

# CURRICULUM VITAE

BENEDITO A. CARNEIRO (FILHO), MD, MSc

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## EDUCATION

**Medical School** **1994 – 2000**  
School of Medicine (6-year program), Federal University  
of Ceará, Fortaleza, CE, Brazil

**Postdoctoral degree** **2008 – 2010**  
Master of Science in Clinical Research, The Institute for  
Clinical Research Education, Clinical and Translational  
Science Institute, University of Pittsburgh, Pittsburgh, PA

## POSTGRADUATE TRAINING

**Residency** **2003 – 2006**  
Internal Medicine Residency McGaw Medical Center of  
Northwestern University/Evanston Hospital, Evanston, IL

**2006 – 2007**  
Chief Medical Resident, Evanston Northwestern  
Healthcare, Evanston, IL

**Fellowship**

**2001 – 2003** Action for Building Capacity Research Fellow (Fogarty  
International Center, NIAID, NIH), Division of Infectious  
Diseases and International Health, Department of  
Medicine, University of Virginia, Charlottesville, VA

- 2007 – 2010** Hematology/Oncology Fellow, Division of Hematology/Oncology, Department of Medicine, University of Pittsburgh, Pittsburgh, PA
- 2014 – 2015** Developmental Therapeutics Fellow, Northwestern Medicine Developmental Therapeutics Institute, Northwestern University Feinberg School of Medicine

### **POSTGRADUATE HONORS AND AWARDS**

- 1996** Best Oral Presentation, Basic Science Research, XXVI National Medical Students Scientific Meeting, Maceio, AL, Brazil.
- 1996** Pharmacology Teaching Assistant Scholarship, Department of Pharmacology, School of Medicine, Federal University of Ceará, Fortaleza, CE, Brazil.
- 1999** Medical Oncology Teaching Assistant Scholarship, Department of Pharmacology, School of Medicine, Federal University of Ceará, Fortaleza, CE, Brazil.
- 2003** Outstanding Research Presentation, The 22nd Annual Department of Medicine Research Day, University of Virginia, Charlottesville, VA.
- 2004** Intern of the Year Award, McGaw Medical Center of Northwestern University/Evanston Hospital, Evanston, IL.
- 2005** The A. Zamin Rizavi MD Award, Resident that Best Exemplifies the Admirable Traits of the late Dr Rizavi, McGaw Medical Center of Northwestern University/Evanston Hospital, Evanston, IL.
- 2006** Resident of the Year Award, McGaw Medical Center of Northwestern University/Evanston Hospital, Evanston, IL.
- 2016** Feinberg School of Medicine Excellence in Teaching Award, Division of Hematology/Oncology, Department of Medicine, Northwestern University

### **PROFESSIONAL LICENSES AND BOARD CERTIFICATION**

- American Board of Internal Medicine (2007)
- American Board of Internal Medicine Medical Oncology (2013)

- State of Illinois Medical License 036-115617
- State of Rhode Island Medical License MD15932
- United States DEA number FC4493398

## **ACADEMIC APPOINTMENTS**

<b>2006 – 2007</b>	Clinical Instructor, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL
<b>2012 – 2013</b>	Assistant Professor of Medicine, School of Medicine, University of Fortaleza, Fortaleza, CE, Brazil
<b>2014 – 2015</b>	Instructor in Medicine-Hematology/Oncology, Division of Hematology/Oncology, Northwestern University Feinberg School of Medicine
<b>2015 – 2017</b>	Assistant Professor in Medicine - Hematology/Oncology, Division of Hematology/Oncology, Northwestern University Feinberg School of Medicine
<b>2016 – 2017</b>	Co-Director, Developmental Therapeutics Program of the Division of Hematology/Oncology, Northwestern University Feinberg School of Medicine
<b>2016 – 2017</b>	Director, Developmental Therapeutics Fellowship, Division of Hematology/Oncology, Northwestern University Feinberg School of Medicine
<b>2017 – present</b>	Assistant Professor of Medicine, Division of Hematology/Oncology, Alpert Medical School, Brown University, Providence, RI
<b>2017 – present</b>	Director of Clinical Cancer Research, Director of Cancer Drug Development Program (Phase I), Lifespan Cancer Institute
<b>2017 – present</b>	Associate Director, Division of Hematology/Oncology, Department of Medicine, Alpert Medical School, Brown University
<b>2019 – present</b>	Co-Leader Cancer Therapeutics Program, Legorreta Cancer Center at Brown University
<b>2022 – present</b>	Associate Professor of Medicine (Research Track), Department of Medicine, Division of Hematology/Oncology, Alpert Medical School, Brown University, Providence, RI

## **HOSPITAL APPOINTMENTS**

<b>2000 – 2001</b>	Internal Medicine Physician, Paraipaba Hospital, Paraipaba, CE, Brazil
<b>2010 – 2014</b>	Medical Oncologist, General Hospital of Fortaleza, Fortaleza, CE, Brazil
<b>2016 – 2017</b>	Medical Director, Developmental Therapeutics Program Clinic, Olson Pavilion, Northwestern Memorial Hospital
<b>2017 – present</b>	Associate Director, Division of Hematology/Oncology, Department of Medicine, Alpert Medical School, Brown University
<b>2019 – present</b>	Co-Leader Cancer Therapeutics Program, Legorreta Cancer Center at Brown University

## **HOSPITAL COMMITTEES**

<b>2014 – 2017</b>	Steering Committee, Bristol-Myers Squibb Rare Malignancies Program and Developmental Therapeutics Program Alliance, Division of Hematology/Oncology, Northwestern University Feinberg School of Medicine
<b>2016 – 2017</b>	Cancer Quality Committee, Northwestern Memorial Hospital
<b>2017 – present</b>	Lifespan Cancer Institute Operations and Performance Monitoring Committee
<b>2018 – present</b>	Lifespan Research Advisory Committee

## **UNIVERSITY COMMITTEES**

<b>2014 – 2015</b>	Scientific Review Committee, The Robert H Lurie Comprehensive Cancer Center, Northwestern University
<b>2014 – 2017</b>	Institutional Review Board, Northwestern University
<b>2014 – 2017</b>	Clinical Trial Audit Committee, The Robert H Lurie Comprehensive Cancer Center, Northwestern University
<b>2017 – present</b>	Brown University Oncology Research Group (BrUOG), Executive Committee Member
<b>2018</b>	Faculty search committee for Scientist or Physician-scientist Cancer Biology, Department of Pathology and Laboratory Medicine, Joint Program in Cancer Biology, Alpert Medical School of Brown University
<b>2022</b>	Faculty search committee for Phase I oncologist in the Department of Medicine, Alpert Medical School of Brown University

<b>2022</b>	Faculty search committee for Immuno-oncologist in the Department of Medicine, Alpert Medical School of Brown University
<b>2022</b>	Faculty search committee for Director of Anatomic Pathology, Department of Pathology and Laboratory Medicine, Alpert Medical School of Brown University
<b>2019 – present</b>	Co-Chair Genitourinary Committee, Brown University Oncology Research Group (BrUOG)
<b>2019 – present</b>	Chair, Scientific Review and Monitoring Committee (SRMC), Lifespan Cancer Institute, Brown University Oncology Research Group (BrUOG), Legorreta Cancer Center at Brown University
<b>2021 – present</b>	Co-Chair Phase I Committee, Brown University Oncology Research Group (BrUOG)

### **NATIONAL COMMITTEES**

<b>2015 – 2017</b>	Southwest Oncology Group (SWOG) Genitourinary Committee
<b>2016 – 2017</b>	National Comprehensive Cancer Network (NCCN), Testicular Cancer Guideline Panel
<b>2020</b>	Program Committee for the American Association for Cancer Research (AACR) Annual Meeting, Biological Therapeutic Agents Section of the Experimental and Molecular Therapeutics Subcommittee
<b>2020 – 2023</b>	American Society of Clinical Oncology (ASCO), Annual Meeting Scientific Program Committee, Developmental Therapeutics – Immunotherapy
<b>2020 – present</b>	American Association for Cancer Research (AACR) Annual Meeting, Clinical Trials Committee

### **MEMBERSHIP IN SOCIETIES**

<b>2007 – present</b>	American Association for Cancer Research
<b>2007 – present</b>	American Society of Clinical Oncology
<b>2014 – present</b>	American Society of Hematology
<b>2018 – present</b>	European Society for Medical Oncology

### **JOURNAL REVIEWER AND EDITORIAL BOARD**

#### **Editorial boards**

<b>2018 – 2022</b>	American Journal of Clinical Oncology, Associate Editor
<b>2019 – present</b>	Cancer Biology & Therapy, Editorial Board
<b>2024 – present</b>	Oncotarget, Editorial Board

