Navigate BioPharma Publications [1]

Journal Publications

1. Orlando E, Han X, Tribouley C, Wood PA, Leary RJ, Riester M, Levine JE, Qayed M, Grupp SA, Boyer M, De Moerloose B, Nemecek ER, Bittencourt H, Hiramatsu H, Büchner J, Davies SM, Verneris M, Nguyen K, Brogdon JL, Bitter H, Morrissey M, Pierog P, Pantano S, Engelman JA, and Winckler W. Genetic alterations in CD19 lead to CD19 negative relapse to CAR19 therapy in children and young adults with relapsed/refractory acute lymphoblastic leukemia. *Nature Medicine* 2018*;* 24(10):1504–1506. doi:10.1038/s41591-018-0146-z [2]
2. Johnson DB, Bordeaux J, Kim J, Vaupel C, Rimm DL, Ho TH, Joseph RW, Daud AI, Conry RM, Gaughan EM, Hernandez-Aya LF, Dimou A, Funchain P, Smithy J, Witte JS, McKee SB, Ko J, Wrangle JM, Dabbas B, Tangri S, Lameh J, Hall J, Markowitz J, Balko JM, and Dakappagari N. Quantitative Spatial Profiling of PD-1/PD-L1 Interaction and HLA-DR/IDO-1 Predicts Improved Outcomes of anti-PD-1 Therapies in Metastatic Melanoma. Clinical Cancer Research, 2018 Nov 1; 24(21):5250-5260. doi:10.1158/1078-0432 [3]
3. Everett AS, Pavlidakey PG, Contreras CM, De Los Santos JF, Kim J, McKee SB, Kaufman HL, and Conry RM. Chronic Granulomatous Dermatitis Induced by Talimogene Laherparepvec Therapy of Melanoma Metastases. J Cutan Pathol. 2017 Sep 22. doi:10.1111/cup.13048 [4]
4. Rost S, Giltnane J, Bordeaux JM, Hitzman C, Koeppen H, and Liu SD. Multiplexed ion-beam imaging (MIBI) analysis for quantitation of protein expression on cancer tissue sections. Lab Invest. 2017 Aug;97(8):992-1003. doi:10.1038/labinvest.2017.50 [5]
5. Blackmon JT, Stratton MS, Kwak Y, Pavlidakev PG, Slominski AT, McKee SB, Viator TM, Kim J, Huang CC, and Conry RM. Inflammatory melanoma in transit metastases with complete response to talimogene laherparepvec. JAAD Case Reports, 2017 Jun 16;3(4):280-283. doi:10.1016/j.jdcr.2017.02.011 [6]
6. Siska PJ, Johnpulle RAN, Zhou A, Bourdeaux J, Kim J, Dabbas B, Dakappagari N, Rathmell JC, Rathmell WK, Morgans AK, Balko JM, and Johnson DB. Deep exploration of the immune infiltrate and outcome prediction in testicular cancer by quantitative multiplexed immunohistochemistry and gene expression profiling. Oncoimmunology. 2017 Mar 20;6(4):e1305535. doi:10.1080/2162402X.2017.1305535 [7]
7. Beckermann KE, Jolly PC, Kim J, Bordeaux J, Puzanov I, Rathmell WK, and Johnson DB. Clinical and immunologic correlates of response to PD-1 blockade in a patient with metastatic Renal Medullary Carcinoma. J Immunother Cancer. 2017 Jan; 5: 1. doi:10.1186/s40425-016-0206-1 [8]
8. Dakappagari N, Gong H, Pollner R, Siva A, Tangri S, and Lameh J. Application of Biomarkers in Oncology Clinical Trials. Clinical Investigation, 2015; 5(1):61-74. doi:10.4155/CLI.14.106 [9]
9. O'Shannessy DJ, Somers EB, Chandrasekaran LK, Nicolaides NC, Bordeaux J, and Gustavson MD. Influence of tumor microenvironment on prognosis in colorectal cancer: Tissue architecture-dependent signature of endosialin (TEM-1) and associated proteins. Oncotarget. 2014 Jun 30;5(12):3983-95. doi:10.18632/oncotarget.2108 [10]

