U.S. Citizen

Dr. Rashmi Pradhan Vaidya, M.D, FACS

Curriculum Vitae

Ironwood Cancer & Research Centers, division of Ironwood Physicians, PC

EDUCATION:

Fellowship, Endoscopy Assisted Oncoplastic Breast Surgery
Kameda Medical Center and Nippon Medical School, Japan — March- July 2015

Course in Introduction to Clinical Research, NIH, Bethesda, MD — October 2014 – March 2015

Fellowship, Breast Surgery — 2008-2009
Cleveland Clinic, Cleveland, OH

Residency, General Surgery — 2004-2008
St. John Hospital and Medical Center, Detroit, MI

PGY1 Residency, General Surgery — 2003-2004
Abington Memorial Hospital, Abington, PA

General Surgery Residency, University of Mumbai — 1997-2000
Seth G. S. Medical College and KEM Hospital, Mumbai, India

Bachelor of Medicine and Bachelor of Surgery, University of Mumbai — 1991- 1996
Mahatma Gandhi Mission Medical College, Navi Mumbai, India

EMPLOYMENT:

Breast Surgeon
Ironwood Physicians, PC — May 1, 2016

Breast Surgeon — Nov 2011 – Nov 2014
Bon Secours Medical Group, Richmond, VA

Breast Surgeon — 2009-2011
Women's Health Institute, Cleveland Clinic Cancer Center at Fairview, Cleveland OH

Senior Registrar, Dept of General Surgery
Seth G.S.Medical College and K.E.M Hospital, Mumbai, India — Feb 2000- July 2000

Senior Registrar, Dept of General Surgery
V.N.Desai Hospital, Mumbai, India — Aug 2000- Jan 2001

ADJUNCT APPOINTMENTS:

Honorary Assistant Professor Dept of Obstetrics and Gynecology – Breast Surgery, University of Virginia, Charlottesville — Sept 2012 - Sept 2014

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TEACHING EXPERIENCE:

- Teaching medical students from University of Virginia breast diseases as part of their rotation in Bon Secours Richmond through the Dept of OBGYN Sept 2012 to Sept 2014
- Teaching medical students, Residents and Fellows at Cleveland Clinic July 2008-March 2011
- Teaching Medical Students and Junior Residents during General Surgery Residency and Senior Registrarship in Mumbai, India Feb 1997 to Jan 2001

ADMINISTRATIVE ACCOMPLISHMENTS:

- Played key role in getting NAPBC and COC certifications for the Bon Secours St Mary's and Memorial Regional Medical Center Breast Cancer programs in Richmond, VA as part of the Bon Secours Cancer Institute.
- Served on the Disease Management Team for Breast Cancer at Bon Secours Cancer Institute to establish and streamline pathways for uniformity in classification, diagnosis and management of patients with breast cancer and those at high risk across the Bon Secours Health System.
- Lobbied for and helped establish a stereotactic unit in Bon Secours Memorial Regional Medical Center, which is a big source of revenue for the hospital today

PROFESSIONAL ACTIVITIES:

- Reviewer for ASBS Ultrasound Certification 2011-present
- Serves on ASBS Breast Imaging Certification and Accreditation Committee 2012-present
- Serves on ASBS Selected Readings Subcommittee 2012-present

BOARD CERTIFICATION:

American Board of Surgery 2009-present

OTHER CERTIFICATIONS:

- Breast Ultrasound and Ultrasound Guided Breast Biopsy- American Society of Breast Surgeons

PROFESSIONAL SOCIETIES:

- American College of Surgeons, Fellow 2008 - present

- American Society of Breast Surgeons, Member 2009 - present

PUBLICATIONS:

- *Minimally Invasive Breast Surgery;* Rashmi Pradhan, M.D., Jill Dietz, M.D., F.A.C.S; *Minimally Invasive Cancer Management*, 2nd Edition, Frederick Greene, et. Al.
- *Cholecystoduodenostomy for leaked duodenal ulcer perforation*, O. S. Rohondia, R. D Bapat, P. Shriyan ,R. Pradhan**,** S. Hussain.,Kumar K S Indian Journal of Gastroenterology. May 2001, vol 20, pp107-108
- *Study of Perforative peritonitis in the elderly, Master of Surgery Thesis*, Seth G. S. Medical College and KEM Hospital, Mumbai, India, 2000