## Reviewer

Cancer Discovery, Clinical Cancer Research, Cancer Letters, Nature Communications, Frontiers in Oncology, Cancer Research Communications, Oncology and Hematology Review, Journal of Interferon & Cytokine Research, PLOS One, British Journal of Cancer, Thyroid, eLife

## GRANT REVIEWER

**2015** Austrian Science Fund

**2021-present** Robert E. Lee and Clara Guthrie Patterson Trust Mentored Research Award:  
Clinical, Health Services and Policy Research Program

## PUBLICATIONS LIST

**h-index 41** (Google Scholar 4/2024)

### **I. Original, peer-reviewed publications.**

1. Souza FGM, Landim RM, Perdigão FB, Morais RM, **Carneiro-Filho BA**. Consumo de drogas e desempenho acadêmico entre estudantes de medicina no Ceará (Drug use and academic achievement among medical students from Ceará). *Revista de Psiquiatria Clínica* 1999; 26(4):188-194
2. **Carneiro-Filho BA**, Souza ML, Lima AA, Ribeiro RA. The effect of tumor necrosis factor (TNF) inhibitors in *clostridium difficile* toxins-induced paw oedema and neutrophil migration. *Pharmacology and Toxicology* 2001; 88(6):313-8. PMID 11453371
3. Viana CF, Melo DH, **Carneiro-Filho BA**, Michelin MA, Brito GA, Cunha FQ, Lima AA, Ribeiro RA. Pro-inflammatory effects of cholera toxin: Role of tumor necrosis factor. *Toxicon* 2002; 40(10):1487-94. PMID 12368119
4. Brito GA, Fujii J, **Carneiro-Filho BA**, Lima AA, Obrig T, Guerrant RL. Mechanism of *clostridium difficile* toxin A induced apoptosis in T84 cells. *Journal of Infectious Diseases* 2002;186(10):1438-47. PMID 12404159
5. **Carneiro-Filho BA**, Lima IP, Araujo DH, Cavalcante MC, Carvalho GH, Brito GA, Lima V, Monteiro SM, Santos FN, Ribeiro RA, Lima AA. Intestinal barrier function and secretion in Methotrexate induced rat intestinal mucositis. *Digestive Diseases and Sciences* 2004; 49(1):65-72. PMID 14992437
6. **Carneiro-Filho BA**, Oria RB, Wood Rea K, Brito GA, Fujii J, Obrig T, Lima AA, Guerrant RL. Alanyl-glutamine hastens morphological recovery from 5-Fluorouracil induced mucositis in mice. *Nutrition* 2004; 20:934-41. PMID 15474885
7. Brito GA, **Carneiro-Filho B**, Oria RB, Destura RV, Lima AA, Guerrant RL. Clostridium difficile toxin A induces intestinal epithelial cell apoptosis and damage: Role of Gln and Ala-Gln in toxin A effects. *Digestive Diseases and Sciences* 2005; 50(7):1271-78. PMID 16047471
8. Alcantara CS, Jim XH, Brito GA, **Carneiro-Filho BA**, Barrett LJ, Carey RM, Guerrant RL. Angiotensin II subtype 1 receptor blockade inhibits clostridium difficile toxin A-induced intestinal secretion in a rabbit model. *Journal of Infectious Diseases* 2005; 191(12):2090-6. PMID 15897995

9. **Carneiro BA**, Fujii J, Brito GA, Alcantara C, Oria RB, Lima AA, Obrig T, Guerrant RL. Caspase and bid involvement in *clostridium difficile* toxin A-induced apoptosis and modulation of toxin A effects by glutamine and alanyl-glutamine *in vivo* and *in vitro*. *Infection and Immunity* 2006; 74(1):81-7. PMID 16368960
10. **Carneiro BA**, Watkin WG, Mehta UK, Brockstein BE. Metastatic basal cell carcinoma: complete response to chemotherapy and associated pure red cell aplasia. *Cancer Investigation* 2006; 24(4):396-400. PMID 16777692
11. **Carneiro BA**, Kaminer L, Eldibany M, Sreekantaiah C, Kaul K, Locker GY. Oxaliplatin-related acute myelogenous leukemia. *Oncologist* 2006; 11(3):261-2 PMID 16549810
12. **Carneiro BA**, Brand RE, Fine E, Knop RH, Khandekar JD, Uhlig W, Locker GY. Phase I trial of fixed dose rate infusion gemcitabine with gefitinib in patients with advanced pancreatic carcinoma. *Cancer Investigation* 2007; 25(5):366-71 PMID 17661212
13. Fujii J, Wood K, Matsuda F, **Carneiro-Filho BA**, Schlegel KH, Yutsudo T, Binnington-Boyd B, Lingwood CA, Obata F, Kim KS, Yoshida SI, Obrig T. Stx2 causes apoptosis in human brain microvascular endothelial cells via CHOP. *Infection and Immunity* 2008; 76(8):3679-89. PMID 18541659
14. **Carneiro BA**, Ramanathan RK, Smitha KS, Lembersky BC, Stoller RG, Lancaster SL, Pinkerton RA, Crandall TL, Schmotzer AR, Potter DM, Bahary N. Phase II study of irinotecan and cetuximab given every 2 weeks as second-line therapy for advanced colorectal cancer. *Clinical Colorectal Cancer* 2012; 11(1):53-9. PMID 21813336
15. **Carneiro BA**, Elvin JA, Kamath SD, Ali SM, Paintal AS, Restrepo A, Berry E, Giles FJ, Johnson ML. FGFR3-TACC3: a novel gene fusion in cervical cancer. *Gynecol Oncol Rep* 2015; 13:53-6. PMID 26425723
16. Chae YK, Anker J, **Carneiro B**, Chandra S, Kaplan J, Kalyan A, Santa-Maria C, Plataniias L, Giles F. Genomic landscape of DNA repair genes in cancer. *Oncotarget* 2016; 7(17): 23312-21 PMID 27004405.
17. Chae YK, Gagliato Dde M, Pai SG, **Carneiro B**, Mohindra N, Giles FJ, Ramakrishnan-Geethakumari P, Sohn J, Liu S, Chen H, Ueno N, Hortobagyi G, Gonzalez-Angulo AM. The association between EGFR and cMET expression and phosphorylation and its prognostic implication in patients with breast cancer. *PLoS One* 2016; 11(4): 0152585. PMID 27055285
18. Chae YK, Davis AA, **Carneiro BA**, Chandra S, Mohindra N, Kalyan A, Kaplan J, Matsangou M, Pai S, Costa R, Jovanovic B, Cristofanilli M, Plataniias LC, Giles FJ. Concordance between genomic alterations assessed by next-generation sequencing in tumor tissue or circulating cell-free DNA. *Oncotarget* 2016; 7(40):65364-65373 PMID 27588476
19. Meeks J, **Carneiro B\***, Pai SG, Oberlin D, Rademaker A, Fedorchak, Balasubramanian S, Elvin J, Beaubier N, Giles F. Genomic characterization of high-risk non-muscle invasive bladder cancer. *Oncotarget* 2016; 7(46): 75176-75184 PMID 27750214 (\*) co-first author
20. Costa R, **Carneiro B**, Agulnik M, Rademaker A, Pai S, Cristofanilli M, Villaflor V, Sosman J, Giles F. Toxicity profile of approved anti-PD-1 monoclonal antibodies in solid tumors: a systematic review and meta-analysis of randomized clinical trials. *Oncotarget* 2017; 8(5):8910-8920. PMID 27852042
21. Costa R, Gill N, Rademaker AW, **Carneiro BA**, Chae YK, Kumthekar P, Gradishar WJ, Kurzrock R, Giles FJ. Systematic analysis of early phase clinical studies for patients with breast cancer: inclusion of patients with brain metastasis. *Cancer Treat Rev* 2017; 55:10-15 PMID 28279895