10. Vassilakopoulou M, Togun T, Dafni U, Cheng H, Bordeaux J, Neumeister VM, Bobos M, Pentheroudakis G, Skarlos DV, Pectasides D, Kotoula V, Fountzilas G, Rimm DL, and Psyrri A. In situ quantitative measurement of HER2mRNA predicts benefit from trastuzumab-containing chemotherapy in a cohort of metastatic breast cancer patients. PLoS One. 2014 Jun 26;9(6):e99131. doi: 10.1371/journal.pone.0099131 [11]
11. Bai Y, Cheng H, Bordeaux J, Neumeister V, Kumar S, Rimm DL, and Stern DF. Comparison of HER2 and Phospho-HER2 Expression between Biopsy and Resected Breast Cancer Specimens Using a Quantitative Assessment Method. PLoS One. 2013 Dec 8(11): e79901. doi:10.1371/journal.pone.0079901 [12]

Abstracts/Poster Presentations

1. Woolfenden S, Diaz E,Giedt J, Santos J M, Meyer R, Shim J, Thiruvamoor R, Kim J, Bordeaux J, Tran T, Deeds J, Dakappagari N, and McLaughlin M. Development of clinical-grade multiplex F-IHC assays to quantify spatial distribution of PD-L1. Novartis Institutes for BioMedical Research Oncology Retreat, Cambridge, MA Novartis Oncology Retreat, October 2018.
2. Tsau J, Sarikonda G, Abadier M, Atzmiller B, Vaupel C, Tarhini A, and Dakappagari N. High Complexity All-in-One Flow Cytometry Assay for the Measurement of T-cell Activation, Checkpoint Inhibitor Expression and Proliferation of T-cells in Periphery as a Biomarker for Novel Immuno-oncology Clinical Trials. International Clinical Cytometry Society (ICCS), Portland, OR, September 2018. Poster link [13]
3. Alfonso Z, Gao J, Sarikonda G, Katkova N, Vaupel C, Tarhini A, and Dakappagari N. Assessment of Monocytes, MDSCs and Myeloid Cell Populations in Immuno-Oncology Clinical Trials by a Standardized High Complexity Flow Cytometry Approach. International Clinical Cytometry Society (ICCS), Portland, OR, September 2018. Poster link [14]
4. Jesus Zaragoza-Alvarez, Christian Laing, Nathan Riccitelli, Reinhold Pollner. High-throughput Analysis of Complex NanoString Expression Datasets. Intelligent Systems for Molecular Biology (ISBM); Chicago, IL; June 2018. Poster link [15]
5. Agoulnik S, Jäger U, Tam CS, McGuirk JP, Foley SR, Jaglowski SM, Andreadis C, Ho PJ, Borchmann P, Waller EK, Mielke S, Schuster SJ, Maziarz RT, Bachanova V, Van Besien K, Zheng D, Tai F, Pacaud L, Awasthi R, Tran T,Dakappagari N, Anak O,Pantano S, and Bishop MR. Biomarker analysis of tisagenlecleucel pre-infusion biopsies of adult patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL). European Hematology Association (EHA); Stockholm, Sweden; June 2018. Poster link [16]
6. Khunger M, Bordeaux J, Dakappagari N, Vaupel C, Khunger A, Hu B, Schalper KA, Rimm DL, and Velcheti V. Tumor PD-L1 heterogeneity in non-small cell lung cancer: Does biopsy size and volume matter? American Society of Clinical Oncology (ASCO), Chicago, IL, June 2018. Poster link [17]
7. Bordeaux J, Dakappagari N, Kim J, Pennell NA, Stevenson J, Khunger M, Vaupel C, Schalper KA, Rimm D, and Velcheti V. PD-1/PD-L1 Interaction and CD25/FOXP3+ T cells Predict Survival Benefit from Adjuvant Chemotherapy in Early Stage Non–Small-Cell Lung Cancer. American Society of Clinical Oncology (ASCO), Chicago, IL, June 2018. Poster link [18]
8. Iams WT, Shiuan E, Meador CB, Roth M, Bordeaux J, Vaupel C, Wang LL, Schneider JT, Warner JL, Zhao Z, and Lovly CM. Clinical Outcomes and Differential Tumor Immune Infiltrate and PD-1/PD-L1 Expression in Tumors from Patients with Small Cell Lung Cancer and Paraneoplastic Syndromes. American Association for Cancer Research (AACR), Chicago, IL, April 2018.
9. Balko JM, Johnson DB, Wang DY, Ericsson-Gonzalez P, Nixon M, Salgado R, Sanchez V, Schreeder D, Kim J, Bordeaux J, Sanders M, and Davis RS. Breast tumor-specific MHC-II expression drives a unique pattern of adaptive resistance to antitumor immunity through MHC-II receptor checkpoint engagement. San Antonio Breast Cancer Symposium (SABCS), San Antonio, TX, December 2017.