PRESENTATIONS:

- "*Management And Outcomes Of Patients With Margins Positive For DCIS After Mastectomy For Early Stage Breast Cancer*", poster presented at American Society of Breast Surgeons 10th Annual Meeting, April 22 – 26, 2009 in San Diego, CA.
- *Study of Lactic Acid and Base Deficit in Trauma Patients.* Presented at Michigan Chapter of American College of Surgeons. Grand Rapids, MI, 2005

MEDIA APPEARANCES:

- http://wtvr.com/2012/11/06/buddy-check-6-menopause-treatment-linked-to-breast-cancer/
- http://wtvr.com/2012/10/17/vtm-pres-bon-secours-cancer-institute/

Clinical Research – Sub Investigator

Lung Cancer Trials

- Novocure Protocol EF-24/Lunar: Pivotal, randomized, open-label study of Tumor Treating Fields (TTFields) concurrent with standard of care therapies for treatment of stage 4 non-small cell lung cancer (NSCLC) following platinum failure (LUNAR) (2018-).
- BeyondSpring Pharmaceuticals Inc. Protocol 450-0001/Dublin-3: Assessment of Docetaxel + Plinabulin Compared to Docetaxel + Placebo in Patients With Advanced NSCLC With at Least One Measurable Lung Lesion (DUBLIN-3) (2017-).
- G1 Therapeutics Protocol G1T28-05: Phase 2 Study of Carboplatin, Etoposide, and Atezolizumab With or Without Trilaciclib (G1T28) in Patients with Untreated Extensive-Stage Small Cell Lung Cancer (2017-)
- Pharma Mar Protocol PM1183-C-003-14: Phase III Randomized Clinical Trial of Lurbinectedin (PM01183)/Doxorubicin (DOX) Versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients With Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line (ATLANTIS Trial) (2016-)
- Eli Lilly and Company Protocol LUN 288/I6A-MC-CBBE: A Phase II Study of the Combination of LY3023414 and Necitumumab After First-Line Chemotherapy for Metastatic Squamous Non-small Cell Carcinoma of the Lung (2016-2018)
- Hoffmann-La Roche Protocol GO29436: A Phase III, Open-Label, Randomized Study of MPDL3280A (Anti-PD-L1 Antibody) In Combination with Carboplatin + Paclitaxel With or Without Bevacizumab Compared With Carboplatin + Paclitaxel + Bevacizumab In Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC) (2015-)
- AstraZeneca Protocol D4191C00004: A Phase III, Open Label, Randomised, Multi-centre, International Study of MEDI4736, Given as Monotherapy or in Combination With Tremelimumab Determined by PD-L1 Expression Versus Standard of Care in Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer (Stage IIIB-IV) Who Have Received at Least Two Prior Systemic Treatment Regimens Including One Platinum Based Chemotherapy Regimen and Do Not Have Known EGFR TK Activating Mutations or ALK Rearrangements (ARCTIC) (2014-2018)
- AstraZeneca Protocol D4191C00001: A Phase III, Randomised, Double-blind, Placebo-controlled, Multi-centre, International Study of MEDI4736 as Sequential Therapy in Patients With Locally Advanced, Unresectable Non-Small Cell Lung Cancer (Stage III) Who Have Not Progressed Following Definitive, Platinum-based, Concurrent Chemoradiation Therapy (PACIFIC) (2014-2017)
- Peregrine Protocol PPHM1202: SUNRISE: A Phase III, Randomized, Double-Blind, Placebo-Controlled Multicenter Trial of Bavituximab Plus Docetaxel Versus Docetaxel Alone in Patients With Previously Treated Stage IIIb/IV Non-Squamous Non Small-Cell Lung Cancer (2014-2017)