22. Costa R, Costa RB, Talamantes SM, Helenowski I, Peterson J, Kaplan J, **Carneiro BA**, Giles FJ, Gradishar WJ. Meta-analysis of selected toxicity endpoints of CDK4/6 inhibitors: palbociclib and ribociclib. *Breast* 2017; 35:1-7 PMID 28618307
23. Costa R, Costa RB, Talamantes SM, Helenowski I, **Carneiro BA**, Chae YK, Gradishar WJ, Kurzrock R, Giles FJ. Analyses of selected safety endpoints in phase 1 and late-phase clinical trials of anti-PD-1 and PD-L1 inhibitors: prediction of immune-related toxicities. *Oncotarget* 2017 PMID 28733528
24. Stoller R, Schmitz JC, Ding F, Puhalla S, Belani C, Appleman L, Lin Y, Jiang Y, Almokadem S, Petro D, Holleran J, Kiesel BF, Czambel RK, **Carneiro BA**, Kontopodis E, Hershberger P, Rashid M, Giranda V, Chen A, Chu E, Beumer JH. Phase I study of veliparib in combination with gemcitabine. *Cancer Chemotherapy and Pharmacology* 2017 80(3):631-43 PMID 28770300
25. Pai S, **Carneiro BA**, Kalyan A, Costa R, Chae Y, Mahalingam D, Giles FJ. Correlation of tumor mutational burden and treatment outcomes in patients with colorectal cancer. *Journal of Gastrointestinal Oncology* 2017; 8(5):858-66 PMID 29184690
26. Costa RB, Costa R, Kaplan J, Cruz MR, Shah H, Matsangou M, **Carneiro B**. A rare case of glioblastoma multiforme with osseous metastases. *Case Reports Oncol Med* 2017:2938319 PMID 29201475
27. **Carneiro BA**, Collier KA, Nagy RJ, Pamarthy S, Sagar V, Fairclough S, Odegaard J, Lanman RB, Costa R, Kuzel TM, Fan A, Chae YK, Hussain M, Cristofanilli M, Abdulkadir SA, Giles FJ. Acquired resistance to the PARP inhibitor olaparib in BRCA2-associated prostate cancer due to biallelic BRCA2 reversion mutations restoring both germline and somatic loss of function mutations. *JCO Precision Oncology* 2018; 2: 1-5 PMID 31501807
28. Zhang Q, Helfand BT, **Carneiro BA**, Qin W, Yang XJ, Lee C, Zhang W, Giles FJ, Cristofanilli M, Kuzel TM. Efficacy against human prostate cancer by prostate-specific membrane antigen-specific, transforming growth factor- $\beta$  insensitive genetically targeted CD8+ T-cells derived from patients with metastatic castrate-resistant disease. *European Urology* 2018; 73(5):648-652 PMID 29275833.
29. Costa RB, Costa RLB, Talamantes SM, Kaplan JB, Bhawe MA, Rademaker A, Miller C, **Carneiro BA**, Mahalingam D, Chae YK. Systematic review and meta-analysis of selected toxicities of approved *ALK* inhibitors in metastatic non-small cell lung cancer. *Oncotarget* 2018; 9(31):22137-146 PMID 29774128
30. **Carneiro BA**, Pamarthy S, Shah AN, Sagar V, Unno K, Yang XJ, Costa RB, Nagy RJ, Lanman RB, Kuzel TM, Ross J, Gay L, Elvin J, Ali S, Cristofanilli M, Chae YK, Giles FJ, Abdulkadir SA. Anaplastic lymphoma kinase mutation (*ALK* F1174C) in a small cell carcinoma of the prostate and molecular response to alectinib. *Clin Cancer Res* 2018;24(12):2732-39 PMID 29559559.  
*This study identified a new therapeutic target in small cell carcinoma of the prostate, a rare and aggressive subtype of prostate cancer.*
31. Chae YK, Chiec L, Adney SK, Waitzman J, Costa R, **Carneiro B**, Matsangou M, Agulnik M, Kopp P, Giles F. Posterior reversible encephalopathy syndrome and takotsubo cardiomyopathy associated with lenvatinib therapy for thyroid cancer: a case report and review. *Oncotarget* 2018;9(46):28281-89. PMID 29963277
32. Marks EI, Pamarthy S, Dizon D, Birnbaum A, Yakirevich E, Safran H, **Carneiro BA**. *ROSI-GOPC/FIG*: a novel gene fusion in hepatic angiosarcoma. *Oncotarget* 2019;10(2):245-51 PMID: 30719217
33. Alves da Silva AV, Martins-Neto F, de Oliveira ACSM, **Carneiro BA**, Alves M, Nogueira CD, Tavora F. The frequency of high PD-L1 expression is low in lung



- adenocarcinoma patients from northeast Brazil. *Surgical and Experimental Pathology* 2019 2,4 <https://doi.org/10.1186/s42047-019-0031-1>
34. Chanzá NM, Xie W, Bilen MA, Dzimitrowicz H, Burkart J, Geynisman DM, Balakrishnan A, Bowman IA, Jain R, Stadler W, Zakharia Y, Narayan V, Beuselinck B, McKay RR, Tripathi A, Pachynski R, Hahn AW, Hsu J, Shah SA, Lam ET, Rose TL, Mega AE, Vogelzang N, Harrison MR, Mortazavi A, Plimack ER, Vaishampayan U, Hammers H, George S, Haas N, Agarwal N, Pal SK, Srinivas S, **Carneiro BA**, Heng DY, Bosse D, Choueiri TK, Harshman LC. Cabozantinib in advanced non-clear cell renal carcinoma: a multicenter retrospective cohort analysis. *Lancet Oncol* 2019; 20(4):581-590 PMID 30827746
  35. Oliveira ACDSM, Silva AVAD, Alves M, Cronemberger E, **Carneiro BA**, Melo JC, Martins Neto F, Tavora F. Molecular profile of non-small cell lung cancer in northeastern Brazil. *J Bras Pneumol* 2019; 45(3):e20180181 PMID 31166373
  36. Yakirevich E, Madison R, Fridman E, Mangray S, **Carneiro BA**, Lu S, Cooke M, Bratslavsky G, Webster J, Ross JS, Ali SM. Comprehensive Genomic Profiling of Adult Renal Sarcomas Provides Insight into Disease Biology and Opportunities for Targeted Therapies. *Eur Urology Oncol* 2019 PMID 31412008
  37. Tatsi C, Faucz FR, Blavakis E, **Carneiro BA**, Lyssikatos C, Belyavskaya E, Quezado M, Stratakis CA. Somatic PRKAR1A gene mutation as a cause of non-syndromic metastatic large-cell calcifying Sertoli cell tumor. *Journal of the Endocrine Society* 2019; 3(7):1375-1382 PMID 31286102
  38. Rini BI, Plimack ER, Stus V, Gafanov R, et al. \* Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma. *N Engl J Med* 2019; 380(12):1116-27 (\*member of the investigative team cited in the appendix of the manuscript).
  39. **Carneiro BA**, Konda B, Costa RB, Costa, RLB, Sagar V, Gursel DB, Kirschner LS, Chae YK, Abdulkadir SA, Rademaker A, Mahalingam D, Shah MH, Giles FJ. Nivolumab in metastatic adrenocortical carcinoma: results of a phase II trial. *J Clin Endocrinol Metab* 2019; 104(12):6193-6200 PMID 31276163.
  40. Vidula N, Rich TA, Sartor O, Yen J, Hardin A, Nance T, Lilly MB, Nezami MA, Patel S, **Carneiro BA**, Fan AC, Brufsky AM, Parker BA, Bridges BB, Agarwal N, Maughan BL, Raymond VM, Fairclough SR, Lanman RB, Bardia A, Cristofanilli M. Routine plasma-based genotyping to comprehensively detect germline, somatic, and reversion *BRCA* mutations among patients with advanced solid tumors. *Clinical Cancer Research* 2020;26(11):2546-2555 PMID 32034076
  41. Vatapalli R, Sagar V, Rodriguez Y, Zhao J, Unno K, Pamarthy S, Lysy B, Anker J, Han H, Yoo Y, Truica M, Chalmers Z, Giles F, Yu J, Chakravarti D, **Carneiro B**, Abdulkadir S. Histone Methyltransferase DOT1L Coordinates AR and MYC Stability in Prostate Cancer. *Nature Communications* 2020; 11(1):4153 PMID 32814769
  42. Henrich SE, McMahan KM, Plebanek MP, Calvert AE, Feliciano T, Parrish S, Tavora F, Mega A, De Souza A, **Carneiro BA\***, Thaxton CS. Prostate cancer extracellular vesicles mediate intercellular communication with bone marrow cells and promote metastasis in a cholesterol-dependent manner. *J Extracell Vesicles* 2020;10(2):e12042 PMID 33408816 (\*) co-corresponding author
  43. Yakirevich E, Pavlick DC, Perrino C, Stanton M, Lu S, **Carneiro B**, Bratslavsky G, Ross JS. NF2 Tumor Suppressor Gene Inactivation in Advanced Papillary Renal Cell Carcinoma. *Am J Surg Pathol* 2021; 45(5):716-718 PMID 32925192
  44. Borden BA, Baca Y, Xiu J, Tavora F, Winer I, Weinberg BA, Vanderwalde A, Darabi S, Korn WM, Mazar A, Giles FJ, Crawford L, Safran H, El-Deiry W, **Carneiro BA**. The