10. Kantarjian KM, Stock W, Cassaday RD, DeAngelo DJ, Jabbour EJ, O'Brien SM, Stelljes M, Wang T, Paccagnella ML, Nguyen K, Sleight B, Vandendries E, Laird AD, and Advani AS. Inotuzumab Ozogamicin for Relapsed/Refractory Acute Lymphoblastic Leukemia in the Global Phase 3 INOVATE Trial: Efficacy and Safety by Baseline CD22 Expression Level. American Society of Hematology (ASH), Atlanta, GA, December 2017.
11. Khaled S, Ganguly S, Perl AE, Kobayashi K, Berisha F, Ding W, Lameh J, and Martinelli G. Concordance between Bone Marrow and Peripheral Blood Samples for Assessment of FLT3 Internal Tandem Duplication (ITD) Mutations: Data from Patients Screened for Participation in Quantum-R, a Global, Randomized, Open-Label, Phase 3 Study Examining the Effect of Quizartinib Monotherapy Vs Salvage Chemotherapy on Overall Survival in Patients with FLT3-ITD - Mutated AML Who Are Refractory to or Have Relapsed after First-Line Therapy. American Society of Hematology (ASH), Atlanta, GA, December 2017. Poster link [19]
12. Diaz E, Kim J, Adams L, Bordeaux J, Roscoe N, Pacia E, Johnson T, Tran T, Chen B, Dabbas B, Lameh J, Tangri S and Dakappagari N. Immuno-Oncology biomarker assessment by novel digital imaging algorithms based on AQUA Technology. National Society for Histotechnology (NSH), Orlando, FL, September 2017. Poster link [20]
13. Johnson D, Bordeaux J, Kim J, Vaupel C, Rimm DL, Ho TH, Joseph RW, Daud AI, Conry RM, Gaughan EM, Dimou A, Smithy J, Witte JS, McKee S, Dominiak N, Dabbas B, Yaomin X, Wang Y, Tangri S, Lameh J, Balko JM, Hall J and Dakappagari N. Quantitative spatial profiling of PD-1/PD-L1 Interaction and HLA-DR/IDO-1 predicts improved outcomes to anti-PD-1 in metastatic melanoma. American Society of Clinical Oncology (ASCO), Chicago, IL, June 2017. Poster link [21]
14. Riccitelli N, Beams A, Summitt IS, Lameh J, and Pollner R. Analytical Evaluation and Applications of the nCounter Vantage™ RNA:Protein Immune Cell Profiling Panel. Association for Molecular Pathology (AMP); Charlotte, NC, November 2016.
15. Shi W, Chin C, Beams A, Lameh J, and Pollner R. Next Generation Sequencing (NGS) Evaluation of CYP11B1 and CYP11B2 Single Nucleotide Variants (SNP) for a Correlation in Hypertension and Cushing Syndrome. American Society of Human Genetics (ASHG), Vancourver BC, October 2016.
16. Bordeaux J, Scott LK, Tran T, Chen B, Paulson J, Nguyen V, Tangri S, Lameh J, Dakappagari N, and Kim J. Novel automated quantitative analysis (AQUA) algorithms for reproducible assessment of PD1-PD-L1 interaction and immune cell subsets by multiplex fluorescence immunohistochemistry in cancer immunotherapy trials. Poster at 23rd International Molecular Medicine Tri-Conference, San Francisco, CA, March 2016.
17. Tran T, Scott K, Singh R, Lee SS, Cogan S, Bordeaux J, Hummel J, Tangri S, Lameh J, Tribouley C, Kassim S, and Dakappagari N. Quantitative multiplexed immunohistochemistry assays for exploring CAR modified T cells and checkpoint inhibitors in lymphoma trials. 57th Annual Meeting of American Society of Hematology (ASH), Orlando, FL, December, 2015. Blood, 2015; 126(23):2659. Poster abstract [22]
18. Pahuja A, Sarikonda S, Ashok D, Lee B, Graber A, Tangri S, Lameh J, and Dakappagari N. Analytical validation and clinical verification of phosphoprotein biomarker modulation using a novel preservation system-based flow cytometry assay in multiple myeloma clinical trials. AACR 106th Annual Meeting 2015, Philadelphia, PA, April 2015. Cancer Research, 2015; 75(15 suppl):3388. Poster abstract [23]
19. Sarikonda G, Ashok D, Pahuja A, Lameh J, Tangri S, and Dakappagari N. High complexity flow cytometry panels to monitor target expression, T-cell activation and suppression by novel immunotherapies in hematomalignancy clinical trials. AACR 106th Annual Meeting 2015, Philadelphia, PA, April 2015. Cancer Research, 2015; 75(15 suppl):1302. Poster abstract [24]
20. Chandrasekaran LK, Bordeaux J, Beruti S, Dakappagari N, Nerenberg M, Lameh J, Graber A, Rimm D, Robbins B, and Rao N. Development of a binary diagnostic immunofluorescence assay by AQUA® technology for accurate detection of HER-2 levels in breast cancer specimens. AACR Annual Meeting 2014, San Diego, CA, April 2014. Cancer Research, 2014; 74:2843. Poster abstract [25]