Breast Cancer Trials

- Protocol Number: ICMBC-02
  Title: Cryoablation of Low Risk Breast Cancers less than 1.5 cm: An evaluation of local recurrence (Ice3 Trial)
- Boehringer Ingelheim BI1280-0022: Xenera-1: A multi-centre, double-blind, placebo-controlled, randomised phase II trial to compare efficacy of xentuzumab in combination with everolimus and exemestane versus everolimus and exemestane in post-menopausal women with HR+ / HER2-metastatic breast cancer and non-visceral disease (2019-)
- Daiichi Sankyo Protocol DS8201-A-U303: A Phase-3, multicenter randomized, open-label, active-controlled trial of DS-8201A, an anti-her2-antibody drug conjugate (ADC) versus treatment of physician's choice for HER2low, unresectable and/or metastatic breast cancer subjects.(2019 -)
- Daiichi Sankyo Protocol DS8201-A-U301: A Phase 3, multicenter, randomized, open-label, active-controlled of DS-8201A, an anti-HER2-antibody drug conjugate, versus treatment of investigator's choice for HER2-positive, unresectable and/or metastatic breast cancer subjects pretreated with prior standard of care HER2 therapies, including T-DM1(2019-)
- Novartis Pharmaceuticals Protocol CLAG525B2101: A phase II open-label, randomized, three-arm, multicenter study of LAG525 given in combination with spartalizumab (PDR001), or with spartalizumab

and carboplatin, or with carboplatin, as first or second line therapy in patients with advanced triple-negative breast cancer (2018-)

- Odonate Therapeutics Protocol ODO-TE-V301: A Multinational, Multicenter, Randomized, Phase 3 Study of Tesetaxel plus a Reduced Dose of Capecitabine versus Capecitabine Alone in Patients with HER2 Negative, Hormone Receptor Positive, Locally Advanced or Metastatic Breast Cancer Previously Treated with a Taxane
- Merrimack Pharmaceuticals Protocol MM-121-02-02-10/ Sherboc: Phase 2 Trial of Seribantumab Plus Fulvestrant in Postmenopausal Women With Metastatic Breast Cancer (SHERBOC) (2018-)
- Macrogenics, Inc. Protocol CP-MGAH22-04: A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients With HER2+ Metastatic Breast Cancer Who Have Received Prior Anti-HER2 Therapies and Require Systemic Treatment (2016-)
- Celgene Corporation Protocol CC-486-BRSTM-001: A Phase 2, Randomized, Open-label, Two-arm Study to Assess the Efficacy and Safety of the Epigenetic Modifying Effects of CC-486 (Oral Azacitidine) in Combination With Fulvestrant in Postmenopausal Women With ER+, HER2- Metastatic Breast Cancer Who Have Progressed on an Aromatase Inhibitor (2015-2017)
- Novartis Pharmaceuticals Protocol CLEE011A2404: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease COMPLEEMENT-1 (2017-)
- Novartis Pharmaceuticals Protocol CLEE011XUS29: A Phase I/II, Single Arm, Open-label Study of Ribociclib in Combination With Everolimus + Exemestane in the Treatment of Men and Postmenopausal Women With HR+, HER2- Locally Advanced or Metastatic Breast Cancer Following Progression on a CDK 4/6 Inhibitor (2017-)
- Novartis Pharmaceuticals Protocol CLEE011XUS29: A Phase I/II, Single Arm, Open-label Study of Ribociclib in Combination With Everolimus + Exemestane in the Treatment of Men and Postmenopausal Women With HR+, HER2- Locally Advanced or Metastatic Breast Cancer Following Progression on a CDK 4/6 Inhibitor (2017-)
- Merck Sharp & Dohme Corp. Protocol MK3475-119: A Randomized Open-Label Phase III Study of Single Agent Pembrolizumab Versus Single Agent Chemotherapy Per Physician's Choice for Metastatic Triple Negative Breast Cancer (mTNBC) - (KEYNOTE-119) (2016-2017)
- Novartis Protocol CBYL719C2301A: Phase III Randomized Double-blind, Placebo Controlled Study of Alpelisib in Combination With Fulvestrant for Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor Treatment (2016-)
- Novartis Protocol CLEE011F2301:A Randomized Double-blind, Placebo-controlled Study of Ribociclib in Combination With Fulvestrant for the Treatment of Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer Who Have Received no or Only One Line of Prior Endocrine Treatment (2015-)
- Eli Lilly Protocol I3Y-MC-JPBM: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Nonsteroidal Aromatase Inhibitors (Anastrozole or Letrozole) Plus LY2835219, a CDK4/6 Inhibitor, or Placebo in Postmenopausal Women With Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer With No Prior Systemic Therapy in This Disease Setting (2015-)
- Novartis Protocol CLEE011A2301:A Randomized Double-blind, Placebo-controlled Study of LEE011 in Combination With Letrozole for the Treatment of Postmenopausal Women With Hormone Receptor Positive, HER2 Negative, Advanced Breast Cancer Who Received no Prior Therapy for Advanced Disease (2014-)
- Pfizer protocol A5481023: Multicenter, Randomized, Double-Blind, Placebo-Controlled,Phase 3 Trial Of Fulvestrant (Faslodex (Registered)). With Or Without PD-0332991 (Palbociclib) +/- Goserelin In Women With Hormone Receptor-Positive, HER2-Negative Metastatic Breast Cancer Whose Disease Progressed After Prior Endocrine Therapy (2013-)
- Puma Biotechnology Protocol PUMA-NER-1301: A Study of Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in Patients With HER2+ Metastatic Breast Cancer Who Have Received Two or More Prior HER2-Directed Regimens in the Metastatic Setting (NALA) (2013-)
- Celgene Corporation Protocol ABI-007-MBC-001: A Phase 2/3, Multi-Center, Open-Label, Randomized Study of Weekly Nab®-Paclitaxel in Combination With Gemcitabine or Carboplatin, Compared to