- Landscape of Glycogen synthase kinase-3 beta (GSK-3 $\beta$ ) Genomic Alterations in Cancer. *Mol Cancer Ther* 2021; 20(1): 183-190 PMID 33087512
45. Marks EI, Matera R, Olszewski AJ, Yakirevich E, El-Deiry WS, Safran H, **Carneiro BA**. Mutations in DNA repair genes and clinical outcomes of patients with metastatic colorectal cancer receiving oxaliplatin or irinotecan-containing regimens. *Am J Clin Oncol* 2021; 44(2):68-73 PMID 33298767
  46. Alves M, Borges DP, Kimberly A, Martins Neto F, Oliveira AC, De Sousa JC, Nogueira CD, **Carneiro BA**, Tavora F. Glycogen synthase kinase-3 beta expression correlates with worse overall survival in non-small cell lung cancer—a clinicopathological series. *Front Oncol* 2021;11:621050 PMID 33767989
  47. Golijanin B, Gershman B, De Souza A, Kott O, **Carneiro BA**, Mega A, Golijanin D, Amin A. p53 Expression, Programmed Death-Ligand 1, and Risk Factors in Urinary Tract Small Cell Carcinoma. *Front Oncol* 2021; 11:651754 PMID 33968753
  48. Powles T, Csoszi T, Ozguroglu M, Matsubara N, et al. (\*) Pembrolizumab alone or combined with chemotherapy versus chemotherapy as first-line therapy for advanced urothelial carcinoma (KEYNOTE-361): a randomized, open-label, phase 3 trial. *Lancet Oncol* 2021; 22(7):931-945 PMID 34051178 (\*member of the investigators team).
  49. Jhaveri AV, Zhou L, Ralff MD, Lee YS, Navaraj A, **Carneiro BA**, Safran H, Prabhu VV, Allen JE, Ross EA, Lee S, El-Deiry WS. Combination of ONC201 and TLY012 induces selective, synergistic apoptosis and significantly delays PDAC xenograft growth. *Cancer Biology and Therapy* 2021; 22(10-12):607-618 PMID 34856854
  50. Kouchkovsky I, Rao A, **Carneiro BA**, Zhang Li, Lewis C, Phone A, Small EJ, Friedlander T, Fong L, Paris P, Ryan CJ, Szmulewitz R, Aggarwal R. A phase 1b/2 study of the CDK 4/6 inhibitor ribociclib in combination with docetaxel plus prednisone in metastatic castration resistant prostate cancer. *Clin Cancer Research* 2022;28(8):1531-39 PMID 35176163
  51. Odia Y, Cavalcante L, Safran H, Powell SF, Munster PN, Ma WW, **Carneiro BA**, Bastos, BR, Mikrut S, Mikrut W, Giles FJ, Sahebjam S. Malignant Glioma Subset from Actuate 1801: Phase 1/1/22 Study of 9-ING-41, GSK- 3 $\beta$  Inhibitor, Monotherapy or Combined with Chemotherapy for Refractory Malignancies. *Neuro-Oncology Advances* 2022; 4(1):vdac012 PMID 35402914
  52. LoRusso P, Ratain MJ, Doi T, Rasco DW, de Jonge MJ, Moreno V, **Carneiro BA**, Devriese LA, Nuthalapati S, Motwani M, Dunbar M, Glasgow J, Medeiros BC, Calvo E. Eftozanermin Alfa (ABBV-621) Monotherapy in Patients With Previously Treated Solid Tumors: Findings of a Phase 1, First-in-Human Study. *Invest New Drugs* 2022; Apr 25;1-11 PMID 35467243
  53. Hsu A, Huntington K, De Souza A, Zhou L, Olszewski AJ, Makwana NP, Treaba DO, Cavalcante L, Giles FJ, Safran H, El-Deiry WS, **Carneiro BA**. Clinical activity of 9-ING-41, a small molecule selective glycogen synthase kinase-3 beta (GSK-3 $\beta$ ) inhibitor, in refractory adult T-Cell leukemia/lymphoma. *Cancer Biology and Therapy* 2022; 23(1):417-423 PMID 35815408
  54. Darabi S, Braxton DR, Xiu J, **Carneiro BA**, Swensen J, Antonarakis ES, Liu SV, McKay RR, Spetzler D, El-Deiry W, Demeure MJ. Reversion mutations in BRCA1/BRCA2 genes in Patients Treated with Poly ADP-ribose polymerase (PARP) Inhibitors or Platinum-Based Agents. *Medicina* Medicina (Kaunas) 2022; 58(12):1818 PMID 36557020.
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## **ABSTRACTS (since 2017)**

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  76. El-Deiry WS, George A, Di Cristofano F, Srinivasan P, Carlsen L, Huntington K, De La Cruz A, Zhang L, Hahn M, Zhao S, Seyhan A, Denardo B, Maxwell A, Kim D, Raufi A, Khan H, Graff S, Dizon D, Azzoli C, Abbas A, Wood R, Lulla R, Safran H, **Carneiro BA**, Navaraj A, Tian X, Zhang S, Zhou L. Inclusive basic and advanced translational laboratory research competencies for research in cancer biology and therapeutics. AACR 2023.
  77. Zhou L, Zhang S, Huntington K, **Carneiro BA**, El-Deiry WS. Heterogeneity of cytokine secretion in single senescent fibroblasts is impacted by ONC201 and ABT-263. AACR 2023.

## 2024

78. **Carneiro BA**, Gbolahan O, Razak AA, Hilton JF, Lambert A, Hood J, Pluta M, Bragulat V, Sanai E, Kumar R, Jodrell D, LoRusso P. Safety and efficacy of AZD8853, an anti-



- growth and differentiation factor 15 (GDF15) antibody, in patients (pts) with advanced/metastatic solid tumors: First-in-human study. AACR 2024
79. Yamamoto N, Doi T, Patel MR, Garrido-Laguna I, Wu S, Nishioka S, Nakajima K, **Carneiro BA**. A phase 1/2, first-in-human study of DS-3939a in patients with advanced solid tumors: A new DXd ADC targeting TA-MUC1. AACR 2024
  80. Schwermann M, Hadfield M, Lu S, Srinivasan P, Tajiknia V, MacDonald V, George A, Zhang S, Zhang L, Meza KS, De Souza A, Golijanin D, Hyams E, Lagos G, Holder S, Mega A, Sedivy J, Safran H, El-Deiry W, **Carneiro B**. Androgen deprivation therapy (ADT) and senescence-associated secretory phenotype (SASP) in vitro: Correlation with SASP in tumor specimens as well as in the serum of patients after ADT. AACR 2024.
  81. Schwermann M, Srinivasan P, MacDonald W, Tajiknia V, Schmidt A, Zhang S, Carlsen L, George A, Purcell C, Lu S, Hadfield M, Mega A, **Carneiro B**, El-Deiry W. TRAIL-NK-92 MI as a novel adoptive therapy for castration-resistant prostate cancer (CRPC): preliminary *in vitro* results. AACR 2024.
  82. Schwermann M, **Carneiro B**, Lu S, De Souza A, Hadfield M, Mega A, Lagos G, Khaleel S, Golijanin D, Holder S, Srinivasan P, MacDonald W, George A, Zhou L, Zhang L, El-Deiry W. Patient-derived MTAP-deleted bladder cancer organoid model: a unique platform for drug development. AACR 2024.
  83. Holder S, Lagos G, **Carneiro BA**, Mega A, De Souza A, McKay RR, Elliott A, Nabhan C, Graff SL. An analysis of proviral insertion site of Moloney murine leukemia virus, PIM1, kinase expression and clinical outcomes in renal cell carcinoma. AACR 2024.
  84. Araoye M, Mega A, Lagos G, **Carneiro B**, Khaleel S, Golijanin D, Holder S. Targeting androgen signaling in urothelial carcinoma. AACR 2024.
  85. Weiskittel T, Huntington K, Zhang L, Koukol A, **Carneiro BA**, Li H, Ugolkov A, El-Deiry W, Mazar A. Identification of potential immune biomarkers for GSK-3 inhibitor elraglusib (9-ING-41) in patients with relapsed/refractory metastatic cancer. AACR 2024.
  86. Ghandali M, Srinivasan P, Xia Y, Wong ET, Sobol RW, Zhou L, **Carneiro BA**, Graff SL, El-Deiry WS. Tumor Treating Fields (TTFields) show efficacy in Triple-Negative breast cancer (TNBC) cells alone and in combination with PARP inhibitor Talazoparib. AACR 2024.
  87. **Carneiro BA**, McKean M, Vicier C, Valerin JB, Tarhini A, Ganju V, Ruisi M, Kirby P, Cuillerot JM, Romano E. A phase 1/1b, first-in-human, multi-part study of DF6215, an engineered IL-2R $\alpha$ -active agonist, to investigate the safety, tolerability, pharmacokinetics, and biological and clinical activity in patients with advanced solid tumors. ASCO Annual Meeting 2024 J Clin Oncol 42, 2024 (suppl 16; abstr TPS2704).