21. Bordeaux J, Chandrasekaran K, Beruti S, Nerenberg M, Ramos C, Rimm D, Lameh J, and Dakappagari N. Evaluation of HER2 RNA and Protein Levels in a Large Cohort of Breast Cancer Specimens to Support Development of a Diagnostic Immunofluorescence Assay Quantified by AQUA® Technology. AACR Annual Meeting 2014, San Diego, CA, April 2014. Cancer Research, 2014; 74:2840. Poster abstract [26]
22. Shi W, Chin C, Tang T, Hipolito L, Srinivasan P, Chiang D, Peng D, Tomaso ED, Tangri S, Lameh J, and Pollner R. Development of a clinical targeted next-generation sequencing (NGS) test for formalin-fixed paraffin-embedded (FFPE) cancer samples. AACR Annual Meeting 2014, San Diego, CA, April 2014. Cancer Research, 2014; 74:1892. Poster abstract [27]
23. Tang T, Shi W, Hipolito L, Mayer J, Lameh J, Tangri S, and Pollner R. Development of a nanostring copy number assay for a customized 55 gene panel using challenging formalin-fixed paraffin-embedded (FFPE) tumor samples. AACR Annual Meeting 2014, San Diego, CA, April 2014. Cancer Research, 2014; 74:3734. Poster abstract [28]

Invited Speaker Presentations

1. Pollner, R. Applications of NanoString Technology in Clinical Trials. American Society of Human Genetics (ASHG); San Diego, CA; October 2018.
2. Diaz E and Kim J. Multiplex FIHC and AQUA Analysis for I-O Clinical Trials: Challenges & Successes. National Society for Histology (NSH), St Louis, MO, September 2018.
3. Sarikonda, G. CAR-T Characterization by Flow Cytometry: Hurdles and Successes. Bioanalytical Conference; Madison, WI; July 2018.
4. Dakappagari N. Novel Multiplexed Digital Pathology Algorithms Identify Superior Predictors of anti-PD-1 Response: A Real World Study. Molecular Medicine Tri-Conference, San Francisco, CA, February 2018.
5. Balko J, Johnson DB, Want, DY, Ericsson-Gonzalez P, Nixon, M, Salgado R, Sanchez V, Schreeder D, Kim J, Bordeaux J, Sanders M, and Davis RS. MHC-II expression drives a unique pattern of adaptive resistance to antitumor immunity through receptor checkpoint engagement. American Society of Clinical Oncology-Society for Immunotherapy of Cancer (ASCO-SITC); San Francisco, CA; January 2018. Abstract link [29]
6. Xu-Monette ZY, Yu L, Tran T, Adams L, Roscoe N, Manyam GC, Visco C, Tzankov A, Dybkaer K, Bhagat G, Chiu A, Tam W, Zu Y, His ED, J. van Krieken H, Huh J, Ponzoni M, Ferreri AJM, Møller MB, Piris MA, Winter JN, Medeiros LJ, Rassidakis GZ, Vaupel C, Li Y, Dakappagari N, and Young KH. Clinical significance of PD-1 and PD-L1 expression and ongoing interaction in the tumor microenvironment in diffuse large B cell lymphoma (DLBCL) treated with R-CHOP. American Society of Hematology (ASH), Atlanta, GA, December 2017. Blood, 2017; 130(Suppl 1):197.
7. Gong, H. Transforming Oncology Drug Clinical Development by Next Generation Sequencing Testing. International Precision Medicine Conference (IPMC); November 2017; Guangzhou, China.
8. Dakappagari N. Flow Cytometry Approaches for Characterizing Functional Persistence. American Association of Pharmaceutical Scientists (AAPS) Annual Conference; November 2017; San Diego, CA.
9. Pollner, R. qPCR Methods for Characterizing Cellular Kinetics. American Association of Pharmaceutical Scientists (AAPS) Annual Conference; November 2017; San Diego, CA.
10. Velcheti V, Bordeaux J, Dakappagari N, Pennell N, Stevenson J, Khunger M, Kim J, Vaupel C, Schalper K, and Rimm D. Quantitative Spatial Profiling of PD-1/PD-L1 Interaction Predicts Response to Adjuvant Chemotherapy in Early Stage Non–Small-Cell Lung Cancer. World Conference on Lung Cancer of the International Association for the Study of Lung Cancer (IASLC), Yokohama, Japan, October 2017. Abstract link [30]
11. Dakappagari, N. Unique biomarker signatures identified by novel quantitative immunohistochemistry algorithms predict outcomes to PD-1 blockers in metastatic melanoma patients. Immuno-Oncology Summit (IOS), Boston, MA, August 2017.