Gemcitabine/Carboplatin, as First Line Treatment in Subjects With ER, PgR, and HER2 Negative (Triple Negative) Metastatic Breast Cancer (2013-2017)

- F. Hoffmann-La Roche Ltd / Genentech Inc Protocol MO27775: A Randomized, Two-arm, Open-label, Multicenter Phase II Trial Assessing the Efficacy and Safety of Pertuzumab Given in Combination With Trastuzumab Plus an Aromatase Inhibitor in First Line Patients With HER2-positive and Hormone Receptor-positive Advanced (Metastatic or Locally Advanced) Breast Cancer (2012-)

Pancreatic Cancer Trials

- Incyte Corporation INCB 18424-362: A Randomized, Double-Blind, Phase 3 Study of the Janus Kinase (JAK) 1/2 Inhibitor, Ruxolitinib, or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study) (2014-2017)

- Gilead Sciences Protocol GS-US-370-1296: A Phase 3, Randomized, Double-blind, Placebo-controlled Study of Gemcitabine and Nab-paclitaxel Combined With Momelotinib in Subjects With Previously Untreated Metastatic Pancreatic Ductal Adenocarcinoma Preceded by a Dose-finding, Lead-in Phase (2014-2017)

Ovarian Cancer Trials

- Tesaro, INC. Protocol PR-30-5020-C: A Phase 2, Open-Label, Single-Arm Study to Evaluate the Safety and Efficacy of Niraparib in Patients With Advanced, Relapsed, High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Received Three or Four Previous Chemotherapy Regimens (2016-2018)

Prostate Cancer Trials

- Roche Ltd Protocol CO39303 IPATential150: Ipatasertib Plus Abiraterone Plus Prednisone/Prednisolone, Relative to Placebo Plus Abiraterone Plus Prednisone/Prednisolone in Adult Male Patients With Metastatic Castrate-Resistant Prostate Cancer (IPATential150) (2017-)
- Bayer Healthcare Pharmaceuticals Protocol BAY 1841788 / 17777: A randomized, double–blind, placebo–controlled Phase III study of ODM–201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone–sensitive prostate cancer
- Janssen Research & Development, LLC on behalf of Aragon Pharmaceuticals, Inc. Protocol 56021927PCR3003: A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects With High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment With Primary Radiation Therapy (ATLAS) (2016-)
- Sotio a.s. SP005: A Randomized, Double Blind, Multicenter, Parallel-group, Phase III Study to Evaluate Efficacy and Safety of DCVAC/PCa Versus Placebo in Men With Metastatic Castration Resistant Prostate Cancer Eligible for 1st Line Chemotherapy (2014-)

Colorectal Cancer Trials

- AbbVie Protocol M14-064: Phase 2 Study Comparing Efficacy and Safety of ABT-165 plus FOLFIRI vs Bevacizumab plus FOLFIRI in Metastatic Colorectal Cancer Previously Treated with Fluoropyrimidine/Oxaliplatin and Bevacizumab.(2018-)