## **INVITED PRESENTATIONS**

### **Local:**

1. Best of ASCO 2020, Developmental Therapeutics Module, September 12th, 2020, Providence Downtown Marriott, Providence, RI.
2. Best of ASCO 2020, Developmental Therapeutics and Genitourinary Modules, October 2<sup>nd</sup>, 2021, Providence Downtown Marriott, Providence, RI
3. Urology Grand Rounds, Advanced Prostate Cancer, Department of Urology, Brown Urology, Providence, RI, November 17<sup>th</sup>, 2021
4. Best of ASCO 2023, Developmental Therapeutics and Genitourinary Modules, October 2<sup>nd</sup>, 2021, Providence Downtown Marriott, Providence, RI

## **National**

1. Future research in genitourinary malignancies at the Robert H Lurie Comprehensive Cancer Center. Hematology/Oncology Grand Rounds, Division of Hematology/Oncology, Feinberg School of Medicine Northwestern University, January 2015.
2. Personalized medicine and recent developments in phase I research. US Too Prostate Cancer Education Support, Lombard, IL, May 2015.
3. Treatment of advanced prostate cancer, Urology Resident Teaching Conference, Department of Urology, Feinberg School of Medicine Northwestern University, July 2015.
4. Cancer treatment using genome sequencing. Healthnetwork Foundation, Pellston, MI, August 2015.
5. What's old is new again: chemotherapy for the M1 prostate cancer patient. Chicago Urological Society Prostate Cancer Meeting, October 2015.
6. Advances in Lung Cancer Clinical Trials, Lung Force Expo, American Lung Association, Warwick, November 2017
7. 1<sup>st</sup> A. Zamin Rizavi, MD Memorial Lecture, Department of Medicine Grand Rounds, NorthShore University HealthSystem, Evanston, IL, January, 2019
8. GSK3-beta inhibition: bridging a pleiotropic therapeutic target with immune modulation, Department of Melanoma Interdisciplinary Collaboration Meeting, MD Anderson Cancer Center, May 28, 2021
9. Immune modulatory functions of GSK-3b and clinical development of the selective inhibitor 9-ING-41. Helen Diller Family Comprehensive Cancer Center, Early Phase Experimental Therapeutics Program Meeting, University of California San Francisco, August 12<sup>th</sup> 2021.

## **International**

1. Advances in Treatment of Metastatic Breast Cancer. VII Regional Symposium of Breast Surgery, Baturité, CE, September 2010
2. Hormonal Treatment of Advanced Breast Cancer. VII Regional Symposium of Breast Surgery, Baturité, September 2010
3. Molecular Biology Principles for Clinicians. Master's Degree Program, Department of Pathology, School of Medicine, Federal University of Ceará, Fortaleza, CE, November 2010
4. Genetic Counseling for High Risk Breast Cancer Patients. II Breast Cancer Weekend, Cumbuco, CE, March 2011
5. Duration of Combined Hormonal Therapy for Prostate Cancer. IV International Symposium of Urologic Laparoscopic Surgery. Fortaleza, April 2011.
6. Advances in the Treatment of Neuroendocrine Tumors. III General Hospital of Fortaleza Endocrinology Symposium, Fortaleza, August 2011

7. Management of Chemotherapy-Induced Adverse Events in the Elderly. Jornada Cearense de Geriatria e Gerontologia, Fortaleza, October 2011
8. Environmental Cancer Risks. Division of Public Health, School of Medicine, Federal University of Ceará, Fortaleza, November 2011
9. Principles of Chemotherapy. School of Medicine, Faculdade Christus, Fortaleza, CE, May 2012.
10. Hereditary Cancer Syndromes. School of Medicine, Faculdade Christus, Fortaleza, CE, May 2012
11. Treatment and Surveillance of Gastrointestinal Stromal Tumors. XI Meeting of Brazilian Society of Digestive System, Fortaleza, November 2012
12. Treatment Strategies for Advanced Colorectal and Gastric Cancer. III Annual Meeting of Pernambuco Institute of Integrative Medicine (IMIP), Recife, PE, Brazil, October 2012
13. Advances in the Treatment of Metastatic Colorectal Cancer, Recife Gastrointestinal Cancer Symposium, Recife, April 2013
14. Phase I study of 9-ING-41, a small molecule selective glycogen synthase kinase-3 beta (GSK-3 $\beta$ ) inhibitor, as a single agent and combined with chemotherapy, in patients with refractory tumors. Oral presentation at ASCO Annual Meeting, 2020.
15. Best of ASCO Brazilian Edition, Genitourinary Module, June 14<sup>th</sup>, 2021
16. Novel immunotherapy agents in development, National Academy of Medicine (Academia Nacional de Medicina), Cancer Immunotherapy Symposium, Rio de Janeiro, Brazil, June 17<sup>th</sup>, 2021.
17. Homologous Recombination Genes: identification and relevance, 1<sup>st</sup> Precision Medicine Symposium, Sao Paulo, Brazil, September 24<sup>th</sup>, 2021
18. Cochair, Clinical Trials Minisymposium Biomarker Advances in Clinical Trials. The American Association for Cancer Research (AACR) Annual Meeting 2022, New Orleans, Louisiana, April 8-13, 2022
19. Session Chair, Poster Discussion Session, Developmental Therapeutics—Immunotherapy Session, The American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago, Illinois, June 2-7, 2022

## **WORKSHOPS**

- 2008** AACR/ASCO Workshop: Methods of Clinical Cancer Research, Vail, Colorado
- 2009** Cancer Education Consortium, Merrill J. Egorin Workshop in Cancer Therapeutics and Drug Development, Leesburgh, VA
- 2009** Cancer Education Consortium, Molecular and Translational Oncology Workshop, Greensboro, GA.

## **RESEARCH PROJECTS**

### **COMPLETED**

#### ***Funded***

- 2001 – 2003** Alanyl-Glutamine as oral rehydration & nutrition therapy [Small Business Innovation Research (SBIR) Award] Goal: To investigate the role of stable

glutamine derivatives in intestinal epithelial damage repair induced bacterial toxins and chemotherapy. Role: Principal Investigator (SBIR/NIH GRANT R43 DK 58419-01A1)

**2015 – 2017**

Multicenter phase II study of nivolumab (anti-PD-1 antibody) for treatment of metastatic adrenocortical carcinoma. Investigator-initiated trial. Sponsor: Bristol-Myers Squibb. Goal: Investigate the anti-tumor activity of immune checkpoint nivolumab in adrenocortical carcinoma. Role: Principal investigator

**2014 – 2017**

Projects in collaboration with Dr. Sarki Abdulkadir's laboratory at Northwestern University. My role as a translational researcher and collaborator in the laboratory was to identify new therapeutic targets in prostate cancer and help guide experiments to inform the development of clinical trials.

1. The Role of DOT1L Inhibitor (EPZ-5676) in preclinical models of castration-resistant prostate cancer (CRPC).
2. Can the PIM inhibitor LGH447 potentiate the anti-tumor effects of the combination of docetaxel and androgen deprivation therapy (ADT) or delay resistance in hormone sensitive prostate cancer preclinical models?
3. Anti-tumor effects of MM-310 (nanoparticle docetaxel) in prostate cancer preclinical models.
4. The effect of antisense against polycomb group protein BMI-1 (B cell-specific Moloney murine leukemia virus integration site 1 protein) in animal models of castration-resistant prostate cancer (CRPC).

**2015 – 2020**

P50 CA180995 (Catalona)  
NIH/NCI SPORE in Prostate Cancer Project 3

The four proposed projects refine our ability to detect lethal prostate cancer (Project 1), identify additional biomarkers for disease aggressiveness and response to targeted therapy in personalized medicine (Projects 1-4) and improve therapy for castrate-resistant prostate cancer (Projects 2-4) in translational cancer research.