12. Gong, H. Transforming Oncology Drug Clinical Development by Next Generation Sequencing Testing. American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference, San Diego, CA, May 2017
13. Dakappagari, N, Phillips, L, Khan, M, Zhang, H and Amaravadi, A. Biomarker Sample Stability: Why do we Care? Roundtable Session. American Association of Pharmaceutical Scientists (AAPS) National Biotechnology Conference, Boston, May 2016.
14. Bordeaux J, Johnson D, Sosman J, Kim J, Vaupel C, Dabbas B, Cates J, Hall J, Lameh J, Tangri S, and Dakappagari N. Novel quantitative multiplexed PD-1/PD-L1 immunohistochemistry test provides superior prediction of treatment response in melanoma patients. AACR 107th Annual Meeting 2016, New Orleans, LA, April 2016. Cancer Research, 2016; 76. Abstract link [31]
15. Lameh J. Development of Bioassays for Checkpoint Immunotherapy. Molecular Medicine Tri Conference Cancer Immunotherapy, San Francisco, March 2016.
16. Lameh J. Biomarkers to Support the Development and Clinical Application of Immunotherapy Combinations. Molecular Medicine Tri Conference Cancer Immunotherapy, San Francisco, March 2016.
17. Pollner R. Promises and Challenges of Using Digital PCR. Molecular Medicine Tri-Conference, San Francisco, CA, March 2016.
18. Gong H. Liquid Biopsy: Non-Invasive Tumor Diagnosis and Treatment Monitoring. 5th SABPA Medical Device and Diagnostics (MDD) Forum, San Diego, February 2016.
19. Lameh J. Biomarkers to Support the Development and Clinical Application of Immunotherapy Combinations. CHI Immunology and Vaccine Summit Rational Combination Cancer Immunotherapy, Boston, August 2015.
20. Dakappagari, N. Philosophy of Outsourcing Clinical Biomarker Assays. AAPS WORKSHOP on Implementing Biomarkers into drug development, San Francisco, June 2015.
21. Pollner R. Copy Number Variations: Digital PCR, Nanostring, and Next Generation Sequencing. Digital PCR Conference, San Diego, CA, June 2015.
22. Oldaker T. The Journey Towards Standardization for Validation of Fluorescent Cell-Based Assays. Oral presentation at International Society of Cell Therapy (ISCT), Las Vegas, NV, May 2015.
23. Pollner R. Digital PCR for Patient Monitoring and Stratification in Clinical Trials. Molecular Medicine Tri Conference, San Francisco, CA, February 2015.
24. Gong H. Next Generation of Precision Medicine in Immuno-oncology. Novartis IO APECHO, 2015
25. Pollner R. Nanostring Assays for Patient Monitoring and Stratification in Clinical Trials. American Society for Human Genetics, 2014, San Francisco.
26. Lameh J. Applications of Biomarkers in Oncology Clinical Development. Molecular Medicine Tri Conference, 2014
27. Dakappagari, N. RPMA and AQUA for Evaluation of Biomarker Modulation in Tumors. Roundtable Session. AAPS National Biotechnology Conference, San Diego, May 2013
28. Gong H. Maximizing Success of Drug Development by Optimal Patient Stratification. AAPS Open Forum, 2013

Links
[1] https://www.navigatebp.com/our-experience/publications
[2] https://www.nature.com/articles/s41591-018-0146-z.pdf
[3] http://clincancerres.aacrjournals.org/content/24/21/5250?iss=21
[4] http://onlinelibrary.wiley.com/doi/10.1111/cup.13048/epdf
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