Lymphoma Trials

- Bayer Healthcare Pharmaceuticals Inc., Protocol BAY 80-6946 / 17833: A Phase III, randomized, double-blind, controlled, multicenter study of intravenous PI3K inhibitor copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma (iNHL) - CHRONOS-4 (2018-)
- TG Therapeutics, Inc Protocol UTX-TGR-205: A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 and TGR-1202 Alone in Patients With Previously Treated Diffuse Large B-Cell Lymphoma (2016-)
- Novartis Protocol OFB114612: A Phase II Open-Label Study of Ofatumumab and Bendamustine Followed by Maintenance Ofatumumab for Indolent B-cell Non-Hodgkin's Lymphoma (B-NHL) Which Has Relapsed after Rituximab Therapy (2011-2017)

- Novartis Protocol CRAD001N2301: A Randomized, Double-blind, Placebo-controlled, Multi-center Phase III Study of RAD001 Adjuvant Therapy in Poor Risk Patients With Diffuse Large B-Cell Lymphoma (DLBCL of RAD001 Versus Matching Placebo After Patients Have Achieved Complete Response With First-line Rituximab-chemotherapy (2010-2016)

Myeloma Trials

- Merck Sharp & Dohme MK-3475-183-01: A Phase III Study of Pomalidomide and Low Dose Dexamethasone With or Without Pembrolizumab (MK3475) in Refractory or Relapsed and Refractory Multiple Myeloma (rrMM) (**KEYNOTE 183**) (2016-)
- Millennium Pharmaceuticals Protocol C16014: A Phase 3, Randomized, Double-Blind, Multicenter Study Comparing Oral IXAZOMIB (MLN9708) Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomide and Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma (2013-)

CLL Trials

- TG Therapeutics Protocol UTX-TGR-304: A Phase 3, Randomized Study to Assess the Efficacy and Safety of Ublituximab in Combination with TGR-1202 Compared to Obinutuzumab in Combination with Chlorambucil in Patients with Chronic Lymphocytic Leukemia (CLL) (2016-)
- TG Therapeutics Protocol UTX-IB-301: Ublituximab in Combination With Ibrutinib Versus Ibrutinib Alone in Patients With Previously Treated High-Risk Chronic Lymphocytic Leukemia (CLL) (2015-)
- Genentech Protocol ML29538: A Phase II, Open-Label Study Of Obinutuzumab Plus Bendamustine (BG) In Patients With Previously Untreated Chronic Lymphocytic Leukemia (2015-)

Melanoma Cancer Trials

- Merck Sharp & Dohme Corp. Protocol 7902-004: A Multicenter, Open-label, Phase 2 Trial to Assess the Efficacy and Safety of Lenvatinib (E7080/MK-7902) in Combination with Pembrolizumab (MK-3475) in Participants with Advanced Melanoma Previously Exposed to an Anti-PD-1/L1 Agent (LEAP-004)
- Polynoma LLC Protocol 103A-301: A Multicenter, Double-blind, Placebo-controlled, Adaptive Phase 3 Trial of POL-103A Polyvalent Melanoma Vaccine in Post-resection Melanoma Patients With a High Risk of Recurrence (2015-)

Head & Neck Cancer Trials

- Merck Sharp & Dohme Protocl MK-3475-040-10: A Phase III Randomized Trial of MK-3475 (Pembrolizumab) Versus Standard Treatment in Subjects With Recurrent or Metastatic Head and Neck Cancer (2016-)

Urothelial Carcinoma Trials

- Merck Sharp & Dohme Corp. Protocol MK3475-361: A 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 (2016-)

Renal Cell Carcinoma Trials

- Bristol-Myers Squibb Protocol CA 209-920: Phase 3b/4 Safety Trial of Nivolumab Combined With Ipilimumab in Subjects With Previously Untreated, Advanced or Metastatic RCC (CheckMate 920: CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 920) (2017-)

Registry Trials

- Guardant Health Protocol 01-MX-003: GEODE: Registry of Guardant360® Use and Outcomes In People With Advanced Cancer