Role: Collaborator leading the development and implementation of a Phase II study evaluating the soluble decoy Ephrin B4 receptor-human serum albumin fusion protein (sEphB4-HSA) in castration-resistant prostate cancer (NCT04033432). Principal investigator for this trial that emerged from Dr. Sarki Abdulkadir's laboratory preclinical results (PI – Prostate Cancer Project 3). Direct amount: \$150,000

**2018 – present**

**Projects at Brown University in collaboration with Wafik El-Deiry, MD, PhD translational cancer therapeutics laboratory**

The therapeutic synergy between androgen receptor antagonists and small molecule ONC201 in preclinical models of prostate cancer. The results of

this ongoing project provided the rationale for an investigator-initiated study in advanced prostate cancer.

Combination of ONC201 with TRAIL agonist TLY012 as a novel therapeutic strategy in solid tumors. Preclinical results of this funded project supported the development of the investigator-initiated trial BrUOG 383: A Phase Ib/II Single Arm Open Label Investigator-Initiated Therapeutic Clinical Study of ONC201 plus TLY012 (SQ TRAIL) in advanced solid tumors.

Novel immune-modulatory functions of Glycogen Synthase Kinase 3 (GSK-3) in preclinical in vitro and animal cancer models. This project is a central topic of Kelsey Huntington's PhD thesis at El-Deiry's lab. These results are being validated in clinical specimens from the phase I clinical trial with 9-ING-41.

## **ONGOING**

- 2024 Investigating cellular senescence as a mechanism of treatment resistance in prostate cancer. Legorreta Cancer Center Translational Pilot Project.  
Co-PI (\$20,000)  
The goal of this project is to characterize senescence markers in prostate cancer tumor specimens and investigate the role of therapy-induced senescence in the development of castration resistance in prostate cancer.

## **CLINICAL TRIALS**

**2015—2017**

***Local principal investigator for the following national and international clinical trials at Northwestern University.***

1. Randomized Phase III Trial Comparing-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 (Alliance A031102).  
Sponsor: National Cancer Institute
2. Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer (SWOG 1216). Sponsor: National Cancer Institute
3. SWOG 1500: A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer (SWOG 1500). Sponsor: National Cancer Institute

4. Phase 1 Study of Durvalumab and IPH2201 in Adult Subjects with Select Advanced Solid Tumors. Sponsor: MedImmune, LLC.
5. Phase 1 Study of MEDI4736 (Anti-PD-L1 Antibody) in Combination with Tremelimumab (Anti-CTLA-4 Antibody) in Subjects with Advanced Solid Tumors. Sponsor: MedImmune, LLC.
6. An open label, non-randomized, Phase I dose escalation study to characterize safety, tolerability, pharmacokinetics and maximum tolerated dose of BAY 1163877 in subjects with refractory, locally advanced or metastatic solid tumors 2016. Sponsor: Bayer
7. Phase I study evaluating the safety, pharmacology and preliminary activity of the co-administration of MM-151 and MM-121 in heregulin positive cancer patients. Sponsor: Merrimack Pharmaceuticals
8. Phase III Randomized, Open-label, Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Axitinib versus Sunitinib Monotherapy as a First-line Treatment for Locally Advanced or Metastatic Renal Cell Carcinoma (mRCC). Sponsor: Merck
9. Phase III randomized, controlled clinical trial of pembrolizumab with or without platinum-based combination chemotherapy versus chemotherapy in subjects with advanced or metastatic urothelial carcinoma. Sponsor: Merck
10. Phase 1 Study Evaluating the Safety and Pharmacokinetics of ABBV-075 in Subjects with Advanced Cancers. Sponsor: Abbvie
11. Phase 1b/2 Study of the Oral CDK4/6 Inhibitor LEE011 (Ribociclib) in Combination with Docetaxel plus Prednisone in Metastatic Castration Resistant Prostate Cancer. Sponsor: Prostate Cancer Clinical Trials Consortium.
12. Randomized phase II study of androgen deprivation therapy with or without palbociclib in RB-positive metastatic hormone-sensitive prostate cancer. Sponsor: University of Michigan.

**2017— present**

***Principal investigator for the following national and international studies at Brown University***

1. A Phase 1b/2 open-label study to evaluate safety, clinical activity, pharmacokinetics and pharmacodynamics of avelumab (MSB0010718C) in combination with other cancer immunotherapies in patients with advanced malignancies. Sponsor: Pfizer.
2. An Open Label Phase 1, First-In-Human Study of TRAIL Receptor Agonist ABBV-621 in Subjects with Previously-Treated Solid Tumors and Hematologic Malignancies (M15-438). Sponsor: Abbvie.

3. A Phase 1 Study of Durvalumab and IPH2201 (monalizumab) in Adult Subjects with Select Advanced Solid Tumors (D419NC00001). Sponsor: MedImmune.
4. A Phase 1 Study Evaluating the Safety, Pharmacokinetics, and Anti-Tumor Activity of ABBV-321 in Subjects with Advanced Solid Tumors Associated with Overexpression of the Epidermal Growth Factor Receptor (EGFR) or its Ligands (M16-438). Sponsor: Abbvie.
5. A Phase 1 First Time in Human Study to Evaluate the Safety, Pharmacokinetics and Immunogenicity of MEDI5083 Alone and in Combination with Durvalumab in Selected Advanced Solid Tumors. Sponsor: MedImmune.
6. An Open-Label, Randomized Phase 3 Study to Evaluate Enfortumab Vedotin vs. Chemotherapy in Subjects with Previously Treated Locally Advanced or Metastatic Urothelial Cancer (EV-301). Sponsor: Astellas.
7. A Phase 1/2 Study of the Oral CDK4/6 Inhibitor Ribociclib in Combination with Docetaxel Plus Prednisone in Metastatic Castration Resistant Prostate Cancer. Sponsor: University of California San Francisco, Prostate Cancer Clinical Trials Consortium.
8. A Phase 1 First-in-Human Study with ABBV-155 Alone and in Combination with Taxane Therapy in Adults with Relapsed and/or Refractory Solid Tumors. Sponsor: Abbvie.
9. Phase II study of Optimized Management of NIVOLUMAB based on REsponse in patients with advanced renal cell carcinoma. Sponsor: Dana Farber Cancer Institute.
10. Phase 1/2 Study of 9-ING-41, a Glycogen Synthase Kinase-3 Beta (GSK-3 $\beta$ ) Inhibitor, as a Single Agent and Combined with Chemotherapy, in Patients with Refractory Hematologic Malignancies or Solid Tumors. Sponsor: Actuate Therapeutics.
11. An Open-Label, Multi-Center, Phase 1b/2 Study to Evaluate the Safety and Efficacy of Copanlisib in Combination with Nivolumab in Patients with Advanced Solid Tumors. Sponsor: Bayer.
12. A Phase 1, Open-label, Dose-escalation and Expansion Study of MEDI1191 Administered Intratumorally as Monotherapy and in Combination with Durvalumab in Subjects with Solid Tumors. Sponsor: MedImmune.
13. BrUOG 360: A Phase Ib/II study of copanlisib combined with rucaparib in patients with metastatic castration-resistant prostate cancer. ***Investigator-initiated trial.***  
Sponsors: Bayer and Clovis. Principal Investigator.
14. A Phase 1, First-in-Human, Multicenter, Open-label, Dose-escalation Study of IPH5201 as Monotherapy or in Combination with Durvalumab  $\pm$  Oleclumab in Advanced Solid Tumors (D6770C00001). Sponsor: AstraZeneca.
15. An Open-label Phase 1 Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of MEDI5395 in Combination with Durvalumab in Subjects with Select Advanced Solid Tumors (D6450C00001). Sponsor: AstraZeneca.

