hispanic Other



## Results

- 51,736 colon cancer patients were identified from OneFlorida EHRs data.
- 656 (1.3%) of these patients had BM.
- Patients with BM had a mean age at colon cancer diagnosis of 58 years, which is significantly different from patients without BM (mean age of 64 years).
- There was no significant difference in the distributions of gender or race/ethnicity between patients with and without BM.
- After controlling for age, gender, and race/ethnicity, the hazard ratio of BM for colon cancer survival was 1.07 ( $p = 0.379$ ).
- Age at colon cancer diagnosis was the dominant predictor of survival, with a hazard ratio of 1.41 ( $p < 0.001$ ).
- Gender also had a significant impact on survival, with males having a hazard ratio of 1.14 ( $p < 0.001$ ).

## Conclusions

- Only a small proportion (1.3%) of colon cancer patients have BM.
- Despite being younger at diagnosis, having BM is not a significant predictor for survival after controlling for age, gender, and race/ethnicity.
- The exclusion of BM patients from colon cancer trials may not be justified based on poorer survival outcomes.