16. A Phase 1/2, First-In-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF6002 as a monotherapy and in combination with Pembrolizumab in Patients With Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications. Sponsor: Dragonfly Therapeutics.
17. Phase 1/2 Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-3500 Alone or in Combination with Talazoparib in Advanced Solid Tumors with ATR inhibitor Sensitizing Mutations. Sponsor: Repare Therapeutics.
18. A Phase 1 Study with ABBV-CLS-484 Alone and in Combination in Subjects with Locally Advanced or Metastatic Tumors. Sponsor: Abbvie.
19. A Phase 1, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of MEDI5752 in Subjects with Advanced Solid Tumors. Sponsor: Astra Zeneca.
20. Phase 1 Study of the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Clinical Activity of RP-6306 in Patients with Advanced Solid Tumors (MYTHIC Study: PKMYT1 Inhibition for the Treatment of Cancers). Sponsor: Repare Therapeutics. 1/2022-present
21. A Phase 1 Study Investigating AGEN1777 as a Single-Agent and in Combination with PD-1 Inhibition in Patients with Advanced Solid Tumors. Sponsor: Agenus.
22. A Phase 1 Open-Label Study of the Safety, Tolerability and Preliminary Clinical Activity of Allogeneic Invariant Natural Killer (iNKT) Non-Transduced Cells (agenT-797) as a Single Agent and in Combination with Approved Immune Checkpoint Inhibitors in Patients with Relapsed/ Refractory Solid Tumors. Sponsor: Agenus.
23. Phase 1 A Phase 1 study of REGN5678 (anti-PSMAXCD28) with cemiplimab (anti-PD-1) in patients with metastatic castration-resistant prostate cancer. Sponsor: Regeneron.
24. A Phase I first in human study evaluating safety and efficacy of ABBV-637 as either monotherapy or in combination in adult subjects with relapsed and refractory solid tumors. Sponsor: Abbvie
25. A Phase 1/2 Open-label Study Investigating the Safety, Tolerability and Efficacy of ASP0739 as a Single Agent and in Combination with Pembrolizumab in Patients with Advanced Solid Tumors known to Express NY-ESO-1. Sponsor: Astellas.
26. A Phase 1 Study Investigating AGEN1571 as a Single Agent and in Combination with a PD-1 Inhibitor and/or Botensilimab (AGEN1181) in Patients with Advanced Solid Tumors. Sponsor: Agenus
27. A Phase I/IIa First-in-human, Open-label, Modular Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of AZD8853. Sponsor: AstraZeneca
28. An Open Label, Phase 1, Treatment Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of IDE397 (MAT2A Inhibitor) In Adult Participants with Advanced Solid Tumors. Sponsor: Ideaya Biosciences



29. A First-in-Human, Open-label, Multicenter, Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of PYX-201 in Participants with Advanced Solid Tumors. Sponsor: Pyxis Oncology
30. A phase I, multicenter, open-label study of TY-2136b, administered orally in patients with advanced or metastatic solid tumors harboring ALK, ROS1 or NTRK1-3 alterations. Sponsor: TYK Medicines
31. Phase 1/2 open-label, multicenter, first-in-human study of DS-3939a in subjects with advanced solid tumors. Sponsor: Daiichi-Sankyo
32. A Phase 1 Study of KSQ-4279 Alone and in Combination in Patients with Advanced Solid Tumors. Sponsor: KSQ Therapeutics.
33. A Phase 1/1b, First-In-Human, Multi-Part, Open-Label Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of DF6215 in Patients with Advanced (Unresectable, Recurrent, or Metastatic) Solid Tumors. Sponsor: Dragonfly.
34. Phase 1/2, Open-label, Multicenter, First-in-Human Study of DS-3939a in Subjects with Advanced Solid Tumors. Sponsor: Daiichi Sankyo
35. A Phase 1 Study of NM32-2668 (Anti-ROR1/Anti-CD3/Anti-HSA Tri-Specific Antibody) in Adult Patients with Selected Advanced Solid Tumors. Sponsor: Numab Therapeutics.
36. A Phase 1, Open-Label, Multicenter Study of INCA33890 in Participants With Advanced or Metastatic Solid Tumors. Sponsor: Incyte.
37. An Open-label, Randomised, Phase I, Multi-centre Study to Investigate the Biological Effects of AZD5305 Alone, Darolutamide Alone, and in Combination Given Prior to Radical Prostatectomy in Men with Newly Diagnosed Prostate Cancer. Sponsor: AstraZeneca.
38. A Randomized, 2-cohort, Double-blind, Placebo-controlled, Phase III Study of AZD5305 in Combination with Physician's Choice New Hormonal Agents in Patients with HRRm and non-HRRm Metastatic Castration-Sensitive Prostate Cancer. Sponsor: AstraZeneca
39. A phase I, open-label, multicenter study of JANX007 in subjects with metastatic castration-resistant prostate cancer. Sponsor: Janux Therapeutics.
40. A First-in-Human, Open-label, Multicenter, Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PYX-106 in Subjects with Advanced Solid Tumors. Sponsor: Pyxis Oncology.
41. Metastatic castration-resistant prostate cancer: first-in-human study of ABBV-969 in metastatic castration-resistant prostate cancer. Sponsor: Abbvie.

***Co-investigator for the following clinical trials at Brown University (selected trials)***

1. BrUOG 387: Phase Ib investigator-initiated trial of heat shock protein 90 inhibitor TAS-116 (pimipib) combined with cyclin-dependent kinase 4/6 inhibitor palbociclib in advanced breast cancer progressing on palbociclib and treatment-refractory solid tumors with

- retinoblastoma (Rb) Deficiency. Role: Co-Investigator. 2024. Sponsor: Brown University Oncology Research Group
2. BrUOG 354: A phase II randomized trial of nivolumab +/- ipilimumab for ovarian and extra-renal clear cell carcinomas. Role: Co-Investigator. 2023. Sponsor: Brown University Oncology Research Group
  3. BrUOG 379: A Phase Ib/II Single Arm Study of ONC201 plus Nivolumab in Microsatellite Stable (MSS) metastatic colorectal cancer (mCRC) patients. Role: Co-Investigator. 2021. Sponsor: Brown University Oncology Research Group
  4. BrUOG 428: Targeting Androgen Signaling in Urothelial Cell Carcinoma - Neoadjuvant (TASUC-Neo). A Pilot Study of Degarelix in Combination with Neoadjuvant Gemcitabine and Cisplatin in Muscle-Invasive Urothelial Cell Carcinoma of the Bladder. Role: Co-Investigator. 2023. Sponsor: Brown University Oncology Research Group
  5. A Phase 1/1b Study of ASP2074 in Participants with Metastatic or Locally Advanced Solid Tumors. Role: Co-Investigator. 2024. Sponsor: Astellas Pharma LLC
  6. A Randomized, Open-Label, Phase II Trial of Nab-paclitaxel + Gemcitabine with or without Botensilimab (AGEN1811) in Patients with Metastatic Pancreatic Cancer Who Have Progressed on Prior 5FU + Leucovorin + Irinotecan + Oxaliplatin (FOLFIRINOX). Role: Co-Investigator. 2023. Sponsor: Agenus, Inc.
  7. A Phase 1/2, First-In-Human, Multi-Part, Open-Label Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of DF9001 as a monotherapy and in combination with nivolumab in Patients with Advanced (Unresectable, Recurrent, or Metastatic) Solid Tumors, and Expansion in Selected Indications. Role: Co-Investigator. 2022. Sponsor: Dragonfly Therapeutics
  8. A Phase 1, 2-Part, Multicenter, First-In-Human Dose-Escalation and Dose-Expansion Study of DS-1103A Combination Therapy in Subjects with Advanced Solid Tumors (DS-1103A Combination Therapy First-Inhuman Study). Role: Co-Investigator. 2023. Sponsor: Daiichi Sankyo
  9. A Phase I/II, First-In-Human, Multi-Part, Open-Label, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics, Biological, and Clinical Activity of DF1001 in Patients with Locally Advanced or Metastatic Solid Tumors, and Expansion in Selected Indications. Role: Co-Investigator. 2020. Sponsor: Dragonfly Therapeutics
  10. A Phase 1 Open-Label Study to Evaluate the Efficacy and Safety of ABBV-400 in Select Advanced Solid Tumor Indications. Role: Co-Investigator. 2024. Sponsor: Abbvie
  11. A Modular Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of Ascending Doses of AZD5335 Monotherapy and in Combination with Anti-cancer Agents in Participants with Solid Tumors. Role: Co-Investigator. 2024. Sponsor: Astra Zeneca

12. First-in-Human, Phase 1/1b, Open-label, Multicenter Study of Bifunctional EGFR/TGF driven; Fusion Protein BCA101 Monotherapy and in Combination Therapy in Patients with EGFR-Driven Advanced Solid Tumors. Role: Co-Investigator. 2023. Sponsor: Bicara Therapeutics
13. A Phase 1/2, Open Label, First-In-Human, Dose Escalation and Expansion Study for the Evaluation of Safety, Pharmacokinetics, Pharmacodynamics, and Anti-Tumor Activity of SAR445877 Administered as Monotherapy in Adults with Advanced Solid Tumors. Role: Co-Investigator. 2023. Sponsor: Sanofi
14. A Phase 1, Multicenter, Open-Label, Dose-Escalation and Expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Clinical Activity of Intravenously Administered KT-333 in Adult Patients with Relapsed or Refractory Lymphomas, Large Granular Lymphocytic Leukemia, and Solid Tumors. Role: Co-Investigator. 2023. Sponsor: Kymera Therapeutics, Inc.
15. A Phase 1, Open-Label, Dose-Escalation and Cohort Expansion First-in-Human Study of the Safety, Tolerability, Activity and Pharmacokinetics of REGN3767 (anti-LAG-3 mAb) Administered Alone or in Combination with REGN2810 (anti-PD-1 mAb) in Patients with Advanced Malignancies. Role: Co-Investigator. 2022. Sponsor: Regeneron
16. A Phase 1/2 Open-Label, First-In-Human, Dose Escalation and Expansion Study for the Evaluation of Safety, Pharmacokinetics, Pharmacodynamics, and Anti-Tumor Activity of SAR444200-Based Regimen in Participants with Advanced Solid Tumors. Role: Co-Investigator. 2023. Sponsor: Sanofi-Aventis Recherche & Development
17. A Phase I, Multicenter, Open-label, First-in Human, Dose escalation and Expansion Study of AZD9592 as Monotherapy and in Combination with Anti-cancer Agents in Patients with Advanced Solid Tumors. Role: Co-Investigator. 2023. Sponsor: Astra Zeneca
18. A Randomized, Open-Label, Phase 2 Study of Botensilimab (Agen1181) as Monotherapy and in Combination with Balstilimab (AGEN2034) for the Treatment of Advanced, Refractory Microsatellite Stable Colorectal Cancer without Liver Metastases. Role: Co-Investigator. 2023. Sponsor:
19. An Open-Label, Single-Arm, Multi-Center Phase I/IIa Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of SHR-A1904 in Subjects with Advanced Solid Tumors Expressing Claudin 18.2. Role: Co-Investigator. 2022. Sponsor:
20. A Phase I, Open-Label, Multicenter, Dose Escalation and Cohort Expansion Study of SPYK04 as Monotherapy in Patients with Locally Advanced or Metastatic Solid Tumors. Role: Co-Investigator. 2020. Sponsor:
21. Open Label Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors. Role: Co-Investigator. 2023. Sponsor:

22. NRG-GU009: Parallel Phase III Randomized Trials for High-Risk Prostate Cancer Evaluating De Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT). Role: Co-Investigator. 2022. Sponsor: NCI
23. A031701: A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations. Role: Co-Investigator. 2023. Sponsor: Alliance
24. A031701: A Phase II Study of Gemcitabine Plus Cisplatin Chemotherapy in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations. Role: Co-Investigator. 2023. Sponsor: Alliance

### **UNIVERSITY TEACHING ROLES**

<b>2009</b>	Oncology Course, University of Pittsburgh School of Medicine, October 2009.
<b>2010</b>	Advanced Physical Examination Course, University of Pittsburgh School of Medicine, March 2010.
<b>2015</b>	Problem Based Learning Course Facilitator, Northwestern University Feinberg School of Medicine
<b>2015 – 2017</b>	Science in Medicine Hematology/Oncology Lecture Series, Second Year Medical Students, Northwestern University Feinberg School of Medicine
<b>2017 – present</b>	Hematology/Oncology Fellows, Division of Hematology/Oncology, Brown University. Supervision of outpatient clinic, fellow weekly tumor board and inpatient consultations.

### **Faculty mentoring:**

Andre De Souza, MD  
Assistant Professor, Division of Hematology/Oncology  
Characterization of advanced urothelial carcinoma with 9q21 deletion

Bradley D. DeNardo, MD  
Assistant Professor, Pediatric Hematology/Oncology  
BrUOG 398: Phase 2 Study of 9-ING-41, a Glycogen Synthase Kinase-3 Beta (GSK-3 $\beta$ ) Inhibitor, Combined with Chemotherapy, in Patients with Advanced Sarcomas. *Investigator-initiated study*

Sheldon Holder, MD, PhD  
Assistant Professor, Department of Pathology and Laboratory Medicine & Division of Hematology/Oncology, Brown University  
Integration community-based participatory research (CBPR) into genitourinary cancer clinical trials program.

Bristol Myers Squibb Foundation Diversity in Clinical Trials Career Development Program (PI: Sheldon Holder).  
10/2021-11/2023; \$120,000/yr  
Role: co-mentor

### **Hematology/Oncology Fellows:**

Ilyas Sahin, MD (2017-2020)

Development of clinical studies in castration-resistant prostate cancer. BrUOG 360: Phase Ib/II study of copanlisib and olaparib in patients with metastatic castration-resistant prostate cancer carrying mutations in DNA repair genes. Concept has been approved and the clinical trial is ongoing.

Eric Marks, MD (2017-2020)

Impact of mutations in DNA repair genes in the outcomes of metastatic colorectal cancer patients treated with FOLFOX and FOLFIRI. Results published on the American Journal of Clinical Oncology.

Kathryn DeCarli, MD (2021-2023)

Impact of a physician-led supportive care intervention among oncology patients on phase I clinical trials

Matthew Hadfield, MD (2021-2024)

Strategies to overcome DNA repair inhibitor-induced senescence-mediated resistance in the tumor microenvironment

### **Internal Medicine Residents:**

Robert Matera, MD (2018-2020)

Prospective evaluation of mechanisms of resistance to PARP inhibitors in patients with solid malignancies.

### **Brown medical students:**

Brittany Borden (Class 2022)

Landscape of molecular alterations in the Glycogen synthase kinase-3 gene in solid organ malignancies. Project selected for oral presentation at the Alpert Medical School Research Symposium, November 2019 and published in the journal Molecular Cancer Therapeutics (PMID 33087512).

Luke Soliman (Class 2023)

Differential gene expression profiling between primary tumors and metastatic sites in advanced prostate cancer. Project received the award recognizing the most outstanding presentation in Basic Sciences at the 13th Annual Warren Alpert Medical School Academic Symposium, November 2020.

Praveen Srinivasan (Class 2023)

Characterizing the molecular alterations in the extrinsic apoptosis pathway in metastatic bladder cancer and their relationship to tumor response to immunotherapy.

Claire Lin (Class 2027)

The role of cFLIP in the treatment of castration-resistant prostate cancer models

#### **Post-doctoral students and visiting scholars:**

Fabio Tavora, MD, PhD (6/2019-1/2020)

Role of Glycogen Synthase Kinase-3 inhibitor 9-ING-41 in preclinical models of prostate cancer and clinical specimens from patients with advanced prostate cancer.

Maximilian Pinho Schwermann, MD (4/2022-present)

Effect of androgen signaling on the regulation of T and NK cells.

#### **Teaching Awards:**

**2016**

Feinberg School of Medicine Excellence in Teaching Award, Division of Hematology/Oncology, Department of Medicine, Northwestern University

#### **Laboratory and other research supervisory and training responsibilities:**

**2015 – 2017**

Sahithi Pamarthi, PhD and Vinay Sagar, PhD. Position: Post-doctoral research fellow at the Developmental Therapeutics Program, Northwestern University. Co-mentored with Sarki Abdulkadir, MD, PhD. Preclinical studies investigating novel therapeutic targets in prostate cancer.

**2015 – 2017**

Ami Shah, MD. Position: Hematology/Oncology fellow at Northwestern University. Protocol development of a phase II study evaluating the decoy Ephrin B4 receptor-human serum albumin fusion protein (sEphB4-HSA) for the treatment of patients with castration-resistant prostate cancer. Dr Shah was selected to participate at the ASCO/AACR Methods in Clinical Research Workshop (Veil, CO 2017) with this proposal. Current position: Assistant Professor at the Division of Hematology/Oncology, Northwestern University.

**2016**

Zachary Reinstein, undergraduate student, Brigham Young University *Recipient*, 2017-2018 American Association for Cancer Research (AACR)-Thomas J. Bardos Science Education Scholar Award. Summer project in collaboration with Sarki Abdulkadir, MD, PhD. Project evaluating combinations of PARP inhibitors with androgen pathway blockers for treatment of prostate cancer. Zachary was accepted to the Medical Scientist Training Program at the Feinberg School of Medicine, Northwestern University (2017).

## **HOSPITAL TEACHING ROLES**

- 2010 - 2014** Medical Oncology Inpatient Consult Service, Hospital Geral de Fortaleza, Internal Medicine and General Surgery Residency Programs.
- 2010 - 2014** Preceptorship of Medical Students, Internal Medicine Interns and Residents, Hospital Geral de Fortaleza, Medical Oncology Outpatient Clinic.
- 2010 - 2014** Invited Lecturer, Oncology Course, School of Medicine, Faculdade Christus, Fortaleza, CE
- 2015 - 2017** Inpatient Oncology Service, Northwestern Memorial Hospital (2 months/yr).
- 2017- present** Hematology/Oncology Inpatient Service, The Miriam Hospital and Rhode Island Hospital, Division of Hematology/Oncology